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KCI Healing by design

InfoV.A.C.® Therapy Unit
Owner Service Manual

KCI®

Important Document

File in your maintenance records.

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WARNING

Important Safety Information Accompanies This Device

Indications, Contraindications, Warnings, Precautions and other Safety Information are contained in the V.A.C.® Therapy System Safety Information Sheet. This information sheet is included with the therapy unit and also included in V.A.C.® Dressing cartons. Please consult the V.A.C.® Therapy System's User Manual and the Safety Information Sheet before applying V.A.C.® Therapy. If there are questions, or if this information sheet is missing, immediately contact your local KCI representative.

Additional product information can be found at www.kci1.com (US) or www.kci-medical.com (outside the US).

As with all prescription medical devices, failure to follow product instructions or adjusting settings and performing therapy applications without the express direction and / or supervision of your trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury. For medical questions, please consult a physician. In case of medical emergency, immediately contact your local emergency services provider.

CAUTION: Federal law (US) restricts this device to sale or rental by or on the order of a physician.

DISCLAIMER OF WARRANTY AND LIMITATION OF LIABILITY

KCI HEREBY DISCLAIMS ALL EXPRESS OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ON THE KCI PRODUCT(S) DESCRIBED IN THIS PUBLICATION. ANY WRITTEN WARRANTY OFFERED BY KCI SHALL BE EXPRESSLY SET FORTH IN THIS PUBLICATION OR INCLUDED WITH THE PRODUCT. UNDER NO CIRCUMSTANCES SHALL KCI BE LIABLE FOR ANY INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES AND EXPENSES, INCLUDING DAMAGES OR INJURY TO PERSON OR PROPERTY, DUE IN WHOLE OR IN PART TO THE USE OR REPAIR OF THE PRODUCT OTHER THAN THOSE FOR WHICH DISCLAIMER OF WARRANTY OR LIMITATION OF LIABILITY IS EXPRESSLY PROHIBITED BY SPECIFIC, APPLICABLE LAW. NO PERSON HAS THE AUTHORITY TO BIND KCI TO ANY REPRESENTATION OR WARRANTY EXCEPT AS SPECIFICALLY SET FORTH IN THIS PARAGRAPH.

Descriptions or specifications in KCI printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties except as set forth in the written limited warranty included with this product. Information in this publication may be subject to change at any time. Contact KCI for updates.

Important Information For Users

In order for KCI products to perform properly, KCI recommends the following conditions. Failure to comply with these conditions will void any applicable warranties.

- Use this product only in accordance with this manual, the device user manual and applicable product labeling.
- Assembly, operations, extensions, re-adjustments, modifications, technical maintenance or repairs must be performed by qualified personnel authorized by KCI. **Certain repairs will require KCI trained technicians. Please contact KCI at (in the US) 1-800-275-4524 for repairs not provided for in this service manual.**
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Use only V.A.C.® Dressings and KCI approved parts with this product.
- Keep this product away from heated surfaces.
- Although this product conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- Avoid spilling fluids on any part of this product.

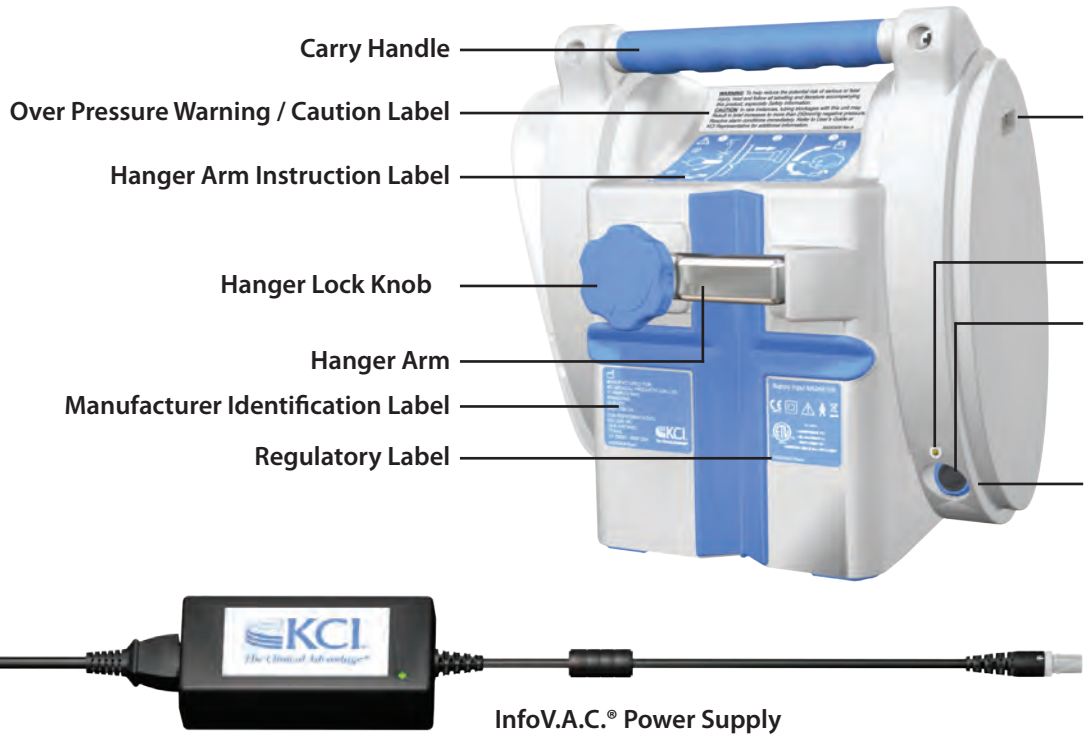
Fluids remaining on the electronic controls can cause corrosion that may cause the electronic components to fail. Component failures may cause the unit to operate erratically, possibly producing potential hazards to patient and staff. If spills do occur, unplug the unit immediately and clean with an absorbent cloth. Ensure there is no moisture in or near the power connection and power supply components before reconnecting power. If the product does not work properly, contact KCI.

- Do not use this product while bathing / showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Disconnect the unit from dressing and contact KCI.
- Refer to the Cleaning and Disinfection chapter of this manual for information on infection control.

Notice

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the product information label for specific voltage.

InfoV.A.C.® Therapy Unit Feature Identification



InfoV.A.C.® Power Supply

Introduction / About This Manual

This manual is designed to assist with routine service procedures for the InfoV.A.C.® Therapy Unit sold by KCI. Following these procedures ensures that the InfoV.A.C.® Therapy Unit is properly cleaned, fully functional and ready for patient use. These procedures include:

- unpacking and initial unit inspection
- cleaning and disinfection
- inspection for damaged and / or missing parts
- verifying unit function
- ensuring battery is fully charged
- verifying default settings are correct

All steps in these procedures must be followed in the order presented to provide proper functionality and reliability of the InfoV.A.C.® Therapy Unit. Opening the therapy unit to gain access to the internal components (other than the battery) may void the warranty.

Each InfoV.A.C.® Therapy Unit must be cleaned, disinfected, inspected and charged between each patient use. For further questions about the required frequency of service procedures, contact KCI (see page 34).

It is recommended that all sections of this manual be reviewed before beginning any routine service procedures on the InfoV.A.C.® Therapy Unit. Please follow all applicable warnings and cautions and use universal precautions where necessary.

Preparation For Use

Preparing the InfoV.A.C.® Therapy Unit for use includes unpacking, inspection for any damaged or missing parts and an initial round of service procedures to ensure the battery is fully charged and the unit is ready for patient use. The following procedures should be performed when the unit is first received from KCI.

Unpack the Unit

1. Inspect the cardboard shipping box for visible signs of damage.
2. Unpack the unit from the shipping box. Use caution when opening to ensure box contents are not damaged.
3. Inspect the contents of the shipping box for damaged items. If damage is noted, contact the shipping company for reporting / return procedures.
4. Inventory all items in shipping box against the packing slip. Contact KCI (see page 34). if there are any items missing.

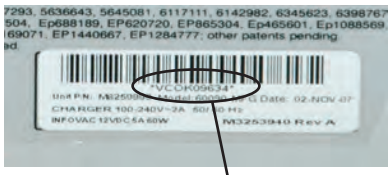
Initial Inspection

The purpose of this inspection is to ensure the unit has arrived without any internal damage and that the battery is fully charged prior to the initial patient placement.

1. Using a copy machine, reproduce the InfoV.A.C.® Therapy System Required Service Record form from the back of this manual. Fill in the required information for the unit in the spaces provided.
2. Ensure the date of the last Pressure Transducer Check is recorded on the form.
3. Perform the required service procedures as listed on the form. Start with **Inspect Unit For Damage** on page 10 of this manual.
4. After initial inspection and service are complete, retain the completed form for each unit as a permanent record.

Serial Number Location

The InfoV.A.C.® has a serial number label, illustrated at right, that is located on the side of the unit in the canister recess. This serial number will be recorded on the InfoV.A.C.® Therapy System Required Service Record form.



Cleaning and Disinfection

Cleaning and disinfection of the InfoV.A.C.® Therapy Unit includes wipedown of all hard surface components.
The InfoV.A.C.® Therapy Unit must be cleaned and disinfected:

1. if it becomes soiled during patient use, or
2. between each patient use.

Infection Control

Institutional policies regarding infection control may vary; however, KCI recommends the following regarding infection control when processing KCI V.A.C.® Therapy devices:

- Designate contaminated and clean areas for separating and storing equipment before and after transport, cleaning and disinfection. Follow protocols to ensure no cross-contamination occurs between unclean and clean units.
- Use personal protective equipment (PPE) and hand hygiene protocols in accordance with the following standards:
  - 29 CFR 1910.1030, OSHA Bloodborne Pathogens Standard
  - MMWR October 2002;51 (No. RR-16), Guidelines for Hand Hygiene in Healthcare Settings
- Clean all organic material from the therapy unit prior to disinfection.
- Use hospital-grade cleaners and disinfectants according to the CDC 2008 Guideline for Disinfection and Sterilization in Healthcare Facilities.
- Do not immerse or saturate the therapy unit with fluids to avoid damage to the electronics in the device. Follow institutional procedures used for the cleaning and disinfection of other hard surface durable electronic medical equipment.

Ensure that the InfoV.A.C.® Therapy Unit and its power supply are not connected to AC power when using cleaning fluids of any nature.

Supplies and Equipment Needed

- antiseptic wipes such as PDI Sani-Cloth® Plus wipes (or equivalent)
- clear plastic bags (as appropriate)
- cotton tipped applicators

General Cleaning Recommendations

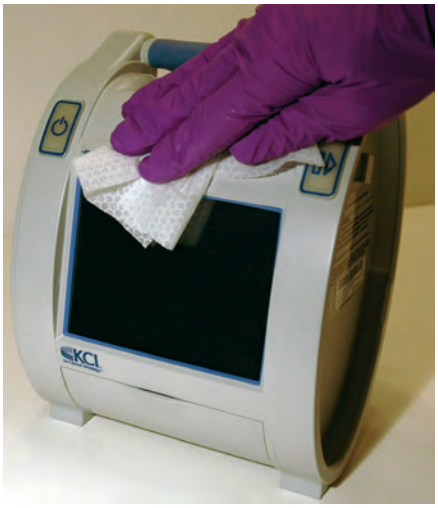
- Use PPE as appropriate.
- For items that are wiped down, ensure item's entire surface is completely covered with the cleaning fluid and remains wet for a minimum of 60 seconds.

Therapy Unit

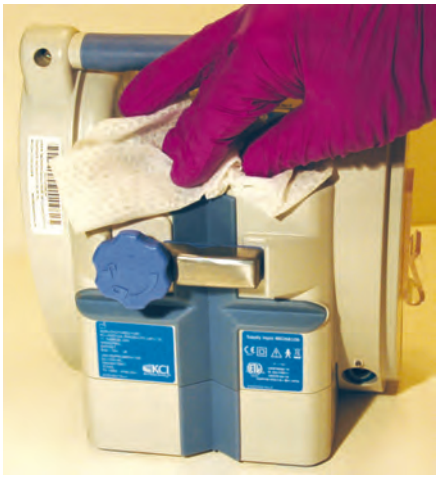
1. Ensure therapy unit is unplugged from power supply.
2. Remove canister bellows from unit. Wipe / clean bellows with an antiseptic wipe. Ensure the bellows cavities and adjacent surfaces are clean of any foreign material. Use a cotton tipped applicator if necessary. Replace canister bellows when finished.

3. Wipe down the unit using an antiseptic wipe.

Do not allow excess fluid to pool in the areas surrounding the touch screen or touch screen gasket.



4. Once the unit is thoroughly cleaned, allow to air dry.
5. Place the clean unit in a clear plastic bag and move it to the service area.



Power Supply

1. Ensure the power supply is unplugged from the therapy unit and / or any power source.
2. Wipe the power supply and cords with an antiseptic wipe. Allow to air dry.

3. Inspect the power supply brick and cords for damage and cracked or exposed wiring. Contact KCI (see page 34) if replacement is necessary.
4. Inspect the caution labels attached to the power cords for legibility. Replace as necessary.
5. Loosely loop the power cords.
6. Place the clean power supply in a clear plastic bag and move it to the service area.

Power Cord Labels

Service Procedures

The following service procedures are used to verify that the InfoV.A.C.® Therapy Unit is functioning properly and that the battery is fully charged. Once these procedures are complete, the unit will be ready for patient use. These procedures should be performed **as listed and in order:**

1. When the unit is first received from KCI, as part of the initial inspection (starting at Inspect Unit for Damage).
2. Between each patient use.

All service should occur in a clean area that is protected from contamination from unclean units or other potential contamination sources. Use PPE as appropriate or as specified in local protocols.

Inspect Unit For Damage

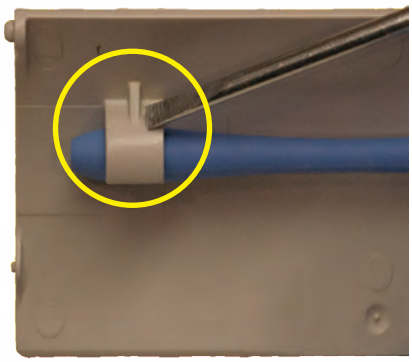
Tools and Supplies:
None.
The following replacement parts may be required:
As needed and identified during inspection.

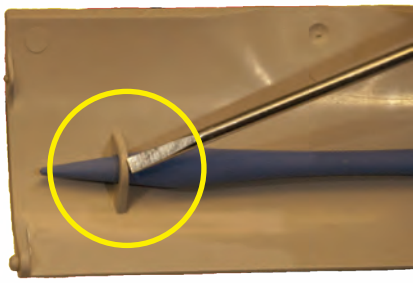
The purpose of this procedure is to inspect the InfoV.A.C.® unit for damage using the following criteria:

1. Examine the unit top, bottom and sides for:
   - Cracks of any size.
   - Holes of any size that expose internal components.
2. Examine the canister recess area for:
   - Cracks of any size.
   - Damage to the canister bellows.
3. Ensure the battery tray (bottom of unit) rubber non-slip strips are present and secure. KCI recommends replacing the battery tray if necessary.

4. Open the User Data Interface (UDI) door and ensure the stylus is present, as shown. Replace the stylus if necessary.

5. Carefully inspect the door and stylus mounting tabs for damage or cracks in the areas shown.
6. If the UDI door needs replacement, it easily snaps out of the front housing by slightly bending the door until one of the hinge pins releases.
7. Install the new UDI door by snapping the hinge pins into place.
8. With the UDI door open, examine the memory slot and data ports and ensure they are clear with no visible bent pins or other obstructions.

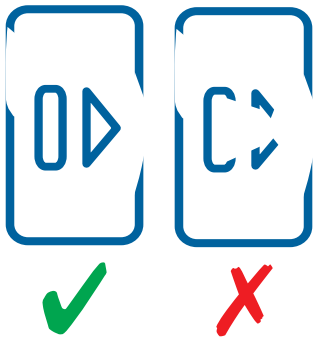




9. Check the touch screen for any visible signs of damage or excessive screen scuffing or scratches that could obscure screen elements. If damage is noted, contact KCI (see page 34).

Deep or extensive screen scratches can be the source of intermittent erratic therapy unit operation.

10. Examine the power and canister eject buttons. Ensure the graphic symbols are legible. Damage to the border is acceptable, as shown at right, but not to the interior graphic.
11. If unacceptable damage is noted, contact KCI (see page 34).



12. Check for cracks on or in the power socket itself and the surrounding rear housing.

A small crack frequently appears on the raised protrusion that holds the battery charging indicator LED. KCI does not replace the rear housing because of a minor crack at this location.

13. If damage is noted, contact KCI (see page 34).
14. Verify all labels are present per illustrations on page 5.
15. Inspect all labels for readability.
16. If labels are missing or unacceptable damage is noted, KCI recommends placing a new label over the old. If necessary, carefully trim any damaged portions of the old label and then place the new label. KCI recommends that no attempt be made to completely remove the old label.

Hanger Arm and Rubber Anti-slip Pad Inspection

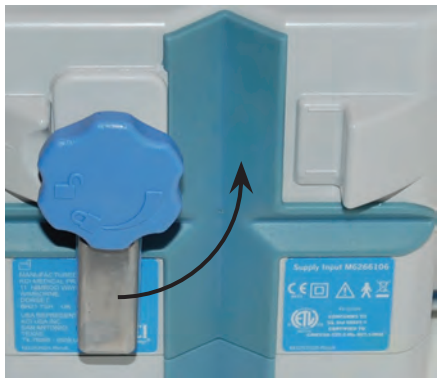
The purpose of this inspection is to ensure correct operation of the hanger arm and that all rubber anti-slip pads are undamaged and properly attached.

If the hanger arm pad is loose, see page 29 for repair procedures.

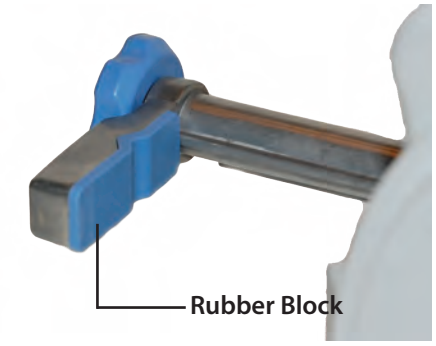
1. Verify that the hanger arm freely moves through its 90º arc when it is fully against the case.

The hanger arm can only move when it is fully retracted against the case.

2. The hanger arm is spring loaded. Verify that the spring mechanism is working correctly by pulling the arm away from the case and returning it to its retracted position. Do not allow the arm to snap back.
3. Exercise the hanger arm by pulling the arm away from the case and turning the knob to verify the arm locking mechanism works correctly and locks the arm in the extended position in both the horizontal and vertical positions. If damage or incorrect function is noted, contact KCI (see page 34).



4. While the arm is extended and locked, verify that the rubber block on the arm and the rubber V channel anti-slip pads on the case are not damaged and are securely in place. If the rubber V channel on the battery tray is missing, KCI recommends the battery tray be replaced.
5. If repair or replacement of the hanger arm rubber anti-slip block is necessary, proceed to the **Hanger Arm Rubber Block Replacement** section on page 29 for instructions.
6. If the rubber V groove anti-slip pads are loose, proceed to the **Rubber V-Groove Anti-slip Pad Repair** section on page 31 for instructions.



Battery Check / Change

The purpose of this procedure is to check the battery for manufacturing date and calculate the battery change date.

Perform this procedure at initial intake or if the battery history label is missing.

Tools and Supplies:
#2 Phillips head screwdriver
Calibrated torque screwdriver
The following replacement parts may be required:
InfoV.A.C.® Battery Pack (KCI PN 340426)
InfoV.A.C.® Battery Tray (KCI PN M4270570)
InfoV.A.C.® Battery History Label (KCI PN 340168)

Reassembly Torque Specifications:
All screws and fasteners used in the InfoV.A.C.® Therapy Unit torque to 4.4 ± .26 in lb.

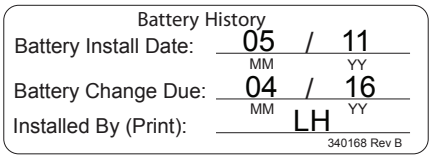
The battery history label, located on the bottom of the unit, shows the battery install date and a calculated battery change date. Testing data has extended InfoV.A.C.® battery life to 60 months. The 60 month life is calculated from the original battery install date as long as the battery manufacturing date is within the previous 12 month period.

1. Verify the battery history label is present and the battery has been checked at initial intake. If the battery history label is missing, continue with this procedure, otherwise proceed to **Charge Battery** on page 15.
2. Ensure the InfoV.A.C.® Therapy Unit is powered off and is disconnected from the power supply.
3. Remove the two screws that hold the battery tray to the housing, as shown.

4. Disconnect the battery connector, as shown.

5. Remove the battery from the battery tray, as shown.
6. Verify the battery manufacturing date on the battery is within 12 months of the install date on the battery history label.

7. Calculate the date for 60 months from the install date. Verify the battery change date on the battery history label matches the calculation, as shown.
8. If the calculated date and the label date coincide, no further action is necessary.
9. If the battery history label is incorrect, install a new battery history label with the correct dates written in with a permanent marker pen.
10. Initial the battery history label to indicate the battery has been checked so this procedure can be bypassed during future service procedures.
11. Once the dates are verified, carefully examine the battery pack for any signs of damage, corrosion or overheating. KCI recommends replacing the battery pack if there is any doubt about its condition.
12. When installing a new battery or replacing the battery tray, ensure that a new battery history label is correctly filled out and placed on the bottom of the battery tray.
13. Reinstall the battery pack in the battery tray.
14. Connect the battery connector.
15. Install the two screws that hold the battery try to the housing.
16. Torque the screws to 4.4 ± .26 in lb.



Charge Battery

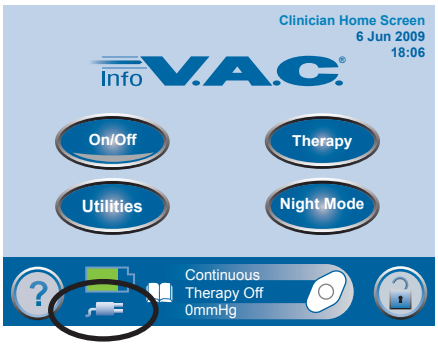
1. Set the unit in a secure place where it can be left while the battery is charging.
2. Plug the power supply cord into the InfoV.A.C.® Therapy Unit.
3. Plug the mains power cord into the power supply.
4. Plug the mains power cord into a grounded AC mains wall socket.

KCI uses commercially available metal racks.

5. Verify the battery charging indicator LED is lit.

An amber light means the battery is charging. A green light means the battery is fully charged.

6. Power the unit on by holding down the power on / off button for a minimum of two seconds.
7. Once the unit has completed its power on self test, verify the plug icon is present on the lower left of the touch screen, as shown.
8. Power the unit off by holding down the power on / off button for a minimum of two seconds.
9. Allow the battery to charge until the battery charging indicator LED is green before continuing with the remaining steps of the service procedures. If necessary, the InfoV.A.C.® Therapy Unit can be left for extended periods connected to the power supply while the charging indicator LED is green.
10. Should the battery charging indicator LED fail to light or the plug icon not appear, contact KCI (see page 34).



Plug Icon

Power On / Screen Inspection

All testing procedures from this point on will be done **WITHOUT** the InfoV.A.C.® Power Supply plugged into the unit to verify that the battery capacity is sufficient. Should the battery low alert be displayed at any point during the following service procedures, contact KCI (see page 34).

The purpose of this procedure is to verify all screen elements are readable.

1. Power the unit on by holding down the power on / off button for a minimum of two seconds **WITHOUT** using the InfoV.A.C.® Power Supply.
2. Verify the power on / off button glows green at power on.
3. Verify all elements of the screen are clear and easy to read.

Power On / Off Button glows green

4. Verify the battery indicator symbol is present on the touch screen and indicates 3/4 charge or more.
5. Should the unit fail any of the above criteria, contact KCI (see page 34).
6. If the unit passes, continue on to Data Transfer.

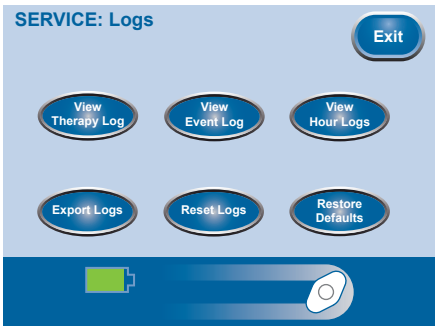
Battery Icon shows 3/4 Charge or more

Data Transfer

If a problem occurs with therapy and you would like assistance diagnosing the problem, please contact KCI (see page 34).

KCI recommends the event history and therapy history files be downloaded and saved as a permanent digital record filed by unit serial number and download date.

1. Ensure the unit is in clinician mode. If the unit is in patient mode, Press the **?** button, then press the **Clinician Mode** button, then press and hold the **OK** button until the mode changes.
2. Press the **?** button.
3. Press the **About** button.
4. Press the and hold the **Wrench icon** on lower right of screen.
5. When the **Enter Access Code** screen appears, enter **772**.
6. Press the **OK** button to acknowledge the warning on the **Entering Service Mode** screen and access the **SERVICE: Logs** screen.



7. Press the **Export Logs** button.
8. Press the **Export to USB** button.
9. Open the UDI Door and insert a USB Flash Drive into the USB slot, as shown.

Do not plug a USB PC cable directly into the InfoV.A.C.® Therapy Unit. Always use a USB Flash Drive.

10. Press the **Next** button and wait until the files are finished downloading.
    - If System Errors 2 through 8 occur, power the unit off and back on and try again.
    - If the error recurs, contact KCI (see page 34).
    - If System Error 1 occurs, contact KCI (see page 34).
11. Press the **Exit** button two times to return to the **Clinician Home Screen**.
12. Remove the USB Flash Drive from the InfoV.A.C.® Therapy Unit.
13. Connect the USB Flash Drive to an external computer.
14. Using a plain text editor program, open the **event.log** and the **therapy.log** files.
15. Combine the two files by copying and pasting one into the other.
16. Save the combined file to a permanent folder with the InfoV.A.C.® Therapy Unit serial number and download date as part of the file name.

Canister Bellows Check

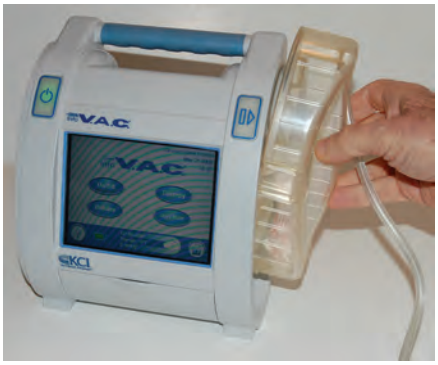
The purpose of this procedure is to check the canister bellows.

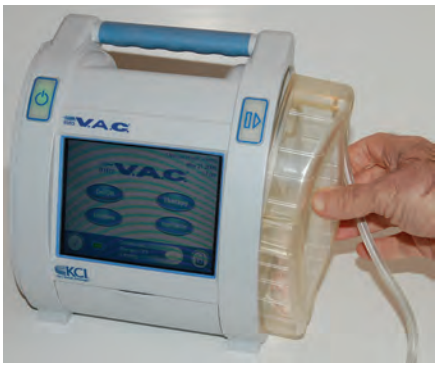
1. Visually inspect the canister bellows (KCI PN M4242003) to ensure they are clean, not damaged, in place and fully seated.
2. Bellows with any scratches, tears or other damage of any kind should be replaced.

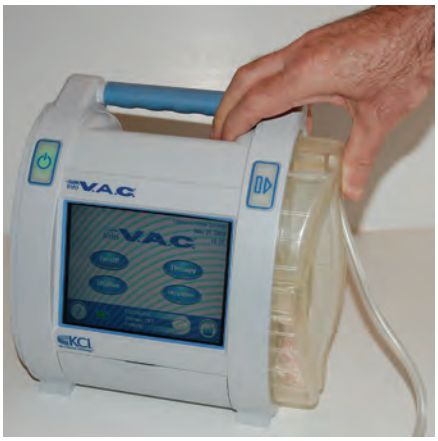
Canister Fit

The purpose of this procedure is to ensure the canister fits and latches securely to the therapy unit.

1. Insert the canister into the canister recess on the side of the unit by fitting the bottom of the canister into the canister recess and sliding it down until it fits into the canister recess.
2. Press the top of the canister firmly toward the therapy unit, listening and feeling the canister latch into place with a slight click.
3. If the canister does not easily fit and latch into place, remove the canister and check that the canister bellows are fully seated. Retry fitting the canister.
4. If the canister still will not easily fit and latch into place, substitute another canister and retry fitting the canister.
5. Once the canister fits properly, remove the canister and set aside.
6. If the canister will not fit the recess properly or latch into place, contact KCI (see page 34).



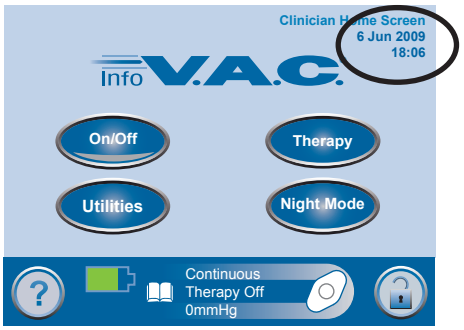




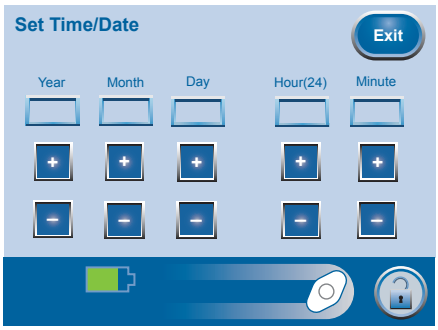
Verify Time and Date

The purpose of this procedure is to verify the unit displays the correct time and date and how to set it if it is incorrect.

1. With the unit powered on and the Clinician Home Screen visible, observe the time and date in the upper right-hand corner of the screen. If the time and date are correct to within five minutes of local time, proceed to **Testing Procedures**, otherwise go to Step 2.
2. Press the **Utilities** button.
3. Press the **Time/Date** button.



4. Set the correct local date and time.
5. Press the **Exit** button two times to return to the **Clinician Home Screen**.



Testing Procedures

Pressure Transducer Check

The purpose of this procedure is to perform the six month pressure transducer check. This check verifies that the InfoV.A.C.® Therapy Unit pressure transducers sense pressure correctly.

Tools and Supplies:
Calibrated digital manometer
Locally sourced flexible tubing
InfoV.A.C.® Canister, one each (KCI PN M8275063 or M8275071)
The following replacement parts may be required:
PM Label (KCI PN 5934), as shown.
Locally produced PM Label similar to KCI PN 5934

1. Identify the InfoV.A.C.® Therapy Unit by its serial number.
2. Access locally maintained unit records.
3. Verify the data on the PM Label on the unit and the locally maintained records coincide.

KCI recommends that a new PM Label be placed on the InfoV.A.C.® Therapy Unit each time the PM check is performed.

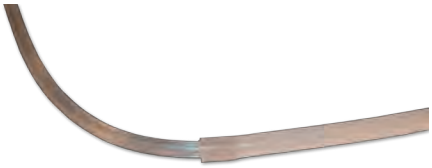
4. If the last PM check was performed more than five and one half (5 ½) months prior, perform the pressure transducer check.

KCI recommends the InfoV.A.C.® Therapy Unit NOT be placed with a patient if the PM check will become due while providing therapy to the patient.

5. If PM Label is missing or the date of the last PM check is not available, perform the PM check.
6. If the PM check is not imminently due, continue on to **Pressure Checks**.

Test Canister Preparation

1. A test canister for this procedure is a standard 500 mL canister with the tubing connector removed.
2. Fit a locally available piece of flexible tubing over the canister tubing. Ensure a snug fit for a secure seal, as shown.

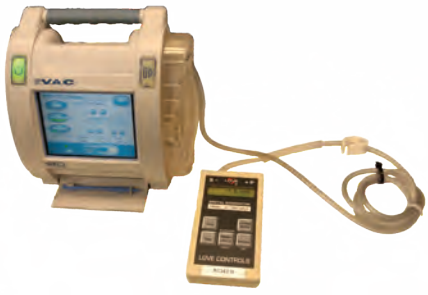


3. Obtain a locally available piece of flexible tubing that will both fit into the over tubing and onto the digital manometer barb. Ensure a snug fit for a secure seal.

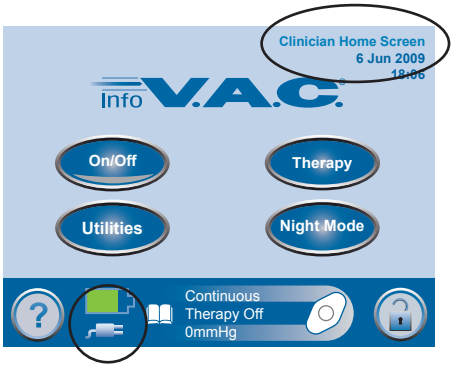
This procedure is performed with the InfoV.A.C.® Therapy Unit plugged into the InfoV.A.C.® Therapy Unit Power Supply.

Unit Preparation

1. Ensure the canister seals are in place. Install the test canister, ensuring it locks into place, as shown.
2. Connect the calibrated digital manometer to the test canister tubing.
3. Turn the manometer on and ensure it is set to read mmHg.
4. Ensure the power supply cord is plugged into the unit and the power supply is connected to an active wall power socket.
5. Power the unit on by holding down the power on / off button for a minimum of two seconds.
6. After POST completes, press the **OK** button.



7. Verify the plug indicator is visible in the lower left portion of the touch screen, as shown.
8. Verify that the unit is in clinician mode as indicated in the upper right of the touch screen. Change to clinician mode if the unit is in patient mode, as shown.

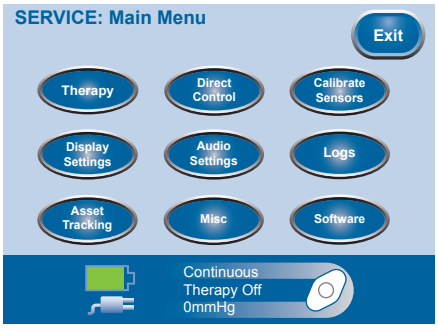


Engineering Screens Access

KCI strongly recommends that the engineering screens section of the software only be accessed as authorized.

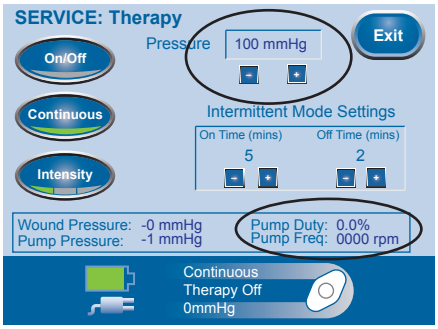
The following screens are located in the engineering screens section of the software.

1. Press the **?** button.
2. Press the **About** button.
3. Press and hold the **Wrench icon** on lower right of screen.
4. Enter **463**, press the **OK** button.
5. Press the **OK** button to access the **SERVICE: Main Menu** screen, as shown.



Sensor Accuracy Test

1. From the **SERVICE: Main Menu** screen, press the **Therapy** button.
2. Use the + or - buttons to set Pressure to 100 mmHg, as shown.
3. Press the **On/Off** button to start the pump.

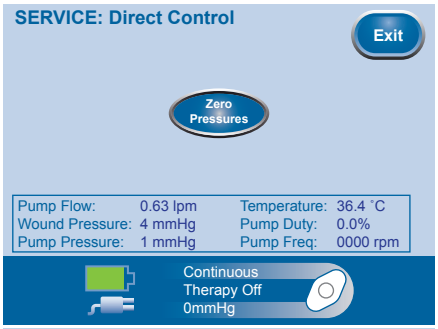


4. As the pump starts, verify that the **Pump Freq: 0000 rpm** display on the lower right of screen goes above zero. This verifies that the pump tachometer is transmitting correctly. If the pump runs but the RPM display does not show a reading above zero, contact KCI to return the unit for repair. See page 34.
5. Verify Pump Pressure and Wound Pressure on the screen read ± 6 mmHg of the set pressure.
6. Verify the digital manometer reading is ± 6 mmHg of the set pressure.
7. If the readings are within tolerance, press the **On/Off** button to stop the pump.
8. Press the **Exit** button to return to the **SERVICE: Main Menu** screen.
9. Press the **Exit** button to return to the **Clinician Home Screen**.
10. Once the PM check is successful, add a new PM Label to the bottom of the battery tray on the unit and record the results in locally maintained unit records.
11. The pressure transducer check procedure is now complete. Press the **Exit** button two times to return to the **Clinician Home Screen**. Continue on to **Pressure Checks**.
12. If the either of the readings are out of tolerance, perform the Zero Pressures procedure and repeat this sensor accuracy procedure.
13. If the unit still fails, contact KCI, (see page 34).

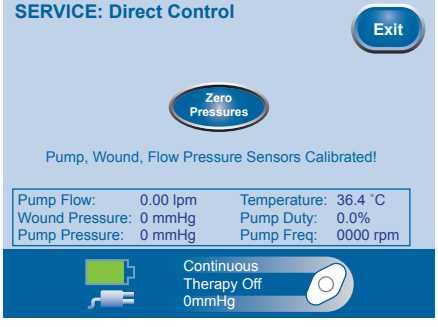
Zero Pressures

Perform this procedure only as directed in this manual.
Do not perform this procedure as a stand-alone procedure.

1. Remove the canister from the unit.
2. Ensure the canister bellows are clear of any obstructions.
3. From the **SERVICE: Main Menu** screen, press the **Calibrate Sensors** button.
4. Press the **Zero Pressures** button, as shown.



5. When the unit has finished its calibration routine, as shown, press the **Exit** button to return to the **SERVICE: Main Menu** screen.
6. Reinstall the test canister with attached digital manometer and repeat the appropriate test procedure.



Pressure Checks

If the entire Pressure Transducer Check procedure was performed, ensure the InfoV.A.C.® Therapy Unit is unplugged from the InfoV.A.C.® Power Supply.

The purpose of this procedure is to ensure the therapy unit pump responds to pressure setting adjustments.

Tools and Supplies:
Calibrated digital manometer
Locally sourced flexible tubing
InfoV.A.C.® Canister, one each (KCI PN M8275063 or M8275071)

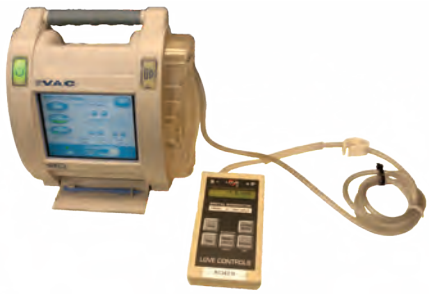
Test Canister Preparation

1. A test canister for this procedure is a standard 500 mL canister with the tubing connector removed.
2. Fit a locally available piece of flexible tubing over the canister tubing. Ensure a snug fit for a secure seal, as shown.

3. Obtain a locally available piece of flexible tubing that will both fit into the over tubing and onto the digital manometer barb. Ensure a snug fit for a secure seal.

Unit Preparation

1. Ensure the canister seals are in place. Install the test canister, ensuring it locks into place, as shown.
2. Connect the calibrated digital manometer to the test canister tubing.
3. Turn the manometer on and ensure it is set to read mmHg.
4. Ensure the unit is **not** connected to the power supply.

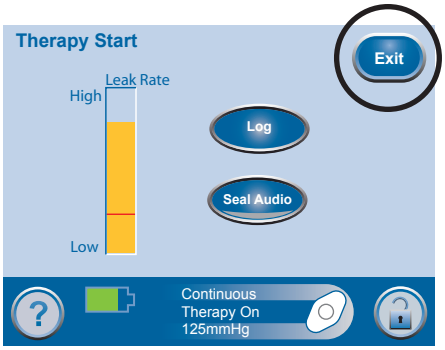


5. Verify that the unit is in clinician mode as indicated in the upper right of the touch screen.

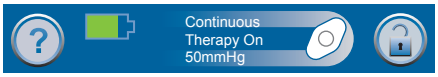
Test Procedure

1. On the **Clinician Home Screen**, press the **On/Off** button.

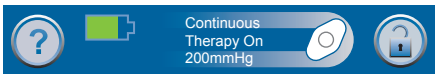
2. The **Therapy Start** screen will appear. Press the **Exit** button.



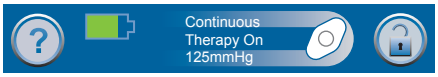
3. On the **Therapy** screen, press the **Therapy** button.
4. Press the **OK** button.
5. Press the **Settings** button.
6. Press the **Pressure** button.
7. Use the minus arrow key to set the pressure to 50 mmHg.
8. Press the **Exit** button two times.
9. Press the **OK** button.
10. The pressure should drop and stabilize at 50 mmHg within 60 seconds, as displayed on the therapy status indicator, as shown.



11. Verify the digital manometer reading is ± 6 mmHg of the set pressure.
12. Press the **Settings** button.
13. Press the **Pressure** button.
14. Use the plus arrow key to set the pressure to 200 mmHg.
15. Press the **Exit** button two times.
16. Press the **OK**. button
17. The pressure should increase and stabilize at 200 mmHg within 60 seconds, as displayed on the therapy status indicator, as shown.



18. Verify the digital manometer reading is ± 6 mmHg of the set pressure.
19. Press the **Settings** button.
20. Press the **Pressure**. button
21. Use the minus arrow key to set the pressure to 125 mmHg.
22. Press the **Exit** button two times.
23. Press the **OK** button.
24. The pressure should drop and stabilize at 125 mmHg within 60 seconds, as displayed on the therapy status indicator, as shown.



25. Verify the digital manometer reading is ± 6 mmHg of the set pressure.
26. Press the **Exit** to return to the **Clinician Home Screen**.
27. If the InfoV.A.C.® Therapy Unit passes all three pressure change procedures, remove the test canister, turn off the digital manometer and continue on to **Alarm Tests**.
28. Should the InfoV.A.C.® Therapy Unit fail any one of these pressure changes within 60 seconds, go to the Pressure Transducer Check section of this manual, enter the service screens via the access code and perform the **Zero Pressure** procedure.
29. Repeat all steps in the **-** procedure.
30. If the unit still fails, contact KCI (see page 34).

Alarm Tests

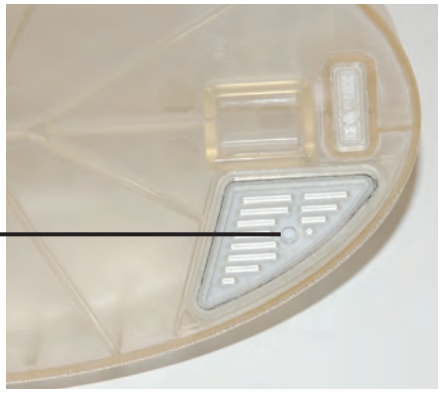
The purpose of these tests are to ensure the InfoV.A.C.® Therapy Unit correctly detects, displays and sounds alert and alarm conditions.

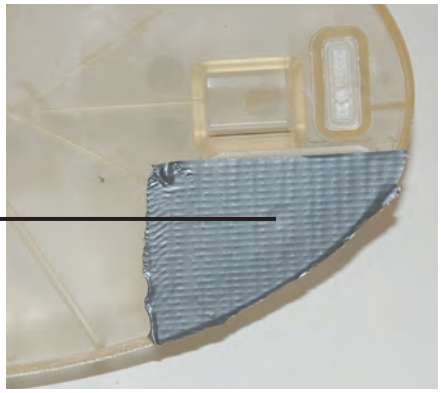
Tools and Supplies:
InfoV.A.C.® Canister, two each (KCI PN M8275063 or M8275071).
Tubing Cap, KCI PN M6275069, one each

Canister Preparation

These are normal InfoV.A.C.® canisters that can be reused for up to 6 months as a test canister. **KCI recommends marking the canisters with Test Canister-Not For Human Use and the in-use date.**

One canister has no modifications.
One canister has a piece of impermeable tape (duct tape illustrated) placed to cover the pump port, as shown. This will simulate a full canister.





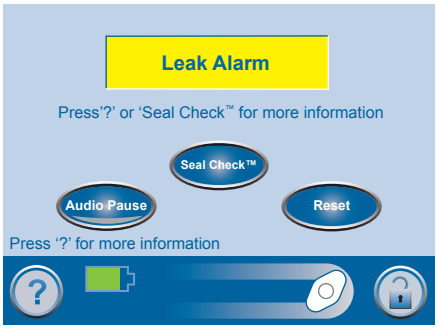
All alarm tests should be performed under battery power.

Unit Setup

1. Ensure the unit is **not** connected to the power supply.
2. Ensure the unit is operating in clinician mode.
3. Press the **Therapy** button.
4. Press the **OK** button.
5. Press the **Settings** button.
6. Press the **Pressure** button.
7. If necessary, use the arrow buttons to set the pressure to **125 mmHg**.
8. Press the **Exit** button two times.
9. Press the **OK** button.
10. Press the **Exit** button to return to the **Clinician Home Screen**.

Leak Alarm

1. Install the no tape test canister on the unit. Ensure the canister is fully seated and latched.
2. Ensure the tubing cap is removed from the canister tubing.
3. Press the **On/Off** button to start therapy. The unit will display the **Therapy Start** screen. The leak rate bar should be yellow and near the top of the range.
4. The Leak Alarm should activate in approximately two minutes or less.
5. Press the **Reset** button to return to the **Therapy Start** screen.
6. Press the **Exit** button to return to the **Clinician Home** Screen.
7. Continue on to **Blockage Alert** if the unit has correctly displayed this **Leak Alarm**.



Blockage Alert

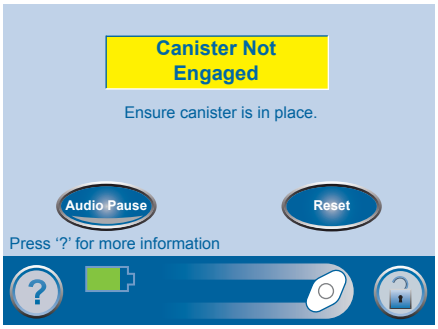
1. From the **Clinician Home Screen**, Press the **On/Off** button to stop therapy.
2. Close the tubing clamp to the maximum possible.
3. Press the **On/Off** button to start therapy.
4. Press the **Exit** button to return to the **Clinician Home Screen**.

5. The **Blockage Alert** should activate in approximately two minutes or less.
6. Press the **Reset** button to return to the Clinician Home Screen.
7. Press the **On/Off** button to stop therapy.
8. Release the tubing clamp.
9. Replace the tubing cap on the canister tubing.
10. Continue on to **Canister Not Engaged** if the unit has correctly displayed this **Blockage Alert**.

Canister Not Engaged

1. Release the canister from the unit by pressing the canister eject button.
2. Press the **On/Off** button to start therapy.
3. Press the **Exit** button to return to the **Clinician Home Screen**.

4. The **Canister Not Engaged** alarm should sound in approximately 30 seconds or less.
5. **Ensure that the alarm sounds with three beeps.**
6. Press the **Reset** button to return to the **Clinician Home Screen**.
7. Continue on to **Canister Full Therapy Interrupted** alarm if the unit has correctly displayed this **Canister Not Engaged** alarm.



Canister Full Therapy Interrupted

1. Remove the canister from the unit and replace it with a canister that has the canister pump port covered with a piece of tape, as previously shown.
2. Ensure the canister latches into place.
3. Press the **On/Off** button to start therapy.
4. Press the **Exit** button to return to the **Clinician Home Screen**.
5. The **Canister Full Therapy Interrupted** alarm should sound in approximately 90 seconds or less.
6. **Ensure that the alarm sounds with three (3) beeps.**
7. **Ensure the Canister Release button flashes blue.**
8. Continue on to **Testing Complete** if the unit has correctly displayed this **Canister Full Therapy Interrupted** alarm.

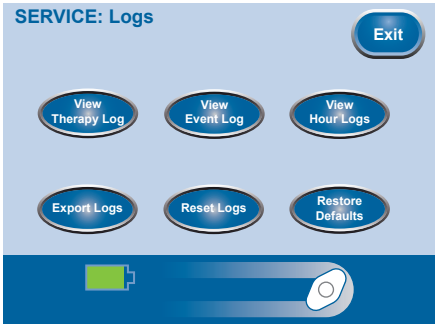
Testing Complete

1. Press the **Reset** button to return to the **Clinician Home Screen**.
2. Remove the test canister from the unit.
3. This completes the testing of the unit.
4. If the unit has passed all tests, continue on to **Final Settings**.

Final Settings

The purpose of this procedure is to restore all settings to their default values and clear all log entries.

1. From the **Clinician Home Screen** press the **?** button.
2. Press the **About** button.
3. Press and hold the **Wrench icon** on lower right of screen.
4. When the **Enter Access Code** screen appears, enter **772**.
5. Press the **OK** button to acknowledge the warning on the **Entering Service Mode** screen and access the **SERVICE: Logs** screen.
6. Press the **Reset Logs** button.
7. Press and hold **Reset** button until the screen returns to the **SERVICE: Logs** screen.
8. Press the **Restore Defaults** button.
9. Press and hold the **Restore Defaults** button until the screen returns to the **SERVICE: Logs** screen.
10. Press the **View Therapy Log** button.
11. Verify the screen shows **Events Cleared**, **Low Intensity** and **125 mmHg Continuous**. These will appear on separate lines with the time and date that the defaults were restored in step 8.
12. Press the **Exit** button two times to return to the **Clinician Home Screen**.
13. Power the unit off by holding down the power on / off button for a minimum of two seconds.
14. Continue on to **Recharge Battery**.



Recharge Battery

The purpose of this procedure is to ensure the InfoV.A.C.® Therapy Unit is delivered to a patient placement with a fully charged battery. Depending on the initial battery charge level, this process may take up to six hours.

1. Set the unit in a secure place where it can be left for a minimum of six hours.
2. Plug the power supply cord into the InfoV.A.C.® Therapy Unit.
3. Plug the mains power cord into the InfoV.A.C.® Therapy Unit power supply.
4. Plug the mains power cord into a grounded AC mains wall socket.
5. Verify the battery charging indicator LED is lit.

An amber light means the unit is charging the battery. A green light means the battery is fully charged.

6. Once the battery charging indicator LED is green, continue on to **Preparation for Transport and Patient Use**.

Preparation for Transport and Patient Use

The following documentation should always accompany the InfoV.A.C.® Therapy Unit when patient placement occurs.

- V.A.C.® Therapy System Safety Information sheet, KCI PN 340405.
- Contact KCI (see page 34) for replacement V.A.C.® Therapy System Safety Information sheets.

The InfoV.A.C.® Therapy Unit should be transported to and from patient placements according to local protocols that ensure the cleanliness of the unit and power supply.

1. Carefully wrap each power cord into a bundle and place them and the power supply into a clear plastic bag.
2. Insert the required documentation into the plastic document holder on the side of the unit.
3. Place the InfoV.A.C.® Therapy Unit into the same plastic bag as the power cords and power supply. Close the bag to ensure unit cleanliness.
4. Follow institutional protocols for transporting the unit to and placing with a patient.

Hanger Arm Rubber Block Replacement

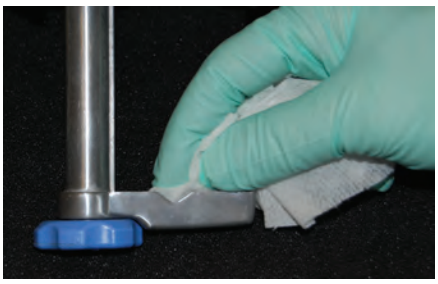
The purpose of this procedure is to provide a recommended method to repair or replace the rubber block located on the hanger arm assembly.

This procedure IS NOT part of the normal service process, but is included here to facilitate potential repairs to the hanger arm rubber block.

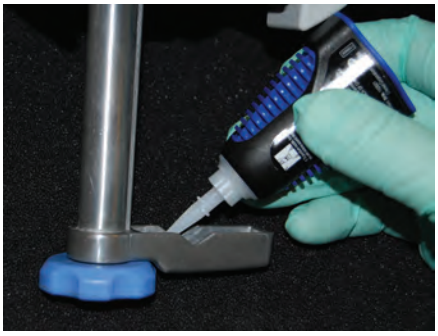
Tools and Supplies:
Loctite® 411™ Cyanoacrylate adhesive or equivalent
Isopropyl alcohol
Cleaning cloth
An appropriate sized tool for removing any residual old adhesive - a standard flat blade screwdriver may work.
Protective gloves
Rubber block (KCI PN M3240627), if required

Procedure:

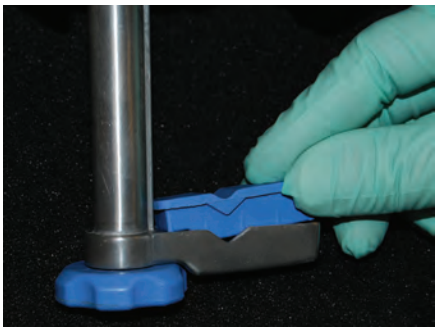
1. Using an appropriate tool, ensure all residual hot-melt adhesive is removed from the interior of the cast metal hanger arm hook.
2. Use Isopropyl alcohol to clean the interior of the cast metal hanger arm hook. Allow to air dry.



3. Apply several drops of Loctite® 411™ or equivalent adhesive to both interior sides of the cast metal hanger arm hook.

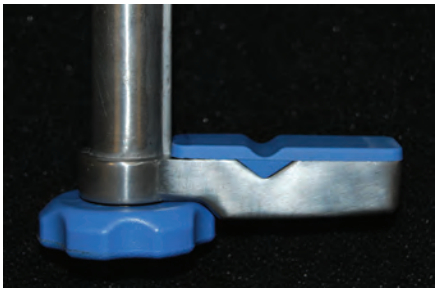


4. Insert the rubber block into the hook cavity, ensuring the adhesive remains inside the hook cavity.



5. Press the rubber block into place.
6. Immediately remove any excess adhesive on the block, hanger arm or cast metal hook.

7. Follow manufacturer directions to allow the adhesive to fully set before use.



Rubber V-Groove Anti-slip Pad Repair

The purpose of this section is to provide instruction for regluing the rubber V-groove pads located on the back of the rear housing.

This procedure IS NOT part of the normal service process, but is included here to facilitate potential repairs to the rubber V-groove anti slip pads.

Tools and Supplies:
Loctite® 411™ Cyanoacrylate adhesive or equivalent
Protective gloves
The following replacement parts may be required:
InfoV.A.C.® Battery Tray (KCI PN M3268561)

The rubber V-groove anti-slip pads are glued in place. Rough handling of the unit may loosen these pads. The pad on the battery tray may be completely missing. There is no replacement PN for the battery tray V-groove anti-slip pad. KCI recommends replacing the entire tray if the pad is missing. If the pads on the rear case are missing, contact KCI, (see page 34).

1. Carefully check all edges of the rubber V-groove pads located on the back of the rear housing.
2. If any are loose, reglue them as shown.

infovac®
KCI Healing by design

Specifications*

InfoV.A.C.® Therapy Unit

Dimensions..... 9.05 x 8.6 x 6.8 in (23 x 22 x 17.5 cm)
Weight.....6.37 lb (2.89 kg)
Pressure Options .....50 to 200 mmHg
Modes .....Continuous and Intermittent

Medical Equipment with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1, EN60601-1, and CAN/CSA, C22.2 No. 601.1.

EMC classification

- Class B device
- Tested to: EN 60601-1-2 / 2001-09; EN 55011 / 05.98 + A1 / 1999; EN 61000-3-2 / 04.95 + A1 / 04.98 + A2 / 04.98 + A14 / 2000; EN 61000-3-3 / 01.95

IEC Classification

- Medical Equipment
- Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Continuous Operation
- Type B Applied Part
- Class II Internally Powered Equipment
- IPX0

Battery

Run Life .....Approximately 12 hours, depending on settings.

Electrical

Charger / External Power Supply Input .....100-240 VAC, 50 / 60 Hz, 1 Amp
Charger / External Power Supply Output .....18 VDC, 2.2 Amp
Patient and Enclosure Leakage Current .....< 100 Microamps

Environmental Conditions

Storage
Temperature Range .....-4° (-20°C) to 140° (60°C)
Relative Humidity Range .....10 to 85% Non-condensing
Atmospheric Pressure Range .....700 hPa to 1060 hPa

Operating
Temperature Range .....50°F (10°C) to 86°F (30°C)
Relative Humidity Range .....30 to 75%
Atmospheric Pressure Range .....50 kPa to 106 kPa

*Specifications subject to change without notice.

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician.

Spare Parts

This spare parts list is current as of September 2011. Contact KCI (see page 34) to verify current part numbers.

Part Number	Description
340405	V.A.C.® Therapy Safety Instruction Sheet
340406	InfoV.A.C.® Manufacturer Identification Label
340426	InfoV.A.C.® Battery Pack Assembly
M3240627	InfoV.A.C.® Hanger Arm Blue Rubber Block
M3244915	V.A.C.® Therapy Safety Instruction Sheet Clip
M3253923	InfoV.A.C.® Hanger Arm Instruction Label
M3253925	InfoV.A.C.® Regulatory Symbols Label
M3253934	Battery History Label
M3253935	Over Pressure Warning - Caution Label
M3253936	InfoV.A.C.® Patient Information Label
M3253940	InfoV.A.C.® Serial Number Label
M3253961	InfoV.A.C.® Logo Label
M3253962	KCI Logo Label
M3268561	InfoV.A.C.® Battery Housing
M3253946	InfoV.A.C.® Power Cord Warning Label
M3268563	InfoV.A.C.® UDI Door
M3268567	InfoV.A.C.® UDI Stylus
M4242003	InfoV.A.C.® Canister Bellows FGA14NK-SO
M4268880	InfoV.A.C.® Mains Power Cord, UK
M4268881	InfoV.A.C.® Mains Power Cord, EU
M4268882	InfoV.A.C.® Mains Power Cord, USA / Canada
M4268883	InfoV.A.C.® Mains Power Cord, Australia
M6252250	InfoV.A.C.® User Manual
M6266106	InfoV.A.C.® Power Supply
M6275069-5	T.R.A.C.™ Tubing Cap (5 Per Package)
M7260522	Battery Box Screw - M4X12 Panhead
M8275063/5	InfoV.A.C.® 500 mL Canister (with Gel) (box of 5 canisters)
M8275071/5	InfoV.A.C.® 500 mL Canister (without Gel) (box of 5 canisters)

Symbols Used

Service Manual

The Warning symbol signifies a possible hazard to system, patient or staff.

The Shock Warning symbol signifies a possible electrical shock hazard.

The Information Point symbol signifies an important note or operational information.

Therapy Unit

Conforms with the Medical Device Directive (94/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

Class II, Internally Powered Equipment

Refer to User Instructions

Type B, Applied Part

UL Rated

This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.

Customer Contact Information

For questions regarding this product, supplies, maintenance, or additional information about KCI products and services, please contact KCI or a KCI authorized representative, or:

In the US call 1-800-275-4524 or visit www.kci1.com

Outside the US visit www.kci-medical.com

Technical Report

Ground Continuity and Earth Leakage

This section is intended for biomedical engineers responsible for safety testing, installing and / or qualifying medical devices.

The InfoV.A.C.® Therapy Unit is certified as meeting the requirements of IEC/UL/EN 60601-1, Medical electrical equipment, Part 1: General Requirements for safety.

 This symbol, appearing on the product label, signifies that the device is designated as CLASS II EQUIPMENT (double insulated). Per clause 2.2.5 of IEC/UL/EN 60601-1, Class II equipment is:

"EQUIPMENT in which protection against electric shock does not rely upon BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions."

For the InfoV.A.C.® Therapy Unit, this means that the ground pin on the AC power supply cord has no functional or safety purpose and therefore has no connection whatsoever inside the device.

Measuring resistance between the ground pin on the AC power supply cord and any other accessible metallic surfaces on the device will therefore produce an open circuit reading. Accessible screw heads on the device have no connection to internal metal parts or chassis (i.e.: they are double insulated from live parts).

Measurement of earth leakage current will yield a reading within the acceptable limits of IEC/UL/EN 60601-1 for both normal condition and single fault condition.

InfoV.A.C.® Therapy System
Required Service Record

- To be used in conjunction with the InfoV.A.C.® Therapy Unit Owner Service Manual
- Complete this form between each patient use and maintain as a permanent record.
- Circle any step not passed and return a copy of this sheet to KCI along with the unit.

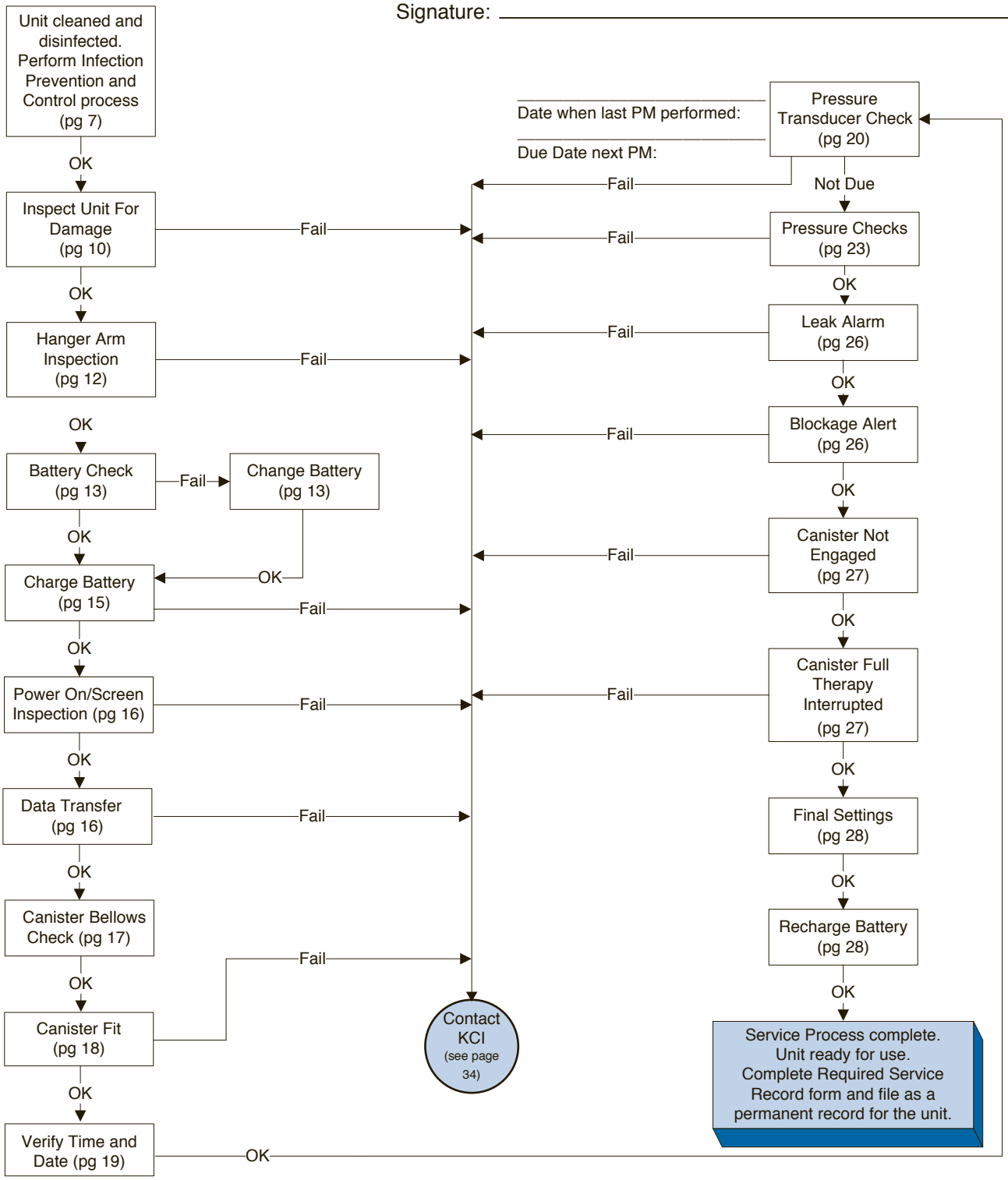
Facility: _____

Unit Serial Number: _____

Date Service Completed: _____

Inspector Name (Please Print): _____

Signature: _____



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