



Service Guide

# Avalon Fetal Monitor

## FM20/FM30

Release J.3 with Software Revision J.3x.xx

Fetal Monitoring

**PHILIPS**



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# Introduction

This Service Guide contains technical details for the Avalon FM20 and FM30 fetal/maternal monitors. It provides a technical foundation to support effective troubleshooting and repair. It is not a comprehensive, in-depth explanation of the product architecture or technical implementation. It offers enough information on the functions and operations of the monitoring systems, so that engineers who repair them are better able to understand how they work. It covers the physiological measurements and the monitor hardware that acquires and displays them.

The Avalon FM20/FM30 Fetal Monitor Service Guide supplements the maintenance and troubleshooting procedures, carried out by the operator that are described in the Instructions for Use. Refer to the Instructions for Use for maintenance and troubleshooting procedures that may be performed during normal operation.

Only qualified and authorized service personnel should attempt to install the system, disassemble the monitor, remove or replace any internal assemblies, or replace the transducer cable or belt buttons.

For detailed information concerning the configuration of the fetal monitor see the Configuration guide.

## Who Should Read This Guide

This guide is for biomedical engineers or technicians responsible for troubleshooting, repairing, and maintaining Philips' Avalon fetal monitors.

You must:

- understand English
- be familiar with standard medical equipment installation procedures
- be familiar with current conventional technical terms as used throughout this guide

## What to Do Next

Familiarize yourself with the contents of this guide and the Instructions for Use before attempting to service or repair the system.

# Repair Strategy

The Service Support Tool software helps you to determine whether a fault is a hardware or software problem. The main replaceable parts are:

- unit exchange for the transducers
- replacement of
  - the top cover assembly
  - the bottom housing
  - the power supply assembly
  - the display assembly
  - the recorder adapter board
  - the paper drawer assembly
  - the paper sensor assembly
  - the stepper motor assembly
  - the SpO<sub>2</sub> assembly
  - the noninvasive blood pressure assembly
  - the main CPU board
  - the bus master board
  - the socket connector block
  - the transducer cable
  - the transducer belt button

See “Parts” on page 125 for part numbers, and “Repair and Disassembly” on page 139 for repair details.

Repair or replacement of individual components on the boards is not supported, and should never be attempted.

For tests that you are required to perform after repairs, refer to “When to Perform Tests” on page 56.

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### **WARNING**

Do not maintain or repair the device in patient vicinity.

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## Manufacturer's Information

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Philips Medizin Systeme Böblingen GmbH

Hewlett-Packard-Str. 2

71034 Böblingen, Germany

# Passwords

In order to access different modes within the monitor a password may be required. The passwords are listed below.

Monitoring Mode: No password required

Configuration Mode: 71034

Demo Mode: 14432

Service Mode: 1345

Refer to “When to Perform Tests” on page 56 before making any changes to the monitor configuration.

## Safety Information

### Warnings and Cautions

In this guide:

- A **warning** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
- A **caution** alerts you where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.

# Electric Hazards

---

### WARNING

**Electric shock hazard:** Do not open the monitor housing. Refer all servicing to qualified service personnel.

- Always use the supplied power cord with the earthed mains plug to connect to an earthed AC mains socket. Never adapt the mains plug from the fetal monitor to fit an unearthed AC mains socket.
- Do not use AC mains extension cords or multiple portable socket-outlets.
- The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. Double and/or reinforced insulation protects this device against electric shock.
- Do not use a device in the patient vicinity if it does not comply with IEC/EN 60601-1 A1: 2012. The whole installation, including devices outside of the patient vicinity, must comply with IEC/EN 60601-1 A1: 2012. Any non-medical device, including a PC running an OB TraceVue/IntelliSpace Perinatal system, placed and operated in the patient's vicinity, must be powered via a separating transformer (compliant with IEC/EN 60601-1 A1: 2012) that ensures mechanical fixing of the power cords and covering of any unused power outlets.
- Do not connect any devices that are not supported as part of a system.
- Any non-medical device placed and operated in the patient's vicinity must be powered via an approved isolation transformer that ensures mechanical fixing of the power cords and covering of any unused power outlets.
- Do not use USB devices with own power supplies unless an appropriate separation device is used (either between USB interface and device or between device and power).
- Only the power cables provided with the system may be used. For reasons of safety, power (mains) extension cables, or adapters shall not be used.
- Observe ESD (electrostatic discharge) precautions when working within the unit.
- The use of accessories, transducers, and cables other than those specified may result in increased electromagnetic emissions, or decreased electromagnetic immunity of the device.
- The fetal/maternal monitor is NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the user can result.
- Do not touch the charging contacts for the cableless transducers at the Avalon base station while you are touching the patient

**Leakage currents:** If several items of equipment used to monitor a patient are interconnected, the resulting leakage current may exceed allowable limits.

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## Use Environment

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### WARNING

#### Explosion Hazard:

- Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, nitrous oxide, or in oxygen rich environment. Use of the devices in such an environment may present an explosion hazard.
- Use only Philips batteries part number M4605A with the FM20 or FM30 with battery option. Use of a different battery may present a risk of fire or explosion.

#### Environmental Specifications:

- The performance specifications for the monitors, measurements, and accessories apply only for use within the temperature, humidity, and altitude ranges specified in .

#### Liquid Ingress:

- Do not operate the monitor if it is wet. If you spill liquid on the monitor, contact your service personnel, or Philips service engineer.
- Never immerse the fetal monitor or the CL base station in liquid. You must protect them against water sprays or splashes. Place the fetal monitor and the CL base station where there is no chance of contact with, or falling into water or other liquids.
- Do not perform underwater monitoring (for example, in a bath or shower) using wired transducers.

#### Heat Exposure:

- Do not dry equipment using heating devices such as heaters, ovens (including microwave ovens), hair dryers, and heating lamps.
- Do not put equipment or accessories in autoclave (for sterilization).

#### Positioning Equipment:

- The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

#### Prohibited Environments:

- The monitors are not intended for use in an MRI environment or in an oxygen-enriched environment (for example, hyperbaric chambers).
-

# Alarms

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### WARNING

- Do not rely exclusively on the audible alarm system for fetal monitoring. Adjustment of alarm volume to a low level or off during monitoring may result in a dangerous situation. Remember that the most reliable method of fetal monitoring combines close personal surveillance with correct operation of monitoring equipment.
  - Alarm systems of the monitor and those of the connected obstetrical information and surveillance system are independent and not synchronized.
  - In **INOP only** mode, no fetal/maternal patient alarms are enabled or indicated.
- 

# Accessories

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### WARNING

**Philips' approval:** Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance, and cause a potential hazard.

**Reuse:** Never reuse disposable transducers, sensors, accessories, and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance, and cause a potential hazard.

**Electromagnetic compatibility:** The use of accessories, transducers, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

**Damage:** Do not use a damaged sensor or one with exposed electrical contacts.

**Cables and tubing:** When connecting devices for acquiring measurements, always position cables and NBP tubing carefully to avoid entanglement or potential strangulation.

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## Installation

### WARNING

- No modification of the fetal monitors and transducers is allowed.
- Perform initial inspection of delivery, unpack, and check the shipment.
- The correct and accurate functioning of the equipment is ensured by the successful completion of the safety tests, performance test, and the system test.
- It is the customer's responsibility to have the attachment of the mounting hardware to the wall, or mounting rail, and the construction of the wall, or mounting rail evaluated for structural integrity and compliance with all local, state, and any other required codes by a registered, professional, structural, and/or mechanical engineer.
- Although considerable effort has been made to ensure the safety of the mounting guidelines, it is to be understood that the installation itself is beyond the control of Philips Medical Systems. Accordingly, Philips Medical Systems will not be responsible for the failure of any such installation.
- Check the mounting of the fetal monitor for integrity as part of your safety precautions. Ensure that the fetal monitor is not able to slip, fall, or be pushed over by accident.
- The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.
- NEVER run power cables through the same conduit or trunking used for system cables.

## Maintenance, Repair and Care

### WARNING

#### Maintenance and Repair:

- Do not maintain or repair the device in patient vicinity.
- Failure on the part of the responsible individual hospital or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Performance verification: do not place the system into operation after repair or maintenance has been performed, until all performance tests and safety tests listed in “Testing and Maintenance” on page 55 of this service manual have been performed. Failure to perform all tests could result in erroneous parameter readings, or patient/operator injury.
- If the troubleshooting procedure requires you to disassemble the monitor, be certain to follow the disassembly and reassembly procedures given in “Repair and Disassembly” on page 139. Whenever parts are replaced in the system, be certain to verify the hardware and software compatibility of the repaired system.
- When replacing the parts, do not over-torque the screws. Excessive torque may damage the plastic screw mountings.

#### Batteries:

- Use only Philips batteries part number M4605A. Use of a different battery may present a risk of fire or explosion.
- Do not open batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak or heat up, causing personal injury.

- If battery leakage should occur, avoid contact with skin.
- Dispose of used batteries promptly and in an environmentally-responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements. Do not expose batteries to liquids.
- Do not crush, drop, or puncture batteries - mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.
- If a battery has been dropped or banged against a hard surface, whether damage is visible externally or not:
  - discontinue use
  - dispose of the battery in accordance with the disposal instructions above.
- Keep batteries out of the reach of children.
- Do not disassemble, heat above 100°C (212°F) or incinerate the batteries, to avoid the risk of fire and burns. Keep batteries in their original package until you are ready to use them.
- Do not install or use pre-damaged batteries.

### **Care and Disinfection:**

- To avoid contaminating or infecting personnel, the environment or other equipment, make sure you disinfect and decontaminate the monitor appropriately before repairing or disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts.
  - For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.
-

# Site Preparation

## Introduction

This section describes the procedures you should follow to plan and prepare a site for an Avalon FM20/FM30 fetal monitor installation:

- Site planning
- Roles and responsibilities for local and Philips personnel

## Site Planning

The careful planning of the site for the FM20/FM30 monitor is essential for its safe and efficient operation. A consulting schedule should be established between the customer and Philips' sales and support representatives to ensure that all preparations are completed when the system is delivered.

The site planning phases prior to equipment installation are:

**Location:** Planning the location of the various system components.

**Environment:** Confirming and correcting, as necessary, the environment of the proposed installation site(s).

**System Capabilities:** Explaining the possibilities for system expansion.

**Mounting:** Referencing the mounting hardware information website for the listing of suitable mounting hardware recommended for use with the various system components, and all details on the available mounts and accessories.

**Cabling:** Identifying the requirements for the cabling, conduiting, and face plates for connecting the various system components.

## Roles and Responsibilities

This section describes the procedures necessary to prepare a site for a system installation. The procedures are grouped into two parts: procedures that local staff or contractors are responsible for, and procedures that Philips' personnel are responsible for.

### Site Preparation Responsibilities

Local Staff:

- Ensure that all safety, environmental, and power requirements are met.
- Provide power outlets.
- Prepare mounts, and consult Philips for detailed mounting requirements.
- Pull cables, install conduit, and install wall boxes.

Philips Personnel:

- Provide the customer with the safety, environmental, and power requirements.
- Assemble mounts as necessary.
- Provide requirements for cabling.

### Procedures for Local Staff

The following tasks must be completed before the procedures for Philips personnel may be started.

- Providing power outlets:
  - Provide a power outlet in the vicinity (1 m or 3 ft.) or any peripheral equipment.

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#### WARNING

Only the power cables provided with the system may be used. For reasons of safety, power (mains) extension cables or adapters shall not be used.

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- Preparing mounts, where ceiling, wall, or shelf mounts are required for mounting the equipment, the customer is responsible for the following:
  - Providing and installing all hardware which is required to install the mounting hardware supplied by Philips as detailed in the installation notes.
  - Making sure that all ceilings, walls, and mounting rails that supports mounting hardware are suitable for their proposed load.

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#### WARNING

It is the customer's responsibility to have the attachment of the mounting hardware to the ceiling, wall, or mounting rail, and the construction of the ceiling, wall, or mounting rail evaluated for structural integrity and compliance with all local, state, and any other required codes by a registered, professional, structural and/or mechanical engineer.

Although considerable effort has been made to ensure the safety of the ceiling mount installation and or mounting guidelines, it is to be understood that the installation itself is beyond the control of Philips Medical Systems. Accordingly, Philips Medical Systems will not be responsible for the failure of any such installation.

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- Providing conduit:
  - Providing conduit and/or trunking of a sufficient cross-sectional area for the planned cables, and possible future expansion (for additional components or systems).
  - Providing and/or installing suitable wall boxes to accommodate the face plates.
- Pulling cables

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**WARNING**

NEVER run power cables through the same conduit or trunking used for system cables.

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- Installing wall boxes

It is the customer's responsibility to provide and install wall boxes to house face plates. The customer must notify the Philips installation coordinator of which size is to be used.

## Procedures for Philips Personnel

Before you begin the procedures in the installation sections, ensure that the customer has completed all necessary preparations outlined in the previous section .

# Site Requirements

The site requirements are listed in this section.

## Space Requirements

The situating of the monitor should be planned such that the nursing staff are able to monitor the patient with relative ease, with all patient connectors and controls readily available, and the displays clearly visible. The location should also allow access to service personnel without excessive disruption, and should have sufficient clearance all round to allow air circulation.

Dimensions and weight:

**Monitor:**

Size (W x H x D): 335 x 286 x 133 mm (13.2 x 11.3 x 5.2 in.)

Weight; 5.1 kg (11.2 lb.) with battery option #25 5.3 kg (11.7 lb.)

**Transducer:**

Size (diameter): 83 mm (3.27 in)

Weight (without cable): 190 g (6.7 oz)

## Environmental Requirements

The environment where the FM20/FM30 monitor will be used should be reasonably free from vibration, dust, and corrosive or explosive gases. The ambient operating and storage conditions for the FM20/FM30 monitor must be observed. If these conditions are not met, the accuracy of the system will be affected and damage can occur.

| <b>Monitor (M2702A/M2703A); Interface Cable for Avalon CTS (M2731-60001)</b> |           |                                                                                                                                                                         |
|------------------------------------------------------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Temperature Range                                                            | Operating | without battery:<br>0°C — 45°C (32°F — 113°F)<br><br>with fully charged battery:<br>0°C — 40°C (32°F — 104°F)<br><br>with battery charging:<br>0°C — 35°C (32°F — 95°F) |
|                                                                              | Storage   | -20°C — 60°C (-4°F — 140°F)                                                                                                                                             |
| Humidity Range                                                               | Operating | <95% relative humidity @ 40°C (104°F)                                                                                                                                   |
|                                                                              | Storage   | <90% relative humidity @ 60°C (140°F)                                                                                                                                   |
| Altitude Range                                                               | Operating | -500 — 3,000 m (-1,640 — 9,840 ft.)                                                                                                                                     |
|                                                                              | Storage   | -500 — 13,100 m (-1,640 to 43,000 ft.)                                                                                                                                  |

| <b>Transducers (M2734A/M2734B/M2735A/M2736A/M2738A)</b> |           |                                       |
|---------------------------------------------------------|-----------|---------------------------------------|
| Temperature Range                                       | Operating | 0°C — 40°C (32°F — 104°F)             |
|                                                         | Storage   | -20°C — 60°C (-4°F — 140°F)           |
| Humidity Range                                          | Operating | <95% relative humidity @ 40°C (104°F) |
|                                                         | Storage   | <90% relative humidity @ 60°C (140°F) |
| Altitude Range                                          | Operating | -500 — 3,000 m (-1,640 — 9,840 ft.)   |
|                                                         | Storage   | -500 — 13,100 m (-1,640 — 43,000 ft.) |

| <b>SpO<sub>2</sub> Sensors</b> |                            |
|--------------------------------|----------------------------|
| Operating Temperature Range    | 0°C — 37°C (32°F — 98.6°F) |

## Safety Requirements (Customer or Philips)

The monitor is an electrical Class II device in which the protection against electric shock does not rely on basic insulation and a protective earth conductor, but on double and/or reinforced insulation.

### WARNING

- Always use the supplied power cord with the earthed mains plug to connect the monitor to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
- The protective earth conductor is required for EMC purposes. It has no protective function against electric shock! The protection against electric shock in this device is provided by double and/or reinforced insulation.
- Do not use additional AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet without an approved separating transformer is used, the interruption of its protective earthing may result in equipment leakage currents equal to the sum of the individual earth leakage currents, so exceeding allowable limits.

## Electrical Requirements (Customer or Philips)

### Line Voltage Connection

- The FM20/FM30 monitor uses supply voltage 100V — 240V (0.7A — 0.4A).
- The M8023A External Power Supply uses supply voltage 100V — 240V (1.3 — 0.7A)
- The FM20/FM30 monitor and the M8023A External power supply may be operated with supply frequency range of 50 Hz to 60 Hz.

## Essential Performance

This section defines the essential performance for Avalon fetal monitors in combination with the specified wired transducers and sensors, and also with the cableless measurements (Avalon CL, Avalon CTS).

Under normal and single fault conditions either at least the performance/functionality listed in the tables below is provided, or failure to provide this performance/functionality is readily identifiable by the user (e.g. technical alarm, no waves and/or numeric values, complete failure of the monitor, readily identifiable distorted signals, etc.).

| Measurement      | Essential Performance                                                                                                                                                                                                   |
|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| General          | <p>No interruption or cessation of current operating mode (e.g. no reboot, display OK).</p> <p>No spontaneous operation of controls (e.g. no activation of touch screen without user interaction).</p>                  |
| ECG (Monitoring) | <p>Measurement of the fetal and maternal heart rate over the specified measurement range and with an accuracy of <math>\pm 5</math> bpm.</p> <p>Alarming on heart rate limit violation within specified delay time.</p> |

| Measurement                   | Essential Performance                                                                                                                                                                                                                                     |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Maternal Pulse from Toco (MP) | Measurement of the maternal pulse rate within the specified limits.<br>MP is susceptible to movement artifact potentially resulting in signal loss. It is not intended for continuous MHR monitoring. Limit alarms are not provided.                      |
| NBP                           | Measurement of non-invasive systolic, diastolic, and mean blood pressure and pulse rate within specified accuracy and error limits.<br>Automatic cycling<br>Alarming on limit violations of systolic, diastolic, and mean blood pressure, and pulse rate. |
| SpO <sub>2</sub>              | Measurement of oxygen saturation and pulse rate within the specified accuracy/error limits<br>Alarming on oxygen saturation and pulse rate limit violation.                                                                                               |
| Temperature (tympanic)        | Measurement of temperature within specified accuracy/error limits.<br>Alarming on temperature limit violation.                                                                                                                                            |
| Toco extern                   | Measurement of the external Toco $\pm 5$ units on display and recorder (with paper adjusted).                                                                                                                                                             |
| Toco intern (IUP)             | Measurement of the internal Toco $\pm 2$ mmHg on display and recorder (with paper adjusted).                                                                                                                                                              |
| Ultrasound                    | Measurement of the fetal heart rate $\pm 5$ bpm on display and recorder (with paper adjusted).<br>Ultrasound energy within safe limits for continuous operation: $p_- < 1$ MPa, $I_{ob} < 20$ mW/cm <sup>2</sup> , $I_{spta} < 100$ mW/cm <sup>2</sup> .  |

The table above also represents the minimum performance when operating under non-transient electromagnetic phenomena according IEC 60601-1-2:

- Radiated electromagnetic fields
- Conducted disturbances induced by RF fields
- Conducted disturbances induced by magnetic fields
- Voltage dips/voltage variations

The following table identifies minimum performance for transient electromagnetic phenomena according IEC 60601-1-2:

- Electrostatic Discharge (ESD)
- Electrical Fast Transients/Bursts
- Surges
- Voltage interruptions

| Measurement | Essential Performance                                                                                                                                                                                                                 |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| All         | After electrostatic discharge, fast transients/bursts, surges and electro surgery interference, the equipment will return to previous operation mode within 10 seconds (SpO <sub>2</sub> 30 seconds) without loss of any stored data. |
|             | After voltage interruptions the equipment returns to previous state without operator intervention and loss of data.                                                                                                                   |

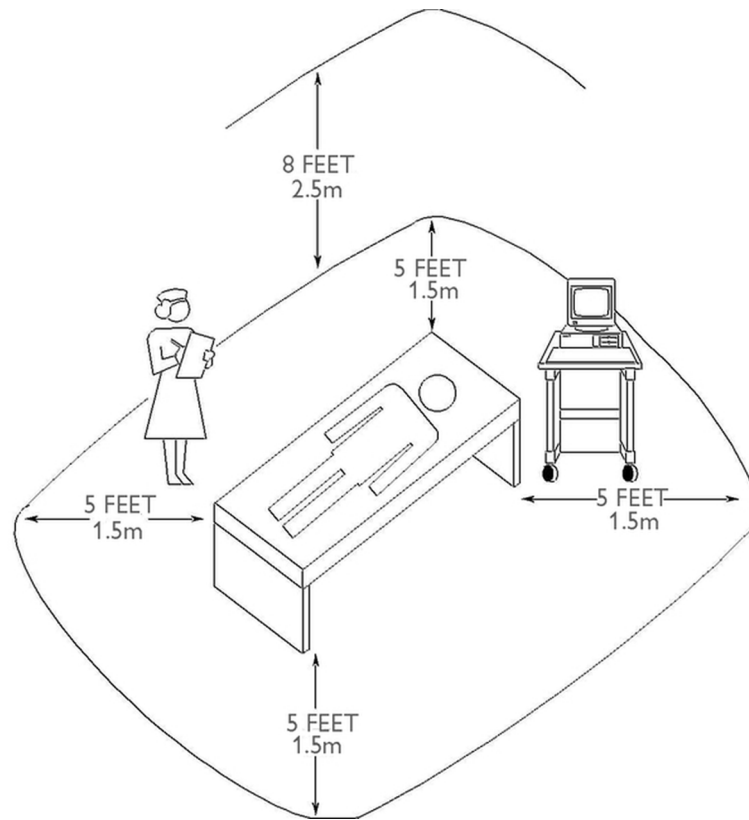
## Connecting Non-Medical Devices

The standard IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 applies to any combination of devices, where at least one is a medical device. Therefore IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 must still be met after all devices are connected.

### WARNING

- Do not use a device in the patient vicinity if it does not comply with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. The whole installation, including devices outside of the patient vicinity, must comply with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. Any non-medical device, including a PC running an OB TraceVue/IntelliSpace Perinatal system, placed and operated in the patient's vicinity must be powered via a separating transformer (compliant with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010) that ensures mechanical fixing of the power cords and covering of any unused power outlets.
- Do not connect any devices that are not supported as part of a system.

Whenever you combine equipment to form a system, for example, connecting the monitor to an OB TraceVue system/IntelliSpace Perinatal system, perform a system test according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 (see "Touchscreen Calibration" on page 96).



Equipment location in the patient vicinity

### **Cabling Options and Requirements for Connection to OB TraceVue/ IntelliSpace Perinatal**

For cabling options and requirements for connection to an OB TraceVue/IntelliSpace Perinatal system, refer to the OB TraceVue/IntelliSpace Perinatal Site Preparation Guide and the OB TraceVue/IntelliSpace Perinatal Service Guide.

## Mounting Options

The following mounting options are available:

| Part Number | 12NC         | Product Option Number | Description                                                    |                                                                                       |
|-------------|--------------|-----------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------|
| M2740-64001 | 451261009061 | M2740A #A01           | MECHASY Wall Mount<br>Flush wall mount for flat wall mounting  |    |
| M2740-64002 | 451261009071 | M2740A #A05           | MECHASY Wall Mounting arm with tray                            |    |
| M2740-64005 | 451261009101 | M2740A #R01           | MECHASY Roll Stand with tray                                   |   |
| 5061-8324   | 451261009111 | M2740A #W01           | MECHASY Wall Channel-19                                        |  |
| n/a         | n/a          | M2740A #C02           | Cart with fixed angle mount and two drawers                    |  |
| n/a         | n/a          | M2740A #U01           | Mounting kit for Avalon CL/Avalon CTS for use with M2740A #C02 |  |

## 2 Site Preparation

| Part Number | 12NC | Product Option Number | Description |                                                                                     |
|-------------|------|-----------------------|-------------|-------------------------------------------------------------------------------------|
| n/a         | n/a  | M2740A #B01           | Bed hanger  |  |

Refer to “Mounting Instructions” on page 28, or contact your local Philips' representative for advice on mounting the monitor.

## Input Devices

The following table describes the input devices which can be connected to the monitor via the optional USB or PS/2 interface.

| Product Option Number | Part Number | 12NC Part Number | Description                                 |
|-----------------------|-------------|------------------|---------------------------------------------|
| M8024A #A01           | 862454      | 9898 031 24741   | Slimline keyboard with integrated trackball |
| M8024A #B01           | M4046-60104 | 4512 610 00661   | Optical mouse USB/PS/2                      |
| M8024A #C01           | M4046-60103 | 4512 610 00651   | Wired track ball USB/PS/2                   |
| M8024A #C02           | M4046-60105 | 4512 610 00671   | Wireless track ball                         |
| M8024A #C03           | M4046-60106 | 4512 610 00681   | Wired off table track mouse                 |

# Installation Instructions

Installation should be carried out by authorized and qualified service personnel, by Philips directly, or a Philips certified service partner/dealer.

**As the first step in preparing the monitor for use, follow the installation instructions given in this chapter.**

The information contained in this chapter, in addition to that given in the Instructions for Use, should enable the monitor to be installed ready for use (the preparation and planning should be adhered to as specified in the “Site Preparation” chapter). Safety checks and inspection procedures for mounts are explained in the “Testing and Maintenance” on page 55 chapter, and the configuration of the system is explained in the Configuration Guide.

Not all accessories and supplies may be available in all geographies. Please contact your local Philips sales representative for details of availability.

Please keep the packing materials until you have completed the initial inspection, in case there is a defect on arrival.

## Installation Checklist Fetal Monitor

Use this checklist to document your installation.

| Step | Task                                                                                                                                                                                                                                          | Check when done |
|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 1    | Perform initial inspection of delivery, unpack, and check the shipment (see “Unpacking and Checking the Shipment Fetal Monitors” on page 26)                                                                                                  |                 |
| 2    | Mount the monitor as appropriate for your installation (see “Mounting Instructions” on page 28)                                                                                                                                               |                 |
| 3    | Connect the fetal monitor to AC mains using the supplied power cord. This configuration varies, depending whether an external power supply/battery option is used (see “External Power Supply (FM20/30 Battery Option #E25 only)” on page 29) |                 |
| 4    | Perform safety tests (see “Safety Tests” on page 59)                                                                                                                                                                                          |                 |
| 5    | Check that default settings (including the line frequency) are appropriate for your institution                                                                                                                                               |                 |
| 6    | Check/set the paper scale (see “Checking/Setting Paper Scale” on page 36)                                                                                                                                                                     |                 |

| Step | Task                                                                                                                                    | Check when done |
|------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 7    | Check/set paper speed (see “Checking/Setting Recorder Speed” on page 36 )                                                               |                 |
| 8    | Perform system test as necessary (see “Performance Assurance Tests” on page 83)                                                         |                 |
| 9    | For monitors with the battery option (#E25) confirm that the battery can be charged, and that the monitor can be powered by the battery |                 |
| 10   | Test transducers (see “Transducers and Patient Modules; Functional Tests” on page 91)                                                   |                 |

## Unpacking and Checking the Shipment Fetal Monitors

Inspect the delivery on arrival. The monitor and any supporting options ordered are packed in protective shipping cartons.

### Initial Inspection

Open the shipping container(s) and examine each part of the instrument for visible damage, such as broken connectors or controls, or scratches on the equipment surfaces. If the shipping carton/ container is undamaged, check the cushioning material and note any signs of severe stress as an indication of rough handling in transit. This may be necessary to support claims for hidden damage that may only become apparent during subsequent testing.

| System Components, Accessories and Supplies                                                                                                       | FM20                  | FM30     |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------|
| Toco <sup>+</sup> Transducer (with belt clip)                                                                                                     | -                     | optional |
| Toco MP Transducer (with belt clip) <sup>1</sup>                                                                                                  | 1                     | 1        |
| US Transducer (with belt clip)                                                                                                                    | 1                     | 1        |
| Patient Module for DECG/MECG/IUP                                                                                                                  | optional <sup>1</sup> | optional |
| DECG Reusable Leg plate Adapter Cable                                                                                                             | -                     | 1        |
| MECG Adapter Cable                                                                                                                                | -                     | 1        |
| IUP Adapter Cable <sup>2</sup>                                                                                                                    | -                     | optional |
| External Power Supply and MSL Cable                                                                                                               | optional              | optional |
| Event Marker                                                                                                                                      | optional              | optional |
| Fetal Paper Pack (country-specific, installed)                                                                                                    | 1                     | 1        |
| Power Cord                                                                                                                                        | 1                     | 1        |
| Printed Instructions for Use                                                                                                                      | 1                     | 1        |
| Documentation DVD: includes FM20/30 Service Guide, FM40/50 Service Guide, Instructions for Use (including localized versions), and Training Guide | 1                     | 1        |

<sup>1</sup> For assessment of maternal heart rate only.

<sup>2</sup> Ships with Patient Module (K03).

## Electrical Inspection

The instrument has undergone extensive testing prior to shipment. Safety testing at installation is not required (except in situations where devices are interconnected forming a system).

An extensive self-check may be performed. This recommendation does not supersede local requirements.

All tests are described in the "Testing and Maintenance" on page 55 chapter of this manual.

### NOTE

#### **FM20/FM30 with battery option #E25:**

After receiving the equipment, the monitor may be in "shipment mode" to prevent that it is unintentionally powered on during shipment.

In this case, press the On/Standby button for 10 seconds to bring the monitor back into normal operation mode, or connect the monitor to AC mains power via the external power supply and the MSL cable.

## Claims for Damage

When the equipment is received, if physical damage is evident, or if the monitor does not meet the specified operational requirements of the patient safety checks, or the extended self-check, notify the carrier and the nearest Philips sales/support office at once. Philips will arrange for immediate repair or replacement of the instrument without waiting for the claim settlement by the carrier.

## Repackaging for Shipment or Storage

If the instrument is to be shipped to a Philips sales/support office, securely attach a label showing the name and address of the owner, the instrument model and serial numbers, and the repair required (or symptoms of the fault). Resend the device only in safe condition and make sure that it is decontaminated. If available and reusable, the original Philips packaging should be used to provide adequate protection during transit. If the original Philips packaging is not available or reusable, please contact the Philips sales/support office who will provide information about adequate packaging materials and methods.

### NOTE

#### **FM20/FM30 with battery option #E25:**

Before repackaging for shipment, switch the monitor on and disconnect the AC mains power (unplug MSL cable). Press the On/Standby button and hold it for approx. 10 seconds until you hear a beeping sound. Then release the button. The monitor is now in "shipment mode". This prevents that it is unintentionally powered on during shipment.

To bring the monitor back into normal operation mode, press the On/Standby button again for 10 seconds, or connect the monitor to AC mains power via the external power supply and the MSL cable. If available and reusable, the original Philips packaging material should be used for repackaging to protect the On/Standby button from pressure during shipment.

For data protection use the **Erase All** function (new with release J.3) to erase all stored fetal/maternal traces before shipping the monitor. The function **Erase All** is available as a pop-up key when the **Stored Data Recording** window is opened. With prior releases erase the data by entering the Service Mode and selecting **Coldstart** in the **Setup Hardware** menu.

## Mounting Instructions

Every type of compatible mounting solution is delivered with a complete set of mounting hardware and instructions. Refer to the “Site Preparation” chapter for a list of mounting options. Refer to the documentation delivered with the mounting hardware for instructions on assembling mounts.

### WARNING

It is the customer's responsibility to have the attachment of the mounting hardware to the ceiling, wall, or mounting rail and the construction of the ceiling, wall, or mounting rail evaluated for structural integrity and compliance with all local, state and any other required codes by a registered, professional, structural and/or mechanical engineer.

Ensure that this commitment has been met before assembling mounts.

## Mounting the External Power Supply (M8023A)

The external power supply (M8023A option #E25) can be rested on its rubber feet on a flat, level surface, or mounted.

The following pictures show some examples of correct and incorrect ways to mount the power supply.

|           |                                                                                     |                                                                                      |                                                                                       |
|-----------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Correct   |  |                                                                                      |                                                                                       |
| Incorrect |  |  |  |

## Line Voltage Selection

You do not need to set the line voltage, as this is done automatically by the power supply. The monitor has a wide-range power supply that allows you to operate the monitor from an AC (alternating current) power source of 100V — 240V ( $\pm 10\%$ ) and 50/60 Hz ( $\pm 5\%$ ).

## Connecting the Monitor to AC Mains

The monitor is an electrical Class II device in which the protection against electric shock does not rely on basic insulation and a protective earth conductor, but on double and/or reinforced insulation.

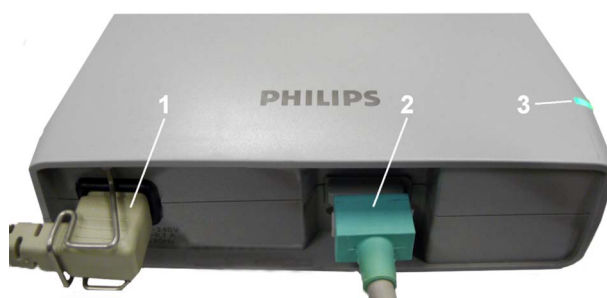
### WARNING

- Always use the supplied power cord with the earthed mains plug to connect the monitor to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
- The protective earth conductor is required for EMC purposes. It has no protective function against electric shock! The protection against electric shock in this device is provided by double and/or reinforced insulation.
- Do not use AC mains extension cords or multiple portable socket-outlets.

Always ensure that the monitor is positioned so that the AC mains plug is easily accessible, to allow disconnection of the monitor from the AC mains.

## External Power Supply (FM20/30 Battery Option #E25 only)

The external power supply M8023A (option #E25) allows you to operate the fetal monitor from an AC (alternating current) power source of 100V — 240V ( $\pm 10\%$ ) and 50/60 Hz ( $\pm 5\%$ ). If this option is used, then the M8023A (option #E25) power supply is included for FM20/FM30.



- 1 AC power cord. Connect to AC mains socket.
- 2 Measurement Link (MSL) cable. Supplies power to the monitor for operation and for battery charging.
- 3 Power-on LED. The green light is on when the external power supply is connected to AC mains.

---

**WARNING**

- Always use the supplied power cord with the earthed mains plug to connect the external power supply M8023A (option #E25) to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
  - Do not use AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet without an approved isolation transformer is used, the interruption of its protective earthing may result in enclosure leakage currents equal to the sum of the individual earth leakage currents, so exceeding allowable limits.
  - Do not connect any devices that are not supported as part of a system.
  - Any non-medical device placed and operated in the patient's vicinity must be powered via an approved isolation transformer that ensures mechanical fixing of the power cords and covering of any unused power outlets.
- 

## Disconnecting the Monitor from AC Mains

### **FM20/30**

To disconnect the monitor from AC power, switch the monitor off using the On/Off switch located on the right side of the device, or unplug the power cord from the AC mains socket.

### **FM20/FM30 with Battery Option**

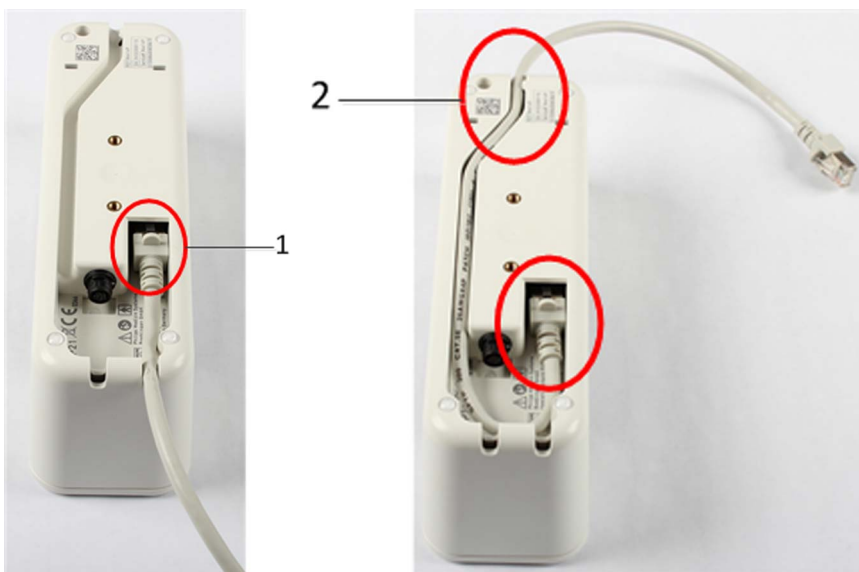
The On/Standby button does not disconnect the monitor from the AC power source. To disconnect, unplug the power cord from the AC mains socket. Note that if the power cord is unplugged from the AC mains socket before the monitor is put into Standby, a beeper is activated. The beeper warns you if the monitor is accidentally disconnected from AC mains.

## Connecting the Monitor to Non-Medical Devices

Connect the monitor to an obstetrical surveillance system, such as OB TraceVue/IntelliSpace Perinatal, via the optional system interface. For cabling requirements, refer to “Cabling Options and Requirements for Connection to OB TraceVue/IntelliSpace Perinatal” on page 22. For safety-related information, refer to “Touchscreen Calibration” on page 96.

## Installing the Tympanic Thermometer

- 1 Insert the communication cable into the connector (1) until it clicks into place. Then route the communication cable through one of the channels (2) in the base station.



- 2 Attach the mounting plate or mounting clamp to the base station. See “Mounting the Tympanic Thermometer” on page 33 for details.
- 3 Insert the thermometer cable into the base station by aligning the white arrows on the cable connector and the base station.



- 4 Route the cable through the strain relief (1) in the base station.

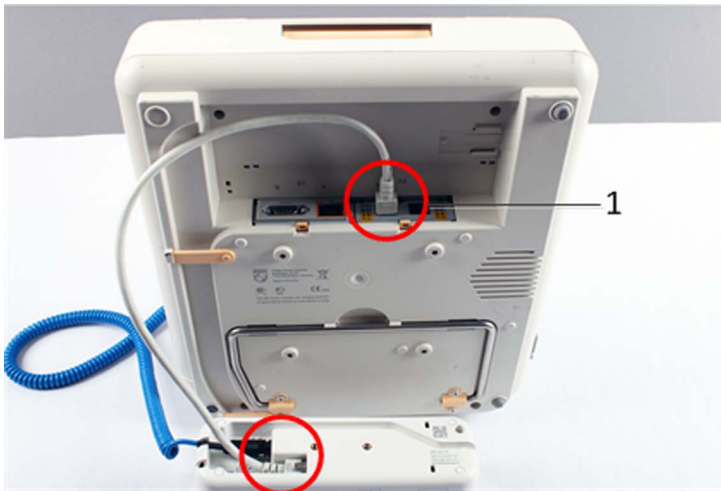


### 3 Installation Instructions

- 5 Insert the probe covers into the base station. Up to two units of 16 probe covers each can be stored within the base station.
- 6 Insert the thermometer into the base station until it clicks into place.



- 7 Insert the other end of the communication cable into the MIB/RS232 (1) port of the monitor.



- 8 Configure the MIB/R232 port at the fetal monitor to iTemp.  
Switch to the Service Mode.  
Select the **Main Setup** SmartKey to open the **Main Setup** window and select **Hardware** from the menu.  
In the **Setup Hardware** window select **Interfaces**.  
In the **Setup Interfaces** window select **iTemp** for the MIB/R232 port.

#### NOTE

When disconnecting the thermometer cable from the base station, DO NOT twist the connector. Pull on the ring of the connector to disconnect the cable.

## Mounting the Tympanic Thermometer

The Tympanic Thermometer can be mounted either to the wall using a mounting plate, or to a pole, or rail mount using the universal mounting clamp.

The picture below shows as an example, how the mounting clamp is attached to the Tympanic Thermometer base station.



## Tympanic Thermometer Biotech Mode

### NOTE

To access the biotech mode, switch off the tympanic thermometer, and remove the probe cover.

The biotech function is used to select the operational mode of the thermometer, and to verify the installed software version. All operational mode settings in biotech mode are stored in nonvolatile memory and retained through system power cycles, such as changing batteries. All factory calibration parameters are also stored in nonvolatile memory.

The factory default settings are shown below:

|                  |               |
|------------------|---------------|
| Temperature mode | °C (unlocked) |
| Site mode        | Ear           |
| Site text        | On            |

The Tympanic temperature has an operating range within the ambient temperature range of 16°C — 33°C (60.8°F — 91.4°F).

The biotech mode is accessed by pressing and holding the timer and °C/°F buttons for four seconds. All LCD segments will light for one second, the thermometer will issue a single beep, and the display will show scrolling dashes. Pressing the timer button cycles through the biotech modes. When options are available within a mode, the °C/°F button cycles through the options.

### 3 Installation Instructions



Pressing the timer button after the site text display will return you to the installed software version. To exit biotech mode, two options are available: (1) press and hold the °C/°F and timer buttons for one second, or (2) the device will automatically exit biotech mode after about 30 seconds of inactivity. Any changes are saved.

The biotech mode sequence is shown below:

#### Software version

Displays the installed software version of device. Where “00” is the current software version.



#### Temperature mode

°C (unlocked)



Locked °C



Locked °F



°F (unlocked)



#### Site mode

Oral



Core



Rectal



Ear



#### Site text

Pressing the °C/°F button when in this mode turns the body site text labels on or off. The labels will remain on when an “X” appears inside the box icon, and the text will remain off when the box is empty.



## Before Using the Monitor

---

### WARNING

- Before starting monitoring, check that the configuration meets your requirements.
  - Be aware that the monitors in your care area may each have different alarm settings, to suit different patients. Always check that the alarm settings are appropriate for your patient before you start monitoring.
- 

Check that the following configuration settings are suitable:

- Line Frequency
- Paper Scale
- Paper Speed
- Equipment Label
- Configured SmartKeys
- Input device configuration (if using an external keyboard or mouse)

If you need to enter configuration mode to change settings:

- 1 In the **Main Setup** menu, select **Operating Modes**.
- 2 Select **Config** and enter the passcode.  
The passcode for Configuration Mode is given in the monitor's service documentation.

The monitor displays **Config** at the right hand side of the status line, and in the center of the screen while you are in Configuration Mode.

Before you leave Configuration Mode, always be sure to store any changes you made. You must store changes made to each Settings Block and to each Profile, individually. As it may be difficult to remember whether the settings you changed belong to a Monitor Settings block or a Measurement Settings block, we recommend that you store each block before you leave Configuration Mode.

To leave Configuration Mode:

- 1 Enter the **Main Setup** menu.
- 2 Select **Operating Modes**.
- 3 Select **Monitoring**.

## Checking and Setting Line Frequency

Before using the monitor, check that the line frequency setting is correct for your location, and change the setting if necessary in Configuration Mode.

### WARNING

An incorrect line frequency setting can affect the ECG filter, and disturb the ECG measurement. Ensure the line frequency setting is correct.

To set the line frequency:

- 1 Enter the **Main Setup** menu.
- 2 Select **Global Settings**.
- 3 Select **Line Frequency** and select **50 Hz** or **60 Hz** from the pop-up list.

## Checking/Setting Paper Scale

Check the paper **Scale Type** (**US** for paper with a scale of 302—40, or **Internat'l** for paper with a scale of 50—210) in the **Fetal Recorder** menu. In Monitoring Mode, you can see this setting (grayed out), but you cannot change it. It can be only changed in Configuration Mode.

- 1 Enter the **Main Setup** menu by selecting the SmartKey.



- 2 Select **Fetal Recorder**.
- 3 Check the current setting for **Scale Type**. If it is not appropriate, change it in the **Fetal Recorder** menu in Configuration Mode: Select **Scale Type** to toggle between **US** and **Internat'l**.

## Checking/Setting Recorder Speed

Check the recorder speed before using the monitor. You can choose a recorder speed of 1, 2, or 3 centimeters per minute (cm/min). The default setting is 3 cm/min. In Monitoring Mode, you can see this setting (grayed out), but you cannot change it. It can be only changed in Configuration Mode.

### NOTE

If **Change Rec Speed** is set to **Monitoring**, the **Recorder Speed** can also be changed in Monitoring Mode.

As a change in **Recorder Speed** results in a change in the appearance of an FHR trace, you are advised to ensure ALL monitors in your institution are set to the same speed.

To set the **Recorder Speed**:

- 1 Enter the **Main Setup** menu using the SmartKey.



- 2 Select **Fetal Recorder**.
- 3 In the **Fetal Recorder** menu, you can see the current speed setting. Select **Recorder Speed**.
- 4 Select the desired speed from the given choices: **1**, **2** or **3** cm/min.

## Configuring the Equipment Label

OB TraceVue/IntelliSpace Perinatal requires a unique equipment label. In OB TraceVue/IntelliSpace Perinatal it is possible to prevent connection to monitors with specific equipment labels by the means of a filtering mechanism. For more details, see the OB TraceVue/IntelliSpace Perinatal Instructions for Use.

- 1 Select the **Bed Label** screen element to call up the **Bed Info** menu.
- 2 Select **Equipment Label** to call up the on-screen keyboard.
- 3 Enter the system identifier.

## Configuring SmartKeys

Check that the configured SmartKeys are suitable. Configure the SmartKeys preferred by the institution from a global list of Global Smart Keys. The global list of SmartKeys is stored as a unique monitor setting in the monitor configuration. See the section Configuring Global SmartKeys in the Configuration Guide for details on how to configure the global SmartKey list.

## USB/PS/2 Keyboard/Mouse

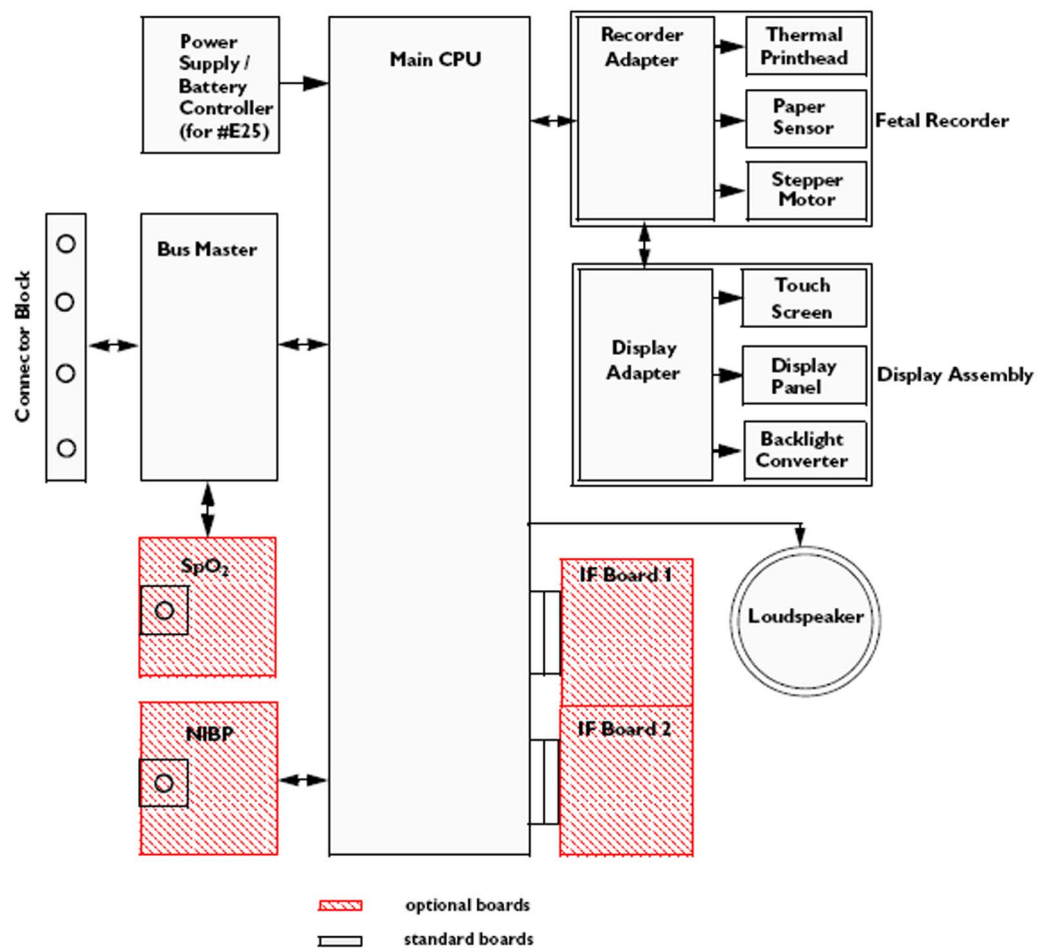
- 1 Switch off the monitor before connecting any USB/PS/2 compatible device.
- 2 Connect the USB/PS/2 connector to the USB/PS/2 Interface board in the monitor at the slot indicated by the appropriate symbol.
- 3 The default keyboard language setting for all initial configurations is "US".
- 4 To configure the keyboard language manually, go to Service Mode, select **Main Setup, Hardware, Keyboard** and then select the proper language. Please note that this setting does not clone.



# Theory of Operation

This chapter describes the functional operation of the monitor and the transducers. It incorporates features of the mechanical design, indicating the physical relationship of the assemblies and components.

## Monitor Hardware Overview



The monitor consists of nine main functional components:

- Power supply M2703-60001

- Connector Block (1253-8415)
- Bus Master Board (M2703-66460)
- Main CPU Board (M2705-66510)
- Fetal Recorder (Thermal Printer Unit)
- Display Assembly (M2703-64503)
- Noninvasive Blood Pressure Board (optional, M2703-64502)
- SpO<sub>2</sub> Board (optional, M2703-66453)
- Input /Output Interface Boards (optional):
  - LAN / RS232 (M2703-67501)
  - Dual PS/2 (M8086-67501)
  - MIB/RS232
  - Flexible Nurse Call
  - Quadruple USB ports

## Power Supply

The power supply is a wide-range input switching unit, with an output of 24V. It is located in the bottom housing assembly.

## Connector Block

Any compatible fetal transducer can be connected in any order to the monitor via the sockets on the Connector Block. The Connector Block is located on the Bus Master Board, and is exchangeable. The assembly made up of the Connector Block and the Bus Master Board is referred to as the Front End Assembly in the chapters “Repair and Disassembly” on page 139 and “Upgrades” on page 213.

## Bus Master Board

The signals from the transducers or sensors are conveyed from the sensor sockets on the Connector Carrier Board (M2703-66421) to the Bus Master Board (M2703-66420).

The Bus Master Board is responsible for transducer detection, communicates with the connected transducers via a CAN bus, and communicates parameter data to the Main CPU Board via a serial link for further processing and display.

## Main CPU Board

The Main CPU Board controls the monitor’s human interface, and is responsible for the final processing of data from the Bus Master Board. It sends this data to the TFT display, and to the thermal printer unit for recording traces, and other patient data. It also controls the optional LAN/RS232, USB, and PS/2 interface boards.

## I/O Boards

A single MIB/RS232, LAN, PS/2, USB, or Flexible Nurse Call Relay board can be added optionally.

An I/O board with three general relays and one dedicated to the power loss condition\*<sup>1</sup>. All relays provide both polarities (active closed, or open contact) at their output. The general relays (#1...#3) can be flexibly configured by the user. Usually they are used to indicated red and yellow alarms.

The board provides one phone jack for backwards compatibility that is connected to the active closed contact of the relay #1, and one full-featured connector with all contacts of all relays. This boards must be plugged into the I/O slot designated for its functionality.

\*1: The power loss indication functionality of the Flexible Nurse Call Relay board is not supported with fetal monitors.

## Fetal Recorder (Thermal Printer Unit)

The fetal recorder is located in the Top Cover Assembly. The recorder consists of the following major parts:

- Recorder Adapter Board
- Thermal Line Printhead (TLPH)
- Paper Sensor
- Stepper Motor

### Recorder Adapter Board

Recorder signals are handled by the Recorder Adapter Board (M2703-66430), connected to the Main CPU Board. Video signals to the display are also wired through this board, and connection to the Display Adapter Board is made via a silver-colored 50-pin ribbon cable.

The recorder unit, including the TLPH, is connected to the Recorder Adapter Board via a white 50-pin, ribbon cable. The stepper motor and the paper sensor are also connected to the Recorder Adapter Board. The Recorder Adapter Board is connected to the Main CPU Board via a 154-pin connector.

### Thermal Line Printhead (TLPH)

The TLPH is located on its own holder in the recorder chassis.

### Paper Sensor

The paper sensor hardware consists of a reflective light sensor that detects the black marks on the trace paper, and paper-out. It is attached to the RFI Bracket, and connected to the Recorder Adapter Board via a removable cable connector.

### Stepper Motor

The stepper motor is a bipolar motor controlled by a micro-stepping motor driver on the Recorder Adapter Board. The motor is located on the recorder chassis, and is connected to the Recorder Adapter Board via a removable cable connector.

# LCD Display and Touchscreen

The LCD Display Assembly consists of a five-wire resistive touchscreen, a 6.5" TFT panel, and an LED back-light, all connected to the Display Adapter Board (M2703-66440), and fitted into the display housing.

The board is connected to the Recorder Adapter Board (M2703-66430) via a 50-pin ribbon cable. The green power LED is incorporated into the Display Adapter Board.

# Noninvasive Blood Pressure Assembly

The optional Noninvasive Blood Pressure Assembly (M2703-64602) is located in the front left-hand corner of the bottom housing assembly. It is connected via a serial link to the Main CPU Board.

# SpO2 Assembly

The optional SpO<sub>2</sub> Assembly (M2703-64603) is physically located on the Bus Master Board, but sends data directly to the Main CPU Board via a serial link.

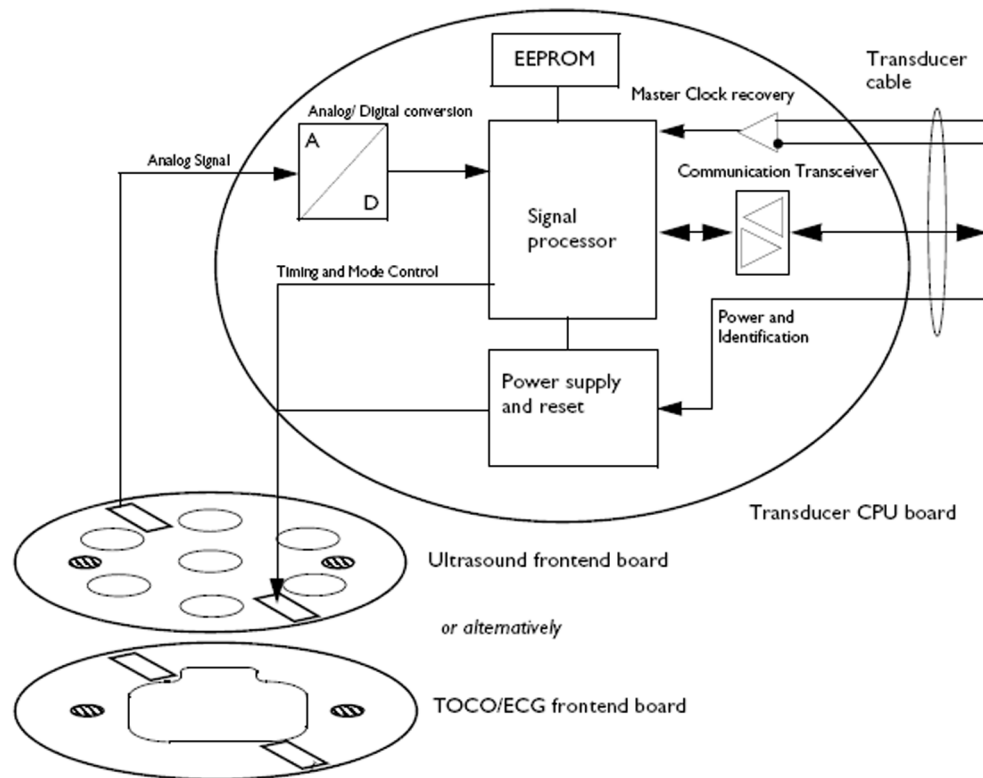
# Input/Output Interface Boards

There are five optional interface boards available:

- LAN/RS232 Interface Board, used for connecting to a PC running the Support Tool and to an obstetrical surveillance and documentation system such OB TraceVue/IntelliSpace Perinatal.
- MIB/RS232 providing two independently configurable ports for connecting Tympanic temperature and providing a data export functionality.
- Quadruple USP ports for connecting a keyboard, bar code scanner, or a mouse.
- Flexible Nurse Call interface to connect to a nurse call system.
- PS/2 Interface Board, used for connecting an external keyboard or mouse.

The interface boards plug into the two interface slots on the underside of the device, and are controlled by the Main CPU Board.

## Transducer Hardware Overview



## Transducer Types

All transducers that can connect to the fetal sensor sockets can be used.

## Functional Description of the Transducer CPU

The CPU section of the transducers is made up of the following main functional blocks:

- CPU (micro controller)
- Analog-to-Digital Converter
- Communication Transceiver (CAN bus driver)
- EEPROM

### CPU (Micro Controller)

A single-chip processor is used to control the transducer, generate the front-end control signals, control the analog-to-digital signal conversion, and to perform the signal processing.

### Analog-to-Digital Converter

Analog-to-digital (A/D) signal conversion is carried out by the 16-bit AD converter. Digital signals are directly communicated from the A/D converter to the CPU.

### Communication Transceiver (CAN Bus Driver)

The communications transceiver (CAN bus driver) communicates directly with the transducer CPU, and allows the transducer to communicate with the Bus Master Board via the CAN bus.

### EEPROM

The serial EEPROM stores all non-volatile data required to operate the transducer (for example, calibration and correction factors for front-end gains and offsets, country-specific information, serial numbers, and error logs).

### Toco Transducer Front-end

Uterine activity is measured by evaluating the hardness of the mother's abdomen with a pressure sensitive resistor bridge (strain gauge sensor element). The strain gauge sensor element requires an excitation voltage and its differential output signal is proportional to the pressure applied to it. A DC excitation voltage is used, and the resulting output signal is fed directly to an A/D signal converter before being sent to the processor.

### Ultrasound Transducer Front-end

The ultrasound front-end is a pulsed Doppler system with a 1.0 MHz ultrasound frequency, and a pulse repetition rate of 3 kHz. Seven ultrasound crystals are used as transmitter and receiver.

### Toco+ Transducer Front-ends

Several parameter front-ends are combined on one board. In addition to the Toco front-end, additional supported parameters are DECG, MEKG, and IUP.

A seven-pin 'D-type' socket carries all parameter related inputs and outputs. An external mode resistor, connected to one of the pins, automatically detects which mode to set when an adapter cable is plugged in (whether it is DECG, MEKG, or IUP).

### IUP Front-end

Intrauterine pressure (IUP) is measured via a piezo resistive bridge with AC excitation connected to the RA/LA input pins of the ECG amplifier. A/D conversion of the IUP signal is done by the 16-bit A/D converter.

### ECG Front-end

The ECG front-end measures both DECG and MEKG, using a 3-lead system (RA, LA, and reference electrode). The ECG mode is automatically detected when an adapter cable is attached. Input lines are ESD protected.

## Patient Module Front-ends

The patient module shares the same parameter front-ends as the Toco<sup>+</sup> transducer, with the exception of the Toco front-end.

## Avalon CTS Interface Cable (TMIF)

The Avalon CTS Interface Cable contains the Telemetry Module Interface (TMIF). The TMIF shares the signal processing circuitry with the rest of the Avalon transducers, with the exception that it has no front-end board. The TMIF is responsible for converting the analog signals from the parameter front-ends of the Avalon CTS transducers into digital signals for transmission to the fetal monitor.



# Interfaces

There are five interface boards available as options for the Avalon fetal monitors:

- LAN / RS232 system interface
- Dual PS/2 interface
- MIB/RS232 interface
- Flexible Nurse call
- USB port



The interfaces are "plug-and-play" boards, and fit into dedicated slots on the underside of the monitor. See "Removing the Interface Boards" on page 197 for details on how to remove and fit the boards.

| Optional Interfaces                                                                 | Description                        |
|-------------------------------------------------------------------------------------|------------------------------------|
|  | Flexible nurse call interface card |
|  | USB ports                          |

## LAN / RS232 Interface

The LAN/RS232 system interface has two fully isolated ports:

- The LAN connection can be used for connecting the monitor to a PC for configuration or upgrade using the Support Tool, for connecting the monitor to an OB TraceVue/IntelliSpace Perinatal obstetrical information system on a network, and for future system expansion.
- The RS232 connection can be used for connecting the monitor to an obstetrical information and surveillance system, such as OB TraceVue/IntelliSpace Perinatal.

If the fetal monitor is connected via a LAN connection to OB TraceVue/IntelliSpace Perinatal or another obstetrical information system, the RS232 interface can be used interdependently to connect e.g. an EMR system on read-only basis. The system connected to the RS232 interface in this case cannot alter any data (such as ADT data or the date and time setting) or interfere with functions of the monitor, but is able to read output data. The obstetrical information system connected via LAN has priority.

## Dual PS/2 Interface

This interface provides two PS/2 ports to enable the monitor to be connected to off-the-shelf, "plug-and-play" input devices:

- Mouse: any specified PS/2 mouse or trackball may be used for navigation and data entry.
- Computer keyboard: a PS/2 computer keyboard can be used for data entry instead of the on-screen pop-up keyboard.

## MIB / RS232 Interface

The MIB interface (IEEE P1073) provides two independently configurable ports for connecting Tympanic Temperature and provides the data export/data out functionality.

If the fetal monitor is connected via a LAN connection to OB TraceVue/IntelliSpace Perinatal or another obstetrical information and surveillance system, the RS232 interface can be used independently to connect e.g. an EMR system on read-only basis. The system connected to the RS232 interface in this case cannot alter any data (such as ADT data or the date and time setting) or interfere with functions of the monitor, but is able to read output data. The obstetrical information and surveillance system connected via LAN has priority.

## Connection of USB Devices

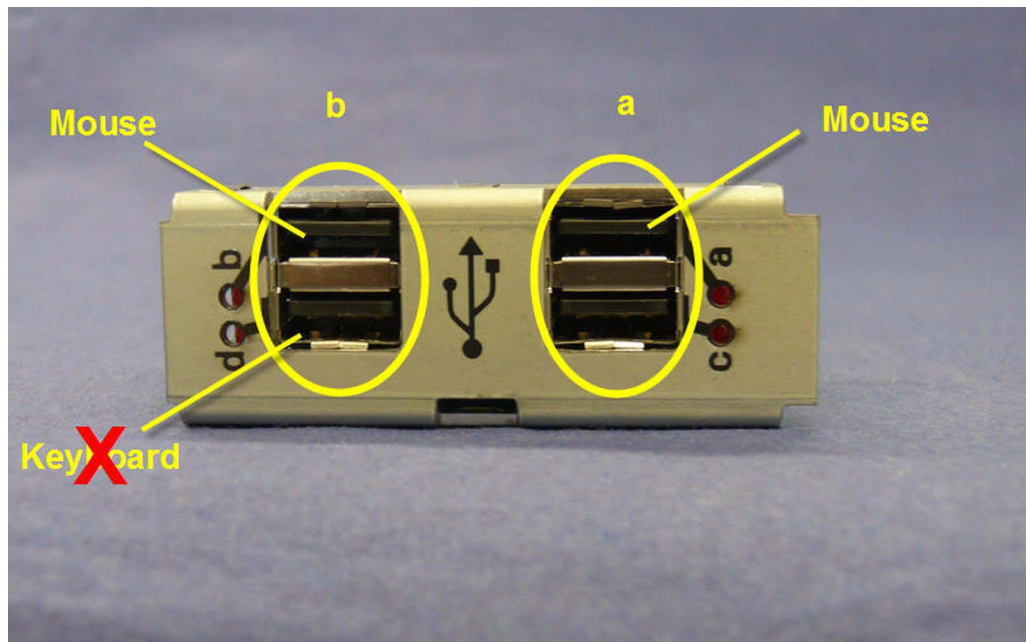
The USB IF board supports the following USB devices:

- keyboard
- barcode scanner
- computer mouse or trackball

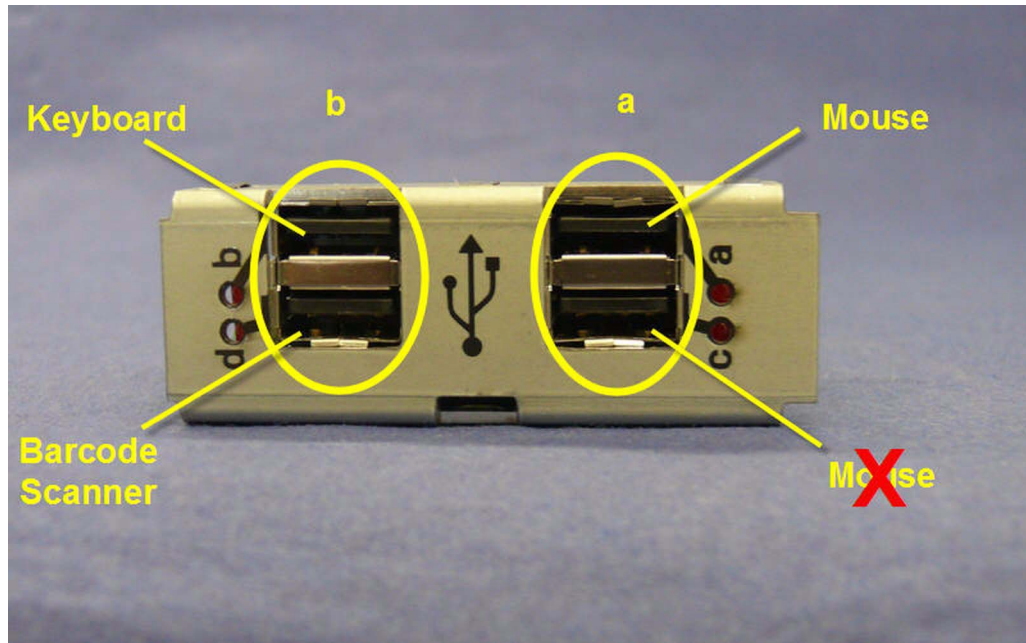
### NOTE

- Connect only the above mentioned devices to the USB interface. Other devices are not supported.

As the fetal monitor software only supports two input devices, only two input devices can be connected to the USB board. For this purpose, the USB ports are divided into two groups, a and b. Only one input device per group is allowed. In the graphic below, a mouse is connected to a port in each group. Therefore the keyboard is not recognized.



It is, however, possible to connect a mouse, a keyboard, and a barcode scanner. In this case, the keyboard and barcode scanner are treated as one input device, and must be connected to two ports of the same group.

**NOTE**

Other USB devices, e.g. USB sticks, iPods etc. are not supported by the USB IF board. **Do not** use USB adapters to connect PS/2 or other devices to the USB board.

## Flexible Nurse Call Relay

The Flexible Nurse Call board contains 2 connectors. A phone jack type connector and a multi-port connector. The phone jack type connector has a single close-on-alarm relay. The multiport connector has three alarm relays which are configurable to be open or closed on alarm.

### Connections



*Flexible Nurse Call Relay Connections at Monitor*

| Nurse Call Relay          | Connectors                                                                                                 | Contact                         | Isolation |
|---------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------|-----------|
| Flexible Nurse Call Relay | 20 pin MDR (Mini D-Ribbon), active open and closed contacts, 3.5 mm phone jack, active closed contact only | $\leq 100$ mA,<br>$\leq 24$ VDC | 1.5 kV    |

See “Multi-Port Nurse Call Connector Test (Flexible Nurse Call)” on page 86 for details on the Flexible Nurse Call relay connector pin assignment.

---

# Connection to a Network

You can connect the fetal monitor to an OB TraceVue/IntelliSpace Perinatal obstetrical information and surveillance system on a network using the LAN connection on the optional LAN/RS232 interface.

## Network Infrastructure Requirements

The Avalon FM20/30 sends Connection Indication messages that OB TraceVue/IntelliSpace Perinatal processes to establish an ethernet connection to the fetal monitor. The general requirements for connecting the Avalon FM20/30 to an OB TraceVue/IntelliSpace Perinatal obstetrical surveillance system over a network are as follows:

- The fetal monitor and the data acquisition PC must be in the same network segment.
- Typically, the Avalon FM20/30 requests its IP address from a DHCP/BOOTP service (preferred). Only if a DHCP/BOOTP server cannot be provided, fixed parameters may be configured manually.

---

### CAUTION

It is mandatory that manual IP address configuration is performed by experienced service personnel. Exercise great caution during installation to avoid problems such as duplicate IP addresses, non-matching subnet mask, etc. Documentation of all related configuration details is mandatory, and must be updated with each change to ensure network reliability, especially when exchanging, repairing, or adding devices on the network at a later time. The customer is responsible for complying with common network configuration rules.

---

If no IP address is entered manually, the Avalon FM20/30 requires a BOOTP service to obtain a valid IP address automatically, therefore DHCP or BOOTP service must be available in each network segment. In domain integrated environments, the domain DHCP servers must respond to BOOTP requests, if the fetal monitor is configured to use BOOTP to obtain an IP address. It is recommended that customer IT configures a fixed list of BOOTP addresses for the fetal monitors.

- The ethernet port of the Avalon FM20/30 supports only 10 Mbit/s half-duplex data transfer.

# Data Privacy and Network Security Requirements

## CAUTION

The customer is responsible for complying with applicable data privacy regulations. Network infrastructure must be protected from unauthorized access.

## Connection Indication Messages

Connection Indication (CI) messages can be sent by the Avalon FM20/FM30 in two ways: by Broadcast or by Unicast.

### Broadcast

When CI messages are sent by Broadcast, they have the potential to reach any data acquisition PC in the same network segment, and the connection to the fetal monitor is made dynamically by the next available host PC (the data acquisition PC with the least active connections).

Broadcast is the default, and recommended method for sending CI messages. This is because if there are multiple host PCs available in the same network segment, the Broadcast method provides greater availability by allowing load balancing and failure-tolerant functionality. If a particular host PC happens to be unavailable, the next available PC takes over the connection. In the **Bed Information** menu, the **IP OB System** entry is **0.0.0.0**.

### Unicast

When CI messages are sent by Unicast, the fetal monitor sends a request to a specific target OB TraceVue/IntelliSpace Perinatal/data acquisition hosting PC in the same network segment. The CI message contains the IP address of the target PC, and only this PC will host the connection.

An example where CI messages are typically sent by Unicast is where the fetal monitor and OB TraceVue/IntelliSpace Perinatal PC are installed in the same cart, and you therefore always want the fetal monitor to be hosted by the same PC.

To avoid conflicts where there are multiple OB TraceVue/IntelliSpace Perinatal systems operating in the same network segment, we recommend that you configure the fetal monitors to send the CI messages by Unicast.

To enter the IP address of the target PC:

- 1 Enter Configuration Mode.
- 2 Select **Main Setup**.
- 3 Select **Bed Information**.
- 4 In the **Bed Information** menu, select **IP OB System**.
- 5 Using the pop-up keypad, enter the IP address of the target server, and press **Enter** when you are done.
- 6 Select **Main Setup**.
- 7 Select **Defaults**.
- 8 Save the **Defaults** to make the IP address change permanent.

## Equipment Label and OB TraceVue/IntelliSpace Perinatal Fetal Monitor Domain Name

For connection to an OB TraceVue/IntelliSpace Perinatal system over a network, OB TraceVue/IntelliSpace Perinatal requires each fetal monitor to have a unique equipment label.

When a fetal monitor is configured with an equipment label, this equipment label is sent as part of the CI message. In OB TraceVue/IntelliSpace Perinatal, it is possible to specify a Fetal Monitor Domain Name in the fetal monitor configuration user interface (see OB TraceVue/IntelliSpace Perinatal Instructions for Use for details). The OB TraceVue/IntelliSpace Perinatal system compares this name with the fetal monitor equipment label. Only if the domain name matches the beginning of the equipment label string, is the CI message processed and accepted. Otherwise the CI message is ignored.

Using this filtering process, you can avoid conflicts where there are multiple OB TraceVue/IntelliSpace Perinatal systems operating in the same network segment by controlling which monitors connect to a specific OB TraceVue/IntelliSpace Perinatal system, and which monitors are excluded.

To enter or change the equipment label:

- 1 Enter Configuration Mode.
- 2 Select **Main Setup**.
- 3 Select **Bed Information**.
- 4 In the **Bed Information** menu, select **Equipment Label**.
- 5 Enter the desired equipment label for your monitor (up to 12 alphanumeric characters are displayed), then press **Enter**.

## Data Export/ Data Out Functionality

Data output/export is possible via LAN, or MIB/R232 interfaces.

The I/O boards typically provide data to externally attached devices, for example to RS232 based data collection devices.

For a multi-purpose card it is necessary to configure the card for a particular purpose first. The MIB/RS232 card can support Tympanic Temperature, data import, data export, external touch display (FM40/FM50 only).

For more detailed information on this subject please refer to the Data Export Interface Programming Guide.

## Configuring the LAN Data Export Setting

The data that can be exported via the LAN interface is configurable. You can choose between the following options: all, anonymous data, off. In case of anonymous data the patient name and given name are not included in the data stream.

- 1 To change the **CentralMonitoring** configuration switch, first switch to Configuration Mode.
- 2 To configure the **LAN Data Export** setting, in Configuration Mode, select **Main Setup** to enter the **Main Setup** menu.
- 3 Select **Global Settings**.
- 4 Select **LAN Data Export** and toggle the appropriate setting.

## Configuring the MIB/RS232 I/O Board Data Export Setting

The configuration of a specific MIB/RS232 port can be viewed in Configuration Mode and altered in Service Mode. **Data Out** can be configured up to two times (on two or more MIB/RS232 boards). Note that only the first MIB/RS232 port configured to **Data Out** (i.e. the first one to receive a request) provides wave export. A second MIB/RS232 port configured to **Data Out** will only export numerics.

- 1 To alter the configuration of an MIB/RS232 port select **Main Setup, Hardware, Data Export 1**, or **Data Export 2**, and select the required setting.

|                   |                                                                           |
|-------------------|---------------------------------------------------------------------------|
| <b>AutoSpeed</b>  | Transport protocol with baudrate negotiation, based on the IrDA protocol. |
| <b>Fix 19200</b>  | Transport protocol with a fixed baudrate of 19.200 baud.                  |
| <b>Fix 115200</b> | Transport protocol with a fixed baudrate of 115.200 baud.                 |

- 2 Exit Configuration Mode. You do not need a password to return to Monitoring Mode.

### NOTE

Be aware that if you change a port assignment, this assignment is not reset upon boot up. If the MIB/RS232 board is removed and replaced with a different type of board, the settings are deleted. If the MIB/RS232 board is then refitted, you must reconfigure the MIB/RS232 port. The configuration of MIB/RS232 is not cloned between monitors.

# Testing and Maintenance

## Introduction

This chapter provides a checklist of the testing and maintenance procedures to ensure the performance and safety of the monitor and accessories.

These tests must be performed only by qualified personnel certified by the responsible organization. Qualifications required are: training on the subject, knowledge, experience, and acquaintance with the relevant technologies, standards and local regulations. The personnel assessing safety must be able to recognize possible consequences and risks arising from non-conforming equipment.

All recurring safety and performance assurance tests must be performed under equal environmental conditions to be comparable.

Preventive Maintenance refers specifically to the series of tests required to make sure the measurement results are accurate. The accuracy and performance procedures are designed to be completed as specified in the following sections or when readings are in question.

For detailed instructions on the maintenance and cleaning of the monitor and its accessories, see Care and Cleaning, and Maintenance and Troubleshooting in the monitor's Instructions for Use.

## Terminology and Definitions

The following terms and definitions are used throughout this chapter and taken from the international standards IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010 and IEC 62353.

**Medical System:** a medical electrical system is a combination of at least one medical electrical device and other electrical equipment, interconnected by functional connection, or use of a multiple portable socket-outlet.

**Patient Vicinity:** any area in which intentional or unintentional contact can occur between the patient and parts of the medical system, or between the patient and other persons who have had contact with parts of the medical system. The patient vicinity is defined anywhere within 1.5 m (5 ft.) of the perimeter of the patient's bed and 2.5 m (8.2 ft.) from the floor.

**Separation Device/Transformer:** a component or arrangement of components with input parts and output parts that for safety reasons prevent a transfer of unwanted voltage, or current between parts of a medical system.

**Multiple Portable Socket-Outlet:** a combination of two or more socket-outlets intended to be connected to or integrated with flexible cables or cords, which can easily be moved from one place to another while connected to the power mains.

**Functional Connection:** an electrical connection for transfer of signals and/or power.

**Tests:** Safety or Performance Assurance test procedures which may consist of several steps.

## Recommended Frequency

Perform the procedures as indicated in the suggested testing timetable. These timetable recommendations do not supersede local requirements.

| Tests                       |            | Frequency                                                                |                                                                                                                                                                                                                                          |
|-----------------------------|------------|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Preventive Maintenance      |            | Noninvasive Blood Pressure Calibration                                   | Once every two years, or as specified by local laws (whichever comes first).                                                                                                                                                             |
|                             |            | Tympanic Temperature Calibration                                         | Once a year. If the unit is dropped or damaged, check it and calibrate it before further use. Or if the unit was stored at less than -25°C or above 55°C.                                                                                |
| Other Regular Tests         |            | Visual Inspection                                                        | Before each use.                                                                                                                                                                                                                         |
|                             |            | Recorder Maintenance                                                     | Once a year, or if the printout is degraded.                                                                                                                                                                                             |
|                             |            | Testing Transducers and Patient Modules                                  | Once a year, or if you suspect the measurement is incorrect.                                                                                                                                                                             |
| Performance Assurance Tests |            | Noninvasive Blood Pressure Performance Tests                             | Once every two years, or if you suspect the measurement is incorrect.                                                                                                                                                                    |
|                             |            | SpO <sub>2</sub> Performance                                             |                                                                                                                                                                                                                                          |
| Safety Tests                | Visual     | Visual Inspection                                                        | After each service event.                                                                                                                                                                                                                |
|                             | Electrical | Protective Earth<br>Equipment Leakage Current<br>Patient Leakage Current | Once every two years and after repairs where the power supply is removed or replaced, or if the NBP assembly, SpO <sub>2</sub> board, or fetal sensor connector block is removed or replaced, or the monitor has been damaged by impact. |
|                             |            | System Test                                                              | Once every two years.                                                                                                                                                                                                                    |

## When to Perform Tests

This table tells you when to perform specific tests. See “Carrying Out and Reporting Tests” on page 88 for test details.

### Installation

| Service Event                                                                                                              | Test Block(s) Required - Complete these tests         |
|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|
| Installation of standalone monitor                                                                                         | Perform Visual Inspection and Power On tests          |
| Installation of a monitor in combination with a medical or non-medical device connected to the same multiple socket outlet | Perform Visual Inspection, Power On and System tests  |
| Installation of networked monitor (LAN)                                                                                    | Perform Visual Inspection, Power On, and System tests |

### Preventive Maintenance

| Service Event                                  | Test Block(s) Required - Complete these tests        |
|------------------------------------------------|------------------------------------------------------|
| Noninvasive Blood Pressure performance testing | Perform Noninvasive Blood Pressure Performance tests |

| Service Event                            | Test Block(s) Required - Complete these tests |
|------------------------------------------|-----------------------------------------------|
| Tympanic Temperature performance testing | Tympanic Temperature calibration              |

#### Other Regular Tests and Tasks

| Service Event                         | Test Block(s) Required - Complete these tests                                                                                                                                            |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Visual Inspection                     | Perform Visual Inspection                                                                                                                                                                |
| Transducer and Patient Module Testing | See                                                                                                                                                                                      |
| Recorder Maintenance                  | Regular cleaning and maintenance (see “Transducers and Patient Modules; Functional Tests” on page 91)<br>Perform the recorder selftest (see “Fetal Recorder Selftest Report” on page 98) |

#### Repairs

| Service Event                                                                                                                                                   | Test Block(s) Required - Complete these tests                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Repairs when the monitor has been damaged by impact, liquid ingress, fire, short circuit, or electrical surge                                                   | Perform Visual Inspection, Power On, all Safety tests, and Full Performance Assurance tests                                            |
| Repairs where the power supply, the mains socket or an interface board is removed, or replaced, or the protective earth ground connection is disrupted          | Perform Visual Inspection, Power On, all Safety Tests, and Basic Performance Assurance tests                                           |
| Repairs where the NBP pump has been replaced                                                                                                                    | Perform Visual Inspection, Power On Test, all Safety tests, Basic Performance Assurance test, and NBP Performance test and calibration |
| All repair events involving any of the following:<br>Noninvasive Blood Pressure connector, SpO <sub>2</sub> connector/<br>board or the red fetal sensor sockets | Perform Visual Inspection, Power On, Full Performance tests, and all Safety tests                                                      |

#### Upgrades

| Service Event                                                                                         | Test Block(s) Required - Complete these tests                                                                                                                        |
|-------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Software upgrades                                                                                     | Perform Visual Inspection, Power On test, and Basic Performance Assurance test unless otherwise specified in the Upgrade Installation Notes shipped with the upgrade |
| Hardware upgrades                                                                                     | Perform Visual Inspection, Power On test, and Basic Performance Assurance test unless otherwise specified in the Upgrade Installation Notes shipped with the upgrade |
| Installation of interfaces or hardware where the power supply, or parameter boards need to be removed | Perform Visual Inspection, Power On test, Basic Performance tests, and all Safety tests                                                                              |
| Noninvasive Blood Pressure hardware upgrade M2702AU Option B71                                        | Perform Visual Inspection, Power On, Noninvasive Blood Pressure performance, and all Safety tests                                                                    |
| SpO <sub>2</sub> hardware upgrade M2703AU Option B72                                                  | Perform Visual Inspection, Power On, SpO <sub>2</sub> performance, and all Safety tests                                                                              |
| Noninvasive Blood Pressure/SpO <sub>2</sub> hardware upgrade M2703AU Option B73                       | Perform Visual Inspection, Power On, Noninvasive Blood Pressure/SpO <sub>2</sub> performance and all Safety tests                                                    |

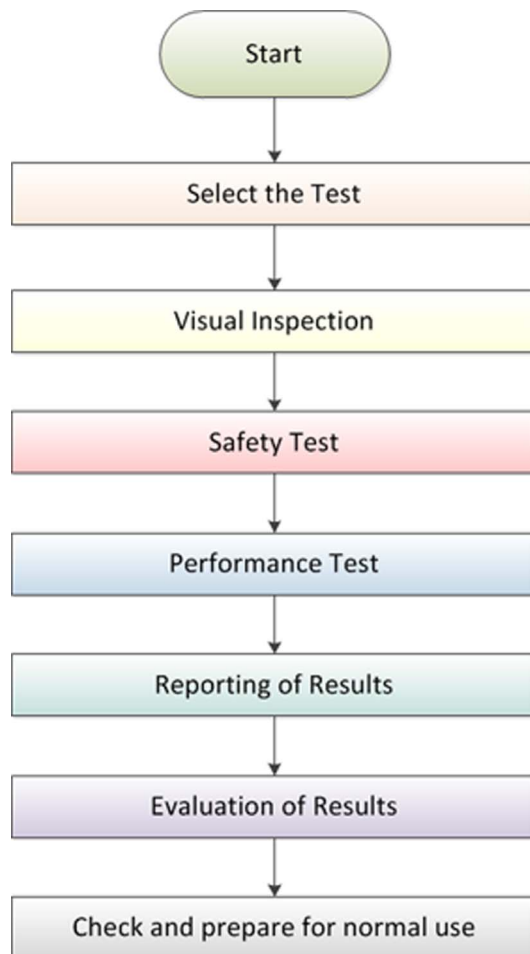
| Service Event                             | Test Block(s) Required - Complete these tests |
|-------------------------------------------|-----------------------------------------------|
| Combining or exchanging system components | Perform the system test                       |

#### NOTE

It is the responsibility of the facility operator, or their designee, to obtain reference values for recurring safety and system tests. These reference values are the results of the first test cycles after an installation. You may also purchase this service from Philips.

## Testing Sequence

Here is a summary of the recommended sequence of testing:



#### NOTE

If any single test fails, testing must be discontinued immediately and the device under test must be repaired or labeled as defective.

# Visual Inspection

## Before Each Use

Check all exterior housings for cracks and damage. Check the condition of all external cables, especially for splits or cracks, and signs of twisting. If serious damage is evident, the cable should be replaced immediately. On the Toco<sup>+</sup> transducer and the patient module, ensure that the adapter cable socket is not damaged. Check that all mountings are correctly installed and secure. Refer to the instructions that accompany the relevant mounting solution.

## After Each Service, Maintenance or Repair Event

Ensure all fuses accessible from the outside comply with the manufacturer's specification.

Check:

- the integrity of mechanical parts, internally and externally.
- any damage or contamination, internally and externally.
- that no loose parts or foreign bodies remain in the device after servicing or repair.
- the integrity of all relevant accessories.

## Power On Test

- 1 Connect the monitoring system to mains and switch on the monitor.
- 2 Make sure that the green LED lights up and switches off again, and the display comes up.

The expected test result: the monitor boots up and display comes up.

# Safety Tests

Safety tests are comprised of the following tests performed on the monitoring system:

- detachable power cord protective earth resistance (optional)
- equipment leakage current
- applied part leakage current
- system test (if required)

Safety test requirements are set according to international standards, their national deviations and specific local requirements. The safety tests detailed in this Service Guide are derived from international standards, but may not be sufficient to meet local requirements. We recommend that you file the results of safety tests. This may help to identify a problem early, particularly if the test results deteriorate over a period of time.

Each individual piece of equipment of the monitoring system, which has its own connection to mains, or which can be connected or disconnected from mains without the use of a tool, must be tested individually. The monitoring system as a whole must be tested according to the System Test procedure.

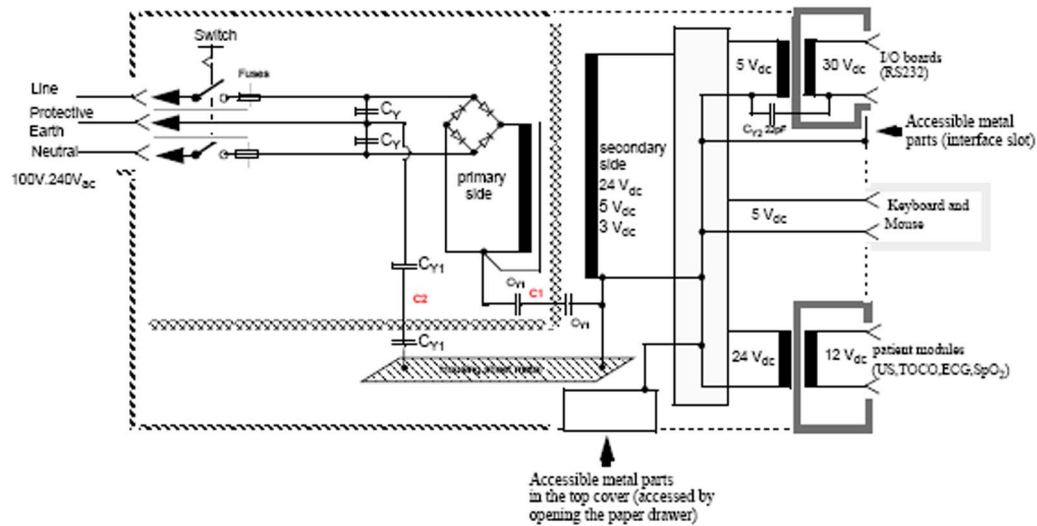
Accessories of the monitoring system which can affect the safety of the equipment under test, or the results of the safety test, must be included in the tests and documented.

## Warnings, Cautions, and Safety Precautions

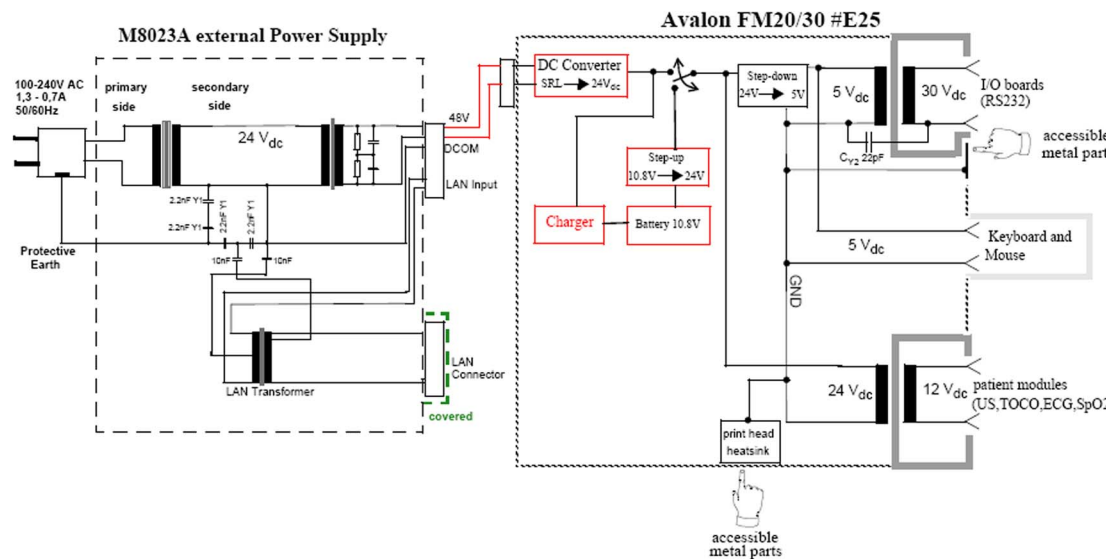
- These tests are well established procedures of detecting abnormalities that if undetected, could result in danger to either the patient or the operator.
- Disconnect the device under test from the patient before performing safety tests.
- Disconnect the device under test from mains before performing safety tests. If this is not possible, ensure that the performance of these tests does not result in danger to the safety analyzer operator, patients, or other individuals.
- Test equipment (for example, a Safety Analyzer) is required to perform the safety tests. Please refer to Annex C of IEC/EN 62353 for exact requirements for the measurement equipment, and for measurement circuits for protective earth resistance, and leakage currents. Refer to the documentation that accompanies the test equipment. Only skilled technicians should perform safety testing.
- The consistent use of a Safety Analyzer as a routine step in closing a repair or upgrade is emphasized as a mandatory step to maintain approval agency status. You can also use the Safety Analyzer as a troubleshooting tool to detect abnormalities of line voltage, and grounding plus total current loads.
- During safety testing, mains voltage and electrical currents are applied to the device under test. Ensure that there are no open electrical conductive parts during the performance of these tests. Avoid that users, patients, or other individuals come into contact with touch voltage.
- For Europe and Asia/Pacific, the fetal monitor complies with: IEC 60601-1:2005+A1:2012/ EN 60601-1:2006+AC:2010
- For USA, the fetal monitor complies with: ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010
- For Canada, the fetal monitor complies with: CAN/CSA C22.2#60601-1-08
- Local regulations supersede the testing requirements listed in this chapter.
- If a non-medical device is connected to the medical electrical device during an installation, the resulting medical electrical system must comply with IEC 60601-1:2005+A1:2012/ EN 60601-1:2006+AC:2010.
- Perform safety tests as described on the following pages.

## Electrical Isolation Diagram

This diagram gives an overview of the electrical isolation of the monitor. Accessible metal parts are identified (see arrows).



*Electrical Isolation Diagram for FM20/30 without battery option*



*Electrical Isolation Diagram for FM20/30 with battery option #E25*

## Safety Test Procedures

Use the test procedures outlined here only for verifying safe installation or service of the product. The setups used for these tests, and the acceptable ranges of values are derived from local and international standards but may not be equivalent. These tests are not a substitute for local safety testing where it is required for an installation or a service event. If using an approved safety tester, perform the tests in accordance with your local regulations, for example IEC/EN 62353, and IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. The safety tester should print results as detailed in this chapter, together with other data.

Please refer to Annex C of IEC/EN 62353 for requirements for the measurement equipment and for measurement circuits for protective earth resistance and leakage currents.

The following symbols are used in the diagrams illustrating the safety tests:



Supply mains



Resistance measuring device

L, N

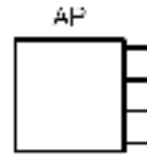
Supply mains terminals

PE

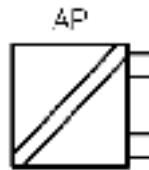
Protective earth terminal



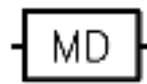
Mains part



Applied part



F-type applied part



Measuring device

.....

Optional connection



Connection to accessible parts

### CAUTION

**After each service, maintenance, or repair event:**

Ensure all fuses accessible from the outside comply with the manufacturer's specification.

Check:

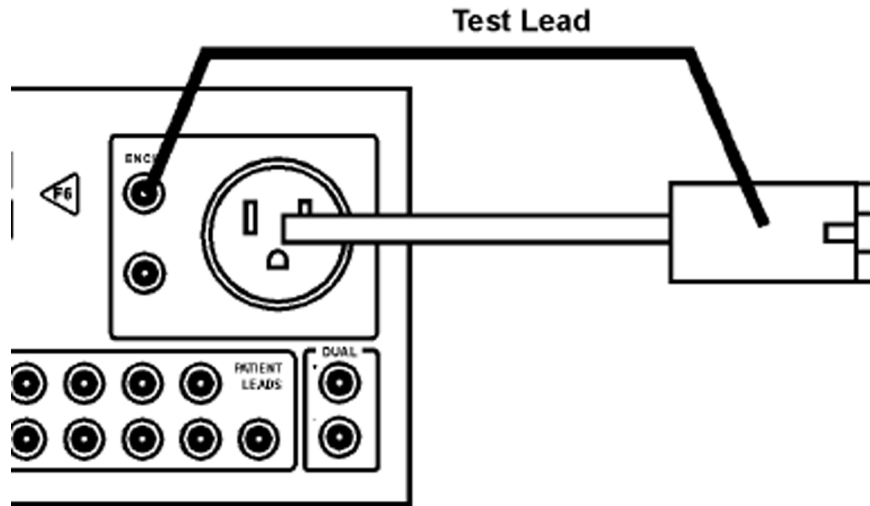
- the integrity of mechanical parts, internally and externally.
- any damage or contamination, internally and externally.
- that no loose parts or foreign bodies remain in the device after servicing or repair.
- the integrity of all relevant accessories.

### Hints for Correct Performance of Safety Tests

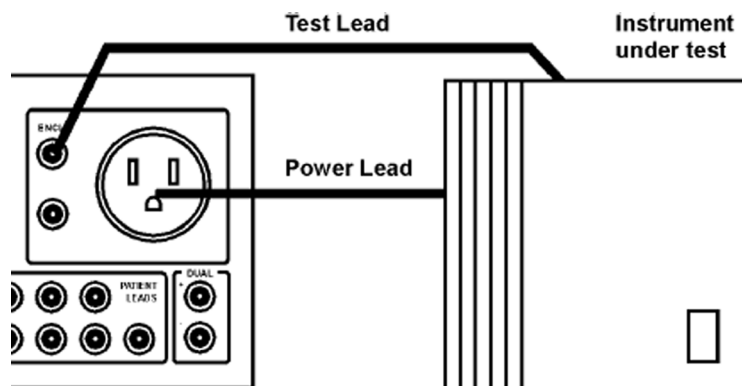
- Perform a visual inspection on all detachable power cords used with the monitoring system, and include these in all safety test procedures.
- Connection lines such as data lines or functional earth conductors may appear to act like protective earth connections. These may lead to incorrect measurements and need to be considered during testing. If necessary, unplug these connections.
- Position all cables and cords in such a manner that they do not influence the safety tests.
- Measurement of insulation resistance is not required.

## General Test Setup for the Performance of Safety Tests

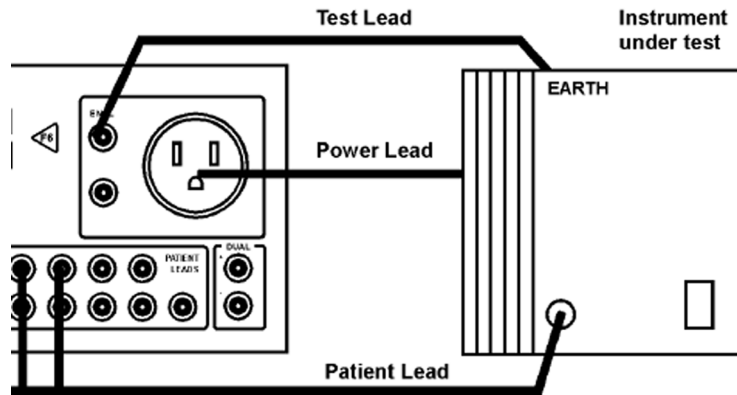
Connect the detachable power cord of the device under test to the safety analyzer's test mains port. For testing the applied part leakage current, connect all applied parts to the safety analyzer using the appropriate patient lead or adapter cable. If necessary, repeat the safety test procedure until all available applied parts have been tested. Refer to the documentation that accompanies the safety analyzer for further details on how to set up and perform the test. Power on the device under test for all tests.



*Protective Earth Resistance Test - Setup Example*



*Equipment Leakage Current Test - Setup Example*



*Applied Part Current Test - Setup Example*

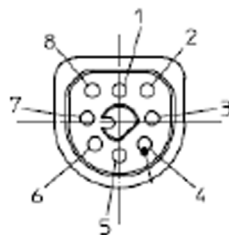
### NOTE

The above graphics resemble the Metron QA-90 setup and are protected by copyright. Copyright owned by Fluke (Metron).

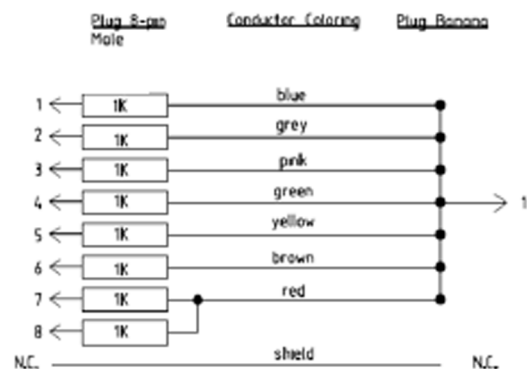
## Safety Test Adapter Cable - Schematics

The following graphics provide schematics of safety test (patient lead) adapter cables which can be used for electrical safety testing. These schematics can also be used as a guideline for making your own safety test adapter cables. Alternatively, other methods to make safety test adapter cables can be used, e.g. using a modified accessory cable.

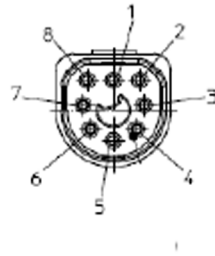
*FM20-FM50 Safety Test Adapter Cable Schematic*



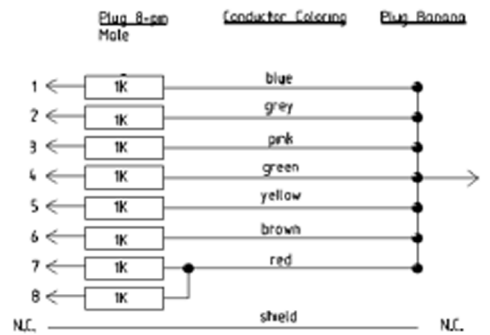
### Wiring Schematic



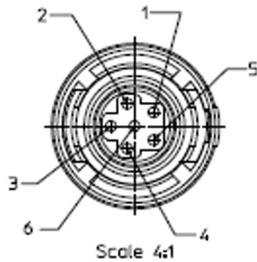
*SpO<sub>2</sub> Safety Test Adapter Cable Schematic*



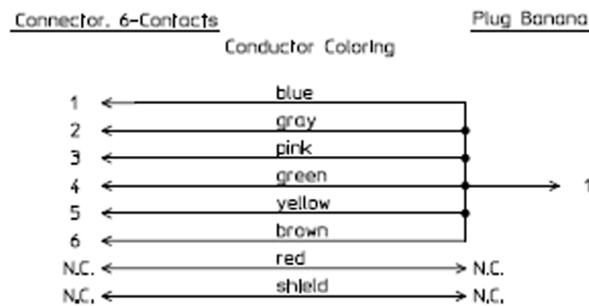
Wiring Schematic



Tympanic Temperature



Wiring Schematic



### S(1): Detachable Power Cord Protective Earth Test (optional)

This test can be performed upon request by the customer. Test to perform:

Use an Ohmmeter to measure the earth wire resistance of the detachable power cord. This safety test is based on IEC/EN 60601-1, IEC/EN 62353, UL2601-1 Ed. 2/UL60601-1:2003 and CSA 601.1-M90. Report the highest value (X1).

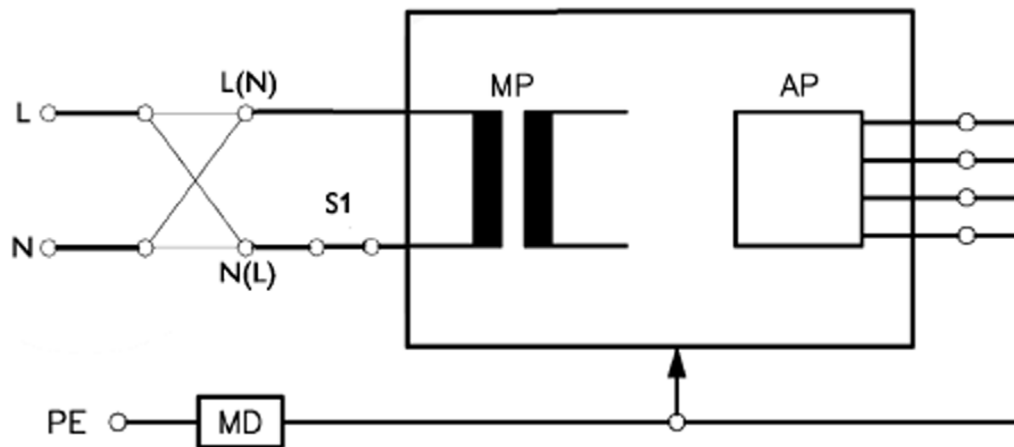
| Test                             | Expected Test Results       |
|----------------------------------|-----------------------------|
| Protective Earth Resistance Test | $X1 \leq 100 \text{ mOhms}$ |

#### NOTE

- If the protective earth resistance test fails, testing must be discontinued immediately, and the device under test must be repaired or labeled as defective.
- Flex the power cord during the protective earth resistance test to evaluate its integrity. If it does not pass the test, exchange the power cord.
- The functional earth conductor is required for EMC purposes. It has no protective function against electrical shock. The protection against electrical shock is provided by double and/or reinforced insulation.

## S(2): Sum of Functional Earth and Equipment Leakage Current Test - Normal Condition

Test to perform:



### Measuring circuit for the measurement of Equipment Leakage Current - Direct method according to IEC/EN 62353

This test measures leakage current of exposed metal parts of the FM20/FM30 monitor and the functional earth leakage current. It tests normal and reversed polarity. Perform the test with S1 closed (normal condition).

#### NOTE

The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. The protection against electric shock is provided by double and/or reinforced insulation.

This safety test is based on IEC/EN 60601-1, IEC/EN 62353, and UL2601-1 Ed. 2/UL60601-1:2003. For measurement limits, refer to test block Safety (1), Option B71. Report the highest value: (X1).

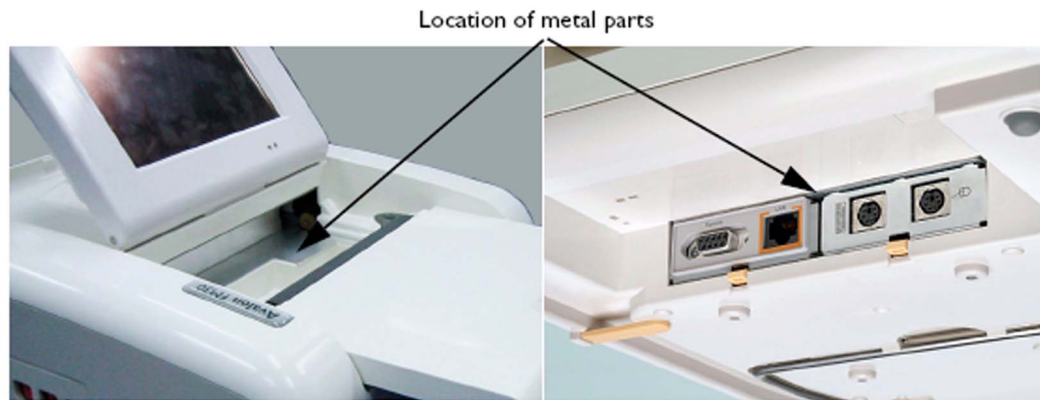
| Test                                                                 | Expected Test Results |
|----------------------------------------------------------------------|-----------------------|
| Equipment Leakage Current test (normal condition - with mains cable) | X1 $\leq$ 100 $\mu$ A |

#### NOTE

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

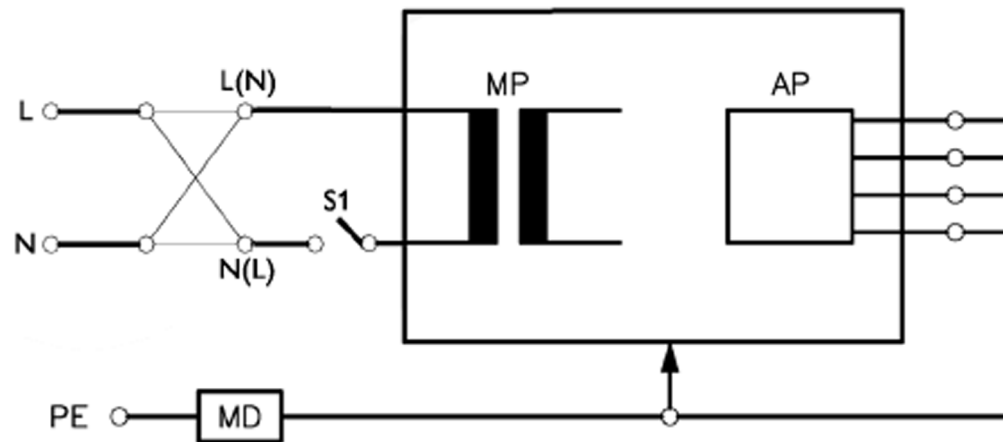
You can find metal parts of the device:

- In the top cover (accessed by opening the paper drawer).
- In an interface slot located in the bottom housing (you need to remove the interfaces if they are fitted).



### S(3): Sum of Functional Earth and Equipment Leakage Current Test - Single Fault Condition

Test to perform:



**Measuring circuit for the measurement of Equipment Leakage Current - *Direct method* according to IEC/EN 62353.**

This test measures leakage current of exposed metal parts of the FM20/FM30 monitor, and the functional earth leakage current. It tests normal and reversed polarity. Perform the test with S1 open (Single Fault Condition).

#### NOTE

The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. The protection against electric shock is provided by double and/or reinforced insulation.

This safety test is based on IEC/EN 60601-1, IEC/EN 62353, and UL2601-1 Ed. 2/UL60601-1:2003. For measurement limits, refer to test block Safety (2), Test and Inspection Matrix. Report the highest value: (X2).

| Test                                                                       | Expected Test Results |
|----------------------------------------------------------------------------|-----------------------|
| Equipment Leakage Current test (Single Fault Condition - with mains cable) | X1 ≤ 100 μA           |

### NOTE

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated

You can find metal parts of the device:

- In the top cover (accessed by opening the paper drawer).
- In an interface slot located in the bottom housing (you need to remove the interfaces if they are fitted).

Refer to the picture showing accessible metal parts under “S(2): Sum of Functional Earth and Equipment Leakage Current Test - Normal Condition” on page 66.

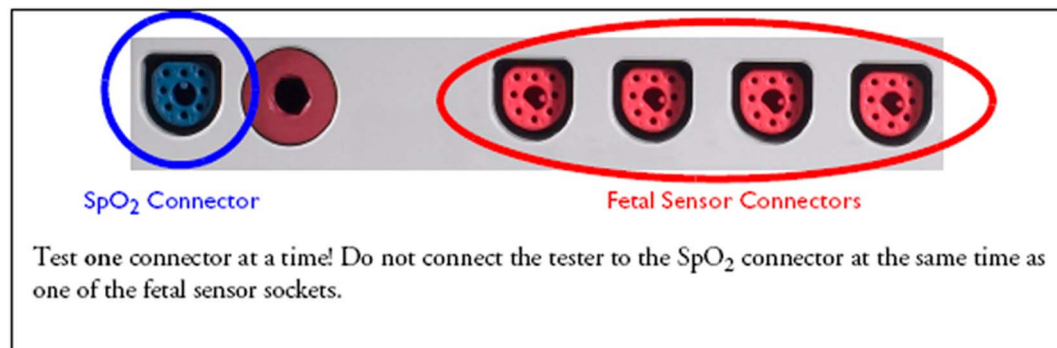
### S(4): Applied Part Leakage Current, Mains on Applied Part

### NOTE

During measurement of the Applied Part Leakage Current it is possible that the measured current can exceed the allowed limit (per IEC/EN 60601-1 or IEC/EN 62353).

This can occur when the safety tester is connected to more than one connector simultaneously, that is, either to two fetal sensor connectors at the same time, or to a fetal sensor connector and the SpO<sub>2</sub> connector at the same time during the applied leakage current measurement.

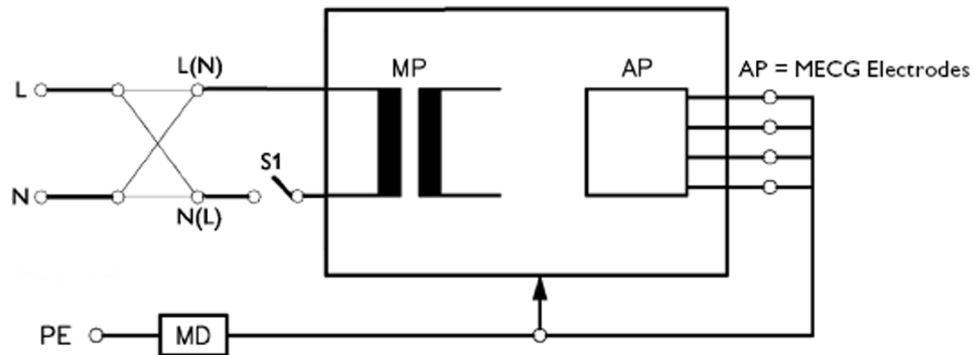
The connectors for the fetal sensors and for SpO<sub>2</sub> are independently functioning connectors.



Although there are individual connectors on the front-end, internally those parameters use the same electrical insulation interface and are hard wired to each other. This results in an electrical short of those connectors during measurement if a test current is applied simultaneously. Therefore this should be avoided.

Due to the combined insulation interface, it is sufficient to connect to only one parameter interface (that is, one of the fetal sensor connectors or SpO<sub>2</sub>) of the fetal sensor/SpO<sub>2</sub> measurement block. This avoids a short and the potential of exceeding the limit for the current.

Test to perform:



**Measuring circuit for the measurement of Applied Part Leakage Current - Direct method according to IEC/EN 62353**

This test measures applied part leakage current from applied part to earth caused by external main voltage on the applied part of 264 V. Each polarity combination possible shall be tested. This test is applicable for ECG measurement inputs.

This safety test is based on IEC/EN 60601-1, IEC/EN 62353, and UL2601-1 Ed. 2/UL60601-1:2003. For measurement limits and test voltage, refer to test block Safety (3), Option B71. Report the highest value: (X1).

| Test                                                                               | Expected Test Results    |
|------------------------------------------------------------------------------------|--------------------------|
| Applied Part Leakage Current test (Single Fault Condition - mains on applied part) | X1 $\leq 50 \mu\text{A}$ |

**NOTE**

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

**Applied Part Leakage Current - Mains on Applied Part for Tympanic Thermometer on Standalone Base Station**

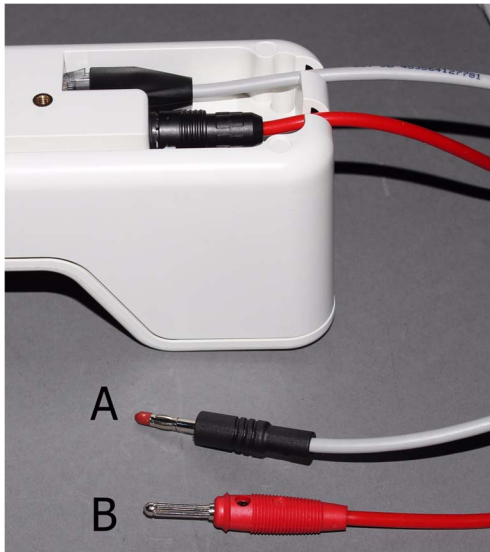
- 1 Remove the interface and the thermometer cable from the base station.

## 7 Testing and Maintenance

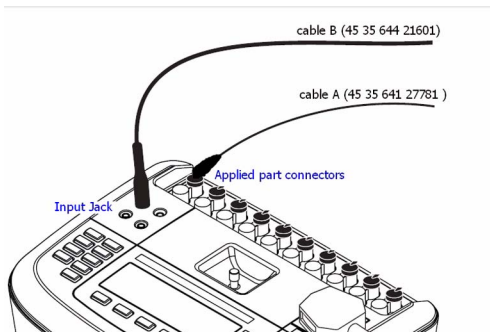
- 2 Insert the two safety test cables as shown below.



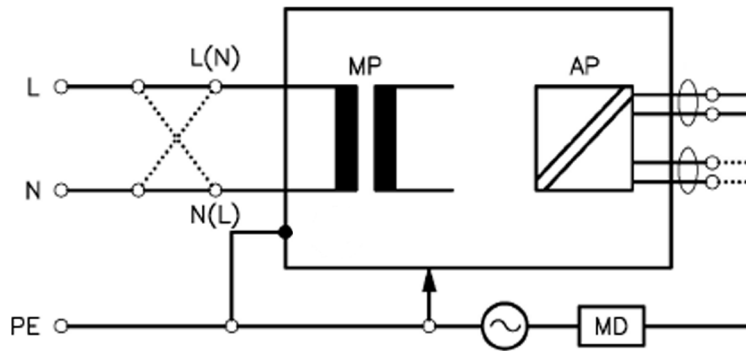
*Cable A (IntelliBridge - 453564127781) and Cable B (Tympanic Temperature - 453564421601)*



- 1 Connect to an appropriate safety tester (e.g. Fluke ESA 620) as shown below.



- 2 Perform the test:



#### Measuring circuit for the measurement of Applied Part Leakage Current - Direct method according to IEC/EN 62353

This test measures applied part leakage current from applied part to earth caused by external main voltage on the applied part. Each polarity combination possible shall be tested. There are no parts of the equipment that are not protectively earthed. This safety test is based on IEC/EN 60601-1, IEC/EN 62353, UL2601-1 Ed. 2/UL60601-1:2003 and CSA 601.1-M90. Report the highest value. (X1).

| Test                                                                               | Expected test results     |
|------------------------------------------------------------------------------------|---------------------------|
| Applied Part Leakage Current test (Single Fault Condition - mains on applied part) | $X1 \leq 5000 \mu A$ (BF) |

#### NOTE

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

In case of an IT-power system, this safety test measurement requires a special measuring circuit, for example with its own integrated TN-system or use of an external isolation transformer attached to the safety test device.

## System Test

After mounting and setting up a system, perform system safety tests according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.

### What is a Medical Electrical System?

A medical electrical system is a combination of at least one medical electrical device and other electrical equipment, interconnected by functional connection or use of a multiple portable socket-outlet.

- Devices forming a system must comply with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.
- Any electrical device such as IT equipment that is connected to the medical electrical equipment must comply with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 and be tested accordingly.

### General Requirements for a System

After installation or subsequent modification, a system must comply with the requirements of the system standard IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. Compliance is checked by

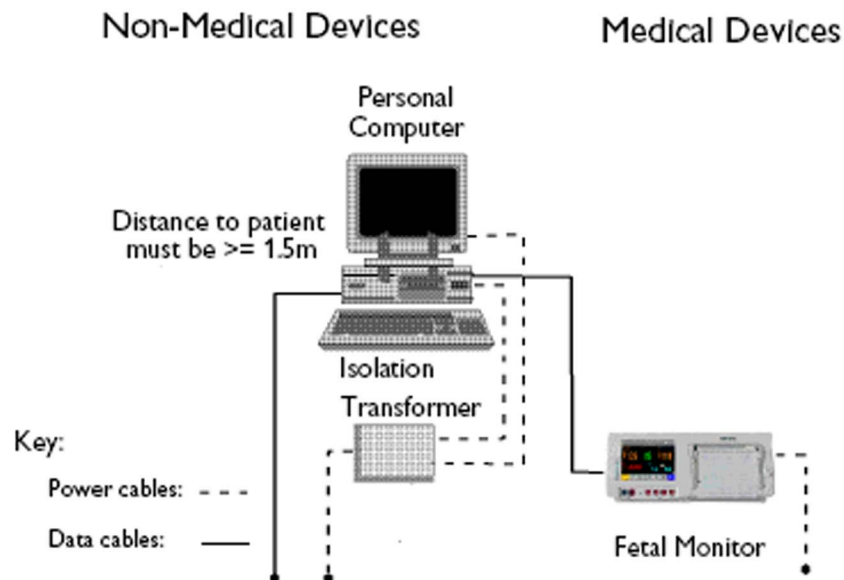
inspection, testing or analysis, as specified in the IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 or in this book.

Medical electrical equipment must comply with the requirements of the general standard IEC/EN 60601-1, its relevant particular standards and specific national deviations. Non-medical electrical equipment shall comply with IEC and ISO safety standards that are relevant to that equipment.

Relevant standards for some non-medical electrical equipment may have limits for equipment leakage currents higher than required by the standard IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. These higher limits are acceptable only outside the patient environment. It is essential to reduce equipment leakage currents when non-medical electrical equipment is to be used within the patient environment.

### System Example

This illustration shows a system where both the medical electrical equipment and the non-medical electrical equipment are situated at the patient's bedside.



#### WARNING

- Do not use additional AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet is used, the resulting system must be compliant with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. Do not place multiple socket-outlets on the floor. Do not exceed the maximum permitted load for multiple socket-outlets used with the system. Do not plug additional multiple socket-outlets or extension cords into multiple socket-outlets or extension cords used within the medical system.
- Do not connect any devices that are not supported as part of a system.
- Do not use a device in the patient vicinity if it does not comply with IEC/EN 60601-1. The whole installation, including devices outside of the patient vicinity, must comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010. Any non-medical device, **including a PC running an OB TraceVue/IntelliSpace Perinatal system**, placed and operated in the patient's vicinity must be powered via a separating transformer (compliant with IEC 60601-

1:2005+A1:2012/EN 60601-1:2006+AC:2010) that ensures mechanical fixing of the power cords and covering of any unused power outlets.

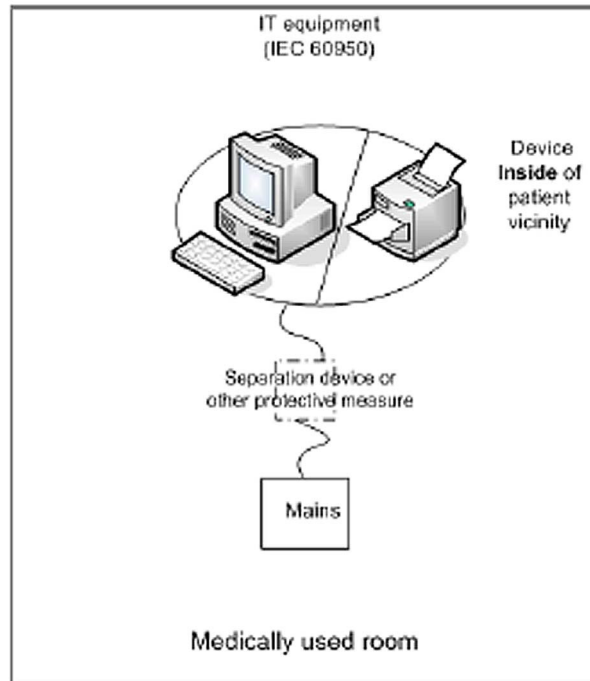
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## System Installation Requirements

- Ensure that the medical electrical system is installed in a way that the user achieves optimal use.
- Make sure the user is informed about the required cleaning, adjustment, sterilization, and disinfection procedures listed in the Instructions for Use.
- The medical electrical system must be installed in such a way that the user is able to carry out the necessary cleaning, adjustment, sterilization, and disinfection procedures listed in the Instructions for Use.
- Ensure that the medical electrical system is installed in a way that an interruption and restoration of power to any part of the medical electrical system does not result in a safety hazard.
- We recommend using fixed mains socket outlets to power the medical system or parts thereof. Avoid using multiple portable socket-outlets.
- Any multiple portable socket outlets used must be compliant with IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.
- Ensure that any part of the system connected to multiple portable socket-outlets is only removable with a tool, i.e. the multiple portable socket-outlet provides a locking mechanism to prevent power cords from being plugged or unplugged unintentionally. Otherwise, the multiple portable socket outlet must be connected to a separation device. Multiple socket outlets used within the medical electrical system must only be used for powering medical electrical equipment which is part of the system.
- Ensure that any functional connections between parts of the medical electrical system are isolated by a separation device according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 to limit increased equipment leakage currents caused by current flow through the signal connections. This only works if the equipment leakage current of the respective medical electrical system parts is not exceeded under normal conditions.
- Avoid increase of equipment leakage currents when non-medical electrical equipment within the medical electrical system is used. This only works if the equipment leakage current of the respective medical electrical system parts is not exceeded under normal conditions. Use additional protective earth connection, separation device, or additional non-conductive enclosures.

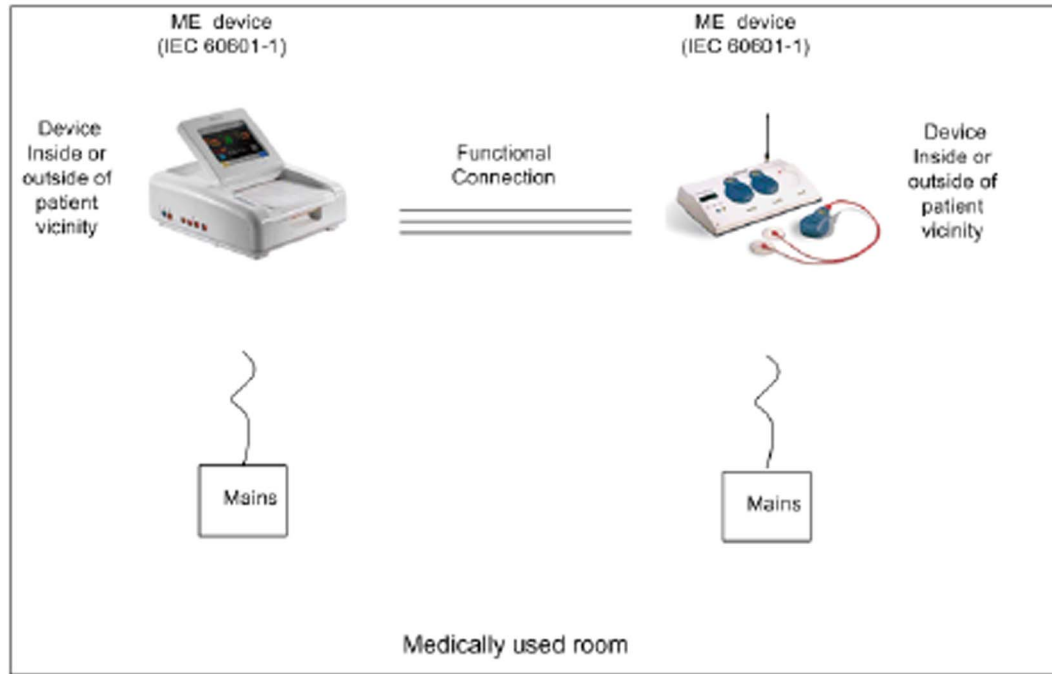
## Required Protective Measures at System Installation

For any IT equipment (IEC 60950) operated in patient vicinity ensure that the equipment leakage current does not exceed the limits described in IEC 60601-1. Use a separation device to ensure compliance. After installation of IT equipment in patient vicinity, an enclosure leakage current test is required.

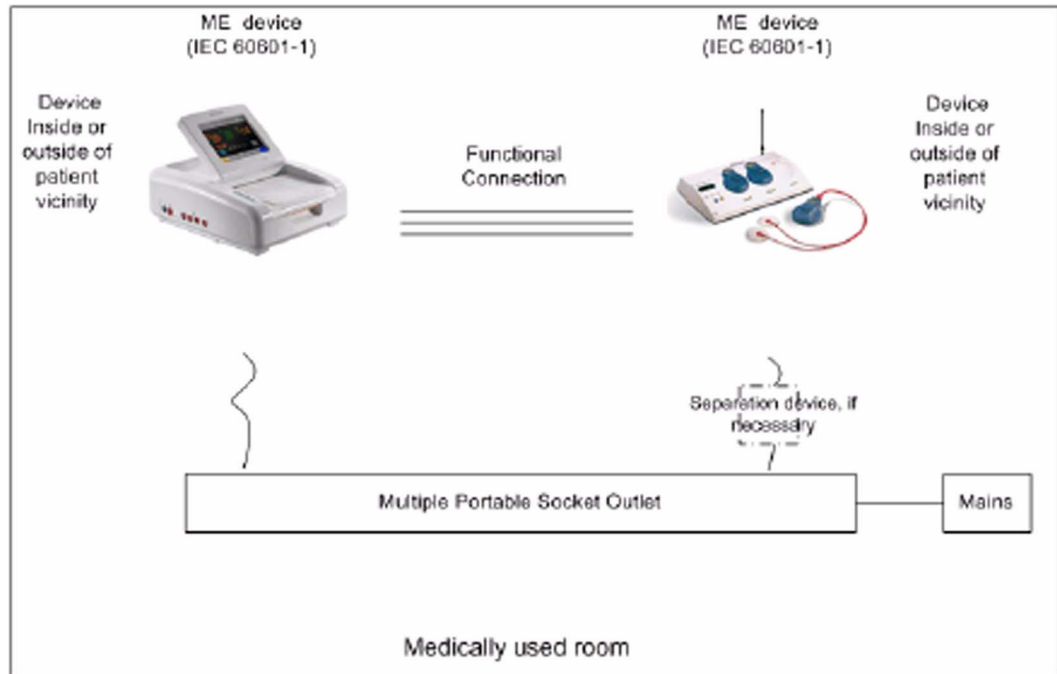


## Case 1: Medical Device Combined with Medical Device

If you combine a medical device with another medical device (incl. Philips specified displays) to form a medical electrical system according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010, no additional protective measures are required. The medical electrical devices may be located in or outside the patient vicinity in a medically used room. This is valid as long as the medical devices are connected to separate mains outlets. No system test is required.

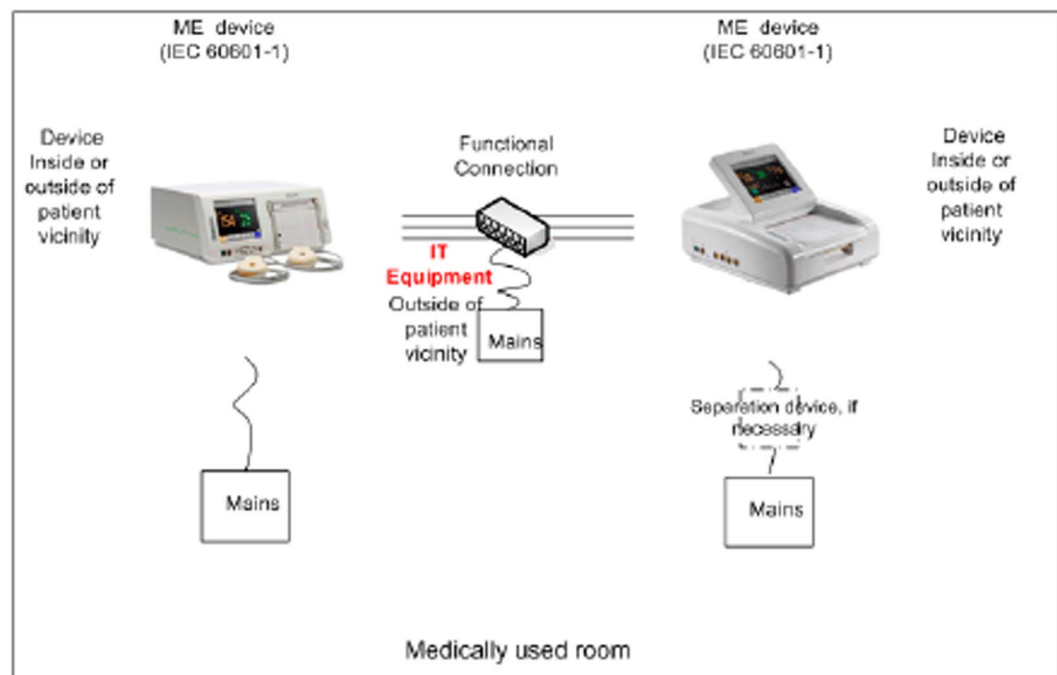


If the combined medical devices are connected to the same multiple portable socket outlet an enclosure leakage current test of the entire device combination on the multiple portable socket outlet is required to ensure that the resulting protective earth leakage current and equipment leakage current does not exceed the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. Avoid using multiple portable socket outlets. The medical electrical devices may be located in or outside the patient vicinity in a medically used room. If the limits are exceeded, additional protective measures are required, e.g. a separation device or the connection of each device to separate mains.

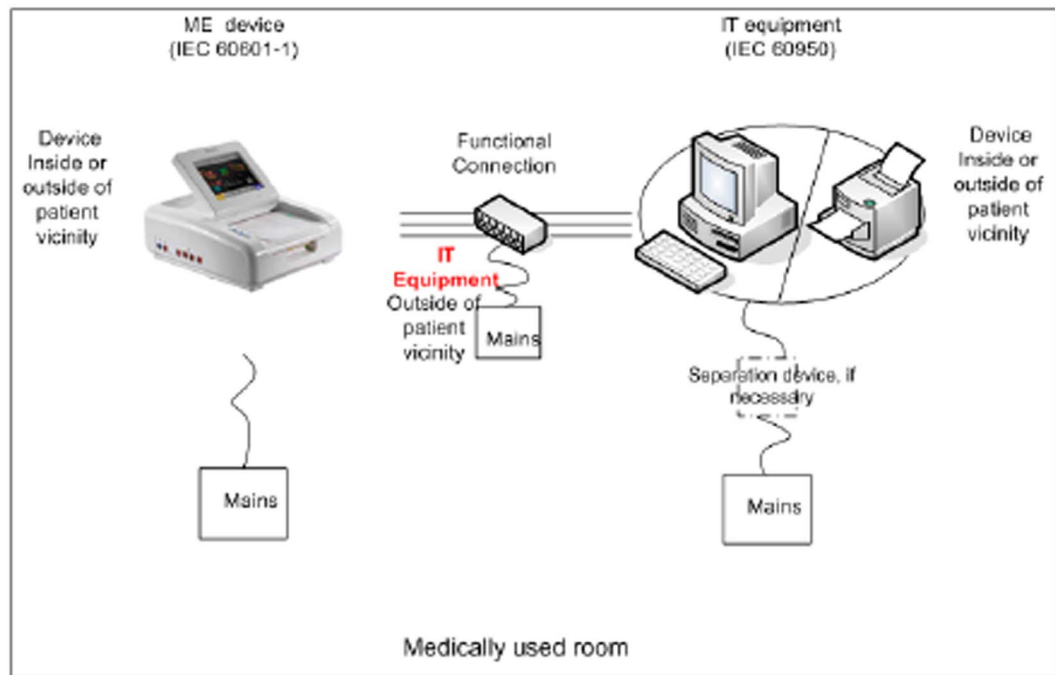


## Case 2: Medical Device Combined with a Non-Medical Device

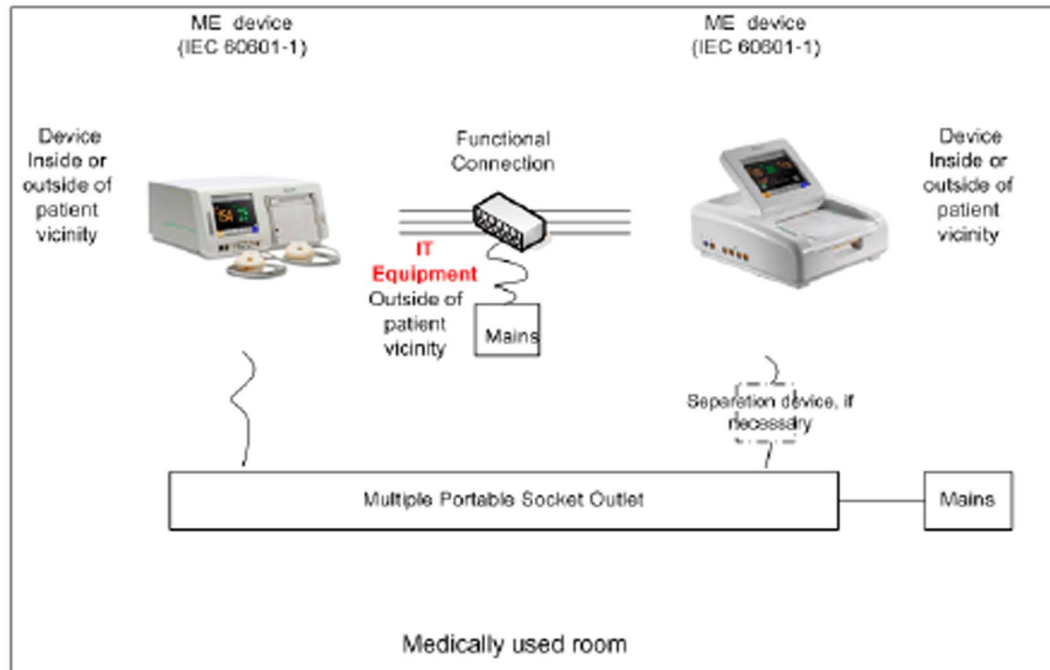
If you combine a medical device with a non-medical device to form a medical electrical system according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010, additional protective measures are required, e.g. usage of a separation device. The medical electrical devices or the IT equipment may be located in or outside the patient vicinity in a medically used room. After system installation incl. protective measures, a system test is required to ensure that the resulting equipment leakage current and applied part leakage current does not exceed the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.



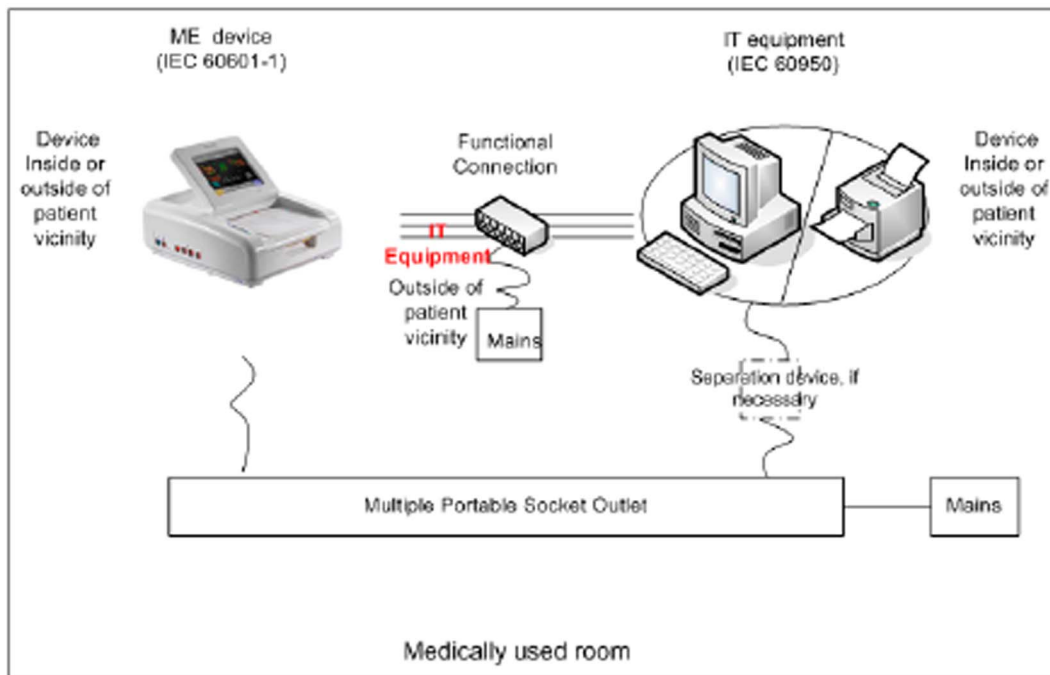
For any IT equipment (IEC 60950) operated in patient vicinity ensure that the equipment leakage current does not exceed the limits described in IEC 60601-1. Use a separation device to ensure compliance. After installation of IT equipment in patient vicinity, an enclosure leakage current test is required.



If the combined devices forming the medical electrical system are connected to the same multiple portable socket outlet, ensure that the resulting protective earth leakage current and equipment leakage current do not exceed the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010. The medical electrical devices or IT equipment may be located in or outside the patient vicinity in a medically used room. Avoid using multiple portable socket outlets. If the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 are exceeded, additional protective measures are required, e.g. a separation device or the connection of each device to separate mains.

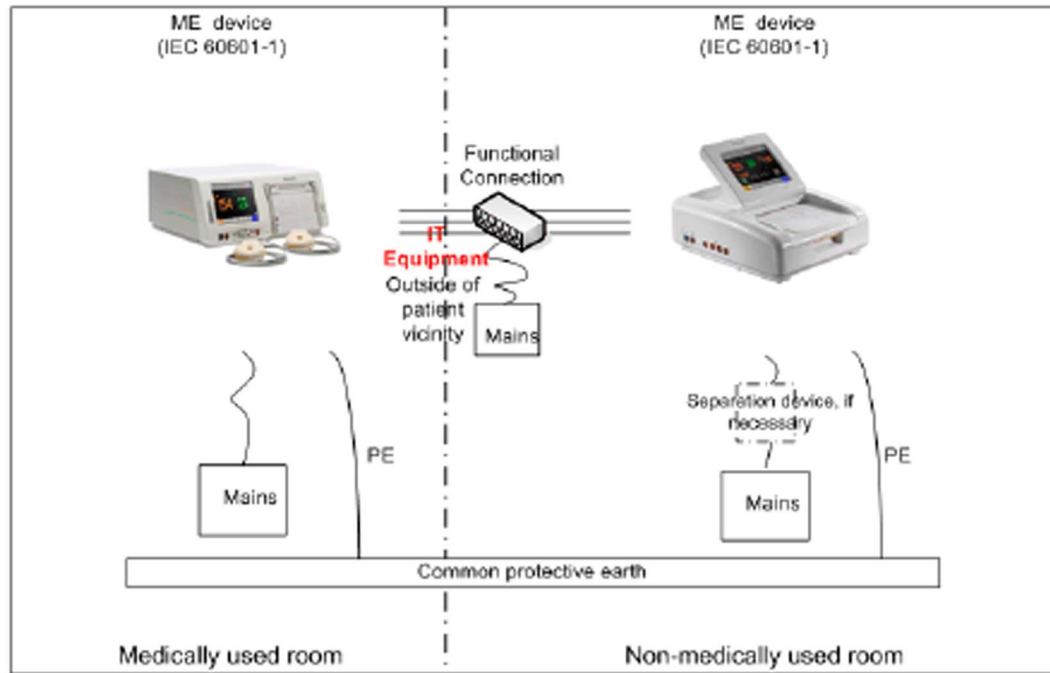


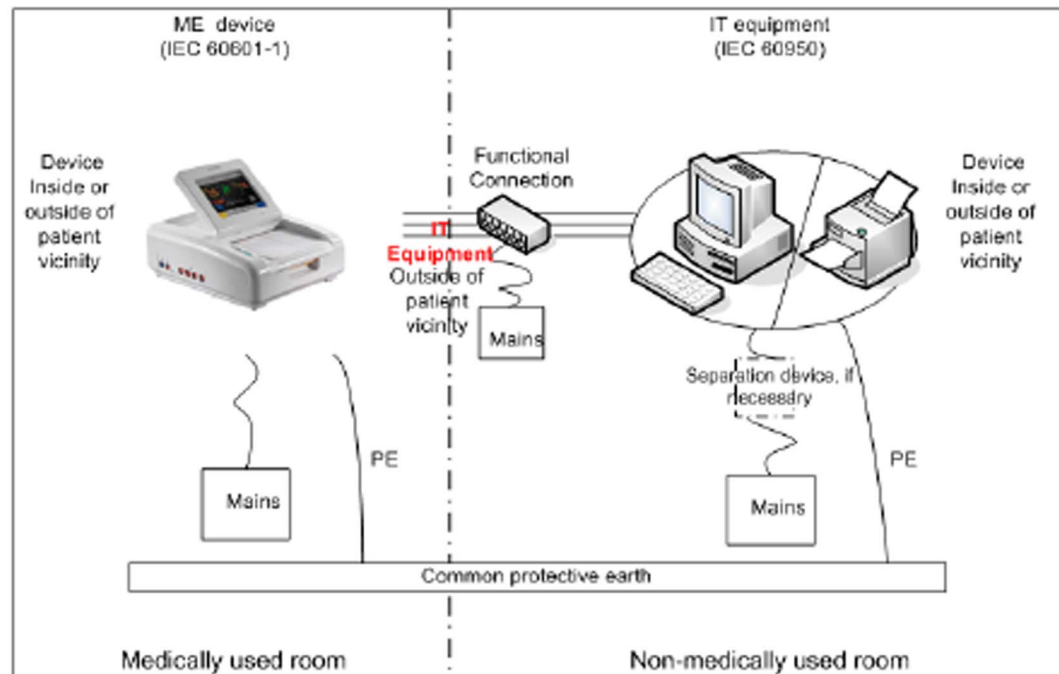
For any IT equipment (IEC 60950) operated in patient vicinity, ensure that the equipment leakage current does not exceed the limits described in IEC 60601-1. Use a separation device to ensure compliance. After installation of IT equipment in patient vicinity, an enclosure leakage current test is required.



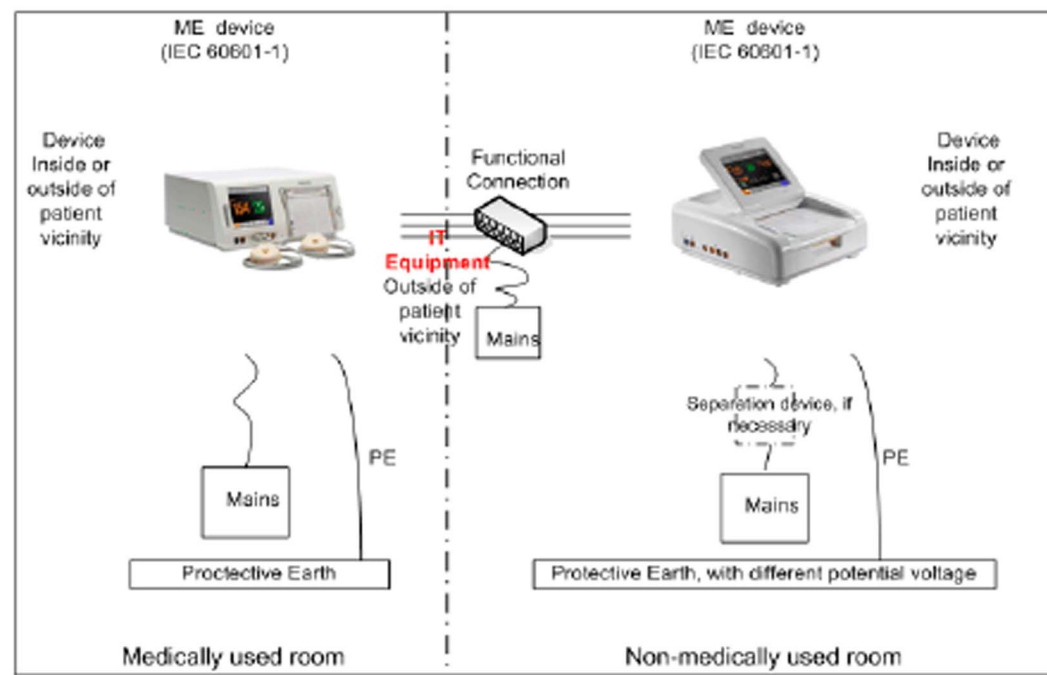
### Case 3: Medical Device Combined with a Medical or Non-Medical Device with one Device in a Non-Medically-Used Room

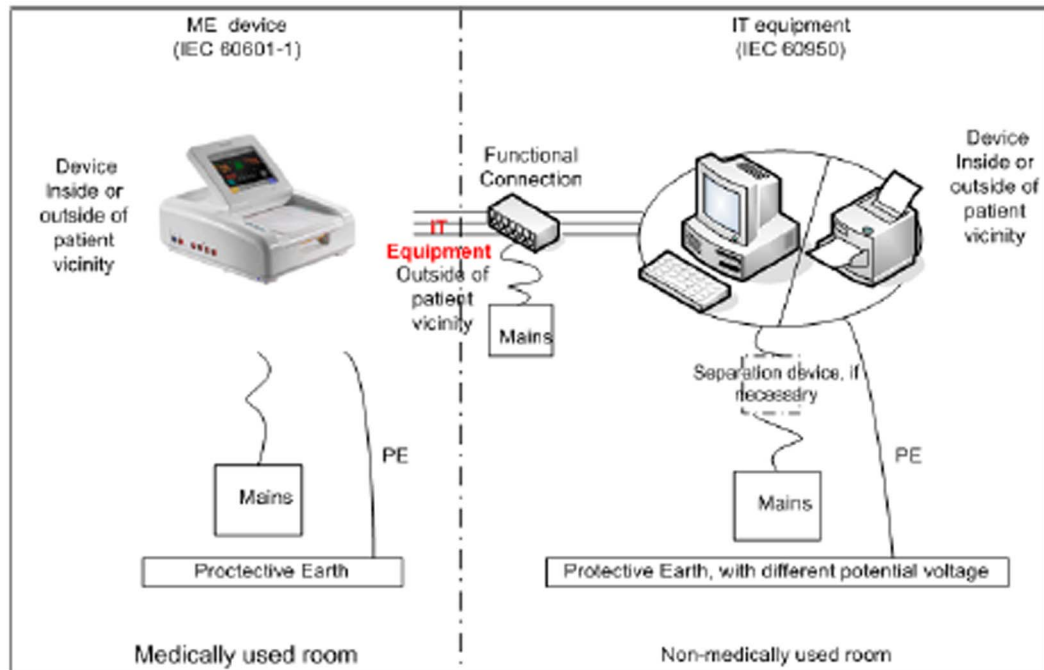
If you combine a medical device with a medical or non-medical device to form a medical electrical system according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 using a common protective earth connection and one of the devices is located in a non-medically used room, additional protective measures are required, e.g. usage of a separation device or additional protective earth connection. The medical electrical devices or IT equipment may be located in or outside the patient vicinity. After system installation incl. protective measures, a system test is required to ensure that the resulting equipment leakage current does not exceed the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.





If you combine a medical device with a medical or non-medical device to form a medical electrical system according to IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010 using two separate protective earth connections and one of the devices is located in a non-medically used room creating a potential voltage difference, additional protective measures are required, e.g. usage of a separation device or additional protective earth connection. The medical electrical devices or IT equipment may be located in or outside the patient vicinity. After system installation incl. protective measures, a system test is required to ensure that the resulting equipment leakage current does not exceed the limits of IEC 60601-1:2005+A1:2012/EN 60601-1:2006+AC:2010.





## System Test Procedure

If the medical electrical device has already been tested as a standalone device e.g. during factory safety testing, an equipment leakage current test must only be performed once the device is connected to another electrical device/system. If the medical electrical system has not been tested as a standalone device, the device has to be tested as a standalone device (without connection to the system) and as part of the system (with connection to the system).

Connect the detachable power cord of the device under test to the safety analyzer's test mains port. Connect the enclosure test lead of the safety analyzer to the enclosure of the device under test, as described in the section dealing with the equipment leakage current test. Refer to the documentation that accompanies the safety analyzer for further details on how to set up the test.

| Test                                                    | Expected Test Results       |
|---------------------------------------------------------|-----------------------------|
| Equipment Leakage Current test (normal condition)       | Sys1 $\leq 100 \mu\text{A}$ |
| Equipment Leakage Current test (Single Fault condition) | Sys2 $\leq 300 \mu\text{A}$ |

After the testing of the device as a standalone device and as part of the system, check that the resulting values (without connection and with connection to the system) do not differ by more than  $\pm 10\%$  from each other.

If the devices in the medical electrical system are connected to a multiple portable socket outlet, the resulting protective earth leakage current needs to be determined. All system components must be connected to the multiple portable socket outlet and be switched on during this measurement.

| Test                                                        | Expected Test Results   |
|-------------------------------------------------------------|-------------------------|
| Protective Earth Leakage Current of Multiple Socket-Outlets | Sys3 $\leq$ 300 $\mu$ A |

Refer to the documentation that accompanies the safety analyzer for further details on how to set up the test.

## Preventive Maintenance Procedures

The preventive maintenance tasks are restricted to the noninvasive blood pressure measurement calibration. Carry out the noninvasive blood pressure measurement performance tests at least every two years, or as specified by local laws (whichever comes first).

### Noninvasive Blood Pressure Measurement Calibration

Carry out the noninvasive blood pressure measurement performance tests at least every two years, or as specified by local laws (whichever comes first).

### Tympanic Temperature Calibration

To verify the performance of the Tympanic Thermometer:

- 1 Purchase a Covidien calibration device, part number 303097. See the Covidien web site for ordering information ([www.covidien.com](http://www.covidien.com)).
- 2 Follow the instructions provided with the calibration device to perform the test.

#### NOTE

The battery compartment in the Tympanic temperature probe is not functional.

#### CAUTION

After performing the calibration, check the body reference site selection of the Tympanic Thermometer to make sure it matches the required settings for your hospital.

## Fetal Recorder Maintenance

The recorder rubber roller, thermal printhead, and paper sensor should be cleaned at least once a year, or when needed (when traces become faint).

Clean the assemblies as follows:

- Clean the recorder rubber roller with a lint-free cloth using a soap/water solution.
- Wipe the printhead using a cotton swab moistened with 70% Isopropyl alcohol based solution.
- Check the paper sensing mechanism is dust free.

# Performance Assurance Tests

Some of the following test procedures must be performed in Service Mode. To enter service mode select **Operating Modes** in the main menu. Then select **Service Mode** and enter the password.

## Basic Performance Assurance Test

This section describes the basic performance test procedure. Please refer to the section “When to Perform Tests” on page 56 for detailed information on when which test procedure is required.

Procedure:

Power on the monitoring system and go into Demo Mode. Check that each parameter displays values.

## Full Performance Assurance Test

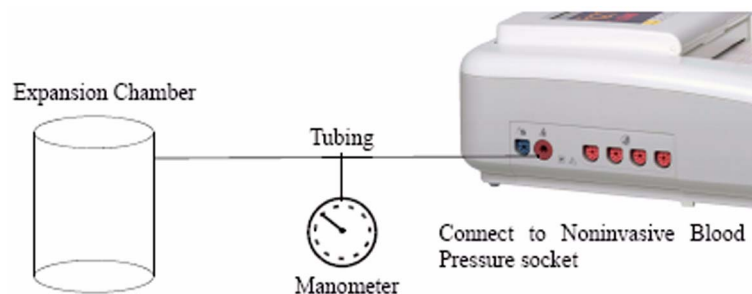
The following sections describe the full performance testing procedures i.e. detailed testing of each parameter with a patient simulator or specified tools. Please refer to the section “When to Perform Tests” on page 56 for information on when which testing procedure is required.

## Noninvasive Blood Pressure Performance Tests

This section describes noninvasive blood pressure test procedures. The monitor must be in Service Mode. The Test and Inspection Matrix gives the expected test results for each of the tests.

### Accuracy Test

This test checks the performance of the noninvasive blood pressure measurement. Connect the equipment as shown:



Tools required:

- Reference manometer (includes hand pump and valve), accuracy 0.2% of reading
- Expansion chamber (volume 250 ml +/- 10%)
- Appropriate tubing

In Service Mode, the systolic and diastolic readings indicate the noise of noninvasive blood pressure channels 1 and 2 respectively. When static pressure is applied, the reading in noninvasive blood pressure channel 1 should be below 50. The value in parentheses indicates the actual pressure applied to the system.

- 1 Connect the manometer and the pump with tubing to the noninvasive blood pressure connector on the monitor and to the expansion chamber.
- 2 In Service Mode, select the **Setup NBP** menu.
- 3 Select **CloseValves On**.

- 4 Raise the pressure to 280 mmHg with the manometer pump.
- 5 Wait 10 seconds for the measurement to stabilize.
- 6 Compare the manometer values with the displayed values.
- 7 Document the value displayed by the monitor (X1).
- 8 If the difference between the manometer and displayed values is greater than 3 mmHg, calibrate the noninvasive blood pressure measurement. If not, proceed to the leakage test.
- 9 To calibrate the noninvasive blood pressure measurement, select **CloseValves** Off then **Calibrate NBP** and wait for the instrument to pump up the expansion chamber. Wait a few seconds after pumping stops until **EnterPrVal** is highlighted and then move the cursor to the value shown on the manometer. If one of the following prompt messages appears during this step, check whether there is leakage in the setup:
  - NBP unable to calibrate—cannot adjust pressure
  - NBP unable to calibrate—unstable signal
- 10 Press **Confirm**.

If the INOP **NBP Equip Malf** message occurs in Monitoring Mode, go back to Service Mode and repeat the calibration procedure.

### Leakage Test

The noninvasive blood pressure leakage test checks the integrity of the system and of the valve. It is required once every two years and when you repair the monitor or replace parts.

- 1 If you have calibrated, repeat steps 2 to 6 from the accuracy test procedure so that you have 280 mmHg pressure on the expansion chamber.
- 2 Watch the pressure value for 60 seconds.
- 3 Calculate and document the leakage test value (X2).  $X2 = P1 - P2$  where P1 is the pressure at the beginning of the leakage test, and P2 is the pressure displayed after 60 seconds. The leakage test value should be less than 6 mmHg.

### Linearity Test

- 1 Reduce the manometer pressure to 150 mmHg.
- 2 Wait 10 seconds for the measurement to stabilize.
- 3 After these 10 seconds, compare the manometer value with the displayed value.
- 4 Document the value displayed by the monitor (X3)
- 5 If the difference is greater than 3 mmHg, calibrate the noninvasive blood pressure measurement (see steps 9 to 10 in the accuracy test procedure).

### Valve Test

- 1 Raise the pressure again to 280 mmHg.
- 2 Select **CloseValves: Off**.
- 3 Wait five seconds and then document the value displayed. The value should be less than 10 mmHg.
- 4 Document the value displayed by the monitor (X4).

## Expected Test Results

| Test           | Expected test results                                       |
|----------------|-------------------------------------------------------------|
| Accuracy test  | x1 = value displayed by monitor<br>Difference $\leq 3$ mmHg |
| Leakage test   | x2 = leakage test value<br>x2 $< 6$ mmHg                    |
| Linearity test | x3 = value displayed by monitor<br>Difference $\leq 3$ mmHg |
| Valve Test     | x4 = value $< 10$ mmHg                                      |

## SpO<sub>2</sub> Performance Test

This test checks the performance of the SpO<sub>2</sub> measurement.

Tools required: none

- 1 Connect an adult SpO<sub>2</sub> transducer to the SpO<sub>2</sub> connector.
- 2 Measure the SpO<sub>2</sub> value on your finger (this assumes that you are healthy).
- 3 The value should be between 95% and 100%.

## Expected Test Results

| Test                              | Expected test results |
|-----------------------------------|-----------------------|
| SpO <sub>2</sub> Performance Test | 95%—100%              |

## Measurement Validation

The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70% and 100% SpO<sub>2</sub> were studied.

The population characteristics for those studies were:

- about 50% female and 50% male subjects
- age range: 19 to 39
- skin tone: from light to dark brown

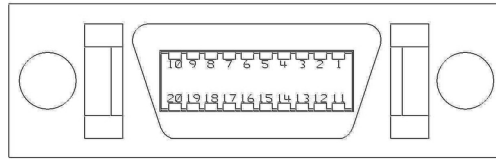
### NOTE

A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor or sensor. However, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.

Pulse rate accuracy has been validated with an electronic pulse simulator.

## Multi-Port Nurse Call Connector Test (Flexible Nurse Call)

This test checks the operation of the Flexible Nurse Call Relay. The Nurse Call Relay test is recommended for customer sites where the nurse call is in use. The following diagram and table show the pins and relay identifiers of the connector:



Front View

| Pin | Cable Color Coding | Relay                           |
|-----|--------------------|---------------------------------|
| 1   | black              | R2-closure                      |
| 2   | brown              | R2-middle                       |
| 3   | red                | R2-opener                       |
| 4   | orange             | R3-closure                      |
| 5   | yellow             | R3-middle                       |
| 6   | green              | R3-opener                       |
| 7   | blue               | n/a                             |
| 8   | purple             | n/a                             |
| 9   | gray               | n/a                             |
| 10  | white              | n/a                             |
| 11  | pink               | R1-closure                      |
| 12  | light green        | R1-middle                       |
| 13  | black/white        | R1-opener                       |
| 14  | brown/white        | n/a                             |
| 15  | red/white          | n/a                             |
| 16  | orange/white       | n/a                             |
| 17  | blue/white         | R_failure_closure <sup>*1</sup> |
| 18  | purple/white       | R_failure_middle <sup>*1</sup>  |
| 19  | green/white        | R_failure_opener <sup>*1</sup>  |
| 20  | red/black          | n/a                             |

\*1: The power loss indication functionality of the Nurse Call Relay board is not supported with fetal monitors.

The Nurse Call relay functions as follows:

- During standard operation R1,R2,R3 \_opener are closed; R1,R2,R3\_closure are open.
- During alarm condition—R1,R2,R3\_opener are open; R1,R2,R3\_closure are closed.

**Tools required:** Ohmmeter.

- 1 Plug an M8087-61001 cable into the Nurse Call Relay connector.
- 2 Connect the ohmmeter and measure the pins as indicated in the diagram and table.
- 3 The relay contacts should behave as described above. The behavior may vary depending on configuration choices. See the Configuration Guide for details on Alarm Relay settings.

- 4 The expected test results depend on the relay contact used. Please check that the correct relay activity is initiated during alarm condition.

| Test                                 | Expected test results                                                  |
|--------------------------------------|------------------------------------------------------------------------|
| Multi-Port Nurse Call Connector Test | Correct relay activity is initiated during alarm condition (pass/fail) |

## Reporting of Test Results

Philips recommends all test results are documented in accordance with local laws. Authorized Philips personnel report the test result back to Philips in a service record. While hospital personnel (biomedical engineers or technicians) do not need to report results to Philips, Philips recommends that they record and store the test results in accordance with local laws.

The following table lists what to record after completing the tests in this chapter. Record the results in the empty column in the following table.

The following is a guide as to what your documentation should include:

- Identification of the testing body (for example, which company or department carried out the tests).
- Name of the person(s) who performed the tests and the concluding evaluation.
- Identification of the device(s) and accessories being tested (serial number, etc.).
- The actual tests (incl. visual inspections, performance tests, safety, and system tests) and measurements required.
- Date of testing and of the concluding evaluation.
- A record of the actual values of the test results, and whether these values passed or failed the tests.
- Date and confirmation of the person who performed the tests and evaluation.

The device under test should be marked according to the test result: passed or failed.

## Carrying Out and Reporting Tests

### Test Report

|                                                         |                                                                                                                                         |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Testing Organization:<br>Name of testing person:        | (Check one of the following three options)<br>Test before putting into service (reference value)<br>Recurrent Test<br>Test after Repair |
| Responsible Organization:                               |                                                                                                                                         |
| Device Under Test:                                      | ID-Number                                                                                                                               |
| Product Number:                                         | Serial No.:                                                                                                                             |
| Accessories:                                            |                                                                                                                                         |
| Measurement Equipment (Manufacturer, Type, Serial No.): |                                                                                                                                         |
| Functional Test (parameters tested):                    |                                                                                                                                         |

### Test and Inspection Matrix

| Test Block        | Test or Inspection to be Performed                                   | Expected Test Results            | Record the Results (mandatory for Philips Personnel only) |                |
|-------------------|----------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------|----------------|
|                   |                                                                      |                                  | What to Record                                            | Actual Results |
| Visual Inspection | Perform Visual Inspection -- see "When to Perform Tests" on page 56. | Pass or Fail                     | V:P or V:F                                                |                |
| Power On          | Power on the unit. Does the self-test complete successfully?         | If Yes, Power On test is passed. | PO:P or PO:F                                              |                |

| Test Block                                   | Test or Inspection to be Performed                                                                                    | Expected Test Results                                                        | Record the Results (mandatory for Philips Personnel only) |                |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------|----------------|
|                                              |                                                                                                                       |                                                                              | What to Record                                            | Actual Results |
| Noninvasive Blood Pressure Performance Tests | Perform the Accuracy Test -- see "Accuracy Test" on page 83.                                                          | X1 = value displayed by monitor<br>Difference $\leq 3$ mmHg                  | PN:P/X1 or<br>PN:F/X1                                     |                |
|                                              | Performance Leakage Test -- see "Leakage Test" on page 84.                                                            | X2 = leakage test value<br>X2 $< 6$ mmHg                                     | PN:P/X2 or<br>PN:F/X2                                     |                |
|                                              | Performance Linearity Test -- see "Leakage Test" on page 84.                                                          | X3 = value displayed by monitor<br>Difference $\leq 3$ mmHg                  | PN:P/X3 or<br>PN:F/X3                                     |                |
|                                              | Performance Valve Test -- page "Leakage Test" on page 84.                                                             | X4 = value $< 10$ mmHg                                                       | PN:P/X4 or<br>PN:F/X4                                     |                |
| SpO <sub>2</sub> Performance Test            | Perform the SpO <sub>2</sub> Performance Test -- see "SpO <sub>2</sub> Performance Test" on page 85.                  | Value should be between 95% and 100%                                         | No reporting necessary                                    |                |
| Safety (2)                                   | Perform Safety Test (2): Sum of Functional Earth and Equipment Leakage Current - Normal Condition.                    | NC with mains cable:<br>Maximum leakage current (X1) $\leq 100 \mu\text{A}$  | S(1):P/X1 or<br>S(1):F/X1                                 |                |
| Safety (3)                                   | Perform Safety Test (3): Sum of Functional Earth and Equipment Leakage Current - Single Fault Condition (Open Earth). | SFC with mains cable:<br>Maximum leakage current (X2) $\leq 100 \mu\text{A}$ | S(2):P/X2 or<br>S(2):F/X2                                 |                |
| Safety (4)                                   | Perform Safety Test (4): Applied Part Leakage Current - Single Fault Condition, mains on applied part.                | Maximum leakage current (X1) $\leq 50 \mu\text{A}$                           | S(3):P/X1 or<br>S(3):F/X1                                 |                |

## 7 Testing and Maintenance

| Test Block                                                    | Test or Inspection to be Performed                                                                                                                  | Expected Test Results                                                                                                                                          | Record the Results (mandatory for Philips Personnel only) |                |
|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|----------------|
|                                                               |                                                                                                                                                     |                                                                                                                                                                | What to Record                                            | Actual Results |
| System (Sys 1-2)                                              | Perform the system test according to sub clause 19.201 of IEC 60601-1:2005+A1:2012/ EN 60601-1:2006+AC:2010, if applicable, after forming a system. | Equipment Leakage Current:<br>Sys1 $\leq$ 100 $\mu$ A (Normal Condition)<br>Sys2 $\leq$ 300 $\mu$ A (Single Fault Condition)                                   | Sys:PSys1/PSys2 or<br>Sys:FSys1/FSys2                     |                |
| System (Sys 3)                                                | Perform the system test according to sub clause 19.201 of IEC 60601-1:2005+A1:2012/ EN 60601-1:2006+AC:2010, if applicable, after forming a system. | Protective Earth Leakage Current if medical electrical system components are connected to the same Multiple Portable Socket-Outlet:<br>Sys3 $\leq$ 300 $\mu$ A | Sys: PSys3 or<br>Sys: FSys3                               |                |
| Key: P = Pass, F = Fail, X = test result value to be recorded |                                                                                                                                                     |                                                                                                                                                                |                                                           |                |

### NOTE

All values for current and voltage are the root mean square (r.m.s.) values, unless otherwise stated.

## Evaluation

|                                                                     | Yes | No |
|---------------------------------------------------------------------|-----|----|
| Safety and Functional Test passed                                   |     |    |
| Repair required at a later date, safety and functional test passed  |     |    |
| Device must be taken out of operation until repair and passed tests |     |    |
| Device failed and must be taken out of operation.                   |     |    |

Notes:

Next Recurrent Test:

Name: \_\_\_\_\_

Date/Signature: \_\_\_\_\_

## Evaluation of Test Results

The evaluation of the test results must be performed by appropriately trained personnel with sufficient product, safety testing, and application knowledge.

If any test results are between 90% and 100% of the respective expected result, the previously measured reference values must be taken into consideration for the assessment of the electrical safety of the device under test. If no reference values are available, you should consider shorter intervals between upcoming recurrent tests.

### NOTE

If any single test fails, testing must be discontinued immediately and the device under test must be repaired or labeled as defective. Be sure to inform the user about the test failure in writing.

## Other Regular Tests

The care and cleaning requirements that apply to the monitor and its accessories are described in the Instructions for Use. This section details the periodic maintenance recommended for the monitor, transducers, and accessories.

## Transducers and Patient Modules; Functional Tests

If any of the following tests fail, repeat the test using another transducer. If the second transducer passes the tests, confirming that the first transducer is defective, contact your service personnel.

If the second transducer also fails the tests, contact your Philips Service Engineer or Response Center.

## Ultrasound Transducer Electrical Check

---

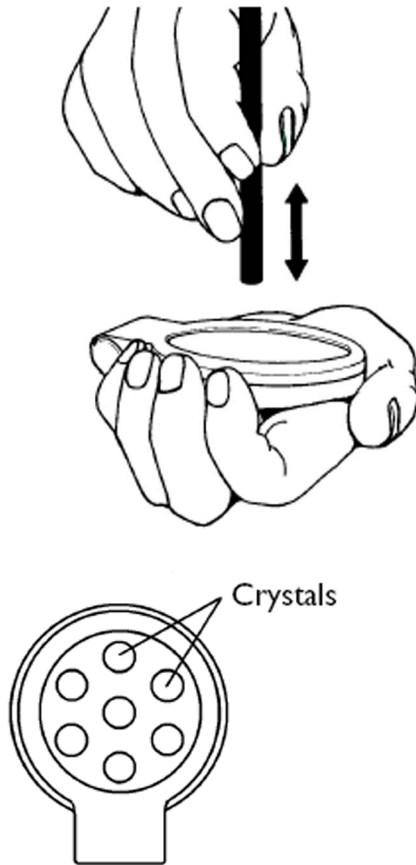
### CAUTION

Use of ultrasound gel that is not approved by Philips may reduce signal quality and may damage the transducer. This type of damage is not covered by warranty.

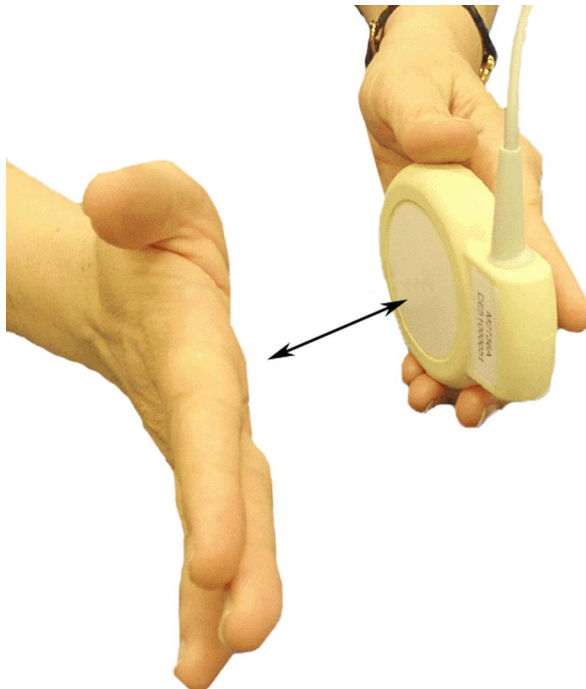
---

## 7 Testing and Maintenance

To test an ultrasound transducer:



- 1 Switch on the monitor and the recorder.
- 2 Connect the transducer to the fetal monitor.
- 3 Select the fetal heart sound for this channel.
- 4 Increase the loudspeaker volume to an audible level.
- 5 The ultrasound transducer contains seven piezoelectric crystals. Basic functioning of each can be verified by holding a flat bottomed pencil or similar above each crystal and moving it up and down as shown.
- 6 A sound should be heard for each crystal tested. The pencil should be held two to three centimeters from the transducer surface when the test is carried out.
- 7 A sound should also be heard when the transducer is moved back and forth over a solid surface, or the hand as shown.



## Toco Transducer Electrical Check

To test a Toco transducer:

- 1 Switch on the monitor and the recorder.
- 2 Connect the transducer to the fetal monitor.
- 3 Lay the transducer face up on a hard, flat surface for a few seconds.
- 4 Press the Toco Baseline Key to re-adjust the Toco display to  $20 \pm 1$ .
- 5 Turn the transducer over so that the Toco sensor is resting on the flat surface. You should see a marked increase in the value of the Toco reading in the Toco display.
- 6 Press the Toco Baseline Key to re-adjust the Toco display to  $20 \pm 1$ .
- 7 Turn the transducer over again. You should see a marked decrease in the value of the Toco reading in the Toco display



## Testing the Patient Module (M2738A)/Toco+ Transducer (M2735A): DECG Mode

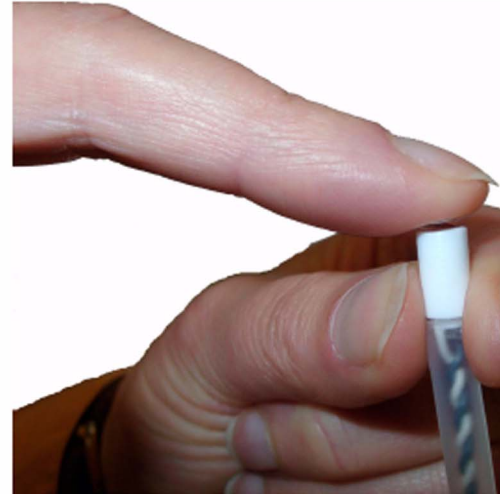
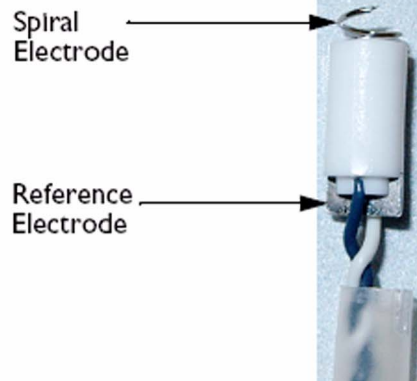
- 1 Switch on the monitor and the recorder.
- 2 Connect the patient module or Toco<sup>+</sup> transducer to the fetal monitor.
- 3 Attach the DECG adapter cable M1362B to the socket on the patient module or Toco<sup>+</sup> transducer.

Ensure that the DFHR channel display on the fetal monitor shows the **DFHRx Leads Off INOP** with the DECG adapter cable attached.

- 1 Take a Fetal Scalp Electrode, and connect it to the DECG adapter cable.
- 2 Either:  
Hold the reference electrode between the thumb and index finger of one hand, and touch the spiral electrode with the index finger of the other hand, as illustrated below. This makes a short between the spiral electrode and the reference electrode (it is best to wet your fingers first). Use a **sterile** Fetal Scalp Electrode.

### CAUTION

The tip of the spiral electrode is sharp. Take care not to injure your fingers.



or

Cut off the plastic tip of the fetal scalp electrode (containing the spiral and reference electrodes) from the end of the wires. Strip the insulation from the end of the wires, and connect them to a patient simulator.

### NOTE

We do not recommend the use of a specific patient simulator. The use of a patient simulator does not allow checking the specification of the ECG-functionality; it allows only a check of general function.

Result: the **DFHRx Leads Off INOP** should disappear.

Viewing the ECG wave: when configured, you can view the DECG wave on the screen, and any noise will be visible as additional verification of the effectiveness of the test.

If the test results are not as outlined above, repeat the test with another ECG transducer. If this does not solve the problem, try the following:

- Check all connections.
- If the **DFHRx Leads Off INOP** is still displayed, the DECG adapter cable may be defective. Replace the adapter cable.

If the problem persists, replace the transducer.

### Testing the Patient Module (M2738A)/Toco+ Transducer (M2735A): MECG Mode

- 1 Switch on the monitor and the recorder.
- 2 Connect the patient module or Toco<sup>+</sup> transducer to the fetal monitor.
- 3 Attach the MECG adapter cable M1363A to the red color-coded socket on the patient module or Toco<sup>+</sup> transducer

- 4 Either:
  - attach electrodes to the M1363A adapter cable, and apply the electrodes to the skin (for example on the wrists).
  - or
  - attach the M1363A adapter cable to a patient simulator.

#### Note

We do not recommend the use of a specific patient simulator. The use of a patient simulator does not allow checking the specification of the ECG-functionality; it allows only a check of general function.

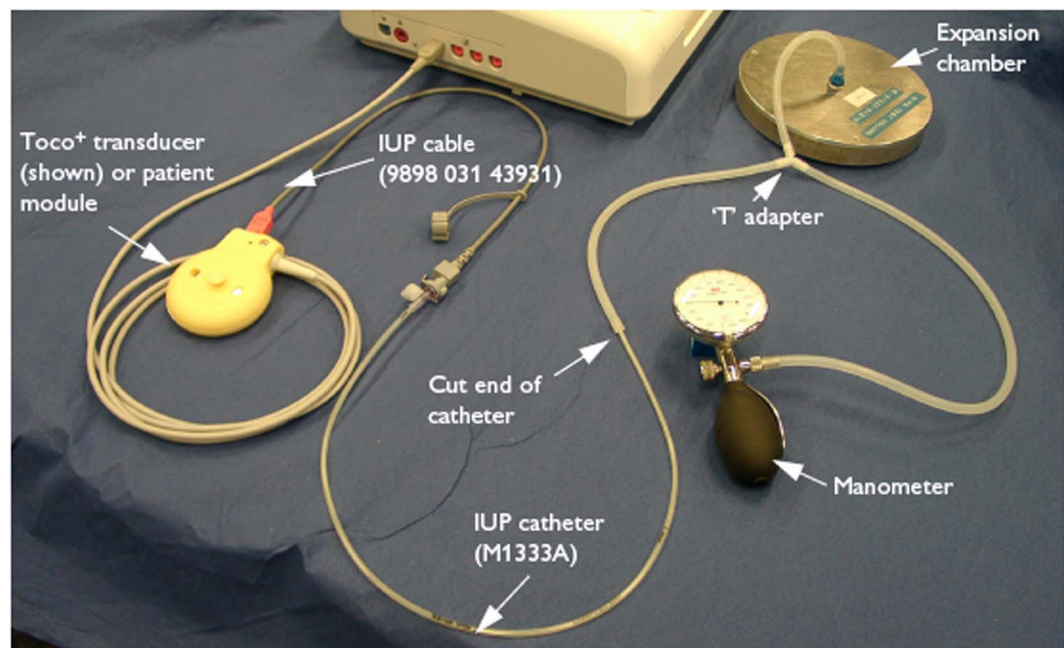
Result: You should see MEEG values displayed on the maternal display or annotated on the recorder trace.

If the test results are not as outlined above, repeat the test with another ECG transducer. If this does not solve the problem:

- The MEEG adapter cable may be defective. Replace the adapter cable, and repeat the test.
- Check all connections.

### Testing the Patient Module (M2738A)/Toco<sup>+</sup> Transducer (M2735A): IUP Mode

- 1 To test the IUP functionality of the patient module or the Toco<sup>+</sup> transducer, you need the following:



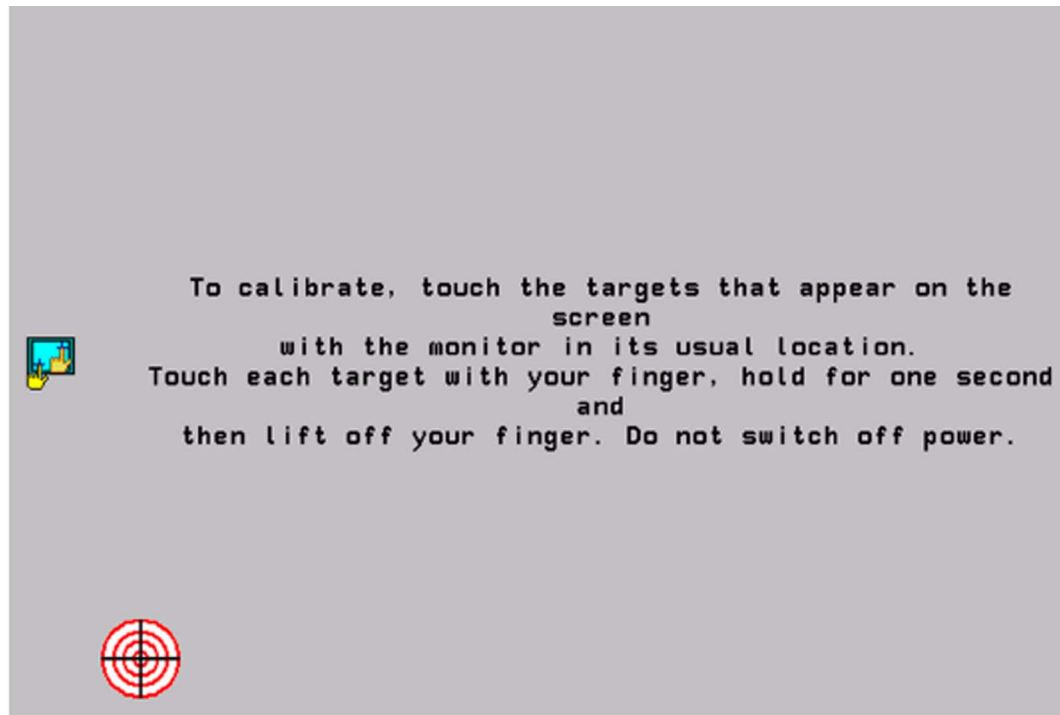
- Manometer.
  - Expansion chamber.
  - Three lengths of silicone tubing with a 'T' adapter.
- 2 Switch on the monitor and the recorder.
  - 3 Connect the patient module or Toco<sup>+</sup> transducer to the fetal monitor.

- 4 Attach the IUP adapter cable (989803143931) to the socket on the patient module or Toco<sup>+</sup> transducer.
- 5 Cut the sensor tip off an IUP catheter (M1333A).
- 6 Connect the catheter to the IUP adapter cable.
- 7 Connect the silicone tubing to the test volume chamber and the manometer as shown in the picture.
- 8 Connect the cut end of the catheter to the silicone tubing.
- 9 Apply a pressure of  $80 \text{ mmHg} \pm 5 \text{ mmHg}$  with the manometer. Check that the value on the display and on trace corresponds to this pressure. Slowly release the pressure, and check that the value on the display and on trace shows this change in pressure.

## Touchscreen Calibration

To access the touchscreen calibration screen:

- 1 Enter Service Mode
- 2 Select **Main Setup**
- 3 Select **Hardware**
- 4 Select **Calibrate Touch**



Make sure you complete the calibration procedure without powering off the monitor mid-way. If the monitor is powered off after the first point is touched, the touch panel will be deactivated until the touch calibration is performed again.

If the touchscreen is accidentally mis-calibrated by selecting the wrong spot, you must use another input device to re-enter calibration mode, for instance, a mouse connected to the PS/2 interface. If you have the support tool, you can select **Start Calibrate Touch** and it will create a rough calibration which will allow you to access the calibration menu again via the touchscreen.

## Disabling/Enabling Touch Operation

To disable touchscreen operation of the monitor, press and hold the **Main Screen** key for about three seconds. A red padlock will blink on the key. Press and hold the **Main Screen** key again for about three seconds to re-enable touchscreen operation.

## Checking the Fetal Recorder Offset

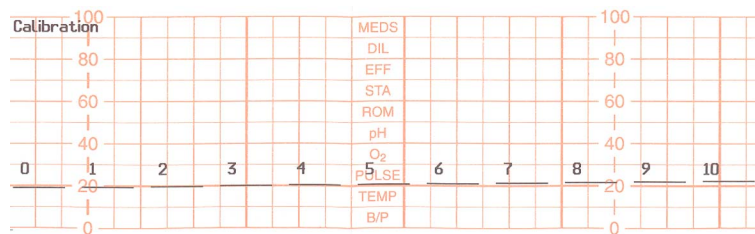
To check the recorder offset:

- 1 Connect a Toco transducer to the monitor.
- 2 Place the Toco transducer on a flat surface so that it is resting on the belt button, and is therefore not under any load.
- 3 Start the recorder, and press the **PaperAdvance** key three times to make sure that at least three pages of paper have advanced.
- 4 If the Toco trace is recording exactly on the 20 unit gridline, then the offset is correctly set.
- 5 If the Toco trace is not recording exactly on the 20 unit gridline, then set the offset as described in "Setting the Fetal Recorder Offset" on page 97.

## Setting the Fetal Recorder Offset

To set the fetal recorder offset, you first need to run the fetal recorder calibration:

- 1 Enter Service Mode.
- 2 In **Main Setup**, select **Fetal Recorder** to enter the **Fetal Recorder** menu.  
The current setting for the recorder offset is shown (but it is still grayed out, and you cannot select it yet).
- 3 Select **Calibration** to start the recorder calibration printout.
- 4 The recorder stops, and the **Cal. Offset** becomes selectable.
- 5 Look at the section of the printout entitled "Calibration".



You will see the numbers 0 to 10, and each number has a line printed below it. See for which number the line best fits the 20 unit gridline (8 in this example).

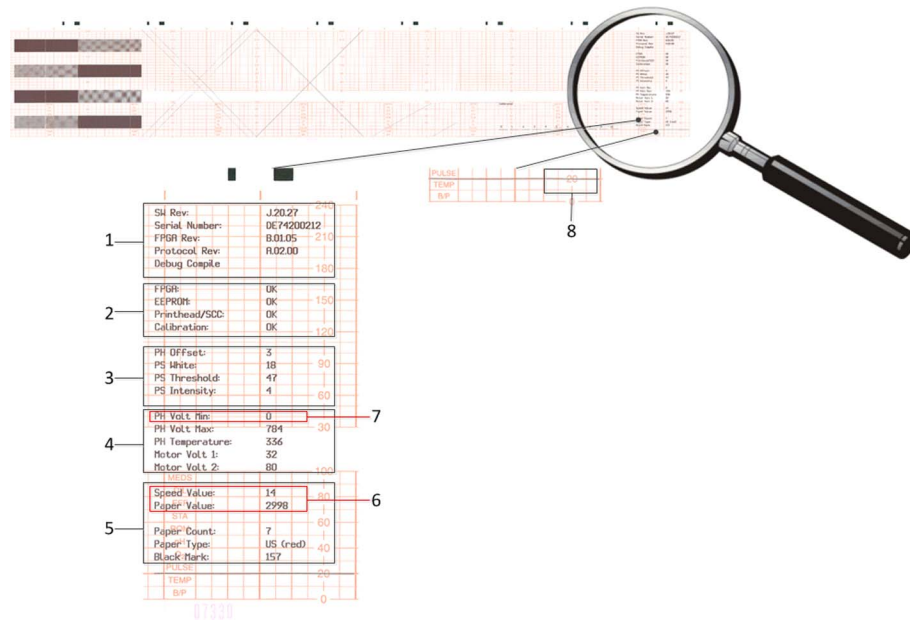
- 6 Select **Cal. Offset**, and select the offset value from 0 to 10 from the list, as determined in step 4.
- 7 The recorder then finishes the calibration printout. Confirm that the line prints on the 20 unit gridline.

# Fetal Recorder Selftest Report

To verify your printer configuration, or if you doubt the performance of the recorder, you may want to print a test report.

To print a selftest report, in Service Mode, select **Main Setup, Fetal Recorder, Selftest**.

Here is an excerpt from a sample test report to give you an idea what it looks like (the exact appearance may vary slightly):



- 1 Same data from the trace header
- 2 Self-test status
- 3 Print quality data
- 4 Recorder electrical data
- 5 Paper related data (paper count is the number of pages detected on this test).
- 6 Speed value is the tolerance for paper detection. If the Speed value is greater than 150, the recorder most likely requires servicing (cleaning or exchanging of parts), assuming the correct paper is being used. A paper value of 2984 is optimal. You may see small variants from this number.
- 7 Expected value for PH Volt Min is 0. If the value is greater than 0 there may be a TLPH voltage problem.
- 8 This line should print exactly on the 20 unit gridline (Toco baseline) if the recorder is correctly calibrated.

Check the test pattern to ensure all the heating elements on the printer head are operational. Ensure that:

- No more than 20 dots are missing over the entire printhead.
- No more than two adjacent dots are inoperative.
- No dots in the mode annotation (for example, FHR1) are inoperative.

If any of the above conditions are not met, replace the printhead -- see “Removing the Thermal Line Printhead (TLPH)” on page 172.

Ensure that all printed lines are straight. If the lines are not straight, there may be a problem with the paper recorder speed.

## Battery Handling, Maintenance and Good Practices

This section provides some information on how to handle and maintain the battery in order to get the best usage from them. Additionally, some good working practices are also given regarding the correct disposal of the batteries. This section only applies if you have the FM20/FM30 battery option #E25.

### About the Battery

The rechargeable Lithium-Ion battery used in the monitor is regarded as a *Smart* battery because it has built-in circuitry (this circuitry communicates battery-status information to the monitor).

To get the most out of the batteries, observe the following guidelines:

- Condition the battery only upon maintenance request prompt on display.
- **If a battery shows damage or signs of leakage, replace it immediately. Do not use a faulty battery in the monitor.**

#### NOTE

- **Battery Disposal**—The battery should be disposed of in an environmentally-responsible manner. Consult the hospital administrator or your local Philips representative for local arrangements. **Do not dispose of the battery in normal waste containers.**
- **Battery Storage** — The battery should be max. 50% charged for storage.

#### NOTE

The battery will discharge over time if it is stored inside the monitor without AC power connection. The reported values “remaining capacity” and “runtime” will become less accurate when the battery is stored inside the monitor without AC power connection for a longer period of time (i.e. several weeks).

### Checking the Battery Status

When the monitor is connected to the AC power supply, the battery charges automatically. The battery can be charged remotely from the monitor by using the battery charger. Use only the 865432 Smart battery conditioner.

Battery status (level of charge) is indicated in several ways:

- LED on the front panel of the monitor
- Battery gauge
- Display of battery time below gauge
- Battery status window
- INOP messages

The AC power LED is only on when the power cord is connected and AC power is available to the monitor. In this case, the battery can be either charging or is fully charged.

The battery LED can be green, yellow, or red depending on the following conditions:

| Battery LED Colors          | If the monitor is connected to AC power, this means | If the monitor is running on battery power, this means |
|-----------------------------|-----------------------------------------------------|--------------------------------------------------------|
| Green                       | battery full ( $\geq 90\%$ )                        |                                                        |
| Yellow                      | battery charging<br>(battery power $< 90\%$ )       |                                                        |
| Red, flashing               |                                                     | $\leq 10$ minutes power remaining                      |
| Red, flashes intermittently | battery or charger malfunction<br>1, 2              | battery or charger malfunction<br>1, 2                 |

## Battery Status on the Main Screen

Battery malfunction symbols:

If a problem is detected with the battery, these symbols are displayed. They may be accompanied by an INOP message, or by a battery status message in the monitor information line (if battery window is open) providing more details.

| Battery Status Symbols                                                              |                                                                               |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
|    | Battery requires maintenance                                                  |
|  | Battery is empty                                                              |
|  | Battery not charging as the temperature is above or below the specified range |
|  | Charging stopped to protect the battery                                       |
| Battery Malfunction Symbols                                                         |                                                                               |
|  | Incompatible Battery                                                          |
|  | Battery malfunction                                                           |
|  | Battery temperature too high                                                  |
|  | Battery has no power left                                                     |

### Explanations of Battery Status and Malfunction Symbols

*Battery requires maintenance:* The battery requires conditioning. Refer to “Conditioning Batteries” on page 104 for details.

*Battery is empty:* The capacity of the battery is  $\leq 10$  min. Recharge the battery as soon as possible.

*Temperature outside specified range:* The charging of the battery is stopped if the temperature is below 15°C or above 50°C in order to protect the battery. Charging is resumed as soon as the temperature is within this range.

*Incompatible Battery:* The inserted battery is checked for certain battery internal parameters. If these are not correct, the incompatible battery symbol is displayed. Please use only M4605A batteries with the FM20/FM30 monitor. Note that the incompatible battery symbol may also appear if there is a communication problem between the battery and the battery board.

*Battery Malfunction:* Communication between the battery and the battery board could not be established within about 4 minutes or battery internal data indicates malfunction. Please see the section for remedies.

*Battery Temperature too high:* This symbol is displayed if the battery temperature goes above 65°C. In addition the INOP message **Check Batt Temp** is displayed. If the battery temperature increases further above 70°C the batteries will switch off for safety reasons. Allow the battery to cool down to avoid the monitor switching off.

*Battery has no power left:* If the monitor is not running on AC power: battery will switch off power delivery at any moment - in this case recharge the battery immediately - or, if the monitor is running on AC power, the battery is in deep discharge and requires pre-charging to restore communication. To avoid this condition charge batteries to 50% for storage. Note that the battery malfunction INOP will eventually be issued if the pre-charging does not restore battery communication within about 4 minutes.

## Battery Status Window

To access the **Battery Status** window and its associated pop-up keys, select the battery status information on the screen, or select **Main Setup, Battery**.

| Battery Status      |       | ×     |
|---------------------|-------|-------|
| TimeToFull:         |       | 1:30  |
| Capacity remaining  | [mAh] | 6072  |
| Capacity fullCharge | [mAh] | 6686  |
| Voltage             | [V]   | 11.63 |
| Current             | [mA]  | 406   |
| Temperature         | [°C]  | 25.3  |

**Capacity, remaining** tells you how much power is left in the battery.

**Capacity, fullCharge** tells you how much power the battery can hold when fully charged.

**TimeToEmpty** tells you approximately how long you can continue to use the monitor with this battery. Note that this time fluctuates depending on the system load (how many measurements and recordings you carry out), the age of the battery, and the remaining capacity of the battery. The time indication appears after AC has been unplugged for about 30 seconds (after finishing calculation of the **TimeToEmpty**)

**TimeToFull** is shown in place of **TimeToEmpty** if the monitor is connected to AC power, and tells you how much time is left until the battery is charged to 90%. Please allow indication to stabilize for 3 —

5 minutes after beginning the charging cycle. If the battery is charged over 90% **Batt full (>90%)** is displayed until they are charged to 100%. Then **Batt fully charged** is displayed.

### Viewing Battery Details

To view detailed information for the battery, select the pop-up key **Battery**.

| Batt            |                   | × |
|-----------------|-------------------|---|
| Model           | PHILIPS M4605A    |   |
| Chemistry       | LION              |   |
| ManufactureDate | 28 Oct 03         |   |
| S/N             | 00315             |   |
| Type            | 10. 80V / 6000mAh |   |
| Request         | 12. 60V / 4500mA  |   |
| Cycles          | 30 ( 3% )         |   |

### Documenting Battery Status

To print all battery information in the **Battery Status** window:

- 1 Enter Service Mode.
- 2 Select the battery status information on the screen or select **Main Setup, Battery** to open the **Battery Status** window.
- 3 Select the **Print Status** pop-up key to print the information on the built-in recorder.

## Conditioning a Battery

### What is Battery Conditioning?

Battery conditioning recalibrate the battery to ensure that it has accurate information on the actual battery capacity.

### Why is Battery Conditioning Necessary?

The capacity of a battery decreases gradually over the lifetime of a battery. Each time a battery is charged its capacity decreases slightly. Therefore, the operating time of a monitor running on batteries also decreases with each charge cycle.

Battery conditioning ensures that the value stored in the battery for its full capacity takes account of this decrease, so that the remaining battery charge can be calculated accurately, and the low battery warning given at the right time.

### When Should Battery Conditioning be Performed?

Battery conditioning should be performed when indicated by the battery status.

#### NOTE

When the battery status signals a conditioning request, the displayed **TimeToFull** or **TimeToEmpty** may not be reliable.

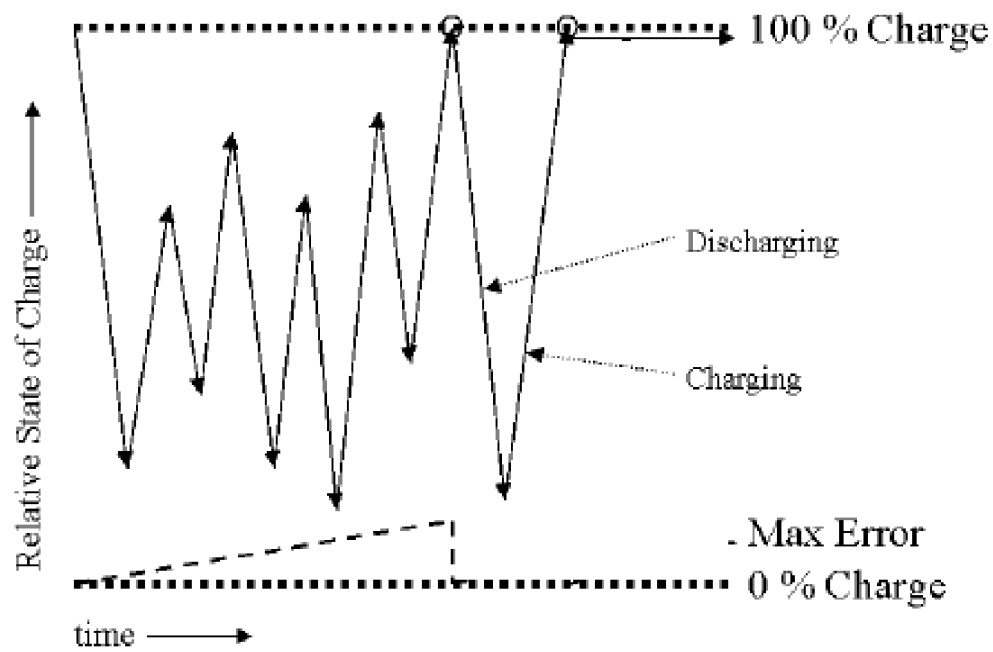
## What Causes the Conditioning Message on the Monitor?

In addition to the value for the full capacity, the battery also stores a value for the Max Error. The Max Error tracks the maximum possible deviation of the estimated charge of a battery from the actual charge.

If a battery is charged or discharged partially, or if it is charged while the monitor is being used, the accuracy of the “reference points” for the fully discharged and fully charged states decreases, causing an increase in the value for the Max Error (see diagram, below).

When the Max Error rises over a certain limit, a message is displayed prompting the user to condition the battery, as described in “Conditioning Batteries” on page 104.

You can reset the value for the Max Error before the battery needs conditioning, by performing the steps described in “Conditioning Batteries” on page 104. The minimum value of the Max Error after conditioning is 2%.



## Conditioning Batteries

You must condition the battery when the “battery requires maintenance” symbol shows on the screen. If conditioning is not performed immediately, the monitor will still function according to specifications. However, the displayed time to empty and time to full will show increasing inaccuracy. Do not interrupt the charge or discharge cycle during conditioning.

---

### CAUTION

Do not use a monitor currently being used in order to condition batteries. The monitor switches off automatically when there is no battery power left.

---

To condition the battery,

- 1 Charge the battery until it is completely full. Switch the monitor off to decrease the charging time. When the battery LED turns green i.e. the battery is >90% charged.
- 2 Switch on the monitor and open the **Battery Status** window.
- 3 Check that the **Batteries fully charged** message is displayed.
- 4 Disconnect the monitor from AC power, and let the monitor run until the battery is empty and the monitor switches itself off.
- 5 Reconnect the monitor to AC power and charge the battery until it is full for use or charge to 50% for storage.

## After Installation, Testing, or Repair

Before handing the fetal monitor over to the end-user, make sure it is configured appropriately and that it is in Monitoring Mode. Ensure that the user receives the current revision of the monitor documentation.

---

# Troubleshooting

A list of system error messages and troubleshooting information for common problems you may encounter while using the monitor and its accessories is given in the *Instructions for Use*. This chapter provides a guide for qualified service personnel for troubleshooting problems that cannot be resolved by the user.

---

## CAUTION

If the troubleshooting procedure requires you to disassemble the monitor or transducers, be certain to follow the disassembly and reassembly procedures given in “Repair and Disassembly” on page 139.

---

## Who Should Perform Repairs

Only qualified and authorized service personnel should open the monitor housing, remove, and replace components, or make adjustments. If your medical facility does not have qualified and authorized service personnel, contact Philips’ Response Center or your local Philips representative.

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## WARNING

**High Voltage** - Voltages dangerous to life are present in the instrument when it is connected to the mains power supply. Do not perform any disassembly procedures with power applied to the instrument. Failure to adhere to this warning could cause serious injury or death.

---

## Replacement Level Supported

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in “Repair and Disassembly” on page 139 to exchange the PCB with a known good replacement. Check to see if the symptom disappears and that the monitor passes all performance tests. If the symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started troubleshooting), and continue troubleshooting as directed in this chapter.

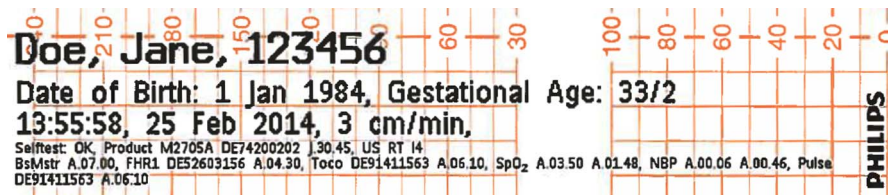
## Checking Revision Information

There are various ways to check revision information:

- Most of the revision information can be checked from reading the contents of the trace header -- see “Trace Header”.
- You can also identify the hardware revision via the **Main Setup** menu -- see “Hardware Revision Check” on page 106.
- You can also identify the software revision via the **Main Setup** menu -- see “Software Revision Check” on page 107.

### Trace Header

The trace header printed when the recorder starts, contains useful information about the monitor and its parameters.



- The first line contains:
  - the patient's name and ID
  - the date of birth of the patient and the gestational age of the pregnancy
  - the time and date, the paper speed and the bed label
- The second line contains:
  - result of the self-test.
  - firmware revision of the FPGA micro controller, responsible for controlling the recorder, the display and the ultrasound tone. This revision is always fixed with a particular software revision.
  - revision of the internal recorder communication protocol. This revision is always fixed with a particular software revision.
  - paper type (US or INT).
  - information on whether the recording is a real-time trace (RT appears), or a stored data/trace recovery printout (RT is not printed).
  - information on the print-head intensity (I).
- The rest of the information contains:
  - product number, serial number and software revision of the monitor.
  - Bus Master firmware revision (OB).
  - serial number and firmware revision of connected devices.

If a transducer is plugged into the monitor after the recorder started, the serial number, and revision information is annotated along the bottom of the trace.

### Hardware Revision Check

Some troubleshooting tasks may require that you identify the hardware revision of your monitor's main board. To check your hardware revision:

- 1 Enter the **Main Setup** menu and select **Revisions**.
- 2 Select **Product**.  
You see the hardware revision in the pop-up window, along with the serial number, part number, and the software revision.

## Software Revision Check

Some troubleshooting tasks may require that you identify the software revision of your monitor. You can find the software revision along with other information, such as the system serial number, in the monitor revision screen. To access the monitor revision screen:

- 1 Enter the **Main Setup** menu and select **Revisions**.
- 2 Select **Product**.  
You see the software revision in the pop-up window, along with the serial number, part number, and the hardware revision.

### NOTE

The part numbers listed in the monitor revision screen do not necessarily reflect the part numbers required for ordering parts. Please refer to “Parts” on page 125 for the ordering numbers. Photos of the parts are included for swift identification. The system serial number can also be found on the rear of the monitor.

## Obtaining Replacement Parts

See “Parts” on page 125 for details on replacement parts.

## Troubleshooting Guide

Problems with the monitor are separated into the categories indicated in the following sections and tables. Check for obvious problems first. If further troubleshooting instructions are required, refer to “Parts” on page 125.

Taking the recommended actions discussed in this section will correct the majority of problems you may encounter. However, problems not covered here can be resolved by calling Philips Response Center or your local representative.

## Checks for Obvious Problems

When first troubleshooting the instrument, check for obvious problems by answering basic questions such as the following:

- 1 Is the power switch turned on?
- 2 Is the AC power cord connected to the instrument and plugged into an AC outlet?

### **Monitors with FM20/FM30 Battery Option #E25 only:**

- 1 Is the power switch turned on?
- 2 Is the battery adequately charged?
- 3 Is the AC power cord connected to the external power supply (M8023A) and plugged into an AC outlet?

## Checks Before Opening the Instrument

You can isolate many problems by observing indicators on the instrument before it is necessary to open the instrument.

### Checks with the Instrument Switched On, AC Connected

The green power LED lights for about 1.5 seconds after switching on, and then goes out, and remains unlit doing normal operation. The location of the green LED is shown in the following photograph:



### Checks with the Instrument switched On, AC Connected, with Battery

This section applies to monitors with FM20/FM30 battery option #E25 only). When the monitor is connected to AC power via the M8023A External Power Supply, the battery LED is either green or yellow. Green means battery power is >90%. Yellow means the battery is charging (battery power <90%).

### Individual Parameter INOPs

If you see any of the following parameter INOPs:

**DFHR1 Equip Malf**

**DFHR2 Equip Malf**

**DFHR3 Equip Malf**

**MECG Equip Malf**

**FetRec Equip Malf**

**FHR1 Equip Malf**

**FHR2 Equip Malf**

**FHR3 Equip Malf**

**IUP Equip Malf**

**NBP Equip Malf**

**Bus Master Malfunc**

**SpO<sub>2</sub> Equip Malf**

**SpO<sub>2</sub> Sensor Malf**

**Toco Equip Malf**

try exchanging the relevant component (transducer, sensor, patient module, or board) with a known good replacement, following the procedures in “Repair and Disassembly” on page 139. Check to see if the INOP disappears, and that you can measure the parameter in question normally. If the INOP persists, swap back the original component and continue troubleshooting as directed in this chapter.

If you see the **Bus Master Malfunc** INOP following a monitor software upgrade, it is likely that the firmware in the bus master board is incompatible with the new software. Check the firmware revision, and upgrade this if necessary with the Support Tool. Contact Philips support for more information regarding software and firmware revisions.

After checking/upgrading the bus master firmware, and you still suspect a defective bus master board, first try plugging the transducers into another monitor. If the transducers work properly with the other monitor, then exchange the bus master board.

In the case of the INOPs **FHR1 Equip Malf**, **FHR2 Equip Malf**, and **FHR3 Equip Malf**, when there are two or more ultrasound transducers attached to the monitor, identify the transducer for which the INOP was issued, using the blue transducer Finder LED. Touching a numeric on the screen turns on the Finder LED light of the transducer providing the measurement. If you cannot identify the suspected transducer directly, because the transducer Finder LED does not light up due to a defect, identify the other functioning transducers by activating their Finder LEDs, thus finding the defective one by a process of elimination.

## Initial Instrument Boot Phase

The following table describes the regular initial boot phase of the monitor. If the boot phase does not proceed as described below, go to “Boot Phase Failures” on page 110 for Troubleshooting information.

| Time (sec.) after Power On | Boot Phase Event                                                                    |
|----------------------------|-------------------------------------------------------------------------------------|
| 0                          | Switch the monitor on using the On/Off switch                                       |
| 2                          | The green AC power LED lights for about 1.5 seconds                                 |
| 3.5                        | Green AC power LED is turned off, and remains off                                   |
| 5                          | You hear a ‘pop’ from the loudspeaker                                               |
| 6-8                        | Boot screen with the Philips logo appears on the display and a test sound is issued |
| 8-10                       | Boot screen with the Philips logo disappears                                        |
|                            | Fixed screen elements (for example smart keys, alarm fields) appear on the screen   |
| 10-15                      | First measurement information appears on the screen, touchscreen is functional      |

## Troubleshooting Tables

The following tables list troubleshooting activities sorted according to symptoms.

### How to Use the Troubleshooting Tables

The possible causes of failure and the remedies listed in the troubleshooting tables should be checked and performed in the order they appear in the tables. Always move on to the next symptom until the problem is solved.

- Boot Phase Failures
- Screen is blank
- Touchscreen not functioning
- General monitor INOP messages
- Alarm tones
- Fetal recorder
- LAN/RS232

## Boot Phase Failures

| Symptoms                                               | Possible Causes of Failure                                 | Failure Isolation and Remedy                                                                                                                                                                                               |
|--------------------------------------------------------|------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Green LED does not light up, and no test tone is heard | No AC mains connection                                     | Check that the power cord is not damaged, and is properly connected to the monitor. Check that the power cord is correctly connected to a powered AC mains socket.                                                         |
|                                                        | Power supply defective                                     | Remove the power supply, and check if the output voltage is within the specifications (24 V). Measure on the multi-colored wired connection between the red and black wires. Exchange the power supply if it is defective. |
|                                                        | Power On/Off switch defective                              | Replace the power supply.                                                                                                                                                                                                  |
|                                                        | Aborted/interrupted or inconsistent software configuration | Perform a software upgrade using the Support Tool.                                                                                                                                                                         |
|                                                        | Main CPU Board defective                                   | Replace the Main CPU Board. Add the boards in reverse order and try again with each board.                                                                                                                                 |
| Green LED does not light up, but you hear a test tone  | Display assembly not connected to the Main CPU Board       | Check if Display assembly is connected correctly to the Recorder Adapter Board. Check the multi-pin connector between the Recorder Adapter Board and the Main CPU Board.                                                   |
|                                                        | Touch controller defective                                 | Replace the Display assembly.                                                                                                                                                                                              |
|                                                        | Display Adapter Board defective                            | Disconnect and reconnect the flat cable of the Display Adapter Board and check again.                                                                                                                                      |
|                                                        | LED defective                                              | Try to switch on the monitor. If it operates normally, the LED is defective. Repair is effected by replacing the Display assembly.                                                                                         |
| Green LED stays on continuously                        | Main CPU Board defective                                   | Try loading new software. If this does not solve the problem, replace the Main CPU Board.                                                                                                                                  |

| Symptoms                                                            | Possible Causes of Failure | Failure Isolation and Remedy                                                                                                                                                                                                                              |
|---------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Green LED blinks<br>(indicating cyclic reboots)                     | Hardware failure           | Connect Support Tool directly to monitor with a crossover cable and start "search for defective devices".<br><br>If no device is detected, proceed as described above in the section "Green LED stays on continuously".                                   |
|                                                                     | Software fault             | If the Support Tool can detect the device and it indicates the Operating Mode is 'Boot', download and store the status log. Reload the software and re-clone the monitor. If this fixes the problem, e-mail the status log to your local response center. |
|                                                                     | Hardware failure           | If this does not rectify the problem, follow the instructions under "Green LED stays on continuously".                                                                                                                                                    |
| No Test Sound issued<br>or<br>INOP <b>Speaker Malfunc</b><br>issued | Speaker cable disconnected | Check the speaker connections.                                                                                                                                                                                                                            |
|                                                                     | Speaker defective          | Check for INOPs and follow the instructions.<br><br>Exchange the speaker.                                                                                                                                                                                 |
|                                                                     | Main CPU Board defective   | Exchange the Main CPU Board.                                                                                                                                                                                                                              |

## Screen is Blank

The information listed in this table is only valid if the boot phase has completed without error. See "Boot Phase Failures" on page 110 table for a description of the boot phase.

| Symptoms                                     | Possible Causes of Failure                | Failure Isolation and Remedy                                                  |
|----------------------------------------------|-------------------------------------------|-------------------------------------------------------------------------------|
| Display is blank or<br>brightness is reduced | Display Adapter Board cable not connected | Check cable connection of the Display assembly to the Recorder Adapter Board. |
|                                              | Backlight tubes defective                 | Replace the Display assembly.                                                 |
|                                              | Back-light inverter defective             |                                                                               |
|                                              | Display adapter board defective           |                                                                               |
|                                              | LCD flat panel defective                  |                                                                               |
|                                              | Main CPU Board defective                  | Replace the Main CPU Board.                                                   |

## Touchscreen Not Functioning

| Symptoms                    | Possible Causes of Failure                              | Failure Isolation and Remedy                                                                                                                                                                                  |
|-----------------------------|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Touchscreen not functioning | Touchscreen functionality has been temporarily disabled | Check if the touchscreen functionality has been temporarily disabled (padlock symbol on <b>Main Setup</b> key). If yes, press and hold the <b>Main Setup</b> key to re-enable the touchscreen operation.      |
|                             | Touch screen cable not connected                        | Check the connection from the Display assembly to the Recorder Adapter Board.<br><br>If the problem is not resolved, check the multi-pin connector between the Recorder Adapter Board and the main CPU Board. |
|                             | Touch controller defective                              | Replace the Display assembly.                                                                                                                                                                                 |
|                             | Touch sensor defective                                  |                                                                                                                                                                                                               |
|                             | Main CPU Board defective                                | Replace the Main CPU Board.                                                                                                                                                                                   |
| Touch Position invalid      | Touch not calibrated                                    | Perform the touch calibration:<br><br>1 Enter the Service Mode.<br><br>2 Enter the <b>Main Setup</b> menu.<br><br>3 Select <b>Hardware</b> .<br><br>4 Select <b>Calibrate Touch</b> .                         |

## General Monitor INOP Messages

| INOP Message              | Possible Causes of Failure                     | Failure Isolation and Remedy                                                                                                                           |
|---------------------------|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Check Monitor Func</b> | Problem with the voltages (5 V) in the monitor | Remove all I/O boards and put them back in one at a time to isolate any defective board. If this does not resolve the problem, replace the main board. |
| <b>Check Monitor Temp</b> | The temperature inside the monitor is too high | Check the environment for possible causes.                                                                                                             |
|                           | Main Board defective                           | Replace the Main Board.                                                                                                                                |

| INOP Message              | Possible Causes of Failure                                                                                                                                  | Failure Isolation and Remedy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Check Settings</b>     | INOP occurs during normal operation, indicating a possible monitor software problem                                                                         | <p>Check the monitor and patient settings before you resume monitoring. If the settings are unexpected, there may be a problem with the monitor software.</p> <ol style="list-style-type: none"> <li>1 Silence the INOP.</li> <li>2 Load the User Defaults.</li> </ol> <p>If this is unsuccessful, try loading the Factory Default and reconfigure the monitor in Configuration Mode, and save the new settings in the User Defaults.</p> <p>If the INOP persists, there is an unresolved software problem. Report the problem to factory support.</p> |
|                           | INOP occurs after a software upgrade, indicating a possible incomplete or unsuccessful upgrade                                                              | Clone the correct settings via the Support Tool.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Check TI Config</b>    | INOP occurs after a software upgrade or option change, indicating that the monitor settings need to be updated to support the software feature "NST Report" | Check the setting item <b>Setup NST Report, Guideline</b> . If set to "none", select the appropriate NST Report Guideline. If no Guideline is available, clone updated settings via the Support Tool (e.g. settings based on an initial configuration file for the installed software revision, plus customer specific adaptations, if required).                                                                                                                                                                                                      |
| <b>Internal.Comm.Malf</b> | Main CPU Board defective                                                                                                                                    | Replace the Main CPU Board.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Settings Malfunct</b>  | Problem during cloning process                                                                                                                              | Reclone the configuration file.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                           | Memory space in which the settings are stored has been corrupted                                                                                            | Reclone the configuration file. This will reload the memory space.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                           | Main CPU Board defective                                                                                                                                    | Replace the Main CPU Board.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

## Battery Related Problems

| Symptoms                                                                                                      | Causes of Failure                                                                           | Failure Isolation and Remedy                                                                                                             |
|---------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Battery symbol is not displayed                                                                               | The monitor is not configured for battery operation.                                        | Make sure a system interface board with battery capability is installed.                                                                 |
| <b>Batt Empty</b> INOP tone, battery LED flashes<br>During this INOP, alarms cannot be paused or switched off | The estimated remaining battery-powered operating time of the battery is $\leq 10$ minutes. | <p>Recharge the battery immediately.</p> <p>If the condition persists, this INOP is re-issued two minutes after you acknowledged it.</p> |
| <b>Batt Incompat</b> INOP tone                                                                                | The indicated battery cannot be used with this monitor.                                     | Replace with the correct battery (M4605A).                                                                                               |

## 8 Troubleshooting

| Symptoms                                                                                                                                                             | Causes of Failure                                                                                                               | Failure Isolation and Remedy                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Batt Low</b> INOP tone                                                                                                                                            | The estimated battery-powered operating time remaining is less than 20 minutes.                                                 | Recharge the battery.                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Battery Malfunc</b> INOP tone, battery LED flashes<br><br>During this INOP, alarms cannot be paused or switched off, if the monitor is not connected to AC power. | The monitor cannot determine the battery status, or there is a communication problem between the battery and the battery board. | Replace the faulty battery. If the condition persists, and the monitor is not connected to AC power, this INOP is re-issued two minutes after you acknowledged it.<br><br>Check the battery in a different monitor or in a battery charger. If the INOP persists the battery is faulty.<br><br>Check the battery board with known good batteries. If the INOP persists, replace the battery board.<br><br>If the problem persists, replace the main board. |
| <b>Charger Malfunc</b> INOP tone, battery LED may flash                                                                                                              | There is a problem with the battery charger in the monitor.                                                                     | Switch the monitor off and back on again. If the problem persists replace battery with a known good battery. If the INOP is shown again, replace the battery board. If the problem persists replace the main board.                                                                                                                                                                                                                                        |
| <b>Check Batt Temp</b> INOP tone                                                                                                                                     | The temperature of the battery is too high.                                                                                     | Check that monitor is not exposed to heat.                                                                                                                                                                                                                                                                                                                                                                                                                 |

### Keyboard/Mouse Not Functioning

| Symptoms                                                        | Possible Causes of Failure                    | Failure Isolation and Remedy                                                                               |
|-----------------------------------------------------------------|-----------------------------------------------|------------------------------------------------------------------------------------------------------------|
| Keyboard/Mouse attached directly to the monitor not functioning | Keyboard/Mouse not connected properly         | Check cabling                                                                                              |
|                                                                 | Keyboard/Mouse defective                      | Replace Keyboard/Mouse                                                                                     |
|                                                                 | USB/PS/2 I/O board is not properly plugged in | Ensure the USB/PS/2 I/O board is properly plugged in. If necessary, remove the board and plug it in again. |
|                                                                 | USB/PS/2 I/O board defective                  | Replace I/O board                                                                                          |

### Network Status Icons

| Icon                                                                                | Explanation                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No Icon                                                                             | LAN cable not connected (monitor does not have a LAN connection).                                                                                                                                                                                                                                                                                                                                                                     |
|  | LAN cable connected, no connection to OB TraceVue/IntelliSpace Perinatal.<br><br>To check whether an IP address has been assigned, enter <b>Main Setup, Bed Information</b> and scroll to <b>IP Address</b> . <b>0.0.0.0</b> means no IP address has been assigned.)<br><br>OB TraceVue/IntelliSpace Perinatal may send a prompt message, giving the reason why a connection to OB TraceVue/IntelliSpace Perinatal cannot take place. |

| Icon                                                                              | Explanation                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>LAN cable connected, IP address assigned, monitor connected to OB TraceVue/IntelliSpace Perinatal.</p> <p>OB TraceVue/IntelliSpace Perinatal may send a prompt message, indicating a possible problem.</p> |

## Alarm Tones

| Symptoms                                          | Possible Causes of Failure                      | Failure Isolation and Remedy |
|---------------------------------------------------|-------------------------------------------------|------------------------------|
| INOP Message <b>Speaker Malfunct</b> is displayed | Speaker cable disconnected                      | Reconnect the speaker cable. |
|                                                   | Speaker defective                               | Replace the speaker.         |
|                                                   | Sound amplifier on the Main CPU Board defective | Replace the Main CPU Board.  |
| An alarm occurs, but no alarm sound is issued.    | Volume is set to 0                              | Increase the volume.         |
|                                                   | Speaker defective                               | Replace the speaker.         |
|                                                   | Sound amplifier on the Main CPU Board defective | Replace the Main CPU Board.  |

## Alarm Behavior

If your monitor did not alarm in the way in which the end user expected it to, please consult the Instructions for Use for possible setup issues, or configuration settings which could affect alarm behavior.

## Fetal Recorder

| Symptom                                                                                               | Possible Cause                 | Corrective Action                                                                                                      |
|-------------------------------------------------------------------------------------------------------|--------------------------------|------------------------------------------------------------------------------------------------------------------------|
| A Paper empty warning is issued in the status line at the bottom of the screen, but paper is not out. | The drawer is open.            | Close the drawer.                                                                                                      |
|                                                                                                       | A paper jam occurred.          | Open the drawer, remove paper, tear off the crumpled paper and re-load, or load a new pack of paper. Close the drawer. |
|                                                                                                       | The paper sensor is dirty.     | Clean the paper sensor.                                                                                                |
|                                                                                                       | The paper sensor is defective. | Exchange the paper sensor -- see "Repair and Disassembly" on page 139 and "Parts" on page 125.                         |

## 8 Troubleshooting

| Symptom                                                                                      | Possible Cause                                                | Corrective Action                                                                                                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No paper transport.                                                                          | Poor connection.                                              | Check all internal connectors.                                                                                                                                                                                                                                                                                                  |
|                                                                                              | A paper jam occurred.                                         | Open the drawer, remove paper, tear off the crumpled section of paper and re-load, or load a new pack of paper. Close the drawer.                                                                                                                                                                                               |
|                                                                                              | The motor cable is disconnected.                              | Check that the motor cable is properly connected to the Recorder Adapter Board.                                                                                                                                                                                                                                                 |
|                                                                                              | The motor is defective.                                       | To test the functioning of the motor, open the drawer and press the recorder <b>Start/Stop</b> key to start the recorder. A good motor should rotate for between one and three minutes (depending on the paper speed).<br><br>If the motor does not rotate, replace the motor -- see "Replacing the Stepper Motor" on page 180. |
|                                                                                              | The drawer is open.                                           | Close the drawer.                                                                                                                                                                                                                                                                                                               |
| The recorder appears to be running normally, but the paper remains blank.                    | The Thermal Printhead is disconnected.                        | Check the connection. Then run the recorder Selftest to verify correct printing -- see "Fetal Recorder Selftest Report" on page 98.                                                                                                                                                                                             |
|                                                                                              | The Thermal Printhead is defective.                           | Replace the Thermal Printhead. Then calibrate the recorder -- see "Setting the Fetal Recorder Offset" on page 97.                                                                                                                                                                                                               |
|                                                                                              | The wrong side of the paper is facing up.                     | Load the paper correctly, the right way up.                                                                                                                                                                                                                                                                                     |
| No recorder key is available on the screen, and the INOP <b>FetRec Equip Malf</b> is issued. | The recorder has not been calibrated.                         | Calibrate the recorder -- see "Setting the Fetal Recorder Offset" on page 97.                                                                                                                                                                                                                                                   |
|                                                                                              | EEPROM on the Recorder Adapter Board is defective             | Exchange the Recorder Adapter Board and calibrate the recorder -- see "Setting the Fetal Recorder Offset" on page 97.                                                                                                                                                                                                           |
|                                                                                              | The Recorder Controller on the Main CPU Board is defective.   | Exchange the Main CPU Board and calibrate the recorder -- see "Setting the Fetal Recorder Offset" on page 97.                                                                                                                                                                                                                   |
|                                                                                              | The recorder cable is disconnected.                           | Ensure the recorder cable is connected firmly at both ends.                                                                                                                                                                                                                                                                     |
| The INOP <b>FetRec Chk Config</b> is issued                                                  | The Recorder Speed and/or Scale Type have not been configured | Perform the configuration settings for Recorder Speed and/or Scale Type.                                                                                                                                                                                                                                                        |

| Symptom                                                       | Possible Cause                                                                                                     | Corrective Action                                                                                                                                                                                                                                       |
|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The INOP <b>Check Paper</b> is issued.                        | The drawer is open and there is paper on the paper sensor.                                                         | Ensure the paper is loaded correctly, and close the drawer.                                                                                                                                                                                             |
|                                                               | A paper jam occurred.                                                                                              | Open the drawer, remove paper, tear off the crumpled section of paper and re-load, or load a new pack of paper. Close the drawer.                                                                                                                       |
|                                                               | The paper sensor is dirty.                                                                                         | Clean the paper sensor.                                                                                                                                                                                                                                 |
|                                                               | The paper sensor is defective.                                                                                     | Exchange the paper sensor -- see “Repair and Disassembly” on page 139 and “Parts” on page 125.                                                                                                                                                          |
|                                                               | The rubber roller is dirty.                                                                                        | Clean the rubber roller.                                                                                                                                                                                                                                |
|                                                               | The paper is not approved by Philips.                                                                              | Use only paper approved by Philips.                                                                                                                                                                                                                     |
|                                                               | An inadequate contrast of paper marks.                                                                             | Use only Philips approved paper.<br>Calibrate the recorder.                                                                                                                                                                                             |
| The INOP <b>Wrong Paper Scale</b> is issued.                  | Paper with the wrong scale has been loaded (for example, International paper has been loaded instead of US paper). | Check, and if necessary, replace the paper pack with one with the correct scale. Check, and if necessary, change the paper scale setting to the correct setting for the paper used.                                                                     |
| The INOP <b>Printhead Overheat</b> is issued.                 | The printhead is too hot.                                                                                          | Wait for the printhead to cool down, then press the recorder <b>Start/Stop</b> key or the <b>Silence</b> key to clear the INOP.                                                                                                                         |
| Bad or distorted printout within the first 1 cm of the trace. | The paper drawer was not fully closed.                                                                             | Always ensure that the paper drawer is fully closed before you start recording.                                                                                                                                                                         |
| Poor print quality.                                           | The heat setting needs adjusting.                                                                                  | Adjust the Thermal Printhead heat setting. Then run the recorder Selftest to verify correct printing -- see “Fetal Recorder Selftest Report” on page 98.                                                                                                |
|                                                               | The Thermal Printhead is dirty.                                                                                    | Clean the Thermal Printhead. Then run the recorder Selftest to verify correct printing -- see “Fetal Recorder Selftest Report” on page 98.                                                                                                              |
|                                                               | Thermal Printhead failure.                                                                                         | Exchange the Thermal Printhead -- see “Removing the Thermal Line Printhead (TLPH)” on page 172 and “Software Revision Check” on page 107. Then run the recorder Selftest to verify correct printing -- see “Fetal Recorder Selftest Report” on page 98. |
| Paper not feeding properly.                                   | The paper is incorrectly loaded.                                                                                   | Load the paper correctly.                                                                                                                                                                                                                               |
|                                                               | The rubber roller is dirty.                                                                                        | Clean the rubber roller.                                                                                                                                                                                                                                |

## 8 Troubleshooting

| Symptom                                                                 | Possible Cause                       | Corrective Action                                                                                   |
|-------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------------------------------------------------------|
| Trace is not printed correctly with a reference to the paper gridlines. | The Offset needs adjusting.          | Calibrate the recorder and change the offset -- see “Setting the Fetal Recorder Offset” on page 97. |
|                                                                         | The wrong paper scale is being used. | Ensure the paper you are using matches the paper scale setting.                                     |

### LAN / RS232

| Symptoms                                                                                                     | Cause of Failure                                                                                                                        | Failure Isolation and Remedy                                                                                                                                |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| External device (such as a surveillance system like OB TraceVue/ IntelliSpace Perinatal) not receiving data. | The LAN/RS232 port is not configured for data export.                                                                                   | Check the configuration of the LAN/RS232 ports in Configuration Mode.                                                                                       |
|                                                                                                              | The cable between the external device and the monitor is not connected correctly or defective.                                          | Check the cable and replace it if necessary.                                                                                                                |
|                                                                                                              | The external device does not support the version of the data export protocol used in the monitor.                                       | Check if the device supports the version of the data export protocol. Upgrade the device or the monitor if necessary (if matching versions exist).          |
|                                                                                                              | A terminal concentrator is used in between the device and the monitor, and a protocol with dynamic speed negotiation is used.           | Some terminal concentrators do not support changing the transmission speed (baud rate) dynamically. Check if the connection works without the concentrator. |
|                                                                                                              | The LAN/RS232 board is in a wrong slot (slot has been changed after software configuration or an additional board has been plugged in). | Verify correct the placement of the I/O boards.                                                                                                             |
|                                                                                                              | The LAN/RS232 board is defective.                                                                                                       | Check the board and replace it if necessary.                                                                                                                |

**MIB / RS232**

| Symptoms                           | Cause of Failure                                                                                                                           | Failure Isolation and Remedy                                                                                                                                |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| External device not receiving data | The MIB/RS232 port is not configured for data export.                                                                                      | Check the configuration of the MIB/RS232 ports in Configuration Mode.                                                                                       |
|                                    | The wrong data export protocol driver is configured in the monitor.                                                                        | Check the export protocol required by the attached device, and configure the monitor accordingly.                                                           |
|                                    | The cable between the external device and the monitor is not connected correctly or defective.                                             | Check the cable and replace it if necessary.                                                                                                                |
|                                    | The external device does not support the version of the data export protocol used in the monitor.                                          | Check if the device supports the version of the data export protocol. Upgrade the device or the monitor if necessary (if matching versions exist).          |
|                                    | A terminal concentrator is used in between the device and the monitor, and a protocol with dynamic speed negotiation is used.              | Some terminal concentrators do not support changing the transmission speed (baud rate) dynamically. Check if the connection works without the concentrator. |
|                                    | The MIB/RS232 board is in the wrong slot (slot has been changed after software configuration, or an additional board has been plugged in). | Verify the correct placement of the I/O boards.                                                                                                             |
|                                    | The MIB/RS232 board, or the connector board (depending on which RS232 port is used) is defective.                                          | Check the board and replace it if necessary.                                                                                                                |
| Detailed Protocol Problem          |                                                                                                                                            | Consult the Data Export Protocol document.                                                                                                                  |

**USB**

| Symptoms                                       | Cause of Failure                                                                                | Failure Isolation and Remedy                                                                                                                |
|------------------------------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| None of the connected devices are functioning. | The USB port in the monitor is defective.                                                       | Depending on location of USB port, exchange either side USB connector, standard system interface board, or advanced system interface board. |
|                                                | An invalid combination of connected devices is present, or the connected devices are defective. | Make sure the combination of the connected devices is valid. Replace the defective devices if necessary.                                    |

## Tympanic Temperature Problems

| Symptoms                                    | Possible Cause of Failure                                                                                                                                  | Failure Isolation and Remedy                                                                                                                                                                                                                                       |
|---------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Tympanic Thermometer does not function. | There is no connection either between the base station and the thermometer, or the base station and the host monitor.<br><br>The thermometer is defective. | Verify that the interface cable between the base station and the host monitor is connected correctly. Verify that the thermometer cable is connected to the base station, and that its connector is not damaged. If the problem persists, replace the thermometer. |
| The Tympanic Thermometer display is blank.  |                                                                                                                                                            |                                                                                                                                                                                                                                                                    |
| The temperature reading is unusually high.  | The probe cover is damaged, or not attached correctly.                                                                                                     | Verify that the probe cover is not torn, and that the probe is inserted into the cover completely. If the problem persists, use a new probe cover.                                                                                                                 |
| The temperature reading is unusually low.   | The probe, probe cover, or the ear canal is obstructed.                                                                                                    | Remove any obstructions from the probe cover, the probe tip, and the patient's ear canal.                                                                                                                                                                          |

## Flexible Nurse Call Relay

| Symptoms                                                  | Cause of Failure                                                                | Failure Isolation and Remedy                                   |
|-----------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------|
| The INOP message Check Nurse Call Relay is issued.        | The Flexible Nurse Call Relay I/O board is defective.                           | Replace the Flexible Nurse Call Relay I/O board.               |
| The monitor alarmed, and the Nurse Call is not activated. | There is an incorrect configuration present (Relay latency, Relay trigger).     | Check the monitor configuration (see the Configuration Guide). |
|                                                           | The connection of the cable to the monitor, or the nurse call system is defect. | Check the cable connections.                                   |
|                                                           | The Flexible Nurse Call Relay I/O board is defective.                           | Replace the Flexible Nurse Call Relay I/O board.               |

## Keyboard/Mouse not Functioning

| Symptoms                                                                 | Possible Causes of Failure                         | Failure Isolation and Remedy                                                                                    |
|--------------------------------------------------------------------------|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|
| The Keyboard/Mouse attached directly to the monitor are not functioning. | The Keyboard/Mouse are not connected properly.     | Check the cabling.                                                                                              |
|                                                                          | The Keyboard/Mouse are defective.                  | Replace the Keyboard/Mouse.                                                                                     |
|                                                                          | The USB/PS/2 I/O board is not properly plugged in. | Ensure that the USB/PS/2 I/O board is properly plugged in. If necessary, remove the board and plug it in again. |
|                                                                          | The USB/PS/2 I/O board is defective.               | Replace the I/O board.                                                                                          |

## No Video on Remote Display

| Symptoms                                | Possible Causes of Failure           | Failure Isolation and Remedy                                      |
|-----------------------------------------|--------------------------------------|-------------------------------------------------------------------|
| No video on a connected remote display. | The cable is not properly connected. | Check that the video cable is securely connected at both ends.    |
|                                         | The remote display has no power.     | Ensure that the remote display is properly connected to AC mains. |

## Transducers

Note that immediately after plugging in a normally functioning transducer, the Finder LED briefly lights twice.

| Symptoms                                                                                                                                                              | Possible Cause                             | Failure Isolation and Remedy                                                                                                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The transducer Finder LED does not light up after plugging in the transducer, and the transducer appears not to work.<br><b>INOP Bus Master Malfunc</b> is displayed. | Defective transducer cable                 | Visually inspect the transducer cable and the cable connector for damage. If there are obvious signs of damage, replace the cable.                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                       | Defective connector block                  | Visually inspect the connector block and the sensor sockets for damage. If there are obvious signs of damage, replace the connector block.                                                                                                                                                                                                                                                             |
|                                                                                                                                                                       | Transducer or connector block is defective | Try plugging the transducer into a different sensor socket. <ul style="list-style-type: none"> <li>If the Finder LED works, then the original socket is defective. Replace the connector block.</li> <li>If the Finder LED still does not light in any of the other sockets, try using a known good transducer. If the Finder LED lights, the original transducer is defective: replace it.</li> </ul> |
|                                                                                                                                                                       | Bus Master Board is defective              | Try using a known good transducer. If the Finder LED does not light in any of the sockets using a known good transducer, then the Bus Master Board is defective. Replace the Bus Master Board.                                                                                                                                                                                                         |
|                                                                                                                                                                       | No power to Bus Master Board               | If both the SpO <sub>2</sub> board and the Bus Master Board are not working, exchange the power supply.                                                                                                                                                                                                                                                                                                |

## 8 Troubleshooting

| Symptoms                                                                                                                                                                                                                                                                                                                                                                                                               | Possible Cause                                                                                                                                                        | Failure Isolation and Remedy                                                                                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| <p>The transducer appears not to work, and:</p> <p>EITHER the transducer Finder LED lights up briefly after plugging in the transducer, and INOP <b>Bus Master Malfunc</b> is displayed, or the transducer Finder LED lights up briefly <i>after</i> plugging in the transducer, and there are no parameters on the screen (transducer is not recognized).</p> <p>The INOP <b>Bus Master Malfunc</b> is displayed.</p> | Transducer is defective                                                                                                                                               | Replace the transducer.                                                                                                        |
| <p>All transducers (US, Toco, IUP, and ECG) do not work.</p> <p>The INOP <b>Bus Master Malfunc</b> is displayed.</p>                                                                                                                                                                                                                                                                                                   | The Bus Master Board is defective.                                                                                                                                    | Replace the Bus Master Board.                                                                                                  |
| The transducer is connected, the INOP <b>Bus Master Malfunc</b> is displayed.                                                                                                                                                                                                                                                                                                                                          | The Main CPU board is defective.                                                                                                                                      | Replace the Main CPU Board.                                                                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                        | The transducer is defective.                                                                                                                                          | Replace the transducer.                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                        | An interrupted transducer upgrade, or software based malfunction of the transducer, including communication problems between the Bus Master Board and the transducer. | Perform a software upgrade of the transducer with the Support Tool.                                                            |
| The transducer belt button is broken or damaged.                                                                                                                                                                                                                                                                                                                                                                       | Mechanical damage                                                                                                                                                     | <p>Replace the belt button.</p> <p>Handle the transducers with care. Never use a transducer with a broken or damaged knob.</p> |

## Status Log

Many events that occur during start-up or regular monitoring are logged in the Status Log. The Status Log can be cleared. Not all entries in the Status Log are errors. You can print the Status Log via the Support Tool.

| Monitor Id. | Code  | No.   | Date             |
|-------------|-------|-------|------------------|
|             |       |       | Time             |
| H           | 18202 | 20100 | 1 4 Apr 05 16:37 |
| C           | 1721  | 21050 | 1 4 Apr 05 15:37 |

The **Status Log** window shows logged events which caused a reboot of the monitor.

To enter the **Status Log** window, select **Main Setup, Revision**. The following list opens up:

- **Status Log**
- **Product**
- **Appl SW**
- **Config**
- **Boot**
- **Language**
- **Settings**
- **OB**
- **FetRec**
- **NBP** (optional)
- **SpO<sub>2</sub>** (optional)
- List of plugged parameters

Select **Status Log**

The first column in the log identifies the event class ("C": caused a cold start, "H": caused a hot start, "N": no restart, for information only). Column 3 and 4 identify the event source and event code. Column 4 counts the number of occurrences of the event. The last column shows the time and date of the last occurrence of the event.

The following pop-up keys overlay the SmartKeys:

|                  |  |        |  |
|------------------|--|--------|--|
| Clear<br>StatLog |  | M2703A |  |
|------------------|--|--------|--|

### Clear Stat Log

This key clears the currently displayed Status Log

### M2703A

This key switches to the Monitor Revision Window

If an event occurs repeatedly, contact your Philips Service representative.

### NOTE

It is possible, using the Support Tool, to download the Status Log and send it to your Philips Service representative as a file (for example via e-mail).

## Troubleshooting with the Support Tool

Using the Support Tool you can:

- access the full status log which can be saved as a file
- reload software
- identify defective devices
- start touch screen calibration

For details on how to perform these tasks see the Support Tool User Manual.

## Troubleshooting the Individual Measurements or Applications

For problems isolated to an individual parameter or application, please consult the Instructions for Use and the Configuration Guide. If the Instructions for Use did not resolve an individual parameter problem, then another transducer or patient module should be tried. If you are getting questionable readings for individual measurements, you may want to do the performance assurance tests. The performance of the individual applications are affected by the configuration of the monitor. When contacting Philips support, you may be asked about the configuration of the monitor to aid in troubleshooting.

# Parts

Spare parts, along with part numbers, are listed in the tables that follow.

## Monitor

| Part Number  | 12NC         | Description                                           |
|--------------|--------------|-------------------------------------------------------|
| M2703-44103  | 451261010311 | AV-FM30 PLAST Cover,Sym wo SpO <sub>2</sub> ,NBP      |
| M2703-44105  | 451261010321 | AV-FM30 PLAST Cover, Sym w NBP                        |
| M2703-44106  | 451261010331 | AV-FM30 PLAST Cover, Sym w SpO <sub>2</sub> ,NBP      |
| M2703-44113  | 451261010341 | AV-FM30 PLAST Cover, Text wo SpO <sub>2</sub> ,NBP    |
| M2703-44115  | 451261010351 | AV-FM30 PLAST Cover, Text w NBP                       |
| M2703-44116  | 451261010361 | AV-FM30 PLAST Cover, Con Text w SpO <sub>2</sub> ,NBP |
| M2703-68001  | 451261007271 | AV-FM30 ASSY-PWR Power Supply Assembly                |
| M2703-60002  | 451261010231 | AV-FM30 CBL Loudspeaker Assembly                      |
| M2703-60003  | 451261010411 | AV-FM30 Paper Sensor Assembly                         |
| M2703-60004  | 451261010401 | AV-FM30 EMCH Stepper Motor Assembly                   |
| M2703-64101  | 451261010221 | AV-FM30 MECHASY Bottom Housing Assembly               |
| M2703-64102  | 451261010391 | AV-FM30 MECHASY Top Cover Housing                     |
| M2703-60502  | 451261011201 | AV-FM30 Top Cover Assembly                            |
| 453564150521 | 453564150521 | AV FM20/30-Display Assy 5-wire (exch.)                |
| 453564180891 | 453564180891 | AV-FM30 CBL Display flex cable                        |
| M2703-68502  | 451261010551 | AV-FM30 NBPA Assy                                     |
| 1253-8416    | 451261010281 | AV-FM20 CONN Housing NBP                              |
| M1020-66514  | 453564119121 | M_SpO <sub>2</sub> PCA PS2+                           |
| 1253-8422    | 451261010301 | CONN Housing SpO <sub>2</sub>                         |
| M2703-64651  | 451261010431 | AV-FM30 MECHASY Paper Drawer Assembly                 |
| M2705-68511  | 453564378621 | AV-FM50 Main CPU Fetal Board*)                        |
| 453564190401 | 453564190401 | AV-FM30 BAT Charger cage PCA w/o Battery              |
| 453564190311 | 453564190311 | AV-FM30 ASSY-PWR External Power Supply                |
| M2703-66520  | 451261011191 | AV-FM30 Bus Master Board                              |

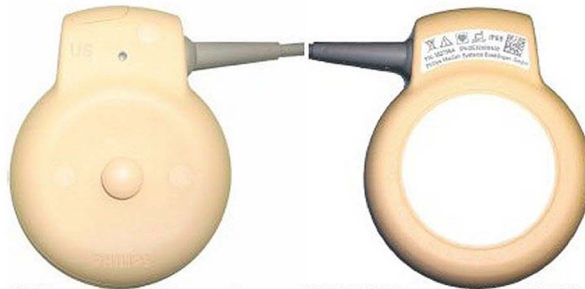
| Part Number  | 12NC         | Description                                  |
|--------------|--------------|----------------------------------------------|
| 1253-8415    | 451261010261 | CONN Block                                   |
| M2703-66530  | 451261011211 | AV-FM30 Recorder Adapter Board               |
| 1810-2440    | 451261010381 | THERMAL PRINT HD, 216mm PRNTWIDTH,<br>800Ohm |
| M2703-67501  | 451261010531 | AV-FM30 ASSY LAN / RS232 Interface           |
| M8086-67501  | 453563469651 | IV I/F; HIF, Integral, PS/2                  |
| M2703-64205  | 451261010521 | AV-FM30 Lever Stop (pack of 5)               |
| M2705-64203  | 451261025031 | FM Small Parts Kit P&L                       |
| M2705-64202  | 451261025041 | FM Small Parts Kit S&C                       |
| 451261026021 | 451261026021 | CBL Safety Test FM20-50 fetal Connector      |
| M8081-67501  | 453563469621 | IV2-STAT I/F; Dual MIB/ RS232                |
| M8087-67501  | 453563469681 | IV2-STAT I/F; Flexible Nurse Call            |
| M8089-67501  | 451261028241 | IV I/F; USB                                  |

\*) 453564378621 provides larger internal trace memory when running SW Rev. J.3 or higher see “Upgrades” on page 213

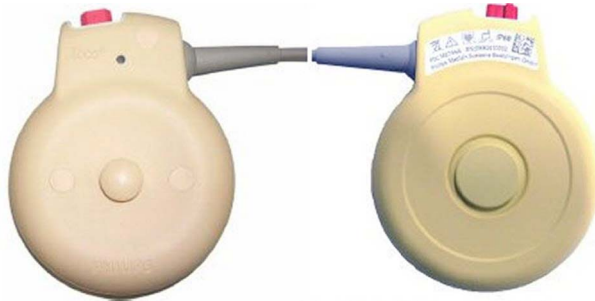
## Transducers



Toco and Toco MP Transducer (M2734A, M2734B)



Ultrasound Transducer (M2736A or M2736AA)



Toco<sup>+</sup> Transducer with ECG/IUP capability  
(M2735A)

| Part Number  | 12NC         | Description                             |
|--------------|--------------|-----------------------------------------|
| M2734A       | 451261011231 | AV-TOCO Transducer                      |
| M2735A       | 451261011241 | AV-TOCO Toco <sup>+</sup> Transducer    |
| 453564207971 | 453564207971 | AV-US Ultrasound XDR FDA reg countries  |
| 453564203931 | 453564203931 | AV-US Ultrasound XDR                    |
| 453564204991 | 453564204991 | AV-TOCO Maternal Pulse Transducer       |
| M2735-64201  | 451261010481 | AV-Cable Assembly                       |
| M2703-64204  | 451261010511 | AV-FM30 Belt Button Kit, w tool, 5ea    |
| 451261026021 | 451261026021 | CBL Safety Test FM20-50 fetal Connector |

## Patient Modules



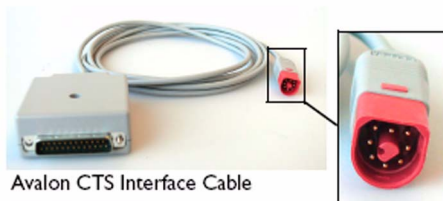
Patient module for ECG/IUP  
(M2738A)



Remote Event Marker  
(989803143411)

| Part Number  | 12NC         | Description               |
|--------------|--------------|---------------------------|
| M2738-60501  | 451261011261 | AV ECG/IUP Patient Module |
| 989803143411 | 989803143411 | Remote Event Marker       |

## Interface Cables



Avalon CTS Interface Cable  
(M2731-60001) for front  
connection

| Part Number  | 12NC         | Description                              |
|--------------|--------------|------------------------------------------|
| 453564180701 | 453564180701 | AV-CTS CBL Cable assy-CTS IF red socket  |
| 453564207981 | 453564207981 | AV-CTS CBL CTS Interf. red conn FDA reg. |
| 453564203941 | 453564203941 | AV-CTS CBL CTS Interf. red connector     |

## Mounting Hardware

| Part Number | 12NC         | Description                         |
|-------------|--------------|-------------------------------------|
| M2740-64001 | 451261009061 | MECHASY Wall Mount                  |
| M2740-64002 | 451261009071 | MECHASY Wall Mounting Arm with tray |
| M2740-64005 | 451261009101 | MECHASY Roll Stand with tray        |
| 5061-8324   | 451261009111 | MECHASY WALL CHANNEL-19             |

## Tympanic Thermometer Part Numbers

| Part Number  | Description                                      | Image                                                                                |
|--------------|--------------------------------------------------|--------------------------------------------------------------------------------------|
| 989803180831 | Genius 2 tympanic temperature probe (commercial) |  |
| 453564331741 | Genius 2 tympanic temperature probe (support)    |                                                                                      |

| Part Number    | Description                   | Image                                                                                |
|----------------|-------------------------------|--------------------------------------------------------------------------------------|
| 453564127781   | CBL Safety Test IntelliBridge |   |
| 453564421601   | IM CBL IRTemp test cable      |   |
| 4535 634 84591 | MIB cable 1,5 m               |  |
| 4535 634 84601 | MIB cable 3,0 m               |                                                                                      |

## Assembly and Kit Contents

The tables in this section provide additional information by listing the contents of assemblies and kits. Assemblies come fully assembled: the contents list details what is contained in the assembly.

### Bottom Housing Assembly



| Bottom Housing Assembly Contents |                 |     |
|----------------------------------|-----------------|-----|
| Sub-Assembly                     | Contents        | Qty |
| Bottom Housing Assembly          | Housing, Bottom | 1   |
|                                  | Feet            | 1   |
| Model/Serial Number Plate        |                 | 1   |

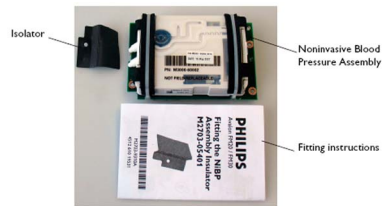
| Bottom Housing Assembly Contents |                                  |     |
|----------------------------------|----------------------------------|-----|
| Sub-Assembly                     | Contents                         | Qty |
| Support Sub-Assembly             | Support                          | 1   |
|                                  | Pin, DIN 6325, 2.5 x 8           | 2   |
|                                  | Hinge Support                    | 2   |
|                                  | Bracket                          | 2   |
|                                  | Screw M3 x 6                     | 4   |
|                                  | Catch, I/O Board                 | 2   |
|                                  | Cable Holder                     | 2   |
|                                  | Pin for Cable Holder             | 2   |
| Main Chassis Sub-Assembly        | Chassis, sheet metal             | 1   |
|                                  | Standoff, M3 x 18                | 2   |
|                                  | Standoff, M3 x 10                | 2   |
|                                  | Standoff, M3 x 6                 | 2   |
|                                  | Press Nut, M3                    | 2   |
|                                  | Clip, RFI                        | 4   |
|                                  | Cover, Board Guide               | 1   |
|                                  | Guide, I/O mid upper             | 3   |
|                                  | Guide, I/O mid lower             | 3   |
|                                  | RFI-Clip                         | 2   |
|                                  | Screw, Torx, with washer, M3 x 6 | 5   |
|                                  | Holder, Loudspeaker              | 1   |
|                                  | Screw, Loudspeaker Holder        | 2   |

## Power Supply Assembly



| Power Supply Assembly Contents |  | Qty |
|--------------------------------|--|-----|
| Power Supply Angle             |  | 1   |
| Power Supply Frame             |  | 1   |
| Nut, press in M3               |  | 3   |
| Insulation                     |  | 1   |
| Screw with washer, M3 x 6      |  | 3   |

## Noninvasive Blood Pressure Assembly



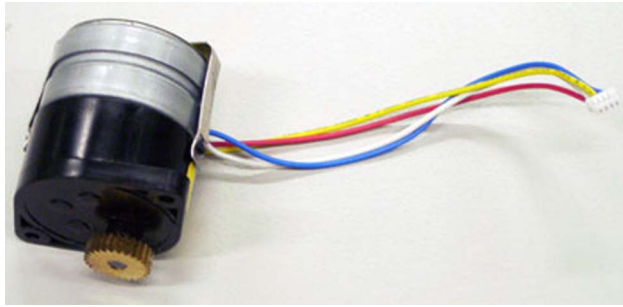
| Noninvasive Blood Pressure Assembly Contents | Qty |
|----------------------------------------------|-----|
| Noninvasive Blood Pressure Assembly          | 1   |
| Isolator                                     | 1   |
| Fitting Instructions                         | 1   |

## Top Cover Housing



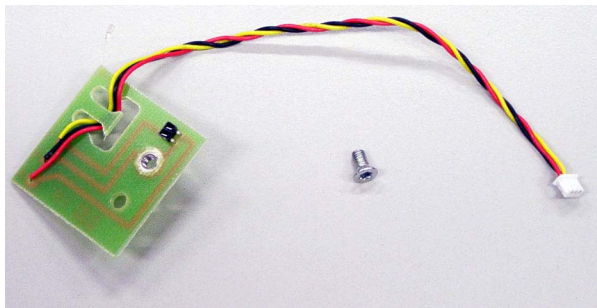
| Top Cover Housing Contents | Qty |
|----------------------------|-----|
| Top Cover                  | 1   |
| Handle                     | 1   |
| Paper Drawer Runner        | 2   |
| Runner End-stop (left)     | 1   |
| Runner End-stop (right)    | 1   |
| Screw, Torx M3 x 8         | 4   |
| Leaf Spring                | 1   |
| Label, Avalon FM20         | 1   |
| Label, Avalon FM30         | 1   |

## Stepper Motor Assembly



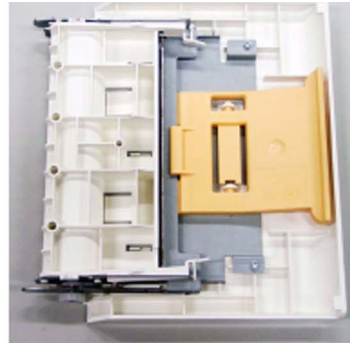
| Stepper Motor Assembly Contents | Qty |
|---------------------------------|-----|
| Stepper Motor                   | 1   |
| Connector Housing               | 1   |
| Connector Contact               | 1   |
| Gearbox                         | 1   |
| Pinion                          | 1   |

## Paper Sensor Assembly



| Paper Sensor Assembly Contents               | Qty |
|----------------------------------------------|-----|
| Paper Sensor, including cable and connectors | 1   |
| Nut, press-in M3                             | 1   |
| Screw, Torx M3 x 6                           | 1   |

## Drawer Assembly



| Drawer Assembly Contents                       | Qty |
|------------------------------------------------|-----|
| Paper Drawer Cover                             | 1   |
| Rubber Roller (including bearing, rod, pinion) | 1   |
| Platen Holder                                  | 1   |
| Chassis Guide                                  | 1   |
| Lever Stop                                     | 1   |
| Latch                                          | 1   |

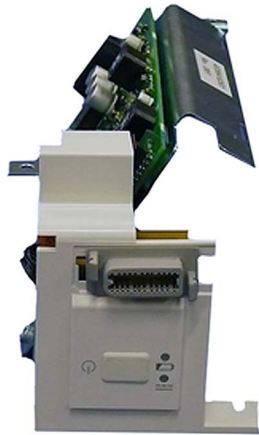
## Display Assembly



| Display Assembly Contents | Qty |
|---------------------------|-----|
| Housing, Bottom           | 1   |
| Housing, Top              | 1   |
| Clamp                     | 1   |
| Pin                       | 2   |
| Display Holder, left-hand | 1   |

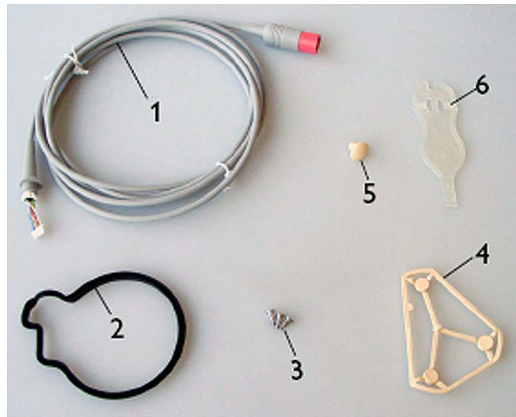
| Display Assembly Contents  | Qty |
|----------------------------|-----|
| Display Holder, right-hand | 1   |
| Back-light Tube            | 2   |
| Hinge                      | 2   |
| Chassis Guide              | 1   |
| Cable Guide, rear          | 1   |
| Board Holder               | 5   |
| Stop Lever                 | 1   |
| Ribbon Cable               | 1   |
| PCA Touch Control          | 1   |
| Inverter Board             | 1   |
| TFT Display Unit           | 1   |
| Touchscreen                | 1   |
| Gasket (1050 mm)           | 1   |

### Battery Assembly (FM20/FM30 with Battery Option #E25 only)



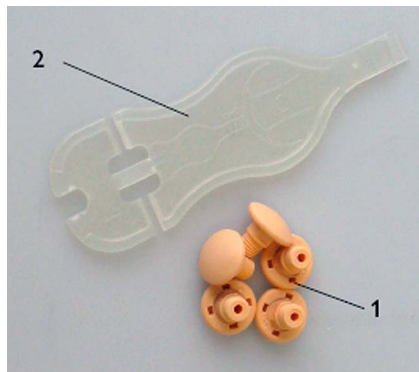
| Battery Assembly Contents | Qty |
|---------------------------|-----|
| Charger board             | 1   |
| Battery metal cover       | 1   |
| Screws                    | 5   |
| Silicon keypad switch     | 2   |
| Cable                     | 1   |

## Transducer Cable Assembly



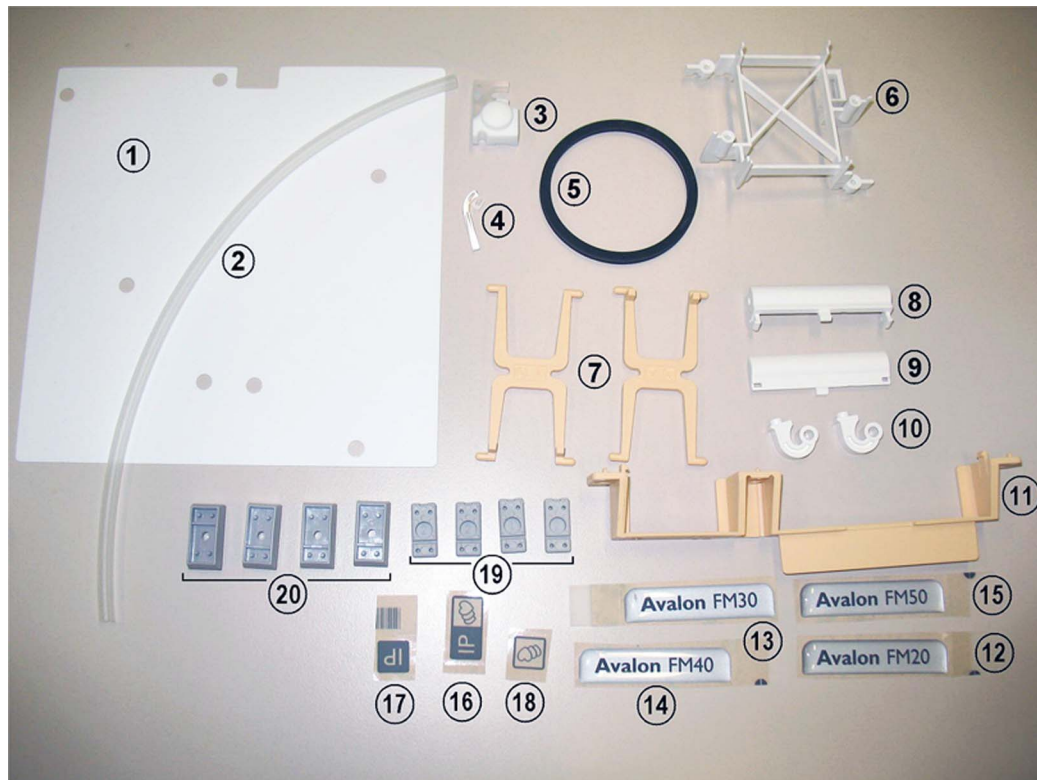
| Item | Cable Assembly Contents                      | Qty |
|------|----------------------------------------------|-----|
| 1    | Transducer Cable (for all fetal transducers) | 1   |
| 2    | Sealing Gasket                               | 1   |
| 3    | Screw M2.5                                   | 3   |
| 4    | Screw Cover (set of 3)                       | 1   |
| 5    | Transducer Belt Button                       | 1   |
| 6    | Avalon Tool                                  | 1   |

## Belt Button Kit



| Item | Belt Button Kit Contents                                     | Qty |
|------|--------------------------------------------------------------|-----|
| 1    | Belt Buttons                                                 | 5   |
| 2    | Avalon Tool (for removing/replacing transducer belt buttons) | 1   |

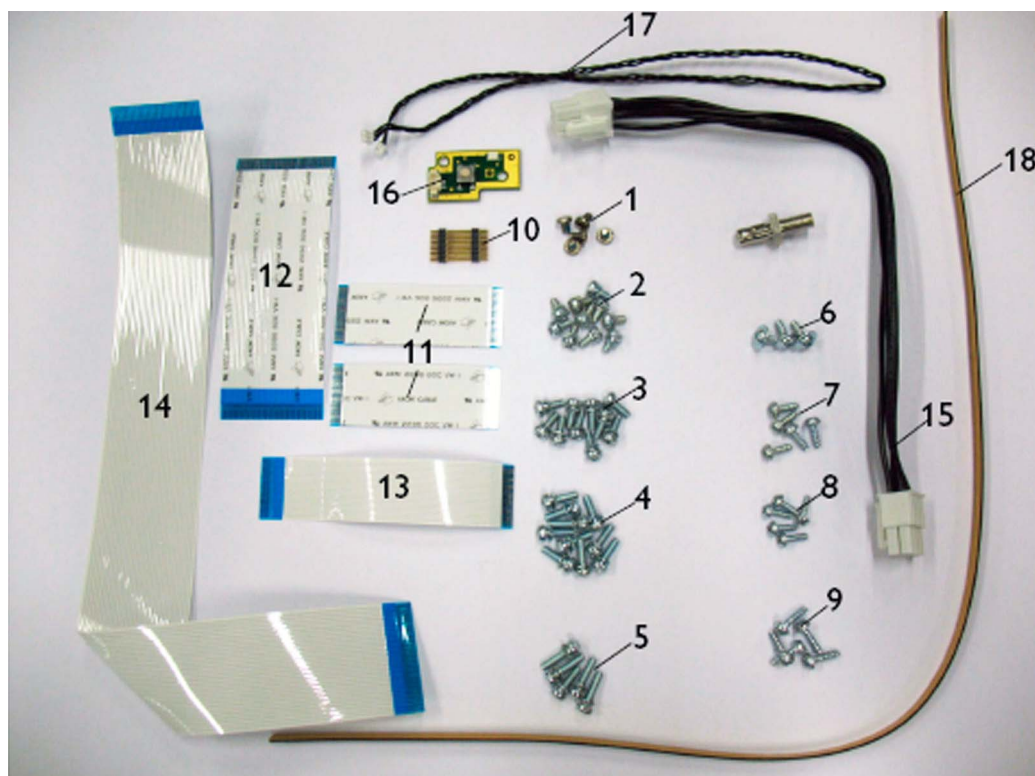
## FM Small Parts Kit - Plastic Parts and Labels



| Item | FM Small Parts Kit Contents - Plastic Parts and Labels | Qty |
|------|--------------------------------------------------------|-----|
| 1    | FM40/50 Insulator, API Board                           | 1   |
| 2    | NBP Tubing                                             | 1   |
| 3    | FM40/50 Silicone ON/OFF Key                            | 1   |
| 4    | FM40/50 Light-pipe                                     | 1   |
| 5    | FM20/30 O-Ring, loudspeaker                            | 1   |
| 6    | FM40/50 Mounting Frame for SpO <sub>2</sub> Board      | 1   |
| 7    | FM20/30 Ratchet Lever/Clip                             | 2   |
| 8    | FM20/30 Cable Guide, Rear                              | 1   |
| 9    | FM20/30 Cable Guide, Front                             | 1   |
| 10   | FM20/30 Hinge                                          | 2   |
| 11   | FM20/30 Connector Frame                                | 1   |
| 12   | Label, FM20                                            | 1   |
| 13   | Label, FM30                                            | 1   |
| 14   | Label, FM40                                            | 1   |
| 15   | Label, FM50                                            | 1   |
| 16   | Intrapartum/Triplets Label                             | 1   |
| 17   | Intrapartum Label                                      | 1   |
| 18   | Triplets Label                                         | 1   |

| Item | FM Small Parts Kit Contents - Plastic Parts and Labels | Qty |
|------|--------------------------------------------------------|-----|
| 19   | FM40/50 Holder, Bumper Foot                            | 4   |
| 20   | FM40/50 Bumper Foot                                    | 4   |

## FM Small Parts Kit - Screws and Cables



| Item | FM Small Parts Kit Contents - Screws and Cables     | Qty |
|------|-----------------------------------------------------|-----|
| 1    | Torx M3 x 4                                         | 5   |
| 2    | Torx M3 x 6 with washer                             | 10  |
| 3    | Torx M3 x 8 with washer                             | 10  |
| 4    | Torx M3 x 10 with washer                            | 10  |
| 5    | Torx M3 x 12 with washer                            | 5   |
| 6    | Screw Ejot K30 x 8                                  | 3   |
| 7    | Screw Ejot 3 x 8                                    | 8   |
| 8    | Screw Ejot 2.5 x 8                                  | 5   |
| 9    | Screw Ejot 3 x 10                                   | 5   |
| 10   | Connector for SpO <sub>2</sub> Board (all monitors) | 1   |
| 11   | Ribbon cable, Bus Master (all monitors)             | 2   |
| 12   | FM20/30 Ribbon cable, Recorder                      | 1   |
| 13   | Ribbon cable, NBP to Main CPU Board (all monitors)  | 1   |
| 14   | FM40/50 Ribbon cable, API Board to Recorder         | 1   |

| Item | FM Small Parts Kit Contents - Screws and Cables | Qty |
|------|-------------------------------------------------|-----|
| 15   | FM40/50 Cable assembly, Power Supply            | 1   |
| 16   | FM40/50 PCA, Switch Board                       | 1   |
| 17   | FM40/50 Switch Board cable to API Board         | 1   |
| 18   | FM40/50 Sealing Gasket, Top Cover               | 1   |
| 19   | FM40/50 Equipotential grounding bolt            | 1   |

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# Repair and Disassembly

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## WARNING

- Before attempting to open or disassemble the monitor, disconnect it from the AC mains supply.
  - Energized circuits are accessible with the covers open. Do not work on the monitor with the covers open and AC power connected. Only qualified service personnel should open or disassemble the monitor.
  - Performance verification: do not place the system into operation after repair or maintenance has been performed, until all performance tests and safety tests listed in chapter “Testing and Maintenance” on page 55 have been performed. Failure to perform all tests could result in erroneous parameter readings, or patient/operator injury.
- 

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## CAUTION

Observe ESD (electrostatic discharge) precautions when working within the unit.

---

## Introduction

Remember to store all screws and parts in a safe place for later refitting.

## How to Use this Chapter

The disassembly sections detail the step-by-step procedures you use to access replaceable parts of the monitor and the transducers.

The monitor consists of two major assemblies:

- The top cover assembly
- The bottom housing assembly

The top cover assembly consists of the top cover housing, the display assembly, the recorder assembly, and the recorder adapter board.

The bottom housing assembly consists of the bottom housing, the power supply assembly, the main CPU board, the bus master board, and depending on the options ordered, the noninvasive blood pressure assembly, the SpO<sub>2</sub> assembly, the input device interfaces, and the RS232/LAN interface.

All part numbers of spare parts are listed in the “Parts” on page 125 chapter of this service guide.

## Tools Required

### CAUTION

When replacing the front cover, do not over-torque the screws. Excessive torque may damage the plastic screw mountings.

You need the following tools:



Flat-head screwdriver, head thickness 0.5 mm to fit transducer screw



Torx-head screwdriver, size T-10, minimum shaft length 80 mm



Small flat-head screwdriver, 2.0-3.0 mm



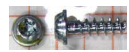
Long-nosed pliers

## Screws Used

The following picture shows the range of screws used in the Avalon FM20/30/40/50 fetal monitors:



Screw Ejot K30x8, T-10



Screw Ejot 3x10, T-10



Screw Ejot 3x8, T-10



Screw Ejot 2.5x8, T-8



Screw M3x12 with washer, T-10



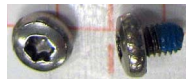
Screw M3x10 with washer, T-10



Screw M3x8 with washer, T-10



Screw M3x6 with washer, T-10



Screw M3x4, T-10

## Serial Numbers

The serial number of the monitor appears on the device nameplate at the rear of the bottom housing. It is also stored electronically in the power supply.

- If you change the bottom housing, remove the nameplate from the old housing and fit it to the new housing.
- If you exchange the power supply of the monitor, you may have to re-enter the monitor serial number afterwards. Check the serial number of the monitor in the Support Tool device view to see whether this is necessary: if the sixth digit of a monitor serial number is an "X", you must re-enter the serial number, which you will find on the nameplate. Refer to the Support Tool Instructions for Use for details of how to change or re-enter a serial number.

## Top Cover Disassembly/Reassembly

This section describes disassembly and reassembly operations for the top cover and its assemblies.

### Removing the Top Cover Assembly

- 1 First fold the display completely flat.

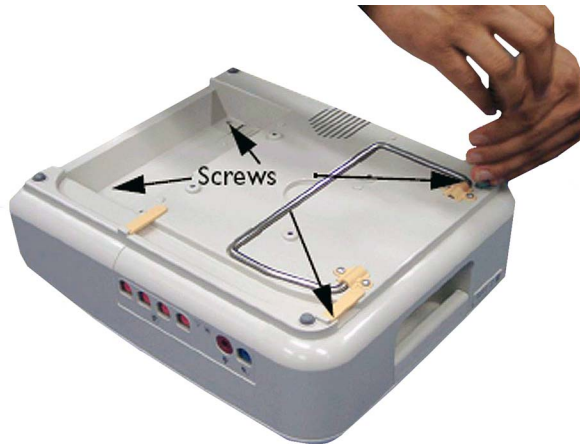


## 10 Repair and Disassembly

- 2 Carefully place the monitor upside down. To avoid scratches, place the unit on some cloth or other soft surface.



- 3 Remove the four screws securing the top cover assembly to the bottom housing, using a T-10 Torx driver.



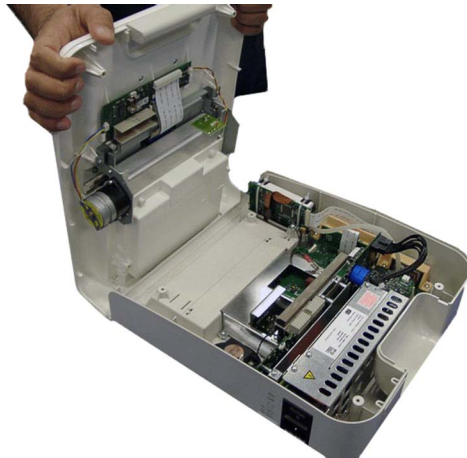
- 4 To gain access to the screw in the rear right hand corner, slide the cable guide aside as illustrated.



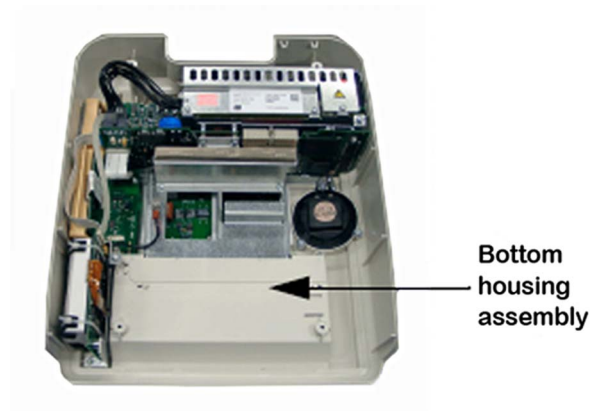
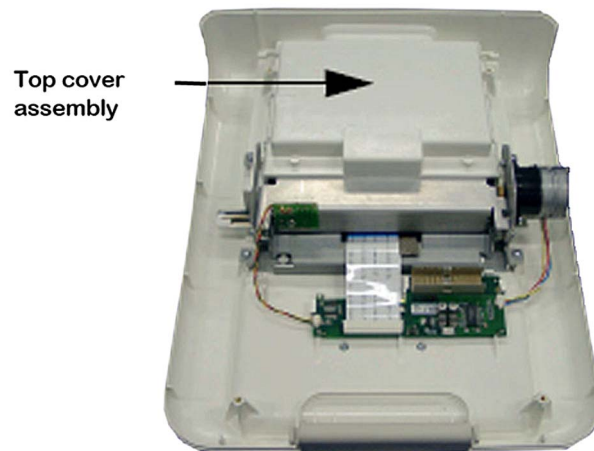
- 5 Holding both top cover and bottom housing assemblies together, place the monitor upright again.



- 6 Separate the top cover from the bottom housing from the front of the monitor as illustrated.



- 7 The top cover assembly is now separated from the bottom housing assembly.



## Removing the Display Assembly

The display assembly can be exchanged without removing the top cover of the monitor. Therefore, no additional safety tests are required after exchanging the display assembly.

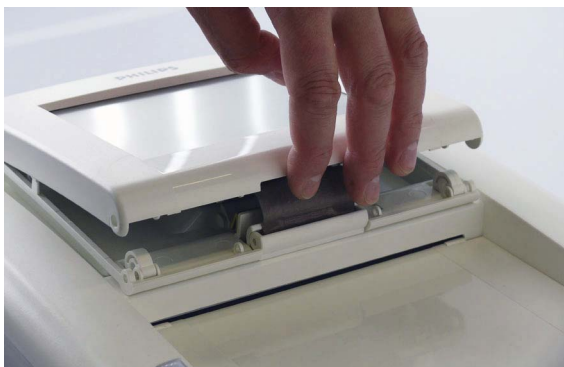
- 1 Squeeze the arms of the ratchet clip to remove it from the slots on the rear of the display housing.



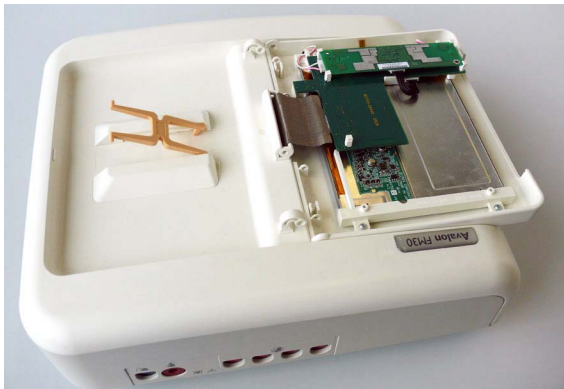
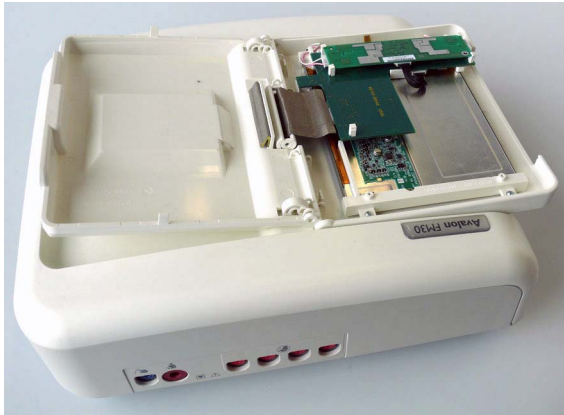
- 2 Remove the two plastic hinge pins on either side of the display housing. Release them by turning the slotted head anti-clockwise with a small flat-bladed screwdriver, then pull them straight out.



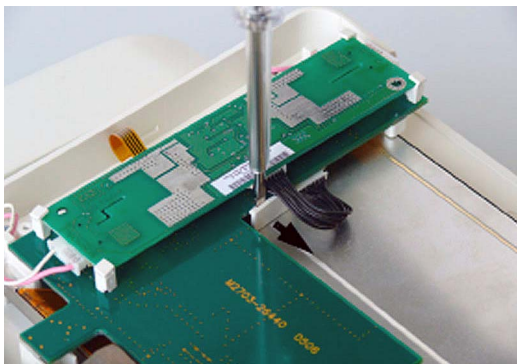
- 3 Starting at the hinge end of the display assembly, separate the two halves of the display assembly.



- 4 Open up the two halves of the display assembly and then remove the back of the display unit.



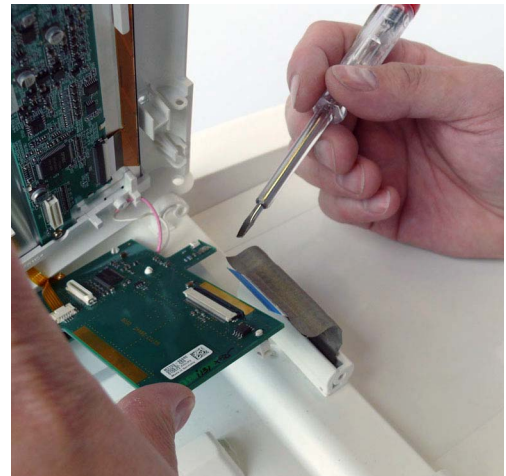
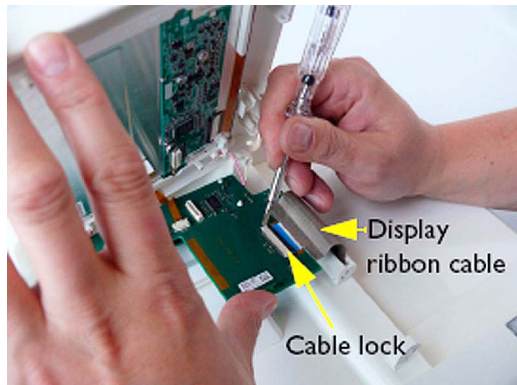
- 5 If you have the old version with back-light tubes, disconnect the back-light inverter cable after gently releasing it with the help of a small, flat-bladed screwdriver.



- 6 If you have the new version with LED back-light, release the white plastic snap on the display board with a screwdriver.

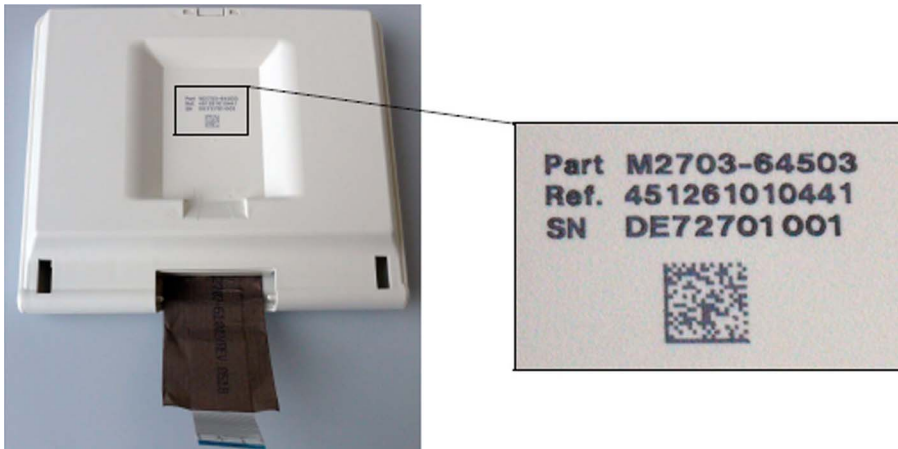


- 7 Disengage the cable lock for the display ribbon cable on the display assembly side using a small, flat-bladed screwdriver, then disconnect the ribbon cable. You will reuse this original ribbon cable to connect the new display assembly (after discarding the ribbon cable that comes with the new display assembly). You have now removed the display assembly.



## Replacing the Display Assembly

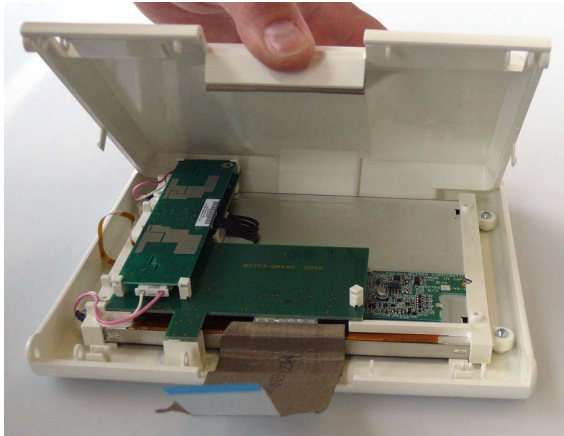
The new display assembly has the part number, reference (ordering) number, and the serial number printed on the rear.



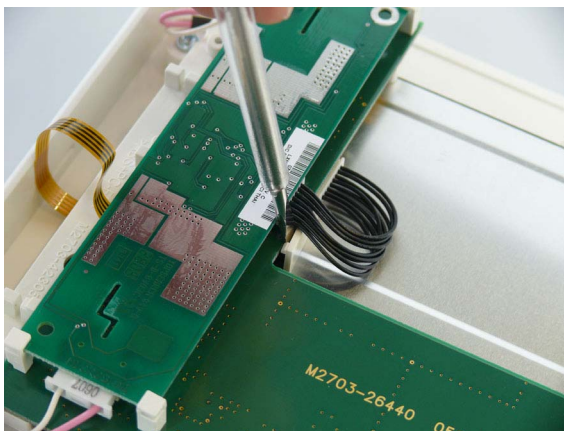
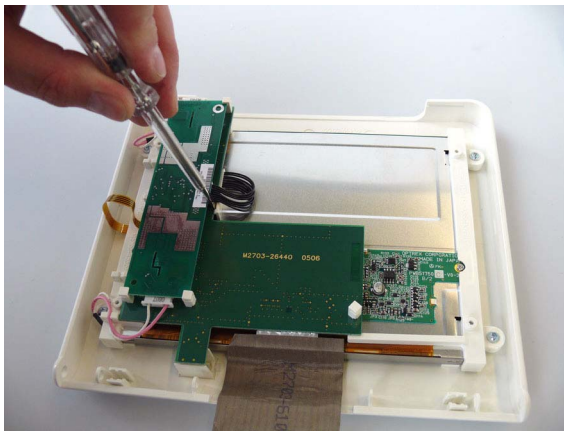
- 1 Remove the two plastic hinge pins on either side of the new display housing. Release them by turning the slotted head anti-clockwise with a small flat-bladed screwdriver, then pull them straight out.



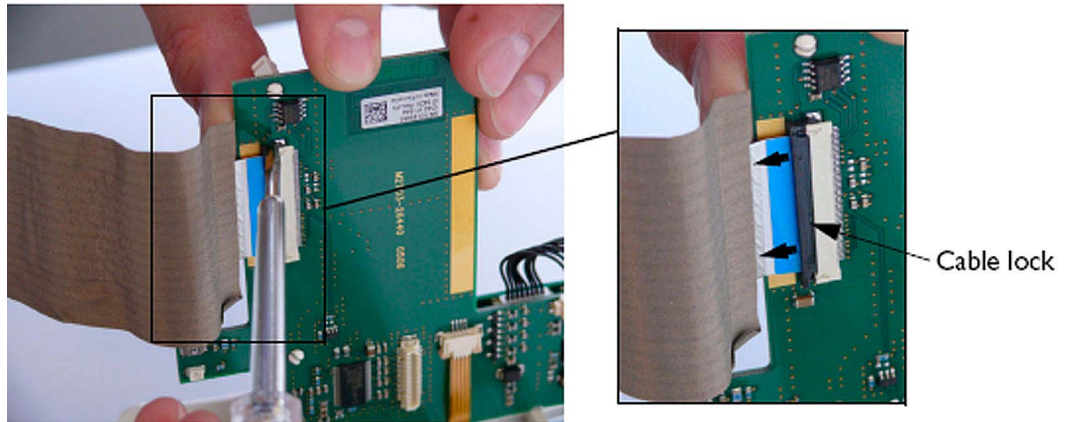
- 2 Open up the new display assembly, and remove the rear of the display housing.



- 3 If you have the old version with back-light tubes, disconnect the back-light inverter cable after gently releasing it with the help of a small, flat-bladed screwdriver.



- 4 Disengage the cable lock for the display assembly ribbon cable with the help of a small, flat-bladed screwdriver. Remove the cable, and discard it. (You will reuse the original ribbon cable, still attached to the monitor, for connecting the new display assembly.)



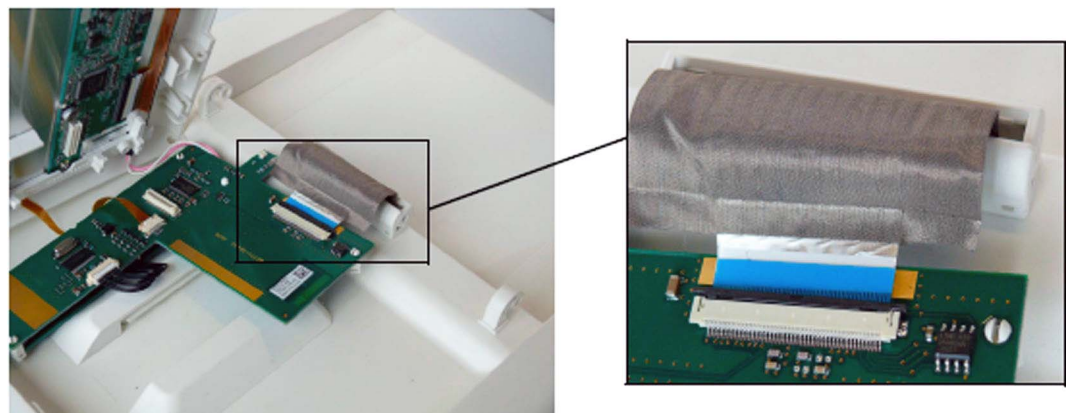
- 5 Remove the cable, and discard it. (You will reuse the original ribbon cable, still attached to the monitor, for connecting the new display assembly.)



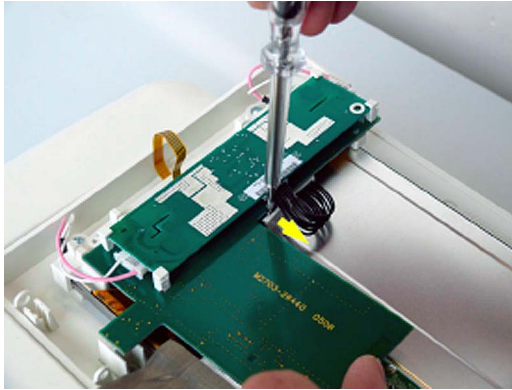
Discard ribbon cable from new display assembly and recycle according to local laws



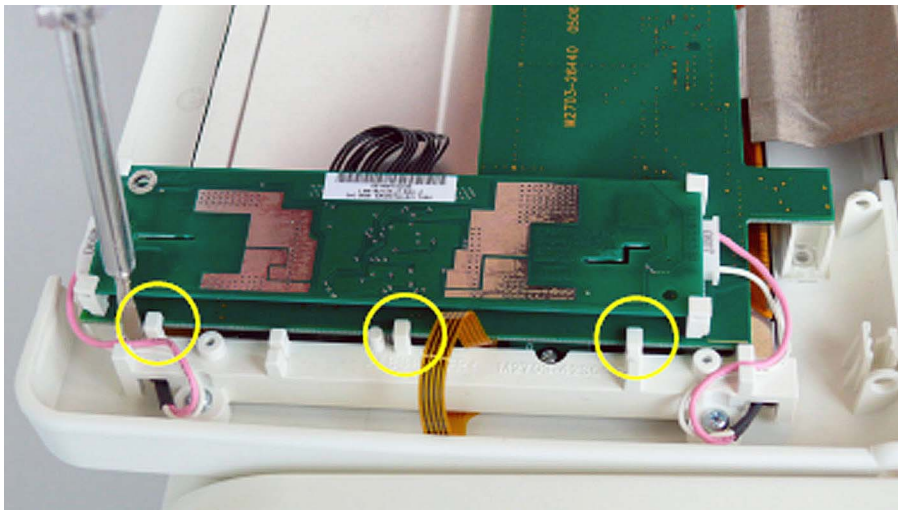
- 6 Connect the open end of the original display ribbon cable (attached to the monitor) to the connector on the new display assembly. Ensure the cable lock is engaged and the cable is firmly connected.



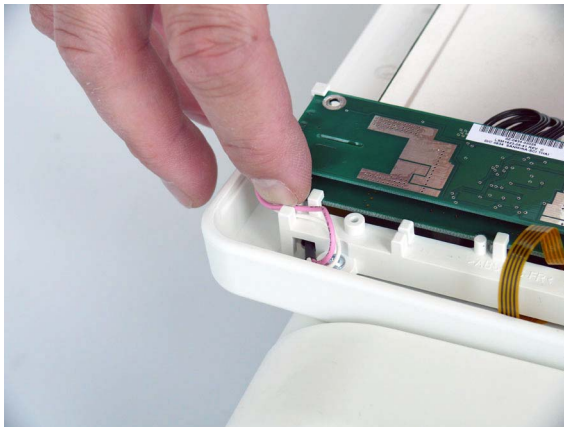
- 7 **Old Version:** Reconnect the back-light converter cable, and then slot the PCBs back into position. Use a small, flat-bladed screwdriver to very gently lever the white plastic snap on the display board and move the back-light converter connector outwards (in the direction of the arrow) to guide the PCB back into position. Otherwise the bPCB would catch on the connector.

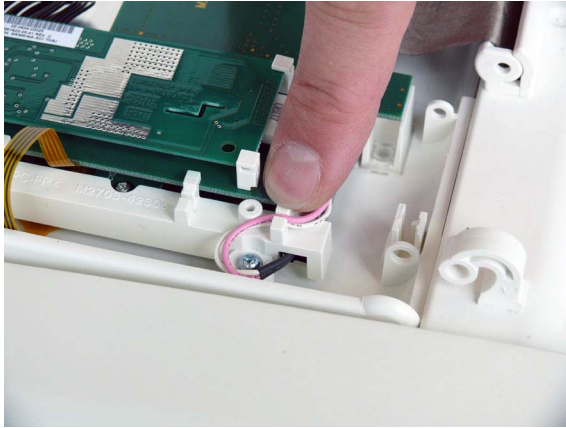


- 8 **New Version:** Slot the PCB back into position and use a small, flat-bladed screwdriver to very gently lever the white plastic snap on the display board.
- 9 Ensure the PCB is located correctly as shown in the photograph.

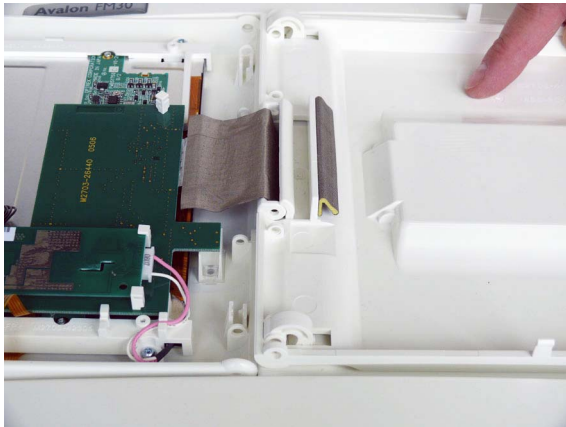
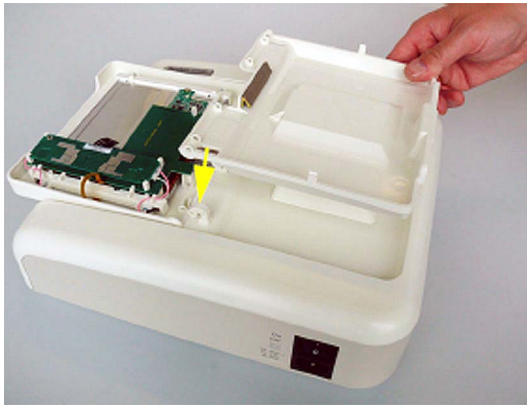


...and that the pink and white cables are correctly routed, and held in place.





- 10 Take the new rear housing cover and place it in the position shown.



- 11 Put the two halves of the display assembly together as shown.



- 12 Insert the new plastic hinge pins.

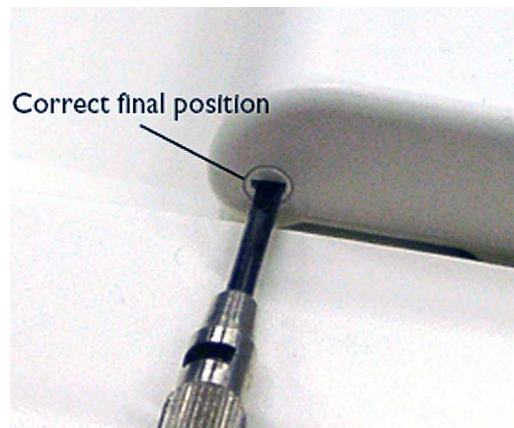


- 13 Do not apply excessive force when refitting the hinge pins. Turn the head of the hinge pin gently with a small screwdriver. You will feel when the pin is seated correctly, and the head should be flush with the surface.





The slot in the head of the pin should be pointing in the same plane as the side of the display assembly housing when the display is folded flat.



- 14 Reattach the ratchet clip to the top cover of the monitor and to the rear of the display housing.





## Recorder Disassembly

The recorder consists of the following major sub-assemblies:

- Drawer Assembly
- Recorder Chassis
- Thermal Line Printhead (TLPH) Holder
- Recorder Adapter Board
- Stepper Motor

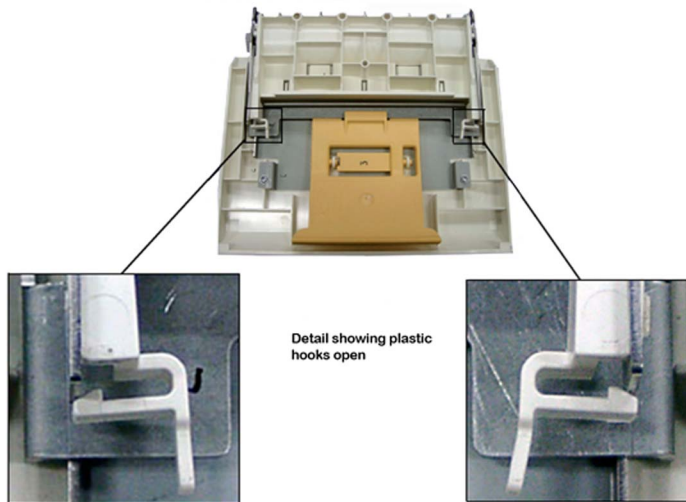
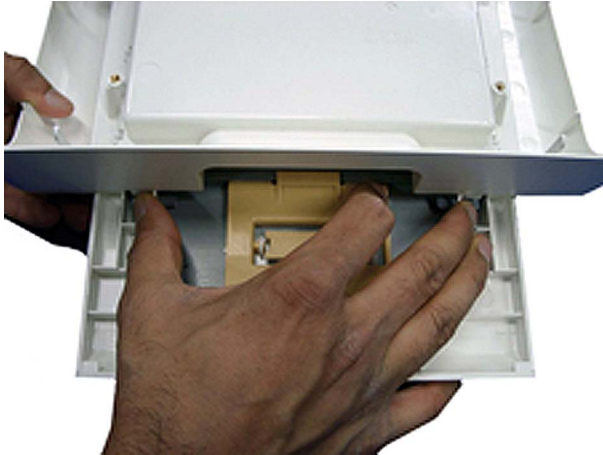
## Removing the Drawer Assembly

- 1 Press the paper table release to unlock the paper drawer, and then pull the table forward to open it fully.



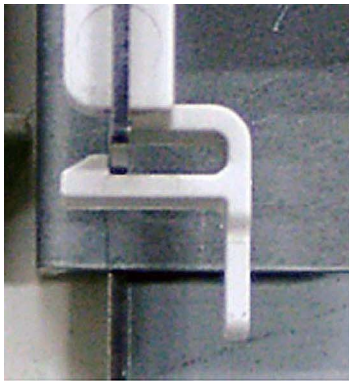
## 10 Repair and Disassembly

- 2 Squeeze the two plastic lugs on the underside of the drawer to release the drawer, and then pull to remove the drawer (here shown with the top cover removed).

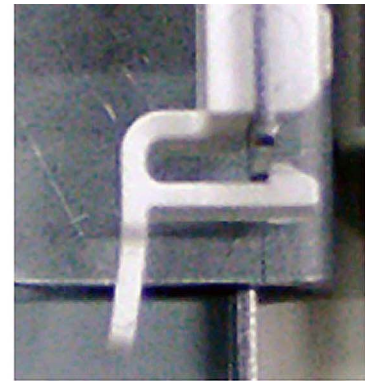


## Replacing the Drawer Assembly

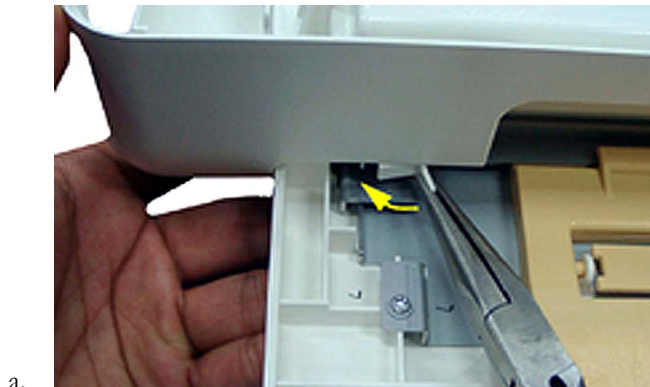
Before replacing the drawer assembly, refer to the previous photographs, and study the detail showing the position of the plastic hooks when the drawer is fixed in position.



Detail showing plastic hooks latched onto metal guide. This is how the hooks should be when the drawer is fixed in position.



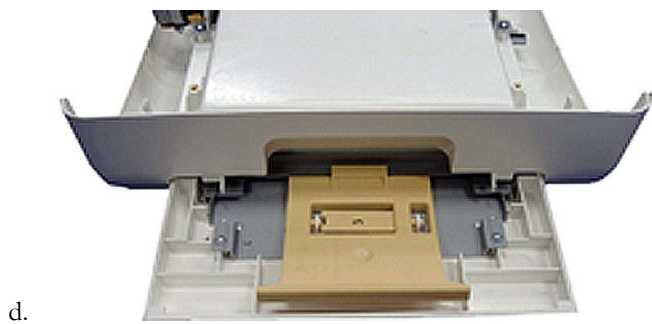
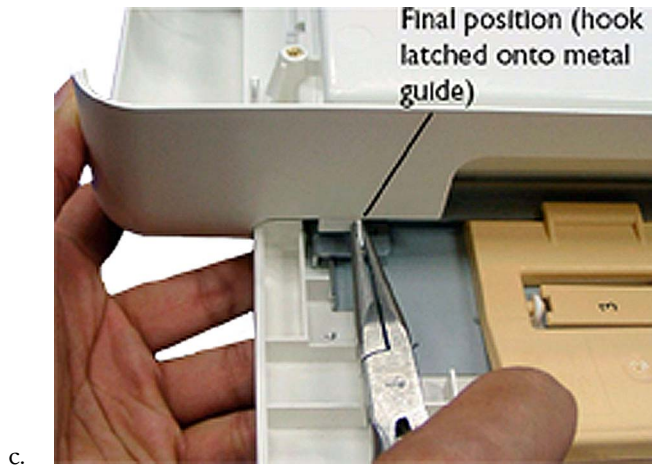
- 1 Slide the drawer into the drawer recess on the top cover, and check that it is located correctly on the runners.
- 2 Latch the two plastic hooks onto the metal guides to secure the drawer in place. You will find it easier to use a long-nosed pair of pliers to move the hook into position, as shown in the following photographs.



a.

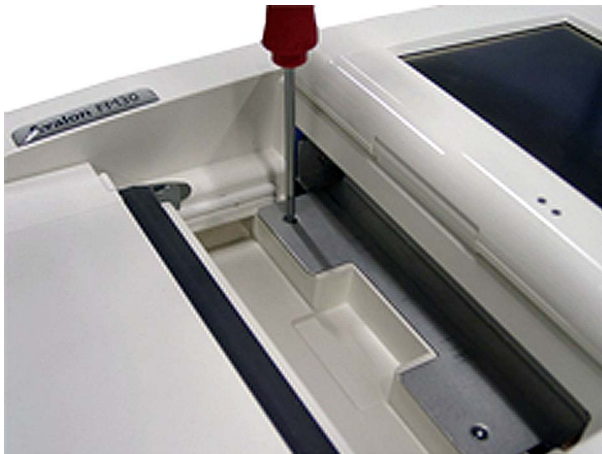


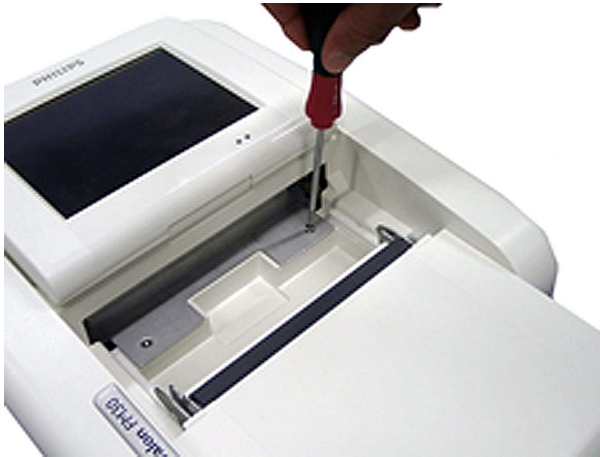
b.



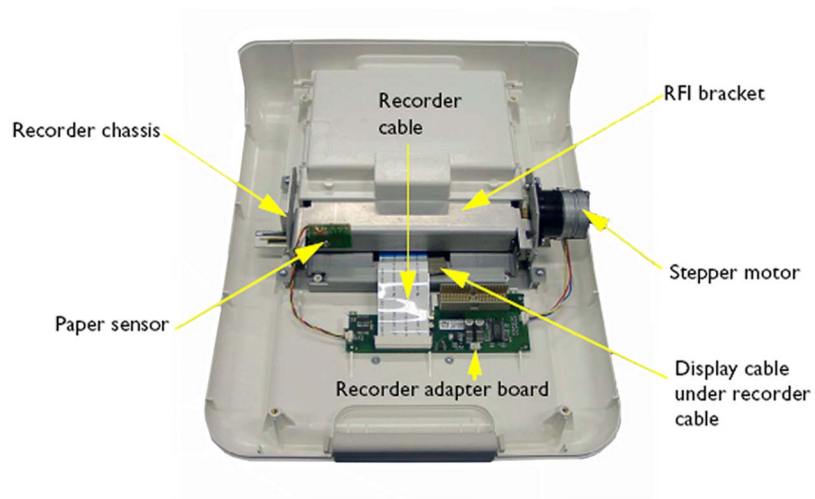
## Removing the Recorder Chassis

- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Slide open the paper drawer, to gain access to the two countersunk screws (in the following photographs, we have removed the drawer assembly).
- 3 Remove the two countersunk screws.

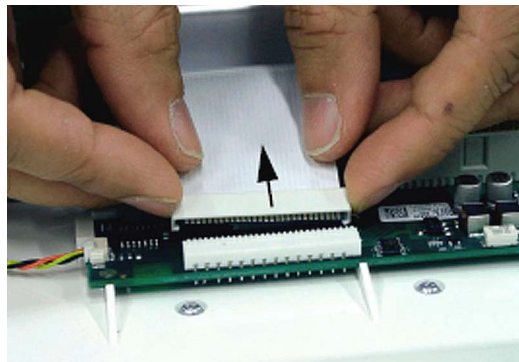
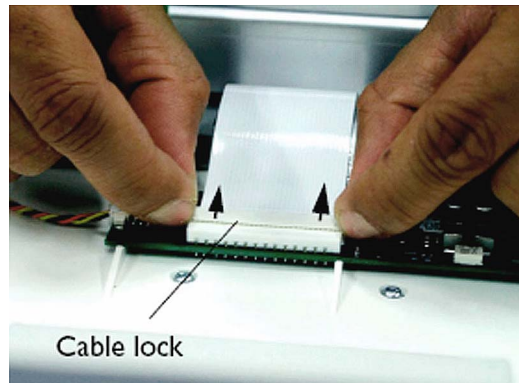




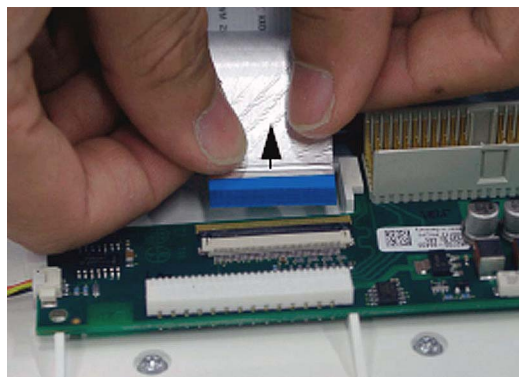
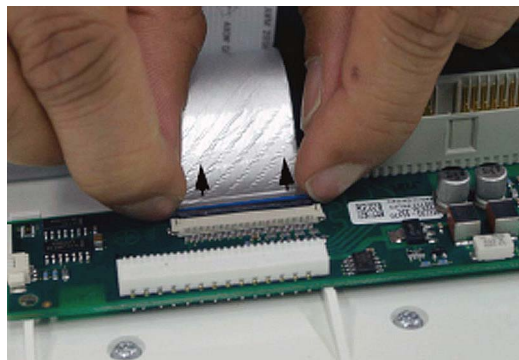
- 4 Turn over the top cover assembly and place it top down on a cloth or other soft surface.



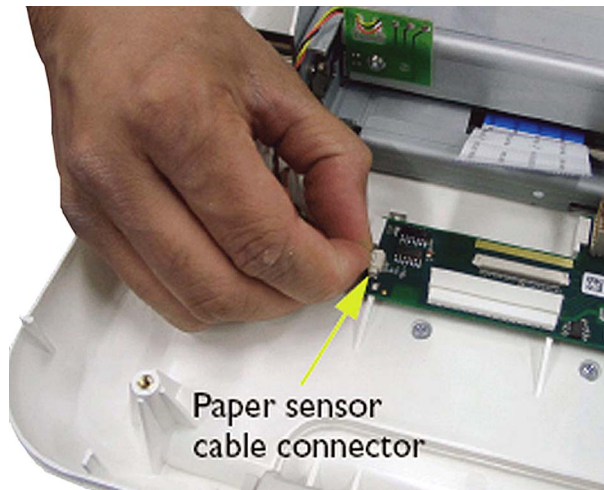
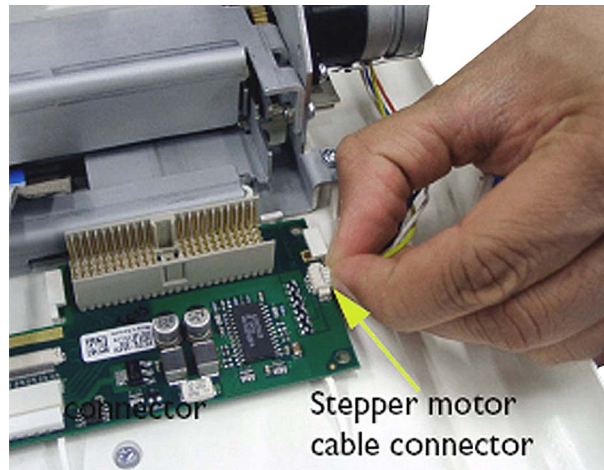
- 5 First release the cable lock by moving it in the direction of the arrows, then disconnect the white recorder ribbon cable from the recorder adapter board.



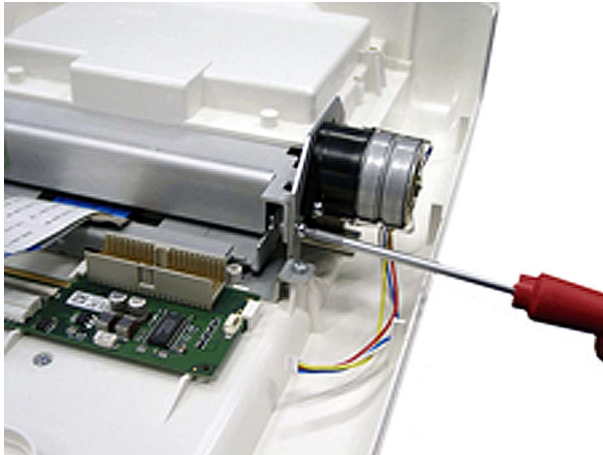
- 6 Next, disconnect the silver display ribbon cable from the recorder adapter board after releasing the cable lock.



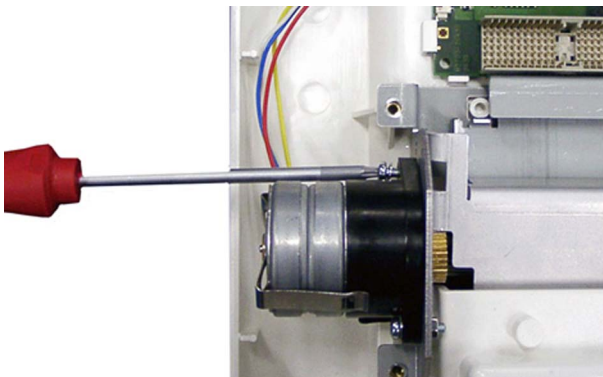
- 7 Disconnect the stepper motor, and the paper sensor cable connectors from the recorder adapter board.



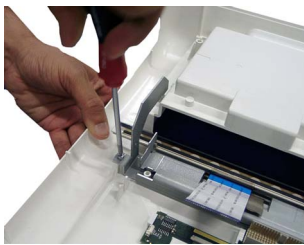
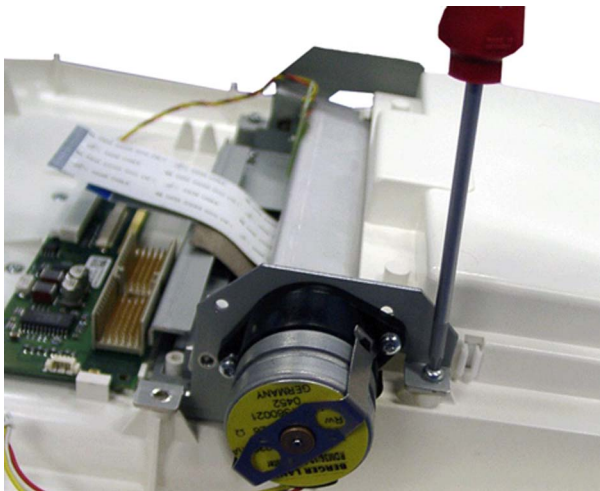
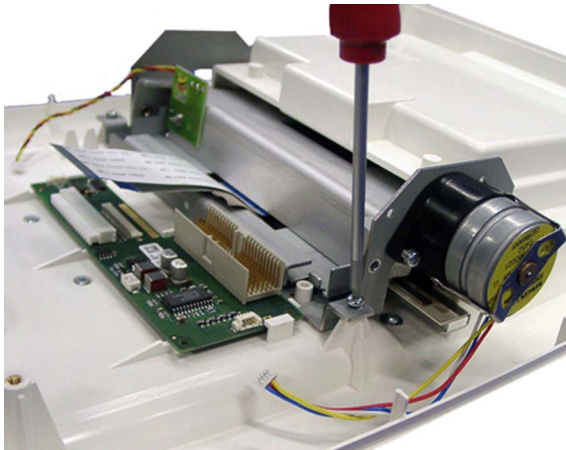
- 8 Remove the two screws (one on each side) fastening the RFI bracket to the recorder chassis.

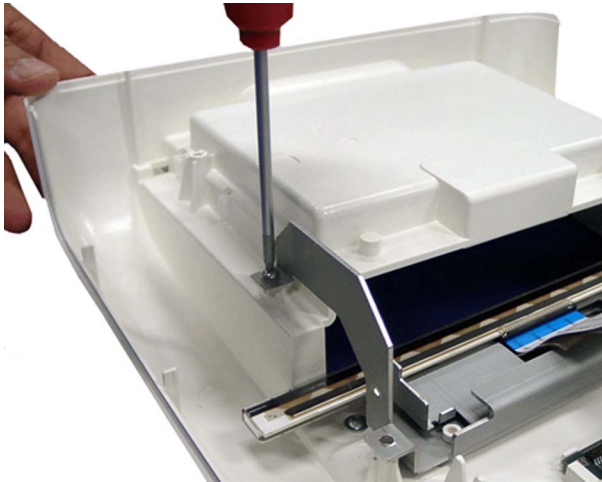


- 9 Partially unscrew the screw nearest the recorder adapter board holding the stepper motor to the recorder chassis, until the thread no longer protrudes. This allows the necessary clearance for removing the RFI bracket.

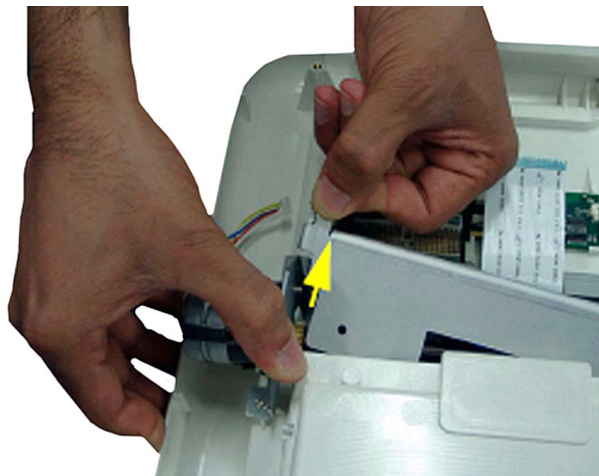
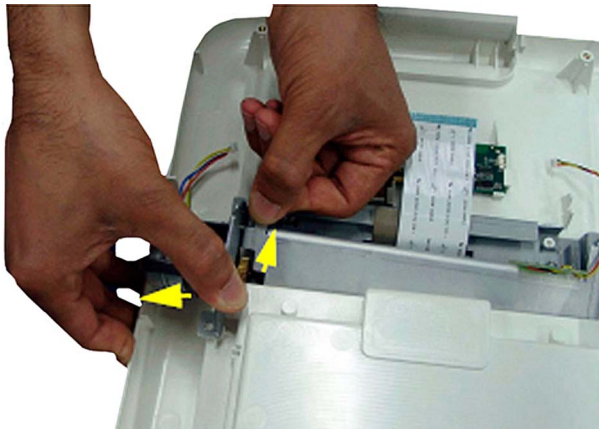


- 10 Remove the four screws holding the recorder chassis.

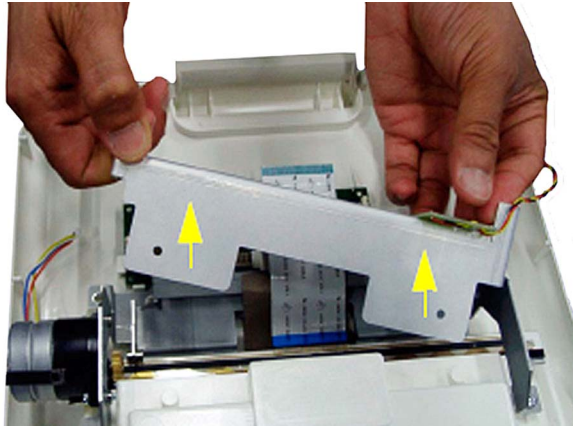




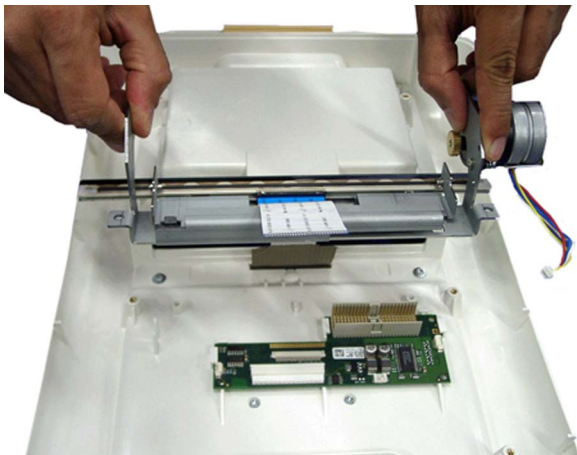
- 11 Free the RFI bracket on the stepper motor side by applying a little sideways pressure to the recorder chassis, while at the same time pulling the RFI bracket forwards.



- 12 Remove the RFI bracket.



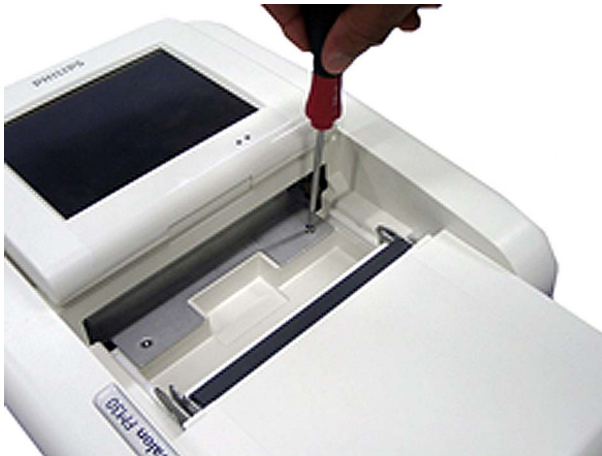
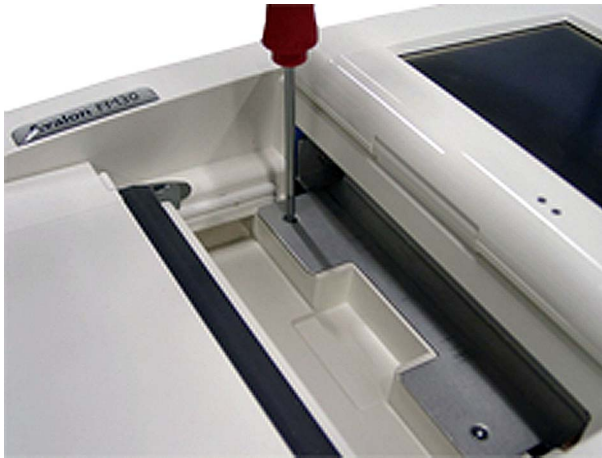
- 13 Lift out the recorder chassis.



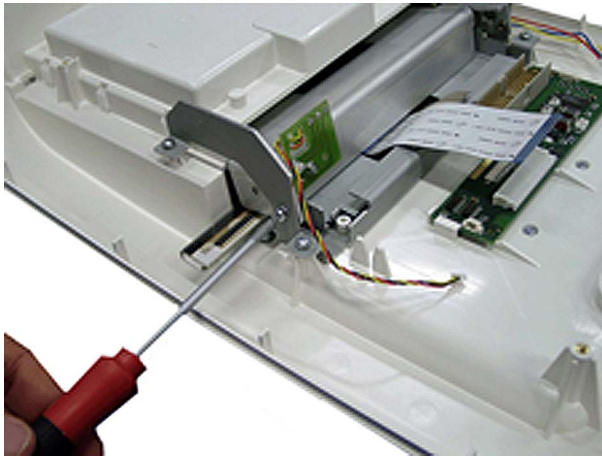
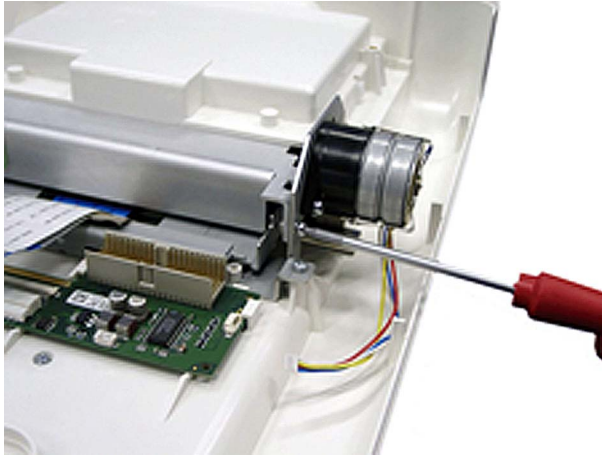
## Replacing the Recorder Chassis

The procedure for replacing the recorder chassis is a reversal of the removal procedure.

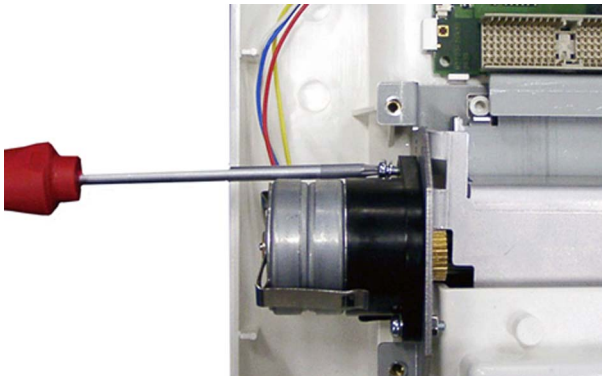
- 1 Ensure that the TLPH holder has been fitted to the recorder chassis, as described in the following section.
- 2 Place the recorder chassis into position, and drive the four fixing screws in lightly. Do not tighten yet!
- 3 Turn over the top cover housing, then secure the two countersunk screws. This centers the recorder chassis correctly.



- 4 Turn over the top cover again, and replace the RFI bracket, reversing the removal procedure. Secure the RFI bracket to the recorder chassis with the two screws.



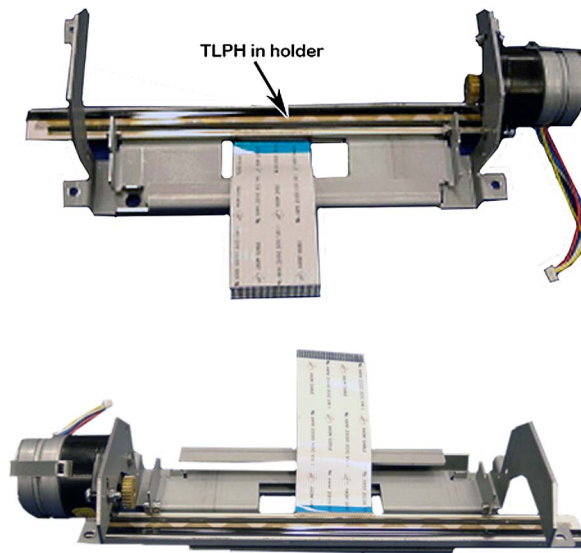
- 5 Tighten the stepper motor screw that you loosened to allow removal of the RFI bracket.



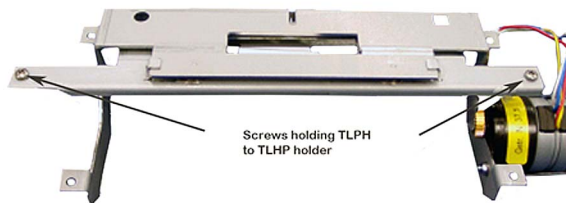
- 6 Now tighten the four screws to secure the recorder chassis.
- 7 Ensure that you reconnect the paper sensor cable and the stepper motor cable to the recorder adapter board.

## Removing the Thermal Line Printhead (TLPH)

- 1 Remove the recorder chassis as described in the section “Replacing the Recorder Chassis” on page 170.



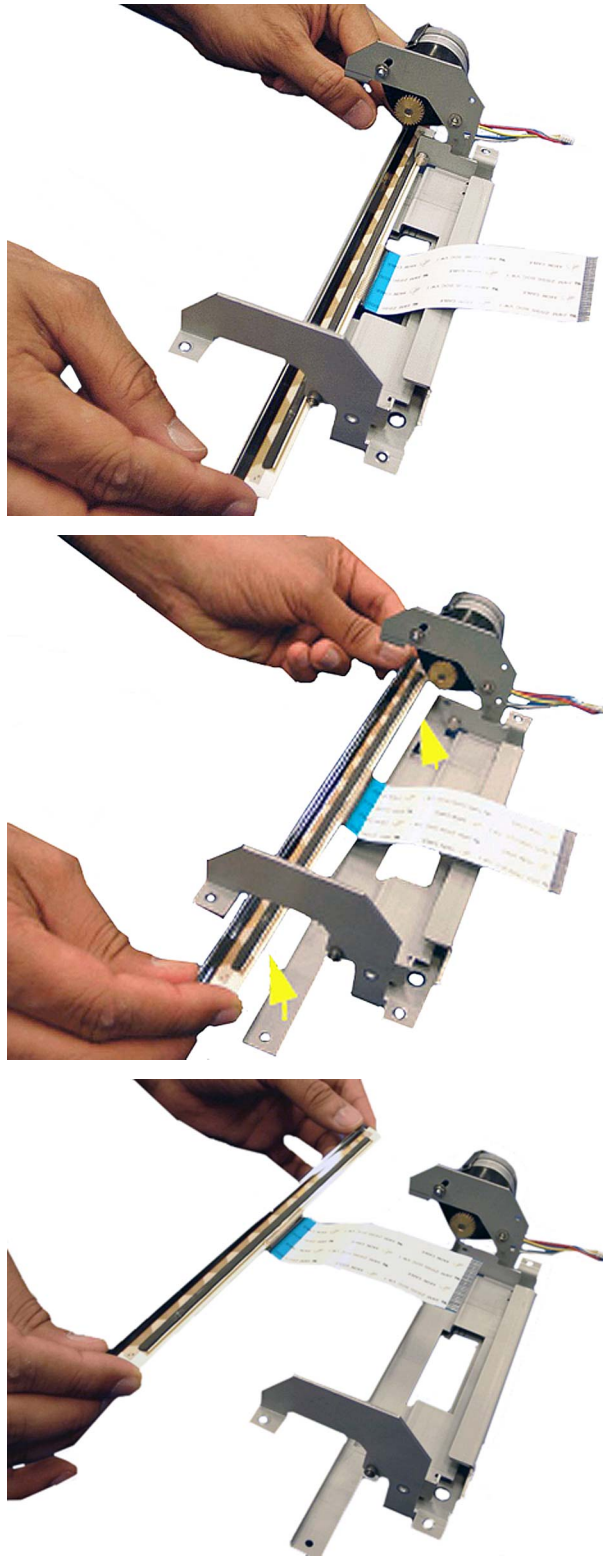
- 2 Turn the recorder chassis over.



- 3 Remove the two screws holding the TLPH to the TLPH holder.



- 4 Turn the chassis assembly over again, and carefully remove the TLPH from the holder as shown.

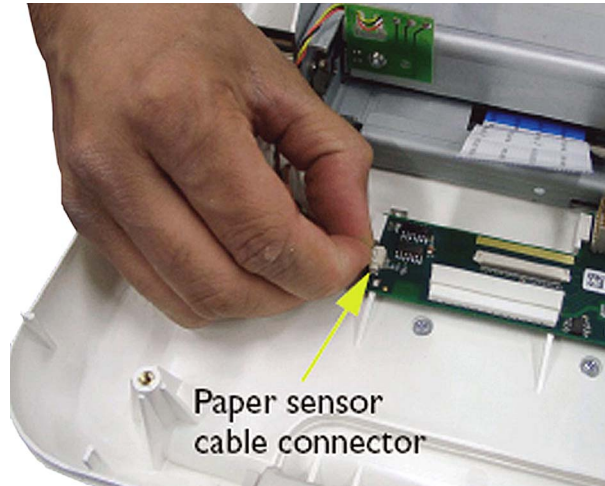


## Replacing the TLPH

The procedure for replacing the TLPH is a reversal of the removal procedure.

## Removing the Paper Sensor Assembly

- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Place the top cover assembly top down on a cloth or other soft surface.
- 3 Disconnect the paper sense cable connector from the recorder adapter board.



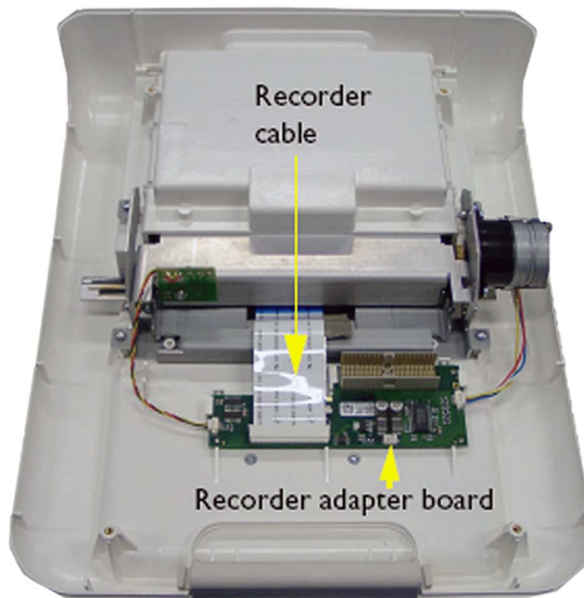
- 4 Turn over the top cover and remove the screw holding the paper sensor to the RFI bracket.

## Replacing the Paper Sensor Assembly

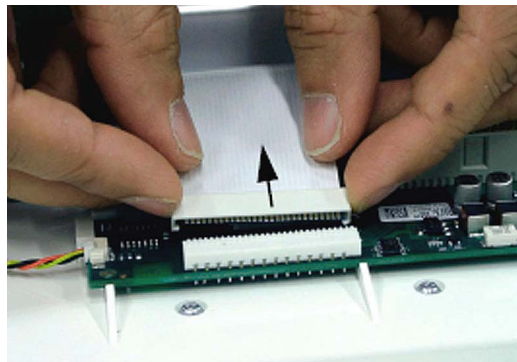
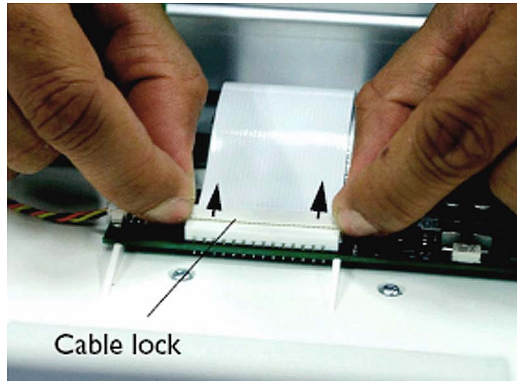
The procedure for replacing the paper sensor is a reversal of the removal procedure. Ensure that the paper sensor cable is properly connected to the recorder adapter board.

## Removing the Recorder Adapter Board

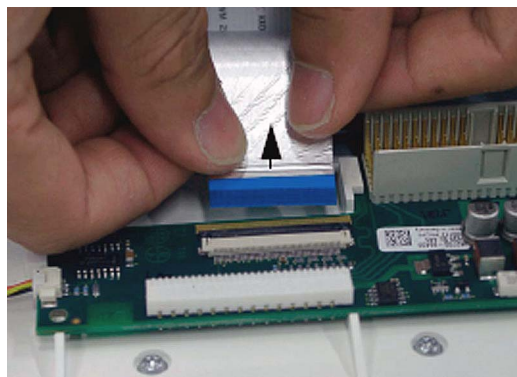
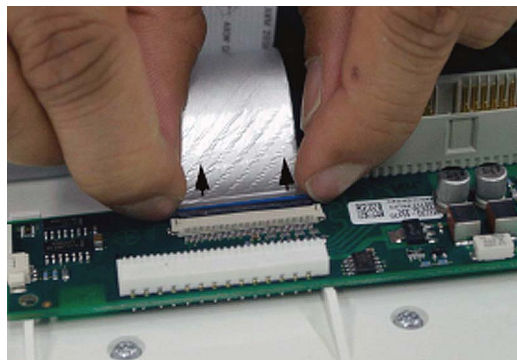
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Place the top cover assembly top down on a cloth or other soft surface.



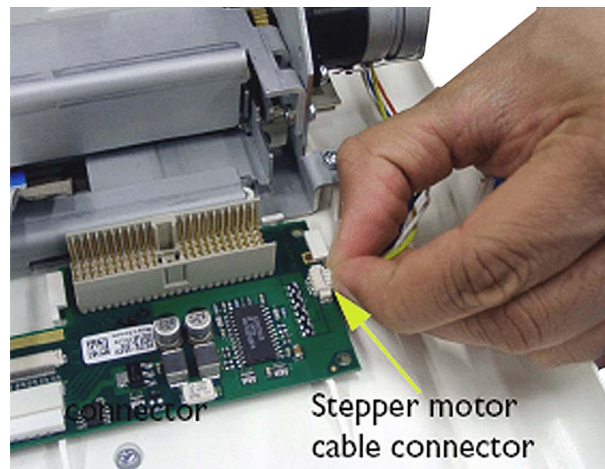
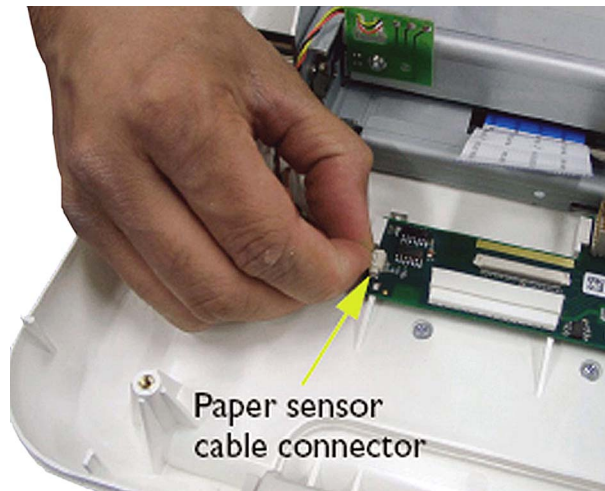
- 3 First release the cable lock by moving it in the direction of the arrows, then disconnect the white recorder ribbon cable from the recorder adapter board.



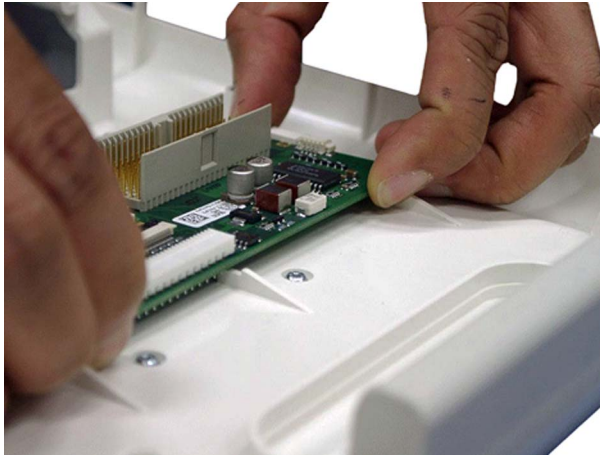
- 4 Next, disconnect the silver display ribbon cable from the recorder adapter board after releasing the cable lock.



- 5 Disconnect the stepper motor the record-sense cable connectors from the recorder adapter board.



- 6 With all cables disconnected, remove the recorder adapter board.



## Replacing the Recorder Adapter Board

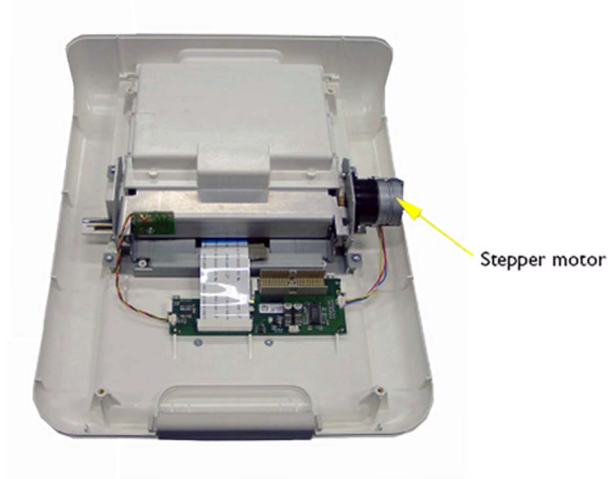
The procedure to replace the recorder adapter board is a reversal of the removal procedure. Ensure that all cables are firmly reconnected.

## Removing the Stepper Motor

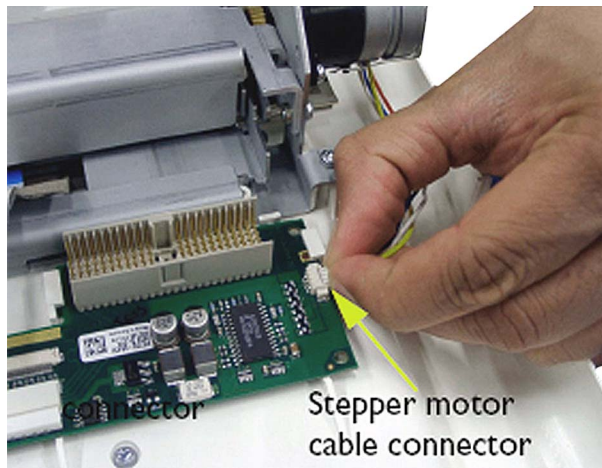
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).

## 10 Repair and Disassembly

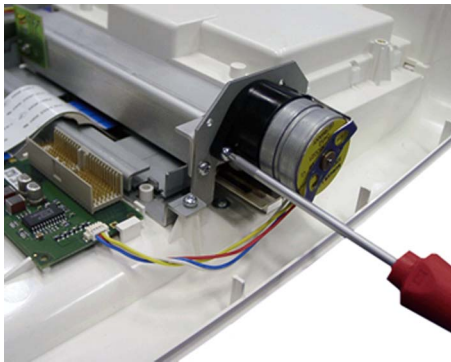
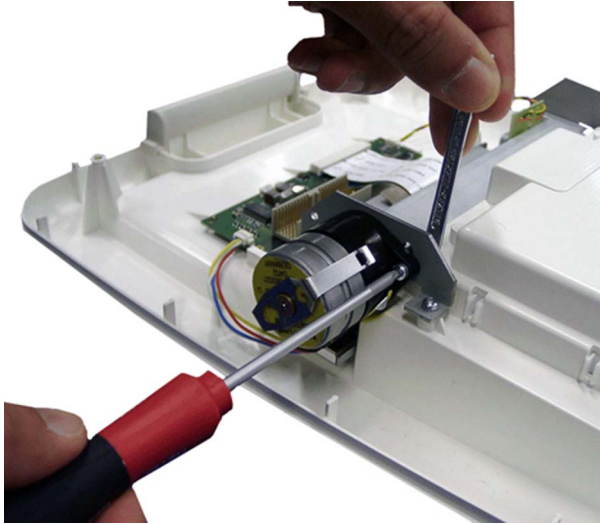
- 2 Place the top cover assembly top down on a cloth or other soft surface.



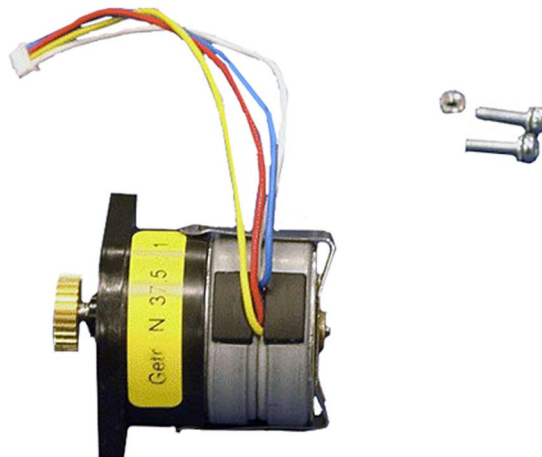
- 3 Disconnect the stepper motor cable connector from the recorder adapter board.



- 4 Remove the two screws holding the stepper motor to the recorder chassis. Note that the upper screw is secured with a small nut.



- 5 Remove the stepper motor.



## Replacing the Stepper Motor

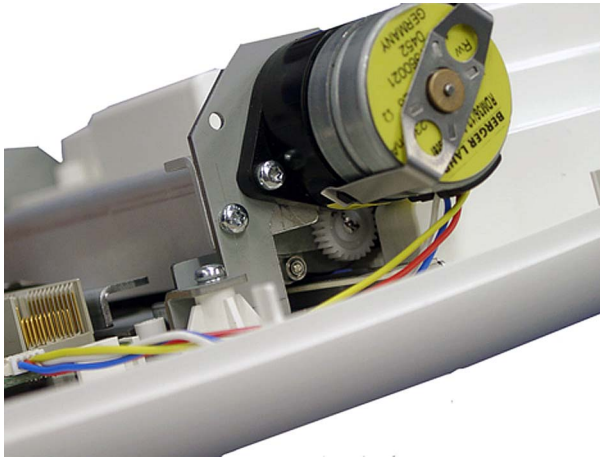
- 1 Refit the stepper motor to the recorder chassis, but do NOT tighten the screws yet! The upper slot on the stepper motor allows fine adjustment when meshing the gears together.
- 2 Close the drawer assembly.
- 3 Gently mesh the stepper motor gear with that of the paper roller.

---

### CAUTION

Do NOT press the gears together or exert any pressure on the stepper motor spindle.

---



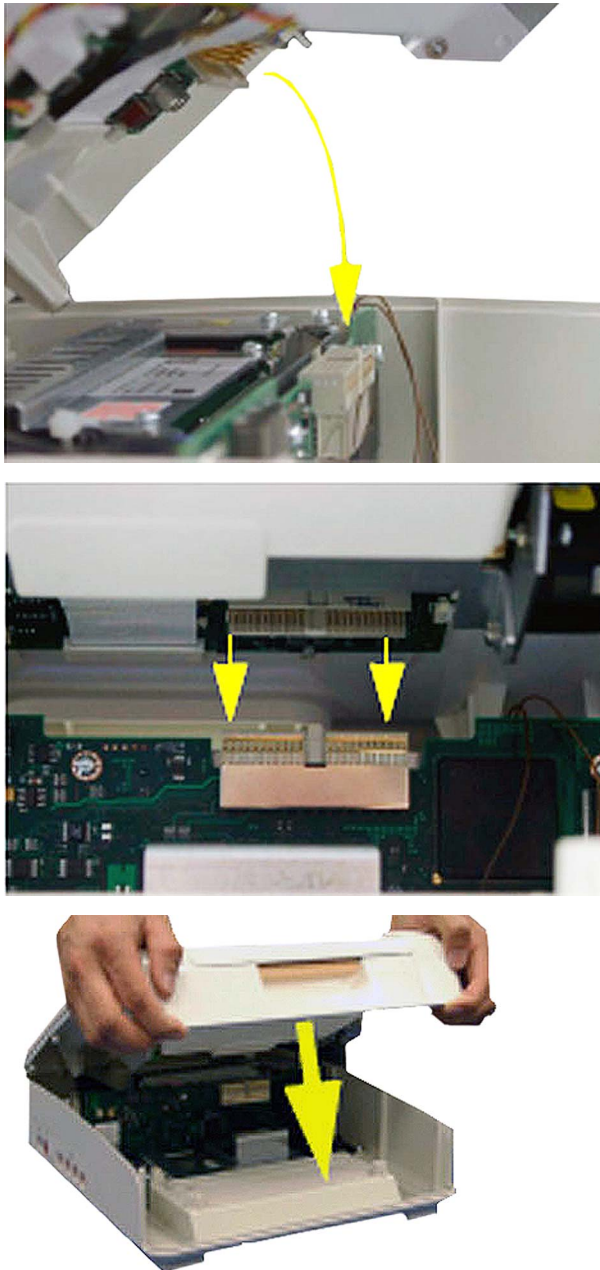
- 4 When in place, tighten the screws, remembering that the upper screw is secured with a small nut.

## Replacing the Top Cover Assembly

- 1 Ensure all items are replaced in the top cover assembly. Check that all the cables are reconnected.
- 2 Carefully align the front edge of the top cover assembly with the front edge of the bottom housing assembly.



- 3 With the front edge of the top cover still located in the front edge of the bottom housing, gently lower the top cover, making sure the multi-pin connector on the recorder adapter board aligns with the socket on the main CPU board.



- 4 Place the top cover back to its normal position. Apply a little pressure to seat the multi-pin connector.

- 5 Holding both assemblies together, carefully place the unit upside down on a soft surface to prevent scratching or other damage.



- 6 Refit the four screws securing the top cover assembly to the bottom housing, using a T-10 Torx driver, as a reversal of the procedure in “Removing the Top Cover Assembly” on page 141. Turn the monitor the right way up.

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### CAUTION

When replacing the top cover, do not over-torque the screws. Excessive torque may damage the screw mountings.

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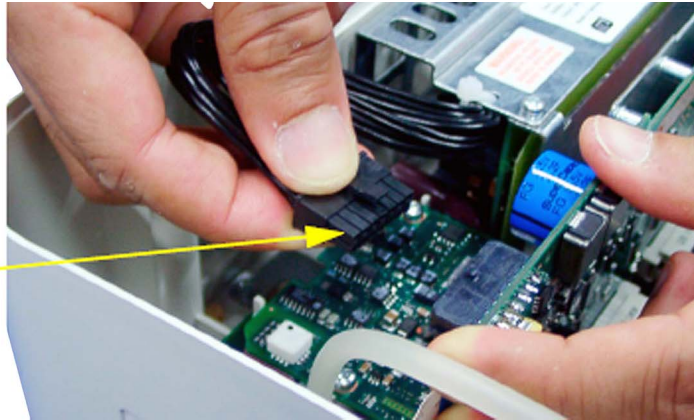
## Bottom Cover Disassembly/Reassembly

This section describes disassembly and reassembly operations for the bottom cover and its assemblies.

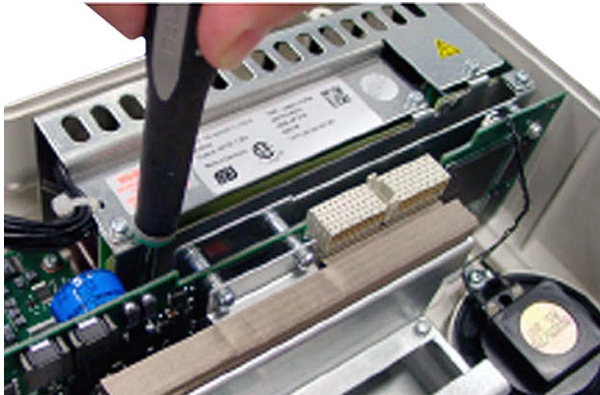
### Removing the Power Supply Assembly

- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Disconnect the power supply cable connector from the main CPU board. While removing the connector, support the end of the main CPU board to prevent excessive flexing.

Remove power  
supply cable

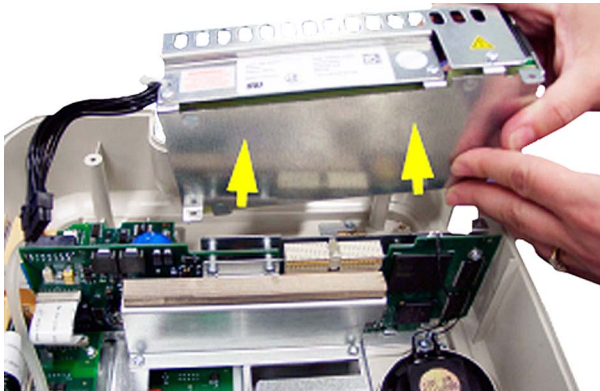


- 3 Remove the three screws securing the power supply





- 4 Lift the cable end of the power supply assembly with one hand, while guiding the power socket/on/off switch free of the aperture in the bottom housing, then lift out the power supply.

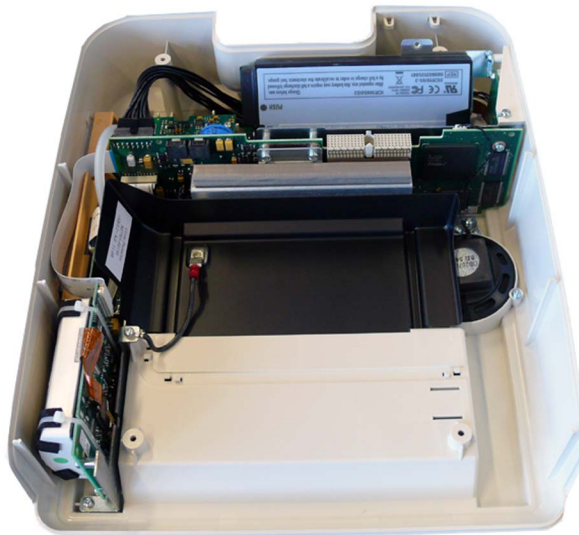
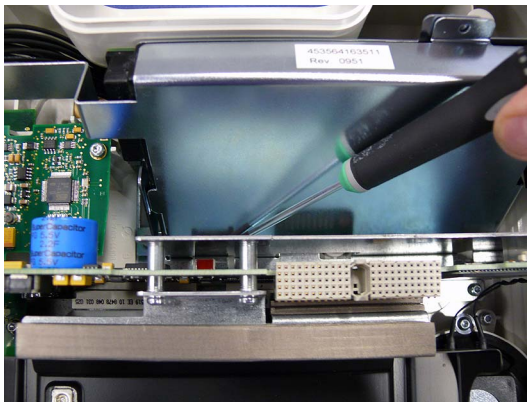
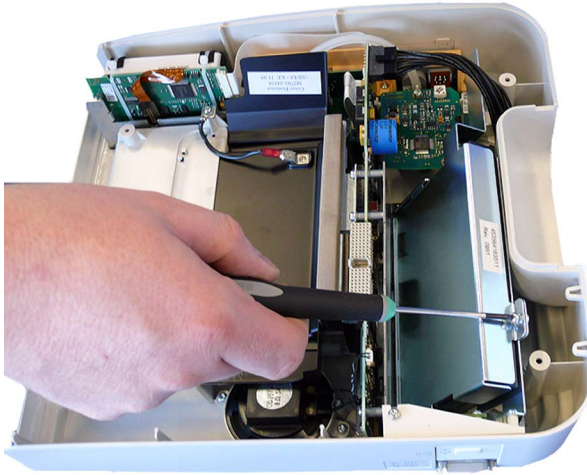


### Replacing the Power Supply Assembly

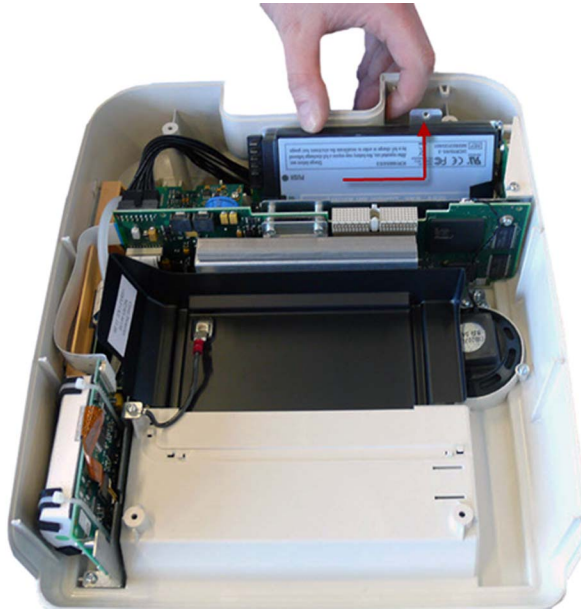
The procedure to replace the power supply assembly is a reversal of the removal procedure. Remember to reconnect the power supply cable connector.

## Removing the Battery and the Battery Assembly (FM20/30 Battery option #E25 only)

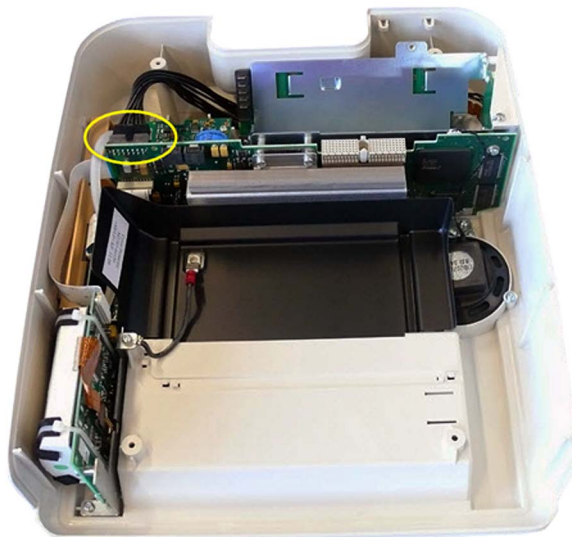
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Remove the screw at the top of the battery assembly. Remove the battery assembly cover by first sliding it to the right, thereby releasing the latches at the left and the bottom of the cover, and then lifting it up.



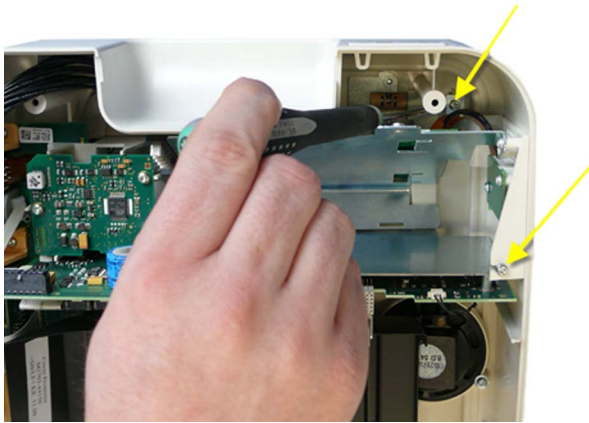
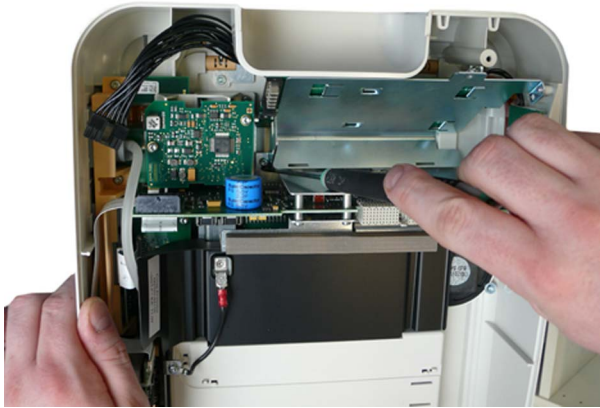
- 3 Remove the battery carefully, by loosening its connector, sliding the battery to the right and then pulling it out.



- 4 If you only want to replace the battery, insert a new battery and perform the above steps in reverse order. If you want to remove the entire battery assembly, continue with the steps below.
- 5 Disconnect the battery board connector from the main CPU board.

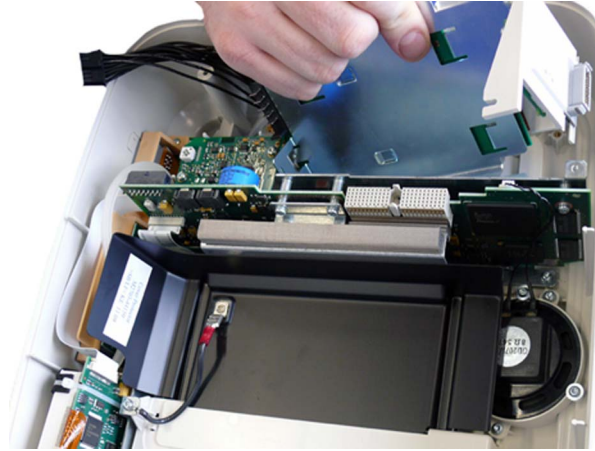


- 6 Remove the remaining three screws on the battery assembly.



- 7 Push in the power button assembly, and then remove the battery assembly and power button assembly together.





## Replacing the Battery and the Battery Assembly (FM20/30 Battery Option #E25 only)

The procedure to replace the battery assembly is a reversal of the removal procedure.

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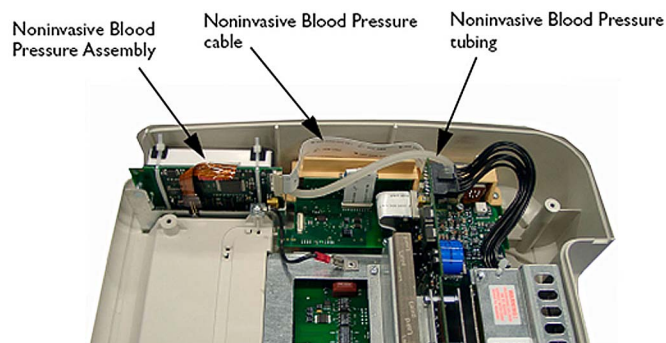
### WARNING

Use only Philips batteries part number M4605A. Use of a different battery may present a risk of fire or explosion.

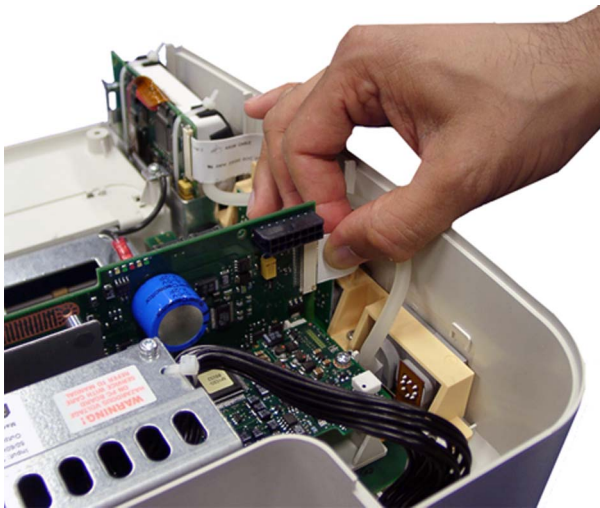
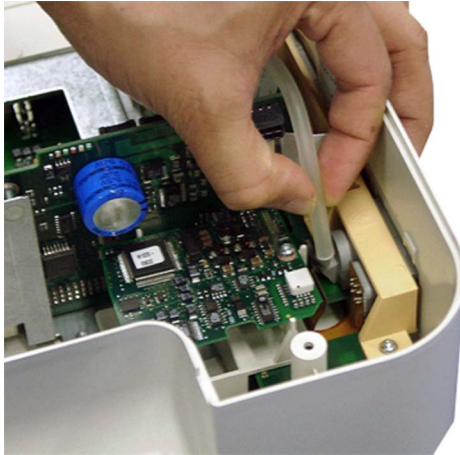
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## Removing the Noninvasive Blood Pressure Assembly

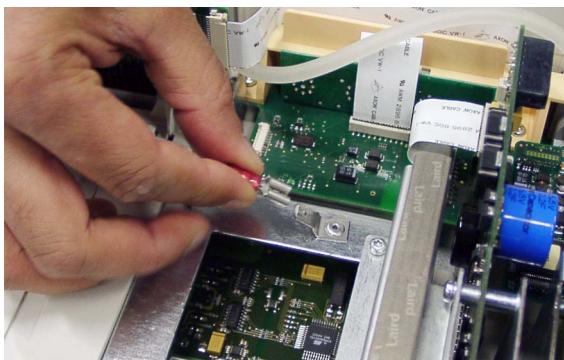
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141). The NBP assembly is identified in the next picture.



- 2 Disconnect the tubing from the noninvasive blood pressure connector, and the ribbon cable from the main CPU board (after first disengaging the cable lock).

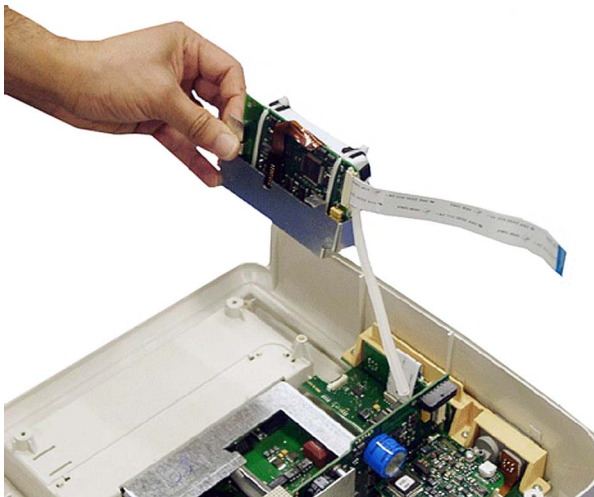
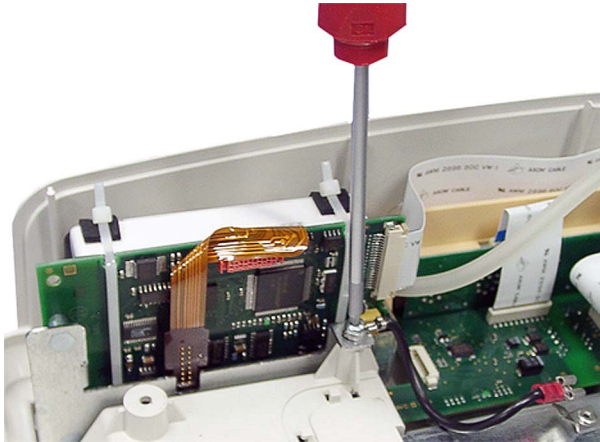


- 3 Disconnect the grounding cable's spade connector.

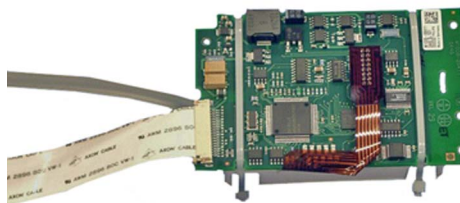
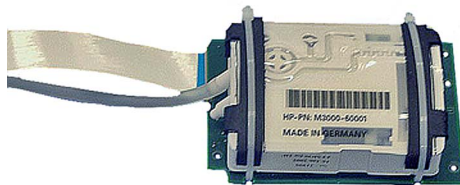


## 10 Repair and Disassembly

- 4 Remove the two screws holding the noninvasive blood pressure assembly to the bottom housing, then remove the noninvasive blood pressure assembly.

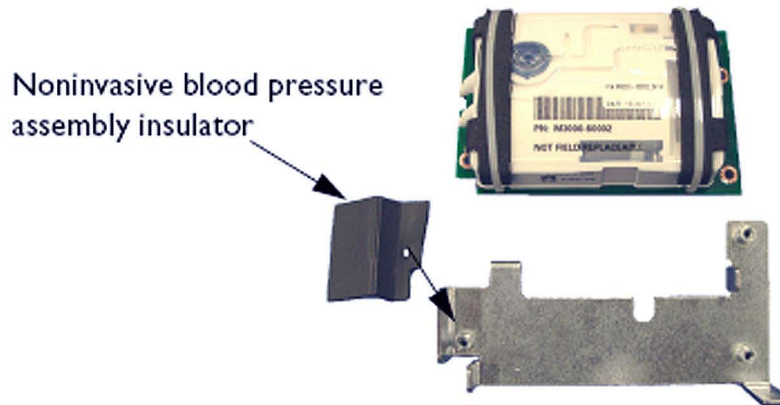


- 5 To separate the noninvasive blood pressure assembly from the noninvasive blood pressure assembly holder, remove the three screws.



## Replacing the Noninvasive Blood Pressure Assembly

- 1 The new noninvasive blood pressure assembly kit comes with an insulator. Place the insulator on the metal holder as shown.



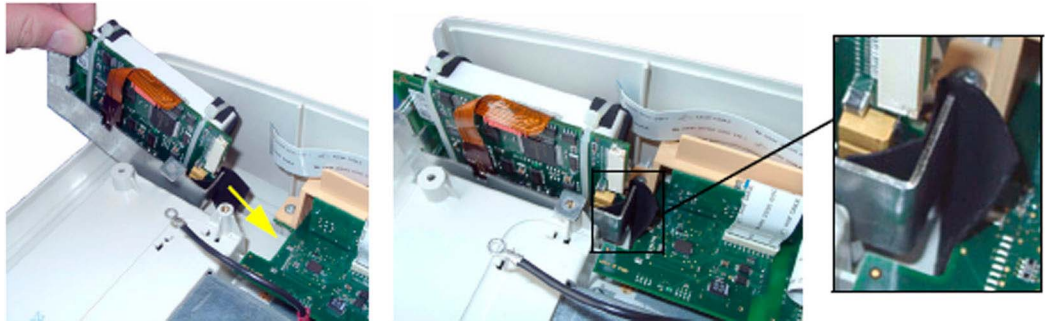
- 2 Place the noninvasive blood pressure assembly onto the metal holder, ensuring the insulator is in place.



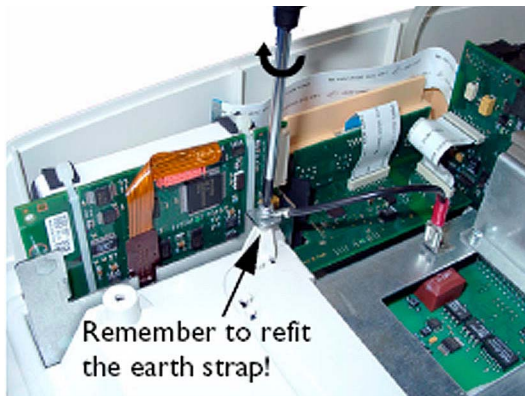
- 3 Refit the three screws securing the NiBP module to the holder.



- 4 Place the noninvasive blood pressure assembly into position, making sure that the insulator is located correctly as shown.



- 5 Refit the earth strap.

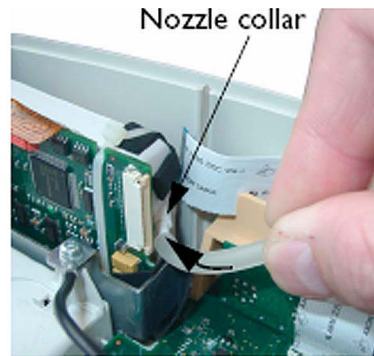


- 6 Refit the remaining screw to secure the noninvasive blood pressure assembly to the bottom housing.

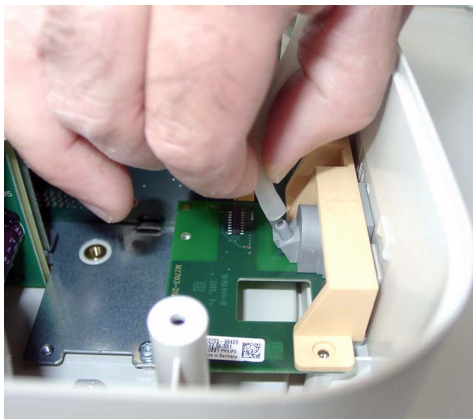


- 7 Refit the noninvasive blood pressure tubing first (before reconnecting the ribbon cable).

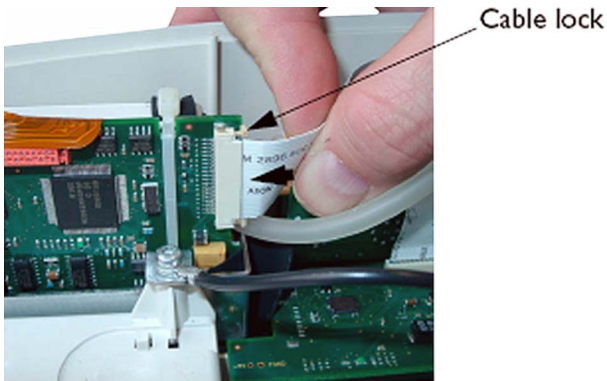
Reconnect the noninvasive blood pressure tubing first. Push it right up to the nozzle collar, and check that it is secure.



When refitting the tubing, also make sure you connect it to the left-hand connector when facing the front of the sockets.



- 8 Then reconnect the ribbon cable. Make sure the cable lock is firmly closed and the cable is secure.

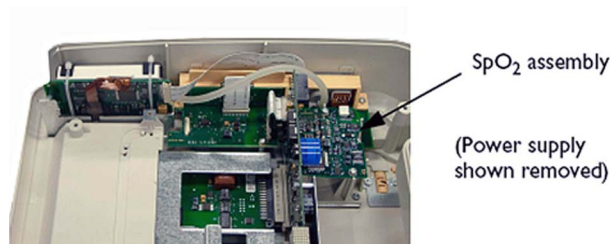


- 9 Replace the top cover (see “Replacing the Top Cover Assembly” on page 180).

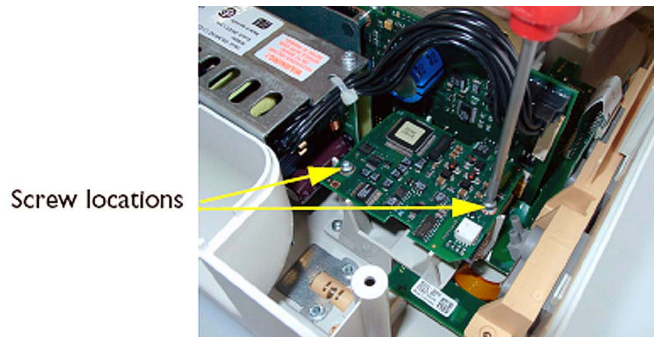


## Removing the SpO<sub>2</sub> Assembly

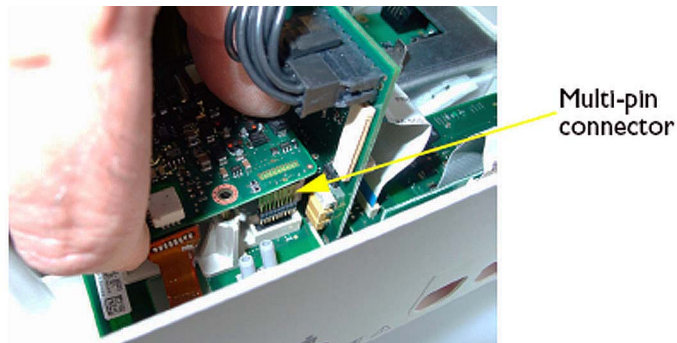
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141). The SpO<sub>2</sub> assembly is identified in the next picture.



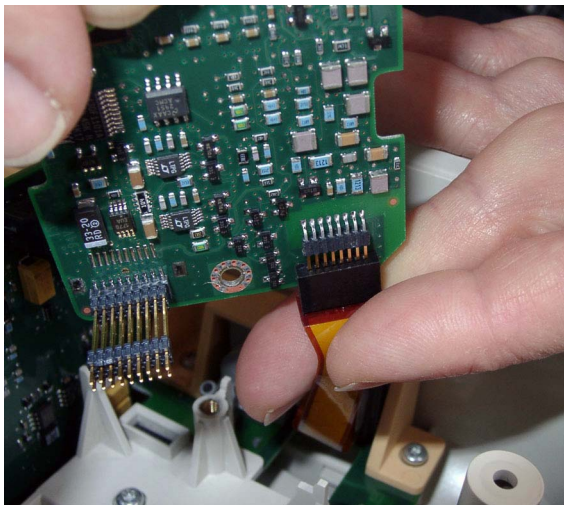
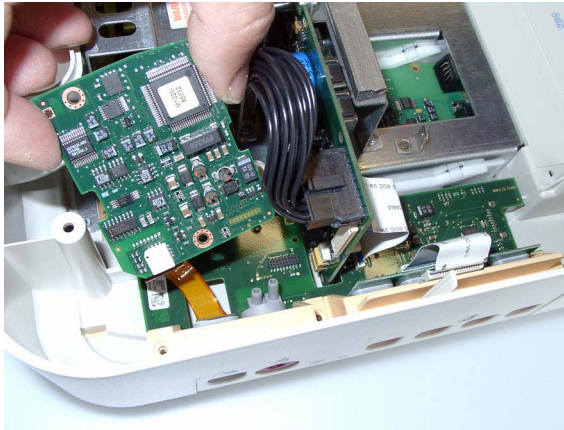
- 2 Remove the two screws holding the SpO<sub>2</sub> assembly.



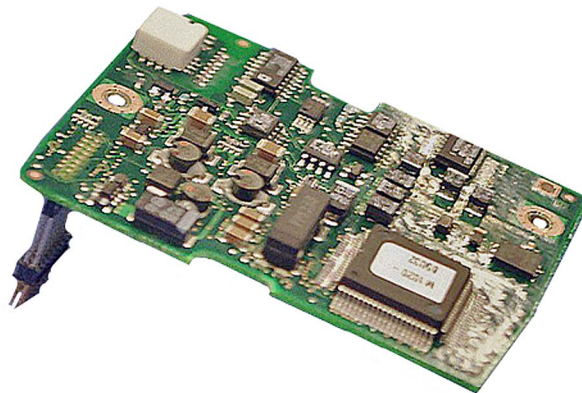
- 3 Lift the side of the SpO<sub>2</sub> assembly nearest the SpO<sub>2</sub> socket, carefully disconnecting the multi-pin connector shown.



- 4 To remove the flat brown SpO<sub>2</sub> socket cable from the multi-pin connector on the underside of the SpO<sub>2</sub> board, it is easier to lift the board first to get better access.



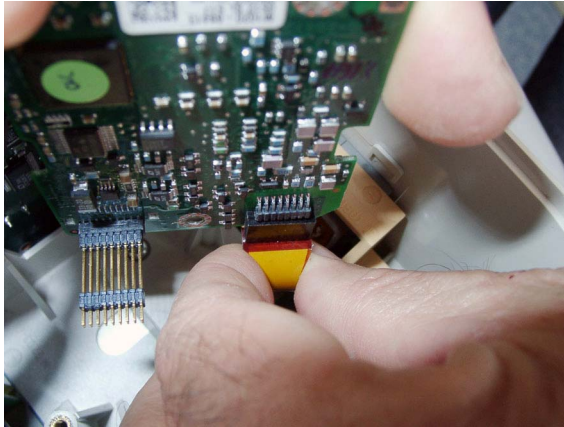
- 5 Remove the SpO<sub>2</sub> assembly.



## Replacing the SpO<sub>2</sub> Assembly

The procedure to replace the SpO<sub>2</sub> assembly is a reversal of the removal procedure.

Hint: When reconnecting the flat brown SpO<sub>2</sub> socket cable to the multi-pin connector on the SpO<sub>2</sub> board, it is easiest to reconnect it while holding the board vertically in line with the cable connector as shown.

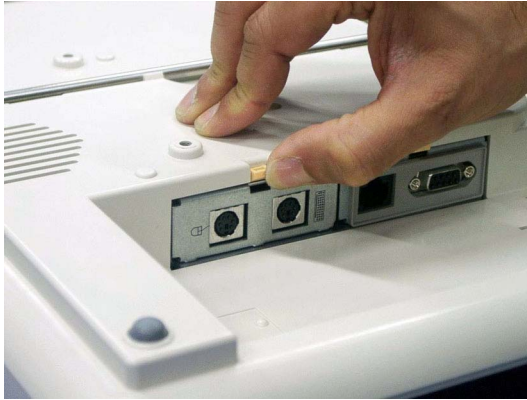


## Removing the Interface Boards

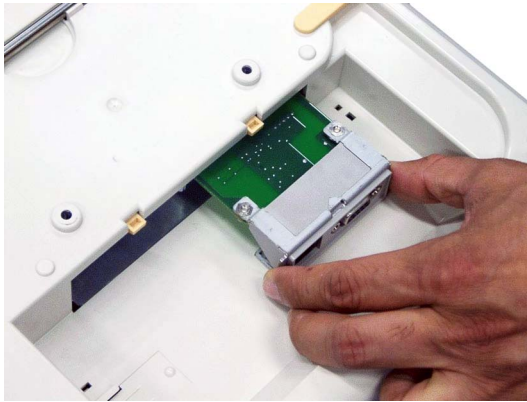
The interface boards can be accessed from the underside of the monitor's housing.

- 1 Turn the monitor upside down on a non-scratch surface.

- 2 Release the board by pressing the clip that keeps the board in place, as shown. Use a small flat-headed screwdriver to gently pry the board out if it is too tight to pull out with your fingers.



- 3 Pull the board out.

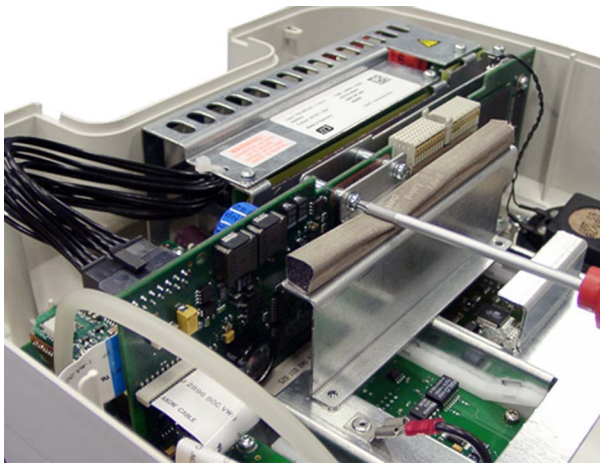
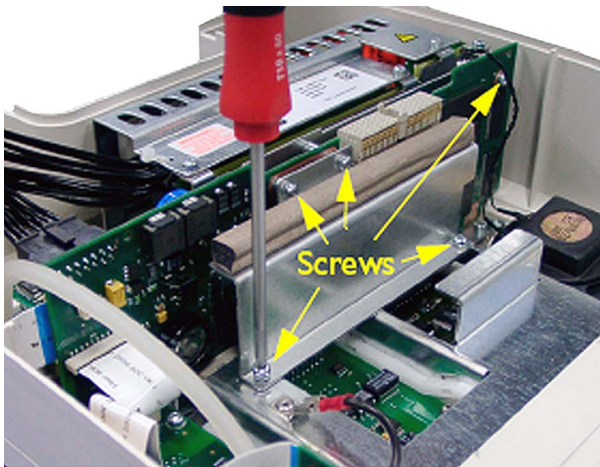


## Removing the Main CPU Board

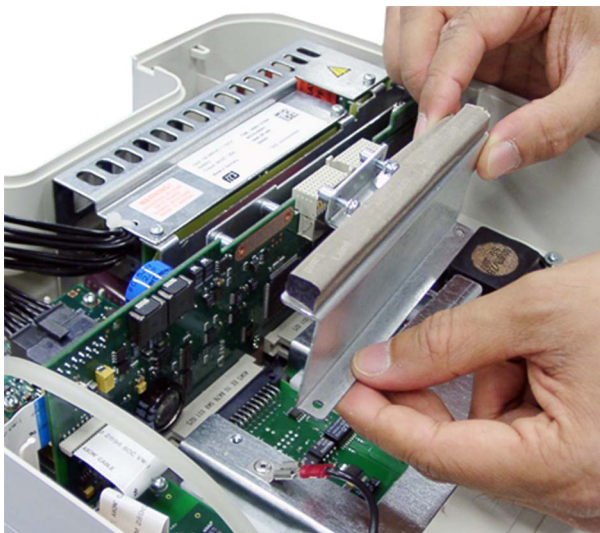
To remove the main CPU board, proceed as follows:

- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).

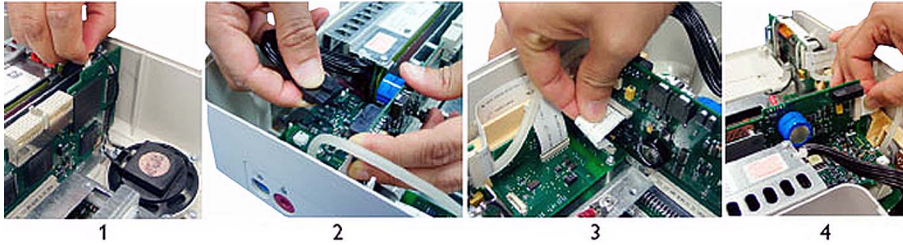
- 2 Remove the screws holding the metal shield.



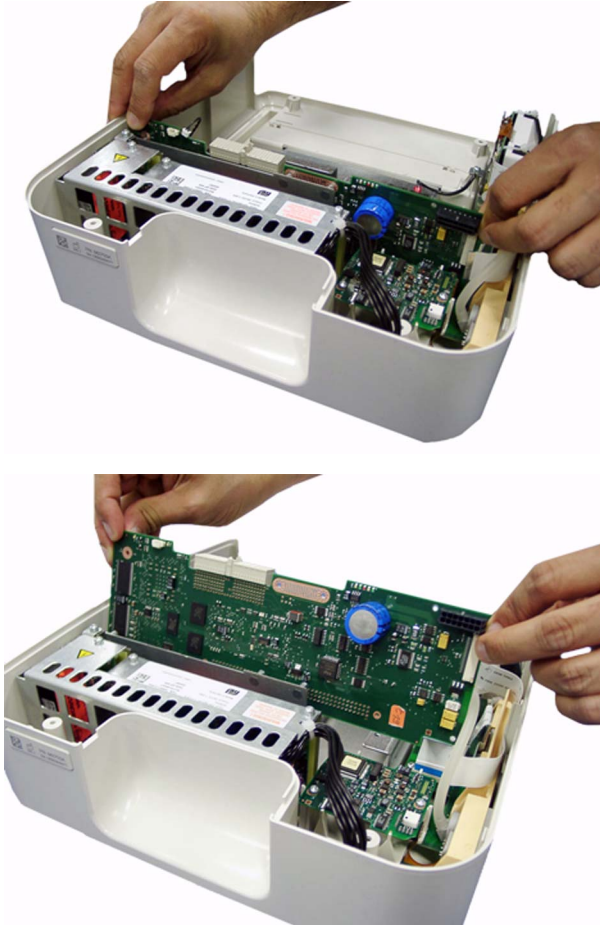
- 3 Remove the shield.



- 4 Disconnect the loudspeaker cable (1), the power supply cable (2), the bus master board cable (3), and the noninvasive blood pressure cable (4) from the main CPU board.



- 5 Remove the main CPU board by lifting it straight up.



## Replacing the Main CPU Board

The procedure to replace the main CPU board is a reversal of the removal procedure. Ensure all the cables are properly reconnected.

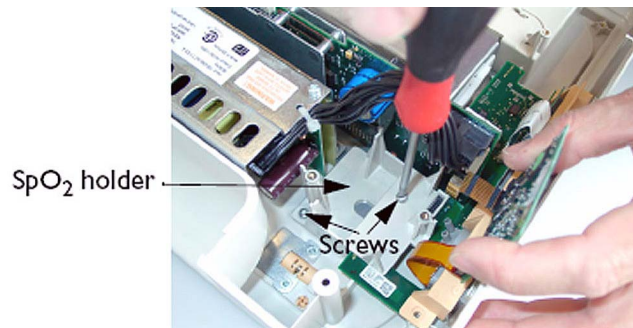
## Removing the Front End Assembly

The front end assembly consists of:

- the fetal sensor socket connectors with ribbon cable
- the bus master board with ribbon cable
- the optional noninvasive blood pressure and SpO<sub>2</sub> socket connectors
- the connector block frame

To remove front end assembly:

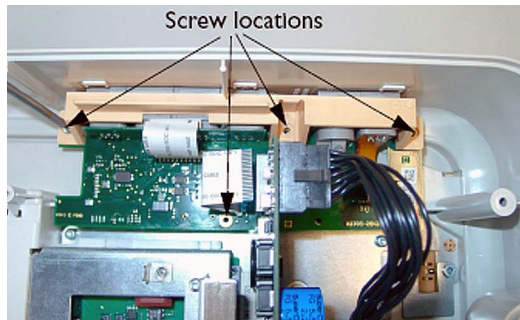
- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 If the noninvasive blood pressure assembly is fitted, remove it (see “Removing the Noninvasive Blood Pressure Assembly” on page 188).
- 3 If the SpO<sub>2</sub> assembly is fitted, remove it (see “Removing the Top Cover Assembly” on page 141). Also remove the SpO<sub>2</sub> board holder by removing the two screws fastening it to the bottom housing.



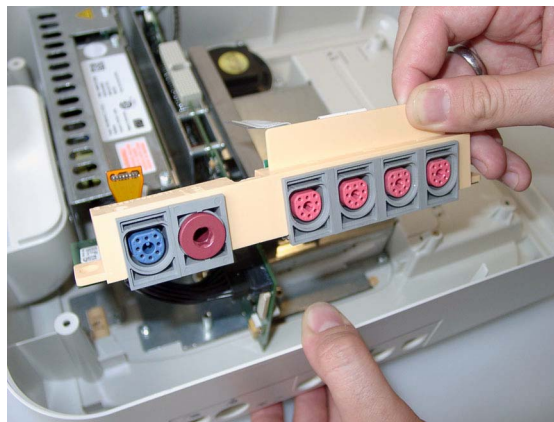
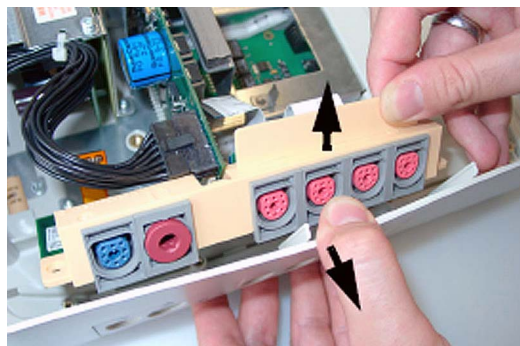
- 4 Disconnect the flat ribbon cable connecting the bus master board to the main CPU board.



- 5 Remove the three screws holding the connector block frame to the bottom housing, and the screw holding the bus master board.



- 6 Lift out the front end assembly. To make the removal easier, apply gentle outward pressure on the bottom housing wall to provide a little more clearance.

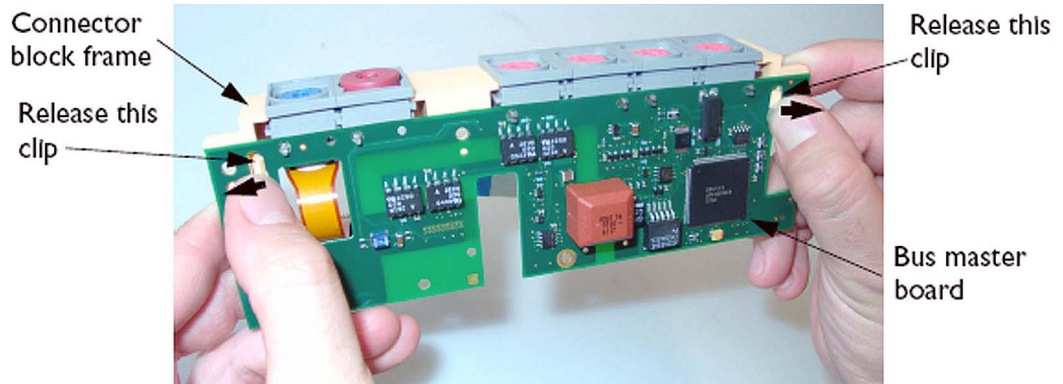


## Replacing the Front End Assembly

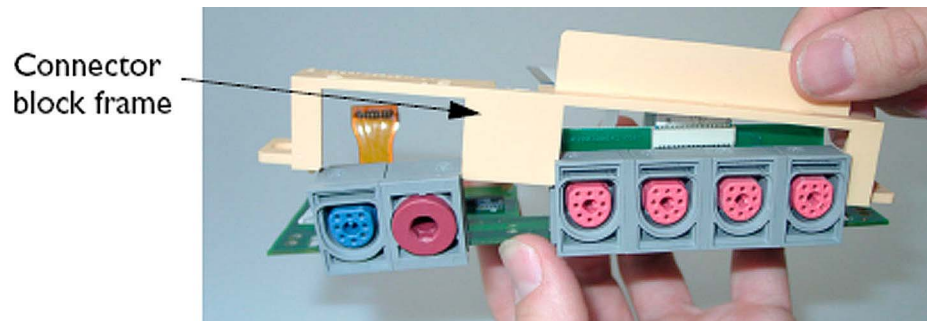
The procedure to replace the front end assembly is a reversal of the removal procedure. Ensure all the cables are properly reconnected.

## Disassembling the Front End Assembly

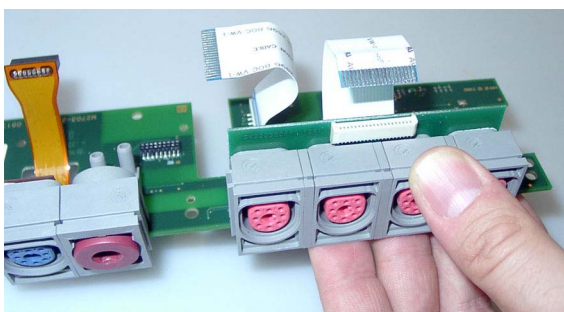
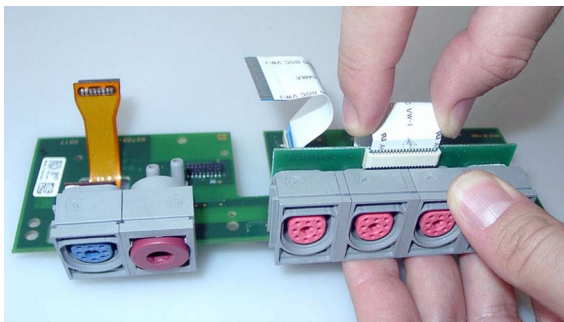
- 1 Remove the front end assembly from the bottom housing (see “Removing the Front End Assembly” on page 200).
- 2 Release the clip at each end of the connector block frame from the slots in the bus master board.



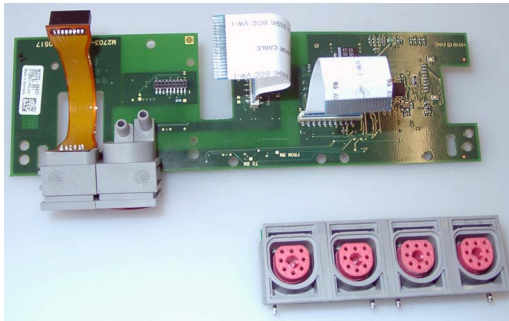
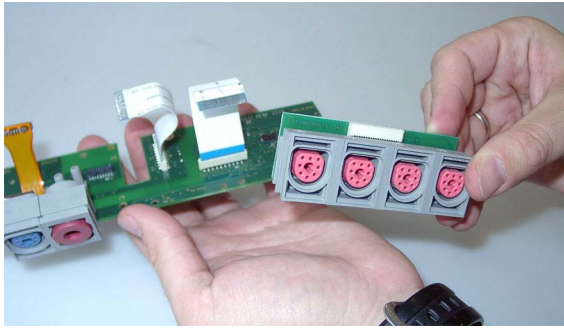
- 3 Remove the connector block frame.



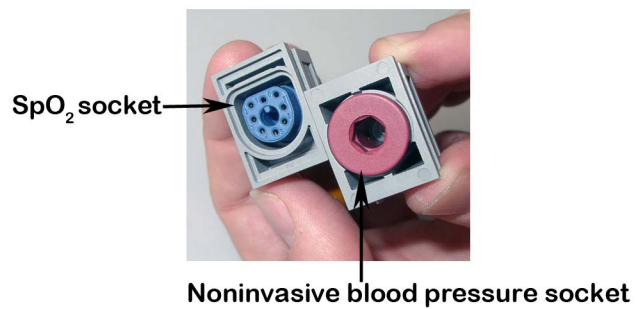
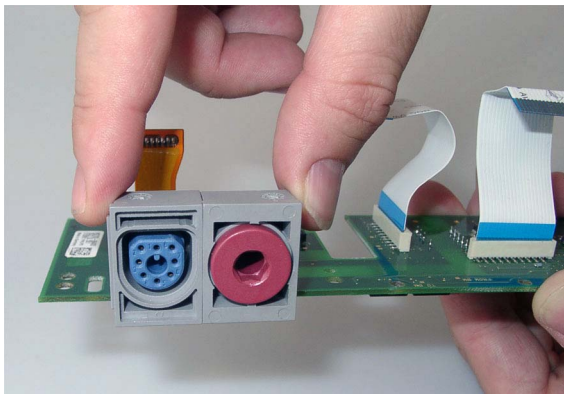
- 4 Disconnect the flat ribbon cable connecting the fetal sensor socket connector block to the bus master board, then remove the connector block.



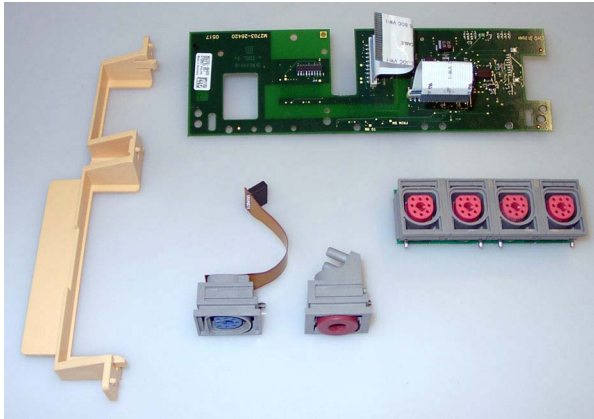
- 5 Remove the fetal sensor socket connector block.



- 6 Remove the optional sockets for noninvasive blood pressure and SpO<sub>2</sub>, if fitted. Note that these sockets slide together.



All components of the front end assembly are now separated.



### Reassembling the Front End Assembly

The procedure to reassemble the front end assembly is a reversal of the removal procedure. Ensure all the cables are properly reconnected.

### Exchanging the Bus Master Board

- 1 Remove the front end assembly -- see “Removing the Front End Assembly” on page 200.
- 2 Strip the front end assembly down to its component parts -- see “Disassembling the Front End Assembly” on page 202.
- 3 Take a new bus master board and reassemble the front end assembly -- see “Reassembling the Front End Assembly” on page 205.

### Exchanging the Fetal Socket Connector Block

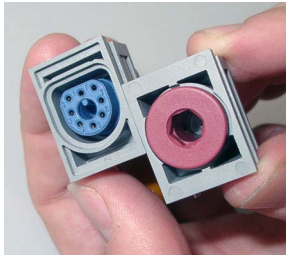
- 1 Remove the front end assembly -- see “Removing the Front End Assembly” on page 200.
- 2 Strip the front end assembly down as far as the end of step 5 under “Disassembling the Front End Assembly” on page 202.
- 3 Take a new fetal socket connector block.



- 4 Reassemble the front end assembly -- see “Reassembling the Front End Assembly” on page 205.

## Exchanging the Noninvasive Blood Pressure/SpO2 Sockets

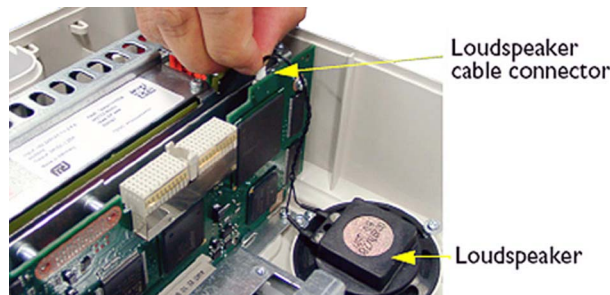
- 1 Remove the front end assembly -- see “Removing the Front End Assembly” on page 200.
- 2 Strip the front end assembly down as far as the end of step 6 on under “Removing the Front End Assembly” on page 200, but without removing the fetal sensor socket connector block.
- 3 Take a new noninvasive blood pressure and/or SpO<sub>2</sub> socket as applicable. If you need to refit both the noninvasive blood pressure and/or SpO<sub>2</sub> socket, you need to slot them together before attaching them back onto the bus master board.



- 4 Reassemble the front end assembly -- see “Reassembling the Front End Assembly” on page 205.

## Exchanging the Loudspeaker

- 1 Remove the top cover assembly (see “Removing the Top Cover Assembly” on page 141).
- 2 Disconnect the loudspeaker cable connector from the main CPU board.



- 3 Remove the three screws holding the loudspeaker, and remove the loudspeaker.
- 4 Refit the loudspeaker, making sure to refit the o-ring gasket. If a new gasket is required, it is available as part of the bottom housing small parts kit. (See “FM Small Parts Kit - Screws and Cables” on page 137).

## Transducer Disassembly/Reassembly

This section describes the disassembly and reassembly operations for the transducers.

### Exchanging the Transducer Cable

See the “Transducer Cable Assembly” on page 135 section for items that come with the cable.

---

#### WARNING

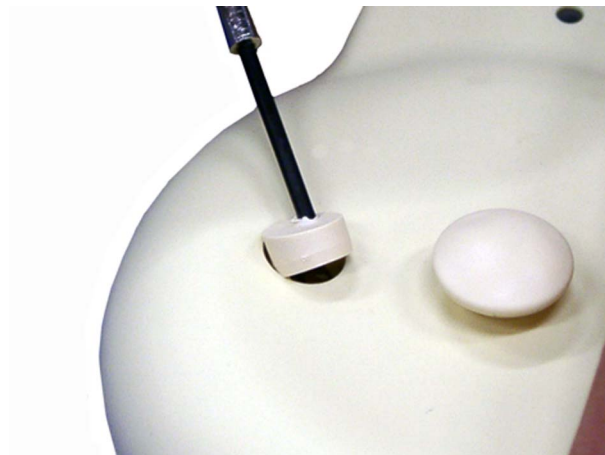
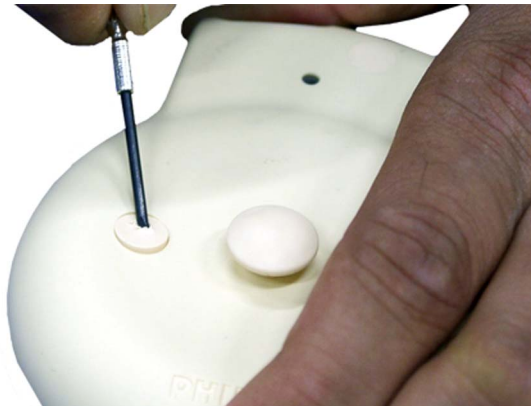
Transducers are calibrated at the factory, and the calibration data for the measurement is stored on the CPU board. Therefore NEVER replace the CPU board with one from another transducer.

---

Important when fitting the screw covers! Do NOT remove the screw covers from the frame to which they are attached. Leave them in place, as it is the only way to align the screw covers correctly. They detach from the frame when you press them into position.

To exchange a transducer cable:

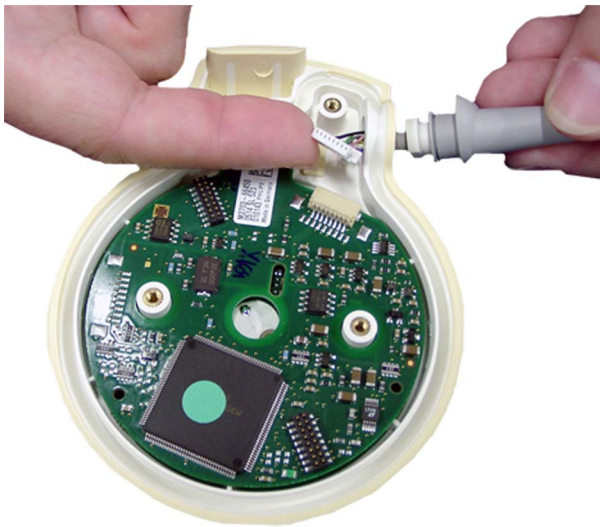
- 1 Pierce a screw cover with a small, flat-bladed screwdriver. Important! Do NOT try to pry out a screw cover from the side, without piercing it, as this will damage the transducer top cover.
- 2 Gently rock the screwdriver back and forth until the screw cover comes out. Repeat to remove all three screw covers.



- 3 Remove the three screws, and remove the transducer top cover.

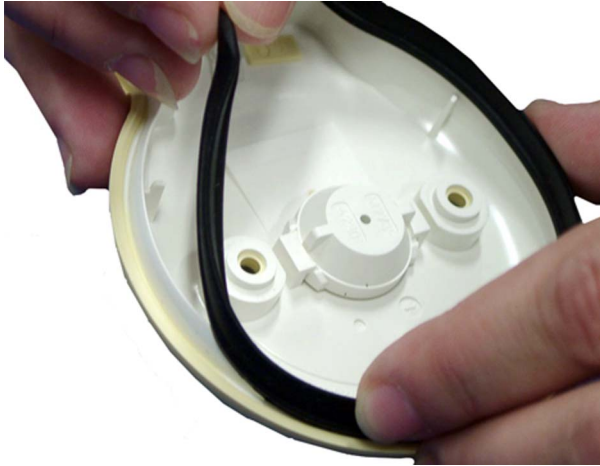


- 4 Disconnect the small cable connector, remove the old cable, and fit the new cable (as a reversal of the removal procedure).



- 5 Remove the sealing gasket from the top cover, and replace it with the new one supplied with the cable. While handling a Toco/Toco+ transducer, take care not to displace the strain gauge. Fit a

new gasket to the top cover, ensuring the gasket is properly seated, replace the top cover and secure it with the three screws.



- 6 Leaving the screw covers attached to the frame, carefully align the screw covers with the screw recesses in the top cover. Next, partially press in two of the covers at the same time, then press in the third one (they detach from the frame as you push them in). Then make sure all three covers are pushed completely into the recesses.



## Exchanging the Transducer Belt Button

### CAUTION

NEVER immerse a transducer in liquid if the belt button has been removed, or is loose, broken or damaged.

**M2703-64204**

**Replacement Belt Button Kit**  
Contents:



x5

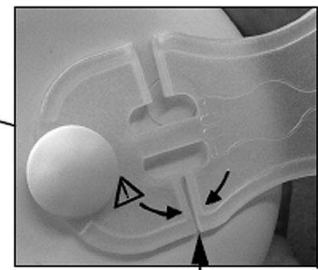
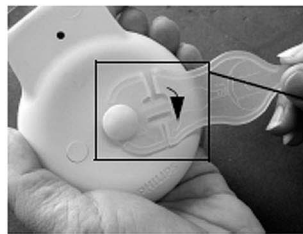


x1

- 1 Remove the belt button using the tool provided with the belt button kit.



- 2 Dispose of the old belt button. Take a new belt button and fit it to the transducer. Initially, screw the button in by hand about four turns, then complete the job with the supplied tool. Stop applying force when the head of the tool makes contact with the body of the tool at the point indicated by the arrows.



If the belt button is broken:



- 3 Remove the threaded part left in the top cover with a small, flat-bladed screwdriver (2.0-3.0 mm).



- 4 Then fit a belt button as described “Exchanging the Transducer Belt Button” on page 211.

# Upgrades

This chapter lists the various upgrade options for the monitors, and describes how to carry out these upgrades.

## FM20/30 Upgrade Options

Upgrade options for the FM20 are prefixed with **M2702AU**.

Upgrade options for the FM30 are prefixed with **M2703AU**.

Options B72 and B73 apply to the FM30 only.

| FM20/30 Upgrade Options |                                                                                                                    |                                     |             |                                      |     |
|-------------------------|--------------------------------------------------------------------------------------------------------------------|-------------------------------------|-------------|--------------------------------------|-----|
| Option Number           | Option Adds                                                                                                        | Parts included with Option          |             |                                      |     |
|                         |                                                                                                                    | Description                         | Part Number | Contents/Comments                    | Qty |
| B71                     | Noninvasive Blood Pressure (NIBP). No supplies included.                                                           | NIBP kit                            | 1253-8416   | Connector housing                    | 1   |
|                         |                                                                                                                    |                                     | 8120-8912   | Ribbon cable                         | 1   |
|                         |                                                                                                                    |                                     | M2703-02301 | NIBP assembly holder                 | 1   |
|                         |                                                                                                                    |                                     | M2703-47301 | NIBP tubing                          | 1   |
|                         |                                                                                                                    |                                     | M2703-64502 | NIBP assembly                        | 1   |
|                         |                                                                                                                    |                                     | M2720-61604 | Ground cable                         | 1   |
|                         |                                                                                                                    |                                     | 0515-4671   | Screw M3x6                           | 5   |
|                         |                                                                                                                    | Either Connector cover with symbols | M2703-44105 | For countries other than USA         | 1   |
|                         |                                                                                                                    | Or Connector cover with text        | M2703-44115 | For USA                              | 1   |
| B72<br>FM30 ONLY        | SpO <sub>2</sub> (only for monitors that already have Noninvasive Blood Pressure installed). No supplies included. | SpO <sub>2</sub> kit                | 1253-8422   | Connector housing                    | 1   |
|                         |                                                                                                                    |                                     | 1253-8429   | Connector for SpO <sub>2</sub> board | 1   |
|                         |                                                                                                                    |                                     | M2703-44108 | SpO <sub>2</sub> assembly holder     | 1   |
|                         |                                                                                                                    |                                     | M2703-66514 | SpO <sub>2</sub> board               | 1   |
|                         |                                                                                                                    |                                     | 0515-4671   | Screw M3x6                           | 4   |
|                         |                                                                                                                    | Either Connector cover with symbols | M2703-44106 | For countries other than USA         | 1   |
|                         |                                                                                                                    | Or Connector cover with text        | M2703-44116 | For USA                              | 1   |

## 11 Upgrades

| FM20/30 Upgrade Options                            |                                                                                                                                                                                                            |                                            |                              |                                                                                                        |         |
|----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|------------------------------|--------------------------------------------------------------------------------------------------------|---------|
| Option Number                                      | Option Adds                                                                                                                                                                                                | Parts included with Option                 |                              |                                                                                                        |         |
|                                                    |                                                                                                                                                                                                            | Description                                | Part Number                  | Contents/Comments                                                                                      | Qty     |
| B73<br>FM30 ONLY                                   | Noninvasive Blood Pressure and SpO <sub>2</sub> . No supplies included.                                                                                                                                    | NIBP kit                                   | See B71                      | See B71                                                                                                | See B71 |
|                                                    |                                                                                                                                                                                                            | SpO <sub>2</sub> kit                       | See B72                      | See B72                                                                                                | See B72 |
|                                                    |                                                                                                                                                                                                            | <i>Either</i> Connector cover with symbols | M2703-44106                  | For countries other than USA                                                                           | 1       |
|                                                    |                                                                                                                                                                                                            | <i>Or</i> Connector cover with text        | M2703-44116                  | For USA                                                                                                | 1       |
| E25<br>Battery Option (M2702AU #E25, M2703AU #E25) |                                                                                                                                                                                                            |                                            | N/A                          | Label for #E25 Battery Option                                                                          | 1       |
|                                                    |                                                                                                                                                                                                            |                                            | M3081-61601                  | MSL Connector Label, 1m                                                                                | 1       |
|                                                    |                                                                                                                                                                                                            |                                            | 453564190401                 | Battery Charger Assembly (without battery)                                                             | 1       |
|                                                    |                                                                                                                                                                                                            |                                            | 453564190311                 | External Power Supply M8023A #E25                                                                      | 1       |
|                                                    |                                                                                                                                                                                                            |                                            | M4605A                       | Lithium Battery                                                                                        | 1       |
|                                                    |                                                                                                                                                                                                            |                                            | 453564234911 (not orderable) | Installation Note                                                                                      | 1       |
| C71                                                | NST Trace Interpretation.                                                                                                                                                                                  | Customer letter - English                  | M8000-9399B                  | Asks customer to contact Philips Support to arrange a software upgrade                                 | 1       |
| C72                                                | Toco MP                                                                                                                                                                                                    | N/A                                        | N/A                          | N/A                                                                                                    | 1       |
| C73                                                | Triplets Monitoring Capability.                                                                                                                                                                            | Customer letter - English & triplet label  | M8000-9399B                  | Asks customer to contact Philips Support to arrange a software upgrade                                 | 1       |
| CL2                                                | Support for cableless maternal measurements (IntelliVue CL NBP and SpO <sub>2</sub> )                                                                                                                      | Customer letter                            | N/A                          | Asks customer to contact Philips Support to arrange a software upgrade. Not available with option E25. | 1       |
| J13                                                | Dual MIB/RS232 interface board<br><br>Touch control functionality of external LCD (M2704A and M2705A only)<br><br>Data Export functionality and for maternal infrared temperature measurement M2702/3/4/5A | Input device assembly                      | 453563469621                 | "Plug & Play" interface                                                                                | 1       |
| J22                                                | Dual PS/2 Interface for connecting a keyboard and mouse                                                                                                                                                    | Input device assembly                      | M8086-67501                  | "Plug & Play" interface                                                                                | 1       |
| J25                                                | Quad. USB Interface (Keyboard, Mouse, Bar Code Reader)                                                                                                                                                     | Input device assembly                      | 451261028241                 | "Plug & Play" interface                                                                                | 1       |
| J30                                                | Flexible Nurse Call Relay Interface                                                                                                                                                                        | Input device assembly                      | 453563469681                 | "Plug & Play" interface                                                                                | 1       |

| FM20/30 Upgrade Options |                                                    |                                        |              |                               |     |
|-------------------------|----------------------------------------------------|----------------------------------------|--------------|-------------------------------|-----|
| Option Number           | Option Adds                                        | Parts included with Option             |              |                               |     |
|                         |                                                    | Description                            | Part Number  | Contents/Comments             | Qty |
| J70                     | System Interface, 1 x RS232 port and 1 x LAN port. | RS232/LAN I/O card assembly            | M2703-67501  | "Plug & Play" interface       | 1   |
| SJ3                     | Rel. J.3 Software Upgrade                          | Fetal Monitoring Documentation DVD-ROM | 453564491101 | -                             | 1   |
|                         |                                                    | Instructions for Use                   | 453564490751 | Appropriate localized version | 1   |

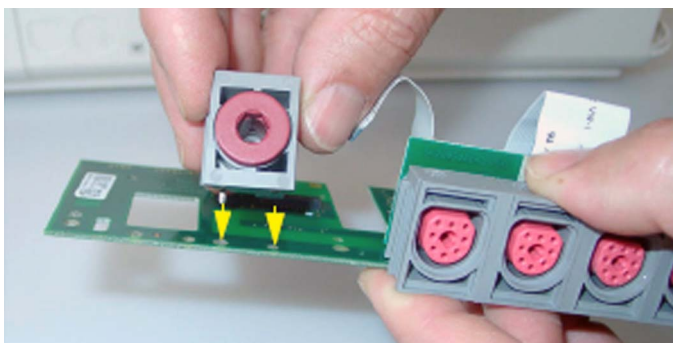
## Installing Upgrade Options

This section covers how to install the options.

### Option B71

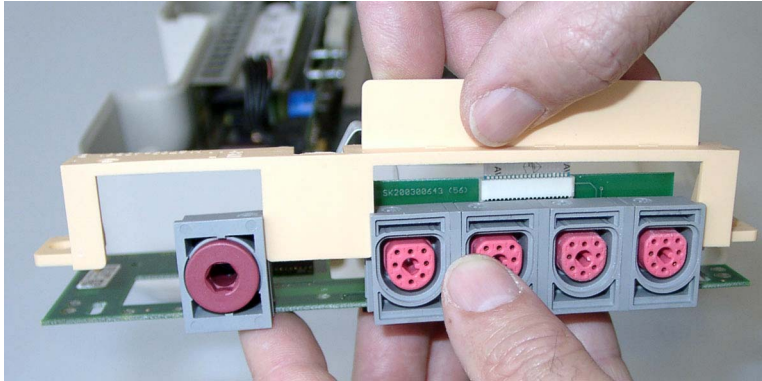
To install the noninvasive blood pressure upgrade:

- 1 Remove the top cover assembly as described in “Removing the Top Cover Assembly” on page 141.
- 2 Remove the front end assembly (see “Removing the Front End Assembly” on page 200).
- 3 Remove the connector block frame from the front end assembly (see “Disassembling the Front End Assembly” on page 202). Leave the fetal sensor socket connector block in place.
- 4 Take the new noninvasive blood pressure socket. Locate the metal pin and the plastic stud on the underneath of the noninvasive blood pressure socket in the corresponding holes in the bus master board.

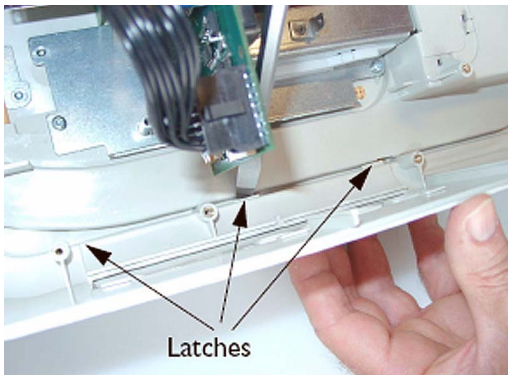


## 11 Upgrades

- 5 Replace the connector block frame, making sure that it snaps securely back into the bus master board.



- 6 To remove the existing connector cover, release the three snap-fit latches holding the connector cover along its bottom edge with a flat-headed screw-driver with a fairly wide blade.



- 7 Then remove the cover.



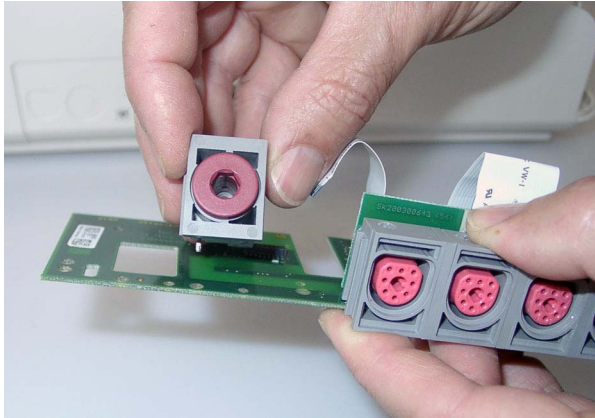
- 8 Fit the new connector cover that comes with the upgrade kit. First, locate the three lugs along the top edge of the connector cover in the corresponding recesses in the bottom housing. Then push the bottom of the cover so that the three latches snap securely into position.



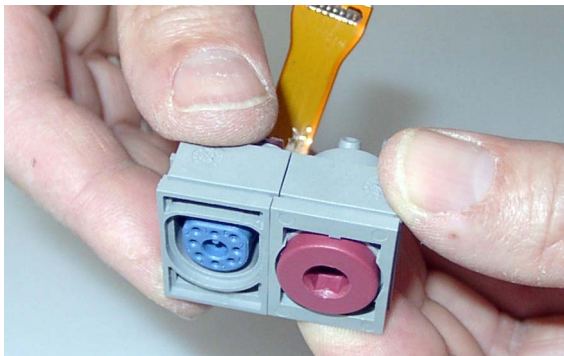
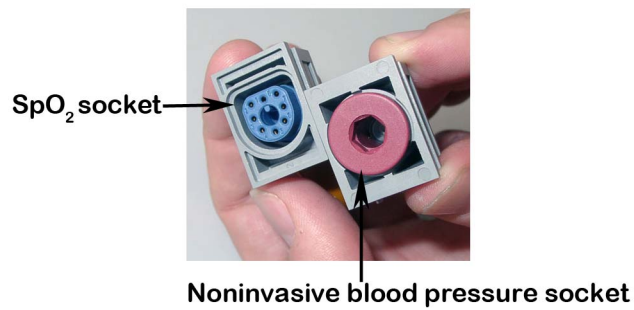
- 9 Replace the front end assembly as described in “Replacing the Front End Assembly” on page 202.
- 10 Fit the noninvasive blood pressure assembly as described in “Replacing the Noninvasive Blood Pressure Assembly” on page 192.
- 11 Replace the top cover assembly as described in “Replacing the Top Cover Assembly” on page 180.
- 12 For tests to perform after upgrading, see “When to Perform Tests” on page 56.

## Option B72 (FM30 only)

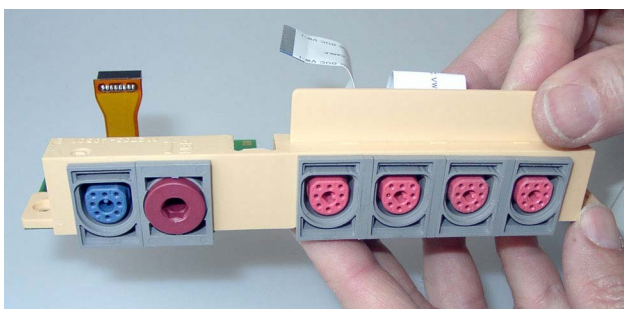
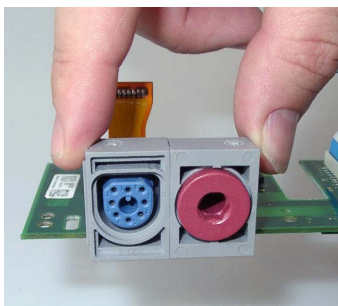
- 1 Remove the top cover assembly as described “Removing the Top Cover Assembly” on page 141.
- 2 Remove the noninvasive blood pressure assembly.
- 3 Remove the front end assembly -- see “Removing the Front End Assembly” on page 200.
- 4 Remove the connector block frame from the front end assembly (see “Disassembling the Front End Assembly” on page 202). Leave the fetal sensor socket connector block in place.
- 5 Remove the blood pressure connector from the bus master board.



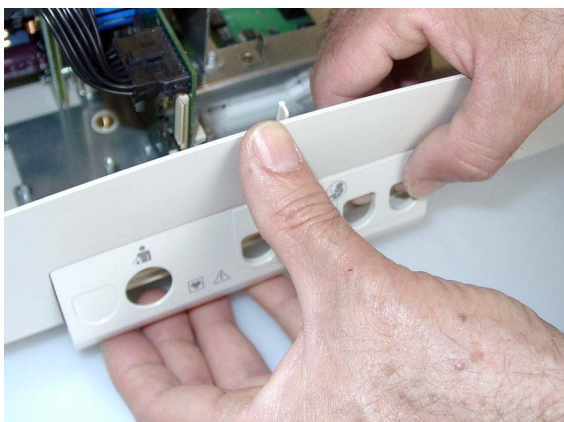
- 6 Join the new SpO<sub>2</sub> connector to the noninvasive blood pressure connector.



- 7 Locate the metal pins and the plastic studs on the underneath of the noninvasive blood pressure/ SpO<sub>2</sub> socket in the corresponding holes in the bus master board. Then replace the connector block frame.



- 8 Remove the existing connector cover as described in step 6 for Option B71 on, then remove the cover.

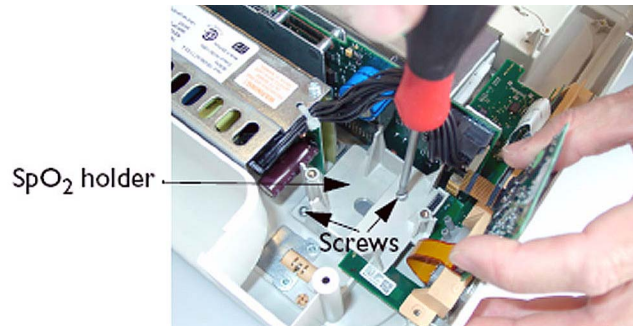


## 11 Upgrades

- 9 Fit the new connector cover that comes with the upgrade kit as described in step 8 for Option B71 on



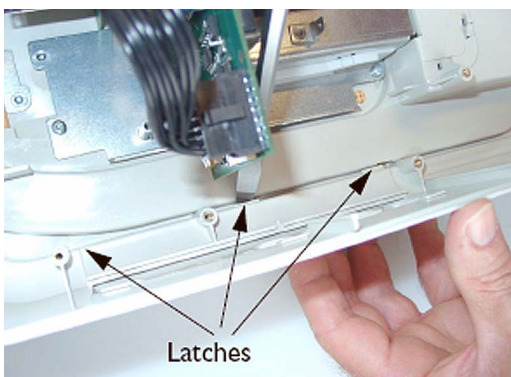
- 10 Replace the reassembled front end assembly as described in “Setting the Fetal Recorder Offset” on page 97.
- 11 Fit the SpO<sub>2</sub> board holder to the bottom housing with two screws from the upgrade kit.



- 12 Next, fit the SpO<sub>2</sub> board as described in “Replacing the SpO<sub>2</sub> Assembly” on page 196.
- 13 Then refit the noninvasive blood pressure assembly as described in “Replacing the Noninvasive Blood Pressure Assembly” on page 192.
- 14 Replace the top cover assembly as described in “Replacing the Top Cover Assembly” on page 180.
- 15 For tests to perform after upgrading, see “When to Perform Tests” on page 56.

## Option B73 (FM30 only)

- 1 Follow steps 1 to 3 inclusive for Option B71.
- 2 Then follow steps 6 and 7 for Option B72.
- 3 To remove the existing connector cover, release the three snap-fit latches holding the connector cover at the bottom with a flat-headed screw-driver with a fairly wide blade.



- 4 Fit the new connector cover that comes with the upgrade kit as described in step 8 for Option B71.



- 5 Follow steps 9 to 14 inclusive for Option B72.
- 6 For tests to perform after upgrading, see “When to Perform Tests” on page 56.

## Option E25

### NOTE

Follow the instructions given in the Battery Option E25 upgrade Installation Note.

The battery option is only to be installed in monitors with SW Revision G.0 or higher with display assemblies that have an LED back-light. You can identify the displays with LED back-light by the new labeling on the back of the display and by the Display Serial No. Prefix starting with DE928xxxxx. For further information see SB86201040A M2702/03A NEW DISPLAY ASSEMBLY IS AVAILABLE.

## Option C71

You enable this feature upgrade to NST Trace Interpretation capability using the Support Tool. Refer to the *Support Tool Instructions for Use* for details of the upgrade procedure.

## Option C72

You enable this feature upgrade for Maternal pulse capability using the Support Tool. Refer to the Support Tool Instructions for Use for details of the upgrade procedure.

## Option C73

You enable this feature upgrade to triplets capability using the Support Tool. Refer to the *Support Tool Instructions for Use* for details of the upgrade procedure.

## Option CL2

You enable this feature upgrade for the cableless maternal measurements (IntelliVue CL NBP and CL SpO<sub>2</sub>) capability using the Support Tool. Refer to the Support Tool Instructions for Use for details of the upgrade procedure.

## All J.x Options

The interfaces require no special upgrade procedures as they are "plug and play" boards. For settings defining a special combination of the boards see the Configuration Guide.

## SJ3

You can upgrade the monitor software to Rel. J.3 or higher using the Support Tool see “Software and Firmware Upgrades” on page 222.

The internal back-up memory is now able to store traces and data from at least the last 3.5 hours with the software revision J.3, and minimum 7 hours with the new main board hardware revision A 00.18

# Software and Firmware Upgrades

The software of the monitor and the firmware of the transducers and other system components can be upgraded by a software download from a PC running the Support Tool. You connect the monitor to the PC via a LAN connection. You need:

- Industry standard PC
- Support Tool
- LAN / RS232 system interface
- LAN interface cable for the Support Tool

Several Avalon fetal monitors can be upgraded in parallel with the Support Tool. All monitors in an installation can be upgraded at once, if desired.

The transducers can be upgraded one at a time, even though more than one may be plugged into the monitor at the same time.

When upgrading to a new monitor software revision, we recommend that you check that all system hardware components have the latest firmware revision, and upgrade these if necessary.

Refer to the *Support Tool Instructions for Use* for details of the upgrade procedure. Contact Philips Support for further details.

For tests to perform after upgrading, see “When to Perform Tests” on page 56.

# Specifications

Specifications for the accuracy of heart rate measurements are given in the Instructions for Use of the fetal monitor.

## Environmental Specifications

The monitor may not meet the given performance specifications if stored and used outside the specified temperature and humidity ranges.

| Monitor (M2702A/M2703A); Interface Cable for Avalon CTS (M2731-60001 and M2732-60001) |                        |                                                          |
|---------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------|
| Temperature Range                                                                     | Operating              | Without battery option: 0°C—45°C (32°F—113°F)            |
|                                                                                       |                        | With battery option/charging: 0°C—35°C (32°F—95°F)       |
|                                                                                       |                        | With battery option/fully charged: 0°C—40°C (32°F—104°F) |
|                                                                                       | Storage/Transportation | -20°C—60°C (-4°F—140°F)                                  |
| Humidity Range                                                                        | Operating              | <95% relative humidity @ 40°C (104°F)                    |
|                                                                                       | Storage/Transportation | <90% relative humidity @ 60°C (140°F)                    |
| Altitude Range                                                                        | Operating              | -500—3,000 m (-1,640—9,840 ft)                           |
|                                                                                       | Storage/Transportation | -500—13,100 m (-1,640—43,000 ft)                         |

| Transducers (M2734A/M2734B/M2735A/M2736A/M2738A) |                        |                                       |
|--------------------------------------------------|------------------------|---------------------------------------|
| Temperature Range                                | Operating              | 0°C—40°C (32°F—104°F)                 |
|                                                  | Storage/Transportation | -20°C—60°C (-4°F—140°F)               |
| Humidity Range                                   | Operating              | <95% relative humidity @ 40°C (104°F) |
|                                                  | Storage/Transportation | <90% relative humidity @ 60°C (140°F) |
| Altitude Range                                   | Operating              | -500—3,000 m (-1,640—9,840 ft)        |
|                                                  | Storage/Transportation | -500—13,100 m (-1,640—43,000 ft)      |

| SpO <sub>2</sub> Sensors    |                        |
|-----------------------------|------------------------|
| Operating Temperature Range | 0°C—37°C (32°F—98.6°F) |

| Tympanic Temperature        |                           |
|-----------------------------|---------------------------|
| Operating Temperature Range | 16°C—33°C (60.8°F—91.4°F) |

**WARNING**

**Explosion Hazard:** Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, nitrous oxide, or in oxygen rich environment. Use of the devices in such an environment may present an explosion hazard.

## Physical Specifications

### Fetal Monitor

| Monitor Physical Specifications               |                                                                               | M2702A/M2703A                                                                                    |
|-----------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| Power                                         | Supply Voltages                                                               | 100 VAC—240 VAC $\pm 10\%$                                                                       |
|                                               | Supply Frequency Range                                                        | 50 Hz—60 Hz                                                                                      |
|                                               | Power Consumption (current)                                                   | 0.7—0.4 A (M2702A/M2703A)<br>1.3—0.7 A (M8023A#E25)                                              |
| Dimensions and Weight                         | Size (without options) mm/ (in):<br>width x height x depth                    | 286 x 133 x 335 mm $\pm 1\%$<br>(11.3 x 5.2 x 13.2 in $\pm 1\%$ )                                |
|                                               | Weight                                                                        | <5.1 kg (11.2 lbs)                                                                               |
| Degree of Protection Against Electrical Shock |                                                                               | Type CF                                                                                          |
| Electrical Class                              |                                                                               | Class II equipment                                                                               |
| Electrical Power Source                       |                                                                               | External (AC) without battery option #E25<br>Internal (LiIo battery) if with battery option #E25 |
| Mode of Operation                             |                                                                               | Continuous operation                                                                             |
| Water Ingress Protection Code                 |                                                                               | IP X1 (provided recorder drawer is shut)                                                         |
| Global Speed                                  |                                                                               | 6.25 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec                                                   |
| Startup Time                                  | Time taken from switching on the monitor to seeing the first parameter labels | <30 seconds                                                                                      |

### Fetal Monitor Sounds

| Source                                   | Description                                                                                                                             |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Patient alarms and INOPs                 | See the sections on Patient Alarms and INOPs, Standard Philips Alarms, and ISO/IEC Standard Audible Alarms in the Instructions for Use. |
| Ultrasound Doppler                       | Direct transmission of Doppler echoes to the speaker of the fetal monitor.                                                              |
| Pulse from SpO <sub>2</sub> , MECG, DECG | QRS tone                                                                                                                                |

| Source               | Description                                                                                      |
|----------------------|--------------------------------------------------------------------------------------------------|
| SpO <sub>2</sub>     | Optional modulation of the QRS tone for changes in the SpO <sub>2</sub> level.                   |
| NST Timer            | Tone for Timer expired.                                                                          |
| Status/Prompt tone   | Configurable volume tone sounded when status or prompt messages are issued by the fetal monitor. |
| Touch feed back tone | Anytime the user touches the display a low beep is issued in response.                           |

## Wired Transducers

| Transducers (M2734A/M2734B/M2735A/M2736A/M2738A) |                 |                                                                              |                                       |
|--------------------------------------------------|-----------------|------------------------------------------------------------------------------|---------------------------------------|
| Shock Resistance                                 |                 | Withstands a 1 m drop to concrete surface with possible cosmetic damage only |                                       |
| Water Ingress Protection Code                    | M2734A&B/35/36A | IP 68 (immersion up to 1 m water depth for 5 hours)                          |                                       |
|                                                  | M2738A          | IP 67 (immersion up to 0.5 m water depth for 30 minutes)                     |                                       |
| Dimensions and Weight                            | M2734A&B/35/36A | Size (diameter)                                                              | 83 mm (3.27 in)                       |
|                                                  |                 | Weight (without cable)                                                       | <220 g (7.8 oz)                       |
|                                                  | M2738A          | Maximum size mm/(in): width x height x depth                                 | 50 x 28 x 135 mm (2.0 x 1.1 x 5.3 in) |
|                                                  |                 | Cable length                                                                 | 2.5 m                                 |
|                                                  |                 | Weight                                                                       | <150 g (5.3 oz)                       |
| Degree of Protection Against Electrical Shock    |                 | Type CF                                                                      |                                       |
| Transducer Identification                        |                 | Optical Signal Element (Finder LED), not M2738A                              |                                       |

## Interface Cable Avalon CTS

| Interface Cable for Avalon CTS (M2731-60001 and M2732-60001) |                                                                              |                                      |
|--------------------------------------------------------------|------------------------------------------------------------------------------|--------------------------------------|
| Shock Resistance                                             | Withstands a 1 m drop to concrete surface with possible cosmetic damage only |                                      |
| Water Ingress Protection Code                                | IP X1                                                                        |                                      |
| Dimensions and Weight                                        | Maximum size mm/(in): width x height x depth                                 | 55 x 28 x 50 mm (2.2 x 1.1 x 2.0 in) |
|                                                              | Cable length                                                                 | 2.5 m                                |
|                                                              | Weight                                                                       | <200 g (7.0 oz)                      |

## External Power Supply Option E25

| M8023A (Option #E25) External Power Supply Weight and Dimensions |                                        |
|------------------------------------------------------------------|----------------------------------------|
| Maximum Weight                                                   | 700 g $\pm$ 10% (1.5 lb $\pm$ 10%)     |
| Size (W x H x D)                                                 | 207 x 70 x 113 mm (8.1 x 2.8 x 4.4 in) |

## Battery Specifications

The battery lifetime is 3 years from manufacturing date or 500 charge/discharge cycles.

| M4605A Battery Specifications       |                                                                                                            |
|-------------------------------------|------------------------------------------------------------------------------------------------------------|
| Physical Specifications             |                                                                                                            |
| W x D x H                           | 149 mm (5.866 in) x 89 mm (3.504 in) x 19.8 mm (0.78 in)                                                   |
| Weight                              | 490 g (1.08 lb) per battery                                                                                |
| Performance Specifications          |                                                                                                            |
| Nominal Voltage                     | 10.8 Volt                                                                                                  |
| Rated Capacity at discharge C/5     | 6000 mAh                                                                                                   |
| Continuous Discharge Capability     | 6.5 A                                                                                                      |
| Environmental Specifications        |                                                                                                            |
| Temperature Range                   | Discharge 0—50°C (32—122°F)<br>Charge 0—50°C (32—122°F)<br>Storage and Transportation: -20—65°C (-4—140°F) |
| Humidity Range                      | Operating: 15%—95% Relative Humidity (RH)<br>Storage and Transportation: 5 %—95 % Relative Humidity (RH)   |
| Battery Type                        | Smart Battery 10.8 V, 6000 mAh, Lithium Ion                                                                |
| Safety                              | complies with UL 2054                                                                                      |
| Electromagnetic Compatibility (EMC) | complies with the requirements for FCC Type B computing Device, and EN 61000-4-2 and EN 61000-3-2          |
| Communication Standard              | complies with the SMBus specification v 1.1                                                                |

## Interface Specification

| Interface Specifications |            |                                                                                        |
|--------------------------|------------|----------------------------------------------------------------------------------------|
| Network                  | Standard   | 100-Base-TX (IEEE 802.3 Clause 25)                                                     |
|                          | Connector  | RJ45 (8 pin)                                                                           |
|                          | Isolation  | Basic insulation (reference voltage: 250 V; test voltage: 1500 V)                      |
| MIB/RS232                | Standard   | IEEE 1073-3.2-2000                                                                     |
|                          | Connectors | RJ45 (8 pin)                                                                           |
|                          | Mode       | Software-controllable<br>BCC (RxD/TxD cross over) or<br>DCC (RxD/TxD straight through) |
|                          | Power      | 5 V $\pm$ 5 %, 100 mA (max.)                                                           |
|                          | Isolation  | Basic insulation (reference voltage: 250 V; test voltage: 1500 V)                      |
| USB Interface            | Standard   | USB 2.0 full-speed (embedded host)                                                     |
|                          | Connectors | USB series "Standard A" receptacle                                                     |
|                          | Power      | Low power port 4.4V min; max. load for all ports together 500 mA                       |
|                          | Isolation  | none                                                                                   |

| Interface Specifications                            |            |                                                                   |
|-----------------------------------------------------|------------|-------------------------------------------------------------------|
| <b>RS232 (Standard)</b>                             | Connectors | RJ45 (8-pin)                                                      |
|                                                     | Power      | none                                                              |
|                                                     | Insulation | Basic insulation (reference voltage: 250 V; test voltage: 1500 V) |
| <b>RS232 (Independent display interface option)</b> | Connectors | RJ45 (8-pin)                                                      |
|                                                     | Power      | none                                                              |
|                                                     | Isolation  | none                                                              |
| <b>Flexible Nurse Call Relay<sup>1</sup></b>        | Connectors | 20 pin MDR (Mini D-Ribbon), active open and closed contacts       |
|                                                     | Contact    | $\leq 100$ mA, $\leq 24$ V DC                                     |
|                                                     | Isolation  | Basic insulation (reference voltage: 250 V; test voltage: 1500 V) |
|                                                     | Delay      | $< [\text{Configured Latency} + 0.5]$ sec                         |

<sup>1</sup> The power loss indication functionality of the Nurse Call Relay board is not supported with fetal monitors.

## Performance Specifications

### NOTE

Your monitor's default settings can be permanently changed in Configuration Mode.

The default settings specified here refer to the settings initially shipped with the monitor.

## Fetal Monitors

| Fetal Monitor Performance Specifications |                                                                                                                                                                                          |                                                                            |
|------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|
| <b>Alarm Signal</b>                      | System alarm delay.<br>The system alarm delay is the processing time the system needs for any alarm to be indicated on the fetal monitor, after the measurement has triggered the alarm. | less than 4 seconds                                                        |
|                                          | Pause duration                                                                                                                                                                           | 1, 2, 3 minutes or infinite, depending on the configuration                |
|                                          | Extended alarm pause                                                                                                                                                                     | 5 to 10 minutes                                                            |
|                                          | Sound pressure range                                                                                                                                                                     | min. 0 dB(A) max. 45—85 dB(A)                                              |
| <b>Review Alarms</b>                     | Information                                                                                                                                                                              | all alarms/INOPs, main alarms on/off, alarm silence and time of occurrence |
|                                          | Capacity                                                                                                                                                                                 | 300 items                                                                  |
| <b>Real time Clock</b>                   | Range                                                                                                                                                                                    | from: January 1, 1997, 00:00 to: December 31, 2080, 23:59                  |
|                                          | Accuracy                                                                                                                                                                                 | better than $\pm 1$ min. per month                                         |
|                                          | Hold Time                                                                                                                                                                                | infinite if powered by AC; otherwise at least 48 hours                     |

## 12 Specifications

### Fetal Monitor Performance Specifications

|                 |           |                                                              |
|-----------------|-----------|--------------------------------------------------------------|
| Buffered Memory | Hold Time | if powered by AC infinite<br>without power: at least 8 hours |
|                 | Contents  | active settings, review alarms, stored trace data            |

## Battery Specifications

### Performance Specifications

|                                       |                                                     |                                                                                                                                                                                                    |
|---------------------------------------|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Avalon FM20/30 Battery<br>Option #E25 | Operating Time<br>(with new, fully charged battery) | Basic monitoring configuration: >2 hours<br>(Display Brightness: 70%, Recorder: "On" at 3 cm/min,<br>NBP: Auto Mode at 15 min, 2 US Transducers, 1 Toco+<br>with MECG, 1 Patient Module with DECG) |
|                                       | Charge Time                                         | When monitor is off: approx. 6 hours<br>When monitor is in use: more than 10 hours (depending on<br>monitor configuration).                                                                        |

## Fetal / Maternal Specifications

### Ultrasound

Complies with IEC 60601-2-37:2007 / EN 60601-2-37:2008

### Performance Specifications

| Ultrasound               |                                                                                        |                                              |
|--------------------------|----------------------------------------------------------------------------------------|----------------------------------------------|
| Measurement Method       |                                                                                        | Ultrasound Pulse Doppler                     |
| Measurement Range        | US                                                                                     | 50—240 bpm                                   |
| Resolution               | Display                                                                                | 1 bpm                                        |
|                          | Printer                                                                                | 1/4 bpm                                      |
| Jitter @ 200 bpm         |                                                                                        | ≤3 bpm                                       |
| Display Update Rate      |                                                                                        | 1 per second                                 |
| US Intensity (M2736A/AA) | Average output power                                                                   | $P = (7.4 \pm 0.4) \text{ mW}$               |
|                          | Peak-negative acoustic pressure                                                        | $p_- = (40.4 \pm 4.3) \text{ kPa}$           |
|                          | Output beam intensity ( $I_{ob}$ )<br>(= spatial average - temporal average intensity) | $I_{sata} = (2.38 \pm 0.59) \text{ mW/cm}^2$ |
|                          | Spatial-peak temporal average intensity                                                | $I_{spta} = (15.0 \pm 3.2) \text{ mW/cm}^2$  |
|                          | Effective radiating area @ -12 dB                                                      | $(3.11 \pm 0.74) \text{ cm}^2$               |
|                          | Thermal index (TI) and mechanical index (MI) are always below 1.0.                     |                                              |

| Performance Specifications                |                                                                                        |                                                   |
|-------------------------------------------|----------------------------------------------------------------------------------------|---------------------------------------------------|
| US Intensity CL (866076)                  | Average output power                                                                   | $P = (12.4 \pm 0.4) \text{ mW}$                   |
|                                           | Peak-negative acoustic pressure                                                        | $p_- = (49.1 \pm 5.2) \text{ kPa}$                |
|                                           | Output beam intensity ( $I_{ob}$ )<br>(= spatial average - temporal average intensity) | $I_{sata} = (2.77 \pm 0.56) \text{ mW/cm}^2$      |
|                                           | Spatial-peak temporal average intensity                                                | $I_{spta} = (21.1 \pm 5.1) \text{ mW/cm}^2$       |
|                                           | Effective radiating area @ -12 dB                                                      | $A_{-12dB} = (4.47 \pm 0.89) \text{ cm}^2$        |
|                                           | Thermal index (TI) and mechanical index (MI) are always below 1.0.                     |                                                   |
| Signal Quality Indication                 | Poor Quality                                                                           | empty                                             |
|                                           | Acceptable Quality                                                                     | half-full                                         |
|                                           | Good Quality                                                                           | full                                              |
| Beat-to-Beat change (max.) for Ultrasound |                                                                                        | 28 bpm                                            |
| US Frequency                              |                                                                                        | 1 MHz $\pm$ 100 Hz                                |
| US Signal range                           |                                                                                        | 3.5 $\mu\text{Vpp}$ —350 $\mu\text{Vpp}$ @ 200 Hz |
| US Burst                                  | Repetition Rate                                                                        | 3.0 kHz                                           |
|                                           | Duration                                                                               | $\leq 100 \mu\text{s}$                            |
| FMP Signal Range @ 33 Hz                  |                                                                                        | 200 $\mu\text{Vpp}$ —40 mVpp                      |

## Toco

| Performance Specifications |         |                                                                                |
|----------------------------|---------|--------------------------------------------------------------------------------|
| <b>Toco</b>                |         |                                                                                |
| Measurement Method         |         | Strain Gauge Sensor Element                                                    |
| Sensitivity                |         | 1 unit = 2.5 g                                                                 |
| Resolution                 | Display | 1 unit                                                                         |
|                            | Printer | 1/4 unit                                                                       |
| Measurement Range          |         | 400 units                                                                      |
| Signal Range               |         | 0—127 units                                                                    |
| Maximum Offset Range       |         | -300 units                                                                     |
| Baseline Setting           |         | 20 units                                                                       |
| Update Rate                | Display | 1 per second                                                                   |
|                            | Printer | ~4 per second                                                                  |
| Auto Offset Correction     |         | 3 seconds after connecting the transducer, the Toco value is set to 20 units   |
| Auto Zero Adjust           |         | Toco value is set to zero following a negative measurement value for 5 seconds |

## 12 Specifications

| Performance Specifications |                                     |
|----------------------------|-------------------------------------|
| Maternal Pulse from Toco   |                                     |
| Emitted Light Energy       | ≤15 mW                              |
| Wavelength Range           | 780—1100 nm                         |
| Range                      | 40—240 bpm                          |
| Resolution                 | 1 bpm                               |
| Display Update Rate        | 1 per second                        |
| Accuracy                   | ± 2% or 1 bpm, whichever is greater |
| Update Rate                | every 4 seconds                     |

## IUP

| Performance Specifications               |                                                                           |               |
|------------------------------------------|---------------------------------------------------------------------------|---------------|
| IUP                                      |                                                                           |               |
| Measurement Method                       | Passive Resistive Strain Gauge Elements                                   |               |
| Measurement Range                        | -100—+300 mmHg                                                            |               |
| Signal Range                             | -99—127 mmHg or (-13.2—16.9 kPa)                                          |               |
| Resolution                               | Display                                                                   | 1 mmHg        |
|                                          | Printer                                                                   | 1/4 mmHg      |
| Sensitivity                              | 5 μV/V/mmHg                                                               |               |
| Offset Compensation                      | +100—200 mmHg                                                             |               |
| Accuracy (not including sensor accuracy) | ±0.5% per 100 mmHg                                                        |               |
| Update Rate                              | Display                                                                   | 1 per second  |
|                                          | Printer                                                                   | ~4 per second |
| Auto Offset Correction                   | 3 seconds after connecting the transducer, the IUP value is set to 0 mmHg |               |

## ECG

Complies with IEC 60601-2-27:2011 / EN 60601-2-27:2006+AC:2006 except clauses listed below:

- 201.6.2, 201.8.5.5
- 201.12.1.101
- 202.6.2.101

| Performance Specifications      |            |                                                      |
|---------------------------------|------------|------------------------------------------------------|
| ECG                             |            |                                                      |
| Performance Specifications Type | DECG       | Single Lead ECG (derived from Fetal Scalp Electrode) |
|                                 | MECG       | Single Lead ECG (derived from RA and LA electrodes)  |
| Measurement Range               | 30—240 bpm |                                                      |

| Performance Specifications                   |          |                                                             |
|----------------------------------------------|----------|-------------------------------------------------------------|
| Resolution                                   | Display  | 1 bpm (display update rate 1 per second)                    |
|                                              | Recorder | 1/4 bpm                                                     |
| Wave Speed (Global Speed)                    |          | 6.25 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec              |
| Accuracy                                     |          | ±1 bpm or 1%, whichever is greater (non-averaging)          |
| Beat-to-Beat change (max.)                   |          | MECG: 28 bpm<br>DECG: 28 bpm (with Artifact Suppression On) |
| Differential Input Impedance                 |          | >15M $\Omega$                                               |
| Electrode Offset Potential Tolerance         |          | ±400 mV                                                     |
| INOP Auxiliary Current (Leads Off Detection) |          | <100 $\mu$ A                                                |
| Input Signal Range                           | DECG     | 20 $\mu$ V <sub>pp</sub> —6 mV <sub>pp</sub>                |
|                                              | MECG     | 150 $\mu$ V <sub>pp</sub> —6 mV <sub>pp</sub>               |
| Dielectric Strength                          |          | 1500 V <sub>rms</sub>                                       |
| Defibrillator Protection                     |          | None                                                        |
| ESU Protection                               |          | None                                                        |
| Paced pulse detection                        |          | None                                                        |

### WARNING

The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

When in doubt, it can be used to identify sources of compromised signal quality, such as noise or muscle artifacts. It can subsequently be used to verify the result of measures taken to resolve them (e.g., checking ECG cable connections or adapting the fetal **ArtifactSuppress** configuration).

The safety and effectiveness of the displayed fetal/maternal ECG waveform (i.e., P, QRS and T segments) for evaluation of fetal/maternal cardiac status during labor have not been evaluated.

| Fetal Heart Rate (Ultrasound/DECG) Alarm Specifications |       |                          |                                                              |
|---------------------------------------------------------|-------|--------------------------|--------------------------------------------------------------|
| FHR Alarm Limits                                        | Range | Bradycardia (low limit)  | 60—200 bpm<br>adjustable in 10 bpm steps<br>Default: 110 bpm |
|                                                         |       | Tachycardia (high limit) | 70—210 bpm<br>adjustable in 10 bpm steps<br>Default: 170 bpm |

## 12 Specifications

| Fetal Heart Rate (Ultrasound/DECG) Alarm Specifications |       |                                |                                                                                    |
|---------------------------------------------------------|-------|--------------------------------|------------------------------------------------------------------------------------|
| FHR Alarm Delay                                         | Range | Bradycardia (low limit) Delay  | 10—300 seconds in steps of 10 seconds + system alarm delay<br>Default: 240 seconds |
|                                                         |       | Tachycardia (high limit) Delay | 10—300 seconds in steps of 10 seconds + system alarm delay<br>Default: 300 seconds |
|                                                         |       | Signal Loss Delay              | 10—30 seconds in steps of 10 seconds + system alarm delay                          |

| MECG Alarm Specifications | Range                                                 | Adjustment                                          | Alarm Delay                                            |
|---------------------------|-------------------------------------------------------|-----------------------------------------------------|--------------------------------------------------------|
| MECG Alarm Limits         | High Range: 31—240 bpm<br>Default: 120 bpm            | 1 bpm steps (30—40 bpm)<br>5 bpm steps (40—240 bpm) | System alarm delay (see “Fetal Monitors” on page 227). |
|                           | Low Range: 30—235 bpm<br>Default: 50 bpm              |                                                     |                                                        |
| Extreme Tachycardia       | Difference to high limit: 0—50 bpm<br>Default: 20 bpm | 5 bpm steps                                         |                                                        |
|                           | Clamping at: 150—240 bpm<br>Default: 200 bpm          | 5 bpm steps                                         |                                                        |
| Extreme Bradycardia       | Difference to low limit: 0—50 bpm<br>Default: 20 bpm  | 5 bpm steps                                         |                                                        |
|                           | Clamping at: 30—100 bpm<br>Default: 40 bpm            | 5 bpm steps                                         |                                                        |

| Maternal ECG Supplemental Information as required by IEC 60601-2-27 |                                                                                                                                                                                                                                                          |                         |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| Heart Rate Averaging Method                                         | The maternal heart rate is computed by averaging the 12 most recent RR intervals. If each of three consecutive RR intervals is greater than 1200 ms (i.e. rate less than 50 bpm), then the four most recent RR intervals are averaged to compute the HR. |                         |
| Display Update Rate                                                 | 2 seconds                                                                                                                                                                                                                                                |                         |
| Ventricular tachycardia alarm for waveforms B1 and B2               | No heart rate is detected for waveforms B1 and B2, resulting in <b>*** Extreme Brady</b> alarm                                                                                                                                                           |                         |
| Response Time of Heart Rate Meter to Change in Heart Rate           | HR change from 80—120 bpm: 10 seconds<br>HR change from 80—40 bpm: 14 seconds                                                                                                                                                                            |                         |
| Tall T-Wave Rejection Capability                                    | M2735A                                                                                                                                                                                                                                                   | 1.2 mV T-Wave amplitude |
|                                                                     | M2738A                                                                                                                                                                                                                                                   | 1.4 mV T-Wave amplitude |
|                                                                     | CL Toco <sup>+</sup> MP, CL ECG/IUP                                                                                                                                                                                                                      | 1.2 mV T-Wave amplitude |

| Maternal ECG Supplemental Information as required by IEC 60601-2-27 |                                     |                                                                                                                                                                         |
|---------------------------------------------------------------------|-------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Response Time of Heart Rate meter to Change in Heart Rate           | M2735A, M2738A                      | HR change from 80—120 bpm Average: 12 seconds<br>HR change from 80—40 bpm Average: 15 seconds                                                                           |
|                                                                     | CL Toco <sup>+</sup> MP, CL ECG/IUP | HR change from 80—120 bpm Average: 10 seconds<br>HR change from 80—40 bpm Average: 12 seconds                                                                           |
| Heart Rate Meter Accuracy and Response to Irregular Rhythm          | M2735A, M2738A                      | Ventricular bigeminy 40—60 bpm<br>Slow alternating ventricular bigeminy 45 bpm<br>Rapid alternating ventricular bigeminy 163 bpm<br>Bidirectional systoles 63—73 bpm    |
|                                                                     | CL Toco <sup>+</sup> MP, CL ECG/IUP | Ventricular bigeminy 40—60 bpm<br>Slow alternating ventricular bigeminy 30 bpm<br>Rapid alternating ventricular bigeminy 70—163 bpm<br>Bidirectional systoles 63—73 bpm |

## Noninvasive Blood Pressure

Complies with IEC 80601-2-30:2009 / EN 80601-2-30:2010.

| Performance Specifications      |                                                                         |                                                                                                       |
|---------------------------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| Measurement Ranges              | Systolic                                                                | 30—270 mmHg (4—36 kPa)                                                                                |
|                                 | Diastolic                                                               | 10—245 mmHg (1.5—32 kPa)                                                                              |
|                                 | Mean                                                                    | 20—255 mmHg (2.5—34 kPa)                                                                              |
| Accuracy <sup>1</sup>           |                                                                         | Max. Std. Deviation: 8 mmHg (1.1 kPa)<br>Max. Mean Error: ±5 mmHg (±0.7 kPa)                          |
| Pulse Rate                      | Range                                                                   | 40—300 bpm                                                                                            |
|                                 | Accuracy<br>(average over noninvasive blood pressure measurement cycle) | 40—100 bpm: ±5 bpm                                                                                    |
|                                 |                                                                         | 101—200 bpm: ±5% of reading                                                                           |
|                                 |                                                                         | 201—300 bpm: ±10% of reading                                                                          |
| Measurement Time                |                                                                         | Typical at HR >60 bpm<br><br>Auto/manual: 30 seconds (adult)<br><br>Maximum time: 180 seconds (adult) |
| Cuff Inflation Time             |                                                                         | Typical for normal adult cuff: Less than 10 seconds                                                   |
| Initial Cuff Inflation Pressure |                                                                         | 165 ±15 mmHg                                                                                          |
| Auto Mode Repetition Times      |                                                                         | 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, or 120 minutes                                               |
| Venipuncture Mode Inflation     |                                                                         |                                                                                                       |
| Inflation Pressure              |                                                                         | 20—120 mmHg (3—16 kPa)                                                                                |
| Automatic deflation after       |                                                                         | 170 seconds                                                                                           |

\*1: Clinical investigation with the auscultatory reference method

- The 5th Korotkoff sound (K5) was used to determine the diastolic reference pressures.

## 12 Specifications

- The approximation  $MAP = (2 \times DIA + SYS) / 3$  was used to calculate reference MAP (mean arterial pressure) values from the systolic and diastolic reference pressures.
- The NBP measurement is suitable for use with pregnant (including pre-eclamptic) patients.

| Alarm Specifications | Range                           | Adjustment                                               | Alarm Delay                                            |
|----------------------|---------------------------------|----------------------------------------------------------|--------------------------------------------------------|
| <b>Systolic</b>      | Adult: 30—270 mmHg (4—36 kPa)   | 10—30 mmHg; 2 mmHg (0.5 kPa)<br>>30 mmHg: 5 mmHg (1 kPa) | System alarm delay (see “Fetal Monitors” on page 227). |
| <b>Diastolic</b>     | Adult: 10—245 mmHg (1.5—32 kPa) |                                                          |                                                        |
| <b>Mean</b>          | Adult: 20—255 mmHg (2.5—34 kPa) |                                                          |                                                        |

| Overpressure Settings       | Adjustment          |
|-----------------------------|---------------------|
| > 300 mmHg (40 kPa) > 2 sec | not user adjustable |

## SpO2

Complies with ISO 80601-2-61:2011 / EN 80601-2-61:2011.

Measurement Validation: The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

Display Update Period: Typical: 2 seconds, maximum: 30 seconds. Maximum with noninvasive blood pressure INOP suppression on: 60 seconds.

| SpO <sub>2</sub> Performance Specifications                                                                                                    |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>SpO<sub>2</sub></b><br>The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values | Range                | 0—100%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                | Accuracy             | <b>Philips Reusable Sensors:</b><br>M1191A/B, M1191AL/BL, M1191ANL, M1192A, M1192AN = 2% (70%—100%)<br><br>M1191T, M1192T, M1194A, M1194AN, M1196A, M1196T = 3% (70%—100%)<br><br><b>Philips Disposable Sensors with M1943A(L):</b><br>M1131A, M1901B, M1903B, M1904B = 3% (70%—100%)<br><br>M1133A, M1134A = ±2% (70%—100%)<br><br><b>NellcorPB® Sensors with M1943A(L):</b><br>MAX-A, MAX-AL, MAX-P, MAX-N, D-25, D-20, N-25, OxiCliq A, P, N = 3% (70%—100%)<br><br><b>Masimo Reusable Sensors® with LNOP MP12 or LNC MP10:</b><br>LNOP DC-I, LNOP DC-IP, LNOP YI, LNCS DC-I, LNCS DC-IP: 2% (70%—100%)<br><br>LNOP TC-I, LNCS TC-I: 3.5% (70%—100%)<br><br><b>Masimo Disposable Sensors® with LNOP MP12 or LNC MP10:</b><br>LNOP Adt, LNOP Adtx, LNOP Pdt, LNOP Pdtx, LNCS Adtx, LNCS Pdtx: 2% (70%—100%)<br><br>LNOP Neo-L, LNCS Neo-L: 3% (70%—100%) |
|                                                                                                                                                | Resolution           | 1%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Pulse</b>                                                                                                                                   | Range                | 30—300 bpm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                                                                                                                | Accuracy             | ±2% or 1 bpm, whichever is greater                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                                                                                                                | Resolution           | 1 bpm                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Sensors</b>                                                                                                                                 | Wavelength range     | 500—1000 nm.<br>Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                                                                                                                                | Emitted Light Energy | ≤15mW                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Pulse Oximeter Calibration Range</b>                                                                                                        |                      | 70%—100%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

| SpO <sub>2</sub> Alarm Specifications | Range                             | Adjustment                                          | Delay                           |
|---------------------------------------|-----------------------------------|-----------------------------------------------------|---------------------------------|
| <b>SpO<sub>2</sub></b>                | 50—100%                           | 1% steps                                            | (0, 1, 2, 3,... 30) + 4 seconds |
| <b>Desat</b>                          | 50—Low alarm limit                | 1% steps                                            |                                 |
| <b>Pulse</b>                          | 30—300 bpm                        | 1 bpm steps (30—40 bpm)<br>5 bpm steps (40—300 bpm) | max. 14 seconds                 |
| <b>Tachycardia</b>                    | Difference to high limit 0—50 bpm | 5 bpm steps                                         | max. 14 seconds                 |
|                                       | Clamping at 150—300 bpm           | 5 bpm steps                                         |                                 |

## 12 Specifications

| SpO <sub>2</sub> Alarm Specifications | Range                            | Adjustment  | Delay           |
|---------------------------------------|----------------------------------|-------------|-----------------|
| Bradycardia                           | Difference to low limit 0—50 bpm | 5 bpm steps | max. 14 seconds |
|                                       | Clamping at 30—100 bpm           | 5 bpm steps |                 |

### Tympanic Temperature

Complies with:

- EN 12470-5 (Clinical thermometers - Part 5:2003: Performance of infra-red thermometers)
- ASTM E1965-98 (Infrared Thermometers for Intermittent Determination of Patient Temperature)

with minor exceptions as noted below.

The fetal monitor additionally complies with ISO 80601-2-56:2009 / EN ISO 80601-2-56:2012

| Performance Specifications                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                             |                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------|
| Temperature Resolution                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                             | 0.1°C or 0.1°F      |
| Response Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                             | less than 2 seconds |
| Temperature Calibrated Accuracy Specifications (out of the Factory)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                             |                     |
| Ambient Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Target Temperature                          | Accuracy            |
| 25.0°C (77.0°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 37.7°C—38.9°C (98.4°F—102.0°F)              | ±0.1°C (±0.2°F)     |
| 16.0°C—33.0°C (60.8°F—91.4°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 33.0°C—42.0°C (91.4°F—107.6°F)              | ±0.2°C (±0.4°F)     |
| Temperature Calibrated Accuracy Specifications (after recalibration using Genius 2 Checker/Calibrator)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                             |                     |
| Ambient Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Target Temperature                          | Accuracy            |
| 16.0°C—33.0°C (60.8°F—91.4°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 36.0°C—39.0°C (96.8°F—102.2°F)              | ±0.2°C (±0.4°F)     |
| 16.0°C—33.0°C (60.8°F—91.4°F)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <36.0°C or >39.0°C<br>(<96.8°F or >102.2°F) | ±0.3°C (±0.5°F)     |
| ASTM laboratory requirement for IR thermometers in the display range 37.0°C—39.0°C (98.0°F—102.0°F) is <b>±0.2°C (±0.4°F)</b> , whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112-86 is <b>±0.1°C (±0.2°F)</b> .<br><br>Clinical accuracy characteristics and procedures are available from Covidien llc on request. To verify the accuracy, use a certified black body as specified in EN ISO 80601-2-56, Annex C, or use a Genius 2 Checker/Calibrator - available from Covidien llc under part number 303097.<br><br>Clinical repeatability: meets section A.5 of EN ISO 80601-2-56(E) per Covidien llc technical report. Data is available from Covidien llc on request. |                                             |                     |

| Displayed Temperature Measurement Range |           |            |
|-----------------------------------------|-----------|------------|
| Mode                                    | Range °C  | Range °F   |
| Ear                                     | 33.0—42.0 | 91.4—107.6 |
| Oral (ear + 0.6°C)                      | 33.6—42.0 | 92.5—107.6 |
| Core (ear + 1.04°C)                     | 34.0—42.0 | 93.2—107.6 |

| Displayed Temperature Measurement Range                            |           |            |
|--------------------------------------------------------------------|-----------|------------|
| Mode                                                               | Range °C  | Range °F   |
| Rectal (ear + 1.16°C)                                              | 34.2—42.0 | 93.6—107.6 |
| <b>Caution:</b> ASTM E1965-98 specifies 34.4°C—42.2°C (94°F—108°F) |           |            |

| Ambient Temperature Range                                                                                                                                                                                                                                                                                                                                                           |            |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-------------|
| Mode                                                                                                                                                                                                                                                                                                                                                                                | Range °C   | Range °F    |
| Operating 10%—95% RH, non-condensing                                                                                                                                                                                                                                                                                                                                                | 16.0—33.0  | 60.8—91.4   |
| Storage up to 95% RH, non-condensing                                                                                                                                                                                                                                                                                                                                                | -25.0—55.0 | -13.0—131.0 |
| <b>Caution:</b> EN ISO 80601-2-56 specifies 16.0°C—35.0°C (60.8°F—95.0°F), 10%—95% RH, non-condensing<br>ASTM E1965-98 specifies 16.0°C—40.0°C (60.8°F—104.0°F), up to 95% RH, non-condensing<br>Storing the thermometer outside the specified temperature/humidity range might adversely affect measurement accuracy. Check the calibration after storage in uncertain conditions. |            |             |

| Tympanic Temperature Alarm Specifications |                                                                                                                           |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Range                                     | 33.0°C—42.0°C (91.0°F—108.0°F)                                                                                            |
| Adjustment                                | 0.5°C steps (33.0°C—35.0°C)<br>0.1°C steps (35.0°C—42.0°C)<br>1.0°F steps (91.0°F—95.0°F)<br>0.2°F steps (95.0°F—108.0°F) |
| Alarm delay                               | System alarm delay (see “Fetal Monitors” on page 227).                                                                    |

### Physical Specifications

| Thermometer                       |                                                                       |
|-----------------------------------|-----------------------------------------------------------------------|
| Dimensions                        | 190 mm x 43 mm x 55 mm (±3 mm)                                        |
| Cable length                      | 60 ±5 cm (spiral cable relaxed)<br>250 ±15 cm (spiral cable extended) |
| Weight (including cable)          | 180 ±10 g                                                             |
| Ingress protection classification | IP 21                                                                 |

| Base Station             |                                |
|--------------------------|--------------------------------|
| Dimensions               | 205 mm x 65 mm x 75 mm (±3 mm) |
| Weight (excluding cable) | 400 g ±10 g                    |

# Recorder Specifications

| Built-in Thermal Array Fetal Trace Recorder           |                                      |                                                                           |                              |
|-------------------------------------------------------|--------------------------------------|---------------------------------------------------------------------------|------------------------------|
| Mechanism                                             | Thermal Array Recorder               |                                                                           |                              |
| Paper & Printing                                      | Type                                 | Standard Z-fold paper                                                     |                              |
|                                                       | Standard Speeds (real-time traces)   | 3 cm/min, 2 cm/min, 1 cm/min                                              |                              |
|                                                       | Fast Print Speed (stored traces)     | Max. 20 mm/s<br>Print speed is variable and depends on the print load     |                              |
|                                                       | ECG Wave Print Speed (not real-time) | Emulated 25 mm/s<br>Print speed is variable and depends on the print load |                              |
|                                                       | Paper Advance                        | 20 mm/s                                                                   |                              |
|                                                       | Sensing                              | Optical Reflex Sensor for black page marks                                |                              |
| Accuracy @ 3 cm/min, 2 cm/min, 1 cm/min               | ±5 mm/page                           |                                                                           |                              |
| Usable Print Width                                    | 128 mm                               |                                                                           |                              |
| Resolution                                            | 8 dots/mm (200 dpi)                  |                                                                           |                              |
| Time Delay to see trace on paper                      | <30s @ 1 cm/min                      |                                                                           |                              |
| Trace Separation Offset for FHR (Ultrasound and DECG) | Twin                                 | Standard                                                                  | FHR2 +20 bpm                 |
|                                                       |                                      | Classic                                                                   | FHR1 +20 bpm                 |
|                                                       | Triplet                              | Standard                                                                  | FHR2 +20 bpm<br>FHR3 -20 bpm |
|                                                       |                                      | Classic                                                                   | FHR1 +20 bpm<br>FHR3 -20 bpm |

| Recorder Symbols                                                                    |                                                                                                                                                                                                          |
|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Symbol                                                                              | Description                                                                                                                                                                                              |
|  | Parameter is capable of alarming and alarms were enabled at the time of printing the annotation. The low limit is printed before the symbol, and the high limit after it.                                |
|  | Parameter is capable of alarming, but alarms were disabled at the time of printing the annotation. (Note: There is no alarm related annotation at all if a parameter does not have alarming capability.) |
|  | FMP detection is on                                                                                                                                                                                      |

| Recorder Symbols                                                                    |                                                                                 |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Symbol                                                                              | Description                                                                     |
|    | Beginning of the date/time annotation                                           |
|    | Warning (INOP)                                                                  |
|    | Measurement from a cableless transducer (printed next to measurement label)     |
|    | Measurement from a cableless maternal measurement Pod (SpO <sub>2</sub> or NBP) |
|    | Pulse from SpO <sub>2</sub>                                                     |
|    | Pulse from Toco MP                                                              |
|    | Pulse from NBP                                                                  |
|   | Trace separation +20 bpm (in label)                                             |
|  | Trace separation -20 bpm (in label)                                             |
|  | Trace separation Off (in trace)                                                 |
|  | Trace separation +20 bpm (in trace)                                             |
|  | Trace separation -20 bpm (in trace)                                             |
|  | Trace separation +20 bpm and -20 bpm (in trace)                                 |
|  | Coincidence of heart rates is detected                                          |
|  | Marker                                                                          |

| Recorder Symbols                                                                  |                                                                                                |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Symbol                                                                            | Description                                                                                    |
|  | Special wave, with different speed and scale (for example, fast printout of MEEG wave on FM30) |

## Manufacturer's Information

You can write to Philips at this address:

Philips Medizin Systeme Boeblingen GmbH

Hewlett-Packard-Str. 2

71034 Boeblingen

Germany

Visit our website for local contact information at: [www.healthcare.philips.com](http://www.healthcare.philips.com)

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## Trademark Acknowledgment

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## Regulatory and Standards Compliance

The fetal monitors are in conformity with the requirements of the European Medical Devices Directive 93/42/EEC and bear the CE marking:



The fetal monitors are classified into Class IIb according to Annex IX rule 10.

The Avalon CL Transducer System is in conformity with the requirements of the European Radio Equipment and Telecommunications Terminal Equipment Directive 99/5/EC. The Avalon CL base station used in this system is class 1 and the Avalon CL transducers of this system are class 1 under the scope of the R&TTE Directive.

To obtain a copy of the original Declaration of Conformity, please contact Philips at the address given in the "Manufacturer's Information" on page 240 section of this manual.

## Safety and Performance

The fetal monitors comply with the following major international safety and performance standards:

- IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010
- IEC 60601-1-6:2010 / EN 60601-1-6:2010
- IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+AC:2010
- IEC 60601-2-49:2011 / EN 60601-2-49:2001
- ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010

- CAN/CSA C22.2#60601-1-08
- JIS T 1303 2005
- AS/NZS 3200.1.0-1998

The possibility of hazards arising from hardware and software errors was minimized in compliance with ISO 14971:2012, IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010.

Alarm sounds are compliant with Standard IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+AC:2010.

## Radio

The Avalon CL Transducer System complies with the following major international radio standards:

- ETSI EN 300 220-1:2012
- ETSI EN 300 220-2:2012
- ETSI EN 301 489-1:2011
- ETSI EN 301 489-3:2003
- FCC 47 CFR Part 95
- IC RSS-210 Issue 8
- ARIB STD-T108
- ETSI EN 300 328:2006
- ETSI EN 301 489-17:2009
- FCC 47 CFR Part 2 & 15
- AS/NSZ 4268
- AS/NSZ 4771:2000+A1:2003
- ARIB STD-T66

## Safety Tests Fetal Monitor

All the safety tests and procedures required after an installation, or an exchange of system components are described in your monitor's Service Guide. These safety tests are derived from international standards, but may not be sufficient to meet local requirements.

---

### WARNING

- Do not use additional AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet is used, the resulting system must be compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010.
  - Do not connect any devices that are not supported as part of a system.
  - Do not use a device in the patient vicinity if it does not comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010. The whole installation, including devices outside of the patient vicinity, must comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010. Any non-medical device, including a PC running an OB TraceVue/ IntelliSpace Perinatal system, placed and operated in the patient's vicinity must be powered via a separating transformer (compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2010) that ensures mechanical fixing of the power cords and covering of any unused power outlets.
  - Do not use USB devices with own power supplies, unless an appropriate separation device is used, (either between USB interface and device or between device and power).
- 

During the installation the fetal monitor is configured for your environment. This configuration defines your custom default settings you work with when you switch on your fetal monitor. See the fetal monitor's Service Guide and the Configuration Guide for details on how to configure your fetal monitor.

## Electromagnetic Compatibility (EMC)

The device and its accessories, listed in the accessories section, comply with the following EMC standards:

- IEC 60601-1-2:2007 / EN 60601-1-2:2007+AC:2010

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this book. Before using the device, assess the electromagnetic compatibility of the device with surrounding equipment.

This ISM device complies with Canadian ICES-003:2012. Cet appareil ISM est conforme à la norme NMB-003 du Canada.

---

### CAUTION

- **FM20/FM30 only:** Although this is an electrical Class II device, it has a protective earth conductor which is needed for EMC purposes.
  - Always use the supplied power cord with the three-prong plug to connect the monitor to AC mains. Never adapt the three-prong plug from the power supply to fit a two-slot outlet.
-

**WARNING**

The use of accessories, transducers, and cables other than those specified, may result in increased electromagnetic emissions, or decreased electromagnetic immunity of the device.

**WARNING**

Do not use cordless/mobile phones, or any other portable RF communication system within the patient vicinity, or within a 1.0 m radius of any part of the fetal monitoring system.

**WARNING**

For paced patients: The radiated SRR power of the CL SpO<sub>2</sub> and CL NBP Maternal Cableless Measurement Devices, and other sources of radio-frequency energy, when used in very close proximity of a pacemaker, might be sufficient to interfere with pacemaker performance. Due to shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring paced patients.

In order to minimize the possibility of interference, avoid positioning and wearing the Cableless Measurement Devices in very close proximity to a pacemaker. Consult the pacemaker manufacturer for information on the RF susceptibility of their products

## EMC Testing

**CAUTION**

Fetal parameters, especially ultrasound and ECG, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

## Reducing Electromagnetic Interference

**WARNING**

The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

The product and associated accessories can be susceptible to interference from continuous, repetitive, power line bursts, and other RF energy sources, even if the other equipment is compliant with EN 60601-1-2 emission requirements. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmissions.

When electromagnetic interference (EMI) is encountered, for example, if you can hear spurious noises on the fetal monitor's loudspeaker, attempt to locate the source. Assess the following:

- Is the interference due to misplaced or poorly applied transducers? If so, re-apply transducers correctly according to directions in this book, or in the Instructions for Use accompanying the accessory.
- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical electrical equipment?

Once the source is located, there are a number of things that can be done to mitigate the problem:

- 1 Eliminating the source. Turn off or move possible sources of EMI to reduce their strength.
- 2 Attenuating the coupling. If the coupling path is through the patient leads, the interference may be reduced by moving and/or rearranging the leads. If the coupling is through the power cord, connecting the system to a different circuit may help.
- 3 Adding external attenuators. If EMI becomes an unusually difficult problem, external devices such as an isolation transformer or a transient suppressor may be of help. Your service provider can be of help in determining the need for external devices.

Where it has been established that electromagnetic interference is affecting physiological parameter measurement values, a physician, or a suitably qualified person authorized by a physician, should determine if it will negatively impact patient diagnosis or treatment.

## System Characteristics

The phenomena discussed above are not unique to this system, but are characteristic of fetal patient monitoring equipment in use today. This performance is due to very sensitive high gain front end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.

## Electromagnetic Emissions and Immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. See Tables 1 to 4 for this detailed immunity information. See Table 5 for recommended minimum separation distances between portable and mobile communications equipment and the product.

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of an electromagnetic disturbance.

Caution should be exercised in comparing immunity levels between different devices. The criteria used for degradation are not always specified by the standard, and can therefore vary with the manufacturer.

In the table below, the term "device" refers to the Avalon FM20/30/40/50 fetal monitor together with its accessories. The table gives details of the electromagnetic emissions, and how these are classified,

for the device, and the electromagnetic environments in which the device is specified to technically function.

| Table 1 - Guidance and Manufacturer's Declaration: Electromagnetic Emissions                                                                                                                                                                                                                                                                                                                                   |            |                                                                                                                                                                                                                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Emissions Test                                                                                                                                                                                                                                                                                                                                                                                                 | Compliance | Avoiding Electromagnetic Interference                                                                                                                                                                                           |
| Radiofrequency (RF) emissions                                                                                                                                                                                                                                                                                                                                                                                  | Group 1    | The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.                                                 |
| Harmonic emissions IEC 61000-3-2                                                                                                                                                                                                                                                                                                                                                                               | Class A    |                                                                                                                                                                                                                                 |
| Voltage fluctuations and flicker IEC 61000-3-3                                                                                                                                                                                                                                                                                                                                                                 | complies   |                                                                                                                                                                                                                                 |
| RF emissions CISPR 11<br>For the Avalon FM20/30 fetal monitor with all accessories except the IUP/ECG patient module M2738A.                                                                                                                                                                                                                                                                                   | Class B    | The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes <sup>1</sup> . |
| RF emissions CISPR 11<br>For the Avalon FM40/FM50 with all accessories.<br>For the Avalon FM20/30 fetal monitor whenever used with the IUP/ECG patient module M2738A.<br>For the Avalon CTS Interface Cable (M2731-60001/M2732-60001) whenever used with the Avalon CTS Cableless Fetal Transducer System.<br>For the Avalon CL Base Station with cableless transducers whenever used with the fetal monitors. | Class A    | The device is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.               |

<sup>1</sup> Note that the device is not intended for home use.

## Electromagnetic Immunity

The monitor is suitable for use in the specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

| Table 2 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity |                                                              |                                                              |                                                                                                                                                |
|-----------------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity Test                                                               | IEC 60601-1-2 Test Level                                     | Compliance Level                                             | Electromagnetic Environment Guidance                                                                                                           |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                              | ±6 kV contact<br>±8 kV air                                   | ±6 kV contact<br>±8 kV air                                   | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst<br>IEC 61000-4-4                            | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial and/or hospital environment                                                         |

| Table 2 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity                            |                                                        |                                                        |                                                                                                                                                                                                                                                                     |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity Test                                                                                          | IEC 60601-1-2 Test Level                               | Compliance Level                                       | Electromagnetic Environment Guidance                                                                                                                                                                                                                                |
| Surge<br>IEC 61000-4-5                                                                                 | $\pm 1$ kV differential mode<br>$\pm 2$ kV common mode | $\pm 1$ kV differential mode<br>$\pm 2$ kV common mode | Mains power quality should be that of a typical commercial and/or hospital environment                                                                                                                                                                              |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | $< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 0.5 cycles   | $< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 0.5 cycles   | Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply. |
|                                                                                                        | $40\% U_T$ (60% dip in $U_T$ ) for 5 cycles            | $40\% U_T$ (60% dip in $U_T$ ) for 5 cycles            |                                                                                                                                                                                                                                                                     |
|                                                                                                        | $70\% U_T$ (30% dip in $U_T$ ) for 25 cycles           | $70\% U_T$ (30% dip in $U_T$ ) for 25 cycles           |                                                                                                                                                                                                                                                                     |
|                                                                                                        | $< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 5 sec        | $< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 5 sec        |                                                                                                                                                                                                                                                                     |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8                                             | 3 A/m                                                  | 3 A/m                                                  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment                                                                                                                        |
| Key: $U_T$ is the AC mains voltage prior to application of the test level.                             |                                                        |                                                        |                                                                                                                                                                                                                                                                     |

## Radio Compliance Notice

### Avalon CL with WMTS

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radio frequency interference and void your authority to operate this equipment.

### Radio Information Canada

Installation of this telemetry device is permitted in hospitals and health care facilities only. This device shall not be operated in mobile vehicles (including ambulances and other vehicles associated with health care facilities). The installer/user of this device shall ensure that it is at least 80 km from the Dominion Radio Astrophysical Observatory (DRAO) near Penticton, British Columbia. The coordinates of DRAO are: latitude N 49° 19' 15", longitude W 119° 37' 12". For medical telemetry systems not meeting this 80 km separation (e.g. the Okanagan Valley, British Columbia) the installer/user must coordinate with, and obtain the written concurrence of, the Director of DRAO before the equipment can be installed or operated. The Director of DRAO may be contacted at 250-497-2300

(telephone) or 250-497-2355 (fax). (Alternatively, the Manager, Regulatory Standards, Industry Canada, may be contacted.)

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

L'utilisation de cet appareil de télémétrie est permise seulement dans les hôpitaux et établissements de soins de santé. Cet appareil ne doit pas être mis en marche dans des véhicules (y compris les ambulances et autres véhicules associés aux établissements de santé). La personne qui installe/utilise cet appareil doit s'assurer qu'il se trouve à au moins 80 km de l'Observatoire fédéral de radioastrophysique (OFR) de Penticton en Colombie-Britannique. Les coordonnées de l'OFR sont: latitude N 49° 19' 15», longitude O 119° 37' 12". La personne qui installe/utilise un système de télémétrie médicale ne pouvant respecter cette distance de 80 km (p. ex. dans la vallée de l'Okanagan (Colombie-Britannique), doit se concerter avec le directeur de l'OFR et obtenir de sa part une autorisation écrite avant que l'équipement ne puisse être installé ou mis en marche. Le directeur de l'OFR peut être contacté au 250-497-2300 (tél.) ou au 250-497-2355 (télécopieur). (Le Directeur des Normes réglementaires d'Industrie Canada peut également être contacté).

## Avalon CL with T108

Japanese Radio Law and Japanese Telecommunications Business Law Compliance.

This device is granted pursuant to the Japanese Radio Law (電波法) and the Japanese Telecommunications Business Law (電気通信事業法).

本製品は、電波法および電気通信事業法に基づき認可されています。

This device should not be modified (otherwise the granted designation number will become invalid).

## Finding Recommended Separation Distances

In the following table,  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and  $d$  is the recommended separation distance in meters (m).

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol:



| Table 3 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity                                                                                                                                                                                          |                                                  |                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conducted RF Immunity Test EN/IEC 61000-4-6                                                                                                                                                                                                                          |                                                  |                                                                                                                                                                   |
| IEC 60601-1-2 Test Level<br>over 150 kHz to 80 MHz                                                                                                                                                                                                                   | Compliance Level                                 | Electromagnetic Environment Guidance:<br>Recommended Separation Distance ( $d$ )<br>(in Meters, at Frequency Range Tested)<br>for Ultrasound and ECG Measurements |
| 3.0 V <sub>RMS</sub>                                                                                                                                                                                                                                                 | 3.0 V <sub>RMS</sub>                             | $d = 1, 2\sqrt{P}$                                                                                                                                                |
| Key: $d$ = Recommended separation distance in meters (m)                                                                                                                                                                                                             |                                                  |                                                                                                                                                                   |
| $P$ = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer                                                                                                                                                          |                                                  |                                                                                                                                                                   |
| $V1$ = Tested compliance level (in Volts) for the Conducted RF Immunity test IEC 61000-4-6                                                                                                                                                                           |                                                  |                                                                                                                                                                   |
| The device meets the compliance level of 3.0 V <sub>RMS</sub> according to IEC 60601-1-2 over the specified test frequency range. Over the frequency range 150 kHz—80 MHz, the recommended separation distance in meters ( $d$ ) is found by the following equation: |                                                  |                                                                                                                                                                   |
| $d = \left(\frac{3, 5}{V1}\right)\sqrt{P}$                                                                                                                                                                                                                           | For a compliance level of 3.0 V <sub>RMS</sub> : | $d = 1, 2\sqrt{P}$                                                                                                                                                |

| Table 4 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity                                                              |                                                  |                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Radiated RF Immunity Test EN/IEC 61000-4-3                                                                                               |                                                  |                                                                                                                                                                        |
| IEC 60601-1-2 Test Level<br>over 80 MHz to 2.5 GHz                                                                                       | Compliance Level                                 | Electromagnetic Environment Guidance:<br>Recommended Separation Distance ( <i>d</i> )<br>(in Meters, at Frequency Range Tested)<br>for Ultrasound and ECG Measurements |
| 3.0 V/m                                                                                                                                  | 3.0 V/m                                          | Over 80 MHz—800 MHz: <i>d</i> = 1, 2√ <i>P</i>                                                                                                                         |
|                                                                                                                                          |                                                  | Over 800 MHz—2.5 GHz: <i>d</i> = 2, 3√ <i>P</i>                                                                                                                        |
| Key: <i>d</i> = Recommended separation distance in meters (m)                                                                            |                                                  |                                                                                                                                                                        |
| <i>P</i> = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer                         |                                                  |                                                                                                                                                                        |
| <i>E1</i> = Tested compliance level (in Volts/meter) for the Radiated RF Immunity test IEC 61000-4-3                                     |                                                  |                                                                                                                                                                        |
| The device meets the compliance level of 3.0 V <sub>RMS</sub> according to IEC 60601-1-2 over the specified test frequency range.        |                                                  |                                                                                                                                                                        |
| Over the frequency range 80 MHz—800 MHz, the recommended separation distance in meters ( <i>d</i> ) is found by the following equation:  |                                                  |                                                                                                                                                                        |
| <i>d</i> = $\left(\frac{3, 5}{E1}\right)\sqrt{P}$                                                                                        | For a compliance level of 3.0 V <sub>RMS</sub> : | <i>d</i> = 1, 2√ <i>P</i>                                                                                                                                              |
| Over the frequency range 800 MHz—2.5 GHz, the recommended separation distance in meters ( <i>d</i> ) is found by the following equation: |                                                  |                                                                                                                                                                        |
| <i>d</i> = $\left(\frac{7, 0}{E1}\right)\sqrt{P}$                                                                                        | For a compliance level of 3.0 V <sub>RMS</sub> : | <i>d</i> = 2, 3√ <i>P</i>                                                                                                                                              |

Field strengths from fixed transmitters, such as base stations, or radio, (cellular, cordless) telephones, and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the

location in which the device is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

If you require further information or assistance, please contact Philips Support.

## Recommended Separation Distances from Other RF Equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

| Table 5 - Separation Distance ( $d$ ) in Meters According to Frequency of Transmitter at IEC 60601-1-2 Test Compliance Level |                                                                      |                                                                      |                                                                       |
|------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|----------------------------------------------------------------------|-----------------------------------------------------------------------|
| Rated Maximum Output Power ( $P$ ) of Transmitter (in Watts)                                                                 | 150 kHz to 80 MHz<br>$d = \left(\frac{3,5}{\sqrt{1}}\right)\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = \left(\frac{3,5}{\sqrt{1}}\right)\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = \left(\frac{7,0}{\sqrt{1}}\right)\sqrt{P}$ |
| 0.01 W                                                                                                                       | 0.1 m                                                                | 0.1 m                                                                | 0.23 m                                                                |
| 0.1 W                                                                                                                        | 0.4 m                                                                | 0.4 m                                                                | 0.7 m                                                                 |
| 1 W                                                                                                                          | 1.2 m                                                                | 1.2 m                                                                | 2.3 m                                                                 |
| 10 W                                                                                                                         | 3.8 m                                                                | 3.8 m                                                                | 7.3 m                                                                 |
| 100 W                                                                                                                        | 12.0 m                                                               | 12.0 m                                                               | 23.0 m                                                                |

## Radio Frequency Radiation Exposure Information

The radiated output power of the device is far below the FCC radio frequency exposure limits.

## Environment

Before operation, make sure that the fetal monitor is free from condensation. This can form when equipment is moved from one building to another, and is exposed to moisture and differences in temperature.

Use the monitor in an environment which is reasonably free from vibration, dust, corrosive or explosive gasses, extremes of temperature, humidity, and so forth. It operates within specifications at ambient temperatures between 0—+45°C (32°F—113°F). Ambient temperatures that exceed these limits can affect the accuracy of the system, and can damage the components and circuits.

Ambient temperature ranges for storage are -20°C—+60°C (-4°F—140°F) for the monitor, and -40°C—+60°C (-40°F—140°F) for transducers.

The transducers are watertight to a depth of 1.0 m for at least five hours (rated IP 68).

---

### WARNING

- **Leakage currents:** If several items of equipment used to monitor a patient are interconnected, the resulting leakage current may exceed allowable limits.
  - **ECG electrodes:** NEVER allow ECG electrodes to contact other electrical conductive parts, including earth.
- 

## Monitoring After a Loss of Power

If the monitor is without power for **less** than one minute, monitoring will resume with all active settings unchanged. If the monitor is without power for **more** than one minute, the behavior depends on your configuration. If **Automat. Default** is set to **Yes**, the **User Defaults** will be loaded when power is restored. If **Automat. Default** is set to **No**, all active settings are retained, if power is restored within 48 hours. The **Automat. Default** setting is made in Configuration Mode.

FM20/30 with  
Battery  
Option,  
FM40/50

When power is lost - no power is available from the AC power source, or from the battery - a beeper will sound. The tone can be silenced by pressing the On/Standby button.

## ESU, MRI and Defibrillation

---

### WARNING

The fetal/maternal monitors are NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the user can result.

---

# Cardiac Pacemakers and Electrical Stimulators

## WARNING

The fetal/maternal monitors are not intended for use for ECG measurements on patients connected to external electrical stimulator, or with cardiac pacemakers.

## Fast Transients/Bursts

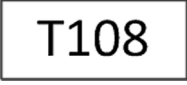
The equipment will return to the previous operating mode within 10 seconds without loss of any stored data.

## Symbols on the System

|                                                                                     |                                                                                                                                                  |                                                                                      |                                                                                                           |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|
|    | This caution/warning symbol indicates that you should consult the Instructions for Use (this document), and particularly any warning messages.   |     | Connection direction indicator<br>FM20/FM30 with battery option                                           |
|   | This symbol indicates that you should consult the Instructions for Use (this document).                                                          |    | Mouse connection indicator<br>(optional)                                                                  |
|  | Power-On/Off Switch - FM20/<br>FM30 without Battery Option                                                                                       |   | Keyboard connection indicator<br>(optional)                                                               |
|  | Power-On/StandBy button -<br>FM40/FM50 and FM20/30 with<br>Battery Option                                                                        |   | Serial/MIB connector<br>(optional)                                                                        |
|  | Power-On LED                                                                                                                                     |   | USB interface<br>(optional)                                                                               |
|  | Electrical Class II equipment, in<br>which the protection against<br>electric shock relies on double or<br>reinforced insulation (FM20/<br>FM30) |  | Analog interface indicator for<br>connection to any analog video<br>display (VGA resolution)<br>FM40/FM50 |

## 12 Specifications

|                                                                                     |                                                                    |                                                                                     |                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | Fetal Sensor Socket symbol                                         | IP 67                                                                               | Ingress Protection code according to IEC 60529. The IUP/ECG patient module (M2738A) is rated IP 67 (protection against dust, access to hazardous parts, and the effects of continuous immersion in water to a depth of 0.5 meter for 30 minutes). |
|    | SpO <sub>2</sub> Socket symbol                                     | IP 68                                                                               | Ingress Protection code according to IEC 60529. All transducers (excluding M2738A) are rated IP 68 (protection against dust, access to hazardous parts, and the effects of continuous immersion in water to a depth of 1.0 meter for five hours). |
|    | Noninvasive Blood Pressure Socket symbol                           | IP X1                                                                               | Ingress Protection code according to IEC 60529. The monitors and interface cable for the Avalon CTS (M2731-60001/M2732-60001) are rated IP X1 (protection against water dripping vertically only).                                                |
|   | Type BF                                                            | IP 31                                                                               | Ingress Protection code according to IEC 60529 (protection against condensation only).                                                                                                                                                            |
|  | Symbol indicating the monitor has the triplets option              | IP 21                                                                               | Ingress Protection code according to IEC 60529 (protection against ingress of water when the water is dripping vertically)                                                                                                                        |
|  | Symbol indicating the monitor is capable of intrapartum monitoring |  | Type CF equipment, not defibrillation proof                                                                                                                                                                                                       |
|  | Button to open paper drawer/paper eject. (FM40/FM50)               |  | Indicates location of service number                                                                                                                                                                                                              |
|  | Protective earth terminal (FM40/FM50)                              |  | Indicates location of serial number                                                                                                                                                                                                               |
|  | Equipotential grounding point (FM40/FM50)                          |  | Indicates location of catalog number                                                                                                                                                                                                              |

|                                                                                                                                                                                               |                                                                                                                             |                                                                                      |                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| <b>Tele</b>                                                                                                                                                                                   | Socket for connecting Avalon CTS interface cable M2732-60001 or Avalon CL interface cable (with black connector, FM40/FM50) |     | Indicates location of the date of manufacture and/or name and address of manufacturer    |
|                                                                                                              | Symbol indication for non-ionizing radiation                                                                                |     | Identifies year and month of manufacture                                                 |
|                                                                                                              | China RoHS                                                                                                                  |     | Symbol indicating separate collection for waste electrical and electronic equipment      |
|                                                                                                              | GOST-R mark                                                                                                                 |    | CSA US mark                                                                              |
| FCC ID                                                                                                                                                                                        | Federal Communications Commission: FCC ID xxxx                                                                              | CMIIT ID                                                                             | Chinese Radio marking: CMIIT ID (China Ministry of Industry and Information Technology)  |
|                                                                                                             | Industrial, Scientific, & Medical radio frequency band (Avalon CL frequency band used e.g. in the EU)                       |   | CE marking accompanied by the VDE NB number 0366                                         |
|                                                                                                            | Association Of Radio Industries And Businesses T108 (Avalon CL frequency band used e.g. in Japan)                           |  | Wireless Medical Telemetry Service (Avalon CL frequency band used e.g. in North America) |
| IC: 8888X-XXXXX8                                                                                                                                                                              |                                                                                                                             | IC-ID (Industry Canada ID)<br>One IC-ID labeling for each built in radio: OBR, SRR   |                                                                                          |
|  202-SMB025  202-SMB026 |                                                                                                                             | Japanese Radio marking: Radio mark + [R]-symbol + ID                                 |                                                                                          |
|  XXXX88XX8888X8                                                                                            |                                                                                                                             | Taiwan Radio Label (NCC Logo) + ID                                                   |                                                                                          |
| <br>KTL XX88888-8888                                                                                       |                                                                                                                             | Korea radio mark: KC logo, KCC ID number, and Conformity assessment information      |                                                                                          |



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