Owner Service Manual

Important Document
File in your maintenance records
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Contact KCI (see page 27) for updates.

Important Information For Users

This manual contains routine service procedures for the ActiV.A.C.® Therapy Unit sold by KCI. This manual is not intended for repair or non-routine service procedures. Contact KCI (see page 27) for any repair or non-routine service not covered by this manual.

Please read and understand all sections of this manual before beginning any service procedures on this equipment.

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

- Assembly, operations, extensions, re-adjustments, modifications, service or repairs must be performed by qualified personnel authorized by KCI. Please contact KCI for more information.
- Access codes to engineering screens are proprietary and remain property of KCI, and may only be used for the limited purpose as outlined in KCI copyrighted documentation.
- The electrical installation of the room must comply with the appropriate national electrical wiring standards. To avoid the risk of electrical shock, this product must be connected to a grounded power receptacle.
- Use this product only in accordance with its user manual and applicable product labeling.
- Ensure that personnel performing the procedures detailed in this manual are properly trained and qualified to perform service on medical devices.
- Follow all procedures as outlined in this manual, including infection control and care and cleaning.
- Document and retain as a permanent record all service procedures performed.
- Use only KCI V.A.C.® Dressings and accessories with this product.

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 ActiV.A.C.® Therapy Unit and also included in every V.A.C.® Dressing carton. Please consult the ActiV.A.C.® Therapy Unit User Manual and Safety Information Sheet before applying V.A.C.® Therapy. If there are questions or these documents are missing, immediately contact your local KCI representative.
Introduction / About This Manual
This manual is designed to assist with routine service procedures for the ActiV.A.C.® Therapy Unit sold by KCI. Following these procedures ensures that the ActiV.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 ActiV.A.C.® Therapy Unit. Opening the therapy unit to gain access to the internal components (other than the battery) may void the warranty.

Each ActiV.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 27).

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

Preparation For Use
Preparing the ActiV.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 to ensure there are no visible signs of damage.
2. Unpack all items from the shipping box.
3. Inspect all items for damage. 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 27) 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. Obtain the ActiV.A.C.® Therapy System Required Service Record form and fill in the required information for the unit in the spaces provided (see serial number location below). Form may be obtained either way as follows:
   - Make photocopies of the ActiV.A.C.® Therapy System Required Service Record form in the back of this manual.
   - Contact KCI (see page 27) to order a 25-pack of these forms.
2. Perform the required service procedures as listed on the form. Start with Inspect Unit For Damage on page 8 of this manual.
3. After initial inspection and service are complete, retain the completed form for each unit as a permanent record.

Serial Number Location
The ActiV.A.C.® has a serial number label, illustrated at right, that is located on the back of the unit. This serial number will be recorded on the ActiV.A.C.® Therapy System Required Service Record form.
Unit Features

Keep all access covers closed during normal use. Open covers only for data transfer.
Cleaning and Disinfection

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

- if it becomes soiled during patient use
- 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 ActiV.A.C.® Therapy Unit and its power supply are not connected to AC power when using cleaning fluids of any nature.

To isolate the therapy unit from supply mains, unplug the AC power from the wall outlet.

Supplies and Equipment Needed

- Hospital grade antiseptic used per label directions
- Clear plastic bags (as appropriate)
- Cotton tipped applicators
- Rubber bands
- Tweezers or similar tool
- #1 Phillips screwdriver

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. Remove the unit from the plastic and / or fabric carrying case, as applicable.
2. Ensure therapy unit is unplugged from power supply.
3. Remove canister seals from unit.
4. Wipe / clean seals with antiseptic. Ensure the seal cavities and adjacent surfaces are clean of any foreign material. Replace seals when finished.
5. Remove the exhaust filter. Discard the filter using local protocols. Moisten a cotton tipped applicator with antiseptic; thoroughly wipe the interior of the filter compartment.

   The exhaust filter is single use only.

6. Wipe down the back of the unit with antiseptic.

   Do not allow excess cleaning fluid into the areas surrounding the touch screen gasket.

7. When wiping the front of the unit, do not allow cleaning fluid to seep into any gaps in the touch screen gasket.

   Cleaning fluids allowed to seep past the gasket may damage the touch screen to the point of requiring replacement.

8. Wipe down the front and sides of the unit with antiseptic.
9. Once the unit is thoroughly cleaned, allow to air dry.
10. Place the clean unit in a clear plastic bag and move 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 cord with antiseptic. Allow to air dry.
3. Inspect the power supply, cords and connectors for damage and cracked or exposed wiring. Contact KCI if replacement is necessary.
4. Inspect the power supply safety labels for legibility. Replace as necessary.
5. Loosely loop the power cord and secure with a rubber band.
6. Place the clean power supply in a clear plastic bag and move it to the service area.

Fabric Carrying Case
The ActiV.A.C.® Fabric Carrying Case (KCI P/N 340122) is designed as a single use item; do not launder or reuse.
Service Procedures

The following service procedures are used to verify that the ActiV.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:

- when the unit is first received from KCI, as part of the initial inspection (starting at Inspect Unit for Damage)
- 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.

Parts and Equipment Needed

- ActiV.A.C.® Canister KCI P/N M8275058, two each
  - These are normal ActiV.A.C.® canisters that can be reused for up to six months as a test canister. KCI recommends marking the canister with Test Canister-Not For Human Use and the in-use date.
- Tubing Cap, KCI P/N M6275069, one each. Note: A tubing cap is attached to the canister tubing as delivered.
- ActiV.A.C.® Therapy System Required Service Record form, KCI P/N 414211, one each
- Canister Seal, KCI P/N 340040, two each (if required)
- Exhaust Filter, KCI P/N 340037, one each
- ActiV.A.C.® Fabric Carrying Case KCI P/N 340122, one each
- ActiV.A.C.® Pressure Accuracy Accessory, KCI P/N 340145, one each
- Calibrated Digital Manometer, customer supplied, one each. Manometer accuracy to be within 2.5 mmHg.

Inspect Unit for Damage

The purpose of this procedure is to inspect the ActiV.A.C.® Therapy Unit for damage.

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 attachment area for:
   - cracks of any size
   - damage to the canister seals
   - missing or damaged canister bumpers
3. Examine the battery charging / power connection and USB data port to ensure they are clear with no visible bent pins or other obstructions.
4. Examine the touch screen area and ensure it is secure in the case.
5. Check for excessive screen scuffing, scratches and / or cracks that could obscure screen elements.

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

6. Verify all labels are present per illustrations on page 5.
7. Inspect all labels for readability. If replacement is necessary, see spare parts list and apply new label over old.
Labels for the ActiV.A.C.* Therapy Unit are designed to be non-removable by patients during normal use. If a label becomes damaged, DO NOT use a sharp object to scrape the label off. The powder coating on the unit may be damaged beyond repair. Apply new label in the same position and orientation as the original. The label manufacturer recommends not using any cleaning fluid or other cleaning material to remove any residual label adhesive.

8. Should the unit fail any of the above criteria, contact KCI (see page 27).

9. With the unit inspection complete, continue on to Replace Exhaust Filter.

Replace Exhaust Filter

The purpose of this procedure is to replace the exhaust filter. This procedure can be skipped if the unit is new and has not been previously placed with a patient.

1. Insert a new exhaust filter.
2. Ensure the filter is fully seated.
3. With the exhaust filter replacement complete, continue on to Data Download.

Data Download

The purpose of this procedure is to download and archive the therapy history file from the most recent use of the ActiV.A.C.* Therapy Unit. This procedure can be skipped if the unit is new and has not been previously placed with a patient.

If a problem occurs with therapy and you would like assistance diagnosing the problem, please contact KCI (see page 27).

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

1. Ensure the unit is powered on and is in Clinician Mode. If the unit is in Patient Mode, press ? button, then press Clinician Mode, then press and hold OK button until the mode changes.
2. Press Therapy button.
3. Press Next button.
4. Press History button.
5. Press Export History button.
6. Press Export to USB button.

Always use a USB flash drive. Do not plug a USB PC cable into the ActiV.A.C.* Therapy Unit.

7. Insert a USB flash drive into the USB data port.
8. Press Next button.
9. Wait while the unit downloads the data to the flash drive.

10. When the download is complete, press OK button.
    • If System Errors 2 through 6 occur, power the unit off and back on and try again.
    • System Errors 7 and 8 are cleared by resetting patient defaults, see Final Settings section.
    • If the error recurs, contact KCI (see page 27).
    • If System Error 1 occurs, contact KCI (see page 27).

11. Press Exit button to return to the Clinician Home Screen.

12. Remove the USB flash drive from the ActiV.A.C.® Therapy Unit.

13. Connect the USB flash drive to an external computer.

   The ActiV.A.C.® Therapy Unit exports a file folder that uses the unit serial number as its name. The folder contains a Comma Separated Values (CSV) file named by date, YYYYMMDD.csv.

14. For the initial save operation, save the entire file folder to a secure computer.

15. For subsequent data exports from the same ActiV.A.C.® Therapy Unit, save the new dated CSV file to the same secure computer into the existing folder named with the ActiV.A.C.® Therapy Unit serial number.

16. With the data download complete, continue on to Battery Check.

Battery Check
The purpose of this procedure is to determine if the battery needs changing.

1. Locate the battery history label located on the bottom of the unit.

2. Verify the battery change date on the battery history label.

3. If the battery is within the date range, skip ahead to Pressure Checks; otherwise proceed to the Change Battery procedure.

Battery Change
The purpose of this procedure is to change the battery.

Ensure that the ActiV.A.C.® Therapy Unit is not connected to the power supply when removing or replacing the battery.

1. Verify that the battery change due date on the battery history label is at or exceeds the current date.

2. Remove the battery history label.

3. Using a #1 Phillips screwdriver, remove the two 4-40 Phillips head screws.

4. Remove the battery cover.
5. Remove the battery from the unit until the wiring connector is accessible.

6. Disconnect the battery from the unit.

7. Remove the old battery and dispose of it properly in accordance with local, state and federal regulations for Lithium-ion batteries.

   The ActiV.A.C.® Therapy Unit battery must be replaced only with batteries supplied by KCI. Use of any other battery may compromise safety and/or cause erratic operation.

8. Obtain a new battery from KCI (KCI P/N 414003).

9. Obtain a new battery history label (KCI P/N 340168).

   Shelf life of the battery is 12 months from battery manufacture date. Verify that the battery manufacture date is within 12 months of the date of installation. If the manufacture date is outside 12 months, contact KCI (see page 27) for a replacement battery.

10. Calculate the next battery change due date as 30 months from the installation date.

11. Record the required information on the battery history label.

12. Slide new battery about halfway into unit until connectors meet. Plug connectors together and ensure locking tabs are fully engaged.

13. Fit the battery into the housing ensuring the wiring harness is not in front or behind the battery and is not tangled or obstructing the battery.

14. Press the Power On / Off switch to ensure the unit powers on properly.

15. Press the Power On / Off switch to turn the unit off.

16. Reinstall the battery cover, ensuring that it easily fits and does not need to be forced into place. If force is required, the battery is not properly installed. Double check that the wiring harness is not preventing the battery from fitting fully into the battery compartment.

17. Install the two screws tightly.

18. Install the new battery history label across the battery cover.

19. With the battery change complete, continue on to Pressure Checks.

Pressure Checks

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

   The ActiV.A.C.® Therapy Unit must be connected to the ActiV.A.C.® Power Supply during this procedure. The needle valve simulates the permeability of a V.A.C.® Drape. The PVC test fixture and hygroscopic filter simulate the ActiV.A.C.® Canister.

Set-up

1. Remove canister seals from unit.
2. Connect the PVC test fixture to the ActiV.A.C.® Therapy Unit as illustrated below.

3. Ensure the calibrated manometer is connected as illustrated and powered on.

4. Ensure the tubing with the hygroscopic filter is connected to the pump port and the plain tubing is connected to the wound port.

5. Power the unit on by pressing the Power On / Off switch for two seconds.

6. After acknowledging the warning screen, ensure the ActiV.A.C.® Therapy Unit is in Clinician Mode by observing the text in the upper right hand corner of the screen, as illustrated.

7. If not in Clinician Mode, press ? button, press Clinician Mode, press and hold OK button until the screen changes to Clinician Mode.
25 mmHg Test
1. Press Therapy button.
2. Press Next button.
3. Press Settings.
4. Press Pressure and use the arrow keys to set the pressure to 25.
5. Press Exit two times.
6. On the Confirm screen, ensure that settings are Pressure: 25 mmHg; Mode: Continuous; Intensity: Low. If these settings are not correct, press Back to change the incorrect setting.
7. Press OK button.
8. Start therapy by pressing the On / Off button.
9. On the Therapy Start screen adjust the needle valve so that the Leak Rate bar graph indicator on the Therapy Start screen indicates green and is below the dividing line on the bar graph (see illustration).
10. Observe the digital manometer and the displayed pressure on the ActiV.A.C.® touch screen. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.
11. Press Exit button.
12. Press Therapy button.
13. Press Next button.

125 mmHg Test
1. Press Pressure and use the arrow keys to set the pressure to 125.
2. Press Exit two times.
3. On the Confirm screen, ensure that settings are Pressure: 125 mmHg; Mode: Continuous; Intensity: Low. If these settings are not correct, press Back to change the incorrect setting.
4. Press OK button.
5. Press Therapy button.
6. Press Next button.
7. Press Seal Check™ button.
8. Adjust the needle valve so that the Leak Rate bar graph indicator on the Therapy Start screen indicates green and is below the dividing line on the bar graph (see illustration).
9. Observe the digital manometer and the displayed pressure on the ActiV.A.C.® Touch Screen. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.
10. Press Exit button one time.
11. Press Settings.
200 mmHg Test

1. Press Pressure and use the arrow keys to set the pressure to 200.

2. Press Exit two times.

3. On the Confirm screen, ensure that settings are Pressure: 200 mmHg; Mode: Continuous; Intensity: Low. If these settings are not correct, press Back to change the incorrect setting.

4. Press OK button.

5. Press Therapy button.

6. Press Next button.

7. Press Seal Check™ button.

8. Adjust the needle valve so that the Leak Rate bar graph indicator on the Therapy Start screen indicates green and is below the dividing line on the bar graph (see illustration).

9. Observe the digital manometer and the displayed pressure on the ActiV.A.C.* Touch Screen. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.

10. Press Exit button.

11. Press Settings.

125 mmHg Test

1. Press Pressure and use the arrow keys to set the pressure to 125.

2. Press Exit two times.

3. On the Confirm screen, ensure that settings are Pressure: 125 mmHg; Mode: Continuous; Intensity: Low.

4. Press OK button.

5. Observe the digital manometer and the displayed pressure on the ActiV.A.C.* Touch Screen. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg, within 60 seconds.

6. If the ActiV.A.C.* Therapy Unit passes all four pressure change procedures, remove the test fixture tubing and reinstall the canister seals onto the unit.

7. Should the ActiV.A.C.* Therapy Unit fail any one of these pressure changes by not displaying the correct pressure within 60 seconds, contact KCI (see page 27).

8. With the Pressure Check complete, continue on to Charge Battery and Six Hour Verification Test.
Charge Battery and Six Hour Unit Verification Test

The purpose of this procedure is to ensure the ActiV.A.C.® Therapy Unit is fully functional and the battery is fully charged. This six hour test is a minimum time. The process can be extended overnight or over a weekend if necessary.

1. Set the unit in a secure place where it can be left for a minimum of six hours. Charging can extend longer than six hours if necessary.

2. Plug the power supply cord into the ActiV.A.C.® Therapy Unit.

3. Plug the mains power cord into the external 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 battery is charging.
   A green light means the battery is fully charged.

6. Ensure the unit is powered on. If necessary, hold down the Power On/Off button for a minimum of two seconds to power the unit on.

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.

8. Unplug the power supply cord from the ActiV.A.C.® Therapy Unit. Verify the battery icon is present on the lower left of the touch screen.

9. Plug the power supply cord into the ActiV.A.C.® Therapy Unit. Verify the plug icon reappears and the Battery Charging Indicator LED is lit.

10. Grasp the power cord approximately 3 inches (75mm) from the end plugged into the ActiV.A.C.® Therapy Unit and wiggle the cord. Observe both the Battery Charging Indicator LED and the plug icon on the touch screen. Should either of these indicators flicker, repeat the wiggle test using a different power supply cord.

11. Should the ActiV.A.C.® Therapy Unit fail any of the above steps, contact KCI (see page 27).

12. Attach a regular ActiV.A.C.® 300 mL canister that has been designated a test canister to the ActiV.A.C.® Therapy Unit.

13. Ensure that a tubing cap is attached to the canister tubing.

14. With the ActiV.A.C.® Therapy Unit still in Clinician Mode, press Therapy button.
15. Press Next button.


17. Press Pressure and if necessary use the arrow keys to set the pressure to 125.

18. Press Exit two times.

19. On the Confirm screen, ensure that settings are Pressure: 125 mmHg; Mode: Continuous; Intensity: Low. If these settings are not correct, press Back to change the incorrect setting.

20. Press OK button.

21. Start therapy by pressing On / Off; the Therapy Start screen will appear.

22. Ensure the Leak Rate indicator is green.

23. Press Exit button to return to the Clinician Mode Home screen.

24. Begin six hour verification period. KCI recommends starting a timer to ensure the six hour time period is achieved.

25. Press On / Off to stop therapy.

26. At the end of the six hour verification period, carefully check the unit for:
   - control buttons not responding
   - excessively hot unit
   - no alarms are displayed

27. Verify that the Battery Charging Indicator LED is lit and showing green.

28. Unplug the power supply cord from the ActiV.A.C.® Therapy Unit.

29. Verify the battery full icon appears.

30. Should the unit fail any of the above criteria, contact KCI (see page 27).

31. With the Charge Battery and Six Hour Verification Test complete, continue on to Verify Time and Date.
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, proceed to Alarm Tests, otherwise go to Step 2.

2. Press Utilities.

3. Press Time / Date.

4. Set the correct date and time.

5. Press Exit button two times to return to the Clinician Home Screen.

Alarm Tests

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

Ensure that the ActiV.A.C.® Therapy Unit is NOT plugged in to the ActiV.A.C.® Power Supply during the alarm test procedures. Ensure the tests are run without interruption as an additional battery capacity check.

Leak Alarm

1. Ensure the test canister is still securely attached to the ActiV.A.C.® Therapy Unit. Remove the tubing cap from the canister tubing and ensure the tubing clamp is completely open.

2. From the Clinician Home screen, press On / Off.

3. From the Therapy Start screen, press Exit button to return to the Clinician Home screen.

4. The Leak Alarm should activate in approximately two minutes or less.

5. Press Reset to return to the Clinician Home screen.

6. Continue on to Blockage Alert if the unit has correctly displayed this Leak Alarm, otherwise contact KCI (see page 27).
Blockage Alert
1. From the Clinician Home screen, press On / Off to stop therapy.
2. Fully close the tubing clamp to the maximum possible.
3. From the Clinician Home screen, press On / Off.
4. From the Therapy Start screen, Press Exit button to return to the Clinician Home screen.
5. The Blockage Alert should activate in approximately two minutes or less.
6. Press Exit button to return to the Clinician Home screen.
7. Release the tubing clamp.
8. Replace the tubing cap on the canister tubing.
9. Continue on to Canister Not Engaged if the unit has correctly displayed this Blockage Alert; otherwise contact KCI (see page 27).

Canister Not Engaged and Check Battery Level
1. From the Clinician Home Screen press On / Off to stop therapy.
2. Release the canister from the unit by pressing the canister latch release.
3. From the Clinician Home screen, press On / Off.
4. From the Therapy Start screen, Press Exit button to return to the Clinician Home screen.
5. While this test is running, check the status of the battery icon on the Clinician Home Screen.
6. If the battery icon is yellow as illustrated, battery capacity is not sufficient for normal operation. Cancel this test and go to the Charge Battery procedure and charge the battery. After charging the battery, repeat the procedures and tests from that point.
7. If the battery icon remains green, continue with this test.
8. The Canister Not Engaged alarm should sound in approximately thirty seconds or less.
9. Ensure that the alarm sounds with three beeps.
10. Press Reset to return to the Clinician Home Screen.
11. Continue on to Canister Full Therapy Interrupted alarm if the unit has correctly displayed this Canister Not Engaged alarm; otherwise contact KCI (see page 27).
Canister Full Therapy Interrupted

1. Remove the canister from the unit and replace it with a test canister that has the sensor port covered with a piece of impermeable tape cut and placed as shown.

2. Ensure the canister latches into place.

3. From the Clinician Home screen, press On / Off.

4. From the Therapy Start screen, Press Exit button to return to the Clinician Home screen.

5. The Canister Full Therapy Interrupted alarm should sound in approximately ninety seconds or less.

6. Ensure that the alarm sounds with three beeps.

7. Press Reset to return to the Clinician Home Screen.

8. Remove this test canister from the unit.

9. If the unit has displayed Canister Full Therapy Interrupted alarm continue to Final Settings. If the Canister Full Therapy Interrupted alarm did not display or sound contact KCI (see page 27).
Final Settings
1. With the ActiV.A.C.® Therapy Unit still powered on the Clinician Home Screen press ? button.

2. On the screen press the About button.

3. On the screen Press and hold the wrench icon until the Service Access screen appears.

4. Enter the code 772; press OK button.

5. On the Service screen, press and hold Patient Defaults (Press/Hold) until Events Cleared (P) appears on the screen.

6. Press Exit button.

7. Press Cancel.

8. Press Exit button to return to the Clinician Home Screen.

9. Power the unit off by holding down the Power On / Off button for a minimum of two seconds.

10. Continue on to Recharge Battery.

Recharge Battery
The purpose of this procedure is to ensure the ActiV.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. With the ActiV.A.C.® Therapy Unit still powered off, 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 ActiV.A.C.® Therapy Unit.

3. Plug the mains power cord into the external 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 ActiV.A.C.® Therapy Unit when patient placement occurs:

- ActiV.A.C.® Therapy Unit Quick Reference Guide, language as appropriate, see Spare Parts (page 24).
- V.A.C.® Therapy System Safety Information, KCI P/N 340404.

Contact KCI (see page 27) for replacement documentation.

The ActiV.A.C.® Therapy Unit should be transported to and from patient placements according to local protocols that ensure the cleanliness of the fabric carrying case, the unit itself and the power supply.

On-Premises Use

Should the ActiV.A.C.® Therapy Unit be used within a care facility without the patient leaving the premises, KCI recommends the following:

Supplies needed:

- ActiV.A.C.® Fabric Carrying Case
- ActiV.A.C.® Therapy Unit Quick Reference Guide - language as appropriate; see Spare Parts (page 24).
- V.A.C.® Therapy System Safety Information
- ActiV.A.C.® Power Supply with country appropriate mains power cord; see Spare Parts (page 24).

Preparation For Use

1. Carefully wrap the power cords into a bundle and place the power supply into a clear plastic bag.
2. Inspect the side of the ActiV.A.C.® Therapy Unit to verify all data port covers are in place, as shown on page 5.
3. Position the ActiV.A.C.® Therapy Unit in the fabric carrying case so the touch screen and battery charging / power connection port line up properly with the cut-outs in the fabric carrying case.
4. Insert the ActiV.A.C.® Therapy Unit Quick Reference Guide and V.A.C.® Therapy System Safety Information sheet into the pocket on the fabric carrying case flap. These documents provide additional protection to the touch screen when the flap is closed.
5. Close the fabric carrying case flap and secure the hook and loop fastener.
6. Fold the shoulder strap in half and wrap it around the fabric carrying case.
7. Place the ActiV.A.C.® Therapy Unit into the same plastic bag as the power cords and power supply. Close the bag to ensure unit cleanliness.
8. Follow institutional protocols for transporting the unit to and placing with a patient.
Off-Premises Use

Should the ActiV.A.C.* Therapy Unit be placed with a patient for use outside a care facility premises, KCI recommends the following:

Supplies needed:
- ActiV.A.C.* Plastic Shipping Case
- ActiV.A.C.* Fabric Carrying Case
- ActiV.A.C.* User Manual - language as appropriate; see parts list
- ActiV.A.C.* Therapy Unit Quick Reference Guide - language as appropriate; see parts list
- V.A.C.* Therapy System Safety Information sheet
- ActiV.A.C.* Power Supply with country appropriate mains power cord; see Spare Parts (page 24).

Preparation For Use
1. Position the ActiV.A.C.* Therapy Unit in the fabric carrying case so the touch screen and battery charging / power connection port line up properly with the cut-outs in the fabric carrying case.
2. Insert the ActiV.A.C.* Therapy Unit Quick Reference Guide and V.A.C.* Therapy System Safety Information sheet into the pocket on the fabric carrying case flap. These documents provide additional protection to the touch screen when the flap is closed.
3. Close the fabric carrying case flap and secure the hook and loop fastener.
4. Fold the shoulder strap in half and wrap it around the fabric carrying case.
5. Place the unit into the plastic shipping case.
6. Carefully wrap the power supply cord into a bundle, ensuring there cord is not kinked near the battery charging / power connector, and place the power supply into the space provided in the plastic carrying case.
7. Carefully wrap the mains power supply cord into a bundle and place into the space provided in the plastic carrying case.
8. Place the ActiV.A.C.* User Manual on top of these components and securely close the plastic carrying case.
9. Follow institutional protocols for transporting the unit to and placing with a patient.
Specifications

Dimensions and Therapy Options

Dimensions: ............................................................................................................................................... 7.6” W x 6” H x 2.5” D (19.3 x 15.2 x 6.4 cm)
Weight (with empty canister attached): ............................................................................................... ~2.4 lbs (~1.08 kg)
Canister Volume: ....................................................................................................................................... ~300 mL
Pressure Options: ........................................................................................................................................ 25 to 200 mmHg (3.3 to 26.6 kPa)
Therapy Delivery Modes: .......................................................................................................................... Continuous or Intermittent

Electrical Data (Power Supply)

Voltage Input ............................................................................................................................................... 100 - 240 VAC
Frequency .................................................................................................................................................. 50 - 60 Hz
Amperage ................................................................................................................................................... 0.8A
External Power Supply Output: .................................................................................................................. 12V, 3.3 A
Patient & Enclosure Leakage Current: .................................................................................................... <100 Microamps

Battery Information

Type: ........................................................................................................................................................... Lithium-ion

Properly dispose of in accordance with local, state and federal regulations for Lithium-ion batteries

Battery Run Life: ................................................................................................................................. Approximately 14 hours, depending on settings
Battery Charge Time: ............................................................................................................................ Approximately 6 hours from a fully discharged state

Environmental Conditions

Storage / Transport Conditions
Temperature Range: .................................................................................................................................. -13°F (-25°C) to 158°F (70°C)
Relative Humidity Range: .......................................................................................................................... 0-93% non-condensing

Operating Conditions
Temperature Range: ................................................................................................................................... 41°F (5°C) to 104°F (40°C)
Relative Humidity Range: .......................................................................................................................... 15 - 93% non-condensing

Atmospheric Pressure: ............................................................................................................................... 1060 hpa to 700 hpa

Expected Service Life: ............................................................................................................................... 3 years

IEC Classification

Medical Equipment
Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
Type BF, Applied Part
Class II
IP22 - Protection against solid objects greater than 12.5 mm and against liquid water falling for short periods of time.

The dressing components of the V.A.C.® Therapy System are considered Applied Parts under IEC 60601-1 Third Edition.
Spare Parts

This spare parts list is current as of August 2012. Contact KCI (see page 27) to verify current part numbers.

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20107-3</td>
<td>SCR, 4-40 X3/8 RHP SS</td>
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<tr>
<td>340033</td>
<td>Assy, ActiV.A.C.* Pump Tubing II</td>
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<tr>
<td>340034</td>
<td>Assy, ActiV.A.C.* Wound Tubing II</td>
</tr>
<tr>
<td>340036</td>
<td>Grommet, ActiV.A.C.* Offset</td>
</tr>
<tr>
<td>340037</td>
<td>Filter, ActiV.A.C.* Exhaust</td>
</tr>
<tr>
<td>340039</td>
<td>Assy, ActiV.A.C.* Wound Tubing</td>
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<tr>
<td>340040</td>
<td>seal, ActiV.A.C.* Main Interface</td>
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<td>340044</td>
<td>Assy, ActiV.A.C.* Exhaust Tubing</td>
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<tr>
<td>340045</td>
<td>Assy, ActiV.A.C.* Pump Tubing</td>
</tr>
<tr>
<td>340058</td>
<td>Cover, ActiV.A.C.* Battery Can</td>
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<tr>
<td>340061</td>
<td>Case, ActiV.A.C. * Molded Shipping</td>
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<tr>
<td>340091</td>
<td>Guide, ActiV.A.C.* Quick Reference</td>
</tr>
<tr>
<td>340091-02</td>
<td>Guide, ActiV.A.C.* Quick Reference (German)</td>
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<tr>
<td>340091-06</td>
<td>Guide, ActiV.A.C.* Quick Reference (French)</td>
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<tr>
<td>340092</td>
<td>Insulation, ActiV.A.C.* Backplate</td>
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<tr>
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<td>ActiV.A.C.* Carrying Case</td>
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<td>340168</td>
<td>Label, ActiV.A.C.* Battery History</td>
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<tr>
<td>340171</td>
<td>Label, ActiV.A.C.* Therapy Unit Logo</td>
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<td>340173</td>
<td>ActiV.A.C.* Battery History Label Ireland</td>
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<td>340404</td>
<td>Instruction, ActiV.A.C.* / InfoVAC Safety - Ireland</td>
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<tr>
<td>360068</td>
<td>Label, ActiV.A.C.* Power Cord and AC Adapter - (2 required)</td>
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<tr>
<td>413628</td>
<td>Cord, ActiV.A.C.* US Power</td>
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<tr>
<td>413374</td>
<td>Cover, ActiV.A.C.* Com. Port (Mod)</td>
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<td>413375</td>
<td>Isolator, ActiV.A.C.* USB Port (Mod)</td>
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<tr>
<td>413377</td>
<td>Cap, ActiV.A.C.* USB Port</td>
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<td>413486</td>
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<td>413626</td>
<td>Cord, V.A.C.* Power, EU-240V</td>
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<td>413708</td>
<td>Cord, ActiV.A.C.* International Desktop</td>
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<td>413951</td>
<td>Label, Modified ActiV.A.C.* Product Information</td>
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<td>413992</td>
<td>Cord, V.A.C.* Power, CH</td>
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<td>414003</td>
<td>Assy, Li Battery (2.6)</td>
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<tr>
<td>414006</td>
<td>Manual, ActiV.A.C.* User, 606013rd Edition</td>
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<td>Part Number</td>
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<tr>
<td>414006-DE</td>
<td>ActiV.A.C.* User Manual (German)</td>
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<td>414006-FR</td>
<td>ActiV.A.C.* User Manual (French)</td>
</tr>
<tr>
<td>414008</td>
<td>Label, ActiV.A.C.* Therapy Unit, 60601 3rd Edition</td>
</tr>
<tr>
<td>414107</td>
<td>Label, ActiV.A.C.* Storage and Distribution</td>
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<tr>
<td>414165</td>
<td>Cord, V.A.C.* Power, China</td>
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<tr>
<td>4000237</td>
<td>SCR, 4-40 X3/8 FHP 82 degree SS</td>
</tr>
<tr>
<td>4000240</td>
<td>SCR, 6/32 X 5/8 PHP SS</td>
</tr>
<tr>
<td>4000399</td>
<td>SCR, 4-40 X1/4 Slot Polycarbonate</td>
</tr>
<tr>
<td>M8275058/5</td>
<td>ActiV.A.C.* 300 mL Canister (box of 5 canisters)</td>
</tr>
</tbody>
</table>
Symbols Used

- **Warning or Caution of possible hazard to system, patient or staff**: IP22 - Ingress Protection
- **Important Operational Information**: Class II
- **Refer to Instruction Manual**: Type BF, Applied Part
- **Keep Dry**: Authorized Representative in the European Community
- **Tripping Hazard**: Temperature Limitations
- **No Bathing or Showering**: CAUTION: Federal (US) law restricts this device to sale / rental by or on the order of a physician
- **Power On / Off**: Manufacturer
- **Consult Instructions For Use**: Date of Manufacturer
- **Humidity Limitations**: 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
KCI USA, Inc. 12930 IH10 West San Antonio, TX 78249
Outside the US visit www.kci-medical.com.
To be used in conjunction with the ActiV.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: ____________________________

Service process complete. Unit ready for use. Complete Required Service Record Form and file as a permanent record for the unit.