



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



Important Document
File in your maintenance records

418474 Rev A
February 2018



Table Of Contents

Introduction / About This Manual.....	3
Preparation For Use.....	3
Unpack The Unit.....	3
Initial Inspection.....	3
Unit Features.....	4
Serial Number Location.....	5
Cleaning and Disinfection.....	5
Infection Control.....	5
Supplies and Equipment Needed.....	5
General Cleaning Recommendations.....	5
Therapy Unit.....	6
Power Supply.....	7
Fabric Carrying Case.....	7
Service Procedures.....	8
Parts and Equipment Needed.....	8
Inspect Unit for Damage.....	8
Replace Exhaust Filter.....	9
Data Download.....	9
Battery Check.....	10
Battery Change.....	11
Pressure Checks.....	13
• Set-up.....	13
• 25 mmHg Test.....	14
• 125 mmHg Test.....	14
• 200 mmHg Test.....	15
• 125 mmHg Test.....	16
Charge Battery and 6 Hour Unit Verification Test.....	17
Verify Time and Date.....	20
Alarm Tests.....	20
• Leak Alarm.....	20
• Blockage Alert.....	21
• Canister Not Engaged and Check Battery Level.....	22
• Canister Full Therapy Interrupted.....	22
Final Settings.....	23
Recharge Battery.....	23
Preparation for Transport and Patient Use.....	24
On-Premises Use.....	24
• Supplies needed:.....	24
• Preparation For Use.....	24
Off-Premises Use.....	25
• Supplies needed:.....	25
• Preparation For Use.....	25
Specifications.....	26
Spare Parts.....	27
Symbols Used.....	28
Service Manual.....	28
Therapy Unit.....	28
Contact Information.....	28
ActiV.A.C.® Therapy System Required Service Record.....	Inside Back Cover



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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 28) 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.
- 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.
- 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 prevention and 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.

Notice

This product has been configured from the manufacturer to meet specific voltage requirements. Refer to the Product Information Label for specific voltage.

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 28).



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

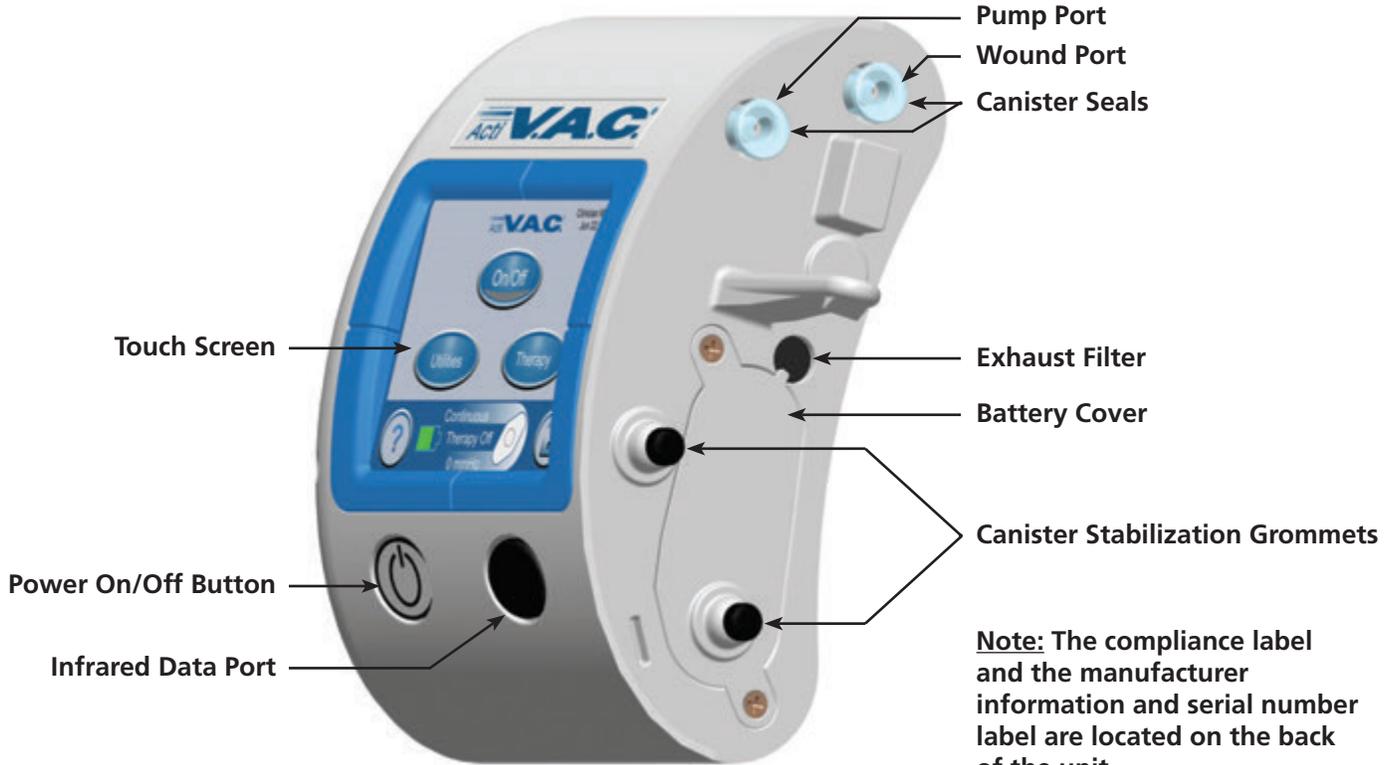
1. Inspect the cardboard shipping box to ensure there are no visible signs of damage.
2. Unpack all items from the shipping box.
3. Inspect all items for damage. If damage is noted, contact the shipping company for reporting/return procedures.
4. Inventory all items in shipping box against the packing slip. Contact KCI (see page 28) if there are any items missing.

Initial Inspection

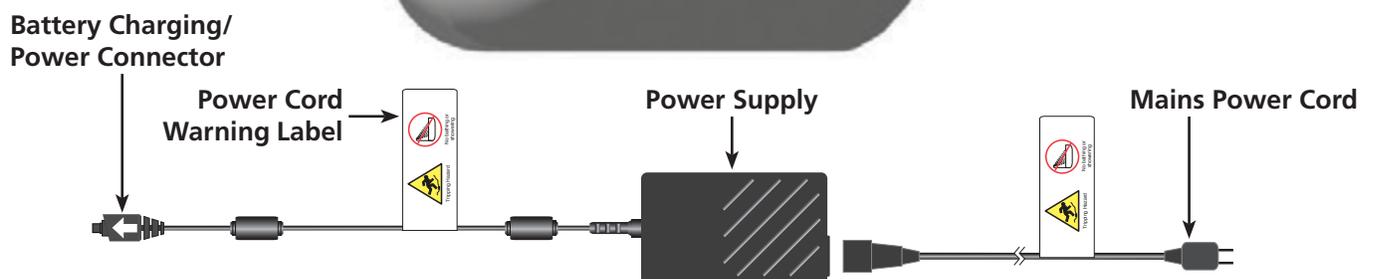
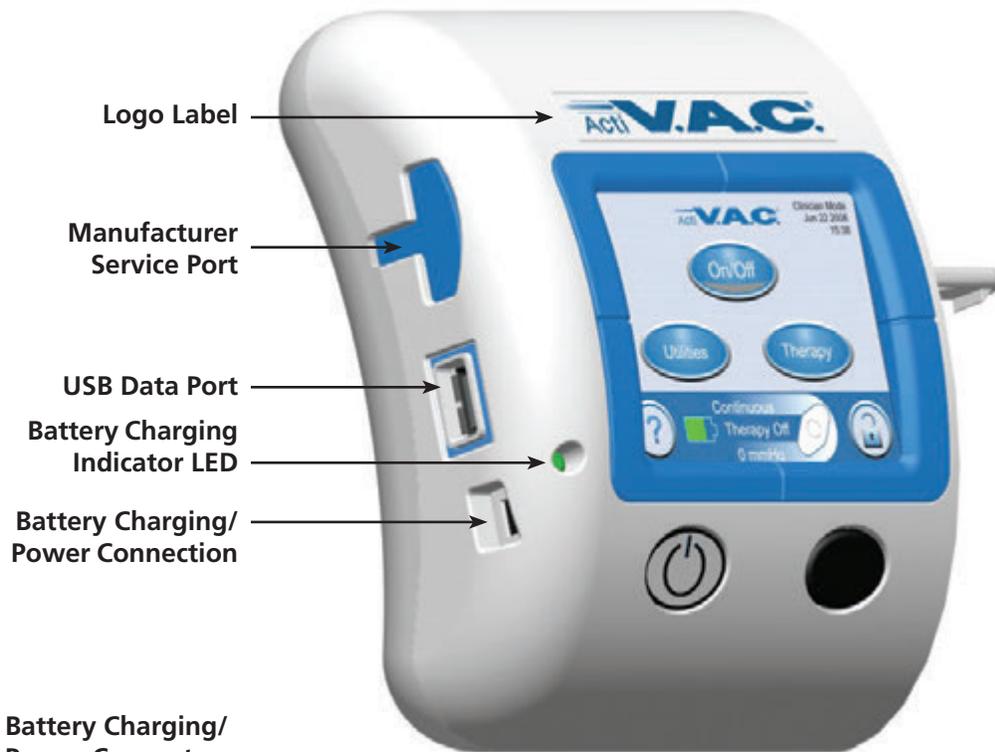
The purpose of this inspection is to ensure the unit has arrived without any internal damage and that the battery is fully charged prior to the initial patient placement.

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:
 - Locate and make photocopies of the form in the back of this manual.
 - Contact KCI (see page 28) to order a 25-pack of these forms. Ask for KCI part number 340141.
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.

Unit Features



Note: The compliance label and the manufacturer information and serial number label are located on the back of the unit.

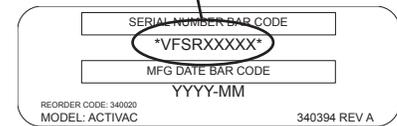


Serial Number Location



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.

Serial Number



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:

1. If it becomes soiled during patient use.
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 ActiV.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

- 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

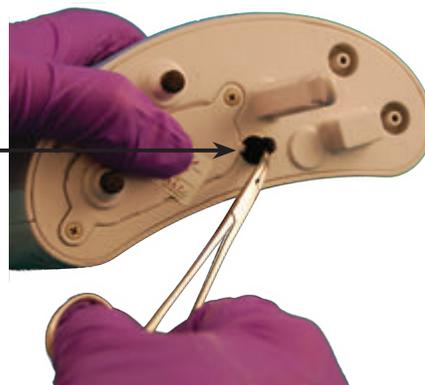
1. Remove the unit from the plastic and/or fabric carrying case, as applicable.
2. Ensure therapy unit is unplugged from power supply.
3. Remove canister seals from unit. Wipe/clean seals with antiseptic. Ensure the seal cavities and adjacent surfaces are clean of any foreign material. Replace seals when finished.

Canister Seals



4. 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.

Exhaust Filter



The Exhaust Filter is single use only.

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



Do not allow excess cleaning fluid into the areas surrounding the Touch Screen Gasket.

6. When wiping the front of the unit, do not allow cleaning fluid to seep into any gaps in the Touch Screen Gasket. Three such typical areas are pointed out in the illustrations below.



Cleaning fluids allowed to seep past the gasket may damage the Touch Screen to the point of requiring replacement.

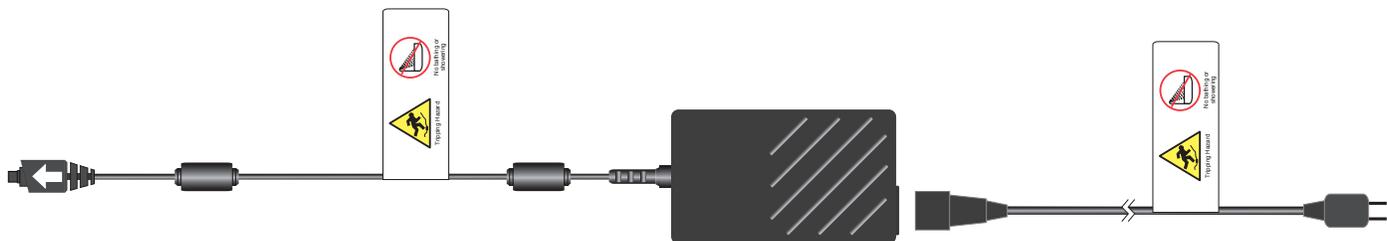


7. Wipe down the front and sides of the unit with antiseptic.
8. Once the unit is thoroughly cleaned, allow to air dry.
9. Place the clean unit in a clear plastic bag and move to the service area.



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 'brick', 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**:

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.

Parts and Equipment Needed

- ActiV.A.C.® Canister KCI P/N M8275058, two (2) each
 - These are normal ActiV.A.C.® canisters that can be reused for up to 6 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 (1) 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 340141, one (1) each
- Canister Seal, KCI P/N 340040, two (2) each (if required)
- Exhaust Filter, KCI P/N 340037, one (1) each
- ActiV.A.C.® Fabric Carrying Case KCI P/N 340122, one (1) each
- ActiV.A.C.® Pressure Accuracy Accessory, KCI P/N 340145, one (1) each
- Calibrated Digital Manometer, customer supplied, one (1) each. Manometer accuracy to be within 2.5 mmHg.

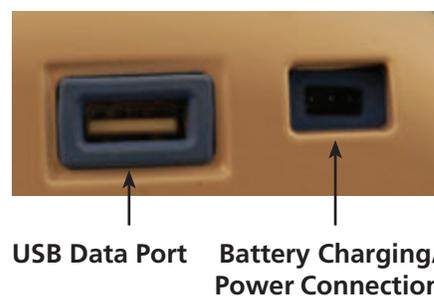
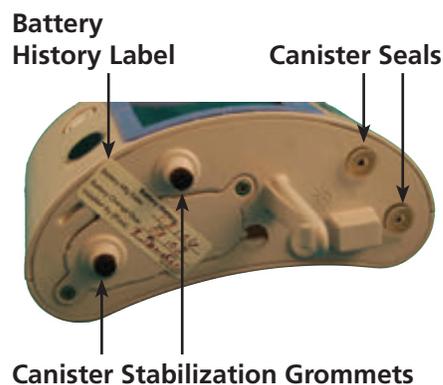
Inspect Unit for Damage

The purpose of this procedure is to inspect the ActiV.A.C.® 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 attachment area for:
 - Cracks of any size
 - Damage to the canister seals
 - Missing or damaged canister stabilization grommets
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 pages 8 and 9.
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.® 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 28).
9. With the unit inspection complete, continue on to 'Replace Exhaust Filter'.

ActiV.A.C.® Logo Label



ActiV.A.C.® Compliance Label

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.® 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 28).

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

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





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'.

9. Wait while the unit downloads the data to the Flash Drive.

10. When the download is complete, Press 'OK'.

- 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 28).
- If System Error 1 occurs, contact KCI (see page 28).

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

12. Remove the USB Flash Drive from the ActiV.A.C.® unit.

13. Connect the USB Flash Drive to an external computer.



The ActiV.A.C.® 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.® unit, save the new dated CSV file to the same secure computer into the existing folder named with the ActiV.A.C.® 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.

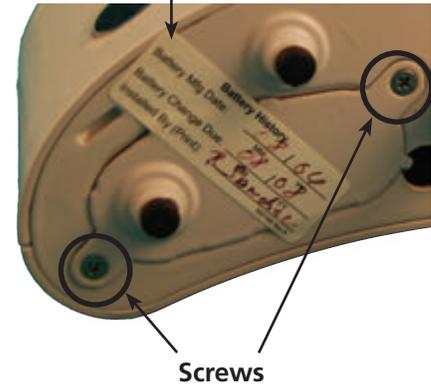
Battery Change

The purpose of this procedure is to change the battery.

! Ensure that the ActiV.A.C.® 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.

Battery History Label



4. Remove the battery cover.



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

Battery Connector





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 (Li-ion) batteries.

i 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.

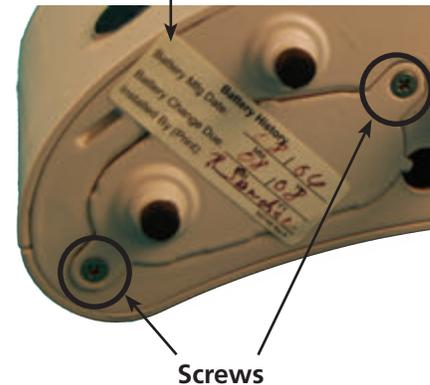
8. Obtain a new battery from KCI (KCI P/N 340079).
9. Obtain a new Battery History Label (KCI P/N 340168).

i 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 28) for a replacement battery.

10. Calculate the next 'Battery Change Due' date as 18 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 on the front side of the battery and *NOT* behind and is otherwise not tangled or obstructing fitting the battery fully into the battery compartment.
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. Fit 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 (2) screws tightly.
18. Install the new Battery History Label across the battery cover.
19. With the Battery Change complete, continue on to 'Pressure Check'.



Battery History Label



Screws

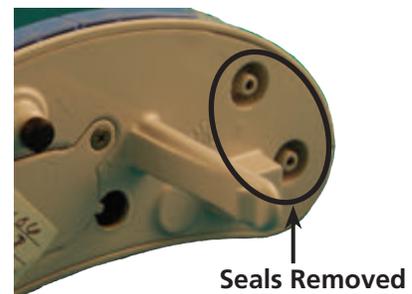
Pressure Checks

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

- i** The ActiV.A.C.® Therapy Unit **MUST** be connected to the ActiV.A.C.® power supply during this procedure.
- i** The needle valve simulates the permeability of a V.A.C.® Drape.
- i** The PVC test fixture and hygroscopic filter simulates the ActiV.A.C.® canister.

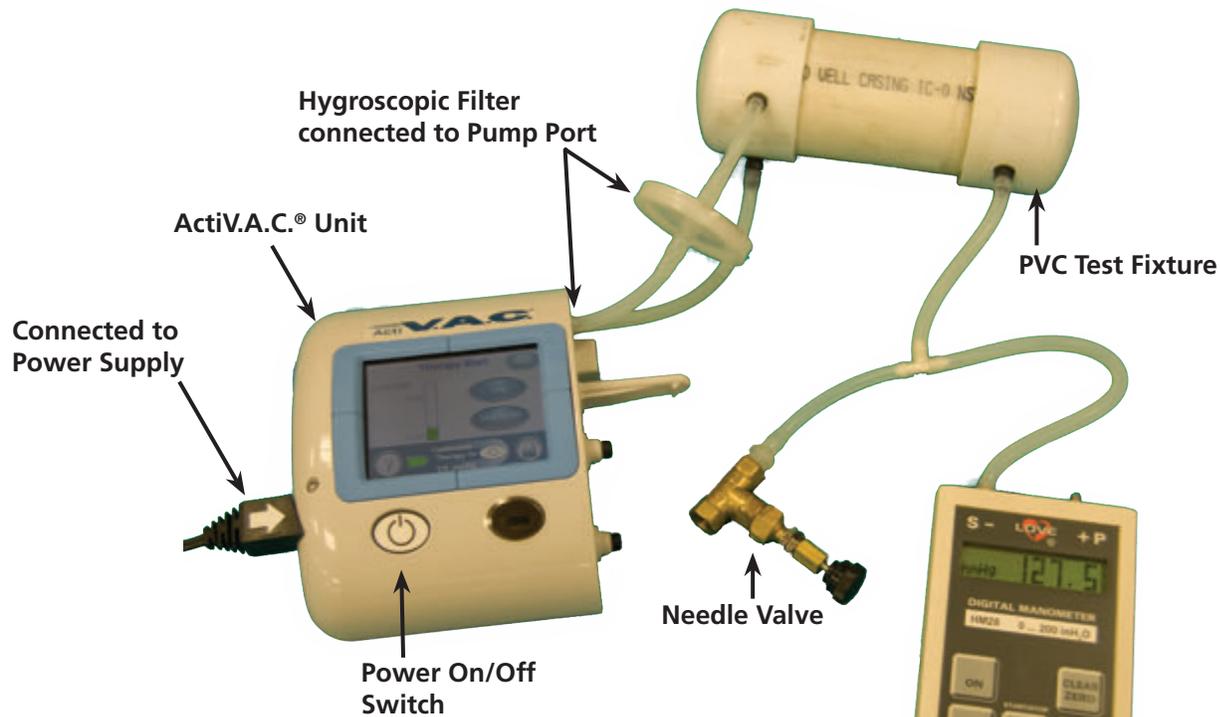
Set-up

1. Remove the Silicone Canister Interface Seals from the unit.

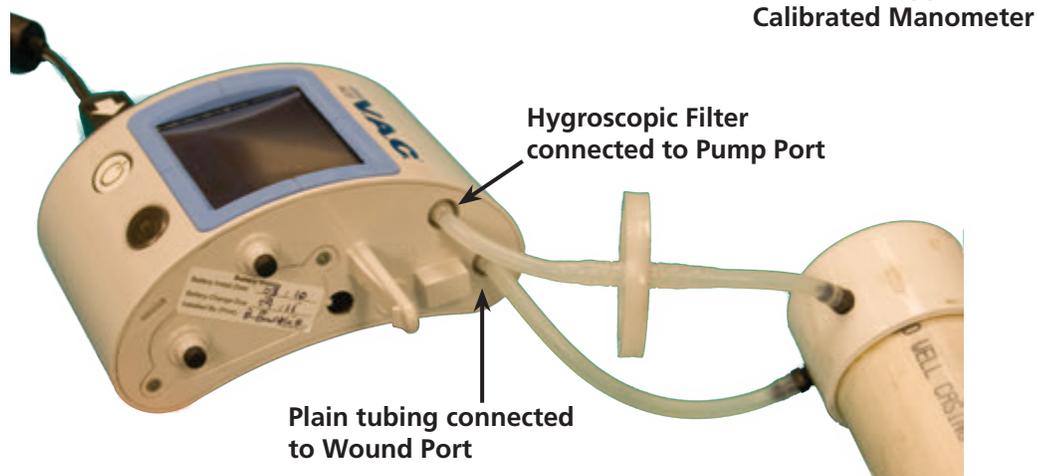


Seals Removed

2. Connect the PVC test fixture to the ActiV.A.C.® 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. Ensure the ActiV.A.C.® Power Supply is plugged into mains power and is also plugged into the ActiV.A.C.® unit. 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.® 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 '?', press 'Clinician Mode', press and hold 'OK' until the screen changes to Clinician Mode.

25 mmHg Test

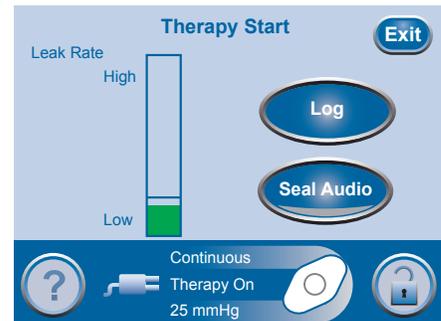
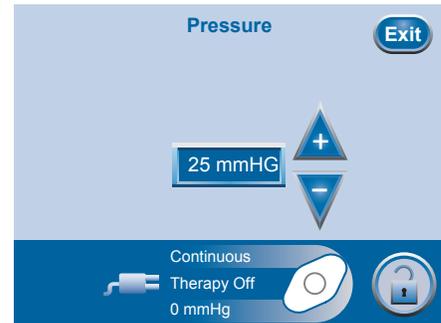
1. Press 'Therapy'.
2. Press 'Next'.
3. Press 'Settings'.
4. Press 'Pressure' and use the arrow keys to set the pressure to 25.
5. Press 'Exit' two (2) times.
6. On the Confirm screen, ensure that settings are Pressure: 25 mmHg; Mode: Continuous; Intensity: Low. If these settings are not correct, press 'Back' to change the incorrect setting.
7. Press 'OK'.
8. Start therapy by pressing 'On/Off', the 'Therapy Start' screen will appear.

9. 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.
11. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.
12. Press 'Exit'.
13. Press 'Therapy'.
14. Press 'Next'.
15. Press 'Settings'.

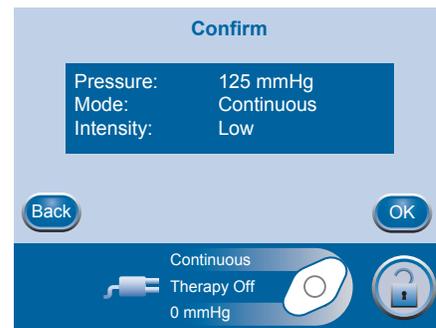
125 mmHg Test

1. Press 'Pressure' and use the arrow keys to set the pressure to 125.
2. Press 'Exit' two (2) times.

Clinician Mode
6 Aug 2009
15:06



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'.

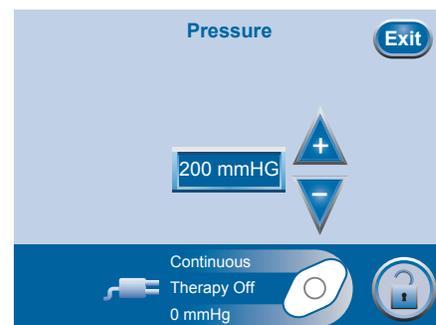


5. Press 'Therapy'.
6. Press 'Next'.
7. Press 'Seal Check™'.
8. Adjust the needle valve so that the Leak Rate bar graph indicator on the 'Therapy Start' screen indicates green and is below the dividing line on the bar graph, see illustration.
9. Observe the digital manometer and the displayed pressure on the ActiV.A.C.® Touch Screen.
10. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.
11. Press 'Exit' one (1) time.
12. Press 'Settings'.

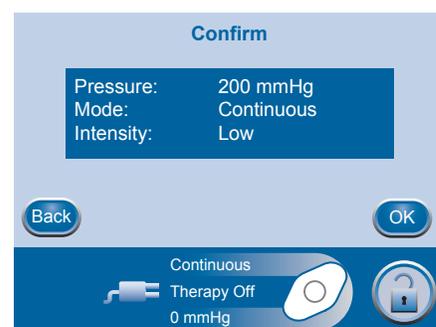


200 mmHg Test

1. Press 'Pressure' and use the arrow keys to set the pressure to 200.
2. Press 'Exit' two (2) 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'.

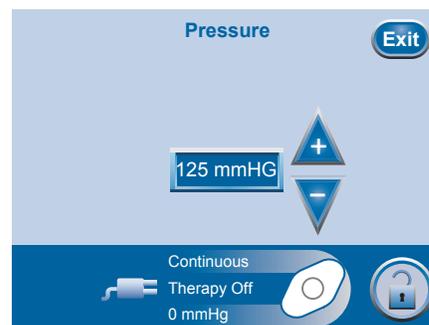


5. Press 'Therapy'.
6. Press 'Next'.
7. Press 'Seal Check™'.
8. Adjust the needle valve so that the Leak Rate bar graph indicator on the 'Therapy Start' screen indicates green and is below the dividing line on the bar graph, see illustration.
9. Observe the digital manometer and the displayed pressure on the ActiV.A.C.® Touch Screen.
10. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg.
11. Press 'Exit'.
12. Press 'Settings'.

125 mmHg Test

1. Press 'Pressure' and use the arrow keys to set the pressure to 125.
2. Press 'Exit two (2) times.

3. On the Confirm screen, ensure that settings are Pressure: 125 mmHg; Mode: Continuous; Intensity: Low.
4. Press 'OK'.
5. Observe the digital manometer and the displayed pressure on the ActiV.A.C.® Touch Screen.
6. The digital manometer should stabilize and indicate the pressure displayed touch screen, ± 10 mmHg, within 60 seconds.
7. If the ActiV.A.C.® Therapy Unit passes all four (4) pressure change procedures, remove the test fixture tubing and reinstall the Silicone Canister Interface Seals on the unit.
8. 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 28).
9. With the Pressure Check complete, continue on to 'Charge Battery and Six Hour Verification Test'.

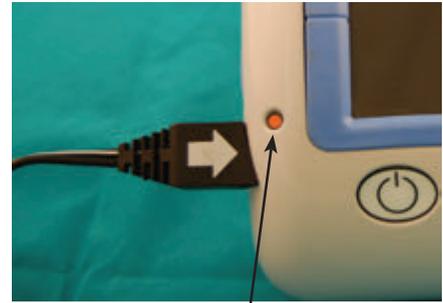


Charge Battery and Six Hour Unit Verification Test

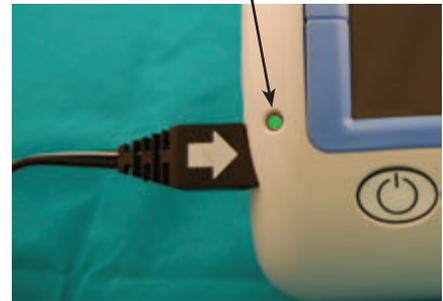
The purpose of this procedure is to ensure the ActiV.A.C.® unit is fully functional and the battery is fully charged. This six hour test is a minimum time. The process can be extended overnight or over a weekend if necessary.

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.® unit.
3. Plug the mains power cord into the external power supply 'brick'.
4. Plug the mains power cord into a grounded AC mains wall socket.
5. Verify the Battery Charging Indicator LED is lit.

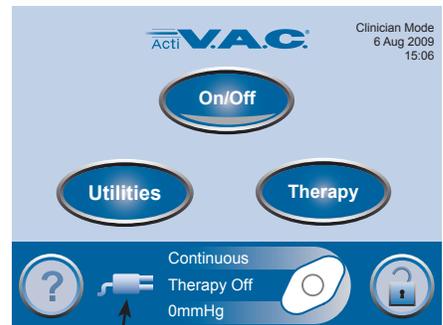
 An amber light means the battery is charging. A green light means the battery is fully charged.



Battery charging in-process
Battery charging complete

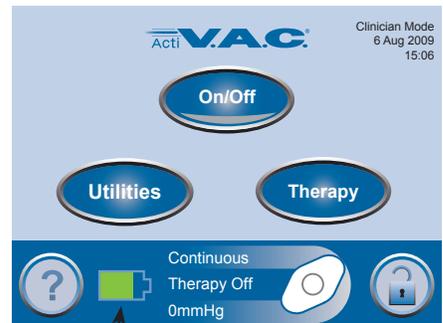


6. Ensure the unit is powered on. If necessary, hold down the Power On/Off button for a minimum of two seconds to power the unit on.
7. Once the unit has completed its power on self test, verify the 'plug' icon is present on the lower left of the touch screen.



'Plug' Icon

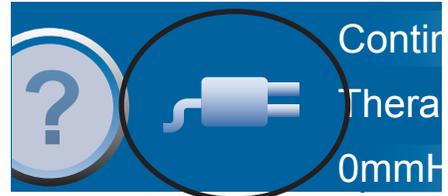
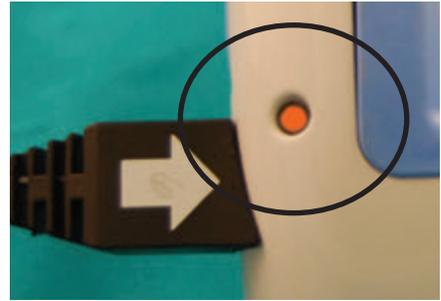
8. Unplug the power supply cord from the ActiV.A.C.® unit. Verify the 'battery' icon is present on the lower left of the touch screen.



'Battery' Icon



9. Plug the power supply cord into the ActiV.A.C.® unit. Verify the 'plug' icon reappears and the Battery Charging Indicator LED is lit.
10. Grasp the power cord approximately 3" (75mm) from the end plugged into the ActiV.A.C.® 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.® unit fail any of the above steps, contact KCI (see page 28).



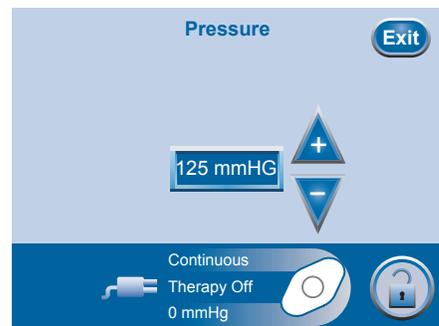
12. Attach a regular ActiV.A.C.® 300 mL canister that has been designated a 'test canister' to the ActiV.A.C.® unit.
13. Ensure that a tubing cap is attached to the canister tubing.



14. With the ActiV.A.C.® unit still in Clinician Mode,



15. Press 'Therapy'.
16. Press 'Next'.
17. Press 'Settings'.
18. Press 'Pressure' and if necessary use the arrow keys to set the pressure to 125.
19. Press 'Exit' two times.



20. 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.
21. Press 'OK'.



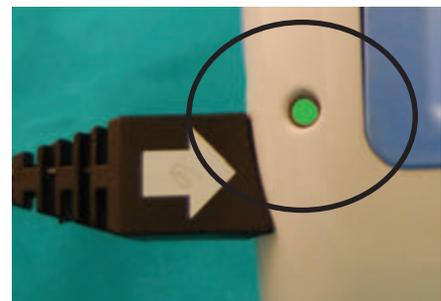
22. Start therapy by pressing 'On/Off', the 'Therapy Start' screen will appear.
23. Ensure the Leak Rate indicator is green.
24. Press 'Exit' to return to the Clinician Mode Home screen.



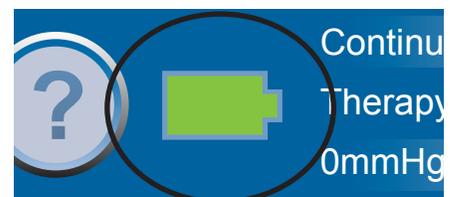
25. KCI recommends starting a timer to ensure the six hour time period is achieved.
26. Press 'On/Off' to stop therapy.
27. At the end of the six hour verification period, carefully check the unit for:
 - Control buttons not responding
 - Excessively hot unit
 - No alarms are displayed



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



29. Unplug the power supply cord from the ActiV.A.C.® unit.
30. Verify the 'battery full' icon appears.
31. Should the unit fail any of the above criteria, contact KCI (see page 28).
32. With the 'Charge Battery and Six Hour Verification Test' complete, continue on to 'Verify Time and Date'.

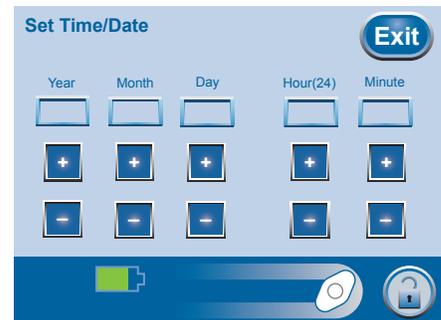
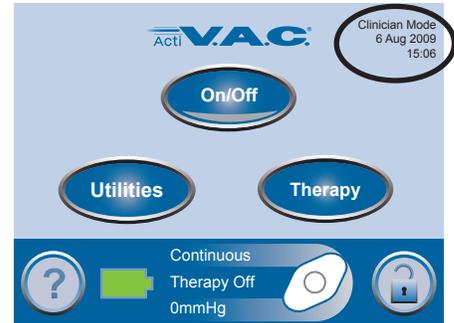




Verify Time and Date

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' 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.



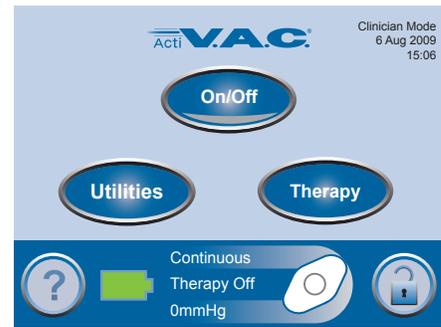
Ensure that the ActiV.A.C.® Therapy Unit is **NOT** plugged in to the ActiV.A.C.® power supply during the alarm test procedures. Ensure the tests are run without interruption as an additional battery capacity check.

Leak Alarm

1. Ensure the 'test canister' is still securely attached to the ActiV.A.C.® 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' 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 28).



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' to return to the Clinician Home screen.
5. The Blockage Alert should activate in approximately two minutes or less.
6. Press 'Exit' 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 28).

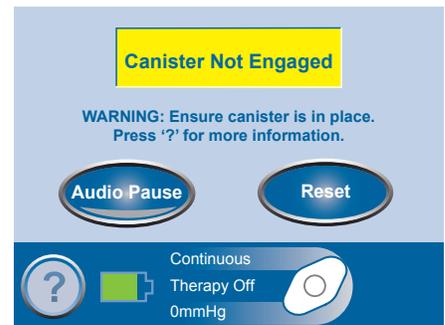


Canister Not Engaged and Check Battery Level

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' 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 'Change Battery' procedure and change the battery. After changing 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 (30) seconds or less.
9. Ensure that the alarm sounds with three (3) 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 28).

Canister Full Therapy Interrupted

1. Remove the canister from the unit and replace it with a canister that has the canister sensing 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' to return to the Clinician Home screen.
5. The 'Canister Full Therapy Interrupted' alarm should sound in approximately ninety (90) seconds or less.
6. Ensure that the alarm sounds with three (3) beeps.
7. Press 'Reset' to return to the Clinician Home Screen.
8. Remove this test canister from the unit.
9. Continue on to 'Final Settings' if the unit has correctly displayed this 'Canister Full Therapy Interrupted' alarm, otherwise contact KCI (see page 28).



Final Settings

1. With the ActiV.A.C.[®] Therapy Unit still powered on with the Clinician Home Screen showing, press '?', press 'About', press and hold the 'Wrench Icon'  until the 'Service Access' screen appears.
2. Enter the code 772, press 'OK'.
3. On the 'Service' screen, Press and hold 'Patient Defaults (Press/Hold)' until 'Events Cleared (P)' appears on the screen.
4. Press 'Exit'.
5. Press 'Cancel'.
6. Press 'Exit' to return to the Clinician Home Screen.
7. Power the unit off by holding down the Power On/Off button for a minimum of two seconds.
8. 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.[®] unit.
3. Plug the mains power cord into the external power supply 'brick'.
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, KCI P/N 340091 (English), 340091-02 (German), 340091-06 (French).
- V.A.C.® Therapy System Safety Information sheet, KCI P/N 340404.
- Contact KCI (see page 28) for replacement V.A.C.® Therapy System Safety Information sheets.



The ActiV.A.C.® Therapy Unit should be transported to and from patient placements according to local protocols that ensure the cleanliness of the soft 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 parts list.
- V.A.C.® Therapy System Safety Information sheet
- ActiV.A.C.® Power Supply with country appropriate mains power cord

Preparation For Use

1. Carefully wrap the power cords into a bundle and place the power supply into a clear plastic bag.
2. 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.



The ActiV.A.C.® Therapy Unit Quick Reference Guide and V.A.C.® Therapy System Safety Information sheet were designed to fit into the pocket on the fabric carrying case flap to provide additional accidental impact protection to the Touch Screen when the flap is properly closed.

3. 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.
4. Close the fabric carrying case flap and secure the hook and loop fastener.
5. Fold the shoulder strap in half and wrap it around the fabric carrying case.
6. 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.
7. 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
- 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

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.



The ActiV.A.C.® Therapy Unit Quick Reference Guide and V.A.C.® Therapy System Safety Information sheet were designed to fit into the pocket on the fabric carrying case flap to provide additional accidental impact protection to the Touch Screen when the flap is properly closed.

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.
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

Classification

Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide.

Medical Equipment

- Type B, Applied Part
- Class II or internally powered Equipment
- IPX0

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 50/60Hz
 Amperage 0.72A @ 115VAC
 External Power Supply Output: 12V, 3.3 A
 Patient & Enclosure Leakage Current: <100 Microamps

Battery Information

Type: Lithium-ion (Li-ion)
 Properly dispose of in accordance with local, state and federal regulations for Lithium-ion (Li-ion) batteries
 Battery Run Life: Approximately 14 hours, depending on settings.
 Battery Charge Time: Approximately 6 hours from a fully discharged state.

Storage and Environmental conditions

Storage Temperature range.....-4°F (-20°C) to 140°F (60°C))
 Operational Temperature Range..... 41°F (5°C) to 104°F (40°C)
 Relative Humidity Range: 0-95% non-condensing
 Altitude Range: 0 to 14,000 feet (0 to 4267 m)
 Optimum Performance: 0 to 8,000 feet (0 to 2438 m)

Spare Parts

This spare parts list is current as of December 2009. Contact KCI (see page 28) to verify current part numbers.

Part Number	Description
340024	ActiV.A.C.® Battery Cover
340036	ActiV.A.C.® Canister Stabilization Grommet (2 required)
340037	ActiV.A.C.® Exhaust Filter
340038	ActiV.A.C.® Infrared Lens
340040	ActiV.A.C.® Canister Seal (2 required)
340054	ActiV.A.C.® Infrared Lens Seal
340122	ActiV.A.C.® Single Use Fabric Carrying Case
340061	ActiV.A.C.® Plastic Shipping Case
340076	ActiV.A.C.® User Manual (English)
340079	ActiV.A.C.® Battery
340091	ActiV.A.C.® Quick Reference Guide (English)
340165	ActiV.A.C.® Power Cord Warning Label (2 required)
340168	ActiV.A.C.® Battery History Label
340171	ActiV.A.C.® Logo Label
340225	ActiV.A.C.® North American Mains Power Cord
340226	ActiV.A.C.® Power Supply
340367	ActiV.A.C.® Compliance Label (International)
340394	ActiV.A.C.® Manufacturer Information Label
340404	ActiV.A.C.® Safety Information Sheet (International)
4000237	ActiV.A.C.® Battery Cover Screw (2 required)
340076-02	ActiV.A.C.® User Manual (German)
340076-06	ActiV.A.C.® User Manual (French)
340091-02	ActiV.A.C.® Quick Reference Guide (German)
340091-06	ActiV.A.C.® Quick Reference Guide (French)
M4268880	ActiV.A.C.® United Kingdom Mains Power Cord
M4268881	ActiV.A.C.® European Union Mains Power Cord
M4268883	ActiV.A.C.® Australia/New Zealand Mains Power Cord
M8275058/5	ActiV.A.C.® 300 mL Canister (box of 5 canisters)
340145	ActiV.A.C.® Pressure Accuracy Accessory



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



Class II, Internally Powered Equipment



Refer to User Instructions



Type B, Applied Part



Conforms with the Waste Electrical and Electronic Equipment Directive (2002/96/EC). At the end of useful life, dispose of all waste according to local requirements, or contact your local KCI subsidiary or agent for advice.

IPX0 Not protected against harmful effects of water.

Contact Information

For parts and other service related information contact your local KCI representative. The latest country specific contact information available at www.kci-medical.com

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ActiV.A.C.[®] Therapy System Required Service Record

- 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.

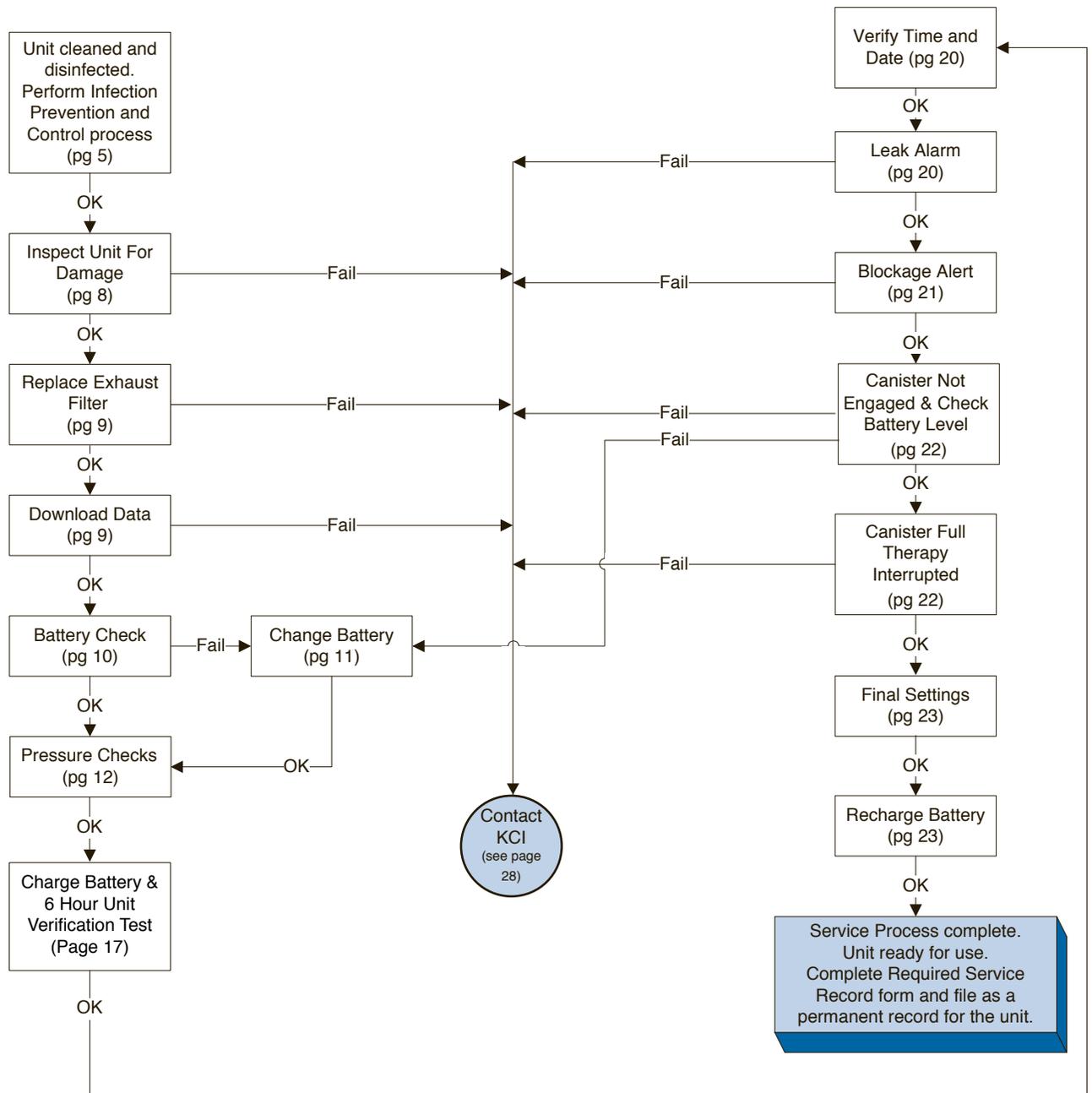
Facility: _____

Unit Serial Number: _____

Date Service Completed: _____

Inspector Name (Please Print): _____

Signature: _____





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