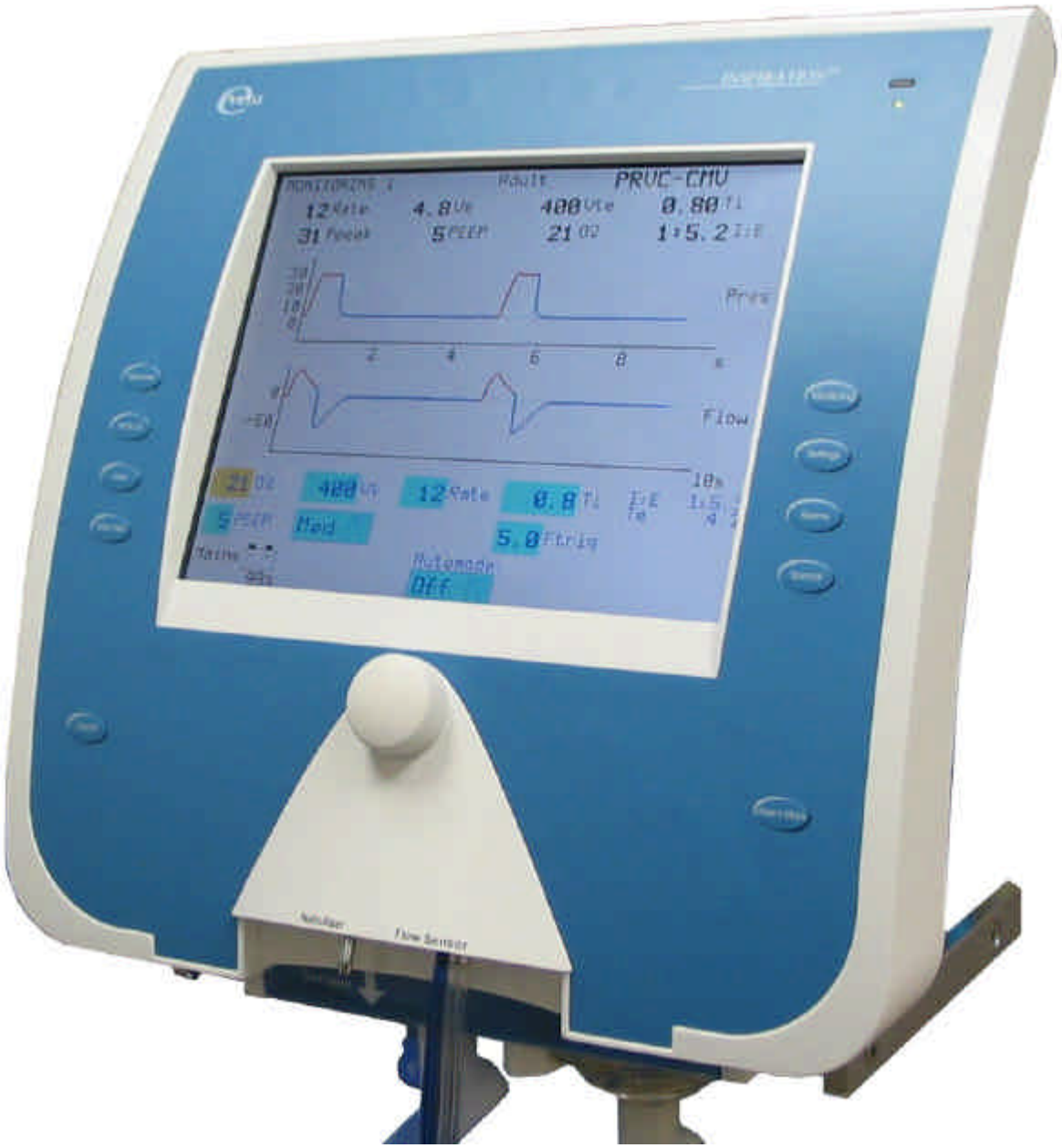
Vent Medical Ltd.

Inspiration Series Ventilator Technical Manual



Inspiration Series Ventilator

Model Numbers:

F7300000-XX
F7200000-XX
F7100000-XX

Technical Manual

eVent Medical Limited
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Ireland

Contents

1. Preface

1.1 Introduction

This manual has been intended to provide the necessary information required to service and maintain the eVent Medical Inspiration Series Ventilator System. It is intended for use by certified biomedical engineers or engineers with equivalent experience in the maintenance of respiratory life support equipment. Engineers wishing to undertake the maintenance of the Inspiration ventilator system should attend a technical training seminar with eVent Medical.

1.2 Copyright Information

 This manual may be revised or replaced by eVent Medical Ltd. at any time without notification. You should ensure that you have the most current applicable version of this manual; if in any doubt contact eVent Medical Ltd. While the information set forth herein is believed to be accurate, it is not a substitute for the exercise of professional judgement.

The Inspiration ventilator system should be operated and serviced only by trained professionals. eVent Medical Ltd's sole responsibility with respect to the ventilator, and its use, is as stated in warranty provided.

Nothing in this manual shall limit or restrict in any way eVent Medical's right to revise or otherwise change or modify the equipment (including its software) described herein, without notice. In the absence of an express, written agreement to the contrary, eVent Medical Ltd has no obligation to furnish any such revisions, changes, or modifications to the owner or user of the equipment (including its software) described herein.

1.3 Definitions

Throughout this manual three types of indicator are to be used in order to convey information in regard to the remaining dangers associated with the proper use of the Inspiration series ventilator system and emphasize important technical requirements.

WARNING

Means that there is a possibility of injury to yourself or other persons.

CAUTION

Means that there is a possibility of damage to the equipment or other property.

NOTE

Indicates a point of particular interest or special emphasis for more efficient and convenient operation of the equipment.

1.4 Product Warranty

The Inspiration series ventilator system is warranted against defects in material and workmanship in accordance with eVent Medical Equipment Warranty for a period of one year from the time of sale. To ensure the validity of the warranty detailed maintenance records should be retained for each device.

1.5 Year Of Manufacture

The Inspiration series ventilator systems year of manufacture may be determined from the device serial number as displayed on the rear panel type label in the following form:

LS / ST – Device Serial No. XXXX W YYZZZZ

Where the digits XXXX report the year of manufacture W denotes eVent manufacturing facility, YY reports model type and digits ZZZZ are a sequential but individual number.

Original – Device Serial No. XXXX / YYYY

Where the digits XXXX report a sequential serial number, and digits YYYY report the year of manufacture.

1.6 Manufacturer

eVent Medical Limited
6A Liosban Business Park,
Tuam Road, Galway,
Ireland,

1.7 Electromagnetic Susceptibility

The Inspiration series ventilator system complies with the requirements of IEC 601-1-2 (EMC Collateral Standard), including E-field susceptibility requirements at a level of 10 volts per meter, at frequencies from 26 Mhz – 2.5 Ghz, and the ESD requirements of this standard.

It should be noted however that even at this level of device immunity certain transmitting devices (cellular phones, cordless phones, paging transmitters eg.) emit radio frequencies that could interrupt ventilator operation if located in a range too close to the ventilator.

Do not operate the ventilator in a magnetic resonance imaging (MRI) environment. Section 8 describes the possible ventilator alarms and what to do if they occur. Consult with your institutions biomedical engineering department in the case of interrupted ventilator operation, and before relocating any life support equipment.

1.8 Customer Assistance

Should further assistance be required contact your local eVent Medical representative.

2. General Information

2.1 Introduction

This section of the manual has been formulated to provide you with introductory information concerning the eVent Medical Inspiration series ventilator system. The section comprises a brief product description, specifications, tooling / maintenance summary and an introduction to the controls and indicators

2.2 How To Use The Manual

The information within is not intended as a sole source of reference and has been intended for use in conjunction with the Inspiration operators manual. Both manuals should be referenced when performing any maintenance to the system.

2.3 Safety Information

Only medical air and medically pure oxygen should be used for ventilation. Anaesthetics and potentially explosive gases should not be used. Please also ensure that the air used is completely **oil-free.**

To avoid any potential fire hazard. Keep all matches, lighted cigarettes and other sources of ignition away from the device.

An alternative source of ventilation should always be available when using the Inspiration ventilator.

Do not replace any accessories or other parts of the Inspiration while a patient is being ventilated.

Maintenance work must always be carried out in compliance with all relevant safety regulations. Repairs, assembly, and use should only be carried out by specialist personnel. Your device should be checked by trained personnel annually.

Insert a bacteria filter between the Inspiration outlet on the Inspiration and the patient breathing circuit, to prevent any contamination of the device.

Do not sterilize the Inspiration.

Before each use, check the water traps on the gas inputs for any residual water and/or particles.

If you notice that the Inspiration is damaged in any way, its life-supporting function can no longer be guaranteed. Stop ventilation with the defective device immediately and use an alternate form of ventilation.

To avoid electrical shock while servicing the ventilator, be sure to disconnect the device from the power source.

US Federal law restricts this device to sale by or on the order of a physician

Do not use the Inspiration Ventilator unless an internal battery with at least a minimal charge is installed.

If the Inspiration Ventilator has been stored for an extended period of time, recharge the battery prior to use.

When the Inspiration Ventilator is connected to another device via the

serial port the power cord should be in place so as to ensure proper grounding.

2.4 Product Description

The Inspiration ventilator system is intended for use with a wide range of infant through adult patients requiring ventilatory and or respiratory support.

The ventilator system has a built in compressor and internal (rechargeable) battery and is therefore not dependent on an external power or air supply for operation. As such it can be used to provide ventilation during patient transport within the hospital.

The Inspiration ventilator system is well equipped with ventilatory, monitoring, and safety features. Listed below are some of the device's key features:

- Inspired oxygen levels at the user's desired concentration.
- Volume or pressure based breaths delivered in a controlled, synchronized intermittent mandatory, or spontaneous mode.
- Flow or pressure triggering of breaths.
- Apnea monitoring and ventilation back-up system.
- Numeric or Waveform display of user defined ventilator data.
- Respiratory Mechanics monitoring.
- Smart Sighs at user desired frequency and breath amplitude.
- User defined Smart Nebulizer functions.
- Prioritized alarm system.

2.5
Product Specifications

2.5.1 Power and gas supply

AC input	100 to 240 VAC, 50/60 Hz
Power consumption	120 VA (W)
DC input	24 VDC +/- 10%
Internal battery operating time (with fully charged battery)	>120 minutes (without compressor) 120 minutes (with compressor) at 8.0 lpm MV, peak flow of 45 lpm, PEEP of 5 cm H2O, average peak pressure of 32 cm H2O and a mean pressure of 7 cmH20
O_2 and air supply pressure range	29 – 86 psi (2 to 6 bar)
Internal compressor	20 lpm Minute Volume @ 14.7 psi (1 bar)
Earth leakage current	< 300 µA
Enclosure Leakage current	< 50 µA

2.5.2 Settings

Ventilation modes	Volume based synchronized mandatory ventilation (V-CMV). Volume based synchronized intermittent mandatory ventilation (V-SIMV). Pressure regulated volume control synchronised mandatory ventilation (PRVC-CMV) a Volume Target Ventilation (VTV) mode. Pressure regulated volume control synchronised intermittent mandatory ventilation (PRVC-SIMV) a Volume Target Ventilation (VTV) mode. Pressure based synchronized mandatory ventilation CMV). Pressure based synchronized intermittent mandatory Ventilation (P-SIMV). Spontaneous Ventilation (SPONT) Pressure Support (PSV) Volume Support (VS) a Volume Target Ventilation (VTV) mode Smart Positive Airway Pressure (SPAP)
Apnea backup	Select back-up from: V-CMV; V-SIMV; P-CMV; P-SIMV
Special functions	Smart Nebulizer Smart Sigh 100% Oxygen Manual Inspiration Inspiratory and expiratory Hold functions

Respiratory Rate	Infant: 1 to 150 b/min ; Pediatric: 1 to 120 b/min Adult: 1 to 60 b/min Accuracy: ± (0.1 b/min +1%)
Tidal Volume	Infant: 10 to 100 ml ; Pediatric: 20 to 500 ml Adult: 300 to 2000 ml Accuracy: 10 to 40ml: ± (2ml + 5%) Accuracy: 41 to 2000ml: ± (10ml + 5%)
Flow Pattern	Decelerating, Decelerating 50%, Square
PEEP/CPAP	0 to 50 cmH20 Accuracy: ± (2 cmH20 + 4%)
Pcontrol, Psupport	0 to 80 cmH20 Accuracy: ± (2 cmH20 + 2.5%)
I : E Ratio	1:9 to 4:1 Accuracy: ± (0.1 + 2%)
I Time	0.1 to 5 seconds
Plateau (Inspiratory Pause)	0 to 70 %. Accuracy: ± (0.05 seconds +1%)
Oxygen	21 to 100 % FIO2. Accuracy: ± (3 %) Full Scale
Pressure Trigger	1 to 20 cmH2O
Flow Trigger	Infant: 0.5 to 10 l/min ; Pediatric: 0.5 to 15 l/min Adult: 0.5 to 25 l/min
Exhalation Sensitivity (Exh Sens %)	10% to 80% of peak flow
Peak Flow	1 to 180 lpm. Accuracy: 1 to 10 l/min: ± (1 l/min +10%) 10 to 180 l/min: ± (5 l/min + 10%)
Apnea Time	10 to 60 seconds
Automode	Off or On

SPAP Mode Settings:

Phigh	Plow setting to 50 cmH2O
Plow	0 to 50 cmH2O
Psup High	0 to (80 – Phigh setting) cmH2O
Psup Low	0 to (80 – Plow setting) cmH2O
Thigh	0.1 to (60 – Tlow setting) seconds
Tlow	0.2 to 59.8 seconds

VTV Settings (PRVC-CMV, PRVC-SIMV, and VS Modes:

Target Vt	Infant: 10 to 100 ml ; Pediatric: 40 to 500 ml Adult: 300 to 2000 ml

2.5.3 Monitoring (patient values)

Pressure values	Ppeak (Peak Pressure) 0 to 120 cmH20 Accuracy: ± (3 cmH20 + 4%) PEEP (PEEP Pressure) 0 to 120 cmH20 Accuracy: ± (3 cmH20 + 4%) Pmean (Mean Pressure) 0 to 120 cmH20 Accuracy: ± (3 cmH20 + 4%) Pplateau (Plateau Pressure) 0 to 120 cmH20 Accuracy: ± (3 cmH20 + 4%)
Volume	Vte (Exhaled Tidal Volume) 0 to 2000 ml Accuracy: 0ml – 40 ml: ± (2ml + 5%) Accuracy: 41ml – 2000ml: ± (10ml + 5%) Exp MinVol 0 to 20 L Accuracy: ± (0.01l + 5%)
Time Parameters	Resp Rate (measured breaths per minute) 0 to 300 b/min. Accuracy: ± (0.01 bpm +1%) Ti (inspiration time) 0.01 to 9.0 seconds Accuracy: ± (0.01 sec) Ti/Ttot (calculated Itime divided by cycle time) H:L (ratio of time at high and low PEEP levels when SPAP is active)
Respiratory Mechanics	Rinsp (inspiratory resistance of airways and tubes): cmH2O/l/sec Cstat (static compliance, lung stiffness): L/cmH2O
Special Values	Oxygen (inspiratory oxygen concentration) 15 to 103% Accuracy: ± (5%) of full O2 scale RSBI (calculated breathing rate divided by tidal volume): b/min / ml
Time Curves and Loops	Pressure over time: measured proximally or internally in cmH2O. Flow over time: measured proximally or internally in cmH2O. Volume over time: measured proximally or internally in ml. Pressure-volume loop: measured proximally or internally in cmH2O and ml. Pressure displayed on x-axis and volume on the y-axis. Flow-volume loop: measured proximally or internally in l/sec and ml. Flow is displayed on the y-axis and volume on the x-axis. Flow-volume loop: measured

2.5.4
Alarms Limit Settings

Resp Rate High (max breath rate)	2 to 200 b/min Auto: P-CMV, V-CMV set rate + 50% All other modes: monitored total rate + 50%
Resp Rate Low (min breath rate)	1 to 199 b/min Auto: P-CMV, V-CMV set rate – 50% All other modes: monitored total rate – 50%
Ppeak High (maximum pressure)	1 to 80 cmH2O Auto: V-CMV, V-SIMV monitored Ppeak+10 cmH2O P-CMV, P-SIMV: Pcontrol + set PEEP+10cmH2O SPONT, SPAP: Psupport + set PEEP +10cmH2O
Ppeak Low (minimum pressure)	0 to 79 cmH2O Auto (all modes): set PEEP + 1 cmH2O
Ve High (high exp minute volume)	0.1 to 50 l/min Uses inspiratory minute volume (Vi) if proximal sensor is disabled. Auto: V-CMV mode: (set rate x set tidal volume) + 50% All other modes: monitored ExpMinVol + 50%
Ve Low (low exp minute volume)	0.0 to 49.9 l/min Uses inspiratory minute volume (Vi) if proximal sensor is disabled. Auto: V-CMV mode: (set rate x set tidal volume) – 50% All other modes: monitored ExpMinVol – 50%
Pmean High (high mean pressure)	1 to 80 cmH2O Auto (all modes): monitored Pmean + 10 cmH2O.
Pmean Low (low mean pressure)	1 to 79 cmH2O Auto (all modes): monitored Pmean – 10 cmH2O.
Vte High (high tidal volume)	10 to 2500 ml Uses inspiratory tidal volume if proximal sensor is disabled. Auto: V-CMV, V-SIMV, PRVC-CMV, PRVC-SIMV, VS: set tidal volume + 50%. All other modes: monitored tidal volume + 50%
Vte Low (low tidal volume)	0 to 2490 ml Uses inspiratory tidal volume if proximal sensor is disabled. Auto: V-CMV, V-SIMV, PRVC-CMV, PRVC-SIMV, VS: set tidal volume – 50%. All other modes: monitored Vte – 50%
Vti Limit High (high inspired tidal volume limit)	10 to 2500 ml Uses inspiratory tidal volume (Vti) if proximal sensor is disabled. Auto: V-CMV, V-SIMV, PRVC-CMV, PRVC-SIMV, VS: set tidal volume + 60%. All other modes: monitored tidal volume + 60%
High Delivered FIO2	Automatic alarm: set to 7% (without compressor) or 15% (with compressor) above oxygen setting
Low Delivered FIO2	Automatic alarm: set to 7% (without compressor) or 15% (with compressor) below oxygen setting

Leak Rate (maximum leak)	(1-Vte/Vti) %
Apnea (Interval)	3 to 60 seconds

2.5.5 Physical Data

Inspiration™ Ventilator System

Width x depth x height of device	13” x 15” x 19” (33 x 38 x 48 cm)
Weight of device	48 lbs (22 kg)
Weight of stand	27 lbs (12 kg)

Inspiration™ LS Ventilator

Width x depth x height of device	16” x 16” x 21” (40 x 40 x 53 cm)
Weight of device	53 lbs (24 kg)
Weight of stand	27 lbs (12 kg)

2.5.6 Environmental Data

Operating temperature	10 to 40 °C at 10 to 80 % relative humidity
Storage temperature	-10 to 60 °C at 5 to 95 % relative humidity
Atmospheric operating pressure	10 psi to 15.6 psi (700 to 1060 mbar)
Operating altitude	< 11,600 ft (3,500m) above sea level
Oxygen inlet supply pressure	29 – 86 psi (2 – 6 bar)
Oxygen inlet supply flow	180 lpm (STPD, dry required)
Air inlet supply pressure	29 – 86 psi (2 – 6 bar)
Air inlet supply flow	180 lpm (STPD, dry required)

2.5.7 Technical Data

Maximum limited pressure	120 cmH20 via a dedicated pressure relief valve.
Maximum operating pressure	80 cmH20 controlled by high pressure alarm setting.
	Pressure measurements are made by solid-state pressure transducers positioned to monitor internal operating, inspiratory and expiratory circuit pressures. (operating ranges: Ptank 0 – 14.7 psi (0 to 1 bar); Ppat and Paw + - 100 cmH_2O; dP n 0 to 350 cmH_2O; dP pat and dPI + - cmH_2O mbar).
Flow and volume measurement	Flow measurements are made by one of two differential pressure flow sensors, and are integrated with time to calculate inspiratory and expiratory volumes. Flow and volume measurement ranges are listed in sections 3.2 and 3.4.
Oxygen measurement	A galvanic cell is positioned in the inspiratory manifold to measure delivered oxygen concentrations and has a range between 0 and 103%
Display of monitored data, alarms and settings.	All data is displayed by a color liquid crystal display (LCD).

2.5.8 Compliance and Approvals

CE 0120

The *INSPIRATION*™ ventilation system complies with the requirements of directive 93/42/ EEC concerning Medical Devices and therefore bears the CE mark.

IEC 601-1
Classified as protection class I, Type B, internally powered, drip-proof equipment, continuous operation.

International Standards
Meets IEC 601-1/ EN60601-1, IEC 601-1-2/ EN60601-1-2, EN794-1, ASTMF1100-90, IEC 60601-2-12: 1988, ASTM F1054-87, ISO 5356-1

CE Notified Body
SGS UK

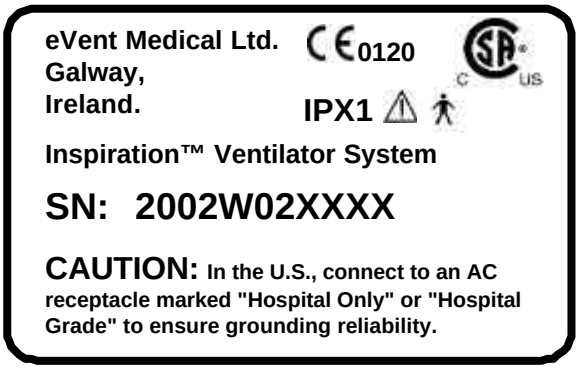
2.5.9 Device Labels and Symbols

These device labels and symbols appear on the *INSPIRATION™:*

	Power switch
	Alarm Mute key
xxx %	Back-up battery time status
BATT	On battery back-up
Nebulizer	Nebulizer nipple connector
Flow sensor	Flow sensor connector
	Device connected to mains
RS232	RS232 connection port
	Nurse call connection port
Ethernet	Ethernet connection port
	Refer to manual for Information or directions/warnings intended to prevent potential damage to the patient, caregiver or device.
	Designates type B equipment per IEC 601-1
IPX1	Indicates the degree of protection (drip-proof) by the enclosure.
O2 2-6bar (29-86psi)	O2 inlet port label
Air 2-6bar (29-86psi)	Air inlet port label

DC –Input: 24V/90W	DC input connector
AC –Input: 100 -240VAC 50/60 Hz 120VA 100V: 1.4A 240V: 0.5A Fuse: 3.15AT	AC input connector
O2 sensor	O2 sensor location
SN:	Device Serial Number
To Patient	Gas Flow To Patient from Device
From Patient	Gas Flow From Patient to Device
Do not obstruct!	Do not obstruct port or outlet
	Internal Battery Compartment

The *INSPIRATION*™ back panel label:



2.6 Tools, Test Equipment & Materials

Description	Manufacturer
Test Equipment:	
Pneumatic Calibration Analyser	eVent Medical PF300
Electrical Safety Tester	Biotek 601 Pro or equivalent.
Cuff Pressure Gauge	VBM 54-05-000 or equivalent.
Desktop / Laptop PC (Pentuim)	Local Supply
Software Download Cable	eVent Medical, F900085
Adult Tubing System	Local Supply
Paediatric Tubing System	Local Supply
Proximal Flow Sensor, Adult	eVent Medical, F910036 eVent Medical, F910265
Proximal Flow Sensor, Infant	eVent Medical, F910036*i* eVent Medical, F910266
Exhalation Cover	eVent Medical, F710214
Exhalation Membrane	eVent Medical, F710213
Test Lung	eVent Medical, F910215
High Pressure Air Supply with Adjustable Pressure Regulator	Local Supply
High Pressure Oxygen Source	Local Supply
External Battery or DC Supply	eVent Medical, F710520
External Battery Charger	eVent Medical, F710521
Extended Ribbon Cable	eVent Medical, F810225
Temperature Drift Fixture (JP)	eVent Medical, F721601
Touch Up Paint, LS, PU front	eVent Medical, F810220
Touch Up Paint, Chassis, Blue	eVent Medical, F810222
Touch Up Paint, Chassis, White	eVent Medical, F810223
Hand Tools:	
Hexagonal Drivers, following sizes: 1.5mm, 2mm, 2.5mm, 3mm, 4mm, 5mm, 6mm,	Local Supply
Torx Drivers, following sizes: T8, T20	Local Supply
Open End Wrench, following sizes: 8mm, 10mm, 14mm, 16mm, 18mm, 19mm, 20mm.	Local Supply
Flat Bladed Screwdriver	Local Supply
Philips Screwdriver No.1 / 2	Local Supply
Static Dissipative Service Kit	Local Supply
Cable Ties, Small	Local Supply

2.7 Recommended PM Intervals

Service Interval	Action Required
250 hours or 1 month of use	Clean or replaced fan inlet filter P/N F910007 – PKG 5
Every year or per hospital protocol	Electrical Safety Test
Every year or as necessary	Replacement of internal O2 sensor P/N F910028
	Replacement of gas inlet filters P/N F910205
	Full performance checkout, as per service manual section 6.
Every 2 years or as necessary	Replacement of internal battery cell P/N F820003 – LS/ST P/N F810003 – Original

3. Theory Of Operation

3.1 Introduction

This section has been provided to detail the operational theory of the Inspiration ventilator system. The section begins with an overview of the ventilator operation and goes on to discuss in great detail the operational principals of both the pneumatic and electronic systems component by component. Finally the section goes on to describe the operation of the ventilators firmware in interfacing and controlling the two systems.

3.2 Overview Of Inspiration Operation.

The Inspiration ventilator system consists of two major systems, the pneumatic system and the electronic system, which combine under software control to deliver respiratory support at operator determined parameters. The pneumatics under the control of the microprocessor, supply air and oxygen to the patient system external to the device. The electronic system inputs and supervises the power sources to the unit and provides electronic control of the ventilators components.

High Pressure air and oxygen enter the unit from an external source via two DISS (Diameter Indexed Safety System) connectors. On entry the gas is conditioned in order to prevent any moisture or large contaminant particles from entering the system. Two supply valves will meter the amount of air and oxygen to be supplied downstream to a 1.5 litre reservoir. Gas to be supplied to the patient system exits the reservoir via a proportional valve which is software controlled using feedback from system of inspiratory sensors. Having passed through the proportional valve the delivered gas exits the device via a 22mm male connector. Control of exhalation is provided by a second proportional valve acting upon a diaphragm in the exhalation system.

Pressure sensors and flow sensors (pneumotachometer) are used throughout the system to provide feedback measurements to the microprocessor. After undergoing digital conversion these measurements are used actively in the calculations which control breath delivery.

Ventilation parameters are programmed by the operator using the Push & Turn device on the user interface in conjunction with the selectable screen displays. The programmed data will be processed by the microprocessor and stored in ventilator non-volatile memory. The microprocessor will use the stored data in the control of breath delivery.

Power to operate the device may come from AC mains supply, external 24 VDC battery supply (optional) or from its own internal 24 VDC battery supply. In the event of a loss of AC the unit will be powered by an external battery if connected, when external battery power is exhausted or not available the internal 24 VDC battery will power the system.

3.3 Inspiration Pneumatic System

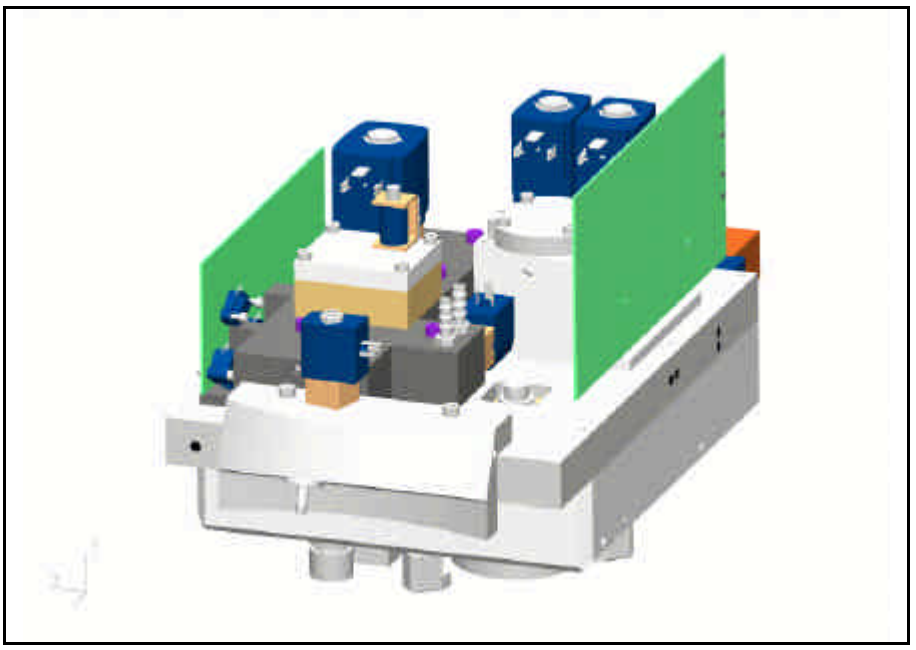
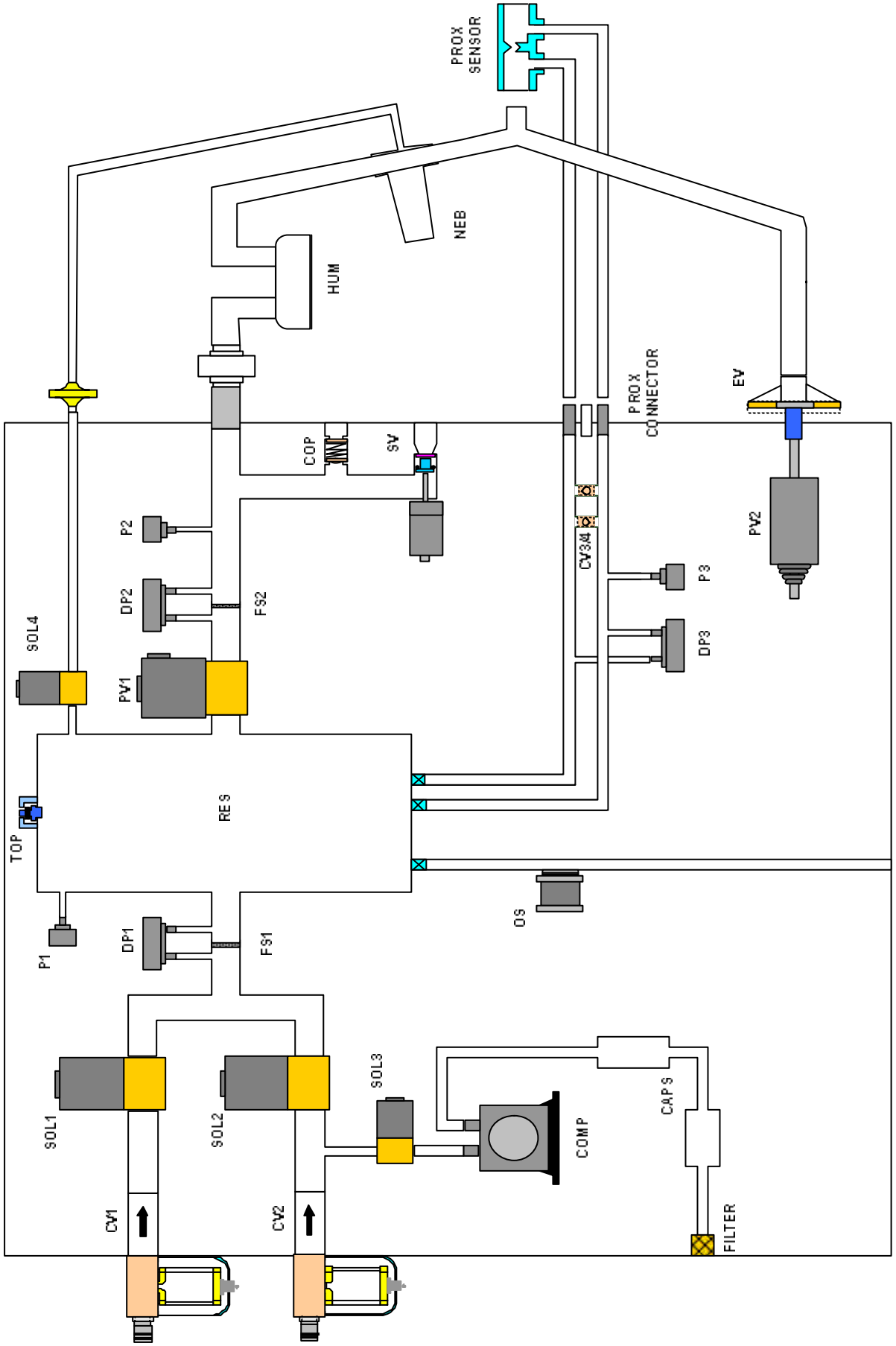


Fig 3-1, Inspiration Pneumatic Chassis

The Inspiration series ventilator pneumatic system incorporates an innovative solid state manifold design concept which virtually eliminates the need for any internal ventilator tubing. The system also incorporates an intelligent blending system eliminating the need for regulators at the gas inlet system. Under microprocessor control the pneumatic system will regulate and mix the high pressure source gasses for delivery to the patient to provide therapeutic respiratory support.

The Inspiration pneumatic system may be categorized into a number of subsystems, these are listed and defined as follows :

- Gas Inlet System
- Gas Blending System
- Gas Delivery System
- Safety Valve Block
- Proximal Measurements
- Exhalation System
- Oxygen Monitoring System
- Nebulizer


PROX SENSOR
NEB
HUM
PROX CONNECTOR
EV
COP
SV
PV2
P2
CV3/4
P3
DP2
FS2
DP3
SOL4
PV1
RES
TOP
OS
P1
DP1
FS1
SOL1
SOL2
SOL3
CAPS
COMP
CV1
CV2
FILTER

3.3.1 Gas Inlet System

The gas inlet system (fig 3.3) permits the connection of two high pressure gas sources (Air / Oxygen) to the ventilator via DISS high pressure connectors. It will condition the gas by removing moisture and filtering contaminants then conduct the gas onward to the blender system. The components which comprise the gas inlet system are described below :

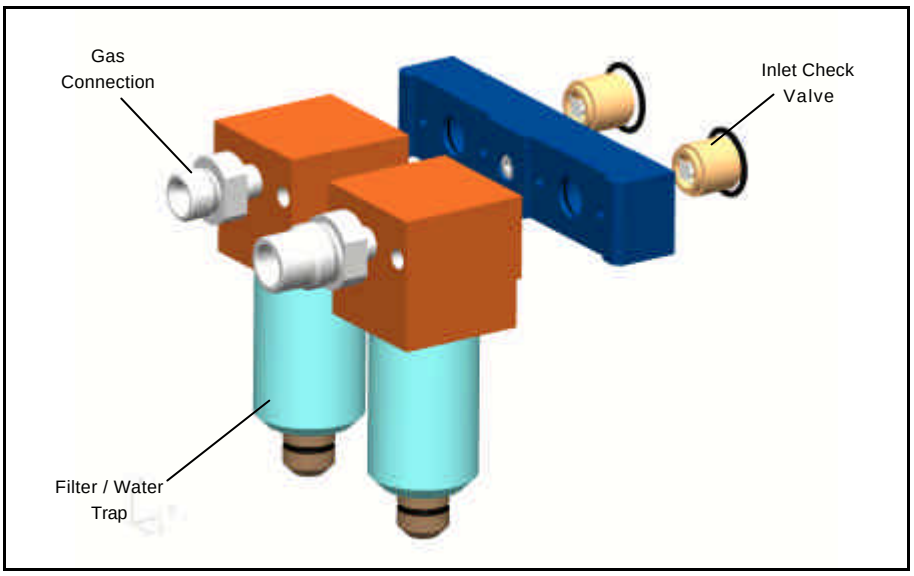


Fig 3-3, Air / O2 Inlet Assemblies

3.3.1.1 High Pressure Connnections

The Inspiration ventilator is supplied as standard with two DISS (Diameter Indexed Safety System) high-pressure fittings for connection of O2 and Air supplies.

On request adapters and high-pressure hoses may be provided to effect connection to other international gas supply standards such as NIST (non interchangeable screw thread) and Air Liquide.

3.3.1.2 Inlet Filters F1 - F2

After passing through the gas inlet, each high-pressure gas entering the ventilator will pass through an inlet particle filters, oxygen will pass through filter F1 and Air through filter F2.

The function of the particle filter is to remove contaminants down to a size as small as .5 microns from the gas coming into the ventilator system. The two filters are common components and must under go replacement at annual intervals.

3.3.1.3 Water Traps WT1 - WT2

The inlet gases pass through the filter and are then directed against the wall of the water trap. As the gas strikes the wall of the water trap its internal pressure will be increased momentarily prompting any carried moisture to be released. Ensuring that the supplied gases are clean and dry in this way will prevent any possible damage to components downstream in the system.

Note:
If ventilator is being operated in a location with a known bad Air or O2 supply the manufacturer recommends the use of an additional large capacity self dumping water trap upstream of the ventilators high pressure inlets.

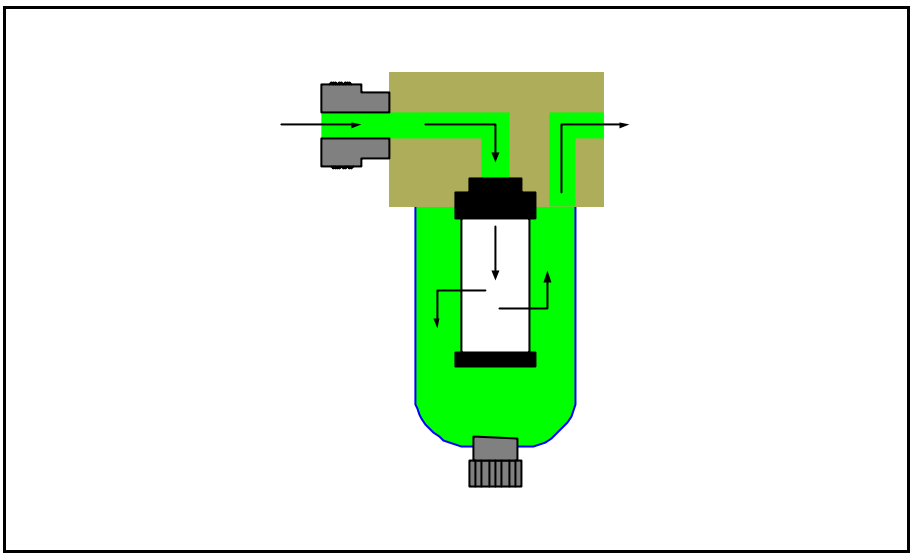


Fig 3-4, Section Through Water Trap

3.3.1.4 Inlet Check Valves CV1 – CV2

Having passed through filter and water trap, each of the high pressure gas supplies entering the ventilator is passed through a check valve (fig 3.5).

Check valve CV1 is located in the O2 supply path, and check valve CV2 is located in the Air supply path. The check valves function and are biased so as to allow an un-obstructed flow of high-pressure gas into the ventilator O2 and Air supply systems.

In the event of a single failure condition in the blending system, the checking action of these valves will prevent any back flow of gas, through to the high-pressure source and will prevent any contamination of the surrounding supply system.

Under no flow conditions the check valve will be forced closed by an internal return spring.

Fig 3-5, Section Through Check Valve

3.3.2 Gas Blending System

Gas blending in the Inspiration ventilator system is achieved through use of two high flow solenoids and a blender flow sensor. The solenoids are microprocessor controlled using feedback from the blender flow sensor, so as to keep the 1 litre reservoir adequately charged with the correct mixture of Air and Oxygen.

The system also incorporates a back-up compressor which will be started automatically in the event of a loss of the high pressure air source supplying the ventilator.

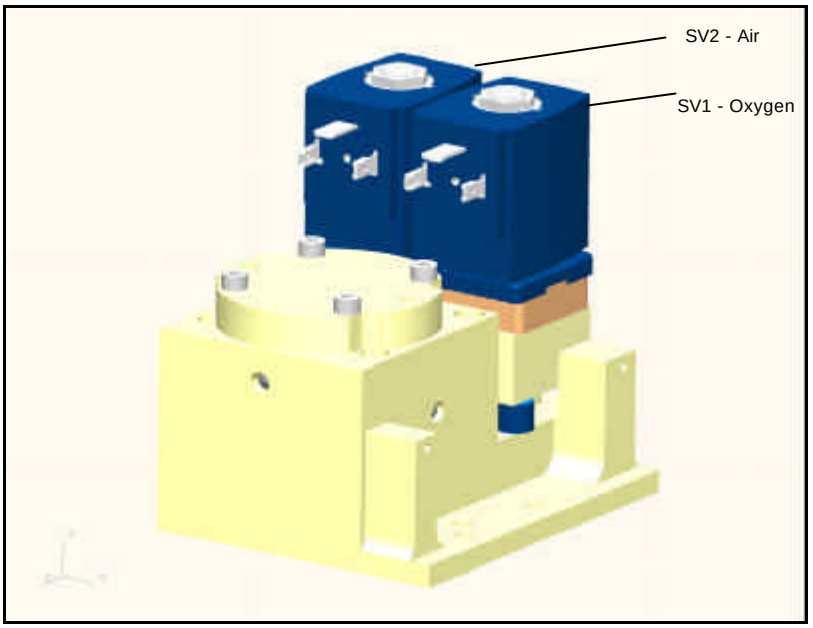


Fig 3-6, Blender Assembly

3.3.2.1 Gas Supply Solenoids SV1 – SV2

Two gas supply solenoids (shown fig 3.6) are incorporated into the blender system and are energised during each mixing cycle to ensure that the correct mixture of gas is maintained within the reservoir. Solenoid 1 (SV1) controls the flow of oxygen through to the reservoir. Solenoid 2 (SV2) controls the flow of air through to the reservoir

3.3.2.2 Blender Flow Sensor (FS1) (DP1)

Flow being delivered through SV1 (Oxygen) and SV2 (Air) during each of the blending cycle is measured by the blender flow measurement system.

The blender flow measurement system consists of a resistive element (FS1), positioned in the path of blender gas flow, and a corresponding differential pressure transducer (dP1) which is located on the Power PCB.

Gas passing through the resistive element FS1 will cause a pressure differential which will be measured at pressure transducer dP1. Pressure measured at dP1 will be directly proportional to the gas flow across the resistive element.

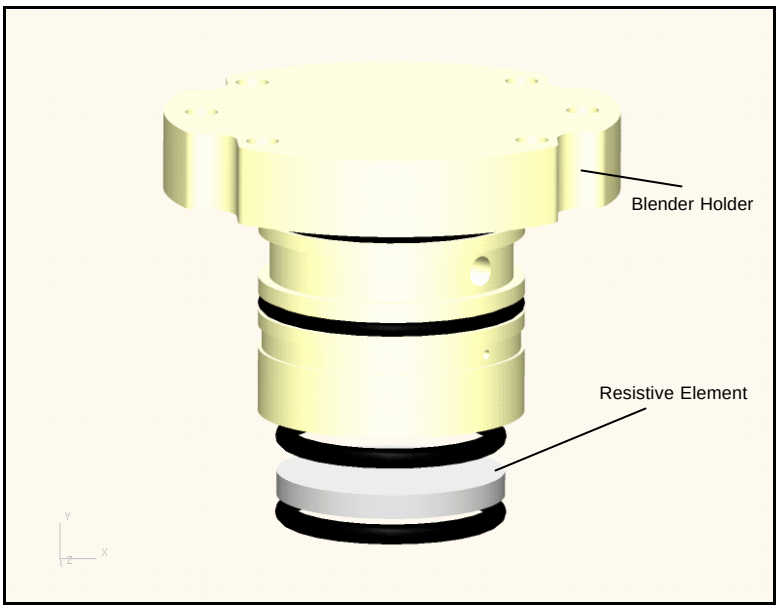


Fig 3.7, Blender Flow Sensor

3.3.2.3 Internal Compressor (COMP)

In the event of a loss of high pressure Air the microprocessor will signal the internal compressor (COMP) to begin operation.

Loss of high pressure air will be declared by the microprocessor using feedback from the blender flow sensor FS1/dP1. During blending, if the flow from SV2 is less than 30 lpm, it is assumed that the high pressure air source has been removed. With the compressor in operation, during blending, if the flow from SV2 is greater than 36 lpm, is assumed that high pressure air is restored and the compressor will be automatically stopped.

Compressor air is drawn into the ventilators pneumatic system through a sintered bronze filter element located on the rear of the pneumatic module. The air is then drawn through a series of chambers adjacent to the main reservoir chambers which reduce the overall sound of the compressor inlet gas. Compressed air exits the compressor and is connected to the main air supply system through the compressor unloading valve SV3.

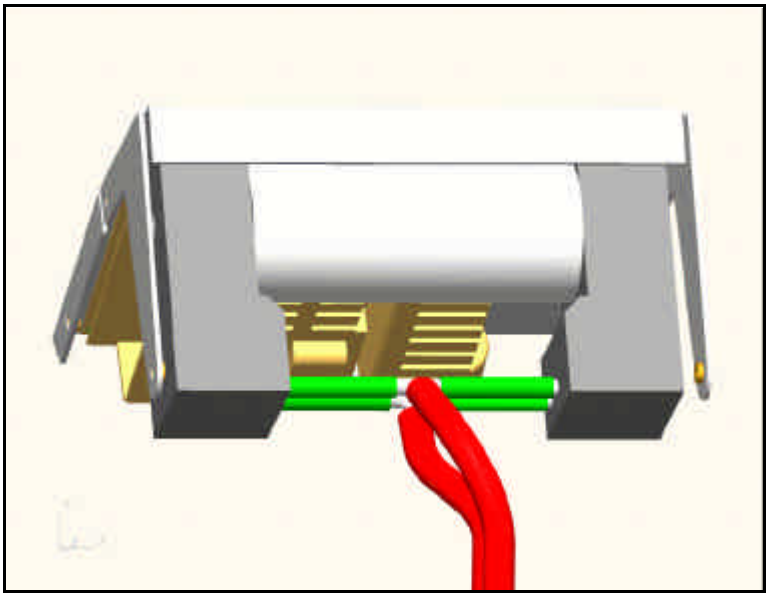


Fig 3.8, Internal Compressor

3.3.2.4 Unloading Valve (SV3)

Compressor air is routed to the main air supply system via a compressor unloading valve SV3. SV3 is a three way solenoid valve whose normally open port is connected to atmosphere.

As the internal compressor is started up SV3 will remain de-energised briefly allowing the compressor to start up in an unloaded condition. SV3 will then be energised to allow compressor output to be routed into the air supply system.

During internal compressor operation, whenever the air supply valve SV2 is closed / de-energised, SV3 will likewise be de-energised allowing compressor gas to vent through its normally open port. A muffler is provided on the normally open port of SV3 in order to silence the sound of the venting gas.

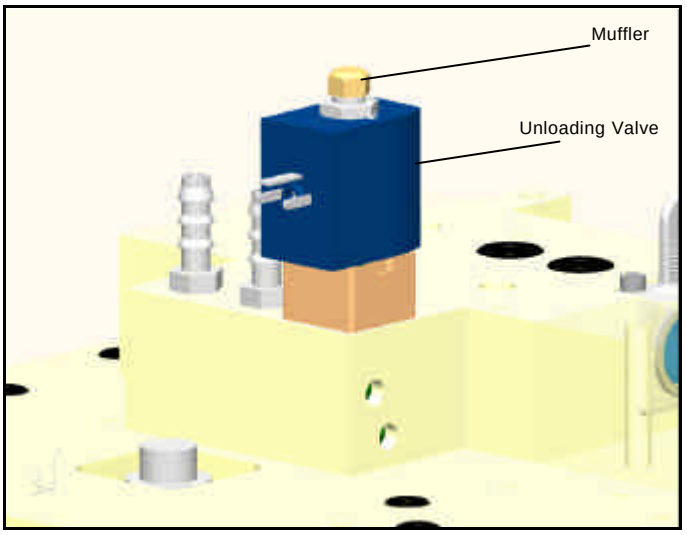


Fig 3.9, Compressor Unloading Valve

3.3.2.5 Gas Reservoir

The Inspiration gas reservoir (RES) serves as a store chamber for mixed gas available for delivery to the patient. The reservoir is made up of a number of separate chambers with a combined volume of approximately 1 litre. The pressure inside the reservoir is controlled within a pressure range specific to the patient type selected.

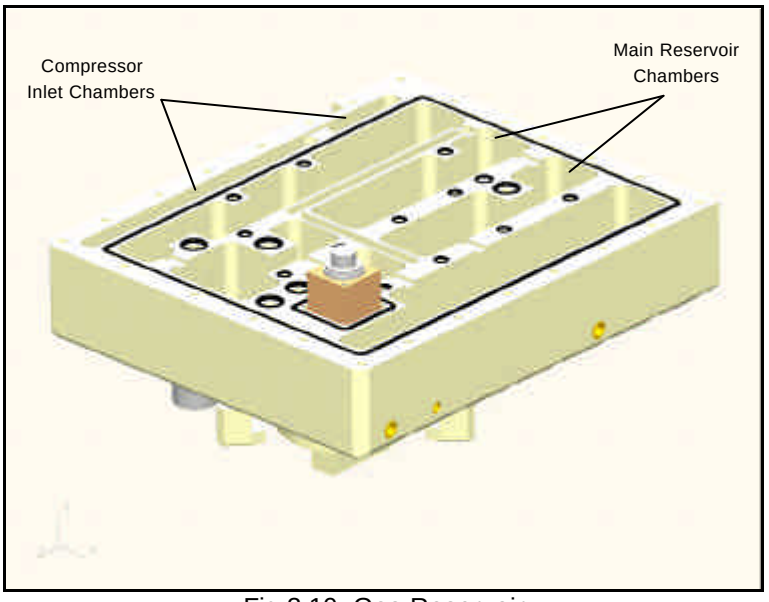


Fig 3.10, Gas Reservoir

3.3.2.6 Reservoir Pressure Transducer

Located on Power PCB the reservoir tank pressure transducer P1 monitors the pressure within the reservoir on a continuous basis. These measurements will be used by the processor to monitor the reservoir condition and determine when further blending cycles must be initiated.

3.3.2.7 Reservoir Over Pressure Valve

The reservoir over pressure valve is incorporated into the top of the gas reservoir. The over pressure valve will open in the event of the reservoirs internal pressure exceeding 1.8 bar, as might happen in the event of a failure within the blender system, regulating the reservoir pressure within a safe level.

This mechanical relief valve is normally closed by means of a retaining spring mechanism. When reservoir system pressure is sufficient to overcome the closing force from the spring, the over pressure valve poppet will be lifted from its seat venting excess pressure within the ventilator enclosure.

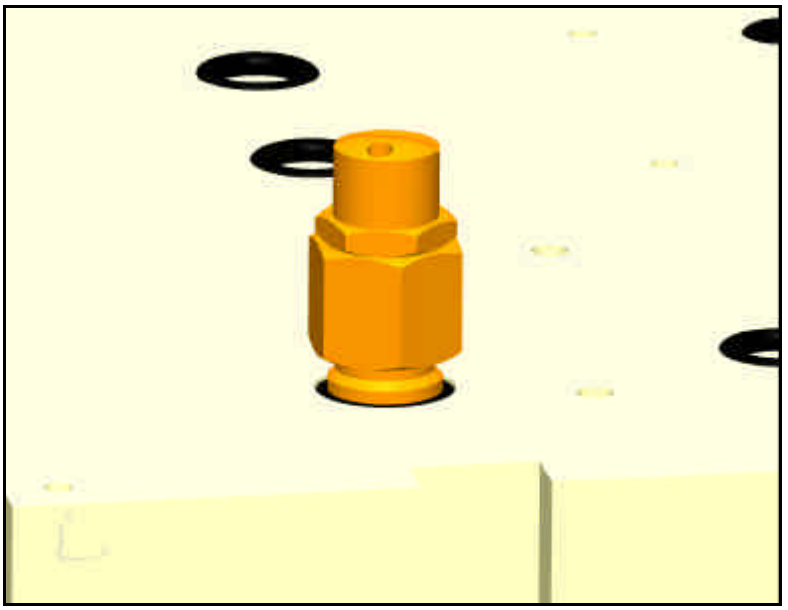


Fig 3-11, Reservoir Over-Pressure Valve

3.3.2.8 Blender System Operation

General Operation:
The frequency of the blending cycles will be dependant upon the amount of gas demanded by current ventilator settings and will be controlled so as to maintain the reservoir pressure within an acceptable operating range. The operating pressure range will vary according to what patient type is selected on the device.

A blending cycle will be initiated whenever the microprocessor determines that there is insufficient gas within the reservoir to maintain the current ventilator settings. The microprocessor decisions take into account set delivery parameters, base flow, proximal purge flow, O2 sensor flow, all which draw upon the main reservoir.

At the initiation of each blending cycle the microprocessor determines what volume of gas is required from each of the supply systems in order to recharge the reservoir appropriately. The supply valves SV1 and SV2 will then be activated sequentially to supply these requirements.

As the first valve is activated the microprocessor will monitor the flow being delivered through it at FS1/dP1 (Blender Flow Sensor). When it

determines that the appropriate volume of gas has been delivered the valve will be closed. After a brief pause the second valve will be activated, monitored and closed in the same way.

Working in this way, by activating the valves only as long as required, the microprocessor maintains an accurate gas mixture regardless of the supply conditions. Were the gas supply pressure and flow to drop the microprocessor will extend the operation time until the required volume is delivered in order to compensate. Likewise if the pressure and flow were to increase the supply valve will be energised for a shorter period of time.

With adequate high pressure air and oxygen sources available the blender will function as described above, and will maintain the reservoir within 1% of the set FiO2 level.

The following blender system statuses are possible:

Gas mixing system status	**Reaction from INSPIRATION**	**Alarm message, information**
O_2 and air supply activated (normal status)	Air and gas are being mixed. This status allows the most exact mixture to be attained, irrespective of the input pressure from both gases (+/- 1% FI O_2).	No alarm messages or information
O_2 and compressor activated (i.e. air supply failure)	As soon as the air supply fails, the compressor is switched on. The mixture is now made up of compressor air and O_2. The mixture accuracy is now $\pm$ 5% FI O_2. The compressor can only be activated if compressor backup has been enabled in the configuration menu (19). Calibrations and nebulizer function are not available.	Info: Flow Trigger Not Available
O_2 activated (i.e. air supply and compressor failure)	If the air supply fails, the INSPIRATION tries to start the compressor. If compressor backup has not been enabled in the configuration menu, the compressor cannot be activated and the gas mixture will only contain 100% oxygen.	Alarm High: High Oxygen Alarm Medium: Air supply
Air only activated (i.e. O_2 failure)	The oxygen supply has failed. Mixture will only contain air.	Alarm High: Low Oxygen Alarm Medium: Oxygen supply
Compressor activated (i.e. O_2 and air supply failure)	The air supply and oxygen have failed. If compressor backup has been enabled in the configuration, the INSPIRATION will start the compressor. Mixture will only contain compressor air.	Alarm High: Low Oxygen Alarm Medium: Oxygen supply
No gas activated	No pneumatic source available to the device	Alarm High: Internal Pressure Low Alarm Medium: Oxygen supply Air supply

3.3.3 Gas Delivery System

During breath delivery all breath parameters, with the exception of FiO2, are controlled by the inspiratory proportional valve (PV1). This valve is microprocessor controlled using feedback from the internal flow sensor (FS2/dP2) and internal pressure sensor (P2) situated at its output. Gas passing through the valve will pass into the patient circuit.

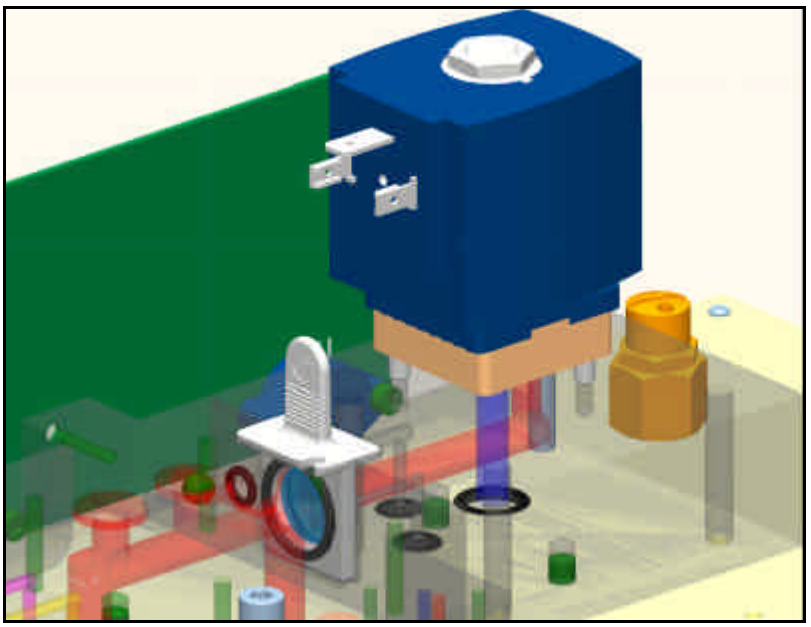


Fig 3-12, Gas Delivery System

3.3.3.1 Delivery Proportional Valve (PV1)

The delivery proportional valve (PV1) may be cycled through steps 1 – 500 by varying the controlling pulse width modulated (PWM) signal applied to it.

As the controlling PWM is increased PV1 will open further allowing more flow through it. As the controlling PWM is decreased PV1 will begin to close resulting in less flow being permitted to pass through.

The operation of the valve will be microprocessor regulated using feedback from the breath delivery transducers.

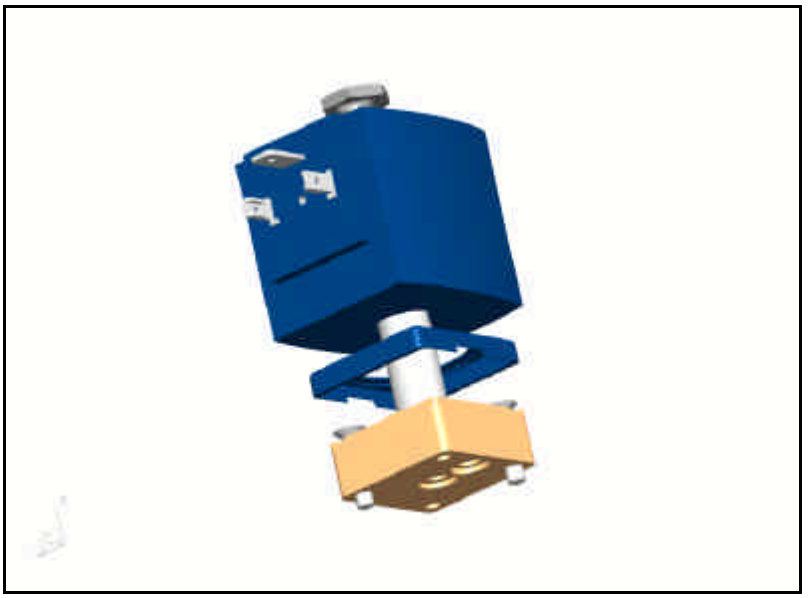


Fig 3-13, Proportional Valve (PV1)

3.3.3.2 Internal Flow Sensor (FS2) (DP2)

Flow being delivered through the inspiratory proportional valve PV1 is monitored at all times by the internal flow measurement system.

The internal flow measurement system consists of a resistive element (FS2), which is positioned in the path of gas delivery, and a corresponding differential pressure transducer (dP2) which is located on the Sensor PCB.

Gas passing through the resistive element FS2 will cause a pressure differential which will be measured at pressure transducer dP2. Pressure measured at dP2 will be directly proportional to the gas flow across the resistive element.

The feedback from this sensor will be used by the microprocessor to regulate the operation of the proportional valve.

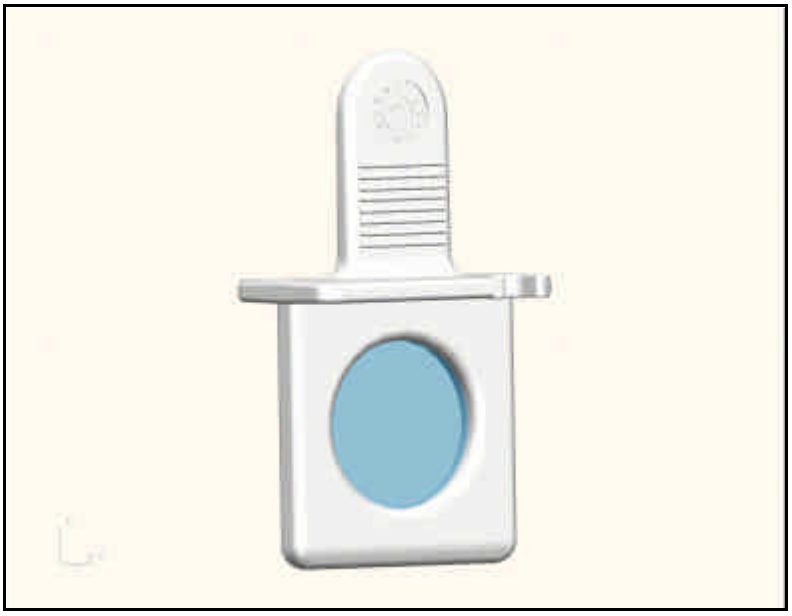


Fig 3-14, Internal Flow Sensor Element

3.3.3.3 Internal Pressure Sensor (P2)

Blended gas being delivered through the Inspiratory valve PV1 also passes an absolute pressure transducer. Feedback from this sensor is used by the microprocessor to regulate the operation of the delivery proportional valve during pressure targeted ventilation modes.

3.3.3.4 Breath Delivery Operation

During operation all aspects of breath delivery will be regulated by the inspiratory proportional valve (PV1) using feedback from the breath delivery transducers FS2/dP2 and P2.

During Inspiration, in volume targeted breath delivery, PV1 will be regulated using feedback from the internal flow sensor FS2/dP2, so as to control the peak flow, volume and breath shape.

During Inspiration, in pressure targeted breath delivery (Pcontrol, Psupport), PV1 will be regulated using feedback from the internal pressure sensor P2 so as to achieve the target pressure.

During exhalation, PV1 will be regulated using feedback from the internal flow sensor FS2/dP2, to achieve the required base flow.

3.3.4
Safety Valve Block

In order to protect the patient during abnormal operation, two safety features are incorporated into the pneumatic safety valve block which interfaces the main patient gas delivery path. The safety valve block incorporates both over pressure protection and a safety valve as described in the following text.

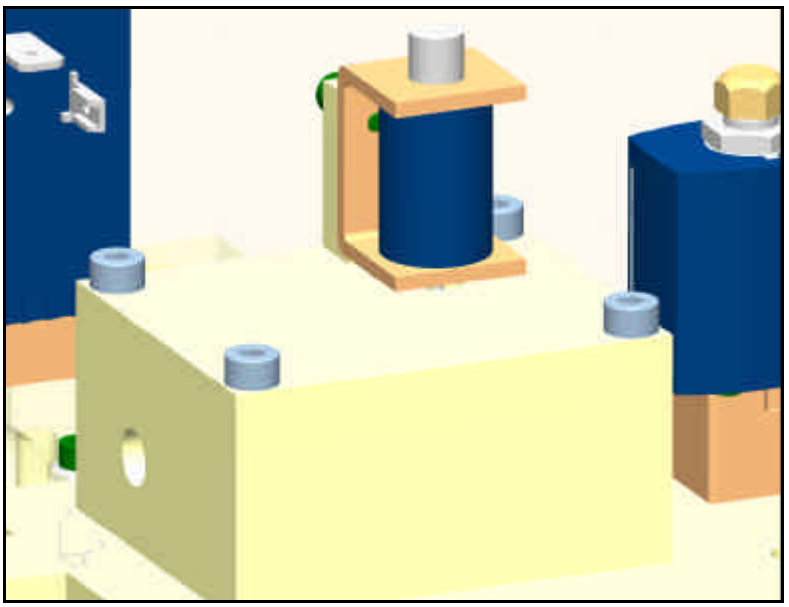


Fig 3-15, Security Block

3.3.4.1
High Pressure Relief Valve (HPRV)

In order to protect the patient from any harm resulting from high circuit pressures a high-pressure relief valve is incorporated into the devices safety valve block.

The circuit high-pressure relief valve is a mechanical relief valve with a set cracking pressure of 120cmH2O. In the event of a pressure in excess of this occurring in the patient system, as might happen in the event of an occlusion, the high pressure relief valve will open automatically to limit pressure to 120cmH2O.

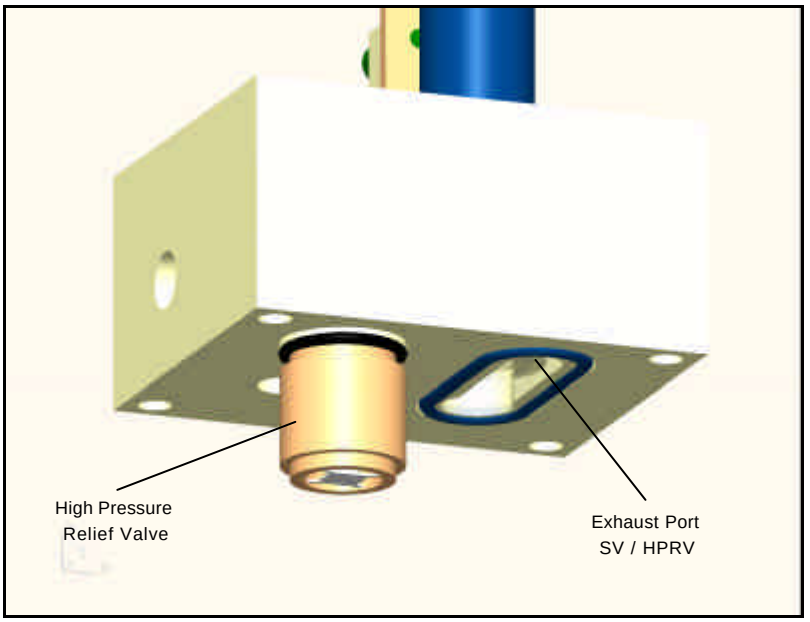


Fig 3-16, High Pressure Relief Valve

3.3.4.2
Safety Valve (SV)

A safety valve is incorporated into the safety valve block in order to provide the patient with an open breathing path to and from ambient in emergency situations.

In normal operation the valve will be closed by energising a normally open solenoid. With this solenoid energised its plunger will press the safety valve seat hard upon a sealing surface, closing of the ambient port.

In the event of an error condition the solenoid is de-energised removing the plunger from the seat. With the plunger removed the seat will remain loosely in position on the sealing surface.

In this condition any inspiratory effort on the part of the patient will result in the seat being displaced and in inspiratory flow being drawn through this path from ambient.

As the patient begins to exhale the seat will fall against the sealing surface and closing off the path once more. In this condition the patient will be able to exhale through the now open exhalation system.

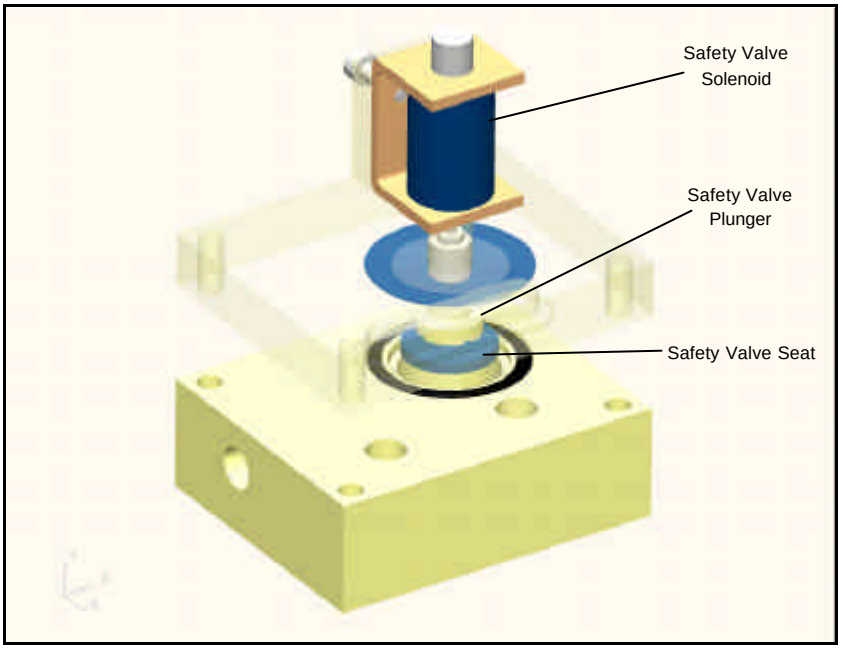


Fig 3-17, Safety Valve

3.3.5 Proximal Measurements

A flow sensor may be used proximally to provide the operator with feedback on the patient's exhaled tidal volume and proximal airway pressures. Additionally use of the proximal flow sensor will permit flow triggering to be used.

3.3.5.1 Proximal Flow Sensor (FS3/dP3)

The proximal flow sensor (FS3) is positioned at the patient wye. The flow sensor is available in adult and Infant versions.

Each sensor has three proximal interface tubes which attach the sensor to the front console of the ventilator. The two outer connections provide the pressures upstream and downstream of a resistive element, the final centre connector is offset to ensure correct connection to the device.

Inspiration LS/ST models will use a sensor version using tubing with a large internal diameter (approx 3.0mm). Earlier original models will use a sensor version using tubing with a small internal diameter (approx 1.5mm)

The two sensing lines are connected internally to a differential pressure sensor (dP3) located on the Sensor PCB with a tee off the downstream line providing a proximal airway pressure measurement.

Gas passing through the resistive element FS3 will cause a pressure differential which will be measured at pressure transducer dP3. Pressure measured at dP3 will be directly proportional to the gas flow across the resistive element.

The feedback from this sensor will be used by the microprocessor for monitored values for exhaled tidal and minute volume, for sensing patient inspiratory effort and for the graphical loops and waveforms.

Fig 3-18, Proximal Flow Sensor

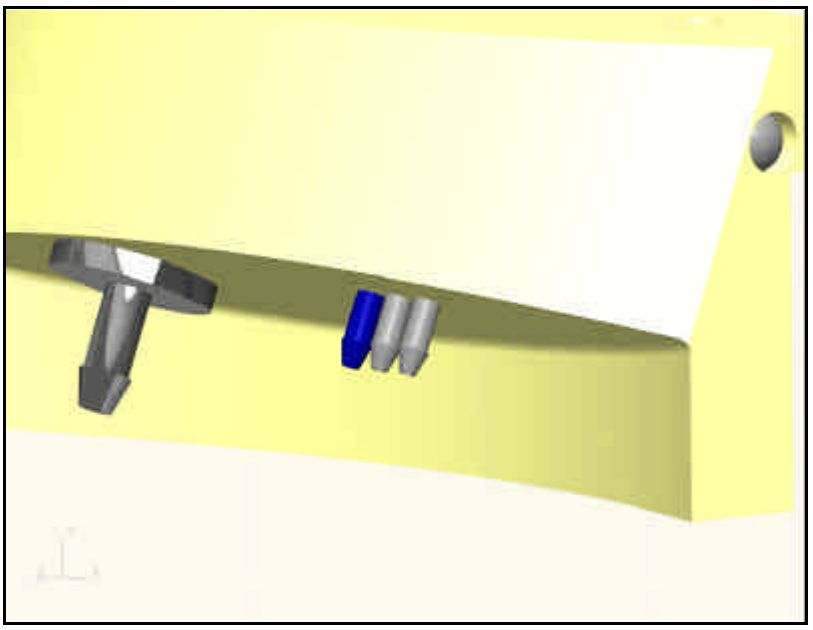


Fig 3-19, Flow Sensor Interface (Nebulizer Module)

3.3.5.2 Proximal Pressure Transducer

In order to provide a measurement of the proximal airway pressure a tap is taken off of the downstream sensing line and applied to the proximal pressure transducer (P3). The pressure transducer is located on the Sensor PCB and interfaces directly at the pneumatic block.

3.3.5.3 Transducer Protection System

To prevent internal contamination of the proximal sensing lines and damage to the pressure transducers, a positive purge flow is provided down through the pneumatic chassis and the sensing lines from the pressurised reservoir system. This purge flow is developed by two restrictors (one for each sensing line) which interface at the Inspiration reservoir and sensor block 2.

In order to prevent damage to the differential pressure transducer dP3 which may result from an occlusion of the proximal sensing lines the system incorporates over pressure protection.

Over pressure protection is in the form of 2 check valves, which connect the 2 proximal sensing lines and which are biased so as to allow flow between the lines in either direction.

These check valves (CV3/CV4) have a cracking pressure of 100mbar. In the event of either of the proximal tubes becoming occluded, the check valve will crack open at this pressure allowing a bleed across and into the other line, equalising the pressure at the transducer.

3.3.6 Exhalation System

The exhalation system functions to seal the patient circuit during the Inspiration and to open the patient circuit as required to maintain the operator set PEEP baseline pressure during the exhalation.

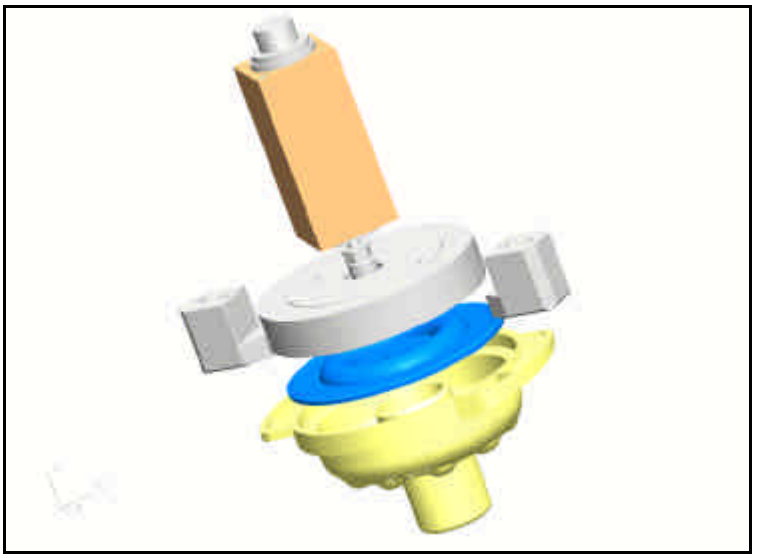


Fig 3-20, Exhalation System

3.3.6.1 Exhalation Proportional Valve (PV2)

The expiratory proportional valve (PV2) may be cycled through steps 1 – 1000 by varying the controlling pulse width modulated (PWM) signal applied to it.

As the controlling PWM is increased, the downward closing force of the plunger within the exhalation valve will be increased; this will allow the EV to retain a greater amount of pressure within the tubing system. As the controlling PWM is decreased the downward closing force of the plunger will be decreased. The plunger will act upon the exhalation membrane and cover in order to seal the tubing system.

The operation of the valve will be microprocessor regulated using feedback from the internal pressure transducer P2.

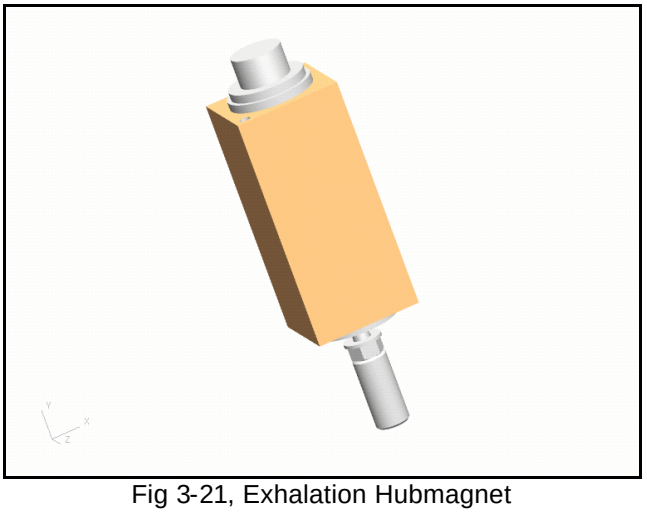


Fig 3-21, Exhalation Hubmagnet

3.3.6.2 Exhalation Compartment

The exhalation compartment comprises of cover and diaphragm which will act to seal the patient system.

The exhalation cover provides the seating for the exhalation diaphragm and includes exhaust ports to provide minimal expiratory resistance. The cover is re-usable and is rated for around 100 autoclave cycles.

The exhalation diaphragm, under the force of the PV2 plunger, will act against the seating surface of the exhalation cover to seal the patient tubing system. The diaphragm is reusable and rated for 10 autoclave cycles.

Fig 3-22, Exhalation Components

3.3.6.3 Exhalation System Operation

The exhalation compartment comprises of a reusable cover and diaphragm which will act to seal the patient system under the control of the expiratory proportional valve (PV2)

During Inspiration, in volume targeted breath delivery, PV2 will be controlled to the fully closed position applying the maximum closing force on the exhalation diaphragm.

During Inspiration, in pressure targeted breath delivery (Pcontrol, Psupport), PV2 will normally be controlled to the fully closed position as above. In the event of any pressure overshoot, as might happen in the event of a patient cough, PV2 will then be controlled proportionally using feedback from the internal pressure transducer P2, so as to maintain the target pressure.

During exhalation, PV2 operation will be regulated using feedback from the internal pressure sensor P2, to achieve the operator set PEEP baseline.

3.3.7 Oxygen Monitoring (OS)

The oxygen monitoring system provides the operator with a real time indication of oxygen percentage delivered to the patient. It incorporates an Oxygen Sensor (OS) using a galvanic measurement technique to produce an output voltage proportional to the partial pressure of the sampled gas. The sampled flow will be developed from the reservoir through a restrictor and directed to the centre of the measurement cell to allow measurement to be taken.

Oxygen measurement may be enabled / disabled in the configuration menu. When activated a preset alarm will be triggered if the delivered O2 percentage falls outside of the required ranges. The alarm range for O2 measurement is set at ± 5% fiO2.

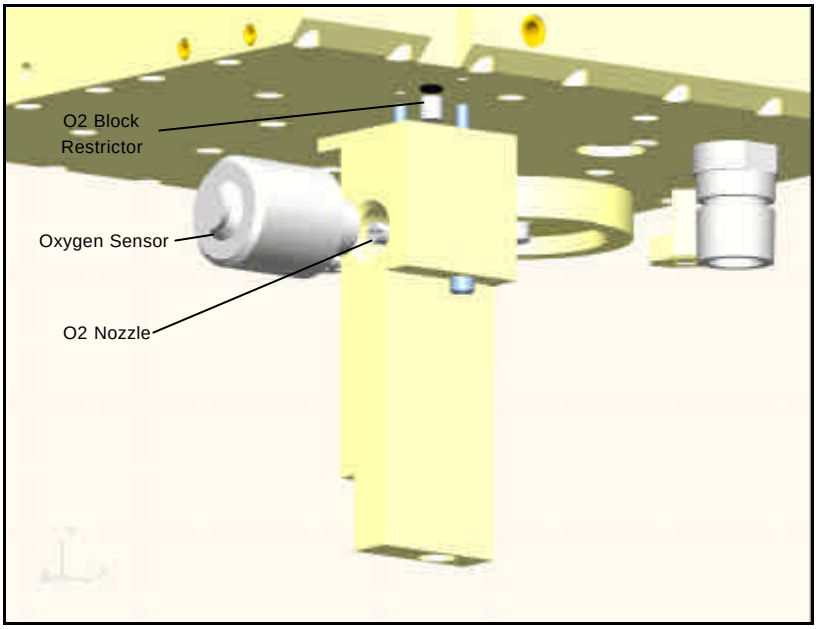


Fig 3-23, Oxygen Sensor

3.3.8
Nebulizer System

The Inspiration ventilator incorporates a smart nebulizer system. At the programmed intervals the ventilator will provide gas to drive an optional nebulizer incorporated into the patient system.

The flow required for nebulizer operation is developed by the restriction of the nebulizer solenoid (SV4) orifice whose inlet side interfaces directly at the reservoir. This pressurised flow of blended gas from the reservoir is applied through a front bezel tubing connection, to the nebulizer vial in the patient system.

The flow of gas into the tubing system is turned on and off by means of a normally closed solenoid valve located on the nebulizer module.

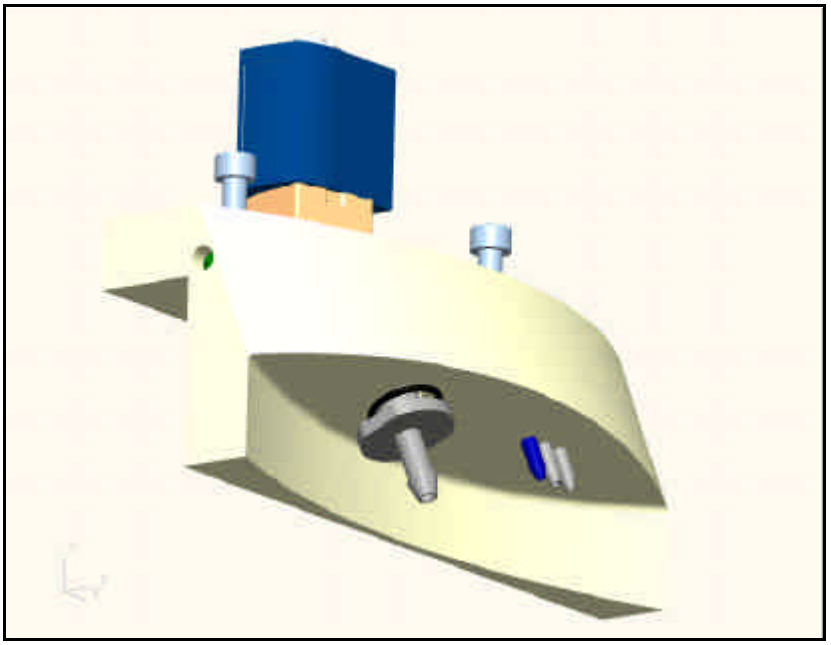


Fig 3-24, Nebulizer Module

3.4 Inspiration Electronic System

The INSPIRATION ventilator electronics system use and regulate one of three sources of electrical power to provide drive to and control of the ventilator pneumatic system.

The system also allows the operator to program settings via the user interface module and hence supervises all ventilator operations. The INSPIRATION electronics system is comprised of the following components :

- Power Input Components
- Power Supply PCB
- DC Power Options
- Power PCB
- Sensor PCB
- Controller PCB
- Processor PCB
- Graphic PCB
- LCD Display
- User Interface Lexan Keypad
- User Interface Rotary control knob
- Mini Web Interface (Optional)

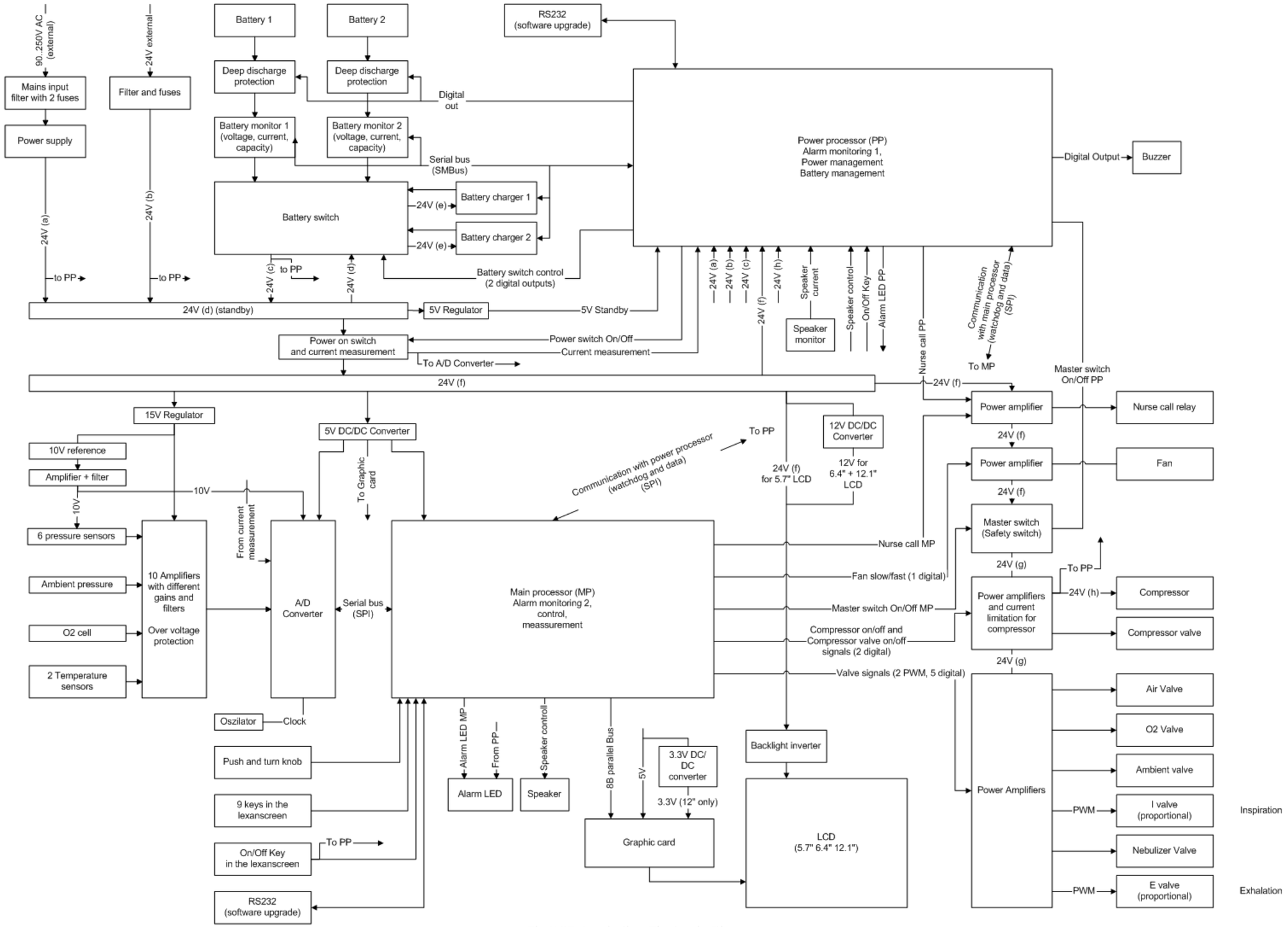


Fig 3.25, Inspiration Electronic Diagram

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3.4.1 Power Input Components

The power input components of the system comprise of the ventilator power cord and an EN60320 power input receptacle and line filter.

The ventilator is rated for supply voltages of 100-240 VAC @ 50-60 Hz and is fused at 3.15 amps to accommodate both high and low voltage ranges.

Fig 3-26, Power Entrance Module

3.4.2 Power Supply PCB

The power supply PCB is a true auto ranging assembly which is rated for supply voltages of 100-240 VAC, 50-60 Hz. It will output a single regulated 24 VDC supply which is routed onward to the Power PCB where the other required supply voltages will be generated.

The power supply assembly incorporates a power fail system which will signal the processor accordingly in the event of a loss of AC supply.

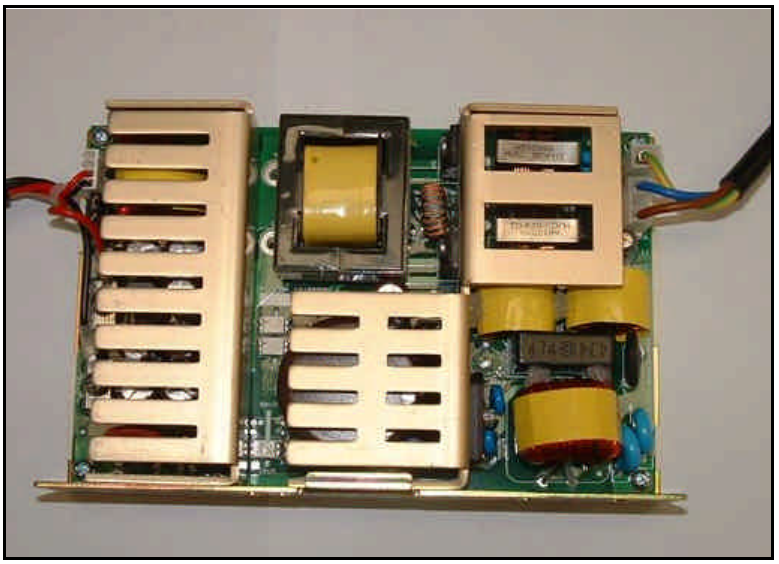

Fig 3-27, Power Supply Module

3.4.3
Internal Battery

Back-up during a loss of AC supply is provided an internal battery pack. The battery pack is comprised of two 12 VDC batteries which are connected serially at the Power PCB in order to provide a 24VDC supply.

In the Inspiration LS/ST the internal battery cells are rated at 7.5 ah, in this Original Inspiration models these are rated at 3.2ah. The batteries are not interchangeable between devices.

Caution:
The internal battery pack should always be connected up as per the label provided on inside of the internal battery cover.

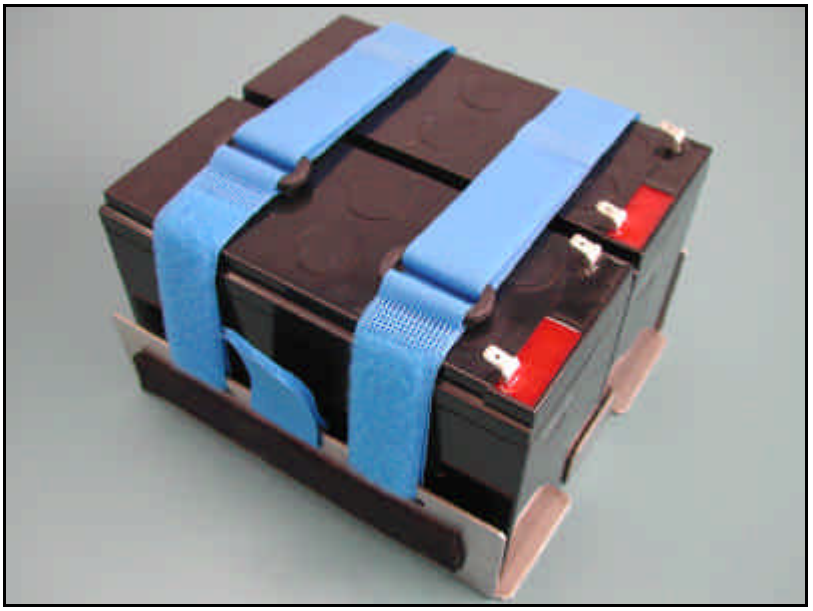

Fig 3.28, Internal Battery Pack LS/ST

3.4.4
External Battery

To supplement the AC supply and the Internal battery back users have the option of an external battery supply. An external DC connector is provided on the ventilators rear panel to allow connection of an external 24 VDC battery pack.

eVent Medical recommends the use of its external battery assembly available as Part no. F-710520.

Fig 3-29, External DC Connector

3.4.5
Power PCB

The Power PCB is located within the ventilators pneumatic compartment. There are two possible configurations for the Power PCB dependant upon the model. Inspiration LS/ST uses Power PCB rev 04 and above (shown in diagram below). Original Inspiration model uses Power PCB rev 03 and below. The critical functions for each of the PCB versions are largely the same and are described as follows:

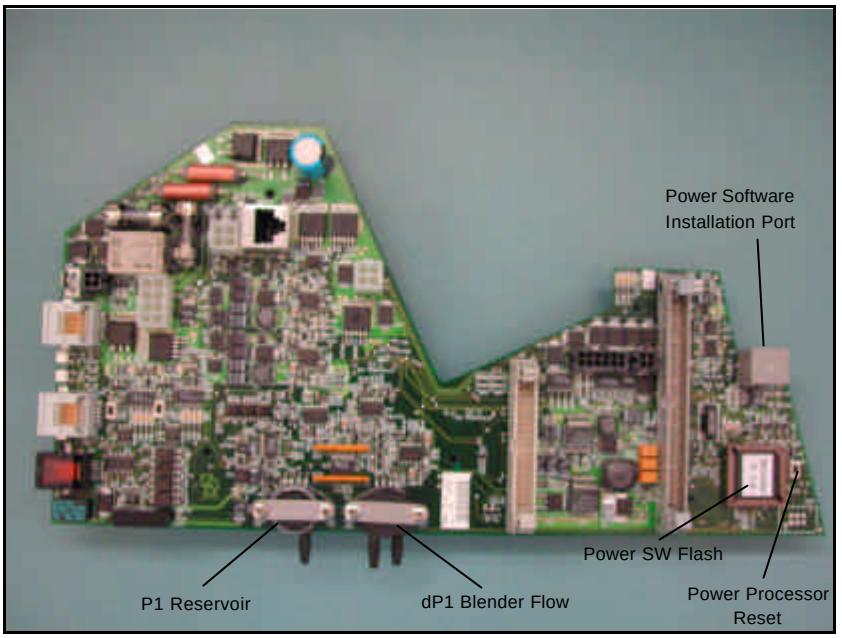

Fig 3-30, Power PCB

Power Software Storage – Resident on the Power PCB, rev 04 and up, is a flash EPROM which is used for storage of power system software. This software may be updated as required through the communication port adjacent to the EPROM.

With Power PCB, rev 03 and below, power system software is stored on a socketted EPROM which must be physically replaced when modifying the software version.

Power Processor Reset – Resident on the rev 04 PCB adjacent to the flash EPROM is a power processor reset switch. This switch will be used as required when installing power system software and may be used during troubleshooting.

Power Source Control – The Power PCB will monitor the three available power inputs and control switching between them.

AC supply is always the first priority and will power the unit if available. In the event of a loss of AC power the 24 VDC from the power supply will be lost, the processor will look to see if external 24 VDC is available and if so will switch to it, if external DC is not available the unit will switch to its internal 24 VDC battery.

The Power PCB is also responsible for the internal battery charging and monitoring functions. The internal battery will be charged at all times when AC or external DC supplies are connected to the ventilator regardless of whether the unit is switched on.

Pneumatic Control – Drive circuits located on the Power PCB are

responsible for the control of all the valves within the pneumatic block. As instructed by the main processor located on the controller PCB this circuitry will switch the valves on / off as required to control the blender, delivery, exhalation, nebulizer, compressor and Safety Valve. Drive circuitry for the audible alarm is also located within this PCB.

Pneumatic Safety Switch – In the event of a technical error the pneumatic safety switch will allow all power to be removed from the ventilators pneumatics in a single operation.

Blender Pressure Measurement – The circuit board contains two pressure transducers, one differential transducer and one absolute transducer. As has been described earlier there transducers are responsible for monitoring within the blender system. The absolute pressure transducer will monitor the reservoir pressure. The differential transducer is used in conjunction with the blender system flow sensor to determine the flow through the Air and O2 supply valves (SV1 / SV2).

Input/Output Interfaces – The Power PCB contains the interface ports for three available communications interfaces, all three interfaces for the Nurses call, RS232, Mini-web interface are in the form of an RJ45 connector.

Main Processor Supervision - The power controller processor monitors at all times the operation of the main processor located on the controller PCB. If it anytime it determines there is a problem which will compromise safe ventilator operation it will annunciate a technical error and put the unit in ambient breathing mode.

3.4.6 Sensor PCB

The purpose of the Sensor PCB located within the ventilator pneumatic chassis is to provide feedback on flow and pressure information to the processor during breath delivery. Incorporated into the PCB are four pressure transducers which are used for breath delivery and proximal measurements.

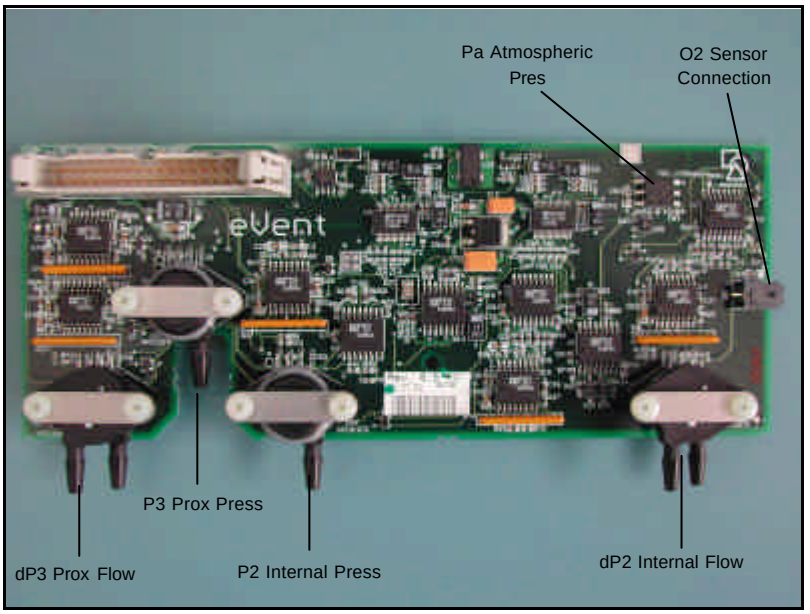

Fig 3-30, Sensor PCB

Breath Delivery Transducers – As described previously two transducers are used as feedback signals for control of the delivery proportional valve (PV1). The differential transducer (dP2) provides feedback to the

microprocessor on internal gas flow through the inspiratory module. The pressure transducer (P2) will provide feedback to the microprocessor on the internal pressure within the inspiratory module.

Proximal Measurements – As described previously two transducers are incorporated to provide feedback and patient data regarding patients exhaled tidal volumes and he proximal airway pressure. The signal from differential transducer (DP3) provides feedback on the patients exhaled flow and tidal volume. The pressure transducer (P3) will provide information on the patients proximal airway pressure.

O2 Sensor Interface – The ventilators integral O2 measurement cell interfaces with the electronic system through an interface circuit located on the sensor PCB.

Barometric Pressure Transducer – On later versions of the Sensor PCB (Rev 04 and above) an additional atmospheric pressure transducer (Pa) is provided. The measurement from this PCB will be used for correction of other pressure measurements.

3.4.7 Motherboard/Controller PCB

The Motherboard/Controller PCB provides the primary interconnect and communication bus between the pneumatic chassis electronics, the Processor PCB, Graphic PCB, Mini-Web PCB, Lexan Front Panel Interface and the backlight.

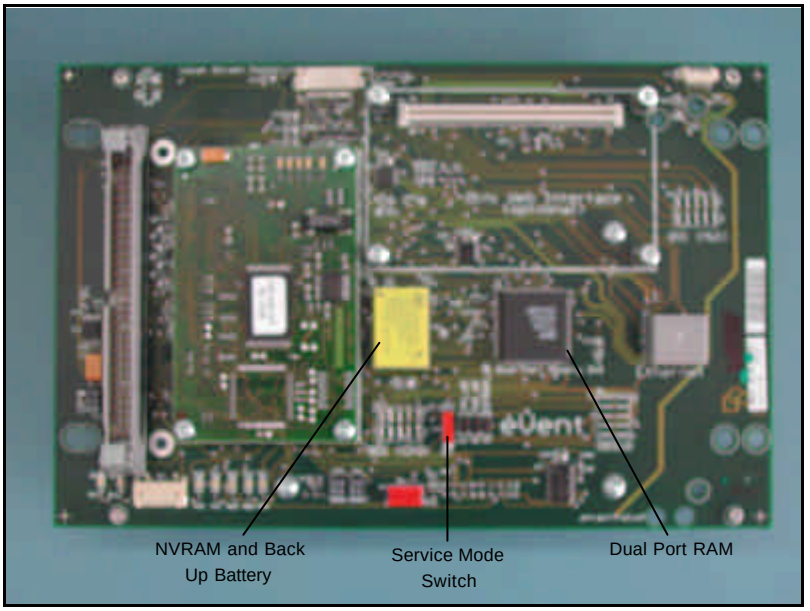

Fig 3-30, Controller PCB

PCB Configuration – Dependant upon whether the device is in the LS/ST configuration, or in the Original configuration will be determine whether the PCB in use is designated as a Motherboard or Controller PCB, where the LS/ST will use the Motherboard (Rev 03 and above), and the Original device will use the Controller PCB (Rev 02 and below).

NVRAM – Resident on this PCB in each configuration is an NVRAM device. Critical data such as calibration look up data, breath and alarm settings, date and time, running hours, alarm log etc will be stored on this device. The information will be retained on this device using a socketted lithium battery which is rated for approximately 10 years continuous storage.

Dual Port RAM – A dual port RAM device is provided on the PCB for temporary data storage for mini-web interface applications.

Service Switch – A single slide switch is provided on the PCB which will allow the device power up directly into the service mode, as may be required for troubleshooting purposes.

Backlight Inverter – A backlight inverter is incorporated into the Controller PCB (rev 03 and below). The inverter will be used to drive the backlight on the Original Inspiration only. LS and ST devices incorporate a separate backlight inverter PCB for this purpose.

3.4.8 Processor PCB

The Processor PCB provides overall control of ventilator operations and breath delivery. It incorporates the following circuits and interfaces:

Front Panel Interface – Reads the outputs from the front panel rotary control knob assembly and senses operation of the front panel keys.

Display Interface – Permits the processor to interface with the LCD driver PCB in order to control flat panel LCD display data.

AD / DC Converters – Provides 16 channels of A/D and D/A conversion as required to interface the microprocessor with associated analog circuits and components.

Ventilation Control – The controller PCB will interface with the Power PCB to control all aspects of ventilation. Will also receive feedback signals from the pressure transducers for proportional valve control, blender control, patient data display and alarm decisions.

Alarm Control – Based upon transducer feedback will make alarm decisions and signal the audible and visual alarms.

Pneumatic Safety Switch – As with the Power PCB, in the event of a technical error, the pneumatic safety switch will allow all power to be removed from the ventilators pneumatics in a single operation.

Power Processor Supervision - A watchdog circuit located on the controller PCB monitors at all times the operation of the power processor located on the Power PCB. If it anytime it determines there is a problem which could compromise safe ventilator operation, it will annunciate a technical error and place the unit in to ambient breathing mode.

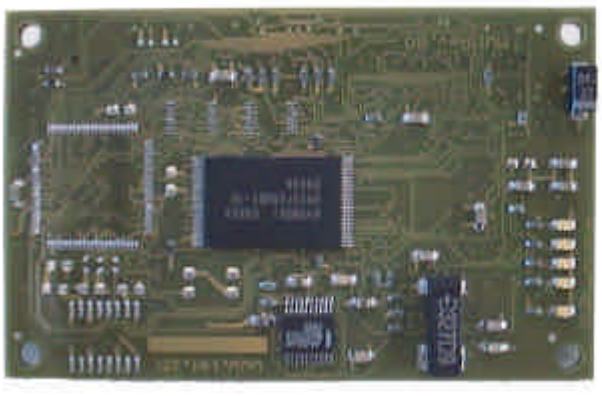

Fig 3-31, Processor PCB

3.4.9
Graphic PCB

The Graphic PCB is mounted inside the graphic module piggy backed to the reverse of the controller PCB. The graphic PCB drives the LCD display by means of an 8 bit parallel interface.

There are three separate versions of this PCB according to the type of device. The different versions appear similar but are not interchangeable.

Information to be displayed will be received from the main processor PCB, then processed locally into the required display format by means of an on board 16 bit micro controller.

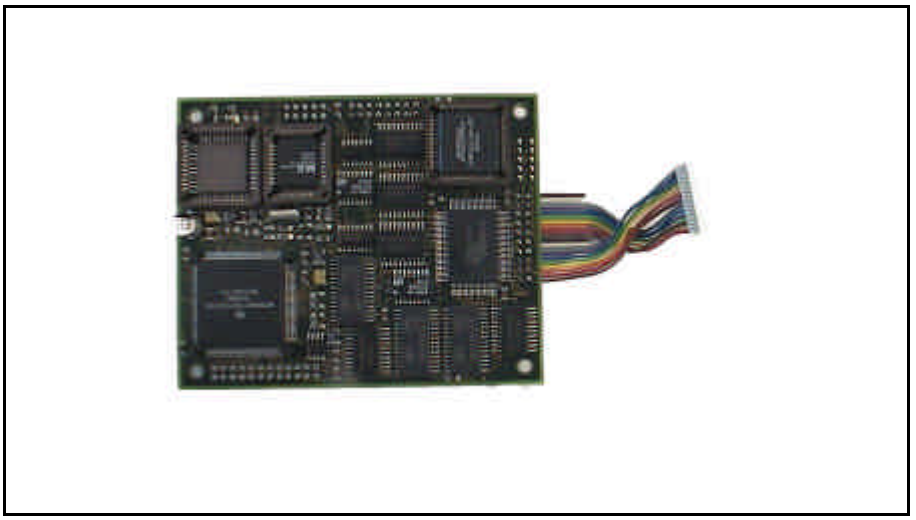

Fig 3-32, Graphic PCB

3.4.10
User Interface Display

A single flat panel colour LCD display is incorporated within the ventilators front panel in order to provide the operator with ventilator settings and patient data information.

Fig 3-33, LCD Display

The versions of the LCD panel are available according to the type of device. The Inspiration LS device uses a 12.1" TFT display panel, Inspiration ST uses a 6.4" full VGA display panel and Original Inspiration model uses a 5.7" ¼ VGA display panel.

As determined by operator keystrokes to the keypad the display will

provide numerical data, graphical data, settings data, special functions data and alarm setting data. Through other dedicated functions the display also permits the device to be configured, calibrated and adjusted for patient use.

Incorporated within the display assembly is a CFL backlight assembly. The LCD panels for LS/ST incorporate dual backlights where as the Original LCD panel incorporates a single backlight.

3.4.11 Lexan / Keypad

The lexan keypad incorporates a total of nine buttons which permit the operator to power the ventilator on/off and allow them select the active screen for display on the flat panel LCD display.

Additionally the keypad incorporates two embedded LED's which will be illuminated to indicate alarm conditions and that AC power is connected to the device.

Fig 3-34, Keypad Assembly

3.4.12 User Interface Rotary control knob

The operation of the rotary control knob permits the operator to select and change ventilation modes and settings. The device comprises of a 16 position rotary encoder permitting navigation and adjustment of ventilator settings.

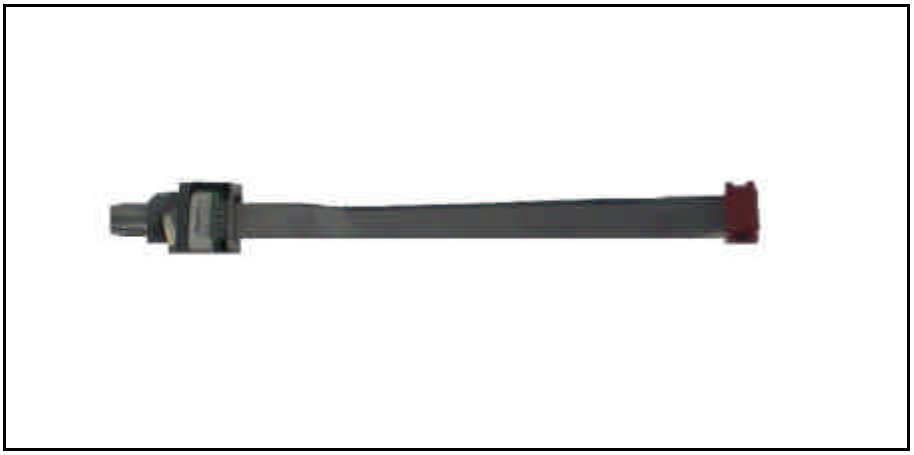

Fig 3-35, Rotary control knob Assembly

3.4.13
Mini Web Interface PCB

The Mini-Web Interface PCB is an optional device which when installed expands the communication capabilities of the Inspiration ventilator system.

The mini web PCB provides the user with a low cost monitoring system. The mini web will allow the connection of a number of Inspiration ventilator systems to a local network for monitoring by a central station or alternatively connection to a standalone monitor. All forms of ventilator data (settings, patient data, waveforms, alarms) are accessible for monitoring (but not for adjustment) through this media.

Additionally the mini web PCB opens up new possibilities in the area of servicing. Using the mini web PCB it is possible to remotely connect to the Inspiration over the internet to access its diagnostic functions eg. service data, statistics, diagnostic logs, alarm logs.

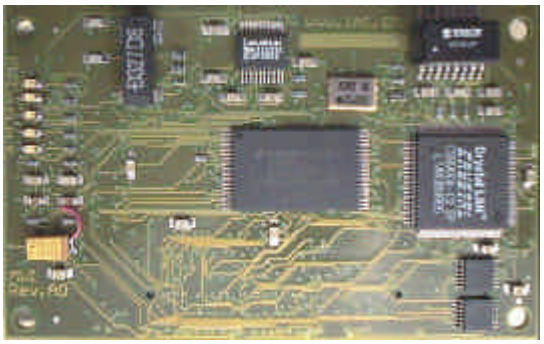

Fig 3-36, Mini Web Interface PCB

3.4.14
Inverter PCB (LS/ST Only)

The Inverter PCB is an additional component included in the LS/ST Inspiration models only. The Inverter PCB has a single 12VDC input from the Motherboard PCB. The Inverter PCB outputs dual supplies as required to drive the backlight on ST and LS Models. The Inverter PCB's for LS and ST models differ only in the positions of their output connections.

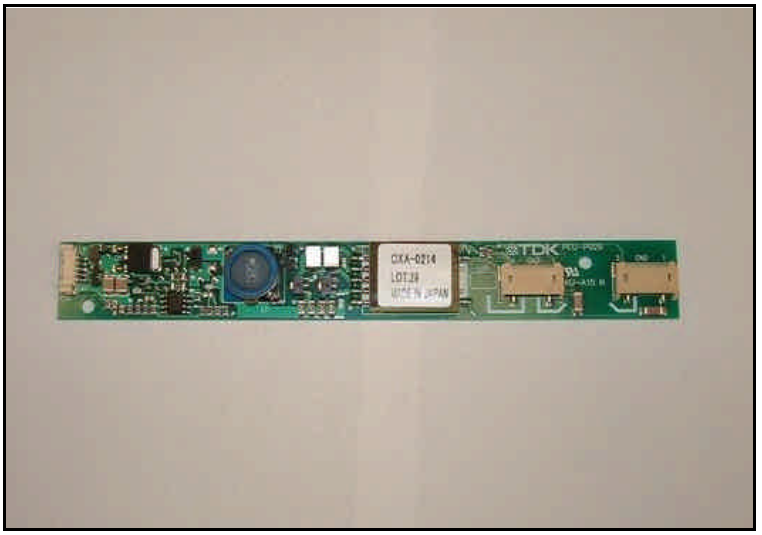

Fig 3-37, Inverter PCB

3.4.15
DC/DC Converter PCB (LS Only)

The DC/DC Converter PCB is used solely on the Inspiration LS model. The DC/DC Converter has a single 5VDC input which is converted to 3.3VDC in order to drive the 12.1 TFT display used in the LS Model.

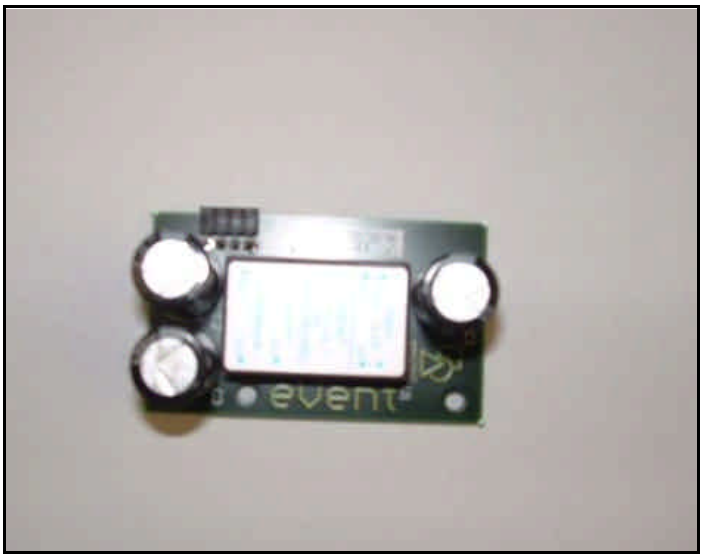

Fig 3-38, DC-DC Converter PCB

4. Self-Test & Configuration Screens

4.1 Introduction

This section of the Inspiration Series Ventilator service manual provides the user with a detailed description of the ventilators many self testing functions and user configuration screens. Some troubleshooting information directly related to these testing areas is added for convenience at each stage.

4.2 Power On Self Test (POST)

Power on self-test or POST is performed each time the ventilator is powered on in order to determine whether the device is in a fully functional condition. The POST is performed after switch on whilst the pre start-up screen, characterised by eVent company logo and/or progress bar, is visible on the LCD display (Fig 4.1).

The following areas are verified during the running of each Power On Self Test:

- POST 1: External RAM (1 MB)
- POST 2: Internal Processor RAM (2 kB)
- POST 3: Correctness Of Used ROM on the Flash
- POST 4: Checks safety zones of RAM (eg. Between stack and variables)
- POST 5: Checks the integrity of NVRAM data, A/D converter initialisation, Integrity of EEPROM's

Generally in the event of an error being detected during the first 4 sections of Power On Self Test the progress bar on the pre start-up screen will continue to the end and then stall. At this time the audible alarm will sound a continuous tone.

In the event of an error being detected during the last section of Power On Self Test, the unit will revert to the normal start up screen and report a technical fault specific to the triggering condition. The ventilator will sound the High priority audible alarm signal and the Alarm LED will flash red.

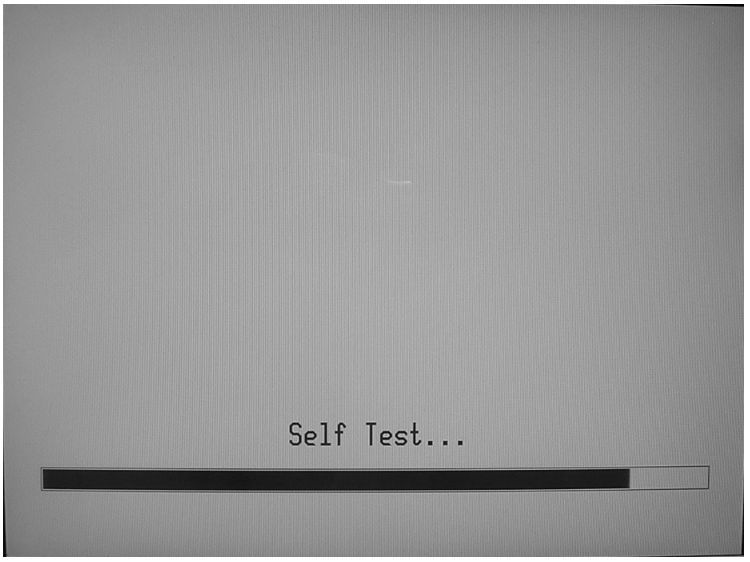

Fig 4.1, Power On Self Test Screen

4.2.1 POST Errors

In the event of a problem being detected during the self test routines the device, on completion of self test, will report an error code specific to the triggering condition.

The respective 'Technical Fault' error codes, a definition there of, along with possible steps for resolution are listed in the table below:

TF01 – Technical Fault	Configuration EEPROM memory defective	1. Replace Controller PCB.
TF02 – Technical Fault	Configuration EEPROM memory defective	1. Replace Sensor PCB.
TF03 – Technical Fault	Pressure Sensor Gain not valid Sensor PCB EEPROM	1. Perform re-zero of all pressure transducers, Fab Test 5 2. Perform temperature drift adjustment, Fab Test 12. 3. Replace Sensor PCB.
TF04 – Technical Fault	Configuration EEPROM memory defective	1. Replace Power PCB.
TF05 – Technical Fault	NVRAM Defective	1. Perform Checksum test on NVRAM, Fab Test 3 2. Clear & Test NVRAM and fully recalibrate the device. 3. Replace Controller PCB.
TF06 – Technical Fault	Log Book data not valid in NVRAM	1. Clear Log Book. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Controller PCB.
TF07 – Technical Fault	Pressure sensor offsets not valid in NVRAM	1. Perform rezero of all pressure transducers. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Sensor PCB. 4. Replace Controller
TF08 – Technical Fault	Internal Flow Sensor data in NVRAM not valid	1. Recalibrate internal flow sensor. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Controller PCB.
TF09 – Technical Fault	Altitude Compensation data in NVRAM not valid.	1. Set appropriate altitude compensation value.
TF10 – Technical Fault	Program ROM Defective	1. Replace Processor PCB.
TF11 – Technical Fault	PIC Version Check	1. Ensure that Power and system software are at compatible revisions. 2. Replace Power PCB.
TF12 – Technical Fault	Data not valid from ADC1	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.

TF13 – Technical Fault	Data not valid from ADC2	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF14 – Technical Fault	Difference of reference voltage OOR ADC1/2	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF15 – Technical Fault	Reference Voltage on ADC1 Out Of Range	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF16 – Technical Fault	Reference Voltage on ADC2 Out of Range	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF17 – Technical Fault	+5v Supply Voltage Out of Range	1.Replace Power PCB
TF18 – Technical Fault	Software Stack Corruption	1. Re-install system software. 2.Replace Processor PCB
TF19 – Technical Fault	Communication with PIC processor dead	1. Verfiy security of all ribbon connectors and cabling to pneumatics. 2. Reset power processer (LS/ST) 3. Replace Power PCB. 4. Replace Processor PCB. 5. Replace Controller PCB.
TF20 – Technical Fault	Value of pressure sensor P2 out of range	1. Perform re-zero of all pressure transducers. 2. Replace Sensor PCB.
TF21 – Technical Fault	Value of pressure sensor dP2 out of range	1. Perform re-zero of all pressure transducers. 2. Replace Sensor PCB.
TF22 – Technical Fault	Not Used	Not Used
TF23 – Technical Fault	Not Used	Not Used
TF24 – Technical Fault	Software Tasks Corruption	1.Replace Processor PCB
TF25 – Technical Fault	Software Tasks Overflow	1.Replace Processor PCB
TF26 – Technical Fault	NVRAM wrong checksum	1.Clear and test NVRAM then recalibrate device. 2.Replace Controller PCB.

TF27 – Technical Fault	PV1 valve data not valid in NVRAM	1.Perform calibration of PV1. 2.Clear and test NVRAM then recalibrate device. 3.Replace Controller PCB.
TF28 – Technical Fault	Difference between temperature sensors out of range.	1.Access Fab Test 2 and verify reading from temperature sensors. 2.Replace Sensor PCB 3.Replace Power PCB

4.3 Self Tests

The Self test and calibration routines of the Inspiration Ventilator system may be accessed through the normal start up screen. On powering the ventilator on the start up screen (Fig 4-2) will offer a CALIBRATIONS option.

Using the rotary control knob knob select the calibration option in order to access the self testing functions.

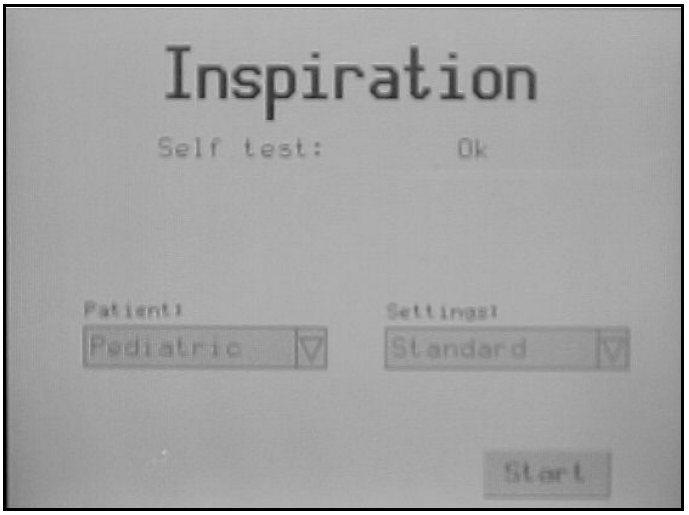

Fig 4-2, Start Up Screen

Fig 4-3 below shows the user calibrations screen. The calibration screen will permit the operator to run a number of self test and calibration routines in order to configure the device for patient use. The calibration routines offered are as follows:

- FIO2 Sensor Calibration
- Proximal Flow Sensor Calibration
- System Test – Leak Test

A detailed description for each of these calibration routines is defined in the following paragraphs.

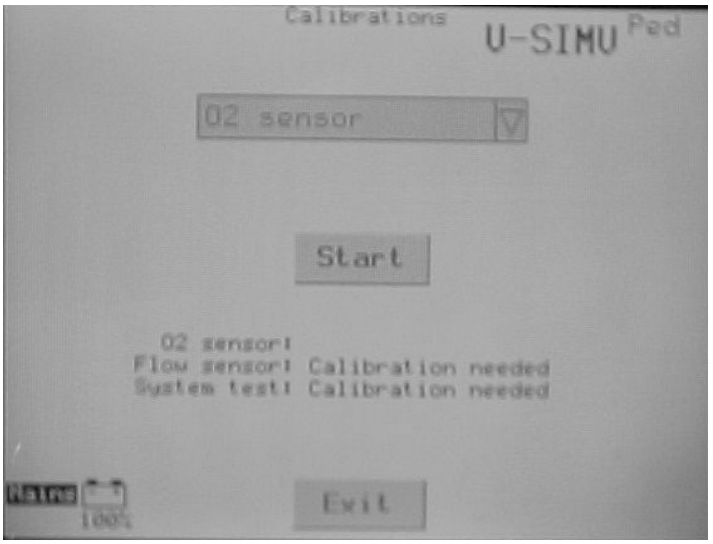

Fig 4-3, User Calibrations Screen

4.3.1 System Leak Test

The system leak test is used in order to verify the integrity of the patient tubing system components. Running the test will allow the operator to quantify and eliminate any leakage from the patient tubing system prior to clinical patient use.

In addition to leakage the system test will also measure the total compliance of the patient tubing system. The measured system compliance factor will then be used to compensate volume delivery on a breath by breath basis in order to ensure accurate volume delivery.

On commencing system test the ventilator will firstly exercise the inspiratory valve PV1 in order to empty the gas reservoir

On completion the device will ensure that the reservoir is adequately charged, if necessary the internal compressor will be started to charge the system (this will take approximately 10 seconds). With zero flow through the patient system transducer dP2 will be zeroed.

When ready the device will prompt the operator to 'Block Wye'. Once acknowledged a flow of 6 lpm will be delivered into the patient tubing in order to pressurise the system. Once the system pressure has reached 10cmH2O compliance and flow detection will be started. System will be pressurised up to a maximum of 50cmH2O after which compliance and flow detection will be stopped.

The device will allow 1 second for the system pressure to stabilise, and will then hold the system closed (PV1 and PV2 fully closed) for a further period of 4 seconds in order to monitor the pressure drop. Pass or fail status will be reported along with the compliance factor.

Note: System test may be performed using either external gas sources or the internal compressor system.

In order to run system leak test the following procedure should be followed:

- Attach the complete patient tubing system, including proximal sensor, to the ventilator.
- Using the rotary control knob select System Test from the pull

down calibration menu.

- When ready select 'Start' in order to commence the test procedure.
- The initial series of tests require the wye piece be left open.
- After a brief pause the device will prompt the operator to 'Block Wye', do so using either a sealing bung or similar device.
- On completion of the test the device will report a pass as 'OK' accompanied by leakage rate, a failure will be reported with a specific error number to prompt further investigation. A full listing of the error codes and appropriate troubleshooting steps is provided at the back of this section.
- System compliance will be displayed at the bottom of the calibration screen and will be expressed as volume required per unit of system pressure.

4.3.2 Proximal Flow Sensor Calibration

The proximal flow sensor calibration is used by the operator in order to define the characteristics of the proximal sensor prior to use. The calibration values will be stored in NVRAM and used during operation to ensure accurate measurement of exhaled tidal volume (Vte).

On commencing system test the ventilator will firstly exercise the inspiratory valve PV1 in order to empty the gas reservoir

On commencing proximal sensor calibration, with zero flow through the delivery system, the internal transducers dP2 and P2, and the proximal transducers dP3 and P3, will all be zeroed.

The device will initially deliver a flow of 30 lpm through the patient system and proximal sensor. The device will record the differential pressure and resulting reference voltage at dP3 and determine the gain. The device will determine from the gain from it whether an adult or infant sensor is connected.

If an infant sensor is connected the device will pass a 6 lpm flow through the patient system and proximal sensor. If an adult sensor is connected the device will pass a 10 lpm flow through the patient system and proximal sensor. The differential pressure and resulting reference voltage at dP3 will be recorded and the gain determined.

The offset and gain data will be stored in NVRAM and used as a look up table during operation to ensure accurate monitoring of exhaled tidal volume (Vte).

As a final step the device will prompt the operator to 'Block wye' then pressurize the system briefly to 30 mbar. This step provides an offset compensation for the proximal sensing system.

Note: Due to the flow requirements of the calibration at least one high pressure gas source MUST be available and connected to the device.

Proximal flow sensor calibration may be run as follows:

- Attach the complete patient tubing system, including proximal sensor, to the ventilator.

- Using the rotary control knob select ‘Proximal Sensor’ from the pull down calibration menu.
- When ready select ‘Start’ in order to commence the test procedure.
- The initial series of tests require the wye piece be left open.
- After brief pause the device will commence the calibration steps as described above.
- After the main series of tests have been successfully performed the device will prompt the user to ‘Block Wye’ in order to complete the final calibration step.
- On completion of the test the device will report a pass as ‘OK’, a failure will be reported with a specific error number to prompt further investigation. A full listing of the error codes and appropriate troubleshooting steps is provided at the back of this section.

4.3.3 O2 Sensor Calibration

The Oxygen sensor calibration will permit the operator to perform a calibration of the integral O2 measurement system prior to use.

The device will perform a 2 point calibration procedure. PV1 will be opened during the calibration to deliver a flow of 30 lpm, and ensure constant draw from the reservoir.

The reservoir will be replenished initially with 100% oxygen, during which the O2 sensor will be monitored for a stable reading. Once a stable reading has been acquired the O2 sensor gain will be recorded and stored in NVRAM.

With 100% calibration completed the flow will be reduced to 21% and the reservoir will then be replenished with 21% oxygen and the sequence will be repeated.

Note: Due to the gas requirements of the Oxygen sensor calibration, high pressure Oxygen supply plus an air source (high pressure or internal compressor) must be connected and available.

Oxygen sensor calibration may be run as follows:

- Using the rotary control knob select ‘Oxygen’ from the available calibrations menu.
- When ready select ‘Start’ in order to commence the test procedure.
- The device will run the 2 point calibration automatically and report an overall pass as ‘OK’ or a failure with a specific error number to prompt further investigation.

4.3.4 User Calibration Errors

On completion of each of the self test routines the device will report a pass or fail status. In the event of a failure of any test the device will report a specific error number indicating the nature of the problem.

The respective error codes, a definition there of, and possible steps for resolution are listed in the table below:

System Leak Test		
Error 6 – Pressure Drop	Excessive Pressure Drop During System Test	1. Ensure closed patient system. 2. Run system test with single tubing limb connect between outlet & exhalation cover. 3. Remove system tubing and verify flow from PV1 4. Perform internal leakage test. 5. Replace Sensor PCB
Error 7 – Pressure Rise	Excessive Pressure Increase During System Test	1. Forward leak through PV1 valve. 2. Forward leak through Solenoid 4 if nebulizer is connected. 3. Replace Sensor PCB.
Error 8 – Max Time To Pressure	Unable To Adequately Pressurize Patient System	1. Ensure closed patient system. 2. Run system test with single tubing limb connect between outlet & exhalation cover. 3. Remove system tubing and verify flow from PV1 4. Perform internal leakage test. 5. Replace Sensor PCB
Error 10 – Deviation High	Flow At Transducer dP2 Out Of Range	1. Verify internal flow sensor calibration, recalibrate as necessary.
Error 11 – Error Emptying Tank	Tank Pressure Remains Above 100mbar	1. Ensure that patient wye is open at the beginning of system test. 2. Verify that PV1 is opening and flow is evident from to patient port. 3. Replace Inspiratory Valve PV1 4. Verify no leakage through blender system.
Flow Sensor Calibration		
Error 12 – High Pressure	Pressure Out Of Range	1. Ensure that the proximal sensor is connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Verify internal flow sensor calibration, recalibrate as necessary. 4. Verify PV1 calibration, recalibrate as necessary.
Error 13 – Deviation High	Zero Adjustment dP2	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.

Error 14 – Deviation High	Zero Adjustment dP3	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.
Error 15 – Deviation High	Zero Adjustment P3	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.
Error 16 – Deviation High	Differential pressure too low @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 17 – Deviation High	Differential pressure between Adult / Infant limits @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 18 – Deviation High	Differential pressure too high @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 19 – Deviation High	Differential pressure too low @ low flow level	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB

Error 20 – Deviation High	Differential pressure too high @ low flow level	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 21 – Deviation High	Coefficient (a) too low	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 22 – Deviation High	Coefficient (a) too high	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 23 – Deviation High	Coefficient (b) too low	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB

Error 24 – Deviation High	Coefficient (b) too high	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 25 – Saving Data	NVRAM Damaged	1 Replace proximal sensor 2.Perform NVRAM test 3.Clear & Test NVRAM, recalibrate device. 4. Replace controller PCB
Error 26 – Emptying Tank	Error Emptying Tank	1. Ensure that patient wye is open at the beginning of system test. 2. Verify that PV1 is opening and flow is evident from to patient port. 3. Replace Inspiratory Valve PV1 4. Verify no leakage through blender system.
Error 27 – Low Pressure	Pressure P2 < 15 mbar	1. Ensure that that the flow sensor outlet is blocked during compensation test. 2. Replace proximal flow sensor 3. Perform calibration of proportion valve PV1.
Error 28 – High Pressure	Pressure P2 > 40 mbar	1. Replace proximal flow sensor 2. Perform calibration of proportion valve PV1.
Oxygen Sensor		
Error 2 – Saving Data	NVRAM Damaged.	1.Replace O2 Sensor 2.Perform NVRAM test 3.Clear & Test NVRAM, recalibrate device. 4. Replace controller PCB
Error 3 – Deviation High	Error during calibration at 100% setting.	1. Ensure O2 supply is connected and adequate flow available. 2. Ensure O2 Sensor connected correctly. 3. Replace O2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor PCB. 6. Replace O2 Sensor interface block.

Error 4 – Deviation High	Error during calibration at 21% setting.	1. Ensure Air supply is connected and that adequate flow is available, or that internal compressor is available and running. 2. Ensure O2 Sensor connected correctly. 3. Replace O2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor PCB. 6. Replace O2 Sensor interface block.
Error 8 – Sensor Not Available	Oxygen sensor is not available for calibration.	1. Enter configuration screen 1 and ensure that the oxygen sensor is enabled.
Error 9 – Oxygen Not Available	Oxygen supply not available for calibration	1. Ensure Oxygen supply is connected and that adequate flow is available. 2. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 3. Confirm operation of the oxygen solenoid, replace as necessary.

4.4 Configuration Mode

The user configuration menu permits the operator to configure the device as required for the patient or institutional application.

The user configuration screens may be accessed as follows:

With the device switched off press and hold the <Special> key first, then press and hold in the <ON/OFF> key to switch on the device. On successful entry and completion of POST the configuration entry screen will be visible on the screen.

Fig 4-4, Configuration Entry Sequence

4.4.1 Configuration Mode Entry

With the configuration start up screen visible, select 'Config' from the available options using the rotary control knob knob.

Once 'Config' has been selected the code entry screen (Fig 4-) will be visible on the device. At the code entry screen select the 'Code' window using the rotary control knob knob and adjust to display the default entry code of '1998'.

On completion, de-select the window using rotary control knob knob once more, then select 'OK' to proceed to the full configuration mode.

Note: Configuration screen 2 will permit an operator defined entry code to be set for future use.

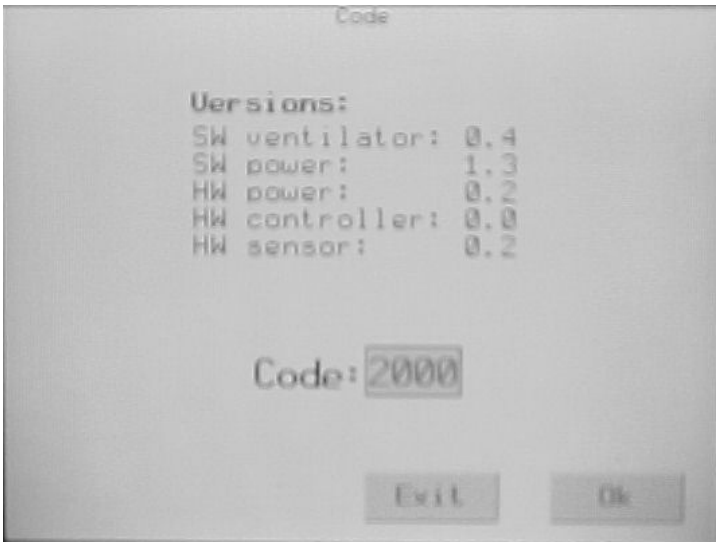

Fig 4-5, Code Entry Screen

4.4.2 Configuration Screen 1

Configuration screen 1 will permit the operator to configure attributes specific to how the ventilator will operate and be monitored during normal operation. The attributes which may be configured are as follows:

Proximal Flow Sensor – Allows the operator to switch proximal flow and pressure sensing On or Off. With the proximal sensor selected 'On' monitored patient data will be derived from the measurements taken at the proximal sensor. Additionally flow triggering is available.

With the proximal sensor selected 'Off' monitored patient data will be derived from measurements taken at the internal sensors. In this condition Vte, ExpMinVol and Rexp may not be monitored and flow triggering is not available.

O2 Sensor – Allows the operator to switch Oxygen monitoring and associated alarms On or Off. Once activated, the oxygen sensor must be calibrated.

Compressor Backup – Allows the operator to switch compressor backup On or Off as required. With the compressor 'On' in the event of an Air supply failure the compressor will automatically switch on.

Buzzer – Allows the operator to adjust the audible alarm intensity up or down on a scale of 20-100% full volume.

Philosophy – Allows the operator to configure the philosophy which will govern the timing of breath delivery during normal operation of the device. Available selections are European or US.

With European philosophy set breath timing will be governed by the operator setting of I:E ratio for both volume and pressure controlled Breaths.

With US philosophy set, breath timing will be governed by the operator setting of Peak Flow for volume control, and Inspiratory Time for pressure control.

Altitude Compensation – Allows the operator to set the altitude at which the device is being operated. Will be used by the device to compensate measurements for pressure.

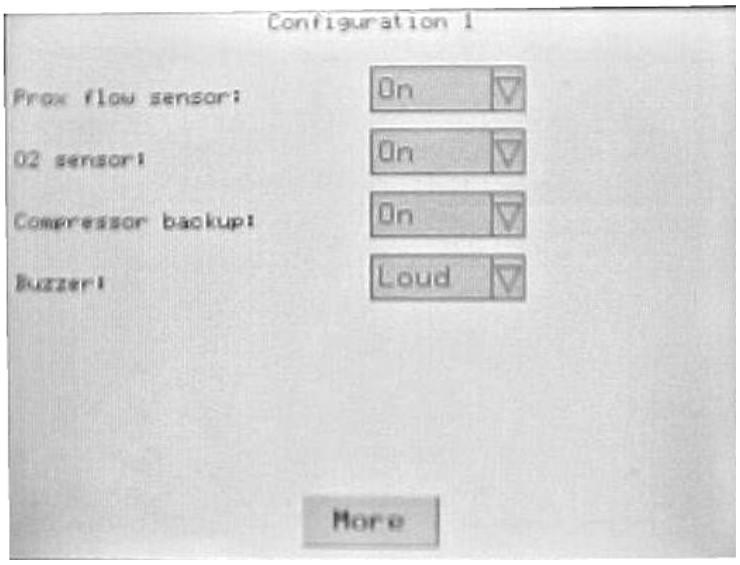

Fig 4-6, Configuration Screen 1

4.4.3 Configuration Screen 2

Configuration screen 2 will permit the operator to configure some of the more general attributes of the ventilator. The attributes which may be configured are as follows:

Language – Allows the operator to configure the operating language of the ventilator from the available selections:

- English
- French
- German
- Italian
- Nemet (Hungarian)
- Polish
- Portuguese
- Russian
- Spanish
- Japanese
- Chinese

Time – Allows the operator to set the current time stored by the device. Correct setting of the time will ensure the accuracy of records stored within the alarm and technical error logs.

Date – Allows the operator to set the current date stored by the device. Correct setting of the date will ensure the accuracy of records stored within the alarm and technical error logs.

Service Code – Allows the operator to define a 4 digit code for use on entry of the configuration menu. The default code of '1998' is always available as a backup.

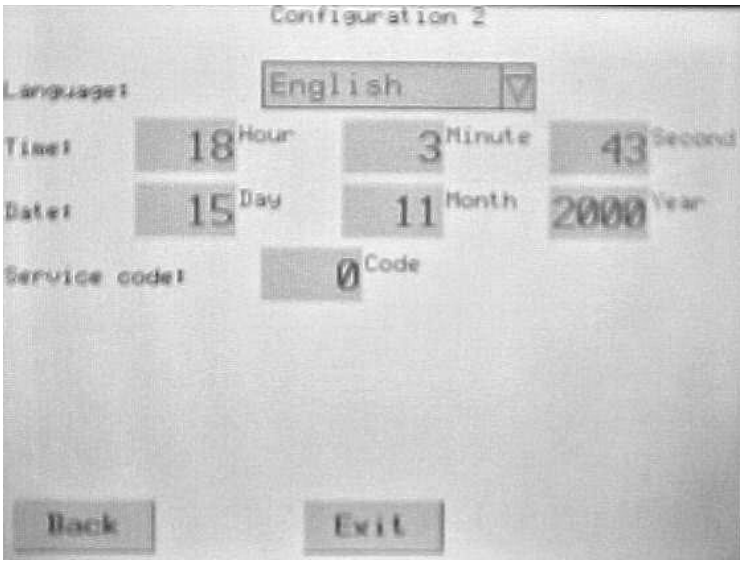

Fig 4-7, Configuration Screen 2

4.4.4 Configuration Screen 3

Configuration screen 3 will permit the operator to configure specific attributes which allow data from the Mini-Web Interface (MWI) to be accessible via a local area network or direct PC connection.

NB. This screen will only be accessible if a device has the MWI hardware installed, along with all applicable MWI software files.

SW web server – Indicates the application software version currently installed to the mini-web interface PCB.

Mac address – Indicates defined Mac address for the mini-web interface. This may be required by network administrator to complete access through local area network.

IP address – Permits the user to assign the mini-web interface with an individual IP address required for local and LAN connection.

Subnet Mask – Permits the user to assign the mini-web interface with the subnet mask details required for local and LAN connection.

Default Gateway – Permits the user to assign the mini-web interface with gateway details required for local or LAN connection to the devices

Access Code – Permits the user to define a password to be used when making connection to the mini-web interface.

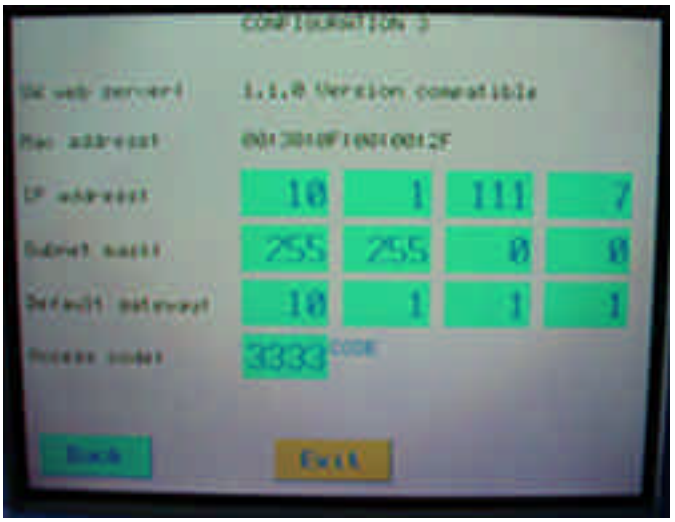

Fig 4-8, Configuration Screen 3

5. Service Mode / Fab Tests

5.1 Introduction

This section of the Inspiration series ventilator service manual is intended to provide the trained technician with details of how to access and use the fabrication screens as a means of testing and troubleshooting the system.

5.2 Accessing & Navigating Engineering Functions

Note : For reasons of patient safety service screens may not be entered while ventilation is in progress. If service screens must be accessed the patient must be removed from the ventilator, and the unit should be switched off.

The service screens are accessed by power firstly power cycling the ventilator. Immediately after the device has been switched the technician should simultaneously press <Man Insp> and <Nebulizer> keys (as shown in Fig 5-1) and the first technical screen will be displayed.

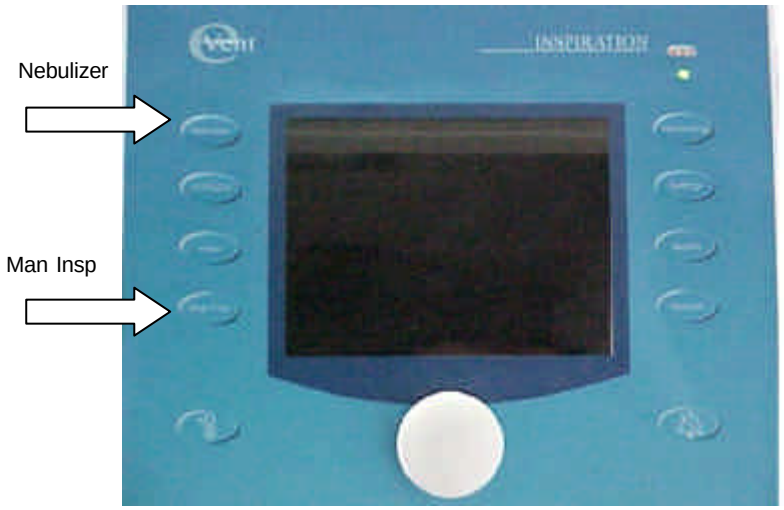

Fig 5-1, Accessing Service Functions

5.3 Technical Screens

There are a total of 13 screens within the service mode of the Inspiration ventilator (as detailed in the following section).

To move between the available screens the technician should select 'next' to move onto the next screen and 'previous' to move back to the previous screen.

5.3.1 Screen 1 Output Tests

Screen 1, Fab Test 1, (Fig 5-2) will allow the trained service technician to perform a manual check on a number of the circuits/components within the pneumatic and electronic systems.

Using this tool each of the pneumatic valves, and associated circuitry, within the system may be energised in order to confirm correct operation. When wishing to perform a test to a given pneumatic circuit the engineer should do the following:

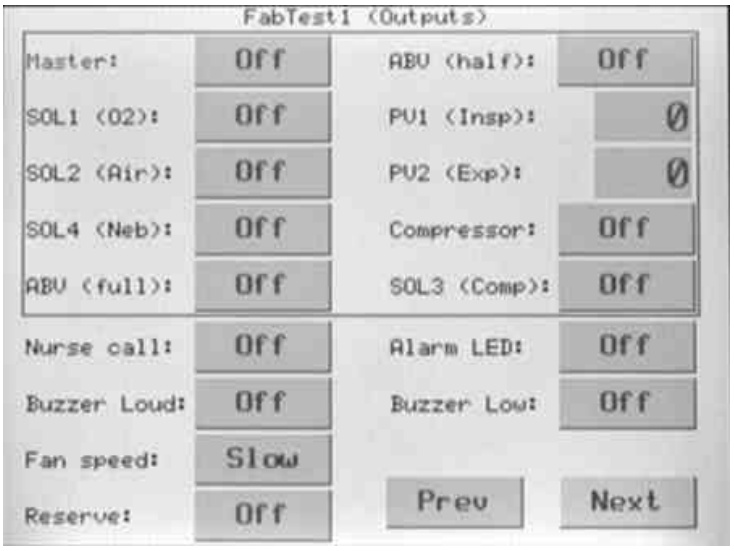

Fig 5-2, Technical Screen 1

- Using the rotary control knob navigate and select 'Master' then switch the circuit on. Note: Master must be enabled before any of the pneumatic valves may be energised.

- Once the master has been enabled, navigate and select the valve or combination of valves to be tested, then switch the circuit on. Note: Proportional valves, once selected, may be cycled through their full control range, 0-500 for PV1 and 0-1000 for PV2

- Once the circuit has been energised technician should observe the device for an appropriate response in order to determine whether it is operating normally.

- Once testing has been completed each of the circuits should once again be de-energised.

- In the same way the lower section of this screen will allow the technician to test a number of the electrical circuits. Once again the technician should navigate and select the appropriate function then observe for desired operation.

- The following circuits may be tested in this way:

Master	Pneumatic Master Valve Feed
SOL 1 (O2)	Blender Supply Valve O2 (SV1)
SOL 2 (Air)	Blender Supply Valve Air (SV2)
SOL 4 (Neb)	Nebulizer Supply Valve (SV4)
ABV (Full)	Ambient Breathing Valve (ABV)
ABV (Half)	
PV1 (Insp)	Delivery Proportional Valve (PV1)
PV2 (Exp)	Expiratory Proportional Valve (PV2)
Compressor	Compressor Pump (Comp)
SOL 3 (Comp)	Compressor Unloading Valve (SV3)
Nurse Call	Nurses Call Relay
Buzzer	On / Off
Buzzer Setting	0-100%
Alarm LED	Front Panel Alarm LED
Fan Speed	Cooling Fan Slow / Fast

5.3.2
Screen 2 Input Data

Screen 2, Fab Test 2, (Fig 5-3) will allow the trained service technician to observe the 16 channels of raw measured data being fed to the A/D converter. The viewable information includes raw data from the pressure transducers within the pneumatics along with values from a number of electronic circuits.

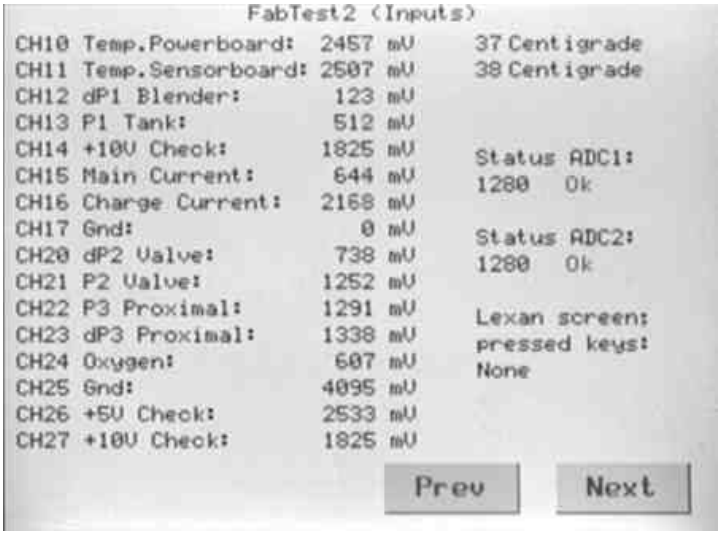

Fig 5-3, Technical Screen 2

The table provided below lists the A/D converter signals along with a more detailed description of each:

CH10	Temp Powerboard	Internal Temperature From Power PCB
CH11	Temp Sensorboard	Internal Temperature From Sensor PCB
CH12	dP1 Blender	Blender Flow Sensor FS1 / DP1
CH13	P1 Tank	Reservoir Pressure P1
CH14	+10v Check	10V Supply Monitor
CH15	Main Current	Main System Current
CH16	Charge Current	Battery Charging Current
CH17	GND	Ground
CH20	dP2 Valve	Delivery Flow Sensor FS2 / DP2
CH21	P2 Valve	Delivery Pressure Sensor P2
CH22	P3 Proximal	Proximal Airway Pressure P3
CH23	dP3 Proximal	Proximal Flow Sensor FS3 / DP3
CH24	Oxygen	O2 Sensor (OS)
CH25	Gnd	Ground
CH26	+5v Check	-5V Supply Monitor
CH27	+10v Check	+10V Supply Monitor

Additionally using this screen the operation of each of the front panel keys may be confirmed. This may be done simply by pressing the desired front panel key, then observing the appropriate area of the screen for the correct response (Fig 5.3).

Using Fab Test 2 allows the internal ventilator temperature, as measured on both Power PCB and Sensor PCB, to be reviewed.

5.3.3
Screen 3 – Peripheral Memories

Screen 3, Fab Test 3, (Fig 5-4) will allow the trained service technician to perform a check on installed software revisions and permit a check sum pattern test to be performed on various areas of EEPROM.

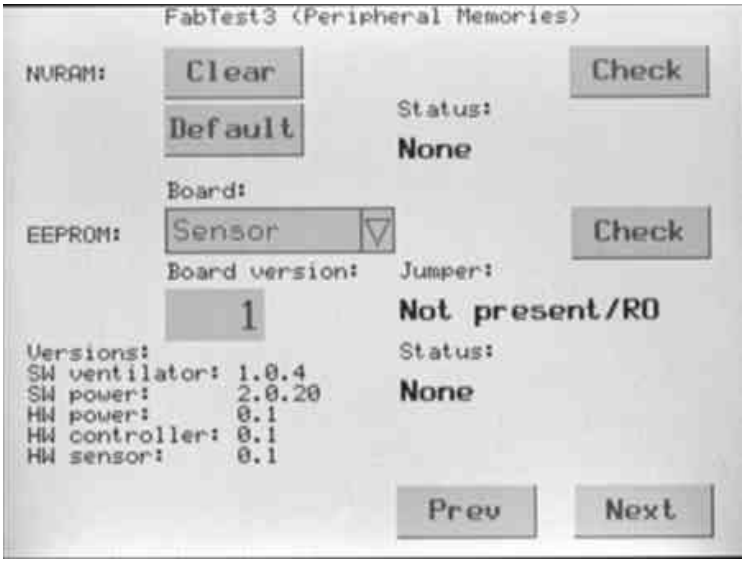

Fig 5-4, Technical Screen 3

Check NVRAM – Using this function will perform full checksum pattern test of the NVRAM device.

EEPROM Board – This function will reveal a pull down menu allowing the engineer to select which board will be available for test. The technician may select from the following:

- Sensor PCB
- Power PCB
- Processor PCB

Check EEPROM – Once the appropriate board has been selected this function may be used to perform a full checksum pattern test of its EEPROM devices.

Board Version – This function allows the revision of the selected PCB to be determined without need for physical inspection.

Jumper – This function allows the engineer to identify whether the selected PCB has any jumpers present without the need for physical inspection.

Versions – Allows the revisions for system and power software plus the hardware revisions of the three primary PCB's to be determined without the need for physical inspection.

5.3.4
Screen 4 - Power Interface Controller (PIC)

Screen 4, Fab Test 4, (Fig 5-5) allows the trained service technician to view data and values pertaining to the Power PCB, power processor and related areas:

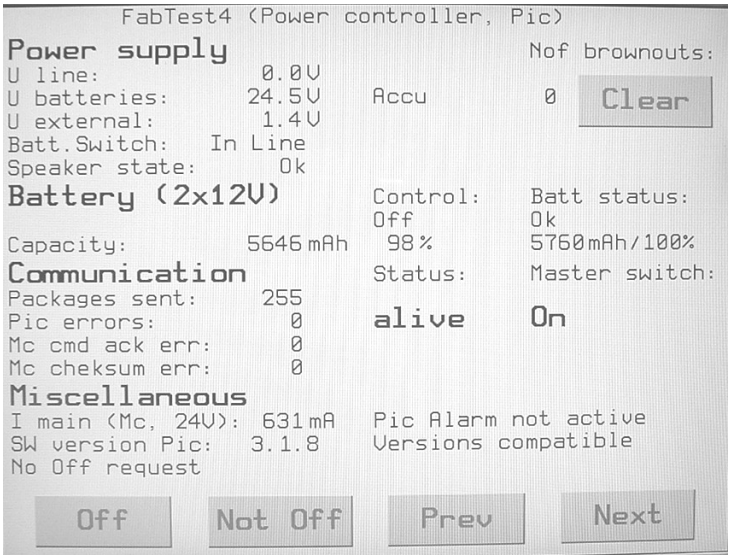

Fig 5-5, Technical Screen 4

Power Supply – This area of screen 6 will permit the service engineer to review the current power supply status. Measured values are available for the following:

- *Vline* – power supply voltage derived from line voltage
- *Vbatteries* – internal battery voltage
- Vexternal – external DC supply voltage

Additionally in this area of the screen the active power source status may be verified. The following values may displayed at any time:

- *Line* – AC power in use
- *Accu* – internal battery in use
- *External* – external DC supply in use

Battery (2 x 12v) – This area of the screen will permit the service engineer to view information pertaining to battery condition and charging status. The values available in this area are as follows:

- Battery Switch – Provides an indication of the status of the 2 battery circuits
- *Capacity* – Current battery capacity, as a value (mAh) and as a percentage of maximum capacity.
- *Control* – Indicates whether battery charging is active, 'ON' denotes battery being charged, 'OFF' denotes no charging.
- *Status* – Indicates whether battery is a function condition. 'OK' denotes battery OK and available for use or charging. 'OFFLINE' denotes battery which is damaged, disconnected or in a severely depleted condition.

Follows a brief table to illustrate how different combinations of values from the above parameters may be used to define the current condition of internal batteries and associated circuitry:

Switch	*Control*	*Status*	*Actual State*
In-Line	Off	OK	1. Internal battery in use
Off	Off	OK	1. Internal battery fully charged
Split	On	OK	1. Internal battery on charge
Off	Off	Damaged	1. Internal battery voltage <10VDC. 2. Battery charging circuit damaged.
Off	Off	Offline	1. Internal batteries not connected. 2. Internal batteries incorrectly connected. 3. Internal battery shorted 4. Replace Power PCB
Off	Off	Shorted	1. Battery charging circuit damaged.

Communications – This area of the screen will permit the service engineer to view information pertaining to communications between the main system processor (Mc) and the power interface controller (Pic). The information available in this areas is as follows:

- *Packages Sent* – Incremental number denoting the number of data packages exchanged between the power processor (PIC) containing power status information..
- *Pic Errors* – Incremental number denoting the number of communication errors detected by the power processor (PIC).
- *Mc cmd ack err* – Incremental number denoting the number package acknowledgement errors detected by the main microprocessor. PIC did not send an acknowledgement for a package sent by main processor.
- *Mc checksum err* – Incremental number denoting the number of checksum errors detected by the main processor. Main processor has received a package with a bad checksum.
- *Status* – Indicates the status of communications between the Pic and the Mc.
- *Master Switch* – Indicates the condition of the pneumatic master control switch.

Miscellaneous – This area of the screen permits the service engineer to review miscellaneous information pertaining the current condition of the Power control system. The information available in this area is as follows:

- *I main (Mc, 24v)* – Indicates the main system current draw measured at the Mc.
- *SW version Pic* – Displays the current SW revision for the Pic.
- *Off request* – Indicates whether there are an pending off requests.

5.3.5
Screen 5 Sensor Adjustment

Screen 5, Fab Test 5, (Fig 5-6) will allow the trained service technician to perform a zero calibration for each of the pneumatic pressure transducers. In order to perform this calibration to any given pressure transducer the technician should use the process below.

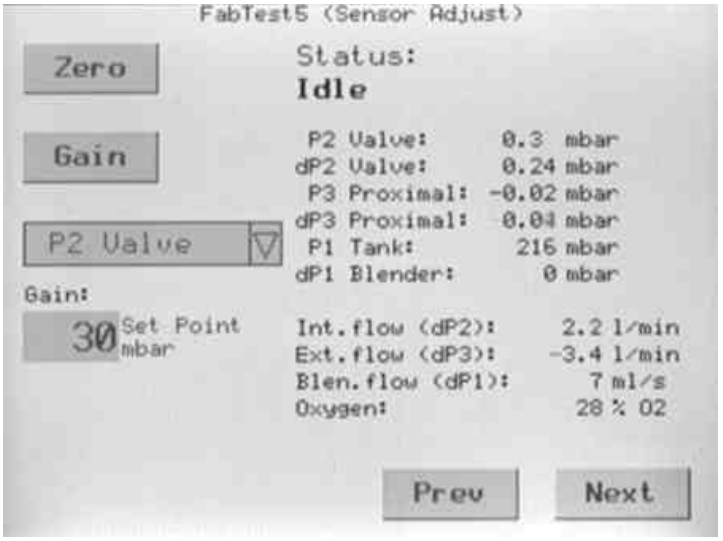

Fig 5-6, Technical Screen 5

Zero calibration is required as part of the installation process for the device, following replacement of the Sensor PCB (F710512), Motherboard PCB (F-720510), Control PCB (F-710510) or when performance testing indicates that it may be necessary.

Note: Before proceeding with the zero process all pressure, including tank pressure, should be removed from the system and patient tubing and proximal sensor should be disconnected.

- Using the rotary control knob locate and select sensor selection menu, shown in default as ‘P2 Valve’. A pull down menu will appear allowing the appropriate sensor to be selected. Select As Applicable.

- Having selected the sensor, and select ‘Zero’ using the rotary control knob, once this has been done zero calibration will be performed automatically.

When performing Oxygen sensor zero, with system software of 3.2.12 and below, the sensor harness must first be disconnected. Software versions above this level allow the zero to be performed at 21% and without disconnection.

5.3.6
Screen 6 Sensor Adjustment Values

Screen 6, Fab Test 6, (Fig 5-7) will allow the trained service technician to view zero and gain calibration values for transducers measuring blender pressure / flow, internal pressure / flow, proximal pressure / flow and for the Oxygen measurement cell. Values are displayed for the following:

- *P1 Tank* – Internal Tank Pressure
- *DP1 Blender* – Blender Flow Transducer
- *P2 Valve* – Internal Pressure Transducer
- *DP2 Valve* – Internal Flow Transducer
- *P3 Proximal* – Proximal Pressure Transducer
- *DP3 Proximal* – Proximal Flow Transducer
- *Oxygen* – O2 Measurement Cell

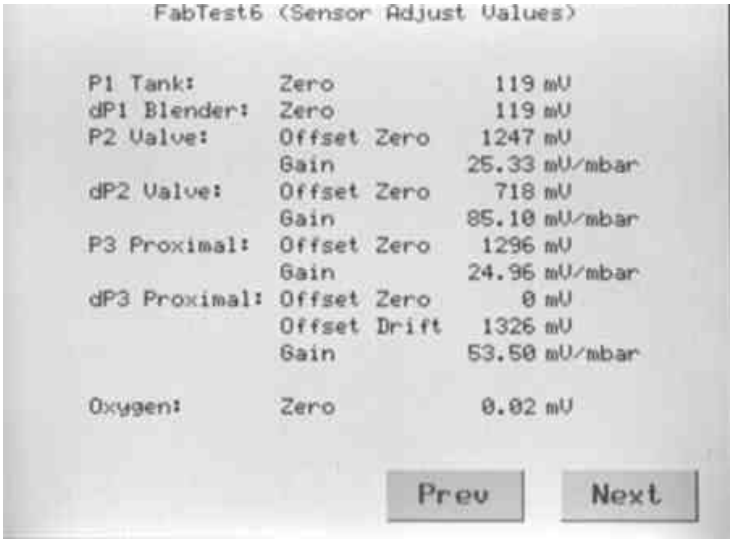

Fig 5-7, Technical Screen 6

5.3.7
Screen 7 Internal Flow Sensor Calibration

Screen 7, Fab Test 7, (Fig 5-8) will allow the trained service technician to perform calibration of the Internal Flow Sensor (FS1) should it prove to be necessary.

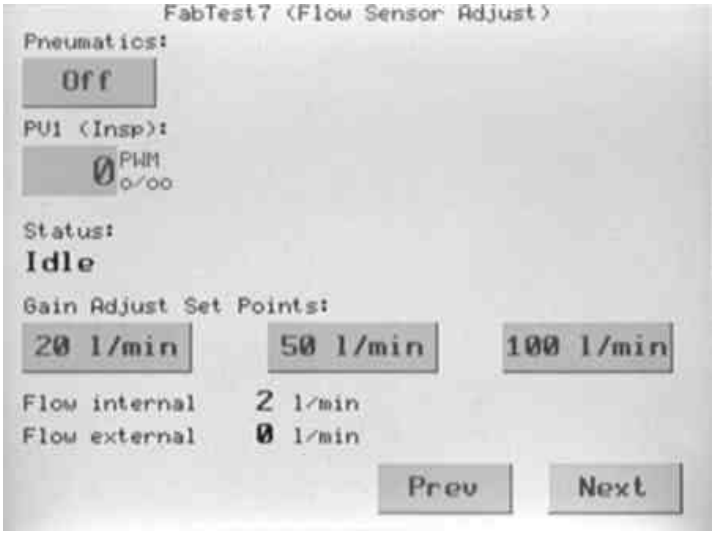

Fig 5-8, Technical Screen 7

Calibration of the Internal Flow Sensor will provide the valve controller

with a look up table for pressure signal (mV as measured @ transducer dP2) versus flow for use during normal breath delivery.

This calibration should be performed following replacement of the devices Internal flow sensor (F-910081), Motherboard PCB (F-720510), Control PCB (F-710510) or when performance testing indicates that it may be necessary.

To perform this operation a calibrated flow measurement device should be used. eVENT Medical recommends the use of its PF300 Flow Lab or equivalent measurement device. Test devices should be configured to measure Flow – Air in ATP mode. Only high pressure AIR should be used for this calibration process.

Note:
Prior to performing this calibration procedure ensure that transducer dP2 has been correctly zeroed using Fab Test 5.

- Connect an adjustable high-pressure AIR source to the ventilators air inlet with output initially set for zero..
- Attach calibrated flow measurement device (0-150 lpm) to the main patient connector using single smooth bore tubing limb.
- Using the rotary control knob select and switch on the 'Pneumatics'. This operation will enable pneumatics master switch and open the air blender valves.
- Using the rotary control knob knob select and adjust the value of PV1 to the fully open position '500'.
- Increase the supply pressure until a flow of 16 lpm ± 0.2 is observed on the flow measurement device.
- With 16 lpm flow present select the gain adjustment set point for 16 lpm. The device will perform a self-calibration and confirm when 16 lpm point has completed successfully.
- With 16 lpm calibration complete, increase the supply pressure once more until a flow of 50 lpm ± 0.5 is observed on the flow measurement device.
- With 50 lpm flow present select the gain adjustment set point for 50 lpm. The device will perform a self-calibration and confirm when 50 lpm point has completed successfully.
- With 50 lpm calibration complete, increase supply pressure once more until a flow of 100 lpm ± 1.0 is observed on the flow measurement device.
- With 100 lpm flow present select the gain adjustment set point for 100 lpm. The device will perform a self-calibration and confirm when 100 lpm point has completed successfully. Calibration is now complete.
- Disconnect the test flow meter from the main patient connector and adjust the gas pressure source back down to zero. Using rotary control knob select and adjust PV1 to read 0, select and switch off the pneumatics.

For reference purposes at the bottom of this screen a measurement of Flow internal (measured at FS2/dP2), and Flow external (measured at FS3/dP3 if connected) is provided.

5.3.8
Screen 8 Calibration Data

Screen 8, Fab Test 8, (Fig 5-9) will allow the trained service operative to view specific calibration values relating to the proximal and delivery flow sensors and to the Oxygen measurement cell.

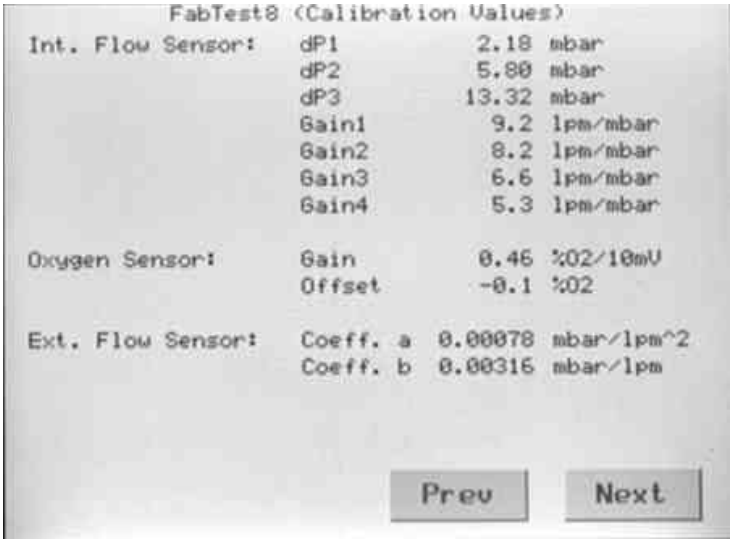

Fig 5-9, Technical Screen 8

Internal Flow Sensor – This function permits the service engineer to observe the differential pressure and associated gain for each of the flows defined during calibration (16, 50, 100 LPM).

O2 Sensor – This function permits the service engineer to observe the gain and offset values for the O2 measurement cell as determined during the O2 sensor calibration procedure.

Ext Flow Sensor – This function permits the service engineer to observe gain values for the proximal flow sensor resulting from its calibration relative to the delivery transducer.

5.3.9
Screen 9 PV1 Calibration Screen

Screen 9, Fab Test 9, (Fig 5-10) will allow the trained service technician to perform calibration of the Inspiratory Valve (PV1) should it prove to be necessary.

During the calibration we introduce an exact pressure (P1 tank) to the reservoir. The device will slowly increment the Inspiratory Valves PWM setting (PV1 (insp) PWM) until a flow of 1 lpm is measured at the Inspiratory Flow Sensor (Flow internal).

This process is repeated for 300, 800 and 1300 mbar respectively and the PWM settings for each are stored to NVRAM. Performing the calibration as we do at a low, medium and high pressure level will provide valve controller with a look up table for lift off signal across the normal pressure range for the reservoir, for use during normal breath delivery.

Calibration of PV1 must be performed following replacement of Inspiratory

valve PV1 (910021), Motherboard PCB (F-720510), Control PCB (F-710510) or when performance testing indicates that it may be necessary.

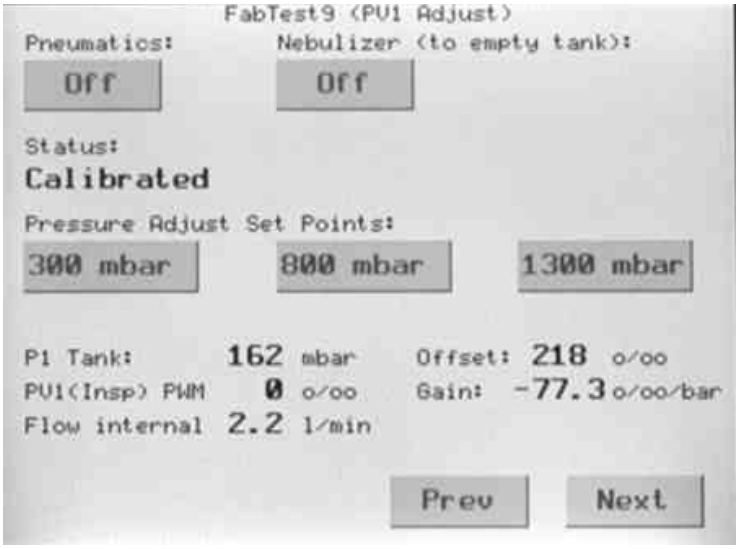

Fig 5-10, Technical Screen 9

Note:
Prior to performing this calibration procedure ensure that transducers P1 and dP2 have been correctly zeroed using Fab Test 5.

Should calibration of PV1 prove necessary the following procedure should be performed:

- With output set all the way off attach an adjustable high-pressure air source to the ventilator.
- Using the rotary control knob select and switch on the 'Pneumatics'. This operation will enable pneumatics and open the blender valves.
- Ensure the P1 tank display reads 0mbar ± 50mbar. If reading is outside of this range select Nebulizer 'ON' using the rotary control knob to relieve the tank pressure. When pressure is observed to be within acceptable range revert the Nebulizer to 'OFF' and continue with the calibration.
- Adjust the output of the high-pressure air source as necessary until a pressure of 300mbar ± 5mbar is observed at P1 Tank on screen.
- Using rotary control knob select 'pressure adjust set point' for 300mbar. Observe that PV1 PWM value is increased until such time that a flow of 1 lpm is detected by the internal flow sensor. Proceed only when the device confirms successful calibration at this level.
- When complete adjust the output of the high-pressure air source as necessary until a pressure of 800 mbar ± 10mbar is observed at P1 Tank on screen.
- Using rotary control knob select 'pressure adjust set point' for 800mbar. Observe that PV1 PWM value is increased until such

time that a flow of 1 lpm is detected by the internal flow sensor. Proceed only when the device confirms successful calibration at this level.

- When complete adjust the output of the high-pressure air source as necessary until a pressure of 1300 mbar ± 10mbar is observed at P1 Tank on screen.

- Using rotary control knob select 'pressure adjust set point' for 1300mbar. Observe that PV1 PWM value is increased until such time that a flow of 1 lpm is detected by the internal flow sensor.

- On successful completion of the calibration switch off the pneumatics and reduce output of high-pressure air source to 0.

5.3.10 *Screen 10 Blender Test*

Screen 10, Fab Test 10, (Fig 5-11) will allow the trained service technician to evaluate the function of the Internal blending system of the Inspiration ventilator. The following settings may be defined:

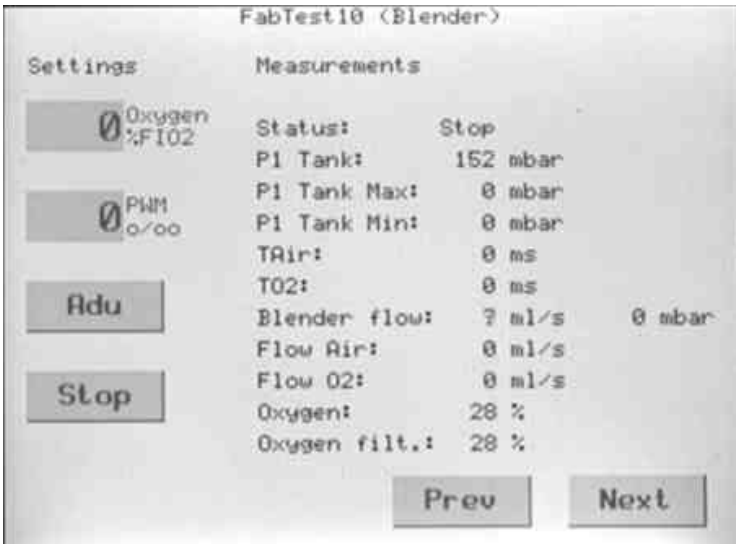

Fig 5-11, Technical Screen 10

- *Oxygen %FIO2* – Oxygen percentage to be delivered.
- *PWM o/oo* – Determines the level to which PV1 will be opened and hence Peak flow demand.
- *ADU* – This pull down menu allows settings for Adult (ADU), Paediatric (PED) and Infant (INF) to be selected in order to determine the maximum tank pressure.
- *Stop* – Allows ventilation to be commenced and stopped.

With the settings defined and in use the measurements area will allow the following values to be monitored:

- *Status* – Start/Stop according to whether ventilation is active.
- *P1 Tank* – Current system tank pressure.
- *P1 Tank Max* – Maximum system tank pressure
- *P1 Tank Min* – Minimum system tank pressure
- *TAir* – Activation time for Air supply valve SV2
- *TO2* – Activation time for O2 supply valve SV1

- *Blender Flow* – Flow measured at FS1/dP1
- *Flow Air* – Flow from SV2 as measured at FS1/dP2
- *Flow O2* – Flow from SV1 as measured at FS1/dP2
- *Oxygen* – O2% as measured at transducer
- *Oxygen filt* – O2% filtered signal

In order to use this function effectively the device should have 2 gas sources available, Air (or) Compressor and Oxygen.

5.3.11 ***Screen 11 Technical Log Screen***

Screen 11, Fab Test 11, (Fig 5-12) will allow the trained service technician to view cumulative and diagnostic data. The data available for this screen is as follows:

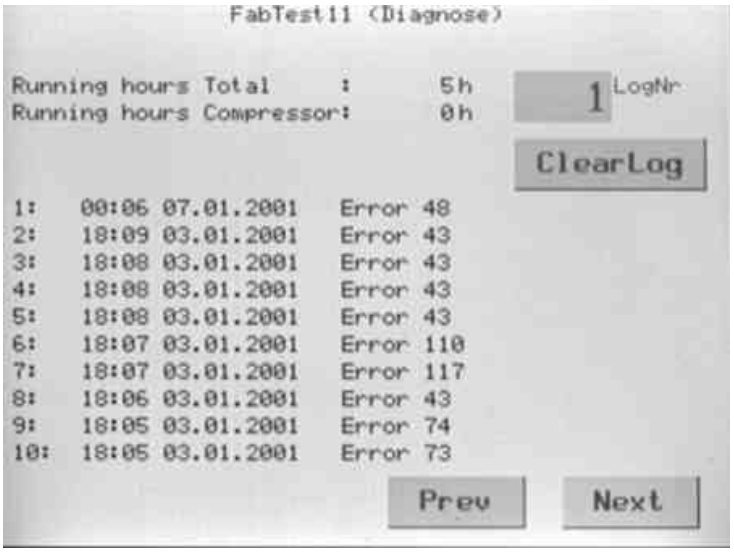

Fig 5-12, Technical Screen 11

Running hours Total – This function will allow the service engineer to determine the total elapsed running hours of the Inspiration system. Total running hours should be consulted when determining requirements for preventive maintenance and should be recorded on the service report whenever work is performed.

Running Hours Comp – This function will allow the service engineer to determine the total running hours of the integral compressor system. Compressor hours should be recorded on the service report whenever work is performed.

Error Logs – Selecting the 'Log Nr' function will permit the service engineer to scroll through the ventilators error log. This log will store up to 229 events including technical errors, high priority and medium priority alarms. Technical errors will be highlighted with an asterix (*) following the alarm number. By turning the rotary control knob the engineer may view the entire contents of the log. Errors will appear in the following form:

A: BB:BB CC.CC.CCCC ERROR XX

A: = Position within the event log (where 1 is the most recent event)
B: = Time the event occurred in 24 hour format
C: = Date on which the event occurred
XX = Two digit number representing the type of even which occurred

For a detailed description of each error and associated troubleshooting data please refer to section 7 of this service manual.

5.3.12 Temp Drift Compensation

Technical Screen 12 (Fig 5-13) will allow the trained service technician to perform a temperature drift compensation for the differential pressure transducers dP2 (Internal flow sensor) and dP3 (proximal flow sensor).

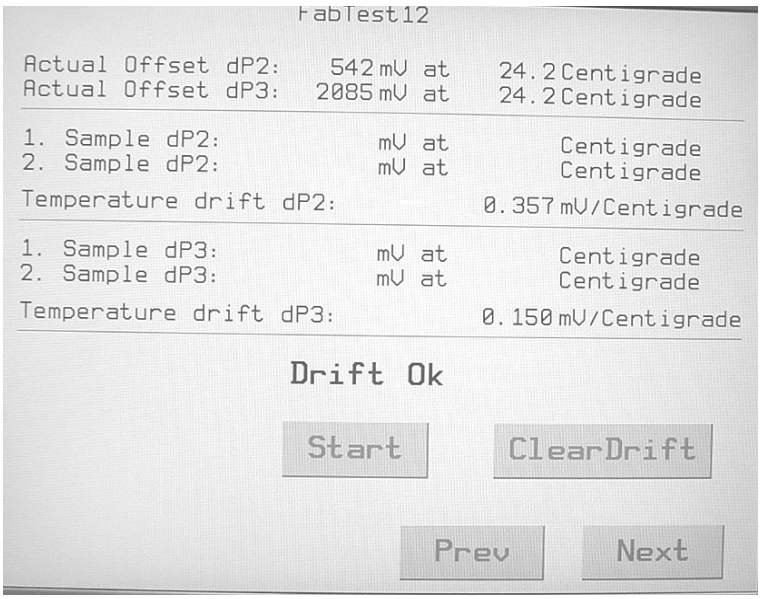

Fig 5-13, Technical Screen 12

Temperature drift compensation should be performed when performance testing indicates that it may be necessary.

Note that if performing temperature drift compensation on devices without internal compressor module, it will be necessary to use temperature drift test fixture (F-721601).

Note:
Observe the temperature display at top of fab test 12 screen. Drift calibration should only be commenced if temperature is below 25 degrees Celsius. If temperature is above this level switch device off in order to allow it to cool down.

The temperature drift compensation is performed as follows:

- Prior to commencing the temperature drift compensation remove side rails and mounting hardware from the device so that front housing is loosely fitted to device.
- Ensure that all patient tubing and the proximal flow sensor have been removed from the device.
- Using the rotary control knob knob select ‘Start’ to commence the procedure.
- The device will prompt you to ‘Connect Jumper’. At this request remove the front module to a point where the electronics is accessible.

- Install a jumper to the vacant position on the top / middle of the Sensor PCB, and then place the front housing back in position.

- Using the rotary control knob knob select 'OK' to confirm that the jumper is in position, then 'OK' once more to confirm that the front housing has been replaced.

- A two point calibration will not be performed by the device. The device will take and store an initial cold reading and then start the internal compressor. The compressor will be allowed to run for an extended period in order to elevate the devices internal temperature following which a second reading will taken and stored.

- On completion the device will prompt you to 'Remove Jumper', remove by reversal of the installation and select 'OK' to acknowledge completion.

The following values will be visible on the screen during and following completion of the calibration process:

- *dP2 Actual* – Current internal temperature and mV reading at dP2
- *dP3 Actual* – Current internal temperature and mV reading at dP3
- *dP2 Sample 1* – Start temperature and mV reading at dP3
- *dP2 Sample 2* – End temperature and mV reading at dP3
- *Temperature Drift at dP2* – Calculated value for drift (mV) per unit temperature (Celsius).
- *dP3 Sample 1* – Start temperature and mV reading at dP3
- *dP3 Sample 2* – End temperature and mV reading at dP3
- Temperature Drift at dP3 – Calculted value for drift (mV) per unit temperature (Celcius)

5.3.13 ***Device Configuration***

Technical Screen 13 (Fig 5-14) will allow the trained service technician to configure, enable and disable various functional attributes.

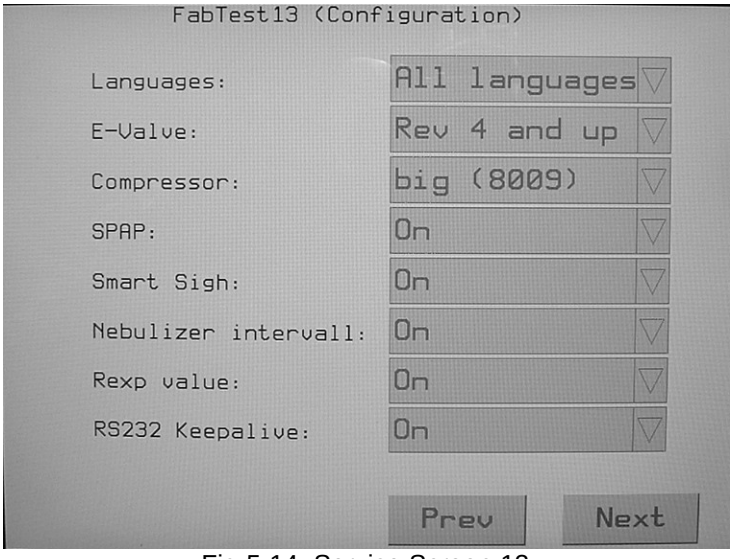

Fig 5-14, Service Screen 13

This screen may be used as necessary to configure the device for use following hardware and software enhancements. Additionally this screen must be used following replacement of Motherboard PCB (F-710510) or Control PCB (F-720510), where these settings will have been return to default values.

The following attributes may be configured in this way:

- *Languages* – Allows the device to be configured for all available language types, or for English language only (US). If set for all, the language may be set in configuration screen 3.
- *Exhalation Valve* – Allows the technician to set according to the revision of expiratory valve which may be installed in the device. Inspiration model ST and LS should always be configured at Rev 04 and above. Original Inspiration models should be configured as appropriate.
- *Compressor* – Allows the technician to set according to the revision of compressor installed in the device. Inspiration model ST and LS should always be configured at 8009 (not JP model). Original Inspiration models should always be configured at 8006. Japanese (JP) ventilator models should be configured at 'No Compressor'.
- *SPAP/VTV/Autom* – Allows Smart Positive Airway Pressure (SPAP), Volume Target Ventilation (VTV), Automode modes to be configured on or off per market requirements.
- *Smart Sigh* – Allows Smart Sigh to be configured on or off per market requirements.
- *Nebulizer Interval* – Allows the nebulizer interval (smart nebulizer) to be configured on or off per market requirements.
- *Rexp* – Allows Expiratory resistance measurement to be configured on or off per market requirements.
- *RS232 Keepalive* – Allows the RS232 timeout to be disabled.

Note:
Nebulizer Interval and Rexp features do not have regulatory clearance in the US and as such must always be configured to OFF when used in the US.

Note:
SPAP/VTV/Automode and Smart Sigh features are currently awaiting regulatory clearance in Japan and as such must always be configured to OFF when used in Japan.

5.4 Service Screens Troubleshooting

On completion of each of the calibration and test routines which are available in the service menu the device will report a pass or fail status. In the event of a failure the device will report a specific error message indicating the nature of the problem.

The respective error codes. A definition there of along with possible steps for resolution are listed in the table below:

Error	*Diagnosis*	*Troubleshooting*
Fab Test 1:		
Valve / Component does not cycle	Valve / Component does not cycles when selected	1. Ensure 'Master' is on. 2. Ensure that that relevant Output is on. 3. Replace component relevant to the output. 4. Replace Power PCB. 5. Replace Processor PCB.
Fab Test 2:		
ADC 1: Error	Error On ADC 1	1. Ensure that ribbon connector between Sensor and Power PCB is seated correctly. 2. Replace Sensor PCB. 3. Replace Power PCB. 4. Replace Processor PCB.
ADC 2: Error	Error On ADC 2	1. Ensure that ribbon connector between Sensor and Power PCB is seated correctly. 2. Replace Sensor PCB. 3. Replace Power PCB. 4. Replace Processor PCB.
No Response From Pressed Button	No machine response to pressing of one lexan button	1. Ensure that ribbon cable from Lexan to controller is secure. 2. Replace lexan screen.
	No machine response to pressing of all lexan buttons.	1. Ensure that ribbon cable from Lexan to controller is secure. 2. Replace Controller PCB. 3. Replace Processor PCB 4. Replace lexan screen.
Fab Test 3:		
NVRAM Check Sum Error	Bad checksum from non volatile memory	1. Ensure that all ribbon cables are securely located. 2. Clear NVRAM & repeat checksum 3. Replace Controller PCB
Sensor PCB Checksum Error	Bad checksum from Sensor PCB	1. Ensure that all ribbon cables are securely located. 2.Replace Sensor PCB
Controller PCB	Bad checksum from Controller	1. Ensure that all ribbon cables are

Checksum Error	PCB	securely located. 2. Replace Controller PCB
Power PCB Checksum Error	Bad checksum from Power PCB	1. Ensure that all ribbon cables are secure. 2. Replace Controller PCB
Fab Test 4:		
V line Low	Power Supply output low	1. Ensure mains supply connected. 2. Ensure inlet fuses ok. 3. Check internal wiring, AC inlet to power supply to power PCB. 3. Using DMM verify output from power supply. If bad replace power supply. 4. Replace Power PCB
V Batteries low	Internal Battery output low	1. Ensure battery is charged sufficiently before proceeding. 2. Replace Internal battery. 3. Check DC power harness. 4. Replace Power PCB.
V External low	External DC Output Low	1. Ensure DC Supply is switched on and harness connected. 2. Check internal DC harness & connections to External supply connector. 3. Replace Power PCB.
Fab Test 5:		
Zero Error (P1, DP1)	Unable to zero pressure transducer	1. Ensure that all pressure is removed from reservoir. 2. Attempt re-zero once more. 3. Replace Power PCB.
Zero Error (P2, DP2, P3, DP3, O2)	Unable to zero pressure transducer	1. Ensure that all pressure is removed from system. 2. Ensure that patient system & proximal sensor are not connected. 3. Attempt re-zero once more. 4. Replace Sensor PCB.
Fab Test 6:		
No Relevant Errors	N/A	N/A
Fab Test 7:		
No flow on PF300	No flow measured on test flow meter.	1. Ensure that tubing is securely connected. 2. Power cycle test flow meter and ensure that it is zeroed. 2. Verfiy electrical connections to PV1 3. Replace PV1 Valve 4. Replace Power PCB
Gain Errors High/Low	Gain error during internal flow	1. Rezero transducer DP2

	sensor calibration	2. Ensure that measured flow is within tolerance. 3. Replace internal flow sensor. 4. Replace sensor PCB
Fab Test 8:		
No Relevant Errors	N/A	N/A
Fab Test 9:		
Error Pressure Drop	Pressure drop out of range during calibration step	1. Ensure that supply to device is stable and holding at required level. 2. Re-zero pressure transducers as in Fab Test 5 3. Re-perform calibration procedure 4. Replace PV1 Valve.
Error Pressure Rise	Pressure risen out of range during calibration step	1. Ensure that supply to device is stable and holding at required level. 2. Replace PV1 Valve.
Fab Test 10:		
No Relevant Errors	N/A	N/A
Fab Test 11:		
No Relevant Errors	N/A	N/A
Fab Test 12:		
Error Temperature	In adequate temperature rise during drift	1. Allow device to cool down and then re-run temperature drift ensuring that the compressor or test fixture is installed and functional.
dP2 Drift Error	Excessive drift on dP2	1. Allow device to cool down and then re-run temperature drift. 2. Replace Sensor PCB
dP3 Drift Error	Excessive drift on dP3	1. Allow device to cool down and then re-run temperature drift. 2. Replace Sensor PCB
Fab Test 13		
No relevant errors	N/A	N/A

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6. Field Verification Procedure

6.1 Introduction

This section of the manual describes the performance testing procedures which should be performed on the device periodically to ensure operation top the manufacturers specifications.

6.2 Notes

Note:

The Inspiration ventilator system is manufactured with accurate pneumatic and electronic test equipment in a controlled envi ronment. As field conditions vary the accuracy of measurement devices becomes less certain. The following test specifications were established with the test equipment as specified in table 6.3. If the accuracy of your institutions test equipment differ from those listed, please make allowances.

Note:

The procedures in this section do not apply to ventilator accessories. Refer to operators or service manuals of the accessories. Malfunctioning accessories may affect some ventilator functions and may result in false test results.

6.3 When To Run Tests

The field verification test and fabrication tests, or parts there of, should be run periodically or after a service has been performed as defined in the table below:

Interval Or Service Performed	*Test Steps Required*
Annually	All Tests
Following annual preventive maintenance	All Tests
Processor PCB, replacement	System Software Installation All Operation Tests (6.6.3)
Controller PCB, replacement	Fab Tests 3,5,7,9,13 All Operation Tests (6.6.3)
Graphic PCB, replacement	All Operation Tests (6.6.3)
VGA Display, replacement	All Operation Tests (6.6.3)
Sensor PCB, replacement	Fab Tests 5, All Operation Tests (6.6.3)
Power PCB, replacement	Power Software Installation Electrical Safety Tests Fab Tests 4,5 All Operation Tests (6.6.3)
Power Supply, replacement	Electrical Safety Tests Fab Test 4 All Operation Tests (6.6.3)

Internal Battery, replacement	Fab Test 4
Inspiratory Valve PV1, replacement	Fab Test 5,9 All Operation Tests (6.6.3)
Internal Flow Sensor, replacement	Fab Test 5,7 All Operation Tests (6.6.3)
Exhalation Valve, replacement	All Operation Tests (6.6.3)
Blender Valve	All Operation Tests (6.6.3)
SV1 / SV2, replacement	
SV3 / Compressor, replacement	Gas Sources Test (6.6.3)
Oxygen Sensor, replacement	Operation Test 4 (6.6.3)
Rotary Control Knob, replacement	POST
Mains Inlet Filter, replacement	Electrical Safety Tests Fab Test 4 POST

6.4 Test Equipment And Service Materials

In order to perform the INSPIRATION ventilator system performance verification the manufacturer recommends the use of the following tools and test equipment

Description	Manufacturer
Test Equipment	
Pneumatic Calibration Analyser	eVent PF300
Electrical Safety Tester	Biotek 601 Pro or equivalent
Desktop / Laptop PC (Pentium)	Local Supply
Adult Tubing System	Local Supply
Paediatric Tubing System	Local Supply
Proximal Flow Sensor, Adult	eVent Medical, F910265
Proximal Flow Sensor, Infant	eVent Medical, F910266
Exhalation Cover	eVent Medical, F710214
Exhalation Membrane	eVent Medical, F710213
Extended Ribbon Cable, Test	eVent Medical, F810225
Lung Simulator	Local Supply
High Pressure Air Supply with adjustable pressure regulator	Local Supply
High Pressure Oxygen Supply	Local Supply
External Battery or DC Supply	Local Supply
Hexagonal Drivers, following size: 1.5mm, 2.0mm, 2.5mm, 3.0mm, 4.0mm, 5.0mm	Local Supply

6.5 Cleaning and Inspection

Warning

To prevent transmission of disease, use personal protective equipment when handling contaminated filters, HME's or other patient accessories.

Caution

To prevent damage to ESD-sensitive components, always follow ESD guidelines when servicing components inside the ventilator/

Note

If you find any problems during the preliminary ventilator inspection, correct them before proceeding with the performance verification. Failure to correct such problems may affect the remainder of the performance verification procedure.

Clean and inspect the ventilator as follows:

- Clean the ventilator exterior.
- Open up the ventilator and clean its interior using an ESD-Safe vacuum cleaner.
- Remove and inspect the fan inlet filter, clean/replace as is necessary.
- Verify the air/oxygen fittings and water traps are securely fastened to the ventilator.
- Visually inspect the ventilators interior and exterior for obvious problems such as missing broken parts; loose assemblies; disconnected wires, connectors or tubes. Repair as necessary.

6.5.1 Ventilator Set Up

Connect the ventilator to Air and Oxygen sources and ensure that both have an adjustable output. Set the output pressure initially to zero for both air and oxygen.

6.5.2 Test Equipment Set Up

To set up your pneumatic test equipment for use during the performance verification test, verify that all equipment hold a valid calibration certificate and that sufficient warm up time has elapsed prior to making any measurements.

6.6 Testing Steps

To ensure systematic performance verification and logical fault diagnosis, perform these tests in the order given. If you need to repeat a test, the current control settings are completely defined at the beginning of each individual test.

Note

If the performance verification is being run in the specified order, you need only make changes to the ventilator control settings shown in boldface.

To locate the cause of any malfunction you should refer the troubleshooting information provided at the back of this section and section 7 of this manual.

Follow these general guidelines when running the performance verification:

- If you note a problem during the performance verification, verify that you have followed all procedures correctly before attempting to make a repair to the ventilator.
- When making ventilator settings, be aware that because of interrelationships between some ventilator settings, you may not always be able to make all settings in the indicated sequence.
- For convenience all alarms should be set to the maximum and minimum ranges available, this will reduce the occurrence of nuisance alarms during the performance verification.
- Use the alarm silence key as required during the performance verification to mute any alarms should they occur.
- Except for the alarm silence key, do not change the control settings during these procedures, unless specifically instructed.
- Refer to section 9 of this manual for service and repair information, and section 10 for identification of repair parts. When repairs have been completed repeat the test. When the test successful, proceed with the next test.

Note:

The following procedures do not verify the performance of accessories. Verify the performance of accessories using the appropriate procedures in the applicable operators or service manual.

6.6.1 Electrical Safety Tests

The electrical safety test verifies that ground resistance and earth leakage current are within safe limits. Perform this test whenever you service the ventilator, per your hospitals requirements.

With the device switched off plug unit under test (UUT) mains cable in the electrical safety tester.

With cable clip connected to a suitable point on the ventilator chassis perform ground resistance test using appropriate function on electrical safety tester. Ground resistance should be < 0.2Ω

Switch on the device and allow power on self-test to pass.

Using appropriate function on electrical safety tester perform leakage current test for forward and reverse polarity.

Earth leakage current values in each case should be <300 µA (all units).

6.6.2 Fabrication Tests

Fab Test 5

Per the detailed instructions contained within section 5 of the service manual perform Fab Test 5 in order to re-zero all pressure transducers.

6.6.3 Operational Tests

Connect high-pressure air and O2 source to the unit under test and ensure outputs are adjusted to 4 bar ± 1 bar.

Connect complete Paediatric patient system inclusive of exhalation cover / diaphragm and proximal flow sensor.

Using the rotary control knob select 'Paediatric' tubing system and 'Standard' settings.

Using the rotary control knob select 'Calibrations' and perform all user calibration procedures, System Test, Flow Sensor and O2 Sensor

Switch on PF300 and allow to warm up (15 minutes). Once the PF300 has been allowed to warm up perform pressure sensor zero calibration, and oxygen sensor calibration prior to proceeding.

On the PF300 proceed to the set up screen. Configure the numerical screens as follows:

Numerical 1:

Tidal Volume	ml	ATP	Trigger Level 3lpm
Respiratory Rate	bpm		
Diff Pressure	cmH2O		
Oxygen	%		

Operational Test 1 – Gas Sources

Connect test lung to the patient tubing system via 6mm ET tube.

Select 'Start' to commence ventilation. Allow device to cycle on standard settings with following exceptions:

Trigger Type	Pressure
Trigger Level	5cmH2O

Verify that machine cycles with no alarms. If any alarms are active adjust limits as necessary to eliminate.

Disconnect high-pressure oxygen hose from source and observe device.

After a number of cycles verify medium priority audible alarm is active and that alarm LED is illuminated. Verify that Oxygen Supply alarm message appears in screen area. Verify that ventilation continues uninterrupted.

After an additional number of cycles verify high priority audible alarm is active and that Low Oxygen alarm message is now visible in screen area. Verify that ventilation continues uninterrupted.

Reconnect high-pressure oxygen hose to source and verify that alarm conditions auto-reset after a number of breaths.

Disconnect high-pressure air hose from source and observe device.

After a number of cycles verify that compressor system starts. Verify that ventilation continues uninterrupted. Confirm that the following info messages are displayed:

FIO2 May Vary
Flow Trigger Not Available

Reconnect high-pressure air source, verify that compressor ceases to operate.

Switch off device and switch back on in configuration menu. Enter code to access configuration screen 1, switch compressor back up to off then switch

device off once more.

Switch device on and select previous settings to commence ventilation. Verify ventilation commences with no alarms.

Disconnect high-pressure air source once more. Verify that Air Supply alarm message appears in screen area. Verify that ventilation continues uninterrupted.

After an additional number of cycles verify high priority audible alarm is active and that High Oxygen alarm message is now visible in screen area. Verify that ventilation continues uninterrupted.

Disconnect high-pressure O2 sources. Verify that high priority 'Internal Pressure Low' audible and visual alarm is active in addition to Air/O2 Supply alarms. Breath delivery should cease.

Restore both high-pressure gas sources and verify that alarm conditions reset.

Switch off device and invoke configuration menu to re-enable compressor back up.

Operational Test 2 – Volume Accuracy (VOL / RR / VTe)

Continue with the ventilator configured as before with a paediatric tubing system and proximal sensor.

Connect the proximal sensor directly to the high flow inlet of the PF300. Place ET tube with test lung still connected, to the high flow exhaust port.

Switch device on once more and at the start screen select 'Last' then 'Next' to enter the proposed settings screen. Configure the ventilator as follows and on completion select 'activate' to commence ventilation:

Ventilation Mode	**VCMV**
Tidal Volume	**100 ml**
Respiratory Rate	**30 bpm**
Peak Flow	**20 lpm**
Waveform	**Decelerating**
Trigger Type	**Pressure**
Trigger Level	**5**
PEEP	**0cmH2O**
Oxygen	**21%**
Alarms	**Adjust As Required**

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured volume for 5

consecutive breaths then calculate average for the delivered tidal volume. Ensure that tidal volume is 100ml ± 20ml. Record result on the final test record.

Observe and record the reading for respiratory breath rate. Reading should be 30bpm ± 3bpm. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that Vte reading is 100ml ± 30ml. Record result on the final test record.

On completion press the On/Off key and put the device into 'stand-by' operation.

Remove the paediatric tubing system and attach a full adult tubing system including proximal sensor to the device.

Enter the 'Calibration' menu and perform 'System Test' and 'Flow Sensor Calibration' with the new system attached.

Configure system as it was previously with proximal sensor connected to high flow inlet. Connect an adult test lung to the proximal sensor via a 6mm ET tube.

Switch device back to the start screen and select 'Last' then 'Next' to enter the proposed settings screen. Configure the ventilator as follows and on completion select 'activate' to commence ventilation:

Ventilation Mode	**VCMV**
Tidal Volume	**300ml**
Respiratory Rate	**25 bpm**
Peak Flow	**45 lpm**
Waveform	**Decelerating**
Trigger Type	**Pressure**
Trigger Level	**5**
PEEP	**1 cmH2O**
Oxygen	**21%**
Alarms	**Adjust As Required**

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured volume for 5 consecutive breaths then calculate average for the delivered tidal volume. Ensure that tidal volume is 300ml ± 60ml. Record result on the final test record.

Observe and record the reading for respiratory breath rate. Reading should be 25bpm ± 2.5bpm. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that Vte reading is 300ml ± 90ml. Record result on the final test record.

On completion make the following changes to the ventilator settings:

Ventilation Mode	**VCMV**
Tidal Volume	**600ml**
Respiratory Rate	**15 bpm**
Peak Flow	**50 lpm**
Waveform	**Decelerating**
Trigger Type	**Pressure**
Trigger Level	**5**
PEEP	**0 cmH2O**
Oxygen	**21%**
Alarms	**Adjust As Required**

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings

On the PF300 numerical screen 1, record the measured volume for 5 consecutive breaths then calculate average for the delivered tidal volume. Ensure that tidal volume is 600ml ± 120ml. Record result on the final test record.

Observe and record the reading for respiratory breath rate. Reading should be 15bpm ± 1.5bpm. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that Vte reading is 600ml ± 120ml. Record result on the final test record.

On completion make the following changes to the ventilator settings:

Ventilation Mode	VCMV
Tidal Volume	**1000ml**
Respiratory Rate	**10 bpm**
Peak Flow	**70 lpm**
Waveform	Decelerating
Trigger Type	Pressure
Trigger Level	5
PEEP	**0 cmH2O**
Oxygen	21%
Alarms	Adjust as Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured volume for 5 consecutive breaths then calculate average for the delivered tidal volume. Ensure that tidal volume is 1000ml ± 200ml. Record result on the final test record.

Observe and record the reading for respiratory breath rate. Reading should be 10bpm ± 1.0bpm. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that Vte reading is 1000ml ± 200ml. Record result on the final test record.

Operational Test 3 – Pressure Accuracy (Pcontrol / PEEP / Sigh)

Adjust the ventilator settings as follows:

Mode	**P-CMV**
Pcontrol	**10 cmH2O**
Respiratory Rate	15 bpm
I time	**1.0 Second**
Rise Time	**Slow**
Trigger Type	Pressure
Trigger Level	5
PEEP	0 cmH2O
Oxygen	21%
Alarms	Adjust As Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured value of peak pressure for 5 consecutive breaths then calculate average. Ensure that peak pressure is 10cmH2O ± 1. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices Ppeak reading is 10cmH2O ± 1. Record result on the final test record.

On completion make the following changes to ventilator settings:

Mode	P-CMV
Pcontrol	**50 cmH2O**
Respiratory Rate	**8 bpm**
I time	**2.5 Second**
Rise Time	**Medium**
Trigger Type	Pressure
Trigger Level	5
PEEP	0 cmH2O
Oxygen	21%
Alarms	Adjust As Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured value of peak pressure for 5 consecutive breaths then calculate average. Ensure that peak pressure is 50cmH2O ± 5. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices Ppeak reading is 50cmH2O ± 5. Record result on the final test record.

On completion make the following changes to ventilator settings:

Mode	P-CMV
Pcontrol	**10 cmH2O**
Respiratory Rate	**15 bpm**
I time	**1.0 Second**
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5
PEEP	**5 cmH2O**
Oxygen	21%
Alarms	Adjust As Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured value of PEEP. Ensure that PEEP is 5cmH2O ± 0.5. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices PEEP reading is 5cmH2O ± 1. Record result on the final test record.

On completion make the following changes to ventilator settings:

Mode	P-CMV
Pcontrol	10 cmH2O
Respiratory Rate	15 bpm
I time	1.0 Second
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5 lpm
PEEP	**30 cmH2O**
Oxygen	21%
Alarms	Adjust As Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured value of PEEP.

Ensure that PEEP is 30cmH2O ± 3. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices PEEP reading is 30cmH2O ± 3. Record result on the final test record.

On completion make the following changes to ventilator settings:

Mode	P-CMV
Pcontrol	10 cmH2O
Respiratory Rate	15 bpm
I time	1.0 Second
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5 lpm
PEEP	**50 cmH2O**
Oxygen	21%
Alarms	Adjust As Required

Allow a minimum of 10 breaths for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 1, record the measured value of PEEP. Ensure that PEEP is 50cmH2O ± 5. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices PEEP reading is 50cmH2O ± 5. Record result on the final test record.

Operational Test 4 – Oxygen Delivery

Adjust the ventilator settings as follows:

Mode	P-CMV
Pcontrol	10 cmH2O
Respiratory Rate	**30 bpm**
I time	1.0 Second
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5
PEEP	0 cmH2O
Oxygen	**30%**
Alarms	Adjust As Required

Allow a minimum of 2 minutes for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 2, record the measured value of Oxygen. Ensure that Oxygen is 30% ± 3%. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices Oxygen reading is 30% ± 3%. Record result on the final test record.

On completion make the following changes to the ventilator settings:

Mode	P-CMV
Pcontrol	10 cmH2O
Respiratory Rate	30 bpm
I time	1.0 Second
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5
PEEP	0 cmH2O
Oxygen	**60%**
Alarms	Adjust As Required

Allow a minimum of 2 minutes for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 2, record the measured value of Oxygen. Ensure that Oxygen is 60% ± 3%. Record result on the final test record.

Switch UUT screen to show 'Monitoring' ensure that devices Oxygen reading is 60% ± 3%. Record result on the final test record.

On completion make the following changes to the ventilator settings:

Mode	P-CMV
Pcontrol	10 cmH2O
Respiratory Rate	30 bpm
I time	1.0 Second
Rise Time	Medium
Trigger Type	Pressure
Trigger Level	5
PEEP	0 cmH2O
Oxygen	**90%**
Alarms	Adjust As Required

Allow a minimum of 2 minutes for the device to stabilise at the current ventilation settings.

On the PF300 numerical screen 2, record the measured value of Oxygen. Ensure that Oxygen is 30% ± 3%. Record result on the final test record.

Switch UUT screen to show ‘Monitoring’ ensure that devices Oxygen reading is 30% ± 3%. Record result on the final test record.

Operational Test 6 – Alarm Operation

Make the following adjustments to the ventilator settings:

Ventilation Mode	**VCMV**
Tidal Volume	**500ml**
Respiratory Rate	**15 bpm**
Peak Flow	**45 lpm**
Waveform	**Decelerating**
Trigger Type	Pressure
Trigger Level	5
PEEP	5 cmH2O
O2	**21%**
Alarms	Adjust As Required

Remove the test lung from tubing system and leave patient wye open to atmosphere.

Verify that after a number breaths High Priority audible and visual alarms are active. Verify that ‘Disconnect’ alarm message is visible on screen. Record on final test record

Press audible alarm silence key, verify that audible alarm is silenced but alarm LED continues to function. Record on final test record.

Press audible alarm silence key, verify that audible alarm functions once more and that LED continues to function. Record on final test record.

Press audible alarm silence once more, using a calibrated stop watch verify that alarm remains silenced for 120 seconds ± 12, following which it functions once more. Record on final test record.

Reconnect patient tubing system to the lung simulator. Verify that ‘Disconnect’ alarm condition auto resets after a number of breaths. Record on final test record.

Remove the lung simulator from patient tubing system once more and occlude at wye.

Verify that after a number of breaths High Priority audible and visual alarms are active once more. Verify that ‘High Pressure’ alarm message is visible on the screen. Record on final test record.

Remove occlusion from the wye and reconnect patient system to the lung simulator. Verify that alarm condition auto-resets after a number of breaths.

Select ‘Special’ menu, ‘Apnea Backup’ and ensure the device is set as follows:

Apnea Backup	**ON**
Ventilation Mode	**PCMV**
Pcontrol	**20cmH2O**
Respiratory Rate	**15 bpm**
Itime	**1.0**
Ramp	**Slow**
Trigger Type	**Pressure**
Trigger Level	**5**
PEEP	**5 cmH2O**
O2	**21%**
Apnea Alarm	**60 seconds**

Return to settings screen and sent unit in Spontaneous (Spont) Mode.

Verify that after a period of 60 seconds a high priority audible and visual alarm occurs accompanied by 'APNEA BACKUP' alarm message in the main screen area.

Verify also that Back Up Apnea Ventilation starts at the parameters previously selected.

Switch off UUT, disconnect high-pressure gas sources and set output to off. Remove all patient tubing system components from the device.

6.7 Performance Verification – Troubleshooting Steps

Operational Test Errors

Error	*Description*	*Corrective Action*
Gas Sources:		
O2 Supply Alarm	O2 supply alarm not active	1. Ensure that the O2 supply has been disconnected.
Compressor Not Available	Compressor not active at removal of air supply	1. Ensure that the Compressor back up is switched to on in configuration. 2. Ensure that the compressor harness is secure. 3. Replace compressor
Compressor Stalls	Compressor stops during operation.	1. Verify operation of compressor unloading valve. 2. Ensure that exhaust is audible. 3. Replace unloading valve. 4. Replace compressor.
Air Supply Alarm	Air supply alarm not active	1. Ensure that Air supply has been disconnected. 2. Ensure that compressor back up is switched to off in configuration.
Volume Accuracy:		
Tidal Volume Readings	Tidal Volume Readings Out of Range High/Low	1.Perform system test in order to calculate system compliance. 2.Verfiy correct compliance and resistance in use on lung simulator.
Exhaled Tidal Volume Readings	Exhaled Tidal Volume Reading Out of Range High/Low	1.Perform system test in order to calculate system compliance. 2.Ensure correct orientation of proximal sensor, sensing lines straight up or down from wye. 2.Perform flow sensor calibration. 3.Replace proximal flow sensor 4.Verfiy internal calibration of PV1 and flow sensor.
Respiratory Rate Readings	Respiratory Rate Readings out of range high/low. (Autocycling)	1.Verfiy trigger type and setting. 2.Perform system test to ensure no leakage from system. 3.Re-zero pressure transducers. 4.Replace Sensor PCB.
Pressure Accuracy:		
Inspiratory Pressure Readings	Inspiratory Pressure readings out of range High/Low	1.Ensure correct configuration compliance / resistance on lung simulator. 2.Rezero all pressure transducers.

		3.Performed System Test. 4.Replace PV1 Valve 5.Replace PV2 exhalation hub-magnet.
PEEP Pressure Reading	PEEP Pressure out of range	1. Ensure correct configuration compliance / resistance on lung simulator. 2. Rezero all pressure transducers. 3. Performed System Test. 4. Replace PV2 exhalation hub-magnet.
Oxygen Delivery:		
PTS O2 Reading	O2 reading out of range on PTS2000.	1. Perform full 2 point calibration of PTS2000 O2 sensor.
Vent O2 Reading	O2 reading out of range on Ventilator	1. Perform calibration of the ventilators O2 sensor. 2.Replace O2 Sensor
Alarm Operation:		
Disconnect	Disconnect alarm is not active	1. Ensure that test lung has been removed from the wye. 2. Verify that alarm settings are appropriate.
Alarm Silence	Alarm silence is not active	1. Press alarm silence key again and verify appearance of icon in display screen. 2. Verify operation of the alarm silence key using fab test 2.
High Pressure	High pressure alarm is not active	1. Ensure that the wye is fully occluded. 2. Verify that alarm settings are appropriate.
Apnea	Apnea alarm is not active	1. Verify the ventilator settings, ensure that device is set to 'Spont' mode and that apnea parameters are appropriately set. 2. Observe monitored data and ensure that monitored respiratory rate is 0.
Apnea Back Up	Apnea back up ventilation is not active.	1. Verify the ventilator settings. Ensure that apnea back up is set to 'On'. 2. Observe monitored data and ensure that monitored respiratory rate is 0.

7. Diagnostic Error Codes

7.1 Introduction

This section of the manual has been devised to allow the trained service technician to interpret the diagnostic codes contained within the devices error log.

7.2 About Diagnostic Codes

In the event of a hardware or software error being detected which would compromise safe breath delivery the operator will be confronted with an alarm message in the following form :

TF – XY Where TF = Technical Fault
XY = the specific error number

In the event of a technical fault being detected power will be immediately removed from the devices pneumatic system, de-energising all valves and putting the device into Safety Valve mode (ref sec 3. for description). The unit will remain in ambient breathing mode until the triggering fault condition has been corrected and the unit has been tested.

When investigating any error condition it is advisable to review the full technical error log (Fab Test 11) in order to establish if there are any contributory problems and whether there is a history of the reported problem.

When viewed in the Fab Test 11 error log technical errors will be highlighted with an asterix (*).

7.3 Technical Error List

Refer to the following table () in order interpret the recorded technical errors. The first column with list in numerical order the specific error codes. The second column will provide a description of the possible cause. The final column will suggest possible steps to identify the specific triggering condition. The suggested steps are sequenced in order of the most probable malfunction in order to give the most efficient corrective action.

It is possible that the suggested steps may not always provide a fix to the particular problem. Should this occur refer to your local technical support specialists for further recommendations

7.3.1 Technical Error List

TF01 – Technical Fault	Configuration EEPROM memory defective	1. Replace Controller PCB.
TF02 – Technical Fault	Configuration EEPROM memory defective	1. Replace Sensor PCB.
TF03 – Technical Fault	Pressure Sensor Gain not valid Sensor PCB EEPROM	1. Perform re-zero of all pressure transducers, Fab Test 5 2. Perform temperature drift adjustment, Fab Test 12. 3. Replace Sensor PCB.
TF04 – Technical Fault	Configuration EEPROM memory defective	1. Replace Power PCB.

TF05 – Technical Fault	NVRAM Defective	1. Perform Checksum test on NVRAM, Fab Test 3 2. Clear & Test NVRAM and fully recalibrate the device. 3. Replace Controller PCB.
TF06 – Technical Fault	Log Book data not valid in NVRAM	1. Clear Log Book. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Controller PCB.
TF07 – Technical Fault	Pressure sensor offsets not valid in NVRAM	1. Perform rezero of all pressure transducers. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Sensor PCB. 4. Replace Controller
TF08 – Technical Fault	Internal Flow Sensor data in NVRAM not valid	1. Recalibrate internal flow sensor. 2. Clear & Test NVRAM and recalibrate device. 3. Replace Controller PCB.
TF09 – Technical Fault	Altitude Compensation data in NVRAM not valid.	1. Set appropriate altitude compensation value.
TF10 – Technical Fault	Program ROM Defective	1. Replace Processor PCB.
TF11 – Technical Fault	PIC Version Check	1. Ensure that Power and system software are at compatible revisions. 2. Replace Power PCB.
TF12 – Technical Fault	Data not valid from ADC1	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF13 – Technical Fault	Data not valid from ADC2	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF14 – Technical Fault	Difference of reference voltage OOR ADC1/2	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.

TF15 – Technical Fault	Reference Voltage on ADC1 Out Of Range	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF16 – Technical Fault	Reference Voltage on ADC2 Out of Range	1. Ensure Sensor ribbon cable is seated correctly. 2. Ensure Controller ribbon cable is seated correctly. 3. Replace Sensor PCB. 4. Replace Power PCB. 5. Replace Processor PCB.
TF17 – Technical Fault	+5v Supply Voltage Out of Range	1.Replace Power PCB
TF18 – Technical Fault	Software Stack Corruption	1. Re-install system software. 2.Replace Processor PCB
TF19 – Technical Fault	Communication with PIC processor dead	1. Verfiy security of all ribbon connectors and cabling to pneumatics. 2. Reset power processer (6.4/12.1) 3. Replace Power PCB. 4. Replace Processor PCB. 5. Replace Controller PCB.
TF20 – Technical Fault	Value of pressure sensor P2 out of range	1. Perform re-zero of all pressure transducers. 2. Replace Sensor PCB.
TF21 – Technical Fault	Value of pressure sensor dP2 out of range	1. Perform re-zero of all pressure transducers. 2. Replace Sensor PCB.
TF22 – Technical Fault	Not Used	Not Used
TF23 – Technical Fault	Not Used	Not Used
TF24 – Technical Fault	Software Tasks Corruption	1.Replace Processor PCB
TF25 – Technical Fault	Software Tasks Overflow	1.Replace Processor PCB
TF26 – Technical Fault	NVRAM wrong checksum	1.Clear and test NVRAM then recalibrate device. 2.Replace Controller PCB.
TF27 – Technical Fault	PV1 valve data not valid in NVRAM	1.Perform calibration of PV1. 2.Clear and test NVRAM then recalibrate device. 3.Replace Controller PCB.
TF28 – Technical Fault	Difference between temperature sensors out of range.	1.Access Fab Test 2 and verify reading from temperature sensors. 2.Replace Sensor PCB 3.Replace Power PCB

7.3.2 Calibration Errors

System Leak Test		
Error 6 – Pressure Drop	Excessive Pressure Drop During System Test	1. Ensure closed patient system. 2. Run system test with single tubing limb connect between outlet & exhalation cover. 3. Remove system tubing and verify flow from PV1 4. Perform internal leakage test. 5. Replace Sensor PCB
Error 7 – Pressure Rise	Excessive Pressure Increase During System Test	1. Forward leak through PV1 valve. 2. Forward leak through Solenoid 4 if nebulizer is connected. 3. Replace Sensor PCB.
Error 8 – Max Time To Pressure	Unable To Adequately Pressurize Patient System	1. Ensure closed patient system. 2. Run system test with single tubing limb connect between outlet & exhalation cover. 3. Remove system tubing and verify flow from PV1 4. Perform internal leakage test. 5. Replace Sensor PCB
Error 10 – Deviation High	Flow At Transducer dP2 Out Of Range	1. Verify internal flow sensor calibration, recalibrate as necessary.
Error 11 – Error Emptying Tank	Tank Pressure Remains Above 100mbar	1. Ensure that patient wye is open at the beginning of system test. 2. Verify that PV1 is opening and flow is evident from to patient port. 3. Replace Inspiratory Valve PV1 4. Verify no leakage through blender system.
Flow Sensor Calibration		
Error 12 – High Pressure	Pressure Out Of Range	1. Ensure that the proximal sensor is connected to the tubing system and that its outlet is open. 2. Replace proximal sensor 3. Verify internal flow sensor calibration, recalibrate as necessary. 4. Verify PV1 calibration, recalibrate as necessary.
Error 13 – Deviation High	Zero Adjustment dP2	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.
Error 14 – Deviation High	Zero Adjustment dP3	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.
Error 15 – Deviation High	Zero Adjustment P3	1. Perform re-zero of pressure transducers, fab test 5 2. Replace Sensor PCB.

Error 16 – Deviation High	Differential pressure too low @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 17 – Deviation High	Differential pressure between Adult / Infant limits @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 18 – Deviation High	Differential pressure too high @ 30 lpm	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 19 – Deviation High	Differential pressure too low @ low flow level	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB

Error 20 – Deviation High	Differential pressure too high @ low flow level	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 21 – Deviation High	Coefficient (a) too low	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 22 – Deviation High	Coefficient (a) too high	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 23 – Deviation High	Coefficient (b) too low	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB

Error 24 – Deviation High	Coefficient (b) too high	1. Ensure that system is leak free by running system test. 2. Ensure that the proximal sensor is correctly connected to the tubing system and that its outlet is open. 3. Replace proximal sensor 4. Perform re-zero of pressure transducers, fab test 5 5. Verify internal flow sensor calibration, recalibrate as necessary. 6. Replace Sensor PCB
Error 25 – Saving Data	NVRAM Damaged	1 Replace proximal sensor 2.Perform NVRAM test 3.Clear & Test NVRAM, recalibrate device. 4. Replace controller PCB
Error 26 – Emptying Tank	Error Emptying Tank	1. Ensure that patient wye is open at the beginning of system test. 2. Verify that PV1 is opening and flow is evident from to patient port. 3. Replace Inspiratory Valve PV1 4. Verify no leakage through blender system.
Error 27 – Low Pressure	Pressure P2 < 15 mbar	1. Ensure that that the flow sensor outlet is blocked during compensation test. 2. Replace proximal flow sensor 3. Perform calibration of proportion valve PV1.
Error 28 – High Pressure	Pressure P2 > 40 mbar	1. Replace proximal flow sensor 2. Perform calibration of proportion valve PV1.
Oxygen Sensor		
Error 2 – Saving Data	NVRAM Damaged.	1.Replace O2 Sensor 2.Perform NVRAM test 3.Clear & Test NVRAM, recalibrate device. 4. Replace controller PCB
Error 3 – Deviation High	Error during calibration at 100% setting.	1. Ensure O2 supply is connected and adequate flow available. 2. Ensure O2 Sensor connected correctly. 3. Replace O2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor PCB. 6. Replace O2 Sensor interface block.

Error 4 – Deviation High	Error during calibration at 21% setting.	1. Ensure Air supply is connected and that adequate flow is available, or that internal compressor is available and running. 2. Ensure O2 Sensor connected correctly. 3. Replace O2 Sensor. 4. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 5. Replace Sensor PCB. 6. Replace O2 Sensor interface block.
Error 8 – Sensor Not Available	Oxygen sensor is not available for calibration.	1. Enter configuration screen 1 and ensure that the oxygen sensor is enabled.
Error 9 – Oxygen Not Available	Oxygen supply not available for calibration	1. Ensure Oxygen supply is connected and that adequate flow is available. 2. Confirm that inlet check valves CV1/2 are correctly installed and undamaged, replace as necessary. 3. Confirm operation of the oxygen solenoid, replace as necessary.

7.3.3 General Operation Errors – High Priority

Error No 40	Alarm – Battery Flat	Internal rechargeable battery is discharged.
Error No 41	Alarm – Occlusion	Pressure at the start of Inspiration is too high.
Error No 42	Alarm – High Pressure	Patient system pressure has reached the high-pressure alarm setting.
Error No 43	Alarm – Internal Pressure Low/Disconnect	Internal system reservoir pressure is too low.
Error No 44	Alarm – Low Pressure	Patient system pressure has not reached low pressure alarm setting during inspiration.
Error No 45	Alarm – Apnea	The apnea interval has elapsed without a patient triggered or mandatory breath being delivered.
Error No 46	Alarm – Low Minute Ventilation	Expiratory minute volume is too low compared with alarm limit ExpMinVol.
Error No 47	Alarm – High Minute Ventilation	Expiratory minute volume is too high compared with alarm limit ExpMinVol.
Error No 48	Alarm – Disconnection	
Error No 49	Alarm – Low Oxygen Delivery	Inspiratory O_2 concentration is too low. Possible causes: gas mixing system error, O_2 cell faulty, monitor value too low compared with control value, O_2 sensor calibration must be performed

Error No 50	Alarm – High Oxygen Delivery	Inspiratory O_2 concentration is too high. Possible causes: gas mixing system error, O_2 cell faulty, monitor value too high compared with control value, O_2 sensor calibration must be performed.
Error No 51	Alarm – Nebulizer Disconnect	Nebulizer tubing has become disconnected from the ventilator or nebulizer vial.
Error No 52	Alarm – Low Tidal Volume	Expiratory tidal volume is too low compared with alarm limit for Vte.
Error No 53	Alarm – High Tidal Volume	Expiratory tidal volume is too high compared with alarm limit for Vte.
Error No 54	Alarm – Apnea Back-Up	The apnea interval has elapsed without a patient triggered or mandatory breath being delivered. Apnea Back-Up ventilation at operator set parameters is now in operation. Is active in V-SIMV, P-SIMV and SPONT modes.
Error No 55	Alarm – Speaker Fault	Internal main alarm speaker may not be functioning correctly. Note: Message will be accompanied by a latching back-up audible alarm signal.
Error No 56	Alarm – Volume is Being Limited	The delivered tidal volume is being limited by the current VTV and/or alarm settings.

7.3.4 General Operation Errors – Medium Priority

Error No 70	Alarm – Check Flow Sensor Tubing	The measuring tubes for the external flow sensor have either come loose or are blocked.
Error No 71	Alarm – Check Flow Sensor	The external flow sensor tubing is loose of may have been attached incorrectly.
Error No 72	Alarm – Air Supply	The air supply is interrupted and compressor backup is switched off in the configuration menu.
Error No 73	Alarm – Oxygen Supply	The O2 supply is not available.
Error No 74	Alarm – Compressor	Internal compressor system has failed or is disabled.
Error No 75	Not Used	Not used
Error No 76	Not Used	Not Used
Error No 77	Alarm – High Frequency	Respiratory rate is too high compared with the High Rate alarm limit.
Error No 78	Alarm – Low Frequency	Respiratory rate is too low compared with the low rate alarm limit.
Error No 79	Not Used	Not Used

Error No 80	Alarm – Check Pcontrol / Pmax	Pcontrol and/or pressure max. settings are incorrect, i.e. Pcontrol > pressure max.
Error No 81	Alarm – Check Psupport / Pmax	Psupport and/or pressure max. settings are incorrect, i.e. Psupport + PEEP > pressure max.
Error No 82	Not Used	Not Used
Error No 83	Alarm – Battery Low	Internal battery voltage is low and will only sustain operation for a short period of time.
Error No 84	Alarm – High Temperature	The internal temperature of the device is too high.
Error No 85	Alarm – High External Voltage	External DC supply voltage is too high.
Error No 86	Alarm – Low Pmean	Mean system pressure is too low compared with alarm limit for Pmean low.
Error No 87	Alarm – High Pmean	Mean system pressure is too high compared with alarm limit for Pmean high.
Error No 88	Alarm – Leak %	The monitored Leak % is too high compared with alarm limit for Leak %.

7.3.5 General Operation Errors – Information

Error No 110	Info – FIO2 and Delivery can vary	The device is operating on internal compressor system.
Error No 111	Info – Battery Not Available	The internal battery is not available. Possible causes: battery flat, battery missing, faulty cable connections.
Error No 112	Info – Logbook Cleared	The alarm log has been cleared. Message will be displayed each time standard settings is selected.
Error No 113	Info – Memory CPU Not Protected	CPU memory is not protected
Error No 114	Info – Memory Sensor Not Protected	Sensor PCB memory is not protected – jumper in place.
Error No 115	Info – Memory Power Not Protected	Power PCB memory is not protacted – jumper in place.
Error No 116	Info – Flow Trigger Not Available	Flow trigger is not available. Possible causes: Flow sensor is attached incorrectly, flow sensor requires calibration, device is running on internal compressor.
Error No 117	Info – Nebulizer Not Available	Nebulizer is not available. Possible causes: Device in infant mode or peak flow is below 7lpm.

Error No 118	Info – 100% O2 Not Available	100% O_2 is not available. Possible causes: no oxygen supply available while 100% O_2 is being administered or O_2 calibration has been started.
Error No 119	Info – O2 Calibration Not Available	O2 Calibration not available. Possible cause: O2 sensor not enabled, High pressure gas sources not available.
Error No 120	Info – Flow Calibration Not Available	Flow Calibration not available. Possible cause: Proximal sensor may be disabled in configuration mode.

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8. Alarm Messages

8.1 Introduction

This section of the manual has been devised to allow the trained service technician to interpret the alarm messages which may occur during normal operation of the device, and which may be contained within the devices alarm log.

8.2 Audible Alarms

All audible and visual alarms comply with the requirements of EN475, the audible signals used are as follows:

High Priority Alarms:	Five signals, repeated periodically
Medium Priority Alarms:	Three signals, repeated periodically
Low Priority Alarms:	One signal, repeated periodically
Information Messages:	One signal

Alarms can be acoustically silenced for a period of two minutes, this is done by pressing the mute key on the front panel of the device. Once this time has elapsed, the audible alarm will re-enunciate.

During the period where alarm silence is active, in the event of any new alarm condition being triggered, the alarm silence will be immediately terminated.

A pre-alarm silence function may be switched on by pushing and holding the mute key for a period of three seconds. With this function active ALL audible alarms will be silenced for a two minute period. Should any alarms occur within this period the Alarm LED will flash according to the priority of the condition, and each applicable alarm message will be displayed on the ventilators VGA panel.

8.3 Alarm Signals

Along with individual audible signals each alarm is easily recognisable by its visual characteristics. These are defined as follows:

Priority	Background Colour	Audible Signal	Alarm LED Frequency	Nurse Call Status	Can Reset
High	Red	5 signals repeated	2.0 Hz	Enabled	No
Medium	Yellow	3 signals repeated	0.5 Hz	Enabled	No
Low	Yellow	1 signal repeated	Continuous	Enabled	No
Informative	White	1 signal	N/A	Disabled	No

8.4 Alarm Log

The Alarm Log lists the last 100 alarm events in chronological order along with the date and time of the occurrence. The alarm log is accessed through the alarm menu screen which may be accessed at any time by pressing the Alarm Key on the ventilators front panel. The contents of the alarm log will be retained when the ventilator is switched off. When the ventilator is switched on, and 'Last' settings selected, the contents of the alarm log will be available once more.

The contents of the alarm log may be cleared by selecting 'Standard' settings, from the start-up screen following power on.

8.5 High Priority Alarms

Follows a full listing of alarms which will be classified a High Priority. In each case a description of the error and the ventilator response is listed:

Alarm Message	Description of Error	Ventilator Response
Battery Flat	Internal rechargeable battery is flat.	Device switches to ambient ventilation mode.
Occlusion	Pressure at the start of Inspiration is too high.	Ventilation continues with Inspiration valve closed.
High Pressure	Patient system pressure has reached the high pressure alarm setting.	Ventilator immediately switches to exhalation for 1 second without PEEP. Ventilation continues but pressure is limited at the alarm setting.
Internal Pressure Low/Disconnect	Pressure within the gas reservoir is too low	Ventilation Continues, nebulizer is switched off
Low Pressure	Pressure cannot be attained in the patient breathing circuit, possible due to a leak or disconnect.	Ventilation Continues
Apnea	The apnea interval has elapsed without a patient triggered or mandatory breath being delivered. Is active in V-SIMV, P-SIMV and Spontaneous modes	Device will look for patients next inspiratory effort. Note: If apnea back-up is switched to off in the apnea back-up screen, apnea alarm will be triggered but back up ventilation will not occur.
Low Minute Volume	Exhaled minute volume is too low compared with the set alarm limit for ExpMinVol.	Ventilation Continues
High Minute Volume	Exhaled minute volume is too high compared with the set alarm limit for ExpMinVol.	Ventilation Continues
Disconnection		
Low Oxygen	Inspiratory O2 concentration is too low. Possible causes: gas mixing system error, O2 cell faulty, monitor value too low compared with the control value, O2 sensor calibration should be performed.	Ventilation Continues
Oxygen Too High	Inspiratory O2 concentration is too high. Possible causes: gas mixing system error, O2 cell faulty, monitor value too low compared with the control value, O2 sensor calibration should be performed.	Ventilation Continues
Nebulizer Disconnect	Nebulizer flow too high. The nebulizer tubing has become disconnected from the ventilator or nebulizer vial	Ventilation Continues, nebulizer switched off automatically.
Low Tidal Volume	Exhaled minute volume is too low compared with the set alarm limit for Vte.	Ventilation Continues
High Tidal Volume	Exhaled tidal volume is too high compared with the set alarm limit for Vte.	Ventilation Continues

Apnea Back Up	The apnea interval has elapsed without a patient triggered or mandatory breath being delivered. Apnea back-up ventilation has ben commenced.	Ventilator will switch to settings as defined in apnea setting screen.
Speaker Fault	A fault has been detected with the main alarm speaker.	Ventilation continues unaffected but with continuous tone audible alarm.
Volume Is Being Limited	Delivered volume is being limited by VTV / Alarm settings.	Ventilation continues with delivered volume limited.
TF-XX	A technical error has occurred, refer to section 7 for further details.	Ventilator switches to ambient breathing mode.

Note:

As all volume monitoring is performed by the ventilators proximal sensor, alarms for High/Low tidal and minute volume will be disabled when the proximal sensor is switched to OFF.

Note:

As oxygen monitoring is performed by the ventilators internal O2 cell, alarms for High/Low Oxygen will be disabled when the oxygen sensor is switched to OFF

8.6 Medium Priority Alarms

Follows a full listing of alarms which will be classified a Medium Priority. In each case a description of the error and the ventilator response is listed:

Alarm Message	Description of Error	Ventilator Response
Check flow sensor tubing	The measuring tubes for the external flow sensor have either come loose or may be blocked.	Ventilation continues. Device switches over to pressure triggering mode.
Check Flow Sensor	The external flow sensor has been attached incorrectly.	Ventilation continues. Device switches over to pressure triggering mode.
Air Supply	The air supply has been interrupted and compressor back up is switched off in the configuration menu.	Ventilation continues with 100% oxygen, where possible.
Oxygen Supply	The oxygen supply has been interrupted.	Ventilation continues with air supply (21%).
Compressor	The internal compressor has failed.	Ventilation continues with 100% oxygen, where possible.
High Respiratory Rate	Respiratory rate is too high when compared with the low rate alarm limit.	Ventilation Continues
Low Respiratory Rate	Respiratory rate is too low when compared with the low rate alarm limit.	Ventilation Continues.
Check Pcontrol / Pmax	Pcontrol and/or high-pressure alarm settings are incorrect ie. Pcontrol > high-pressure alarm setting.	Ventilation Continues Pressure will be limited at the high-pressure alarm setting until the settings are corrected.

Check Psupport / Pmax	Psupport and/or high-pressure alarm settings are incorrect ie. Psupport > high-pressure alarm setting.	Ventilation Continues Pressure support will be limited at the high-pressure alarm setting until the settings are corrected.
Battery Low	Internal battery voltage is too low.	Ventilation Continues
High Temperature	The temperature inside the device is too high.	Ventilation continues.
External voltage too high	The external DC supply voltage is too high.	Ventilation Continues
Pmean Low	Patient system mean pressure is too low compared with the set alarm limit for Pmean.	Ventilation Continues
Pmean High	Patient system mean pressure is too high compared with the set alarm limit for Pmean.	Ventilation Continues
High Leak	Monitored value for Leak % is too high compared with the set alarm limit for Leak %.	Ventilation Continues

8.7 Low Priority Alarms

Follows a full listing of alarms which will be classified a Low Priority. In each case a description of the error and the ventilator response is listed:

Alarm Message	Description of Error	Ventilator Response
N/A	N/A	N/A

8.8 Information Messages

Follows a full listing of alarms which will be classified a High Priority. In each case a description of the error and the ventilator response is listed:

Message	Description of Information	Ventilator Response
FIO2 and delivery can vary	Internal compressor is in use. FIO2 and deliver may vary according to settings.	Ventilation Continues
Battery Not Available	The internal battery is not available. Possible causes: battery flat, battery missing, faulty cable connections.	Ventilation Continues
Logbook Cleared	Standard ventilator settings have been selected during start up. Alarm Log has been cleared.	Ventilation Continues.
Memory CPU not protected	EEPROM on the CPU is not write protected	Ventilation Continues
Memory sensor not protected	EEPROM on the Sensor PCB is not write protected	Ventilation Continues
Memory power not protected	EEPROM on the Power PCB is not write protected	Ventilation Continues
Flow trigger not available	Flow triggering is not available. Possible causes: flow sensor is attached incorrectly, flow sensor requires calibration.	Device switches over to a pressure trigger mode.
Nebulizer not available	Nebulizer is not available.	The nebulizer is switched off.

100% O2 not available	100% O2 function is not available. Possible causes: oxygen supply not available while 100% O2 is being administered or O2 calibration has been started.	100% O2 cannot be started and is therefore not displayed on the monitor.
O2 calibration not available	O2 calibration is not available because there is no oxygen supply or the O2 sensor has been disabled in the configuration menu.	O2 calibration is interrupted.
Flow calibration not available	The flow sensor cannot be calibrated because it is disabled in the configuration menu.	Flow calibration interrupted.

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9. Service & Repair / Disassembly

9.1 Introduction

This section of the manual describes how to repair the ventilators major subassemblies and their major components. These repair procedures will include removal, installation as applicable.

This section does not provide a complete breakdown of all assemblies and complete disassembly rather disassembly to what the manufacturer deems necessary and reasonable. Repair procedures are provided for all major assemblies and a complete illustrated parts breakdown is included within section 10 of this manual.

9.2 Repair Safety

When servicing the Inspiration ventilator system be sure to familiarise yourself with and adhere to all posted and stated safety warning and caution labels on the ventilator and its components. Failure to adhere to such warnings at all times may result in injury or property damage

To prevent patient injury do not use the ventilator if it requires repair.

To prevent personal injury or death, do not attempt any service to ventilator while a patient or other person is connected to it.

To prevent electric shock hazard always ensure that all electrical power has been removed from device prior to commencing service. This statement requires that not only mains power be removed but also the devices internal batteries and any external DC source as applicable. If the device must be serviced with the power on be careful to avoid electrical shock. At all times follow accepted safety practices for electrical equipment when performing any repairs.

To prevent possible personal injury, always ensure that high pressure air and oxygen sources have been removed.

To prevent possible personal injury and equipment damage never attempt to push or pull a ventilator installed on its stand with the brakes set on.

To prevent possible personal injury and equipment damage always ensure that the brakes are set on to prevent inadvertent movement when performing service.

9.3 Repair Guidelines

The following general guidelines should be considered at all times when performing service to the Inspiration ventilator system.

Follow repair safety guidelines at all times.

The majority of hardware on the ventilator system is metric sized. Always ensure that only metric tools are used when performing service. Use of non-metric tooling may result in damaged hardware.

To prevent any possible damage caused by electrostatic discharge always ensure that appropriate ESD guidelines are followed when performing service to the equipment.

Use only recommended tools, test equipment, and service materials when servicing the ventilator.

When performing service take precautions to prevent dirt and other

particles from entering the ventilator interior, particularly the pneumatic manifold assemblies.

Inspect any removed parts including those removed to gain access to a suspected faulty component. Inspect and clean the exposed area behind removed parts as required. Clean removed parts to facilitate further inspection.

Investigate and determine the cause of any detected abnormality. Repair the unit or consult your local eVENT technical support location for assistance on unsolved problems.

Replace or repair any parts which are found to be worn, missing, damaged, cracked or otherwise show signs of any physical abnormalities.

9.4 Cleaning

If needed, follow these general cleaning guidelines when cleaning the ventilator during servicing. Procedures for periodic cleaning and sterilisation of the ventilator and accessories is listed in the INSPIRATION ventilator system operators instructions. Specific procedures for periodic cleaning and inspection done during the ventilators performance verification are listed in the relevant section of this manual.

Clean ventilator exterior surfaces before disassembly. Use isopropyl alcohol, a bactericidal agent, or a mild detergent and warm water solution, and a clean, lint-free cotton cloth.

Vacuum ventilator interior using ESD-safe equipment. Do not clean the ventilator interior with high pressure air.

During disassembly, clean parts as necessary with isopropyl alcohol. Any excessively dirty items which cannot be cleaned should be replaced.

9.5 Electrical Cables And Pneumatic Connection

To ensure correct reassembly of the device take note of or label wire or tube positions before disconnecting parts.

Make sure that all tubes and harnesses are correctly installed and do not interfere with and can not be damaged by any moving parts.

9.6 ESD Control

It is important to follow appropriate ESD control procedures whenever the ventilator system is being serviced.

9.7 General Information

ESD can permanently damage ESD-sensitive microelectronic components or assemblies when they are handled and even when no direct contact is made with the component or assembly. ESD damage may not be immediately apparent, however, ESD damage will show up at a later time, either as a premature failure of a component or assembly, or as an intermittent failure, which can be difficult and time consuming to locate.

9.8 Procedures And Precautions

Follow these minimum procedures and precautions to prevent ESD damage to the ESD sensitive microelectronic components and assemblies of the INSPIRATION ventilator system.

Use a personnel grounding system. Before opening the ventilator

enclosure, ensure that a personnel grounding system (incorporating wrist strap, static-dissipative mat and ground cord) is worn correctly and is properly connected to reliable ground.

Follow correct procedures for use of static dissipative mat. Place tools, test equipment and the ESD sensitive device on the mat before starting any repairs. Conduct all work from the mat. Never place nonconductive items on the mat.

Handle ESD-sensitive components properly. Do not handle ESD-sensitive component connection points, connector pins, leads or terminals.

Keep nonconductive materials away from work space. Static charges from nonconductive material may not be removed by grounding. Items of this nature should be kept well clear of the work space when handling ESD sensitive devices.

Follow correct procedures for static shielding bags. Store and transport all ESD sensitive devices in the shielding bags at all time except when being worked on. Never place more than one ESD sensitive device in a static shielding bag. Never place static generating nonconductive material inside a static shielding bag with an ESD sensitive device. Place any faulty ESD sensitive devices in a static shielding bag immediately after removal to prevent additional damage. Close and seal the bag to ensure that the shield is effective.

9.9 Repainting

Before repainting or touching up the ventilator, smooth out the area with a fine sandpaper, and make sure it is free from any grease, corrosion, or dust. Remove the part to be painted or mask off the surrounding area to prevent over-spray or spills.

9.10 Non Conforming Parts

When investigating reported problems identify the cause of the failure and repair / replace the component as necessary. Any failed, non-conforming parts, should be retained until the subject device has been successfully repaired. Following completion of the repair any non-conforming parts should be returned to the manufacturer to allow failure analysis to be performed.

To arrange for return of non-conforming parts contact your local dealer. The dealer will request and receive a returns authorisation from the manufacturer. Prior to despatch non-conforming parts should be suitably packaged with a copy of any relevant service documentation enclosed. The return authorisation number provided by the manufacturer should be clearly marked on all shipping documentation and on the exterior of the packaging.

9.11 Replacement Parts

To order correct parts identify the ventilator version and part, then using section 9 (Parts List) identify the manufacturers part number for the item. Should you find that the specific item is not available as a field replaceable unit (FRU) or that it is not stocked order the next higher assembly. Retain the part to be replaced until the replacement part is obtained, and compare the two for compatibility, if possible.

9.12 Post Repair

After successfully completing any ventilator repair the following should be done prior to returning it to normal operation:

Visually verify that all pneumatic and electrical parts are properly connected and that all parts are properly installed. With a light tug, verify that connections are secure and that parts are securely attached. Listen for any uncharacteristic sounds (pneumatic leaks, vibrations, grinding, etc). Be sure that the cooling fan and casters move freely. Check for any unusual odours.

Run the appropriate portions of the Inspiration ventilator performance verification procedure as indicated in section 5 of the before placing the ventilator on a patient.

Keep a detailed record of all maintenance performed on each device. Make sure that service records and other documentation are completed.

9.13 Post Repair Testing

On completion of any ventilator repair run any necessary calibration procedures and any appropriate portions of the Inspiration field check out procedure. For detail on the tests which must be performed per repair refer to the table at the beginning of section 6.

9.14 Repair Documentation

For convenience a service record sheet has been provided as an appendix to this manual. Repairs or any work performed on the device should be recorded on this sheet or similar and retained for future reference.

9.15 Patient System & Accessories

For maintenance of the patient system and accessory items, consult the Inspiration ventilator system operators instructions and refer to the applicable accessory manuals.

9.16
Service And Repair Procedures

9.16.1
Ventilator Stand Removal / Installation

To remove the ventilator from its stand assembly use the following procedure. Installation should be completed by reversal of the removal procedure.

Ensure that the brakes have been engaged to the casters on the base of the stand.

Ensure that all accessory items, tubing system, gas supply hoses and electrical source cables, have been removed from the ventilator.

While supporting the ventilator, using a 5mm hex driver, remove the four M5 screws and flat washers securing the ventilator head to the stand mounting plate.

Lift the ventilator head off of the stand and place on a secure flat surface.

9.16.2
Front Housing Module Removal / Installation

To remove the top cover enclosure from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Ensure that the ventilator is positioned on a secure flat surface. If the ventilator is secured to its stand ensure that each of the five casters has its brake engaged.

Using a 6mm hex driver remove the 4 CSK screws securing the 2 x mounting rails to the ventilator chassis. Support the rail and sleeve during the removal of each screw. Set components aside.

Lift the top cover from the rear and rotate slowly forward to allow access to the inside of the front bezel.

Disconnect the ribbon cable running from Controller PCB at the Power PCB end. Disconnect internal Ethernet cable at the Power PCB end. Disconnect the single spade ground cable from the front bezel.

Following removal place the top cover enclosure on to a grounded static dissipative mat or into a static shielding bag.

9.16.3
Removal Of PU Front Bezel (LS Only)

To remove the PU front bezel from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Ensure that the front housing is placed onto a secure flat surface.

Using a 2.5mm hex driver remove the 4 x CSK screws securing the PU front bezel to the front housing.

Grab PU front bezel, lift and rotate forward from the top. Reach inside and disconnect 2 x ground cables at the front housing.

Carefully lift the PU front bezel up and clear of the front housing, disengaging the hinges.

Following removal place the PU front bezel on to a grounded static dissipative mat or into a static shielding bag.

9.16.4 Rotary control knob Removal / Installation

To remove the rotary control knob assembly from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Disconnect the rotary control knob assembly cable from the Controller PCB.

Using 2mm hex driver, loosen the set screw securing the knob to the rotary control knob device.

Using nut driver or wrench remove the nut and washer from the shaft of the rotary control knob.

Remove the rotary control knob from the top cover enclosure retaining all mounting hardware.

9.16.5 Mini Web Interface PCB Removal / Installation

To remove the Mini Web Interface PCB from the ventilator system, use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

With attention to appropriate anti-static precautions and using 2.5mm hex driver remove 2 x Cap Head screw securing the Mini Web Interface PCB to the Controller PCB.

Carefully unplug the Mini Web Interface PCB from the Controller PCB and place into static shielding bag.

Note:
Replacement MWI PCB's are provided in an un-programmed state. MWI application and applet software files must be installed following the repair. Refer to appendix A for detailed instructions.

9.16.6 Processor PCB Removal / Installation

To remove the Processor PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

With attention to appropriate anti-static precautions and using 2.5mm hex driver remove 4 x Cap Head screw securing the Processor PCB to the Controller PCB.

Carefully unplug the Processor PCB from the Controller PCB and place into static shielding bag.

Note:
Replacement Processor PCB's are provided in an un-programmed state. Ventilator system software must be installed following the repair. Refer to appendix A for detailed instructions.

9.16.7 LCD Display Removal / Installation

To remove the Graphic PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Disconnect ribbon cable from rotary control knob from the Controller PCB.

Disconnect ribbon cable from the lexan keypad from the Controller PCB.

ST and Original Devices:
With attention to appropriate anti-static precautions and using 3.0mm hex driver remove 4 x cap head screw securing the complete graphic module to the front housing.

Remove the complete graphic module and plate on to static dissipative mat with display facing upward.

Using 3.0mm hex driver remove 4 x cap head screw securing the LCD display to stand offs. If Inspiration LS the LCD display panel will now be

Carefully disconnect the backlight cable from the Controller PCB, and the display ribbon cable from LCD.

LS Devices Only:
With attention to appropriate anti-static precautions and using 3.0mm hex driver remove 4 x cap head screw securing the complete graphic module to the front housing.

Carefully disconnect the backlight cable from the Controller PCB, and the display ribbon cable from LCD.

All Devices:
Place LCD and remaining Graphic module components into a static shielding bag.

9.16.8 Graphic PCB Removal / Installation

To remove the Graphic PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Remove Graphic module and LCD display panel (9.16.7).

Using 2.5mm hex driver remove 4 x cap head screw securing the Graphic PCB to the Controller PCB.

Carefully unplug the Graphic PCB from the Controller PCB and place into static shielding bag.

9.16.9 Inverter PCB Removal/Installation (LS/ST Only)

To remove the Inverter PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Remove Graphic module and LCD display panel (9.16.7).

Carefully disconnect the red inverter ribbon cable from the Inverter PCB.

Using a 2.5mm hex driver remove 2 x cap head screw securing the Inverter PCB to the Controller PCB/graphic plate.

Set the Inverter PCB aside and place into a static shielding bag.

9.16.10 Power Converter PCB Removal/Installation (LS Only)

To remove the Power Converter PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Remove Graphic module and LCD display panel (9.16.7).

Using a 2.0mm hex driver remove 2 x cap head screw securing the Power Converter PCB to the graphic plate.

Carefully disconnect the Power Converter PCB from the Graphic PCB and place into a static shielding bag..

9.16.11 Controller PCB Removal / Installation

To remove the Controller / Motherboard PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Note:
Record the ventilator and compressor operating hours, and any relevant error code information on service record prior to replacing the Controller PCB. This information is available on fab test 11.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Remove Graphic PCB and LCD display panel (9.16.7).

Remove the Mini Web Interface PCB (9.16.5).

Remove the Processor PCB (9.16.6).

Remove the Graphic PCB (9.16.8).

Using a 2.5mm hex driver remove 4 x cap head screw securing the Controller/Motherboard PCB to the Graphic Plate.

Remove stand-offs and place Controller PCB into a static shielding bag

9.16.12 Lexan Keypad Removal / Installation

To remove the Lexan / Keypad from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat, if Inspiration LS separate PU front bezel from front housing (9.16.3).

Disconnect ribbon cable from the lexan keypad from the Controller PCB.

Using 2mm hex driver, loosen the set screw securing the knob to the rotary control knob device.

Using 2.5mm hex driver remove 3 x cap head screw securing the nose cone to the front housing.

Starting in one corner lift and peel the lexan keypad up and clear of the front housing.

Following removal ensure that front housing is cleaned and that the front lens is secure prior to installing new lexan keypad.

9.16.13 Compressor Platform Removal / Installation

To remove the compressor platform from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Using 2.5mm hex driver remove 4 x cap head screws securing the compressor platform to the top edge of the bottom housing.

Loosen the 2 remaining screws and rotate compressor platform to an upright position allowing free access to all connections, then retighten the screws.

Using flat bladed screwdriver loosen 2 x hose clamps, then disconnect 2 x pneumatic hoses connecting the compressor to the pneumatic module.

Disconnect the electrical harness running from the compressor pump at the Power PCB, then disconnect from Sol 3 (unloading valve).

Disconnect electrical harness running from the mains inlet module to power supply module at the inlet end.

Disconnect the Power Supply output cable at the Power PCB.

While supporting the compressor platform, use 2.5mm hex driver to remove the 2 remaining screws securing the compressor platform to the bottom enclosure.

Remove the compressor platform and place on static dissipative mat or in static shielding bag.

9.16.14 Compressor Pump Removal / Installation

To remove the compressor pump from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Remove the compressor platform (9.16.13)

Using 2.5mm hex driver remove 4 x CSK screws securing the 2 plastic mounting brackets into position.

Pull the mounting brackets and damping inlays from either end of the compressors plate and set aside for re-installation.

Using a flat blade screwdriver loosen 2 x jubilee clips and remove the 2 compressor hoses from the device.

9.16.15 Power Supply Module Removal / Installation

To remove the power supply module from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Remove the compressor platform (9.16.13).

Using Philips No.2 screwdriver, remove 4 x CSK screws securing the power supply module to the compressor platform.

Place power supply module into a static shielding bag.

9.16.16 Sensor PCB Removal / Installation

To remove the sensor PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Remove the compressor platform (9.16.13).

Disconnect the flat ribbon cable from the Power PCB at the sensor PCB end.

Disconnect O2 sensor interface cable from the Sensor PCB.

Using 2.5mm hex driver, remove the 1 x cap head screw securing the sensor PCB to the pneumatic module (access through right side cut out).

Ease the sensor PCB up out of the pneumatic module. Care should be taken not to flex the PCB excessively or damage the transducer connections

Place the sensor PCB into a static shielding bag.

9.16.17 Power PCB Removal / Installation

To remove the Power PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Remove the compressor platform (9.16.13)

Disconnect flat ribbon cable from the sensor PCB at the Power PCB end.

Disconnect the DC supply harness, cooling fan harness and grounding cable from the Power controller.

Disconnect connecting harnesses from air/O2 blender valves, Inspiration and exhalation proportional valves, nebulizer valve, Safety Valve, compressor system,

Using Philips No.2 screwdriver loosen 4 x CSK screws securing the rear panel to the bottom enclosure. Ensure adequate space to disengage communications connectors from rear panel. If sufficient room is not available rear panel should be removed (Section Ref).

Using 2.5mm hex driver, remove the 2 x cap head screws securing the Power PCB to the pneumatic module (access through right side cut out), and 3 x cap head screws securing the Power PCB to the lower housing.

Ease the Power PCB up out of the pneumatic module. Care should be taken not to flex the PCB excessively or damage the transducer connections

Place Power PCB into a static shielding bag

Note:
Replacement Power PCB's are provided in an un-programmed state. Power system software must be installed following the repair. Refer to appendix A for detailed instructions.

9.16.18
Air / O2 Inlet Assembly Removal / Installation

To remove the air and O2 inlet assemblies from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Using 3.0 mm hex driver remove 2 x cap head screws securing the relevant inlet assembly to the check valve block.

Remove inlet and set aside or disassemble as required.

9.16.19
Air / O2 Inlet Filter Removal / Installation

To remove the inlet filters from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Firmly grip the inlet assembly water trap and rotate counter-clockwise to remove.

Grip inlet filter and rotate counter-clockwise to remove. Replace as is necessary per PM schedule.

9.16.20 Rear Panel Removal / Installation

To remove the rear panel from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove top cover enclosure (9.16.2) and place on static dissipative mat.

Remove Air and O2 inlet assemblies (9.16.18)

Using a 2mm hex driver remove 4 x CSK screws securing the rear panel to the ventilators bottom housing.

Disconnect harness from ventilators mains inlet filter while noting the orientation of the connections.

Disconnect all ground connectors from the primary grounding point on the rear panel while noting the orientation of the connections.

Noting the orientation of the connections disconnect the main DC harness from the external DC connector.

Disconnect cooling fan harness from the Power PCB.

9.16.21 Oxygen Sensor Removal / Installation

To remove the oxygen sensor from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Original Devices:
Loosen the single captive screw securing the O2 cell compartment panel. to the ventilators bottom housing.

LS/ST Devices:
Using a 2.5mm hex driver remove CSK screws securing the O2/battery plate from lower housing.

Disconnect ground cable and set aside the O2 cell compartment panel.

Grip the O2 cell and rotate counter-clockwise to disengage from the pneumatic assembly. Replace as is necessary per PM schedule.

9.16.22 Internal Battery Removal / Installation

To remove the internal battery assembly from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedures.

Remove air and O2 inlet water traps (9.16.18)

Using a 2.5 mm hex driver remove 4 x CSK screws securing the battery compartment panel to the bottom housing.

Disconnect the battery harness noting the orientation of the connectors. Replace batteries as is necessary per PM schedule.

9.16.23 Complete Pneumatic Removal / Installation

To remove the complete pneumatic chassis from the ventilator system complete the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover assembly (9.16.2).

Remove the compressor platform (9.16.13).

Remove Gas Inlet Assemblies (9.16.18).

Remove Rear Panel (9.16.20).

Remove 4 x CSK screws securing the battery/O2 sensor compartment cover and disconnect DC harness from the battery terminals.

Remove the 2 x CSK screws securing the pneumatic chassis to either side of the bottom housing.

Carefully lift the complete pneumatic chassis out of the bottom housing and place on a secure surface.

9.16.24
Removal Of Blending System

To remove the Blender System from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Remove the Power PCB (9.16.17).

Disconnect the main pneumatic harness from the gas supply valves SV1 and SV2.

Using hex driver remove 4 x cap head screw securing the blender system to the upper pneumatic chassis.

9.16.25
Removal Of Blender Valve

To remove either blender valve from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Note:
Observe and note the orientation of blender valves prior to removal. Valve body must be oriented such that number stamped surface faces front of the device.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Remove the Power PCB (9.16.17).

Disconnect the main pneumatic harness from the gas supply valves SV1 and SV2.

Using hex driver remove 4 x cap head screw securing the blender system to the upper pneumatic chassis.

Using a 14mm open end wrench remove the nut securing the hub-magnet of valve (SV1/2) to the valve body, lift hub-magnet off and set aside.

Using a T20 torx driver remove 2 x CSK screws securing the blender valve to the blender block.

9.16.26 Removal Of Inspiration Valve Assembly

To remove the Inspiration Valve from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Note:
Observe and note the orientation of Inspiration valve prior to removal. Valve body must be oriented such that surface stamped with an arrow faces front of the device.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Disconnect main pneumatic harness from the Inspiratory valve PV1.

Using a 14mm open end wrench remove the nut securing the hub-magnet of PV1 to the valve body, lift hub-magnet off and set aside.

Using a T20 torx driver remove 2 x CSK screws securing PV1 to the sensor block 1.

9.16.27 Removal Of Internal Flow sensor

To remove the Internal Flow Sensor from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Using 2.5mm hex driver remove 2 x cap head screw securing the internal flow sensor between sensor blocks 1 and 2.

Firmly grip flow sensor handle and slide the component up and out from between the blocks.

9.16.28 Removal Of The Security Block

To remove the sensor PCB from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Using hex driver remove 4 x screws securing the security block to sensor block 2.

Set security block on a secure clean surface for further disassembly.

9.16.29 Removal Of The Over Pressure Valve

To remove the over pressure valve from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Remove the security block (9.16.28).

Pull the over pressure valve cartridge out from the security block.

9.16.30
Removal Of The Security Valve

To remove the security valve from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the compressor platform (9.16.13).

Remove the security block (9.16.28).

Lift top block from the security block.

Manually unscrew the security valve plunger from the actuator. Set the plunger and top diaphragm aside.

Using hex driver remove 2 x cap head screw securing the security valve to the top block.

9.16.31
Removal Of The Nebulizer Valve

To remove the Nebulizer valve from the ventilator system us the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Disconnect nebulizer harness from the terminals of the nebulizer valve.

Using a 14mm open end wrench remove the nut securing the hub-magnet of SV4 to the valve body. Lift hub-magnet off and set aside.

Using a T8 torx driver remove 2 x CSK screws securing SV4 to the front block.

9.16.32
Removal Of The Front Block

To remove the Front Block from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Remove the nebulizer valve (9.16.29).

Using hex driver remove 2 x cap head screws securing the front pneumatic block to the upper pneumatic chassis.

Using an 18mm open end wrench remove the nebulizer connector from the front block and retain.

9.16.33
Removal Of The Exhalation Valve

To remove the exhalation valve from the ventilator system use the following procedure. Installation should be completed by reversal of the removal procedure.

Remove the top cover enclosure (9.16.2).

Disconnect the exhalation valve at the Power PCB.

Using hex driver remove 2 x cap head screw securing exhalation cover locking ring in position. Set locking ring components aside.

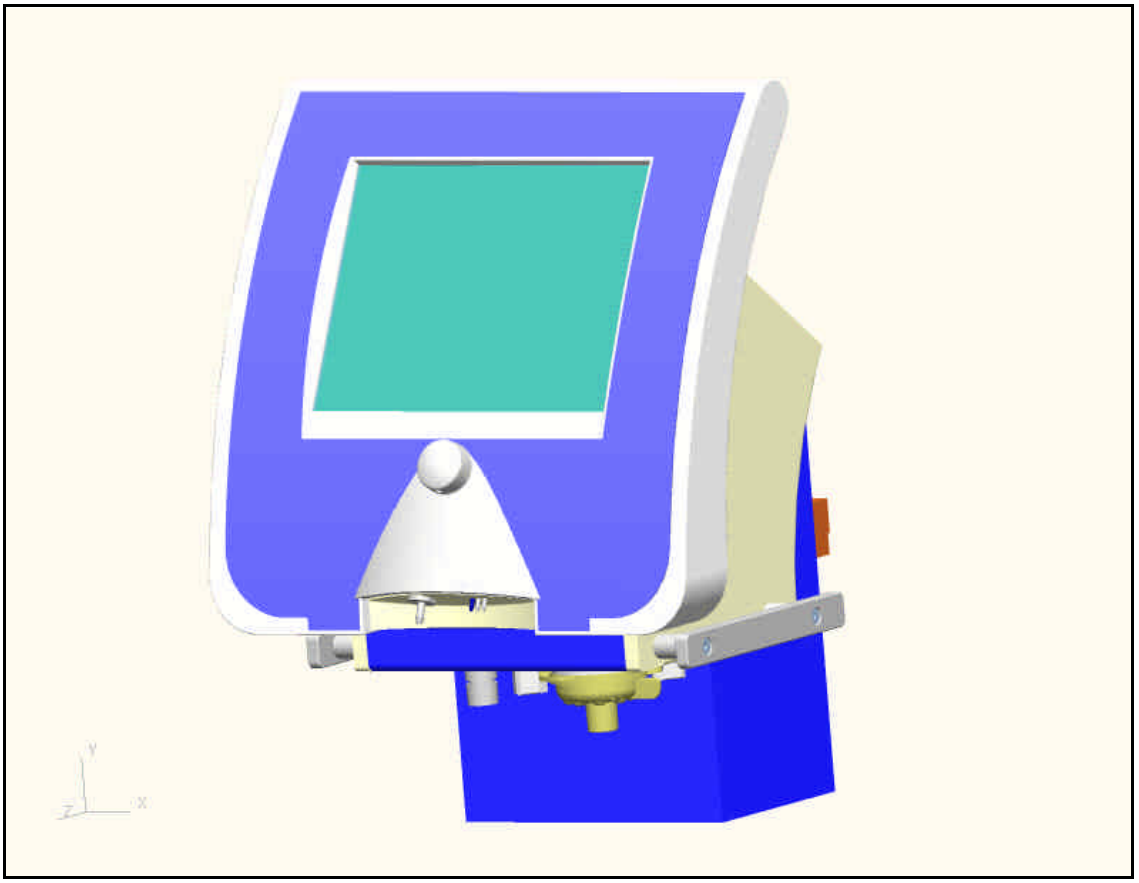
Using hex driver remove 2 x cap head screw securing the exhalation valve to the bottom pneumatic chassis. Withdraw exhalation valve from the pneumatic chassis and set aside.

10. Parts Lists

10.1 Introduction

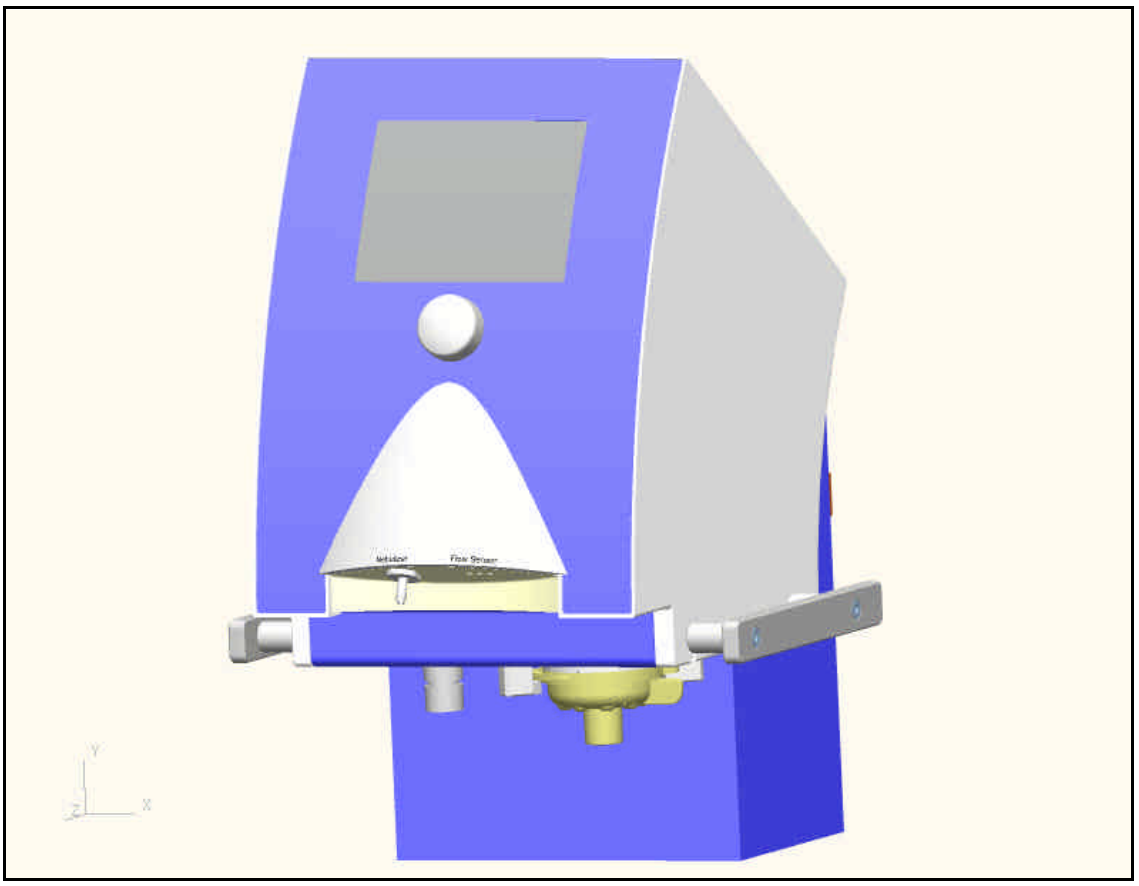
This section begins by showing the entire ventilator system, including accessory items. Subsequent figures show ventilator subassemblies and their component parts. Alphabetic and numeric parts indexes are also included at the back of this section to assist in the identification of the correct components.

10.2 Ventilator Assembly



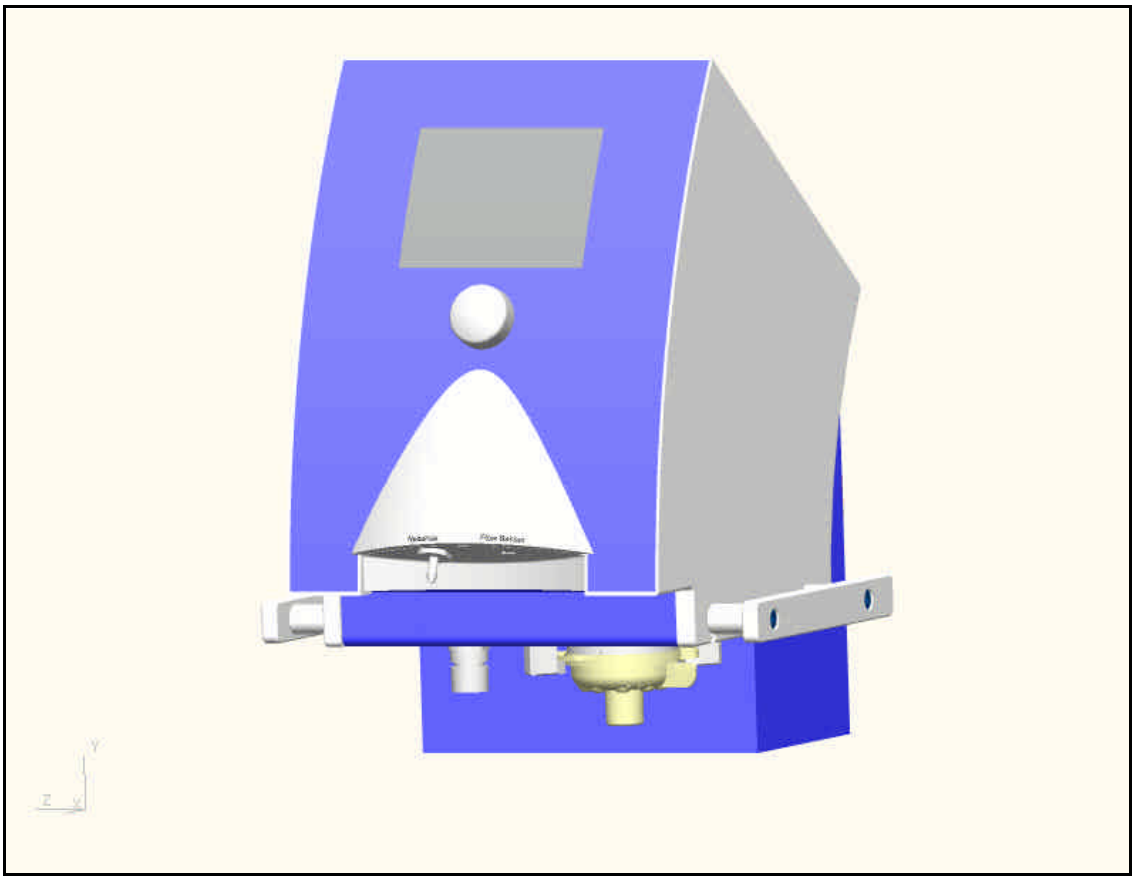
10.2.1 VENTILATOR ASSEMBLY – MODEL F7300000 – INSPIRATION *LS*

Item No	*Part No.*	*Description*
01	F-7300000-DE	Inspiration Ventilator, German
	F-7300000-ES	Inspiration Ventilator, Spanish
	F-7300000-FR	Inspiration Ventilator, French
	F-7300000-GB	Inspiration Ventilator, English (UK)
	F-7300000-IN	Inspiration Ventilator, English (IN)
	F-7300000-IT	Inspiration Ventilator, Italian
	F-7300000-JP	Inspiration Ventilator, Japanese
	F-7300000-PL	Inspiration Ventilator, Polish
	F-7300000-PT	Inspiration Ventilator, Portuguese
	F-7300000-RU	Inspiration Ventilator, Russian
	F-7300000-US	Inspiration Ventilator, US
Not Shown	F-710102	Inspiration Ventilator Cart, Standard
Not Shown	F-710513	Inspiration Ventilator Cart, Transport
Not Shown	F-710522	Inspiration Ventilator Cart, Deluxe



10.2.2 VENTILATOR ASSEMBLY – MODEL F7200000 – INSPIRATION ST

Item No	*Part No.*	*Description*
01	F-7200000-DE	Inspiration Ventilator, German
	F-7200000-ES	Inspiration Ventilator, Spanish
	F-7200000-FR	Inspiration Ventilator, French
	F-7200000-GB	Inspiration Ventilator, English (UK)
	F-7200000-IN	Inspiration Ventilator, English (IN)
	F-7200000-JP	Inspiration Ventilator, Japanese
	F-7200000-IT	Inspiration Ventilator, Italian
	F-7200000-PL	Inspiration Ventilator, Polish
	F-7200000-PT	Inspiration Ventilator, Portuguese
	F-7200000-RU	Inspiration Ventilator, Russian
	F-7200000-US	Inspiration Ventilator, US
Not Shown	F-710102	Inspiration Ventilator Cart, Standard
Not Shown	F-710513	Inspiration Ventilator Cart, Transport
Not Shown	F-710522	Inspiration Ventilator Cart, Deluxe

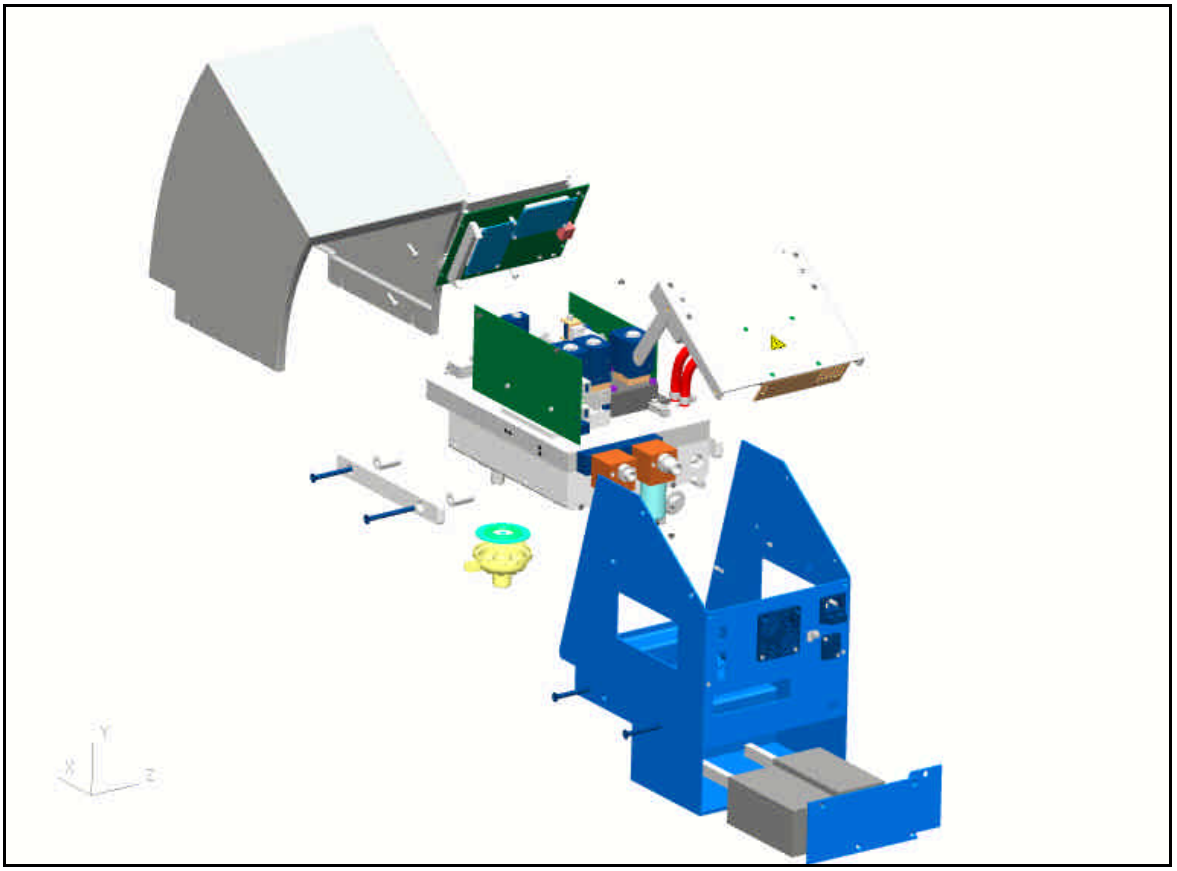


10.2.3 VENTILATOR ASSEMBLY – MODEL F7100000

Item No	*Part No.*	*Description*
01	F-7100000-DE	Inspiration Ventilator, German
	F-7100000-ES	Inspiration Ventilator, Spanish
	F-7100000-FR	Inspiration Ventilator, French
	F-7100000-GB	Inspiration Ventilator, English UK
	F-7100000-IN	Inspiration Ventilator, English Int
	F-7100000-IT	Inspiration Ventilator, Italian
	F-7100000-PL	Inspiration Ventilator, Polish
	F-7100000-PT	Inspiration Ventilator, Portuguese
	F-7100000-RU	Inspiration Ventilator, Russian
Not Shown	F-710100	Stand Assembly
Not Shown	F-710102	Stand Stay Plate
Not Shown	F-710101	Ventilator Mounting Plate

10.3 Ventilator Accessories

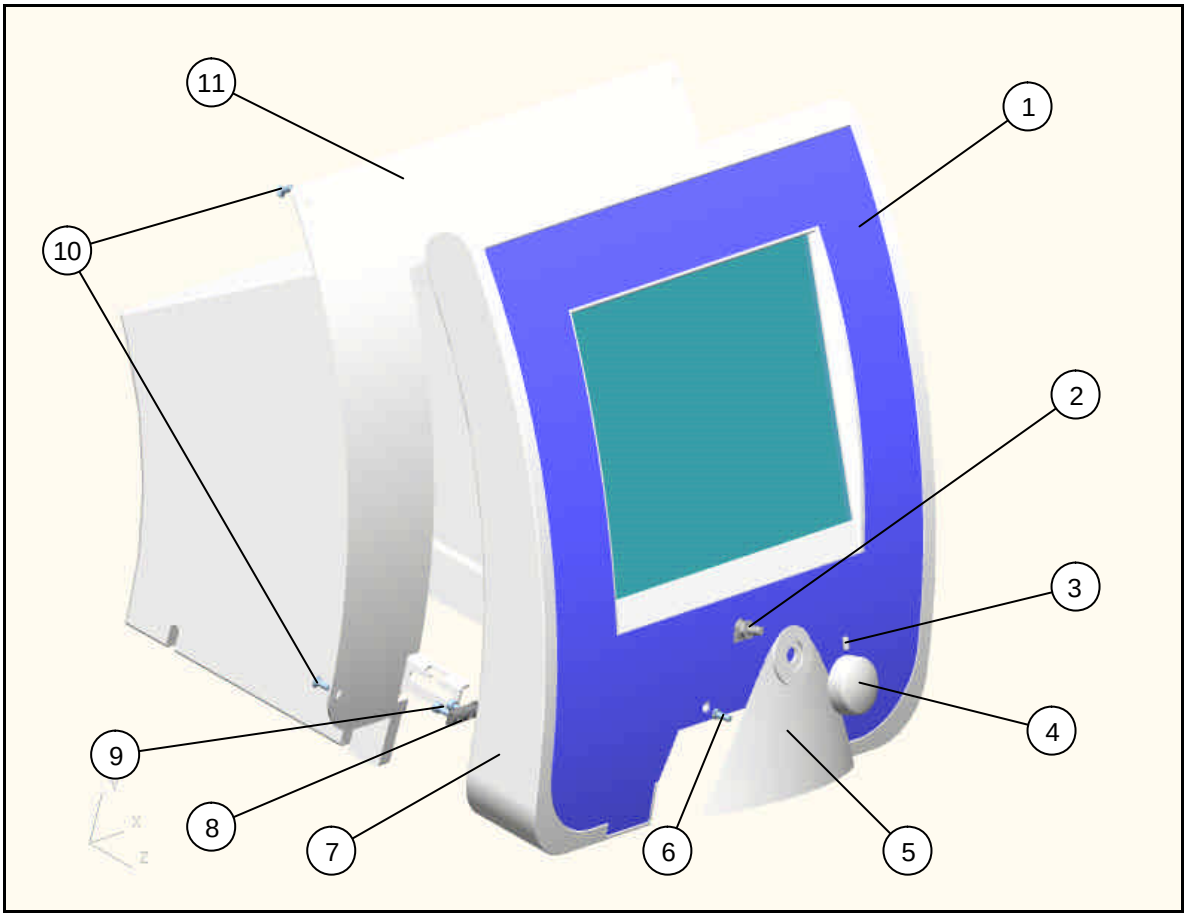
Item No	*Part No.*	*Description*
Not Shown	F-910036	Proximal Flow Sensor, Orig, Pkg 10
Not Shown	F-910036i	Infant Flow Sensor, Orig, Pkg 10
Not Shown	F-910203-PKG	Disposable Adult Sensor, Pkg 10
Not Shown	F-910204-PKG	Disposable Infant Sensor, Pkg 10
Not Shown	F-910232	Tube Sizer
Not Shown	F-910260	Flow Sensor Tubing, Disposable
Not Shown	F-910265	Reusable Adult Sensor
Not Shown	F-910266	Reusable Infant Sensor
Not Shown	F-710213-PKG	Exhalation Diaphragm, Pkg 10
Not Shown	F-710214	Exhalation Cover
Not Shown	F-910034	Tubing Support Arm
Not Shown	F-910035	Support Arm Clamp
Not Shown	F-710216	DISS Adapter, Air
Not Shown	F-710215	DISS Adapter, Oxygen
Not Shown	F-910037	DISS Hose Assembly, Air
Not Shown	F-910038	DISS Hose Assembly, Oxygen
Not Shown	F-910217	NIST Hose Assembly, Air
Not Shown	F-910218	NIST Hose Assembly, Oxygen
Not Shown	F-910219	High Pressure Hose, Italian, Air
Not Shown	F-910220	High Pressure Hose, Italian, Oxygen
Not Shown	F-910085	Software Download Cable
Not Shown	F-710102	Inspiration Ventilator Cart, Standard
Not Shown	F-710513	Inspiration Ventilator Cart, Transport
Not Shown	F-710519	Cylinder Mounts, Dual US E Cylinder
Not Shown	F-710522	Inspiration Ventilator Cart, Deluxe
Not Shown	F-710523	Cylinder Mounts, Dual Euro Cylinder



10.4 VENTILATOR CHASSIS

Item No	*Part No.*	*Description*
01	Reference Only	Front Housing Assembly
02	Reference Only	Bottom Housing Assembly
03	Reference Only	Rear Housing Assembly
04	Reference Only	Compressor Module
05	Reference Only	Complete Pneumatic Module

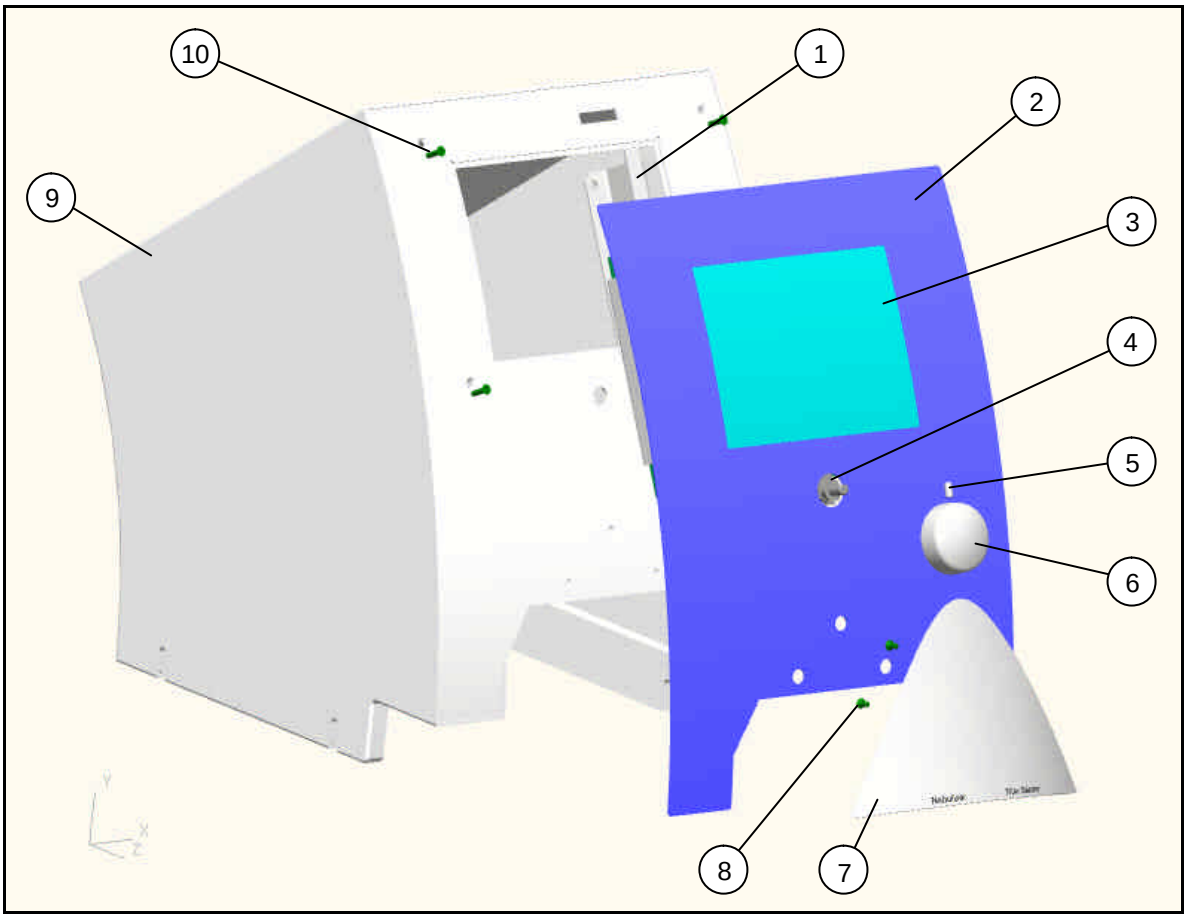
10.5 Front Housing Module



10.5.1 FRONT HOUSING MODULE – INSPIRATION LS

Item No	*Part No.*	*Description*
01	F-730515-DE F-730515-ES F-730515-FR F-730515-GB F-730515-IT F-730515-JP F-730515-PL F-730515-PT F-730515-RU	Lexan Screen, German Lexan Screen, Spanish Lexan Screen, French Lexan Screen, English Lexan Screen, Italian Lexan Screen, Japanese Lexan Screen, Polish Lexan Screen, Portuguese Lexan Screen, Russian
02	F-910005	Rotary control knob Encoder
03	F-810011	Set Screw, Knob
04	F-730210	Knob, Rotary control knob

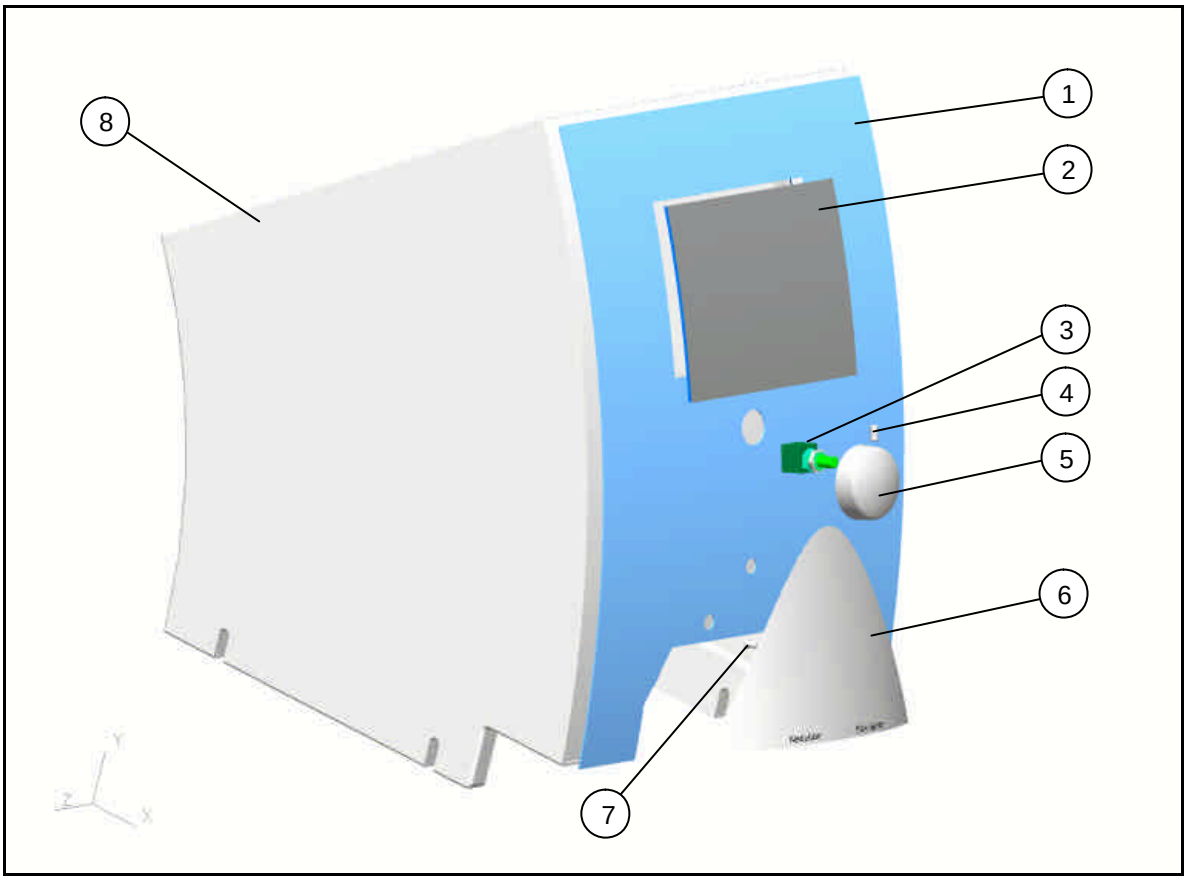
05	F-730203-DE F-730203-ES F-730203-FR F-730203-UK F-730203-IT F730203-JP F-730203-PL F-730203-PT F-730203-RU	Nose Cone, German Nose Cone, Spanish Nose Cone, French Nose Cone, English Nose Cone, Italian Nose Cone, Japanese Nose Cone, Polish Nose Cone, Portuguese Nose Cone, Russian
06	F-830001	Screw, Nose Cone
07	F-910244	Front Housing PU Complete (includes ref 01)
08	F-730221	Hinge, Front Bezel
09	F-810016	Screw, Hinge
10	F-830023	Screw, Front Chassis
11	F-730202	Front Chassis
Not Shown	F-930003	Earth Cable, Front Bezel



10.5.2 FRONT HOUSING MODULE – INSPIRATION ST

Item No	*Part No.*	*Description*
01	F-720701	Bracket, Graphic Module
02	F-720515-DE F-720515-ES F-720515-FR F-720515-UK F-720515-IT F-720515-JP F-720515-PL F-720515-PT F-720515-RU	Lexan Screen, German Lexan Screen, Spanish Lexan Screen, French Lexan Screen, English Lexan Screen, Italian Lexan Screen, Japanese Lexan Screen, Polish Lexan Screen, Portuguese Lexan Screen, Russian
03	F-720211	Lens Cover
04	F-910005	Rotary control knob Encoder
05	F-810011	Set Screw, Knob
06	F-710210	Knob, Rotary control knob

07	F-710203-DE F-710203-ES F-710203-FR F-710203-UK F-710203-IT F710203-JP F-710203-PL F-710203-PT F-710203-RU	Nose Cone, German Nose Cone, Spanish Nose Cone, French Nose Cone, English Nose Cone, Italian Nose Cone, Japanese Nose Cone, Polish Nose Cone, Portuguese Nose Cone, Russian
08	F-810132	Screw, Nose Cone
09	F-910241	Front Housing (includes Ref 01,02,03)
10	F-810082	Screw, Graphic Module

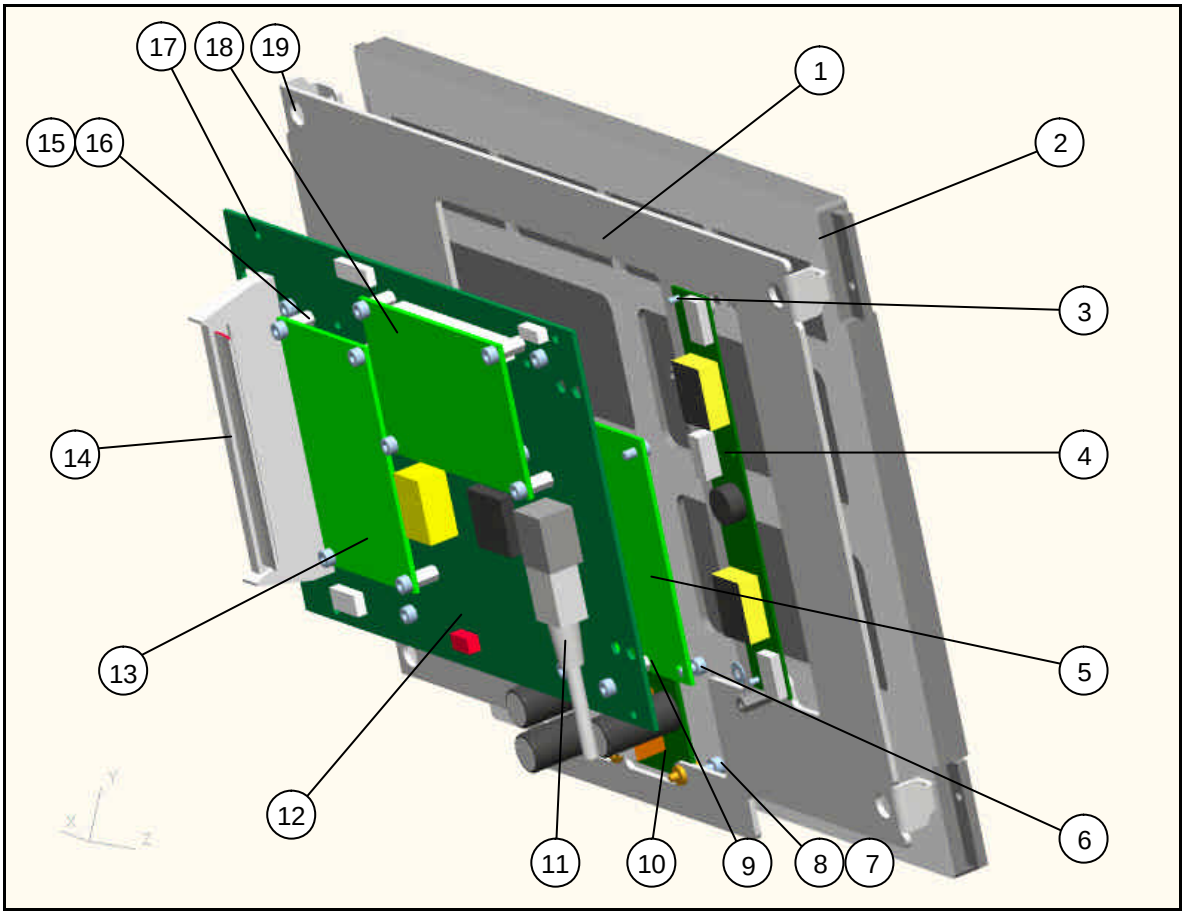


10.5.3 FRONT HOUSING MODULE – INSPIRATION ORIGINAL

Item No	*Part No.*	*Description*
01	F-710212-DE F-710212-ES F-710212-FR F-710212-GB F-710212-IT F-710212-PL F-710212-PT F-710212-RU	Lexan Screen, German Lexan Screen, Spanish Lexan Screen, French Lexan Screen, English Lexan Screen, Italian Lexan Screen, Polish Lexan Screen, Portuguese Lexan Screen, Russian
02	F-710211	Glass Lens, Display
03	F-910005	Rotary control knob Encoder
04	F-810011	Set Screw, Knob
05	F-710210	Knob, Rotary control knob

06	F-710203-DE F-710203-ES F-710203-FR F-710203-UK F-710203-IT F710203-JP F-710203-PL F-710203-PT F-710203-RU	Nose Cone, German Nose Cone, Spanish Nose Cone, French Nose Cone, English Nose Cone, Italian Nose Cone, Japanese Nose Cone, Polish Nose Cone, Portuguese Nose Cone, Russian
07	F-810132	Screw, Nose Cone
08	F-910238	Front Housing (includes ref 01, 02)
Not Shown	F-710701	Bracket, Graphic Module
Not Shown	F-810082	Screw, Graphic Module

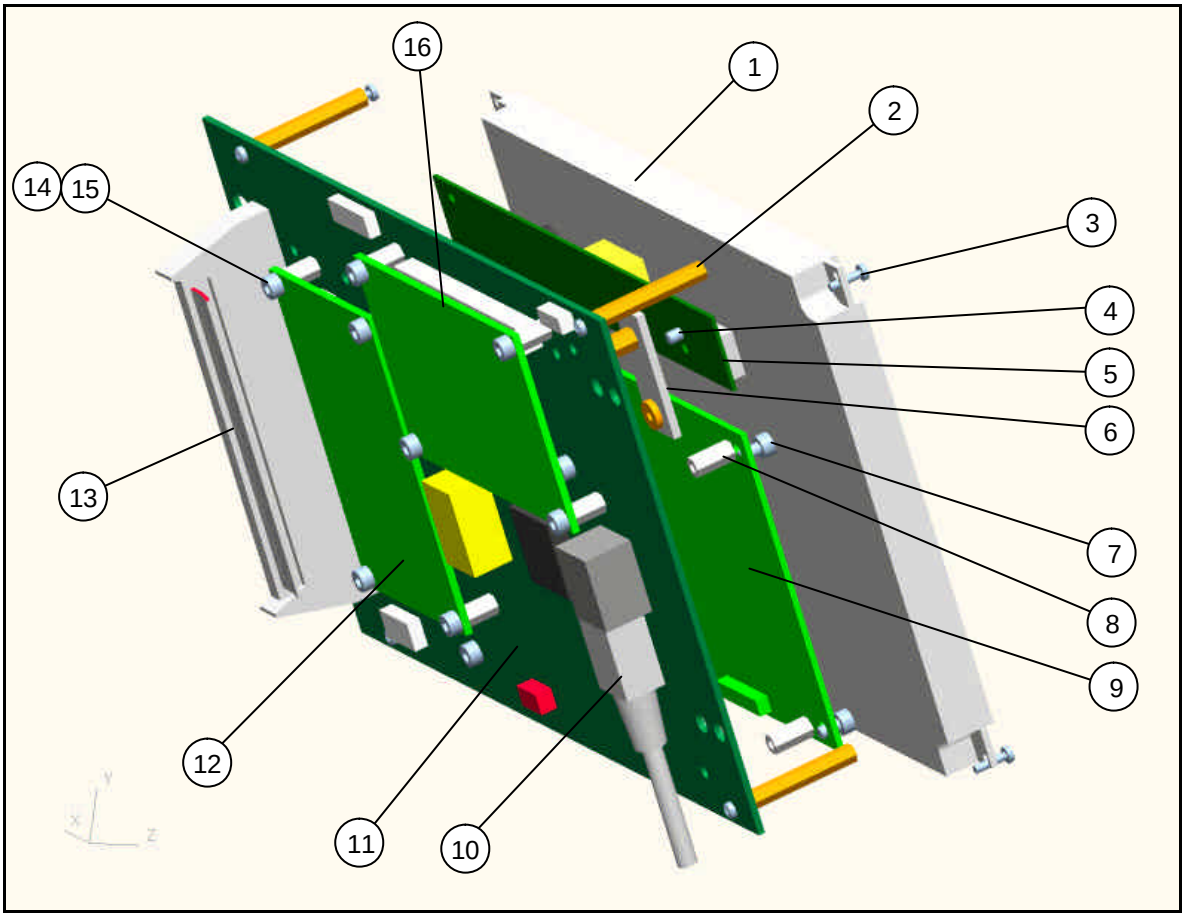
10.6 GRAPHIC MODULE



10.6.1 GRAPHIC MODULE – INSPIRATION *LS*

Item No	*Part No*	*Description*
01	F-730701	Graphic Plate
02	F-910250	12.1 Display Screen, FRU, LS only
03	F-830005	Screw, Inverter
04	F-930104	Inverter PCB, LS only
05	F-930108	Graphic PCB, LS only
06	F-810075	Screw, Graphic PCB
07	F-830006	Screw, DC Converter
08	F-830007	Spacer, DC Inverter
09	F-820016	Stand Off, Graphic PCB
10	F-730513	DC Converter PCB, LS only
11	F-920062	Ethernet Cable
12	F-720510	Motherboard PCB
13	F-910015	Processor PCB
14	F-920060	Ribbon Cable, Motherboard
15	F-810088	Screw, MWI / Processor

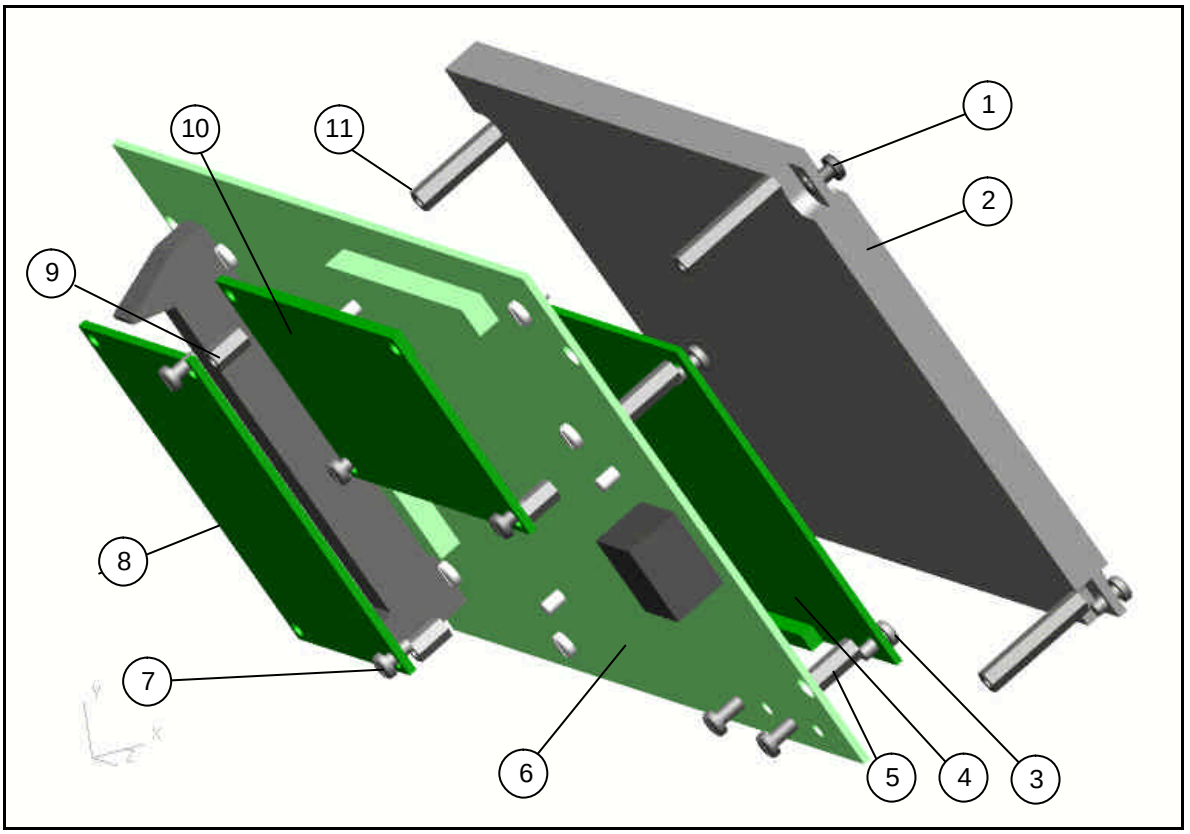
16	F-810087	Stand Off, MWI / Processor
17	F-810075	Screw, Motherboard
18	F-Ethernet	Mini Web Interface PCB
19	F-820007	Screw, Graphic Plate
Not Shown	F-930107	Display LCD Cable
Not Shown	F-930070	Inverter Cable
Not Shown	F-930105	Backlight Assembly
Not Shown	F-820024	Ferrite Bead
Not Shown	F-820025	Clip, Ferrite



10.6.2 GRAPHIC MODULE – INSPIRATION *ST*

Item No	*Part No*	*Description*
01	F-920001	6.4” Display Screen, ST Only
02	F-820015	Stand Off, Display
03	F-820018	Screw, Display
04	F-810088	Screw, Inverter
05	F-920104	Inverter PCB, ST Only
06	F-720703	Print Support Sheet
07	F-810075	Screw, Graphic PCB
08	F-820016	Stand Off, Graphic PCB
09	F-920002	Graphic PCB, ST Only
10	F-920062	Ethernet Cable
11	F-720510	Motherboard PCB
12	F-910015	Processor PCB
13	F-920060	Ribbon Cable, Motherboard
14	F-810088	Screw, MWI / Processor
15	F-810087	Stand Off, MWI / Processor
16	F-Ethernet	Mini Web Interface PCB

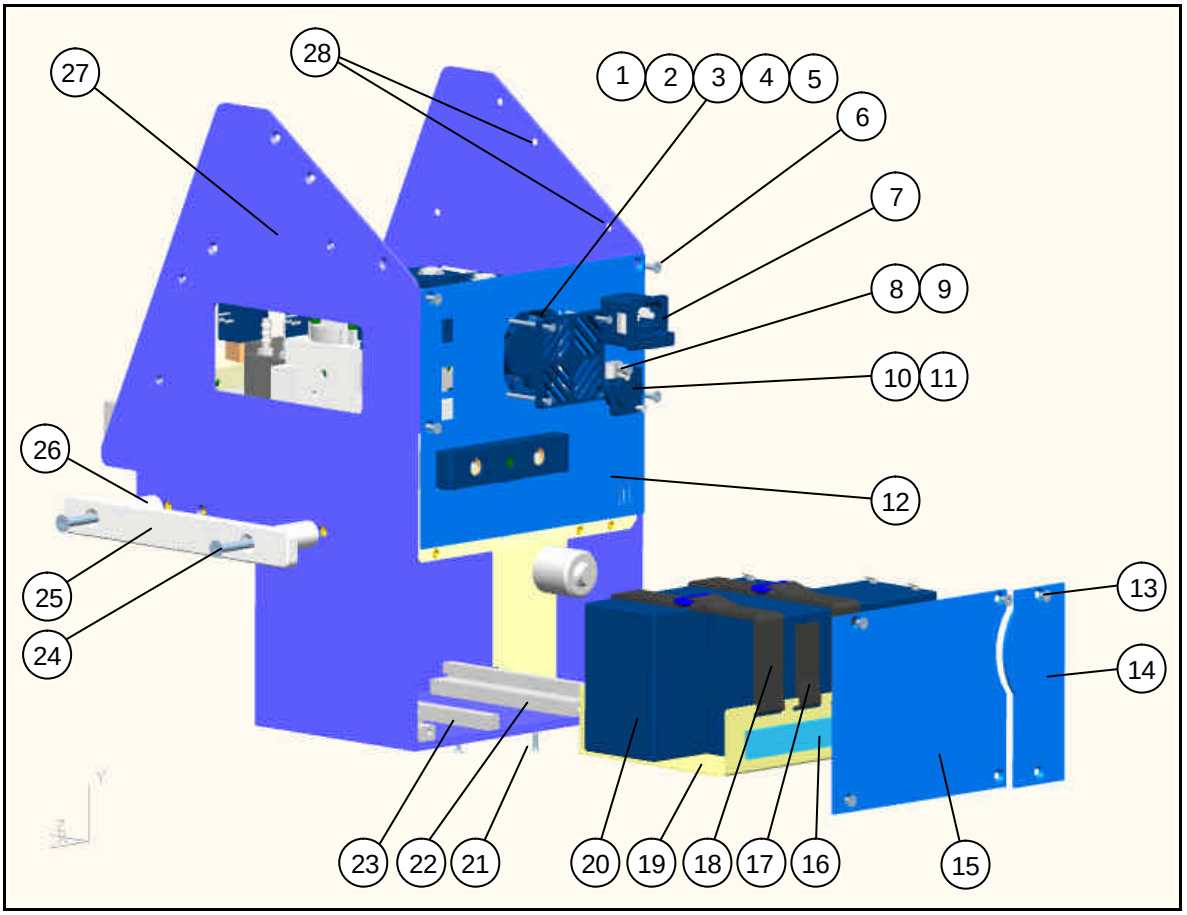
Not Shown	F-920069	Display LCD Cable
Not Shown	F-920070	Inverter Cable
Not Shown	F-920105	Backlight Assembly
Not Shown	F-820024	Ferrite Bead
Not Shown	F-820025	Clip, Ferrite
Not Shown	F-810016	Screw, Graphic Module



10.6.3 GRAPHIC MODULE – INSPIRATION ORIGINAL

Item No	*Part No*	*Description*
01	F-810088	Screw, Display
02	F-910001	Display Assembly, Original Only
03	F-810088	Screw, Graphic PCB
04	F-910002	Graphic PCB, Original Only
05	F-820016	Stand Off, Graphic PCB
06	F-710510	Controller PCB, Original Only
07	F-810075	Screw, MWI / Processor
08	F-910015	Processor PCB
09	F-810087	Stand Off, MWI / Processor
10	F-Ethernet	Mini Web Interface PCB
11	F-810085	Stand Off, Display
Not Shown	F-920060	Ribbon Cable, Motherboard
Not shown	F-910069	Display Cable, Original Only

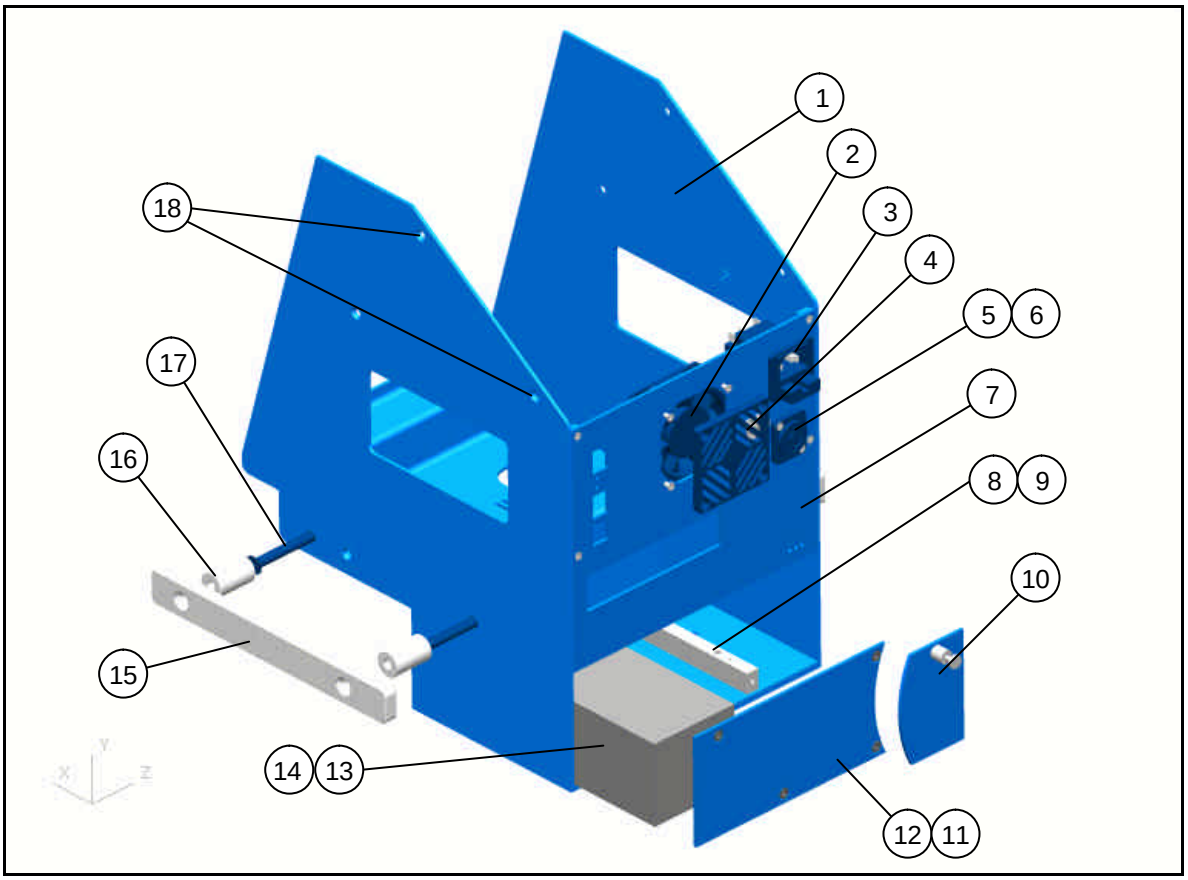
10.7 Ventilator Housing Assembly



10.7.1 LOWER HOUSING – INSPIRATION *LS* / *ST*

Item No	*Part No*	*Description*
01	F-910252	Cooling fan, FRU
02	F-910007	Guard, cooling fan
03	F-810015	Screw, cooling fan
04	F-810018	Nut, cooling fan
05	F-810019	Serrated Washer, cooling fan
06	F-810017	Screw, rear panel
07	F-910008	Mains Inlet Assembly
08	F-910009 F-810217	Cord retainer, General Cord retainer, US / Japan
09	F-810016	Screw, cord retainer
10	F-810001	External DC connector
11	F-810017	Screw, DC connector
12	F-720204	Rear Connection Panel
13	F-810216	Screw, O2 / battery cover
14	F-720207	O2 Cover

15	F-720206	Battery Cover
16	F-820006	Damping Mat
17	F-820005	Short Belt
18	F-820004	Securing Strap
19	F-720241	Battery Plate
20	F-910251	Internal Battery Pack, FRU
21	F-810017	Screw, Guide Rail
22	F-720205	Guide Rail
23	F-720217	Battery Support
24	F-810004	Mounting Screw, Rail
25	F-710209	Rail
26	F-710208	Support, Rail
27	F-720201	Bottom housing, LS/ST
28	F-810008	Screw, compressor module
Not Shown	F-920007	Filter, cooling fan
Not Shown	F-710222	Drip guard
Not Shown	F-810017	Screw, drip guard
Not Shown	F-910210	Label, do not obstruct
Not Shown	F-910211	Label, to/from Patient (JP only)
Not Shown	F-920071	Earth Cable, 10cm, Inlet Filter / Chassis
Not Shown	F-920072	Earth Cable, 18cm, Power PCB
Not Shown	F-920073	Earth Cable, 35cm, O2 Cover
Not Shown	F-920074	Earth Cover, 50cm, Front Chassis
Not Shown	F-810135	Fuse, Mains Inlet, 3.15A

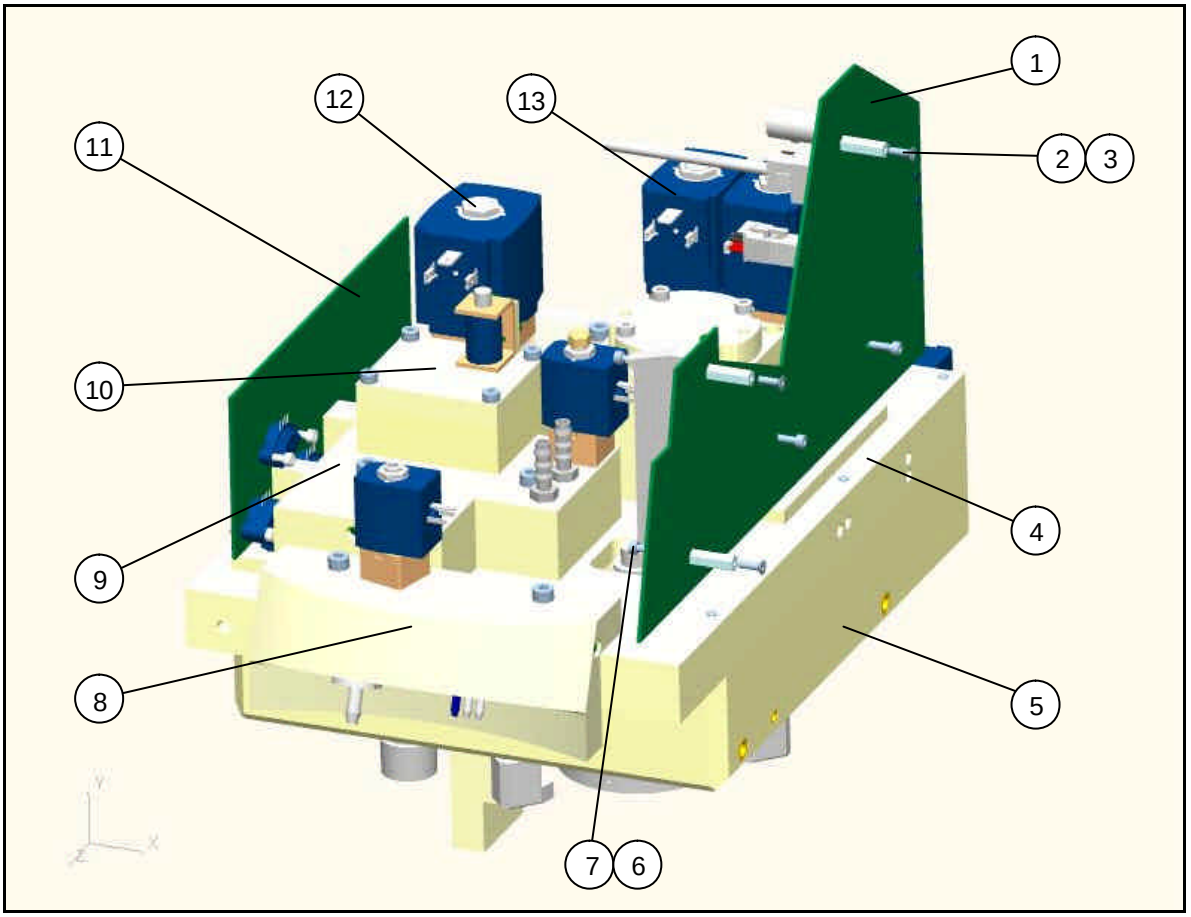


10.7.2 LOWER HOUSING – INSPIRATION ORIGINAL

Item No	*Part No*	*Description*
01	F-710201	Bottom Housing
02	F-910252	Cooling Fan, FRU
03	F-910008	Mains Inlet Assembly
04	F-910007	Cooling Fan Guard
05	F-810001	External DC Connector
06	F-810017	Screw, DC Connector
07	F-720204	Rear panel,
08	F-710205	Battery support
09	F-810017	Screw, support
10	F-710207	O2 Cell cover
11	F-710206	Battery cover
12	F-810008	Screw, battery cover
13	F-910253	Internal Battery, FRU
14	F-920063	DC Power Harness
15	F-710209	Rail
16	F-710208	Inserts, Rail

17	F-810004	Mounting Screw, Rail
18	F-810008	Screw, compressor module
Not Shown	F-920007	Filter, cooling fan
Not Shown	F-810015	Screw, cooling fan
Not Shown	F-810018	Nut, cooling fan
Not Shown	F-810019	Serrated washer, cooling fan
Not Shown	F-910009	Power cord retainer
Not Shown	F-810016	Screw, retainer

10.8 Ventilator Pneumatic Chassis

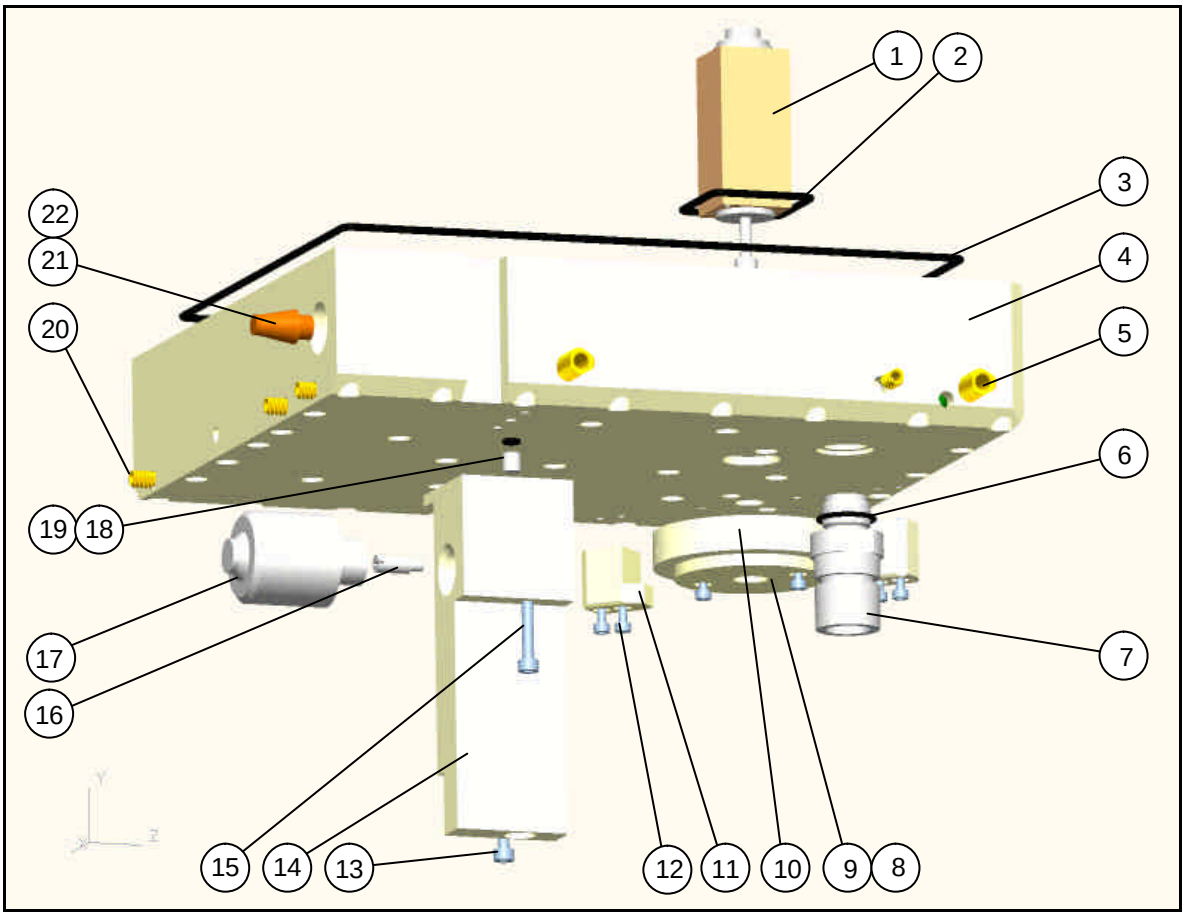


10.8.1 VENTILATOR PNEUMATIC CHASSIS

Item No.	*Part No.*	*Description*
01	F-720511	PCB Assembly, Power Board (LS and ST)
02	F-820022	Screw, Countersunk,
03	F-820019	Stand Off, Power PCB
04	Reference Only	Upper Block Assembly
05	Reference Only	Lower Block Assembly
06	F-820021	Screw, Cap Head, Power/Sensor PCB
07	F-820020	Insulating washer
08	Reference Only	Front Block Assembly
09	Reference Only	Sensor Block 2 Assembly
10	Reference Only	Safety Valve Block Assembly
11	F-710512	PCB Assembly, Sensor Board
12	Reference Only	Sensor Block 1 Assembly
13	Reference Only	Blender Block Assembly
Not shown	F-710511	PCB Assembly, Power Board (original only)
Not shown	F-920060	Ribbon Cable, Motherboard

Not Shown	F-920061	Ribbon Cable, Sensor Board
Not Shown	F-920067	Pneumatic Valve Harness (LS/ST only)
Not Shown	F-910067	Pneumatic Valve Harness (original only)

10.9 *Pneumatic Lower Module*

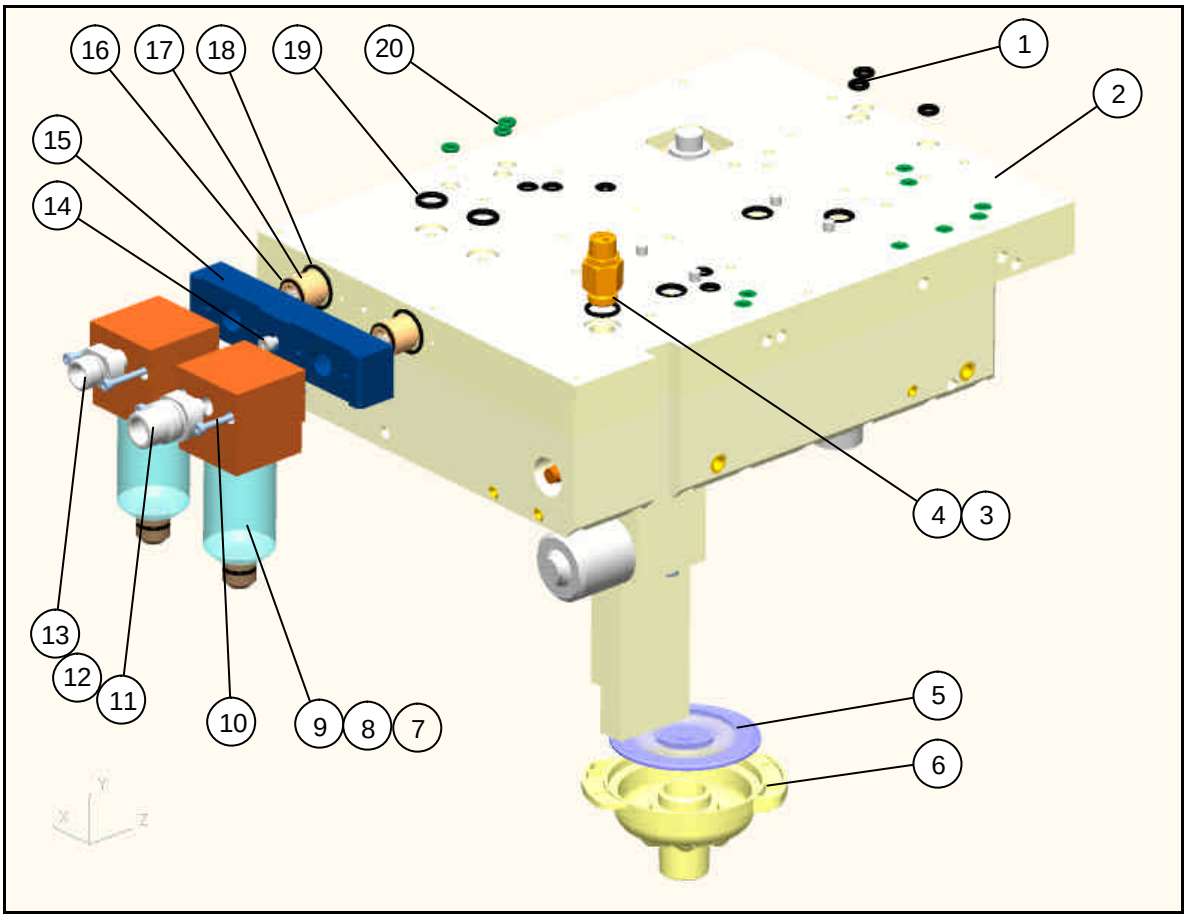


10.9.1 *PNEUMATIC LOWER MODULE*

Item No.	*Part No.*	*Description*
01	F-910087	Valve, Exhalation
02	F-910246	O-ring, EValve Enclosure
03	F-910245	O-ring, Tank Main
04	F-910242	Pneumatic Bottom Block, FRU
05	F-820010	Threaded Insert, M6
06	F-810042	O-ring, to patient
07	F-710305	To Patient Connector
08	F-710309	Inner ring, exhalation – inner
09	F-810012	Screw, inner ring
10	F-710310	Outer ring, exhalation
11	F-710311	Hook, Exhalation
12	F-810041	Screw, hook
13	F-810016	Screw, O2 block, short
14	F-910243	O2 sensor block, LS & ST, FRU

15	F-820009	Screw, O2 block, long
16	F-710308	Nozzle, O2 sensor
17	F-910028	O2 Measurement Cell
18	F-910027	Restrictor, O2 sensor
19	F-810063	O-ring, restrictor
20	F-810203	Threaded Insert, M4
21	F-810044	Filter, Compressor Inlet
22	F-920100	Blank, Filter Port
Not Shown	F-710314A	Block Assembly, O2 sensor, Original
Not Shown	F-810039	Screw, O2 block, Original
Not Shown	F-920064	O2 sensor Harness
Not Shown	F-810008	Screw, pneumatic chassis

10.10 Pneumatic Upper Block

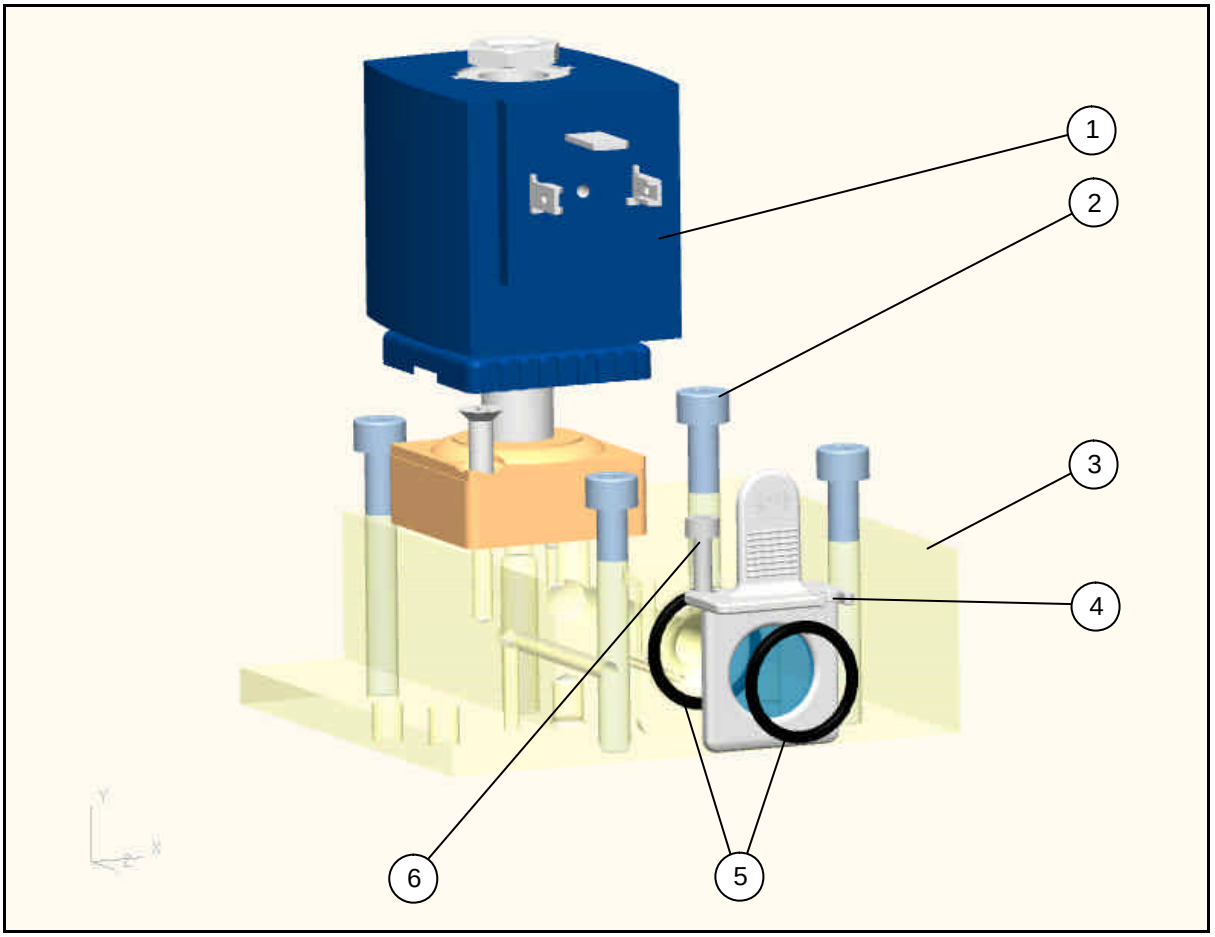


10.10.1 PNEUMATIC UPPER BLOCK

Item No.	Part No.	Description
01	F-810031	O-ring, blocks, small
02	F-710302	Block assembly, top pneumatic
03	F-910201	Tank over pressure valve
04	F-810204	O-ring, over pressure valve
05	F-710213	Exhalation membrane
06	F-710214	Exhalation cover
07	F-910036	Filter / water trap assembly
08	F-910205	Filter, replacement inlet
09	F-910216	Replacement Bowl, Water Trap
10	F-810008	Screw, water trap
11	F-710216	Connector, high pressure air
12	F-810007	O-ring, high pressure connectors
13	F-710215	Connector, high pressure oxygen
14	F-810059	Screw, connection block
15	F-710313	Connection Block

16	F-810042	O-ring, inlet check valve
17	F-810061	Inlet check valve
18	F-810037	O-ring, connection block
19	F-810032	O-ring, blocks, large
20	F-810085	O-ring, transducer

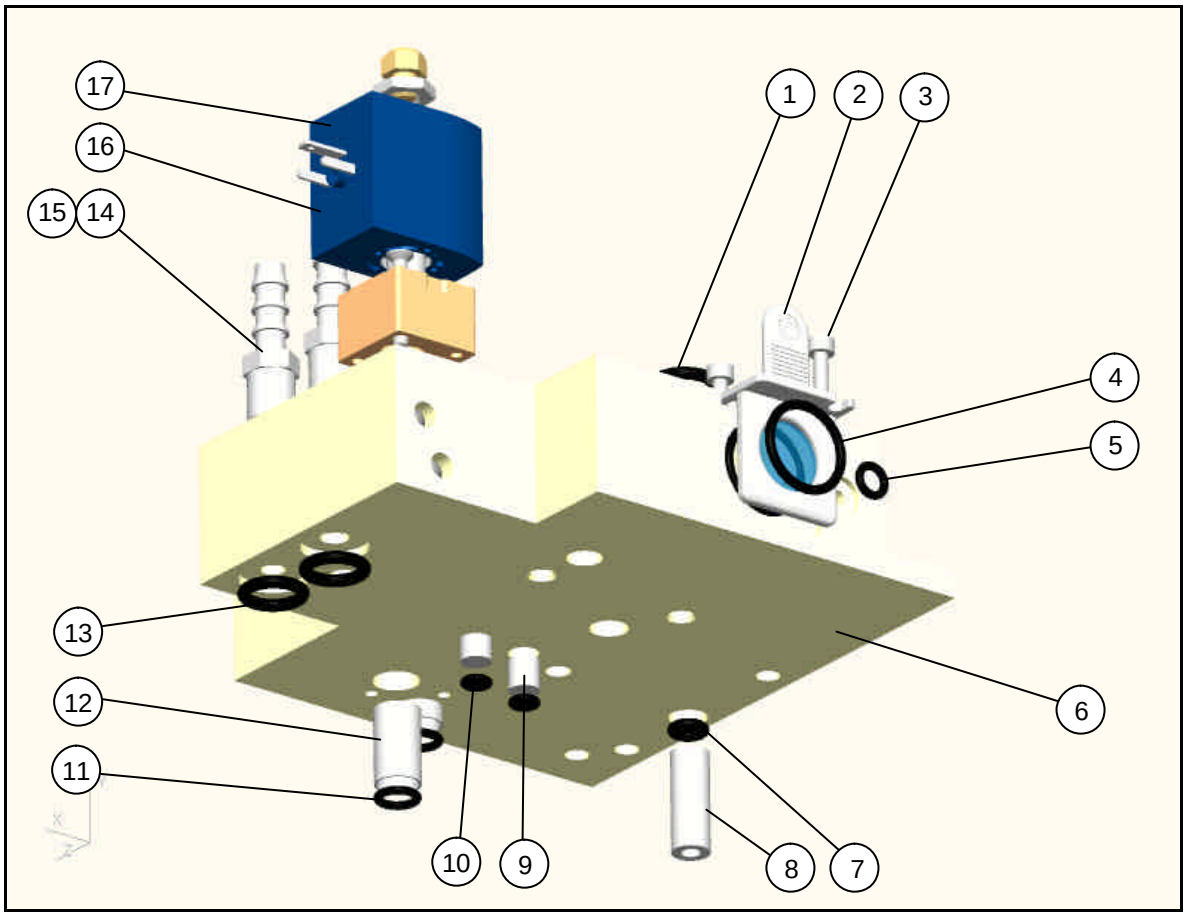
10.11 Sensor Block 1



10.11.1 SENSOR BLOCK 1

Item No.	Part No.	Description
01	F-910021	Valve, inspiratory proportional (PV1)
02	F-810072	Screw, Sensor Block
03	F-710301	Block assembly, Sensor Block 1
04	F-910081	Internal Flow Sensor
05	F-810034	O-ring, internal flow sensor
06	F-810039	Screw, internal flow sensor

10.12 SENSOR BLOCK 2

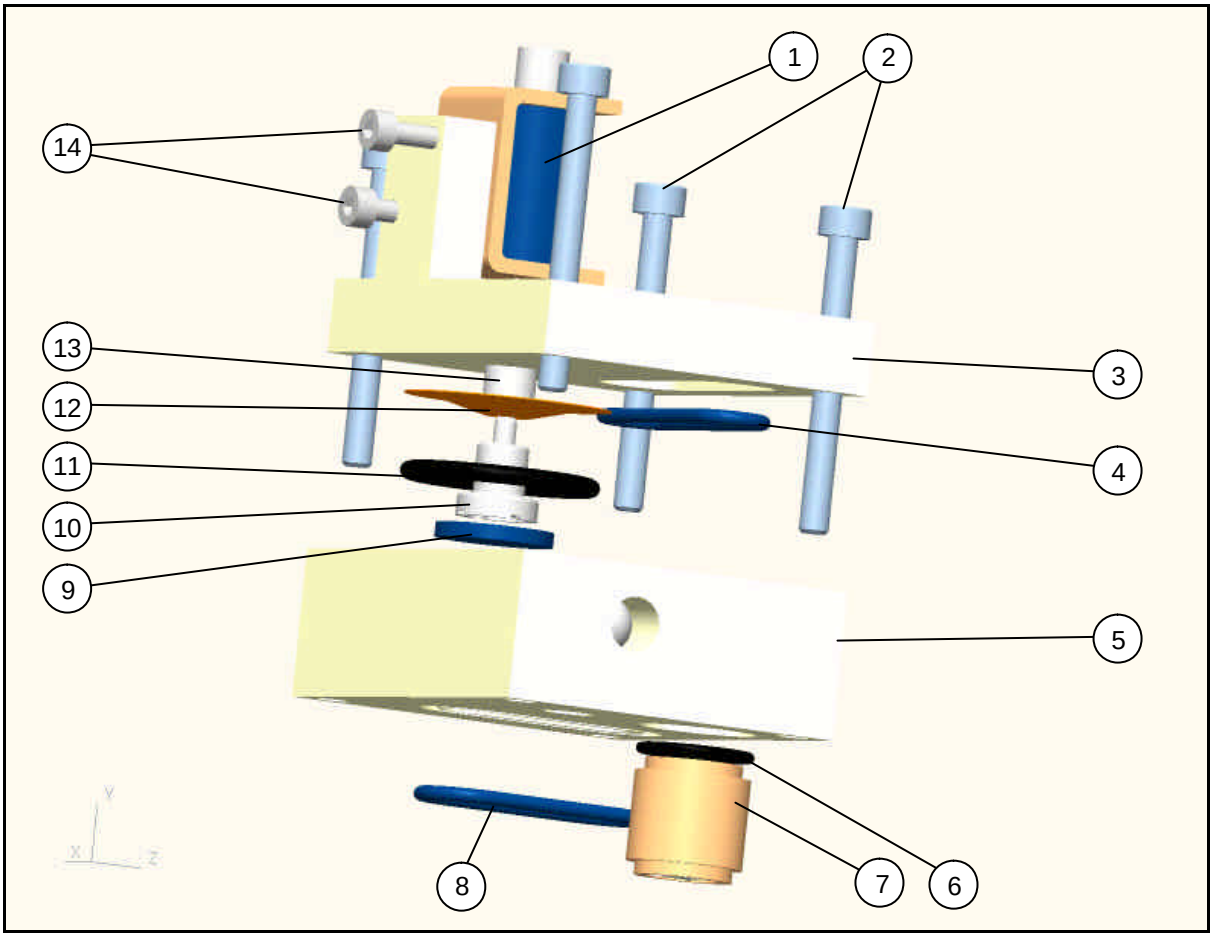


10.12.1 SENSOR BLOCK 2

Item No.	Part No.	Description
01	F-810032	O-ring, SV Block
02	F-910081	Internal Flow Sensor
03	F-810039	Screw, Internal Flow Sensor
04	F-810034	O-ring, internal flow sensor
05	F-810033	O-ring, sensor blocks
06	F-910240	Sensor Block 2, FRU
07	F-810030	O-ring, spacer
08	F-710321	Spacer
09	F-920023	Restrictor, purge flow
10	F-810063	O-ring, restrictor
11	F-810029	O-ring, check valve
12	F-910022	Check valve, Proximal over pressure
13	F-810032	O-ring, compressor
14	F-910025	Compressor Inlet / Outlet Port

15	F-920100	Compressor Blank (JP units only)
16	F-910021	Compressor Unloading Valve
17	F-910200	Muffler, Unloading Valve
Not Shown	F-920101	Blanking Seal (JP units only)
Not Shown	F-920102	Blanking Screw (JP units only)

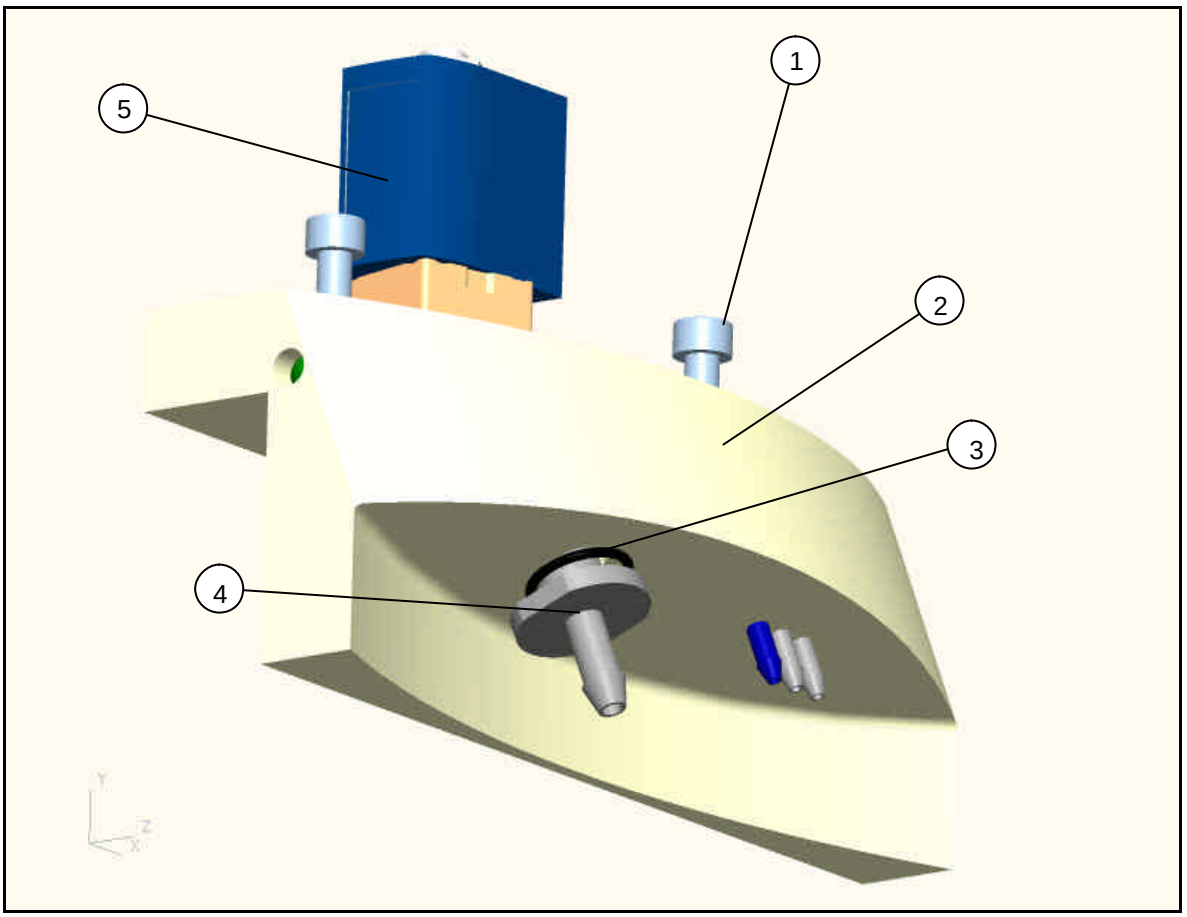
10.13 Safety Valve Block



10.13.1 SAFETY VALVE BLOCK

Item No.	Part No.	Description
01	F-910247	Safety Valve Assembly, FRU
02	F-810010	Screw, safety valve block cover
03	F-710325	Block Assembly, Cover
04	F-810067	O-ring, cover slotted
05	F-710312	Block assembly, safety valve block
06	F-810037	O-ring, check valve
07	F-910030	Check valve, system over pressure
08	F-810067	O-ring, security block slotted
09	F-710326	Sealing disc, safety valve
10	F-710327	Plunger, safety valve
11	F-810069	O-ring, membrane seal
12	F-710332	Membrane, safety valve
13	F-710331	Adapter, safety valve
14	F-810012	Screw, safety valve

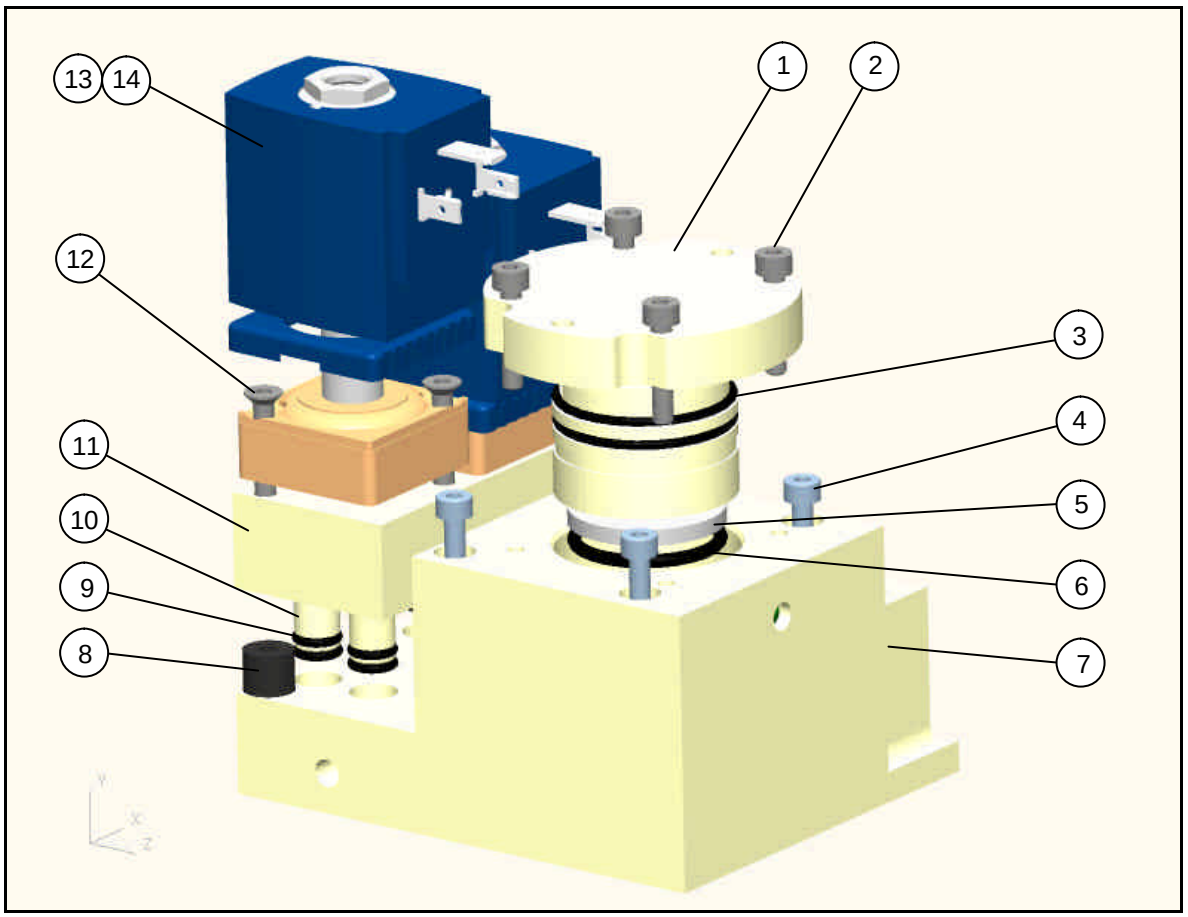
10.14 *Front Pneumatic Module*



10.14.1 *FRONT PNEUMATIC MODULE*

Item No.	*Part No.*	*Description*
01	F-810005	Mounting Screws
02	F-910239	Front Block Module, FRU
03	F-810037	Nebulizer Connector O-Ring
04	F-710329	Nebulizer Block O-Ring
05	F-910026	Nebulizer Solenoid, SV4

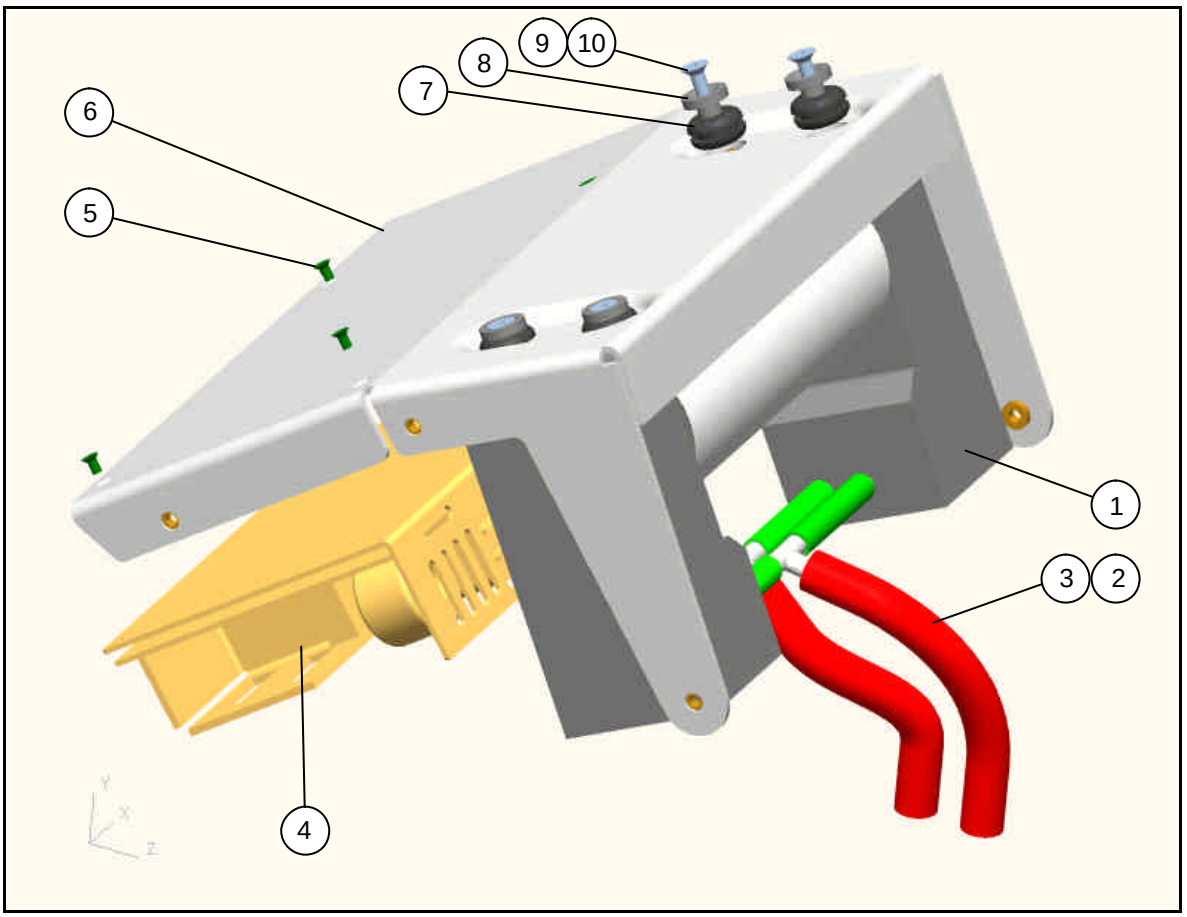
10.15 *Blender Module*



10.15.1 *BLENDER MODULE*

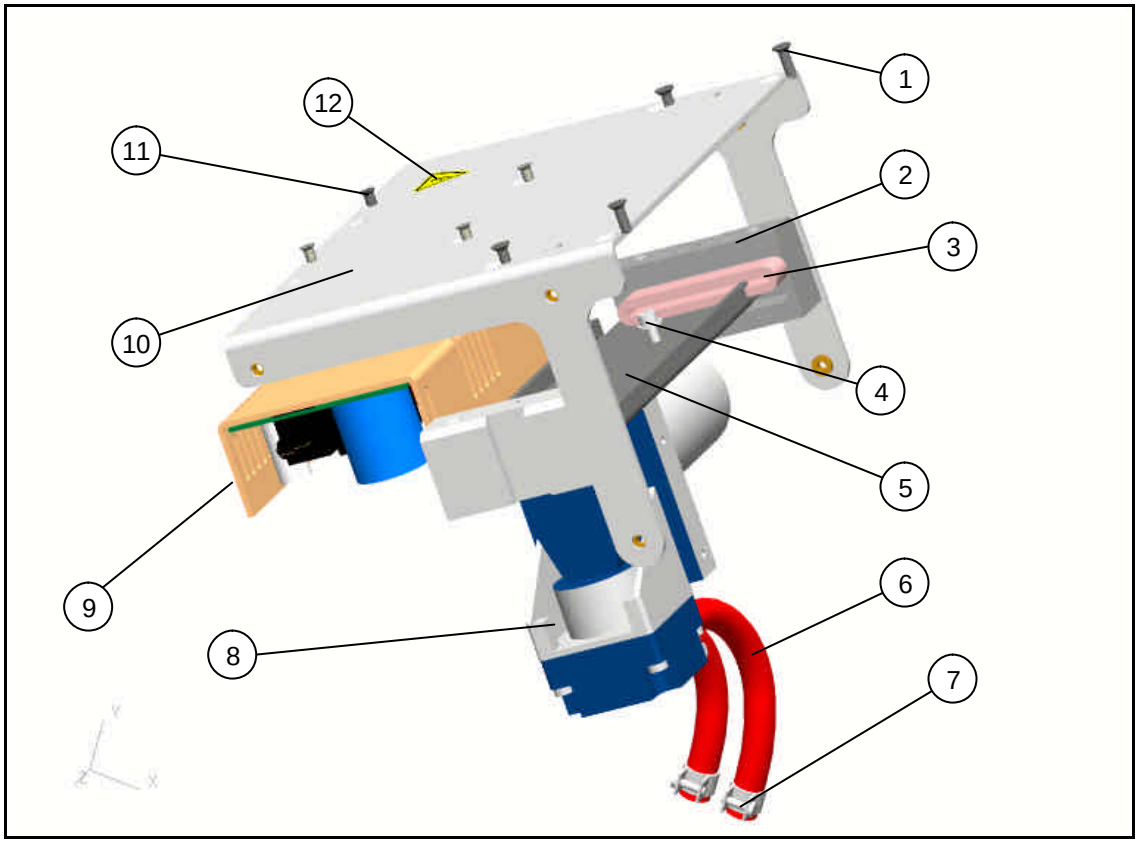
Item No.	*Part No.*	*Description*
01	F-710401	Block assembly, flow sensor retainer
02	F-810023	Screw, flow sensor retainer
03	F-810024	O-Ring, Retainer Seal
04	F-810090	O-Ring
05	F-910019	Blender Flow Sensor
06	F-810025	O-Ring, Flow Sensor Seal
07	F-710403	Block assembly, blender base
08	F-810026	Rubber Buffers
09	F-810029	O-Ring, Extension Tube Seal
10	F-710404	Extension Tubes
11	F-710402	Block assembly, muffler
12	F-810021	Screw, blender valve
13	F-910018	Blender Valve, SV2, Air
14	F-910018	Blender Valve, SV1, Oxygen

10.16 Compressor Module



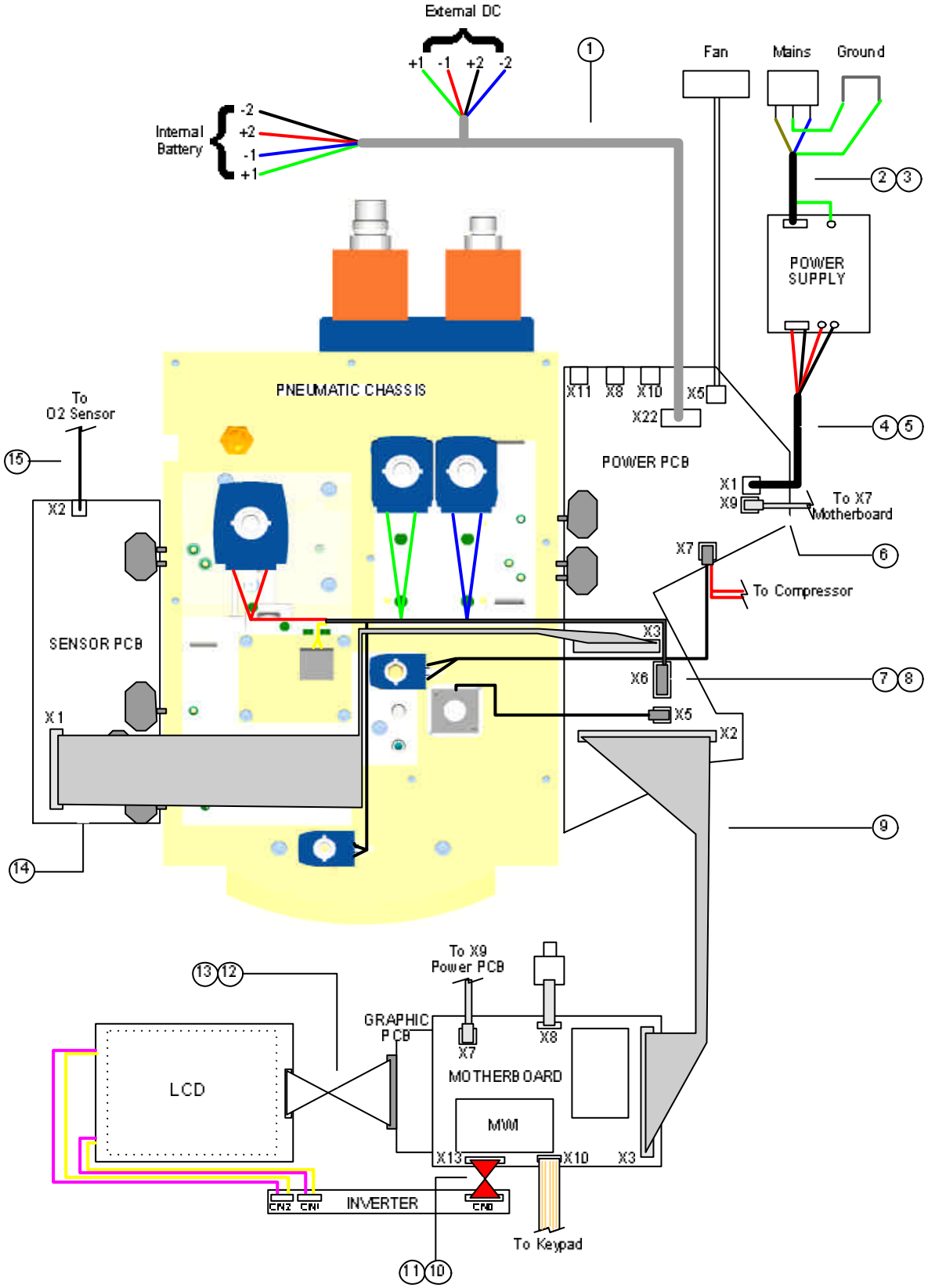
10.16.1 COMPRESSOR MODULE – INSPIRATION LS / ST

Item No.	*Part No.*	*Description*
01	F-910249	Compressor Assembly, 8009,
02	F-810079	Compressor Hose
03	F-810080	Compressor Hose Clamps
04	F-920010	Power Supply Assembly
05	F-820023	Power Supply Screws
06	F-720601	Compressor Module Plate
07	F-820013	Rubber Mount, Compressor
08	F-720606	Compressor Support Bolt
09	F-820011	Screw, Compressor Mount
10	F-820012	Washer, Compressor Mount
Not Shown	F-910033	Warning Sticker
Not Shown	F-920071	Mains Harness, LS / ST
Not Shown	F-920064	Power Supply Harness, LS / ST



10.16.2 COMPRESSOR MODULE – INSPIRATION ORIGINAL

Item No.	Part No.	Description
01	F-810137	Screw, Compressor Bracket
02	F-710603	Compressor Retaining Brackets
03	F-810146	Damping Inlays
04	F-810139	Screw, Compressor Mount
05	F-710602	Compressor Mounting plate
06	F-810079	Compressor Hoses
07	F-810080	Compressor Hose Clamps
08	F-910248	Compressor Assembly, 8006
09	F-910010	Power Supply Assembly
10	F-710601	Compressor Module Plate
11	F-810081	Screw, Power Supply
12	F-910033	Warning Label, Compressor Plate
Not Shown	F-910071	Mains Hamess, Original
Not Shown	F-910064	Power Supply Harness, Original

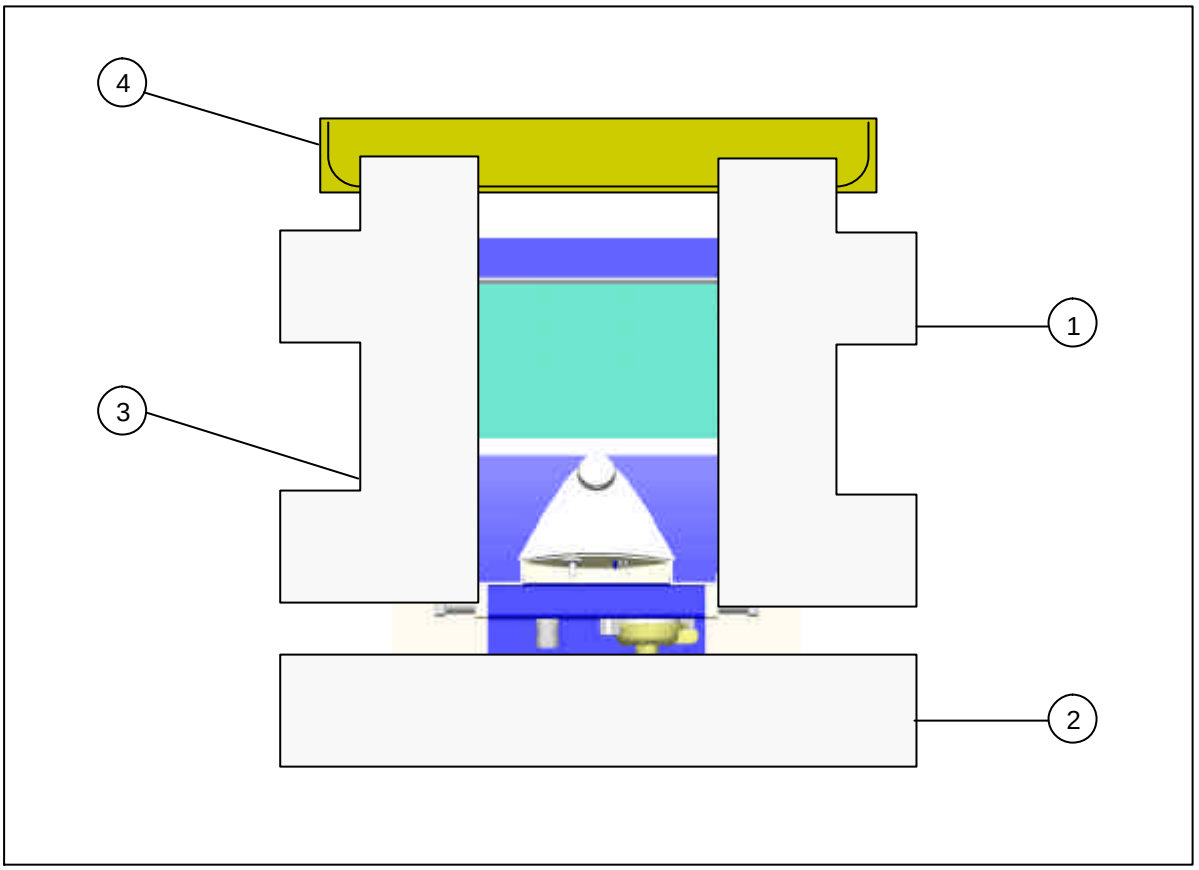


INSPIRATION SERIES WIRING DIAGRAM

10.17 Ventilator Wiring

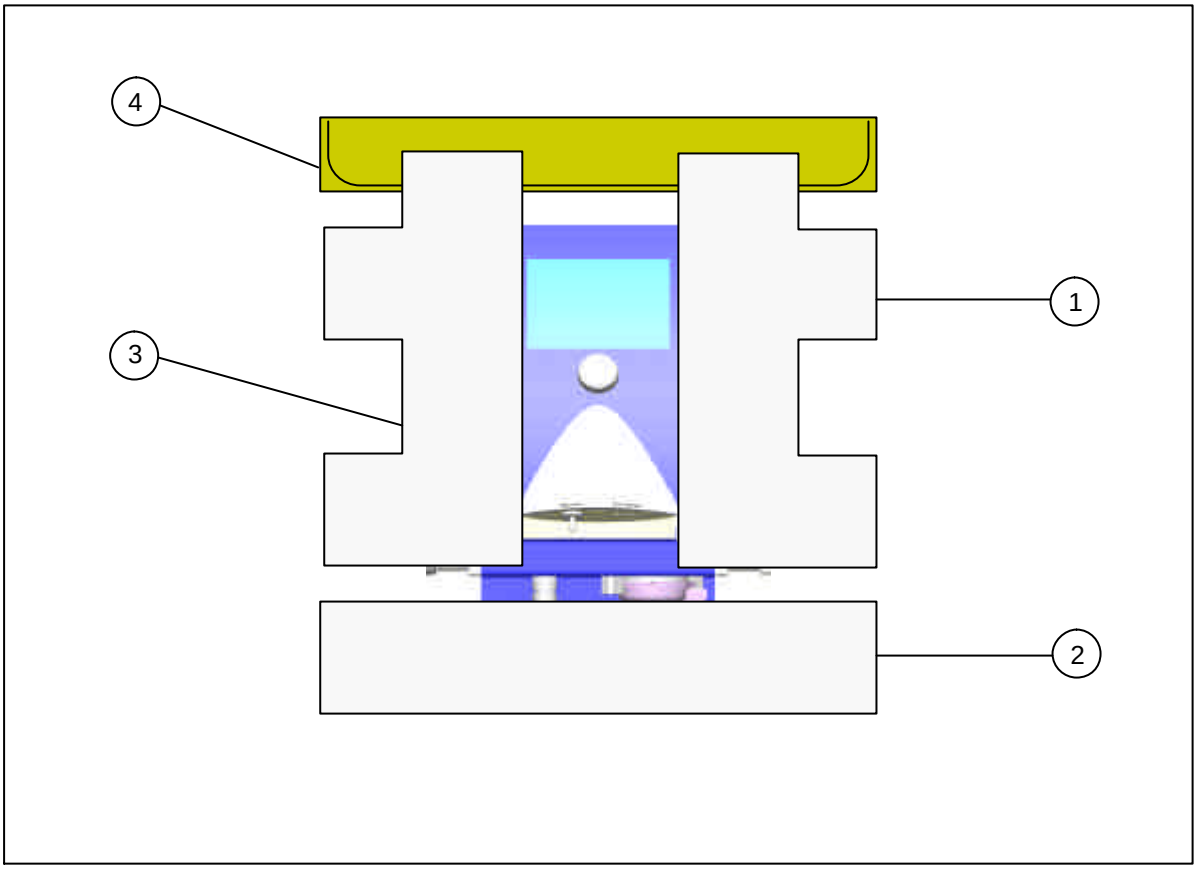
Item No.	*Part No.*	*Description*
01	F-920063	DC input cable
02	F-910071	Mains input cable (Original only)
03	F-920068	Mains input cable (LS/ST only)
04	F910064	Power supply cable (Original only)
05	F-920066	Power supply cable (LS/ST only)
06	F-920062	Ethernet cable
07	F-910067	Pneumatic chassis harness (Original only)
08	F-920067	Pneumatic chassis harness (LS/ST only)
09	F-920060	Controller ribbon cable
10	F-920070	Inverter cable (ST only)
11	F-930070	Inverter cable (LS only)
12	F-920069	LCD cable (ST only)
13	F-930107	LCD Cable (LS only)
14	F-920061	Sensor ribbon cable
15	F-920064	O2 sensor cable
Not Shown	F-920071	Earth Cable, 10cm, Filter/Chassis
Not Shown	F-920072	Earth Cable, 18cm, Power PCB
Not Shown	F-920073	Earth Cable, 35cm, O2 sensor cover
Not Shown	F-920074	Earth Cable, 50cm, front cover
Not Shown	F-930003	Earth Cable, PU front (LS only)

10.18 Ventilator Packaging



10.18.1 Inspiration LS Packaging

Item No.	Part No.	Description
--	F-930500	Packaging FRU, LS (includes ref 01,02,03,04)
01	F-930503	Foam Insert, LS, Right
02	F-930502	Foam Insert, LS, Left
03	F-930504	Bottom Insert
04	F-920507	Accessory Carton
Not Shown	F-930501	Ventilator Carton
Not Shown	F-920506	Device Bag, LS
Not Shown	F-920505	Desiccant Pack



10.18.2 *Inspiration ST/Original Packaging*

Item No.	*Part No.*	*Description*
--	F-920500	Packaging FRU, ST, (includes ref 01,02,03,04)
01	F-920503	Foam Insert, LS, Right
02	F-920502	Foam Insert, LS, Left
03	F-920504	Bottom Insert
04	F-920507	Accessory Carton
Not Shown	F-920501	Ventilator Carton
Not Shown	F-920506	Device Bag, LS
Not Shown	F-920505	Desiccant Pack

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System Software Installation Appendix A

For convenience a full copy of the Software Installation Instructions for the Inspiration ventilator system has been included on the following pages.

This detailed procedure should be followed exactly when installing each new version of system or mini-web application software.

Inspiration™ ventilator system – Software Installation Instructions

Definition of statements:

Statements preceded by the following are of special significance:

WARNING
Means that there is a possibility of injury to yourself or other persons.

CAUTION
Means that there is a possibility of damage to the equipment or other property.

NOTE
Indicates a point of particular interest or special emphasis for more efficient and convenient operation of the equipment.

Description:

These instructions describe in detail how to successfully install new main system and mini-web interface software to the Inspiration™ Ventilator system.

WARNING
In order to ensure proper operation and avoid the possibility of physical injury, only qualified personnel should attempt to service, perform installations, or make other authorised modifications to the ventilator.

The user of this product shall retain sole responsibility for any ventilator malfunction due to operation or maintenance performed by persons not trained by the manufacturer.

Suggested Tools and Equipment (Table 1):

Description	Manufacturer
Computer (Minimum Win 95, Pentium based system)	Local Supplier
Software Download Cable	eVent Medical, F910085
Inspiration Download Software	eVent Medical, Download.exe
Software File	eVent Medical, eventXYZ.tim

Installation Process:

Pre Installation Tests:

Verify the operational status of the ventilator prior to proceeding with the software installation:

- Switch subject ventilator ON in normal operation mode.
- Verify that the subject ventilator completes self-test without reporting technical errors.
- Should any errors be reported refer to the Inspiration Ventilator service manual for further details and correct the triggering condition prior to proceeding.
- Switch the device on in configuration mode. On completion of power on self-test record the Main SW Revision level from the start up screen.
- Switch device off.

Verify that the software download utility is installed to desktop on your computer:

- Installation of Inspiration system software requires the use of a proprietary download utility called download.exe.
- Download.exe should be installed to desktop prior top commencing the software download process.
- Download.exe may be requested from eVent Medical directly or downloaded from the service section of our website http://www.event-medical.com.
- On receipt install the utility program to desktop or to a convenient file location.

Verify that the required version of software is available on your computer:

- During software download you will be required to install the latest version of system software to your ventilator.
- The required software file should be stored to a convenient file location prior to commencing the download.
- To verify that you have the latest version of software available you should refer to the service section of our website http://www.event-medical.com.
- In the event that you do not have the latest version filed locally it may be downloaded from this website location.
- Save the software file eventX.Y.Z.tim to a convenient file location.

CAUTION
For safety and convenience only the current release version of system software should be retained on your PC. As each new software version is released and downloaded please ensure that old versions are deleted or archived.

Software Download Procedure (Ventilator / MWI Software):

- With your computer powered on ensure that you have at least one serial communications port available for communication with the ventilator.
- Attach the software download cable (F910085) to an available RS232 port on your PC as shown in figure 1.
- If installing main ventilator system software connect the opposite end of the software download cable to the RS232 port on the ventilators rear panel.
- If installing mini-web interface software connect the opposite end of the software download cable to the Ethernet port on the ventilators rear panel.

CAUTION
As defined above ensure that the software download cable is attached to the correct rear panel port for the software to be installed. In correct connection will result in corruption of NVRAM calibration data.

Figure 1, Download Cable Connection

- With connections secure double-click the download.exe icon located on your desktop (previously installed) in order to start the download process and follow the on screen instructions.
- On the download start-up screen select 'Next' to proceed and the firmware selection screen, shown in figure 2, will appear.
- At the firmware selection screen choose select file and a further window will appear listing the software files available locally on your PC.
- Select the appropriate file for the software to requiring installation. Software files available are broken down as follows:

- Main System Software eVentVX.X.X.tim
- Mini Web System Software eVentMWIVX.X.X.tim
- Mini Web Applet Software eVentWebAppletV.X.X.X.tim

- Ensure that correct file and extension is now listed on the main screen then select ‘Next’ to proceed to next step.

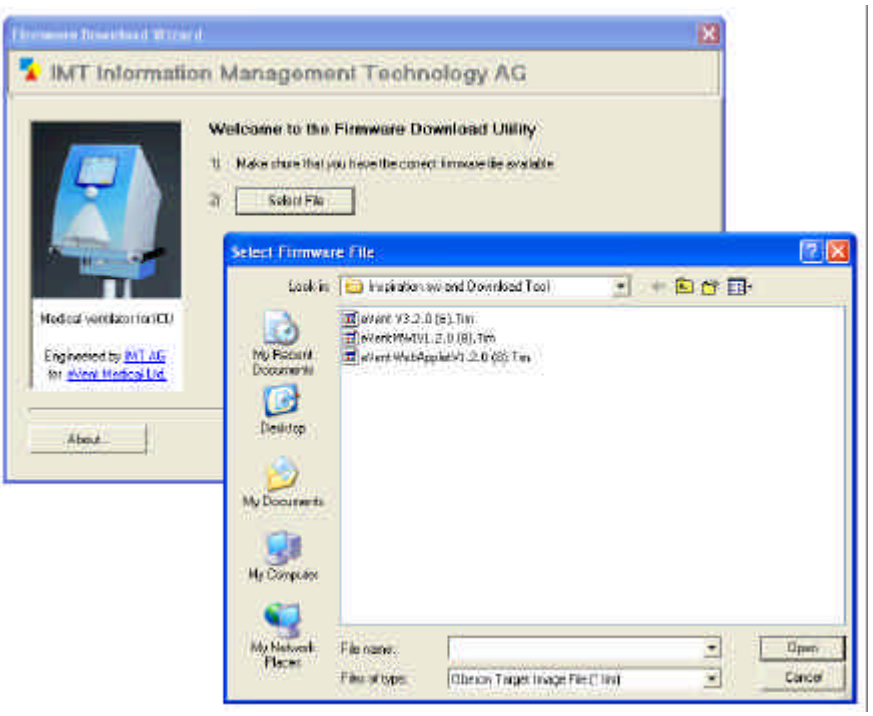

Figure 2, File Selection Screen

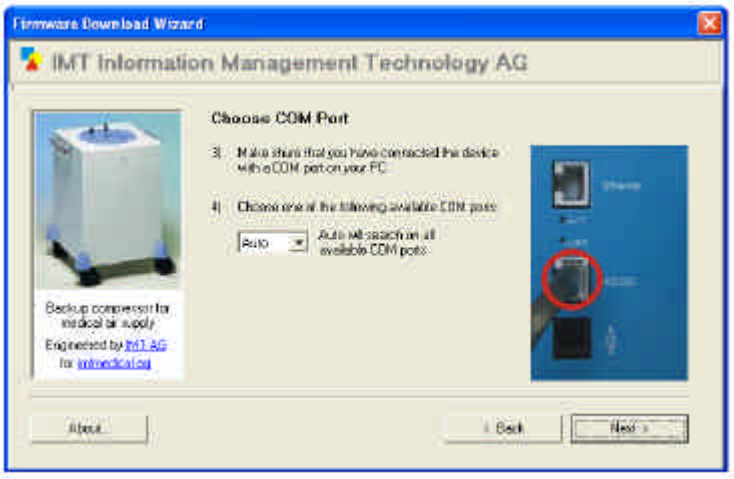

Figure 3, Com Port Selection

- The next screen, shown in figure 3, will prompt you to select which of your computers communication ports you will use for the download process.
- This may be set for com 1 or com 2, alternatively if using any other port (such as a PCMCIA serial connection) select ‘Auto’ and the download utility will sense which port is in use.
- Select ‘Next’ when complete to proceed to the next step.

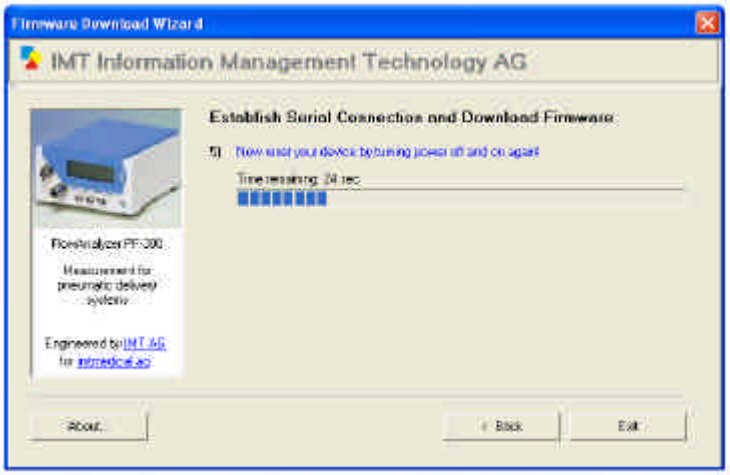

Figure 4, Establishing Serial Connection

- The next step, shown in figure 4, will attempt to establish communication with the ventilator through the appropriate Com port.
- You are prompted at this point to reset the subject device. If the device is off simply switch ON within the 30 second time window, if it is on already simply switch OFF then ON once more within the 30 second time window.

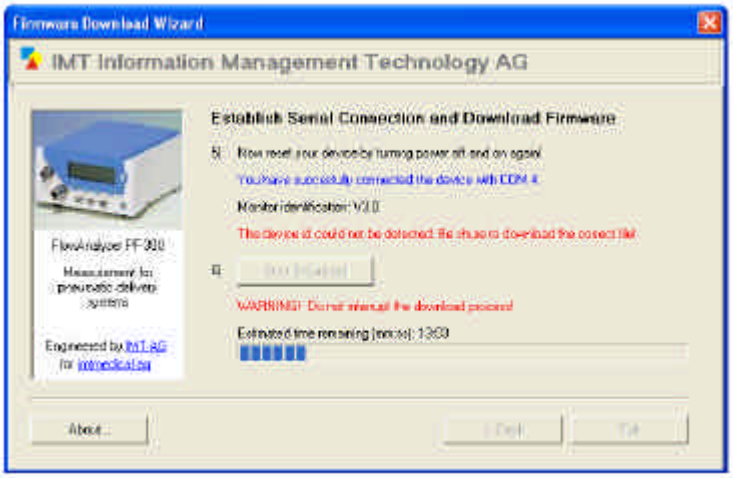

Figure 5, Download Progress Screen

- Observe the screen for confirmation of a successful connection then select 'Next' to proceed to the next step.
- In the event that connection is not confirmed repeat the complete process and troubleshoot connections as is necessary.
- With a successful connection the next screen will confirm that the device is ready for download.
- Select 'Start Download' and the process will commence.
- The download will take approximately 6 minutes in total and progress may be monitored by means of the download progress bar shown on the screen and also in figure 5.

CAUTION
The download procedure should not be interrupted once it is in progress.

- The download window will confirm when the process has been successfully completed.
- On completion switch the device OFF and remove the download cable.

Power Software Installation Procedure

- In accordance with the Inspiration Series Service Manual, remove and set aside the ventilators top housing.
- With your computer powered on ensure that you have at least one serial communications port available for communication with the ventilator.
- Attach the software download cable to the available serial port on your PC as shown in figure 1.
- Attach the other end of the software download to the vacant connector on the Power PCB immediately adjacent to the SW Flash EPROM shown in figure 6.
- The procedure is performed largely as described above with the following alterations.
- At the firmware selection stage, change file type to **.hex** and select file in the form eVent PowerboardVX.X.X.hex.
- As with system software installation, you will be prompted by the download application screen to power cycle (off/on) the ventilator at the beginning and end of the download process.
- Whenever prompted to do this you press the power processor reset switch positioned immediately adjacent to the Power PCB Flash EPROM.

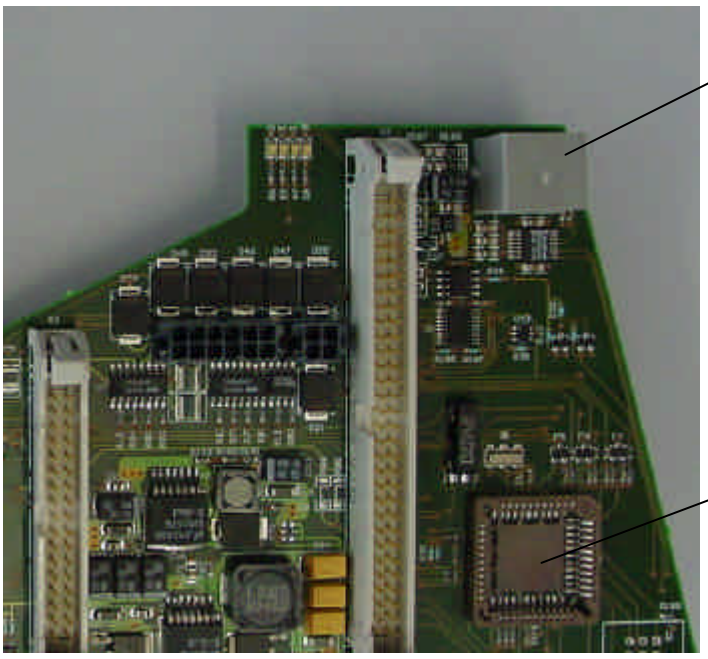

Figure 6, Power Software Download Port

Post Software Installation Checks

- Switch on the subject device and allow it to run through system test.
- Should self-test report an OK status the device may be switched off and returned to operational use.
- Should self-test report any status other than OK refer to the troubleshooting section of this procedure.

NOTE
Some releases of system software may require that additional calibration, configuration and other steps be performed before the device may be returned to operational use. Refer to the software release notes or applicable Technical Information Bulletins for verification of these additional requirements.

Troubleshooting

- In the event of experiencing any problems or technical errors refer to the troubleshooting section of the Inspiration Ventilator system service manual.

Technical Assistance

- Should you experience any problems during or following the upgrade process please contact you local eVent Medical representative.
- Alternatively you may contact eVent Medical directly at our group email address service@event-medical.com or at our technical hotline +44-788-4366160.

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Inspiration Communication Interface Appendix B

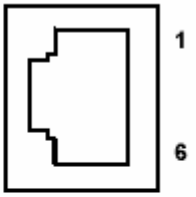
For convenience the following pages provide a detailed description of how to configure the Inspiration Ventilators nurse call and serial communication ports.

For the serial communication interface a full listing is provided for all relevant commands and SNDA responses.

Nurse Call Port Configuration

The nurse call port allows the Inspiration series ventilator to be connected to a remote alarm system. Nurse call pin assignments (floating contacts) are shown in figure 1 below.

Pin	Function
1	Not in use
2	NC (Normal Closed)
3	NO (Normal Open)
4	Not in use
5	Common
6	Not in use



Ventilator connector: Nurse Call

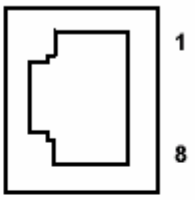
Figure 1, Nurse Call Pin Assignments

Serial (RS-232) Port Configuration

Pin assignments for the Serial (RS-232) Port of the Inspiration series ventilator are as shown on figure 2, below.

RS232 interface pin assignments:

Pin	Function
1	DCD (Data Carrier Detect)
2	RTS (Ready To Send)
3	CTS (Clear To Send)
4	DTR (Data Terminal Ready)
5	GND (Ground)
6	DSR (Data Set Ready)
7	RXD (Receive Data)
8	TXD (Transmit Data)



Ventilator connector: RS232

Figure 2, RS232 Pin Assignments

Serial (RS-232) port setup

Serial port parameters for the Inspiration series ventilator are pre-configured and may not be adjusted by the user. The settings in use are as follows:

Baud Rate: 9600
Data Bits: 8
Stop Bits: 1
Parity: OFF
Flow Control: OFF

Serial (RS-232) port commands

The communications port responds to these commands facilitating communication to and from the ventilator using the serial ports:

- RSET: clears the data from the ventilator's receive buffer
- SNDA: tells the ventilator to send ventilator settings and monitored data to the host system

RSET (clear ventilator buffer)

Enter the RSET command exactly like this:

RSET<CR>

- Where <CR> is a carriage return. The ventilator only responds if it receives a carriage return. When the ventilator receives the RSET command, it clears its receive buffer. The ventilator does not send a response to the host system.

SNDA (send ventilator settings and data)

Enter the SNDA command exactly like this:

SNDA<CR>

Where <CR> is a carriage return. The ventilator responds only if it receives a carriage return. When the ventilator receives the SNDA command, it responds with a code MISCA, followed by the ventilator settings and monitored data information.

The MISCA response follows the format shown in Figure 3 below.

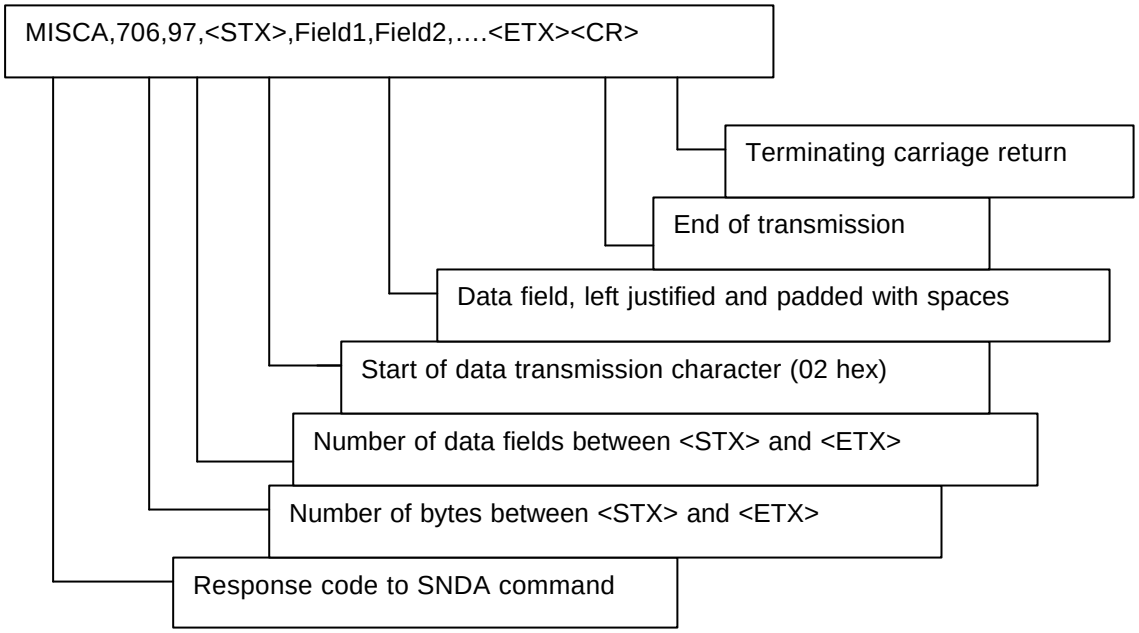


Figure 3, MISCA Response

Note:

The MISCA command response is designed to be compatible with the MISCA command response from Puritan-Bennett Ventilators, including the 7200, 700 series and 800 series. In the fields where the command response differs from that of the Puritan-Bennett ventilators, the difference is noted in the field description.

Field Number	Field Content
1	MISCA (5 characters)
2	706 (3 characters; the number of bytes between <STX> and <ETX>)
3	97 (2 characters; the number of fields between (<STX> and <ETX>)
4	<STX> (start of transmission)
5	Ventilator time (HH:MM_) (6 characters)
6	Not used (13 characters)
7	Not used (6 characters)
8	Not used (12 characters)
9	Mode setting (6 characters)
10	Respiratory rate setting (6 characters)
11	Tidal volume setting (6 characters)
12	Peak flow setting (6 characters)
13	O2% setting (6 characters)
14	Not used (6 characters)
15	PEEP/ CPAP setting (6 characters)
16	Plateau time (6 characters)
17	Not used (6 characters)
18	Not used (6 characters)

19	Not used (6 characters)
20	Not used (6 characters)
21	Apnea interval (6 characters)
22	Apnea tidal volume setting (6 characters)
23	Apnea respiratory rate setting (6 characters)
24	Apnea peak flow setting (6 characters)
25	Apnea O2% setting (6 characters)
26	Pressure support setting (6 characters)
27	Inspiratory flow pattern (6 characters)
28	Not used (6 characters)
29	Nebulizer setting (On or Off) (6 characters)
30	100% O2 setting (On of Off) (6 characters)
31	Not used (6 characters)
32	Not used (6 characters)
33	Not used (6 characters)
34	Total respiratory rate (6 characters)
35	Exhaled tidal volume (6 characters)
36	Exhaled minute volume (6 characters)
37	Spontaneous minute volume (6 characters)
38	Peak airway pressure (6 characters)
39	Mean airway pressure (6 characters)
40	End inspiratory pressure (6 characters)
41	Not used (6 characters)
42	High pressure limit (6 characters)
43	Low inspiratory pressure (6 characters)
44	Not used (6 characters)
45	Low tidal exhaled tidal volume (6 characters)
46	Low exhaled minute volume (6 characters)
47	High respiratory rate (6 characters)
48	High pressure alarm status (6 characters)
49	Low inspiratory pressure alarm status (6 characters)
50	Not used (6 characters)
51	Low tidal volume alarm status (6 characters)
52	Low minute volume alarm status (6 characters)
53	High respiratory rate alarm status (6 characters)
54	Low O2 supply alarm status (6 characters)
55	Not used (6 characters)
56	Low internal battery alarm (6 characters)
57	Apnea alarm status (6 characters)
58	Not used (6 characters)
59	Not used (6 characters)
60	Not used (6 characters)
61	Not used (6 characters)
62	Not used (6 characters)
63	Static compliance (6 characters)
64	Static resistance (6 characters)
65	Dynamic compliance (6 characters)
66	Dynamic resistance (6 characters)
67	Not used (6 characters)
68	Not used (6 characters)
69	Not used (6 characters)
70	Not used (6 characters)

71	Flow sensitivity setting (6 characters)
72	Not used (6 characters)
73	Not used (6 characters)
74	Not used (6 characters)
75	Not used (6 characters)
76	Not used (6 characters)
77	Not used (6 characters)
78	Not used (6 characters)
79	Not used (6 characters)
80	Not used (6 characters)
81	Not used (6 characters)
82	Not used (6 characters)
83	Not used (6 characters)
84	Not used (6 characters)
85	PC inspiratory pressure setting (6 characters)
86	Inspiratory time setting (6 characters)
87	Not used (6 characters)
88	PC apnea pressure setting (6 characters)
89	PC apnea rate setting (6 characters)
90	PC apnea inspiratory time setting (6 characters)
91	PC apnea O2% setting (6 characters)
92	Not used (6 characters)
93	Alarm silence state (6 characters)
94	Apnea alarm status (6 characters)
95	Disconnect alarm status (6 characters)
96	Not used (6 characters)
97	Not used (6 characters)
98	Not used (6 characters)
99	Not used (6 characters)
100	Not used (6 characters)
101	Monitored I:E ratio (6 characters)
102	<ETX>
103	<CR>

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Field Service Record Appendix C

For your convenience and use you will find on the following pages a Field Service Record/Customer complaint form. You should use and complete this document whenever possible when performing any procedures on the Inspiration Ventilator system.

In the event of performing repairs or upgrades to any device you are kindly requested to forward a completed copy to eVent Medical, at fax number provided, for our information.

In the event of any failure to the device this document should completed and sent to eVent Medical to allow us to promptly process your customer complaint and warranty claim (if applicable) accordingly.

Completed field service record / customer complaint forms should be forwarded as appropriate to one of the following locations:

Worldwide:
eVent Medical Ltd.
6A Liosban Business Park
Tuam Road, Galway,
Ireland.

Phone: +353 91 764472
Fax: +353 91 764379
trevor@event-medical.com / service@event-medical.com

United States:
eVent Medical Ltd.
5950 Priestly Drive
Carlsbad CA, 92008,
United States Of America.

Phone: +1 760 4319613
Fax: +1 760 4317993
davidb@event-medical.com / service@event-medical.com

Customer / Distributor Details	
Name:	
Occupation:	
Company Name & Address:	

Customer Details	
Hospital Name:	
Hospital Address:	

Equipment Details			
Model		Serial Number	
Ventilator Hours		Compressor Hours	
SW Version (pre service)		SW Version (post service)	
Power SW (pre service)		Power SW (post service)	
Date of Installation		Date of Event	

Details of Work Performed	
Problem Description Where possible please depict full contents of error and test logs; Alarm Details; PM Due; FOOB	
Problem Resolution Describe actions taken to resolve the problem	

Details of Patient involvement (DORSI)	
Was there a patient involvement?	
Did Death or Serious Injury Occur?	
Was medical intervention required?	
Condition of the patient at the time of event and current condition	
Name & Contact Details (Details of medical professional confirming DORSI status)	

Any other relevant information

Parts Used During Service / Repair				
Part Number	Description of Part	SN Removed	SN Installed	Warranty Claim (Y/N)

Service Completion:	
Service Completed By:	
Signature:	
Date:	

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Performance Verification Record Appendix D

INSPIRATION SERIES VENTILATOR – PERFORMANCE VERIFICATION RECORD

Customer: _____ Software Vent: _____

_____ Software Power: _____

Model: ☐ Inspiration LS ☐ Inspiration ST ☐ Original Hardware Power: _____

Serial Number: _____ Hardware Controller: _____ _____

Next PM Due: Hardware Sensor: _____

Ventilator Hours: (Fab Test 11)	Compressor Hours: (Fab Test 11)

Electrical Safety Tests (6.6.1)	Target	Actual	Adjusted
Ground Resistance	<0.2 OHM	Ω	Ω
Forward Current Leakage	≤300µA (all units)	µA	µA
Reverse Current Leakage	≤300µA (all units)	µA	µA

Power On Self Test / Configuration	Limit	*Result*	*Pass Y / N*	
Self Test Status	OK		☐ Yes	☐ No

Fabrication Test /Fab Test 5 (6.6.2)	Limit	*Result*	*Pass Y / N*	
Re-Zero All Pressure Transducers	OK		☐ Yes	☐ No

Calibrations and System Leak Test:	Limit	Result	Pass Y / N	
System Leak Test Results	OK		☐ Yes	☐ No
System Compliance	N/A		☐ Yes	☐ No
Proximal Sensor Calibration	OK		☐ Yes	☐ No
Oxygen Sensor Calibration	OK		☐ Yes	☐ No

Operational Tests: (6.6.3)				
Chapter 1 Gas Sources: Test 1	**Limit**	**Result**	**Pass Y / N**	
Loss O2	Loss O2 Alarm		☐ Yes	☐ No
O2 Reset	Alarm Cancels		☐ Yes	☐ No
Loss Air	Compressor Starts		☐ Yes	☐ No
Air Reset	Compressor Stops		☐ Yes	☐ No
Loss Air / Compressor	Loss Air Alarm		☐ Yes	☐ No
Loss All Supply	Loss Air / O2		☐ Yes	☐ No
Loss All Supply	Int. Pressure Low		☐ Yes	☐ No

Gas Volume Accuracy: Test 2	Limit	Result	Pass Y / N	
Tidal Volume	100ml +/- 20ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte)	100ml +/- 30ml		☐ Yes	☐ No
Respiratory Rate	30bpm +/- 3bpm		☐ Yes	☐ No

Tidal Volume	300ml +/- 60ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte)	300ml +/- 90ml		☐ Yes	☐ No
Respiratory Rate	25bpm +/- 2.5bpm		☐ Yes	☐ No

Tidal Volume	600ml +/- 120ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte)	600ml +/- 120ml		☐ Yes	☐ No
Respiratory Rate	15bpm +/- 1.5bpm		☐ Yes	☐ No

Tidal Volume	1000ml +/- 200ml		☐ Yes	☐ No
Tidal Volume Exhaled (Vte)	1000ml +/- 200ml		☐ Yes	☐ No
Respiratory Rate	10bpm +/- 1bpm		☐ Yes	☐ No

Pressure Accuracy: Test 3	**Limit**	**Result**	**Pass Y / N**	
P Control (10cmH20)	10cmH20 +/- 1cmH20		☐ Yes	☐ No
P Control (50cmH20)	50cmH20 +/- 5 cmH20		☐ Yes	☐ No
PEEP (5cmH20)	5cmH20 +/- 0.5 cmH20		☐ Yes	☐ No
PEEP (30cmH20)	30cmH20 +/- 3 cmH20		☐ Yes	☐ No
PEEP (50cmH20)	50cmH20 +/- 5 cmH20		☐ Yes	☐ No

Oxygen Delivery: Test 4	**Limit**	**Result**	**Pass Y / N**	
Oxygen 30% Analyzer	30% +/- 3		☐ Yes	☐ No
Oxygen 30% Vent	30% +/- 3		☐ Yes	☐ No
Oxygen 60% Analyzer	60% +/- 3		☐ Yes	☐ No
Oxygen 60% Vent	60% +/- 3		☐ Yes	☐ No
Oxygen 90% Analyzer	90% +/- 3		☐ Yes	☐ No
Oxygen 90% Vent	90% +/- 3		☐ Yes	☐ No

Alarm Operation: Test 6	**Limit**	**Result**	**Pass Y / N**	
Disconnect Alarm	On		☐ Yes	☐ No
Alarm Silence – On	On		☐ Yes	☐ No
Alarm Silence – OFF	Off		☐ Yes	☐ No
Alarm Silence – Time	120 sec 12		☐ Yes	☐ No
Disconnect Alarm	Reset		☐ Yes	☐ No

HIP Alarm On	On		☐ Yes	☐ No
Alarm Reset	Off		☐ Yes	☐ No

Apnea Alarm On	On		☐ Yes	☐ No
Apnea Ventilation	On		☐ Yes	☐ No

Test Completion Record:

Service Representative:_____ Date: _____