ACTIV.A.C.™

THERAPY SYSTEM

User Manual

For Patients and Clinicians

Acelity™

Rx Only

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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

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

ACTIV.A.C.™

THERAPY SYSTEM

For Patient Use

Acelity™

Patient Table of Contents

PATIENT

Important Safety Information Accompanies this Device 3
Warnings: Important Information for Users 4
Introduction 5
- ACTIV.A.C.™ Therapy Unit 6
- Patient Mode Home Screen 6
- Common Screen Control Buttons 7
- Static Electricity 7
- Charge the Battery 8
- Battery Level 9

Canister 10
- Canister Changes 10

Carrying Case 12
- Power Supply Retainer Instructions 14

Therapy Unit Disconnect 15
Operating Instructions 16
- Power Therapy Unit On or Off 16
- Therapy On or Off 16
- SEAL CHECK™ Leak Detector 17
- Find and Fix the Leak 18

Alerts and Alarms 19
- Battery Low Alert 20
- Battery Critical Alarm 21
- Canister Full Therapy Interrupted Alarm 22
- Canister Not Engaged Alarm 23
- Leak Alarm 24
- Leak Alarm Therapy Interrupted 25
- Blockage Alert 26
- Blockage Alarm Therapy Interrupted 27
- Low Pressure Alert 28
- Low Pressure Alarm Therapy Interrupted 29
- Therapy Inactive Alarm 30
- System Error Alarm 31
- Service Timer Expired Alert 31

Help Menu 32
- Change Languages 32
- Onscreen Operating Instructions 33
- Clinician Mode 33

Care and Cleaning 34

PATIENT

Disposal 34
Cleaning the Touch Screen 34
Cleaning the Therapy Unit 34
Frequently Asked Questions 35

Important Safety Information Accompanies this Device

This manual includes important warnings for your safety. Before using the ACTIV.A.C.™ Therapy System:

- Review this manual with your doctor or nurse.
- Review the quick reference guide. This guide is kept in the pocket on the therapy unit carrying case.
- Review the safety information sheet with your doctor or nurse. This sheet is also kept in the pocket on the therapy unit carrying case.

Do not make any changes to the settings on the therapy unit without instructions from your doctor. The dressing should only be applied or removed by or on the advice of your doctor. Call your doctor or nurse if you have any questions about the ACTIV.A.C.™ Therapy System.

In case of emergency, call your local emergency service (i.e. 911) immediately.

Warnings: Important Information for Users

The ACTIV.A.C.™ Therapy System is a medical device, not a toy. Keep away from children, pets and pests as they can damage the dressing and therapy unit and affect performance. Keep the therapy unit free of dust and lint as they can also damage the dressing and therapy unit and affect performance.

Cell phones or similar products could affect the therapy unit. Move the therapy unit away from these devices if interference is suspected.

Small Parts - Choking Hazard

Allergic Reaction - The V.A.C.® Dressing may cause an allergic reaction if you are sensitive to acrylic adhesives or to silver. The following symptoms may mean you are having an allergic reaction. Call your doctor right away if you:

- notice redness
- notice swelling
- develop a rash
- develop hives
- develop itching

If you feel short of breath, your allergic reaction may be more serious. Immediately call your local emergency service.

Do not modify the therapy unit or dressing. Do not connect the therapy unit or dressing to other devices that you might be using.

Do not operate the therapy unit if it has a damaged power cord, power supply or plug. If these items are worn or damaged, call KCI.

Do not drop or insert any object into any opening or tubing on the therapy unit.

Keep the therapy unit away from heated surfaces.

Do not spill fluids on any part of the therapy unit. If spills do occur, unplug the unit immediately if plugged in. Clean the fluid from the therapy unit. Ensure there is no moisture on the unit and power supply before plugging in. If the unit does not work correctly, call KCI.

Do not use the therapy unit in the bath or shower. Do not place the therapy unit where it can fall or be pulled into a tub, shower or sink.

Do not reach for a therapy unit that has fallen into water. Unplug the unit immediately if plugged in. Disconnect the unit from the dressing and call KCI.

Introduction

The ACTIV.A.C.™ Therapy System is a prescription medical device. Please read and follow all the instructions in this user manual so the product can perform properly while in use. This manual will show you:

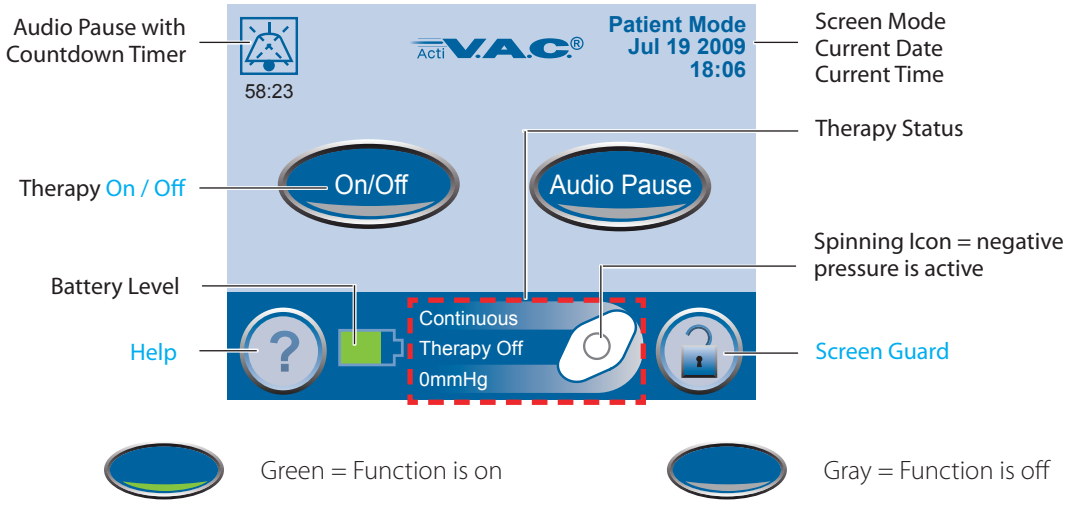
- How to charge the battery in the therapy unit.
- How to change a canister.
- How to use the therapy unit's carrying case.
- How start and stop therapy.
- How find and fix leaks using the SEAL CHECK™ Leak Detector feature.
- How to handle alerts and alarms.

ACTIV.A.C.™ Therapy Unit

The ports on the therapy unit may have a cover.

Keep all access covers closed during normal use. Open covers only for data transfer (doctor or nurse only).

Patient Mode Home Screen



Common Screen Control Buttons

Most screens have one or more common control buttons. These are:

Help - Access *Help* screens

Screen Guard - Turn on Screen Guard to help prevent accidential changes to the unit settings. Use this feature when cleaning the touch screen.

Exit - Leave the current screen.

Cancel - Stop the action in progress.

Next - Go to the next screen.

Back - Return to the previous screen.

OK - Confirm the selection.

Battery Charging Instructions

The ACTIV.A.C.™ Therapy Unit contains a rechargeable battery. This battery is charged using the power supply and cord that comes with the unit.

The battery is not user accessible or serviceable.

To avoid damage to the therapy unit, use only the power supply and cord that come with the unit.

Static Electricity

Static electricity may build up on the unit when it is out of its carrying case and plugged into a wall outlet. This happens most often when the humidity is very low.

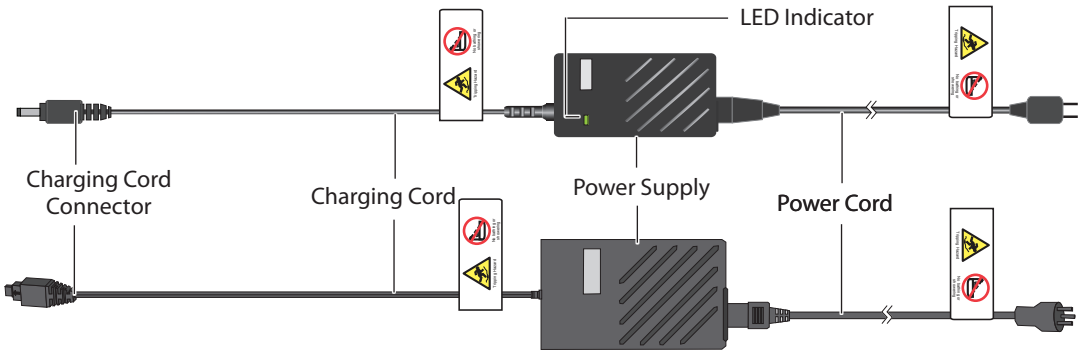
A static discharge may cause:

- The screen to darken
- The therapy unit to reset
- The therapy unit to turn off.

If this happens, turn the unit off then back on. If the unit will not come back on, call KCI.

WARNING: If therapy stops or the unit shuts off for any reason, call your doctor or nurse right away. Without active therapy, your dressing will need to be replaced within two hours.

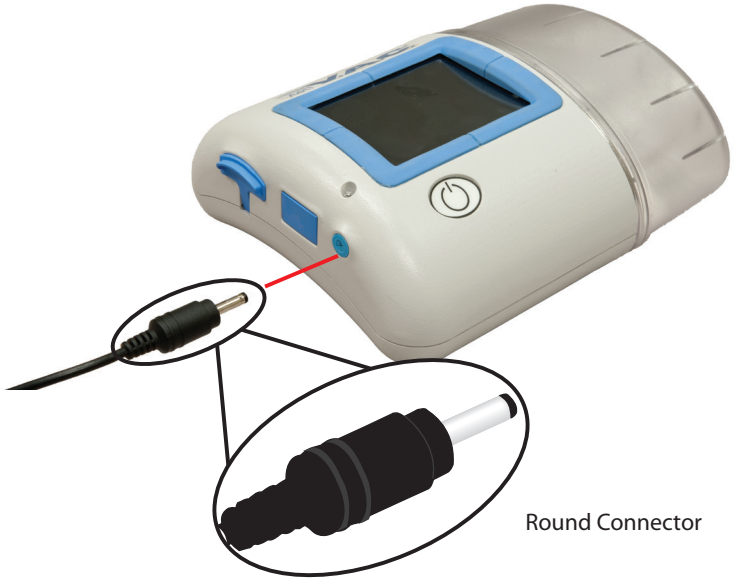
Charge the Battery

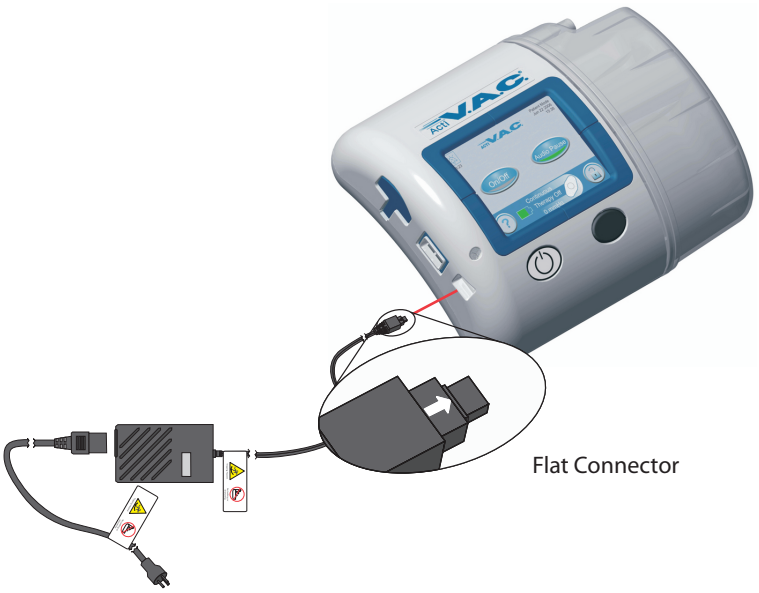


1. Plug the power cord into the power supply.
2. Plug the power cord into an AC wall outlet.

3. Plug the charging cord connector into therapy unit.

Your unit may have a round connector or a square flat connector.

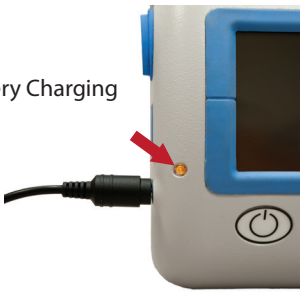




4. Keep the unit plugged in whenever possible.

The plug icon appears on the touch screen when the unit is plugged in.

The battery charging light will glow amber while unit is charging. The light will change to green when the unit is fully charged.



It should take about six hours to fully charge the battery.

The power cord may be a trip hazard. Ensure that all cords are out of areas where people may walk.

Unplug the power cord from the wall outlet to disconnect the unit from main power.

Battery Level

The battery level is shown on the bottom of the touch screen (see ***Patient Mode Home Screen*** section).

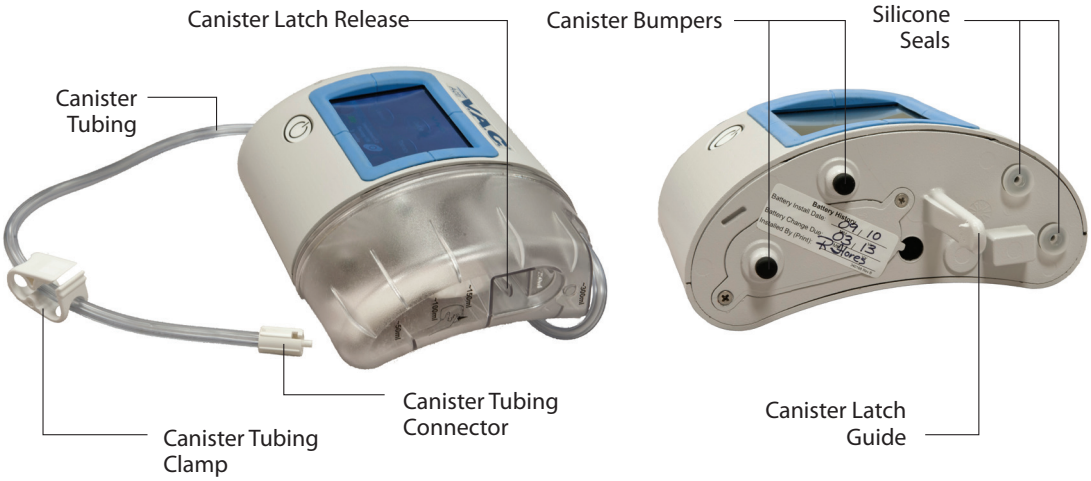
Fully Charged

In Use

Battery low. Charge battery soon.

Battery critical. **Charge battery immediately.**

Canister



The canister latch guide on the therapy unit may have sharp edges. Do not handle the therapy unit by the canister latch guide.

Always apply the canister straight on and straight off the therapy unit. Do not twist or turn canister when installing or removing it.

When the therapy unit is not in use, store it in the carrying case without a canister in place.

Contact KCI if the silicone seals, canister latch guide or the canister bumpers are damaged or missing from the therapy unit.

Canister Changes

The canister should be changed:

- When full (the alarm will sound and therapy will stop)
- At least once a week to control odor

WARNING: If therapy stops or the unit shuts off for any reason, call your doctor or nurse right away. Without active therapy, your dressing will need to be replaced within two hours.

1. Do not turn the therapy unit off.

2. Press On / Off to stop therapy.

During a Canister Full Alarm, therapy will already be off.

3. Slide both tubing clamps toward the tubing connector.

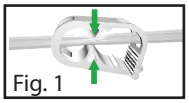


Fig. 1

4. Tightly close both tubing clamps to avoid spilling tubing contents (Fig. 1).

5. To disconnect the dressing tubing from the canister tubing:

   - Push the connectors together.
   - Twist the connectors to unlock (Fig. 2).
   - Pull the connectors apart (Fig. 3).

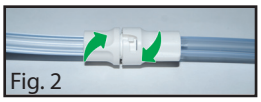


Fig. 2

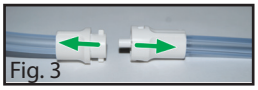


Fig. 3

Fig. 4

6. To remove the canister:

   - Press down on the canister latch release (Fig. 4).
   - Pull the canister directly away from the therapy unit (Fig. 5).

Fig. 5

Call your doctor or nurse about canister disposal. Do not discard the canister with household trash. This could violate local laws regarding hazardous waste.

7. To install a new canister:

   - Slide the canister over the canister latch guide.
   - Do not twist or turn the canister as it is being installed.
   - Press the canister firmly onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit
   - An audible click should be heard when the canister is properly installed.

8. Connect the new canister tubing to the dressing tubing:

   - Push the connectors together (Fig. 6).
   - Twist the connectors to lock (Fig. 7).

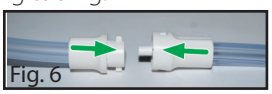


Fig. 6

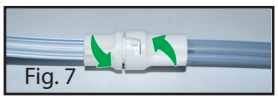


Fig. 7

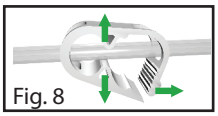


Fig. 8

9. Open both tubing clamps (Fig. 8).

10. Press On / Off on the touch screen to restart therapy.

11. Make sure the dressing collapses.

Carrying Case

Storage Pocket for the ***ACTIV.A.C.™ Quick Reference Guide*** and the ***V.A.C.® Therapy System Safety Information Sheet***

Access Flap with Hook and Loop Fastener

Tubing Storage Straps

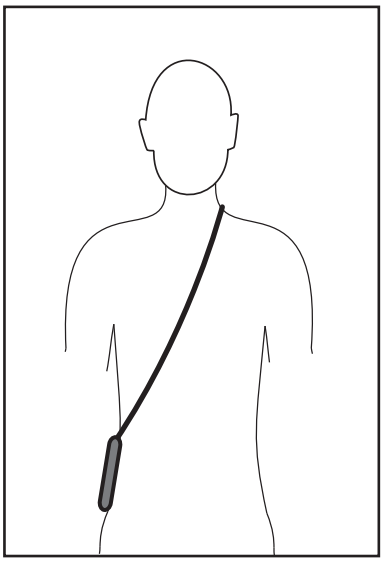
Insert the therapy unit into the carrying case so that the touch screen and power button are visible through the cut out windows.

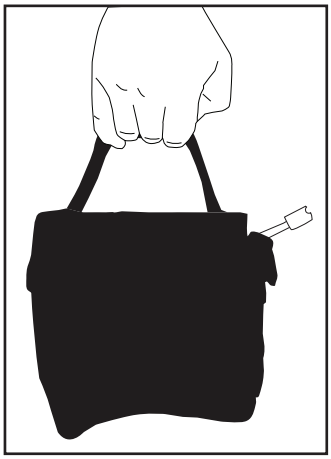
Keep the therapy unit in the upright position.

Keep the therapy unit in the carrying case when in use.

Keep the touch screen facing up if the therapy unit is laid on a level surface such as a table.

Use the adjustable strap to wear the carrying case across your chest.





Do not wrap the carrying case strap, power cord or dressing tubing around neck.

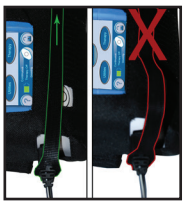
Power Supply Retainer Instructions

Some of the ACTIV.A.C.™ Therapy Units may include a retainer strap for the power cord. This strap helps keep the power cord in place. This strap is used only with power cords that have the square flat connector.

1. Wrap the end tabs of the retainer strap around the charging cord connector.

2. Press the hook-and-loop closure together to secure.

3. Plug the charging cord connector into the therapy unit.



4. Pull the retainer strap tight and press it securely onto the hook-and-loop fastener at the base. Be sure there is no slack in the retainer strap.

5. Fold the access flap over to close the carrying case.

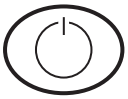
6. Firmly press on the access flap hook-and-loop fastener to secure the retainer strap to the carrying case.

Therapy Unit Disconnect

You can disconnect the therapy unit from the dressing tubing for short amounts of time.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

1. Press On / Off to stop therapy.



2. Press the Power button to turn the therapy unit off.
3. Unplug the unit if it is plugged in.
4. Slide both tubing clamps toward the tubing connector.
5. Tightly close both tubing clamps to avoid spilling tubing contents (Fig. 1).
6. To disconnect the dressing tubing from the canister tubing:
   - Push the connectors together.
   - Twist the connectors to unlock (Fig. 2).
   - Pull the connectors apart (Fig. 3).
7. Cover the tubing ends with gauze to collect any spillage from tubing.

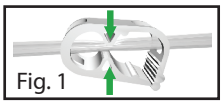


Fig. 1

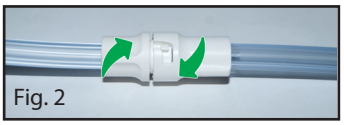


Fig. 2

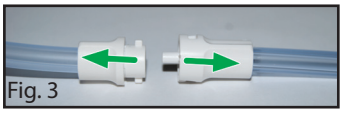


Fig. 3

Operating Instructions

Before starting therapy, ensure that the dressing is in place, the canister is connected, and all clamps are open.

Power Therapy Unit On or Off

The Power button is located below the touch screen (see ***Patient Mode Home Screen*** section).

1. Press and hold the Power button for about two seconds to turn the therapy unit on or off. The therapy unit will go through a self-check and then display a warning message screen.

2. Press OK to continue to the Patient Mode *Home* screen (see ***Patient Mode Home Screen*** section).

If unit alarms during start up refer to the *Alerts and Alarms* chapter of this manual for more information and troubleshooting tips.

Therapy On or Off

Press On / Off to start or stop V.A.C.® Therapy.

Green = function is on

Gray = function is off

Spinning icon = negative pressure is active

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

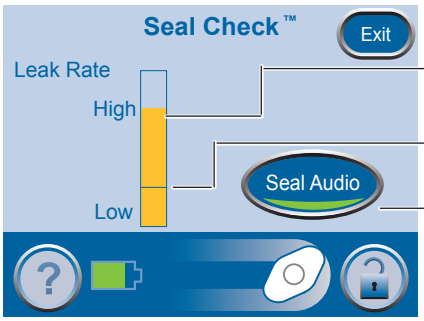
SEAL CHECK™ Leak Detector

If the therapy unit detects a significant leak, the Leak Alarm will activate. See Alerts And Alarms - ***Leak Alarm*** section.

Flashing Green Oval

Press the SEAL CHECK™ button on the *Leak Alarm* screen to use the SEAL CHECK™ Leak Detector.

The SEAL CHECK™ Leak Detector feature uses an audible tone and a bar graph to help find leaks. The frequency of the audible tone and the height of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph gets shorter as the leak is found.



Orange bar graph = a significant leak.

Green bar graph = the therapy unit is operating normally.

If the bar is below the line, the unit is operating normally.

If the bar is above the line, the unit is detecting a leak.

Press to turn the Seal Audio tone off.

Find and Fix the Leak

Most leaks occur:

- Where the drape meets the skin.
- Where the SENSAT.R.A.C.™ Pad is attached to the drape.
- At tubing connectors.
- When the canister is not securely connected to the therapy unit.

To fix the leak:

1. Check the tubing connectors between the dressing and the canister. Make sure they are properly locked.

2. Make sure the canister is properly installed onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit.

3. Use the SEAL CHECK™ Leak Detector to find the leak at the dressing.

    - Make sure therapy is on.
    - Using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad.
    - Watch the bar graph and listen to the audible tone. The bar will get shorter and the frequency of the audible tone will decrease when the leak is found.

4. When the leak is fixed, press Exit to return to the Patient Mode *Home* screen.

5. If the leak alarm persists or you cannot find the leak, call your doctor, nurse or KCI.

Alerts and Alarms

When the therapy unit detects certain conditions, it will activate an alert or an alarm.

Low Priority Alarm / Alert

- Requires patient or caregiver attention.
- Indicated by a single audible tone.

Medium Priority Alarm

- Requires immediate attention to ensure your prescribed therapy is being delivered.
- Indicated by a repeating audible tone.

Refer to the following pages for instructions to fix each alert or alarm condition.

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alert / alarm condition has not been fixed.

Press Help for more information about the alert or alarm.

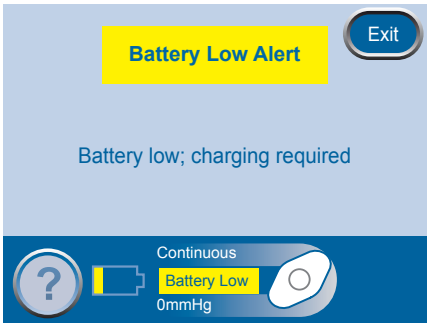
If the alarm condition cannot be fixed, call your doctor or nurse right away.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Battery Low Alert

Low Priority Alert - This alert screen appears about two hours before the battery power runs out. It is indicated by a single audible tone.

Therapy will continue during this alert.



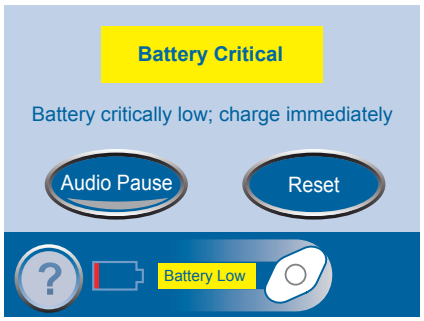
This alert is fixed by recharging the battery.

1. Connect the therapy unit to a wall outlet using the power supply. Refer to the ***Battery Charging Instructions*** section for more information.

2. Press Exit to return to the Patient Mode *Home* screen.

Battery Critical Alarm

Medium Priority Alarm - This alarm screen appears about 30 minutes before the battery power runs out. It is indicated by a repeating audible tone.



Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

Therapy will continue during this alarm. However, if the unit is not plugged in within 30 minutes, therapy will turn off.

This alarm is fixed by recharging the battery.

1. Connect the therapy unit to a wall outlet using the power supply. Refer to the ***Battery Charging Instructions*** section for more information.

2. Press Reset to return to the Patient Mode *Home* screen.

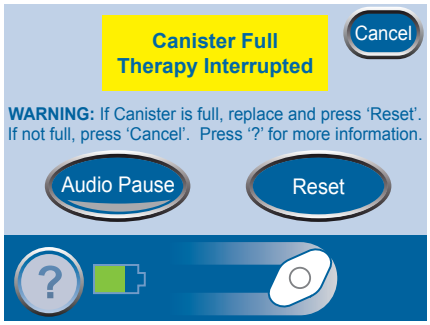
3. Make sure therapy is on. The On / Off button will be green.

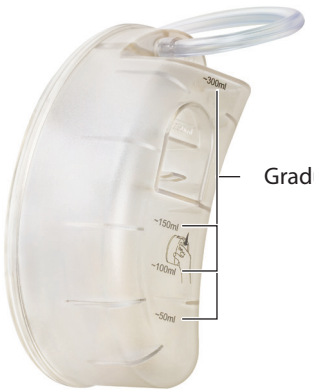
4. Press On / Off to restart therapy if needed.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Canister Full Therapy Interrupted Alarm

Medium Priority Alarm - This alarm screen appears when the canister is full and should be replaced. It is indicated by a repeating audible tone.





Audio Pause

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

Therapy will stop during this alarm.

This alarm is fixed by changing the canister.

1. Use the graduated marks on the canister to check the fluid level. A full canister is about 300 mL.

Cancel

2. If canister is not full, press Cancel.
3. If the canister is full, change canister (see ***Canister Changes*** section).

Reset

4. Press Reset to return to the Patient Mode *Home* screen.

On/Off

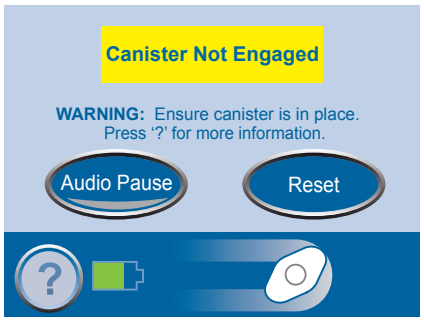
5. Restart therapy by pressing On / Off.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

To avoid a false alarm, keep the therapy unit upright.

Canister Not Engaged Alarm

Medium Priority Alarm - This alarm screen appears when the canister is not properly installed. It is indicated by a repeating audible tone.



Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

Therapy will stop during this alarm.

This alarm is fixed by reinstalling the canister.

1. Press the canister latch release to remove the canister (see ***Canister*** section).

2. Inspect the canister and therapy unit for:

   - Debris between the canister and therapy unit.
   - Two silicone seals (see ***Canister*** section).
   - Two canister bumpers (see ***Canister*** section).

3. If seals or bumpers are missing or damaged, contact KCI.

4. Reinstall the canister. Make sure that it is fully engaged and latched. An audible click should be heard when the canister is properly installed.

5. Press Reset to return to the Patient Mode *Home* screen.

6. Press On / Off to restart therapy.

7. If the alarm continues, install a new canister (see ***Canister Changes*** section).

8. If the alarm cannot be fixed, call KCI or your doctor or nurse.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Leak Alarm

Medium Priority Alarm - This alarm screen appears when the therapy unit detects a significant leak. It is indicated by a repeating audible tone.

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

If the alarm is not fixed within three minutes, therapy will stop. The Leak Alarm Therapy Interrupted Alarm will appear.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

This alarm is fixed by finding and fixing the leak.

Most leaks occur:

- where the drape meets the skin.
- where the SENSAT.R.A.C.™ Pad is attached to the drape.
- at tubing connectors.
- when the canister is not securely connected to the therapy unit.

To fix the leak:

1. Check the tubing connectors between the dressing and the canister. Make sure they are properly locked.
2. Make sure the canister is properly installed onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit.
3. Using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad.
4. If the leak is fixed within three minutes, the unit will return to the Patient Mode home screen.

5. Make sure therapy is on. The On / Off button will be green.

6. Press On / Off to restart therapy if needed.

7. If the leak alarm persists or you cannot find the leak, call KCI or your doctor or nurse.

Use the SEAL CHECK™ Leak Detector feature:

You can also find a leak using the SEAL CHECK™ feature (see ***SEAL CHECK™ Leak Detector*** section). Press SEAL CHECK™ on the *Leak Alarm* screen to use the SEAL CHECK™ Leak Detector.

Leak Alarm Therapy Interrupted

Medium Priority Alarm - This alarm screen appears when the Leak Alarm has not been fixed and therapy has stopped. It is indicated by a repeating audible tone.

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

This alarm is fixed by finding and fixing the leak.

1. Fix any leaks as described in the ***Leak Alarm*** section.

2. Press Reset to return to the Patient Mode *Home* screen.

3. Press On / Off to restart therapy.

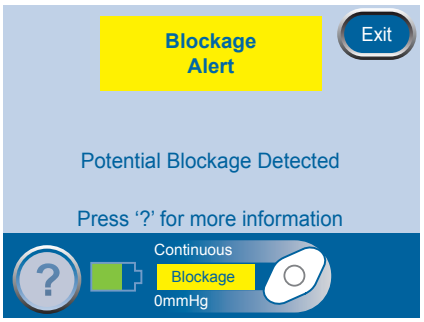
4. If the alarm persists or you cannot find the leak, call KCI or your doctor or nurse.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

If the leak condition is not fixed, the Leak Alarm will reappear. Continue troubleshooting the leak as described in the previous section.

Blockage Alert

Low Priority Alert - This alert screen appears when the tubing may be blocked. It is indicated by a single audible tone.



Therapy will continue during this alert.

This alert is fixed by checking the tubing.

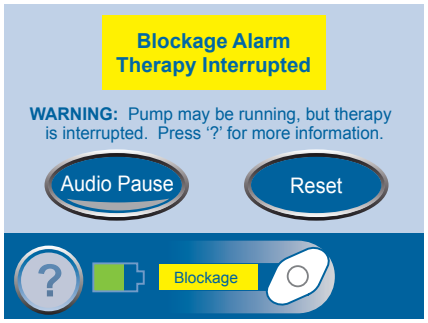
1. Make sure both clamps on the tubing are open.
2. Make sure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.

Exit

4. Press Exit to return to the Patient Mode *Home* screen.

Blockage Alarm Therapy Interrupted

Medium Priority Alarm - This alarm screen appears when the tubing is blocked. This alarm will be accompanied by a repeating audible tone.



Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

Therapy will continue during this alarm. However, therapy may not be at the proper pressure.

This alarm is fixed by checking the tubing.

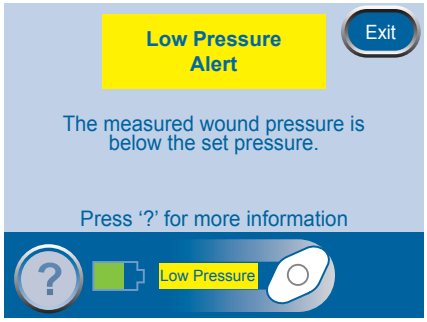
1. Make sure both clamps on the tubing are open.
2. Make sure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alarm Therapy Interrupted remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.

4. Press Reset to return to the Patient Mode *Home* screen.
5. If the alarm persists or you cannot find the blockage, call KCI or your doctor or nurse.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Low Pressure Alert

Low Priority Alert - This alert screen appears when the set therapy pressure is not being reached. It is indicated by a single audible tone.



Therapy will continue during this alert. However, therapy may not be at the proper pressure.

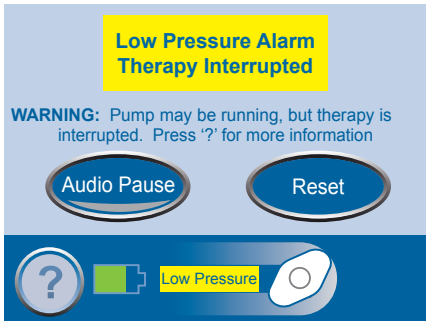
This alert is fixed by checking the tubing.

1. Make sure both clamps on the tubing are open.
2. Make sure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.

4. Press Exit to return to the Patient Mode *Home* screen.

Low Pressure Alarm Therapy Interrupted

Medium Priority Alarm - This alarm screen appears when the set therapy pressure is not being reached. This alarm will be accompanied by a repeating audible tone.



Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

Therapy will continue during this alarm. However, therapy may not be at the proper pressure.

This alarm is fixed by checking the tubing.

1. Make sure both clamps on the tubing are open.
2. Make sure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Therapy Interrupted alarm remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.

4. Press Reset to return to the Patient Mode *Home* screen.
5. If the alarm persists, call KCI or your doctor or nurse.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Therapy Inactive Alarm

Medium Priority Alarm - This alarm screen appears when therapy has been off for 15 minutes (with the unit powered on). This alarm will be accompanied by a repeating audible tone.

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

This alarm is fixed by restarting therapy.

1. Press Reset to return to the Patient Mode *Home* screen.

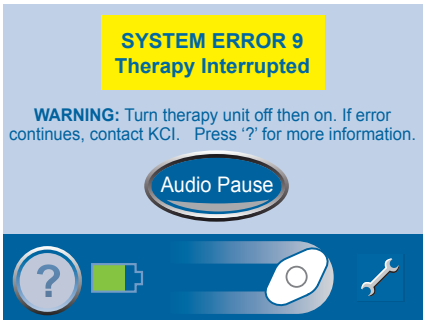
2. Press On / Off to restart therapy.

If therapy is not desired, turn the therapy unit off using the Power button on the front of the unit.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

System Error Alarm

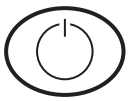
Medium Priority Alarm - This alarm screen appears when there is a technical fault within the therapy unit. A number will appear in the yellow alarm box that represents the error number of the technical fault. This alarm will be accompanied by a repeating audible tone.



Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alarm condition has not been fixed.

This alarm is fixed by restarting the therapy unit.

1. Record the error number.



2. Turn the unit off and then on using the Power button on the front of the unit.

3. If the alarm persists, call KCI. Be sure to give them the error number.

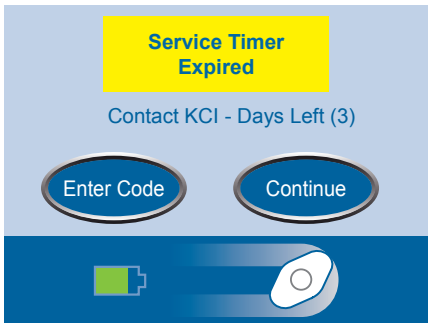
WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Service Timer Expired Alert

Medium Priority Alarm - This alert screen appears when the therapy unit has reached its service time limit. When the service time limit has expired, this alert will appear every time the unit is turned on.

Press Continue to go on to the Patient Mode *Home* screen and restart therapy (see ***Patient Mode Home Screen*** and ***Therapy On or Off*** sections).

When Days Left reaches zero, this alert will appear during therapy.



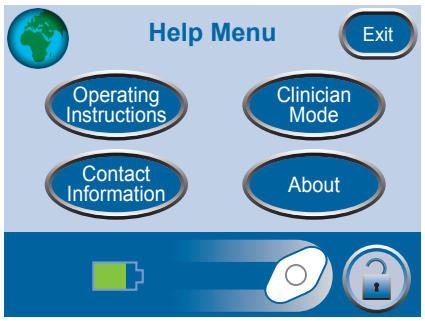
This alarm is fixed by entering a new service time code into the unit.

1. Contact KCI for a new service timer code.

2. Press Enter Code to enter the code into the therapy unit.

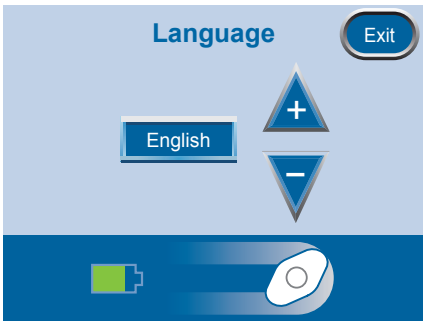
Help Menu

Change Languages



1. Press Help to access the *Help Menu*.

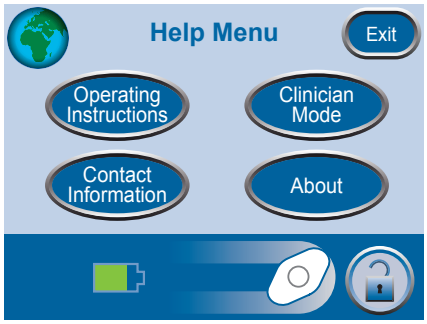
2. Press the Globe to access the *Language* screen.



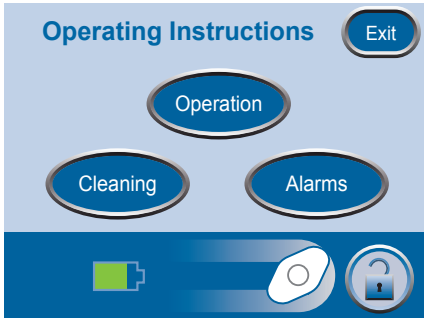
3. Use the + and - buttons to select language.

4. Press Exit when finished.

Onscreen Operating Instructions



1. Press Help to access the *Help Menu*.
2. Press Operating Instructions to access the *Operating Instructions* selection screen and browse the various available *Help* screens.



3. Choose from Operation, Cleaning instructions and Alarms for alarm descriptions and suggested resolutions.

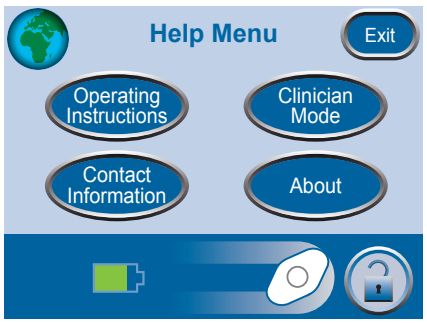
4. Press Exit when finished.

Operation - Access basic operating guidelines.

Cleaning - Access basic cleaning guidelines.

Alarms - Access general information for pausing or silencing alarms.

Clinician Mode



Press Help to access the *Help Menu*.

Clinician Mode has no patient operating screens. Patients should not proceed unless authorized by caregiver.

Care and Cleaning

The following are the KCI recommended cleaning procedures for the ACTIV.A.C.™ Therapy Unit.

Disposal

The dressing and all other disposable items (tubing, connectors, clamps and used canisters) should be removed by your doctor or nurse. Do not discard these items with household trash. This could violate local laws regarding hazardous waste.

Cleaning the Touch Screen

1. Press the Screen Guard button on the *Home* screen (see ***Patient Mode Home Screen*** section).

2. Use a soft cloth to gently clean the touch screen.

   - Do not use any liquid on the touch screen.
   - Do not press too hard on the touch screen while cleaning.

3. Press the 1 button, then the 2 button on the *Screen Guard* screen to return to the *Home* screen.

Cleaning the Therapy Unit

1. Unplug the therapy unit.

2. Clean the therapy unit and the carrying case with a damp cloth and mild soap and water solution. Do not use bleach.

Q: How much does the therapy unit weigh?
A: The therapy unit weighs about 2.4 lbs (about 1.08 kg) with an empty canister installed.

Q: How long does it take to charge the battery?
A: It takes about six hours to fully charge the battery.

Q: How long will a fully charged battery last?
A: The battery charge will last up to 14 hours.

Q: The therapy unit is sometimes noisy. Why is this and what can I do about it?
A: Though the therapy unit may be very quiet at times, it may also make noises to enable the accurate delivery of negative pressure to the wound. Noise may seem louder at night when surrounding noise level is greatly decreased. When a leak is present, unit noise may increase and the unit will begin to alarm. Once the leak is fixed, the unit will no longer alarm and become quieter. The unit may also make a burping sound occasionally.

Placing the therapy unit below the level of the wound may allow the system to work more efficiently and more quietly. It is normal to hear on-again, off-again noise from the ACTIV.A.C.™ Therapy Unit.

Q: What happens if the therapy unit alarms?
A: The therapy unit is built with your safety in mind. The therapy unit has alarms that you can see and hear which will alert you to a potential problem. Most of the time, the alarm can be easily fixed (see ***Alerts and Alarms*** chapter). Review this information with your doctor or nurse, so you are comfortable with this alarm system.

Q: How do I know if the therapy unit is working properly?
A: The Therapy Status Bar at the bottom of the touch screen displays specific therapy information. The spinning icon shows that negative pressure is active (see ***Therapy On or Off*** section). Another way to tell negative pressure is active is the foam dressing will be collapsed. You may see wound fluid may moving in the tubing.

Q: What if I do not hear an audible click when installing a canister onto the therapy unit?
A: An audible click should be heard when installing the canister. If you do not hear an audible click, gently pull the canister away from the therapy unit. If it is properly installed, it will not come off.

Q: What steps should I take before bathing?
A: Do not take the therapy unit into the shower or tub. See the ***Therapy Unit Disconnect*** section for more information. The clear drape is waterproof; you may wash or shower with dressings in place. Take care not to roll the edges of the drape while bathing.

Q: Is the ACTIV.A.C.™ Canister compatible with all V.A.C.® Therapy Units?

A: No, the 300 mL canister is to be used only with the ACTIV.A.C.™ Therapy Unit and INFOV.A.C.™ Therapy Unit.

Q: What languages are available in the ACTIV.A.C.™ Therapy Unit?

A: The therapy unit is pre-programmed with the following languages: English, German, Dutch, French, Italian, Spanish, Danish, Swedish, Brazilian Portuguese, Turkish, Greek, Finnish and Norwegian.

Q: When should I order more dressings and canisters?

A: Order more supplies when you have only one case of dressings OR five canisters left. Call KCI to place your order at least three to five business days before the supplies are needed.

Q: Can I travel with the ACTIV.A.C.™ Therapy System?

A: Talk to your doctor or nurse before traveling to determine if it is safe for you to travel. Do not travel unless you have:

- Medical approval
- Complete understanding of all of the risks related to your medical condition
- Complete understanding of all of the risks related to V.A.C.® Therapy.

Risk of bleeding during travel can have serious and potentially fatal consequences.

Once you have medical approval, you should have the following items with you during travel:

- Your prescription for V.A.C.® Therapy, which includes therapy settings and dressing supplies.
- Enough supplies (such as foam dressings, drape, tubing and canisters) for dressing and canister changes at the recommended time intervals or as needed.
    - Dressing changes should be performed no less than three times a week.
    - Canisters should be changed when full or at least once a week.
- An alternate dressing recommended by your doctor or nurse. This dressing would be used in the event V.A.C.® Therapy needs to be discontinued.
- A fully charged therapy unit and power cord.
- The ACTIV.A.C.™ Therapy Unit User Manual and QRG.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Q: Can the ACTIV.A.C.™ Therapy System be used during diagnostic procedures?

A: Use the chart below to determine whether V.A.C.® Therapy can continue during specific procedures.

Diagnostic Procedures	Therapy Unit Compatible	Therapy Unit NOT Compatible	Dressing Compatible	Dressing NOT Compatible
MRI		X	X	
HBO		X		X
X-Ray	X		X	
Cat Scan (CT)	X		X	
Dye Tests	X		X	
Fluoroscopy	X		X	
Ultrasound	X		X	

If you need:

- Magnetic Resonance Imaging (MRI) - Your doctor or nurse must remove the therapy unit. The dressing can remain in place.
- Hyperbaric Oxygen Therapy (HBO) - Your doctor or nurse must remove the therapy unit and dressing.

Your doctor or nurse should review the safety information sheet for important information about these diagnostic procedures. This document is kept in the pocket on the therapy unit carrying case.

WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

If the area needing imaging is under the foam dressing, there is a possibility of shadow casting. The V.A.C.® GRANUFOAM™ Bridge Dressing contains additional synthetic materials which may pose a risk during HBO Therapy. Other V.A.C.® Dressings are compatible with all imaging modalities. The decision whether or not to keep the V.A.C.® Dressing in place should be made by the radiologist, radiology technician and / or your doctor or nurse.

ACTIV.A.C.™

THERAPY SYSTEM

For Clinician Use Only

Patients: Refer to Previous Section of This Manual

Acelity™

Clinician Table of Contents

Important Safety Information Accompanies This Device 44
Warnings: Important Information For Users 45
Introduction 46
- Clinician Mode Home Screen 47
- Common Screen Control Buttons 48
- Battery Level 48
- Audio Pause 48

Operating Instructions 49
- Power Therapy Unit On or Off 49
- Therapy On or Off 49
- Access Manual Therapy Settings 50
- Settings 50
  - Pressure Settings 51
  - Intensity Control 51
  - Continuous and Intermittent Modes 52
  - Intermittent Settings 52
- Settings Confirmation 52
- Settings Guide 53
- Settings Guide Confirmation 54

Starting Therapy 55
- SEAL CHECK™ Leak Detector 56
- How to Use the SEAL CHECK™ Leak Detector When Starting Therapy 56
- Finding the Leak Using the SEAL CHECK™ Leak Detector 57
- Log Tool 57
- How to Use the Log Tool When Starting Therapy 57

View or Export Therapy History 59
- View Therapy History 59
- Export Therapy History Report 60
- USB Export Issues 60

Help Menu 61
- Change Languages 61
- Onscreen Operating Instructions 62
- Change to Patient or Clinician Mode 63

Utilities 64
- Change Time and Date 64
- Change Pressure Units and Date Format 65

Change Screen Brightness 65
Change AC Light 65
Care and Cleaning 66
Standard Precautions 66
Waste Disposal 66
Cleaning the ACTIV.A.C.™ Therapy Unit 66
Cleaning the Touch Screen 67
Electromagnetic Compatibility (EMC) 68
Explanation of Symbols Used 72
Specifications 74
Customer Contact Information 75
See The Following Pages Of The ***Patient Section*** Of This User Manual For Additional Information
Important Safety Information Accompanies this Device 3
Warnings: Important Information for Users 4
Introduction 5
ACTIV.A.C.™ Therapy Unit 6
Patient Mode Home Screen 6
Common Screen Control Buttons 7
Static Electricity 7
Charge the Battery 8
Battery Level 9
Canister 10
Canister Changes 10
Carrying Case 12
Power Supply Retainer Instructions 14
Therapy Unit Disconnect 15
Operating Instructions 16
Power Therapy Unit On or Off 16
Therapy On or Off 16
SEAL CHECK™ Leak Detector 17
Find and Fix the Leak 18
Alerts and Alarms 19
Battery Low Alert 20
Battery Critical Alarm 21
Canister Full Therapy Interrupted Alarm 22
Canister Not Engaged Alarm 23
Leak Alarm 24
Leak Alarm Therapy Interrupted 25
Blockage Alert 26
Blockage Alarm Therapy Interrupted 27
Low Pressure Alert 28

CLINICIAN

Low Pressure Alarm Therapy Interrupted 29
Therapy Inactive Alarm 30
System Error Alarm 31
Service Timer Expired Alert 31
Help Menu 32
Change Languages 32
Onscreen Operating Instructions 33
Clinician Mode 33
Care and Cleaning 34
Disposal 34
Cleaning the Touch Screen 34
Cleaning the Therapy Unit 34
Frequently Asked Questions 35

Important Safety Information Accompanies This Device

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

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

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

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

Warnings: Important Information For Users

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

- Use this product only in accordance with this manual and applicable product labeling.
- Assembly, operations, extensions, re-adjustments, modifications, technical maintenance or repairs must be performed by qualified personnel authorized by KCI. For these authorized personnel, KCI will make available upon request circuit diagrams, component parts lists, etc. as required for repairs.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards. To avoid the risk of electrical shock, this product must be connected to a grounded power receptacle.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Use only V.A.C.® Dressings with this product.
- Keep this product away from heated surfaces.
- Although this product conforms to the intent of standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- Avoid spilling fluids on any part of this product.

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

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

Notice

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

Introduction

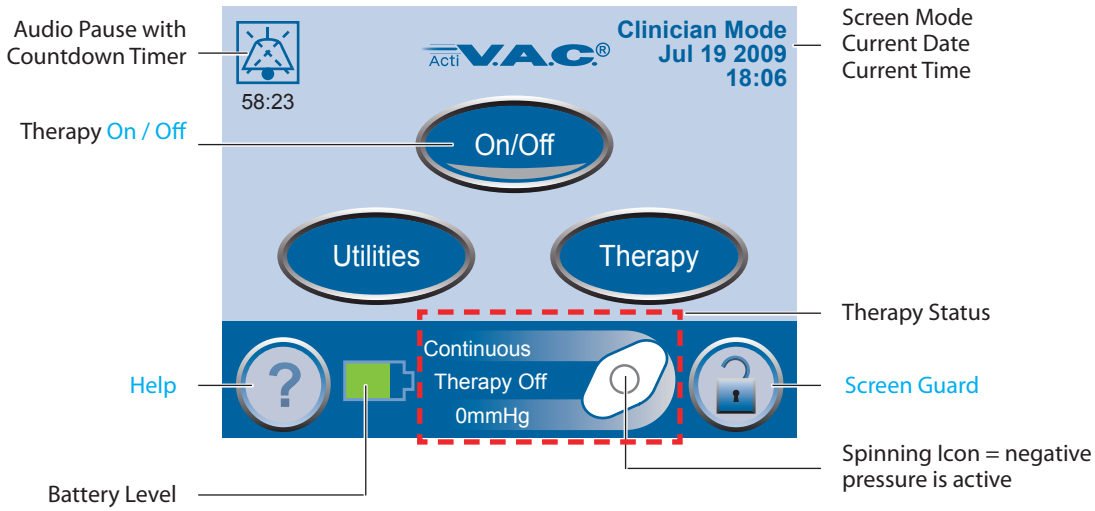
This Clinician information provides operating instructions for the ACTIV.A.C.™ Therapy Unit to the healthcare professional. Many features described are not available in Patient Mode. Patient Mode allows the patient to start and stop therapy, find leaks using the SEAL CHECK™ feature, and attend to alerts and alarms, but does not allow changes to therapy settings.

V.A.C.® (Vacuum Assisted Closure®) Therapy is a system that uses controlled continuous or intermittent negative pressure (vacuum) to create an environment that promotes wound healing by:

- preparing the wound bed for closure
- reducing edema
- promoting granulation tissue formation and perfusion
- removing exudate and infectious material

The ACTIV.A.C.™ Therapy System provides Negative Pressure Wound Therapy (NPWT) and Therapeutic Regulated Acute Care (SENSAT.R.A.C.™) for use on a variety of chronic and acute wound types. This advanced wound healing therapy can be readily integrated into the healthcare provider's wound healing practice, helping to optimize patient care and manage costs. It is a flexible therapy that, with appropriate precautions in place, may be used in both hospital and community settings. This advanced wound healing technology is coupled with microprocessor-controlled therapy units and 24-hour customer service and support.

Clinician Mode Home Screen



Green = function is on

Gray = function is off

On / Off - Start or stop V.A.C.® Therapy.

Utilities - Access Region Settings and Time/Date buttons, Screen Brightness and AC Light buttons.

Therapy - Access Settings, SEAL CHECK™ Leak Detector, Settings Guide, and History buttons.

The plug icon appears on the touch screen when the unit is plugged in.

Common Screen Control Buttons

Most screens have one or more common control buttons. These are:

Help - Access *Help* screens

Screen Guard - Turn on Screen Guard to help prevent accidential changes to the unit settings. Use this feature when cleaning the touch screen. To turn off Screen Guard, press 1 and then 2.

Exit - Leave the current screen.

Cancel - Stop the action in progress.

Next - Go to the next screen.

Back - Return to the previous screen.

OK - Confirm the selection.

Battery Level

The battery level is shown on the bottom of the touch screen (see ***Patient Mode Home Screen*** and ***Clinician Home Screen*** sections).

Fully Charged

In Use

Battery Low. Charge battery soon.

Battery Critical. **Charge battery immediately.**

Audio Pause

Press Audio Pause to silence the audible tone. The audible tone will come back on in two minutes if the alert / alarm condition has not been fixed.

The Audio Pause and Countdown Timer will be displayed in the upper left corner of the screen.

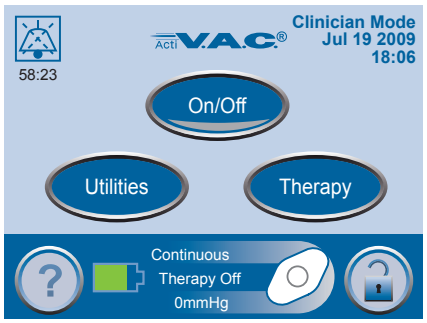
Alarms needing immediate attention override the Audio Pause feature. See the *Alerts and Alarms* chapter in the patient section of this manual for details on alarms and how to resolve them.

Before starting therapy, ensure that the dressing is in place, the canister is connected, and all clamps are open.

Power Therapy Unit On or Off

The Power button is located below the touch screen (see ***Patient Mode Home Screen*** section).

1. Press and hold the Power button for approximately two seconds to turn the therapy unit on or off. The therapy unit will go through a self-check and then display a warning message screen.



2. Press OK to continue to the Clinician Mode *Home* screen.

Therapy On or Off

Press On / Off to start or stop V.A.C.® Therapy.

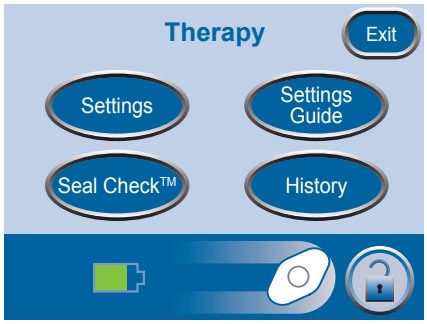
Green = function is on

Gray = function is off

Spinning icon = negative pressure is active

WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

Access Manual Therapy Settings



1. From the Clinician Mode *Home* screen, press Therapy, then Next to access this screen.

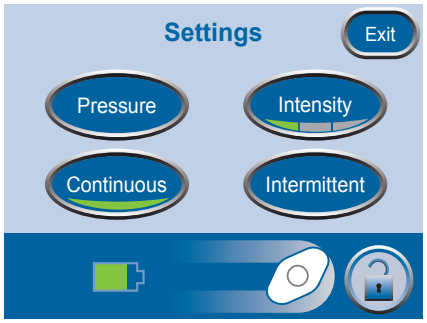
2. Select desired option from the *Therapy* screen:

   - Settings - Manually set therapy.
   - SEAL CHECK™ - Helps to find leaks.
   - Settings Guide - Helps select preset therapy settings.
   - History - View or export therapy history.

3. Press Exit to return to the Clinician Mode *Home* screen.

Settings

Settings changed manually take immediate effect when therapy is on.



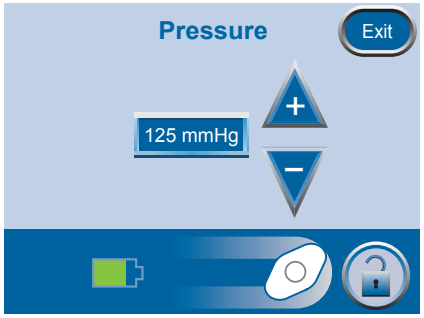
1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings to access this screen.

2. Select desired option from the *Settings* screen:

   - Pressue - Change pressure settings.
   - Intensity - Change Intensity.
   - Continuous - Toggle between Continuous and Intermittent therapy.
   - Intermittent - Set Intermittent therapy times.

3. Press Exit to continue to the *Confirm* screen.

Pressure Settings



1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings, then Pressure to access this screen.

2. Use the + and - buttons to change the desired pressure. Pressure can be set from 25 to 200 mmHg in increments of 25 mmHg.

3. Press Exit to return to the *Settings* screen.

Default setting is 125 mmHg (accuracy + / - 10 mmHg).

Intensity Control

1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings, then Intensity to change intensity level.

   - Intensity is related to the time it takes to reach the target therapy level after the initiation of therapy.
   - The lower the intensity setting, the slower the target therapy level will be reached.
   - It is recommended that new patients begin therapy at the lowest intensity setting as this allows for slower increase of negative pressure once the foam is compressed in the wound.
   - The intensity can remain at the minimum setting throughout the entire length of treatment, if desired.

2. Press to change levels. Green crescent changes with each setting.

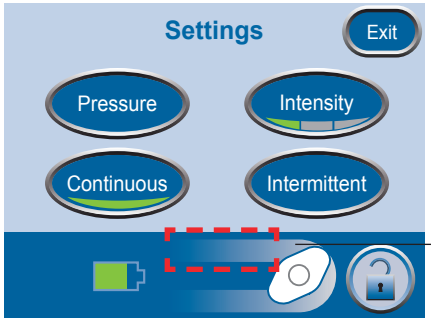
Low

Medium

High

Default setting is Low.

Continuous and Intermittent Modes



1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings, then Continuous to toggle between Continuous and Intermittent therapy.

Green = Continuous mode is active.

Gray = Intermittent mode is active.

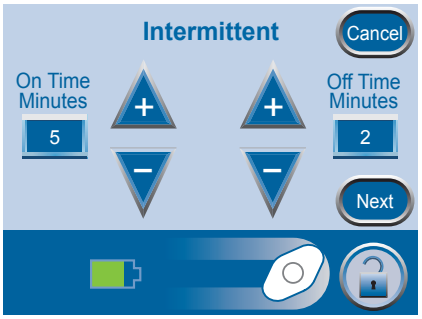
Continuous or *Intermittent* will appear here as modes are switched.

Default setting is Continuous.

2. Press Exit to continue to the *Confirm* screen.

Intermittent Settings

Changes to Intermittent time intervals will take effect next therapy cycle.



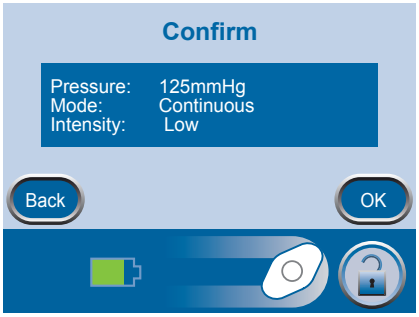
1. From the Clinician Mode *Home* screen, press Therapy, then press Settings, then press Intermittent to access this screen.

2. Use the + and - buttons to change the desired on and off time. Both times can be set from one minute to ten minutes in one minute increments.

Default setting is On Time = five minutes, Off Time = two minutes.

3. Press Exit to return to the *Settings* screen.

Settings Confirmation



1. Press Exit when finished with the *Settings* screen to go to the *Confirm* screen.

2. Press OK to continue to the Clinician Mode *Home* screen if the displayed settings are as desired, or press Back to change settings.

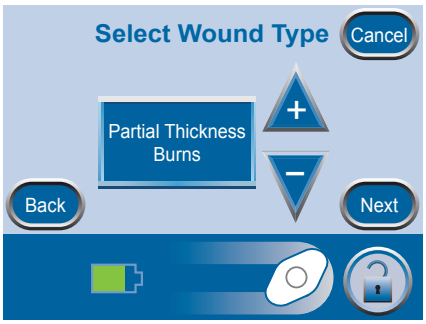
If settings were changed with V.A.C.® Therapy off, press On / Off to start therapy.

CLINICIAN

Settings Guide

The Settings Guide helps select pre-set therapy ranges according to wound type and treating physician's orders. Selected ranges are a guide based on common settings for different wound types. Individual patient conditions may vary. Consult physician to verify settings for each patient.

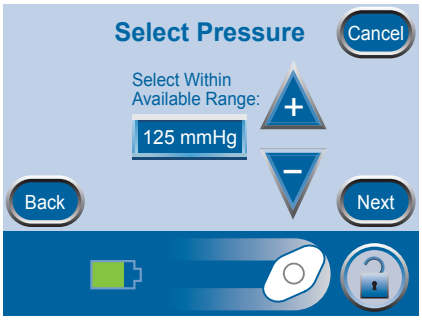
Should physician orders fall outside the pre-set therapy ranges, select Other in this mode or use the Manual Therapy Settings (see *Access Manual Therapy Settings* section).



1. From the *Clinician Mode* home screen, press Therapy, then Next, then Settings Guide, then OK to access the *Select Wound Type* screen.

2. Use + and - to scroll through the available wound type selections.

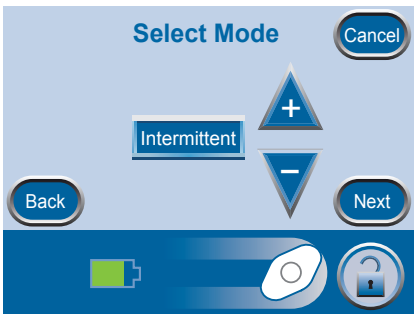
3. Press Next to continue to the *Select Pressure* screen.



4. Use + and - to scroll through the pressure selections. Pressure selections are in ranges for the wound type selected on the previous screen.

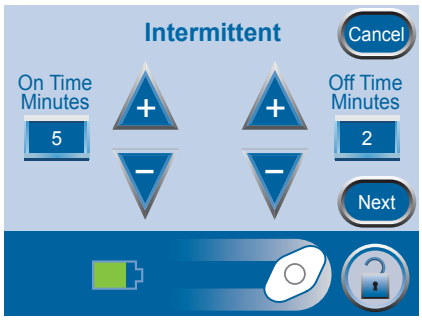
5. Press Next when finished to continue to the next screen.

For wound types in which Intermittent is an option, the *Select Mode* screen will appear. If Intermittent is not an option, the *Confirm* screen will appear.



6. Use + and - to choose Continuous or Intermittent therapy.

7. Press Next to continue.

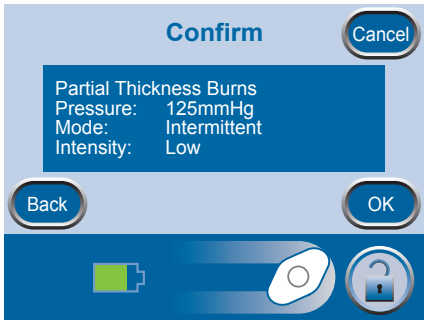


8. If Intermittent therapy was chosen on the previous screen, the *Intermittent* screen will appear.

9. Use + and - to change the desired on and off time. Both times can be set from one minute to ten minutes in one minute increments.

10. Press Next to continue to the *Confirm* screen.

Settings Guide Confirmation



1. Once the settings are chosen, the *Confirm* screen will appear.

2. Press OK to continue to the Clinician Mode *Home* screen if the displayed settings are as desired, or press Back to change settings.

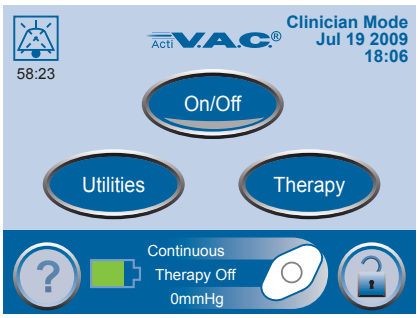
Settings take effect after OK is pressed.

Settings Guide Intensity default is Low. Intensity can only be changed using Manual Therapy Settings (see *Access Manual Therapy Settings* section).

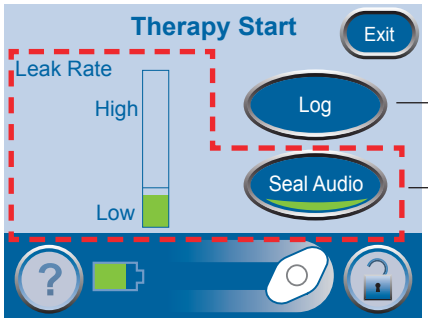
Starting Therapy

WARNING: Ensure that a new V.A.C.® Dressing has been applied and therapy settings have been selected per physician's orders before starting therapy.

Canister should be properly engaged for therapy to start.



Press On / Off to start therapy.



The *Therapy Start* screen will appear.

Log Tool

SEAL CHECK™ Leak Detector

Options available from this screen:

- SEAL CHECK™ Leak Detector - Use to view the integrity of the V.A.C.® Dressing and find any leaks.
- Log Tool - Use to record canister change or the number of foam pieces used during a dressing change.

SEAL CHECK™ Leak Detector

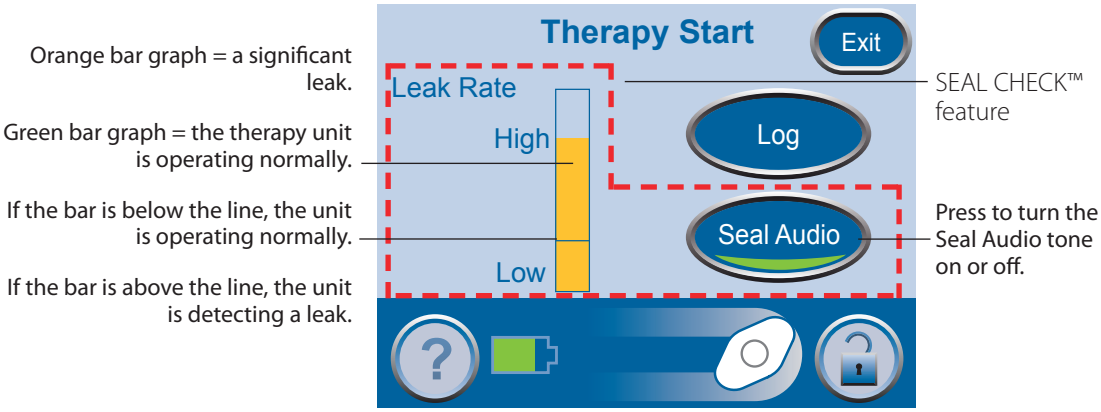
The SEAL CHECK™ feature is used to help find negative pressure leaks and may be accessed in the following ways:

- When therapy is started from the Clinician Mode *Home* screen.
- When SEAL CHECK™ is pressed from the *Therapy* screen.
- When SEAL CHECK™ is pressed on the *Leak Alarm* screen after the ACTIV.A.C.™ Therapy Unit detects a possible leak.

Patients only have access to the SEAL CHECK™ feature through the *Leak Alarm* screen when the therapy unit detects a possible leak.

How to Use the SEAL CHECK™ Leak Detector When Starting Therapy

Press On / Off located on the Clinician Mode *Home* screen to continue to the *Therapy Start* screen.



The SEAL CHECK™ feature uses an audible tone and a bar graph to help find leaks. The frequency of the audible tone and the height of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph gets shorter as the leak is found.

During initial dressing draw down, the bar graph should turn orange and then return to green if there are no significant leaks.

Most leaks occur:

- where the drape meets the skin.
- where the SENSAT.R.A.C.™ Pad is attached to the drape.
- at tubing connections.
- when the canister is not securely connected to the therapy unit.

Finding the Leak Using the SEAL CHECK™ Leak Detector

1. Ensure the connector between dressing tubing and canister tubing is properly locked.

2. Ensure the canister is securely installed on the therapy unit. If the canister is properly installed, it cannot be removed by gently pulling it directly away from the unit.

3. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad. The bar graph will lower and the frequency of the audible tone (if Seal Audio is on) will decrease when the leak is found.

4. Refer to the instructions for use provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area.

5. When finished press Exit to return to the Clinician Mode *Home* screen.

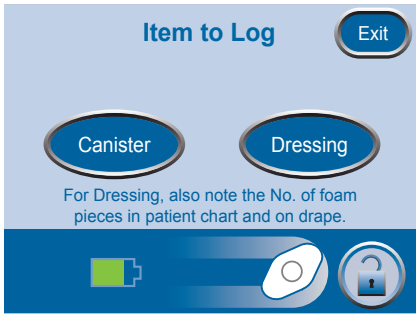
Log Tool

The Log Tool can be used to track:

- the number of foam pieces used during a dressing change.
- canister changes.

Logged information can be viewed and exported from the *Therapy History* screens.

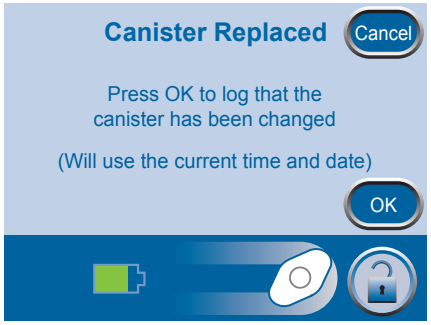
How to Use the Log Tool When Starting Therapy



1. Press Log on the *Therapy Start* screen to access the *Item to Log* screen.

2. Choose Canister or Dressing.

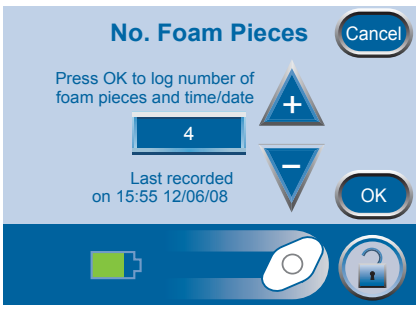
3. Press Exit to return to the Clinician Mode *Home* screen.



1. Press Canister to access the *Canister Replaced* screen.

2. Press OK to log that the canister has been replaced and return to the *Item to Log* screen. The current time and date will be recorded.

3. Press Cancel to return to the *Item to Log* screen without logging an entry.



1. Press Dressing to access the *No. Foam Pieces* screen.

Information displayed represents the last logged entry.

2. Use + and - to select the number of foam pieces used during the current dressing change.

3. Press OK to log the number of foam pieces used and return to the *Item to Log* screen. The current time and date will be recorded.

4. Press Cancel to return to the *Item to Log* screen without logging an entry.

Always count the total number of pieces of foam used in the wound. Document the foam quantity and dressing change date on the drape or Foam Quantity Label if available, and in the patient's chart.

Logged information will appear in Therapy History as follows:

dd/mm/yy	Time	Event
12/06/06	15:54	Canister Changed
12/06/06	15:55	Dressing Changed, 4

Numeral after Dressing Changed represents the number of foam pieces recorded on the above screen.

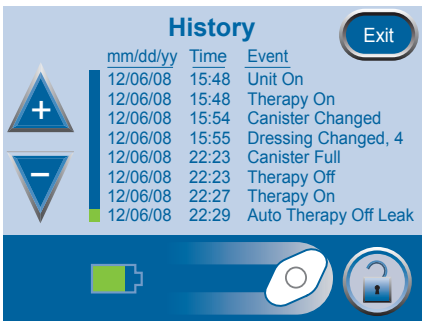
View or Export Therapy History

Therapy History is a chronological log of dates and times for therapy starts and stops, therapy settings, unit inactivity that exceeds 15 minutes, alarm occurrences, and manually logged canister / dressing changes.

Data can be reviewed on screen or transferred from the ACTIV.A.C.™ Therapy Unit electronically in the form of a Therapy History Report.

1. Starting from the Clinician Mode *Home* screen, press Therapy, then Next then History to access the *Therapy History* screen.
2. Select desired option on the *Therapy History* screen:
   - View History - View Therapy History on screen.
   - Export History - Access screens where the Therapy History Report can be transferred via USB.

View Therapy History



1. Press View History on the *Therapy History* screen to access the on-screen therapy history display.

2. Use + and - to scroll through the Therapy History Report.
3. Hold the + and - buttons to rapidly scroll through the recorded information.

   Due to space limitations, the Therapy History Report does not spell out wound types. A number is used instead, according to the following chart:

   1 = Acute/Traumatic
   2 = Partial Thickness Burns
   3 = Dehisced Wounds
   4 = Meshed Grafts
   5 = Pressure Ulcers
   6 = Chronic Ulcers
   7 = Flaps
   8 = Other

4. Press Exit to return to the *Therapy History* screen.

Export Therapy History Report

This data is protected by copyright law and is likely confidential. It is intended only for use by or for KCI personnel or clinicians using KCI products, and is not directly associated with a particular patient. Since this data can be altered if transferred to a different media, the data may only be considered original when downloaded directly from a KCI product.

To access the USB Data Ports, the ACTIV.A.C.™ Therapy Unit must be removed from the carrying case.

1. Press Export History on the *Therapy History* screen to access the *Export History* screen.

USB devices should be connected directly and only unpowered USB mass storage devices should be attached to the therapy unit. AC or battery powered drives, computers, computer equipment, other devices or USB extension leads should not be connected to this device.

2. Press Export to USB to begin data transfer. Follow screen directions.

3. Press Exit to return to the *Therapy History* screen.

USB Export Issues

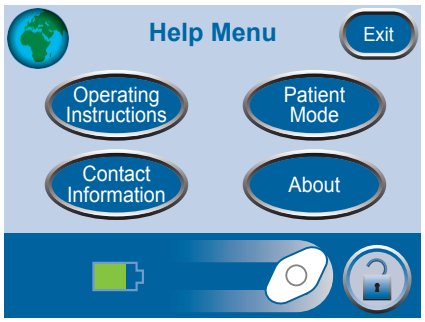
USB:

- Ensure that the USB flash drive (memory stick) being used is USB 2.0 compatible.
- Ensure that the flash drive is fully plugged into the therapy unit. It may be necessary to unplug and re-plug the flash drive into the therapy unit.
- Try using a different USB flash drive.
- Remove the flash drive. Press Power to power the unit off and then on. Retry exporting Therapy History.

If the above steps do not resolve the problem, contact KCI for further assistance.

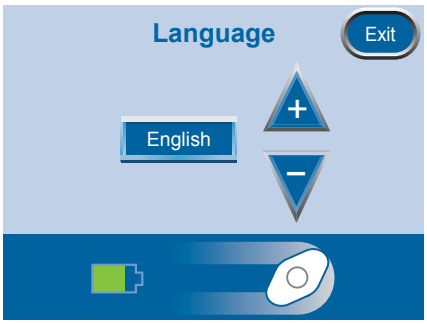
Help Menu

Change Languages



1. Press Help to access the *Help Menu*.

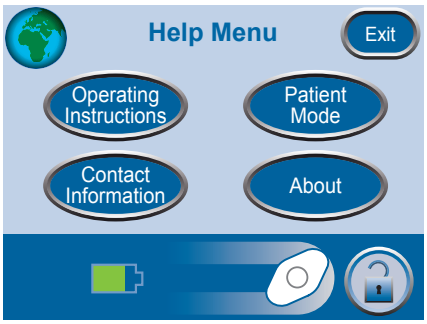
2. Press the Globe to access the *Language* screen.



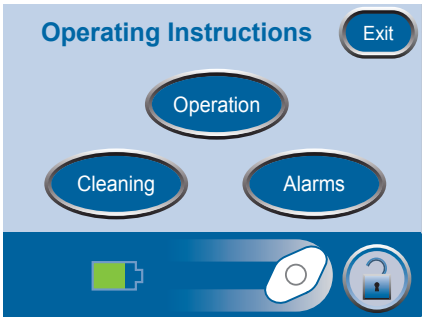
3. Use + and - to select the desired language.

4. Press Exit when finished.

Onscreen Operating Instructions



1. Press Help to access the *Help Menu*.
2. Press Operating Instructions to access the *Operating Instructions* selection screen and browse the various available *Help* screens.



3. Choose from Operation, Cleaning instructions and Alarms for alarm descriptions and suggested resolutions.

4. Press Exit when finished.

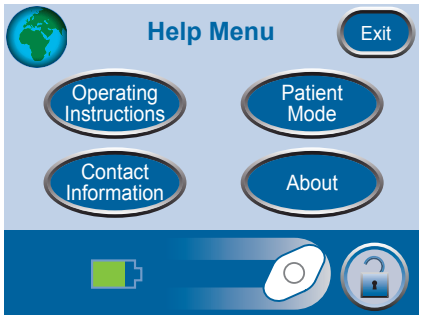
Operation - Access basic operating guidelines.

Cleaning - Access basic cleaning guidelines.

Alarms - Access general information for pausing or silencing alarms.

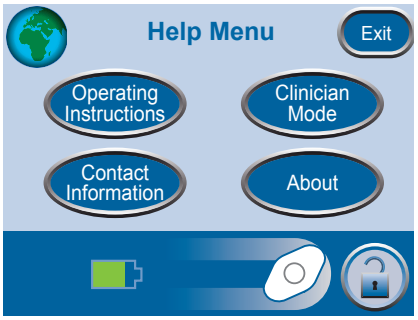
Change to Patient or Clinician Mode

Press Help to access the *Help Menu*.



Patient Mode

Press Patient Mode to change to *Patient Mode*.



Clinician Mode

Press Clinician Mode to change to *Clinician Mode*.

A screen will appear to confirm which mode is set.

Only authorized caregivers should access Clinician Mode. <u>Select Cancel unless authorized.</u>

OK

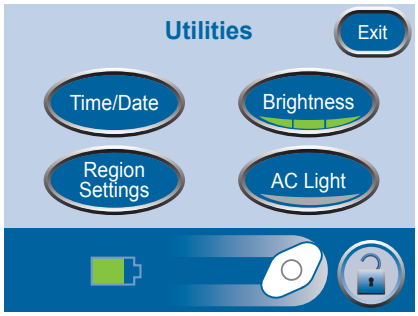
Press OK to return to *Patient Mode*. Press and hold OK for at least 5 seconds to proceed to *Clinician Mode*.

Cancel

Press Cancel to return to the respective *Help Menu* screen.

Utilities

From the Clinician Mode *Home* screen, press Utilities to access this screen.



Press Time/Date to set the current time and calendar date.

Press Region Settings to set the displayed Pressure Unit and Date Formats.

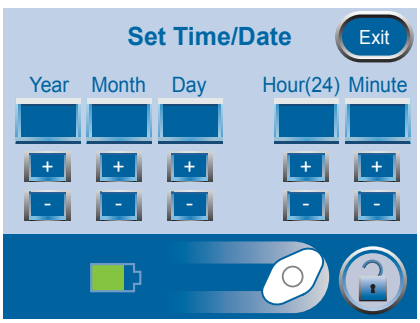
Press Brightness to set the display brightness of the touch screen.

Press AC Light to turn the AC Light on and off.

Press Exit to return to the Clinician Mode *Home* screen.

Change Time and Date

From the Clinician Mode *Home* screen, press Utilities then Time/Date to access this screen.



1. Use + and - to set current time and calendar date.

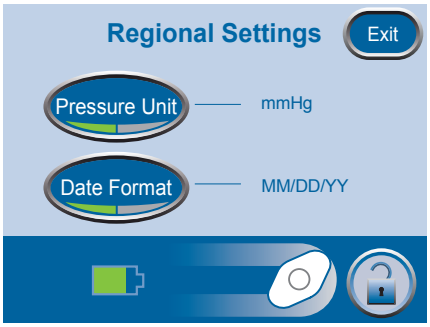
Hold + and - to rapidly scroll through available selections.

2. Press Exit to return to the *Utilities* screen.

Change Pressure Units and Date Format

The ACTIV.A.C.™ Therapy Unit is designed to show two units of measure with mmHg (millimeters of mercury) as the default. If you prefer kPa (kilopascals), follow the directions in this section to change the Pressure Unit.

From the Clinician Mode *Home* screen, press Utilities then Region Settings to access the *Regional Settings* screen.



Default settings are mmHg and MM DD YY.

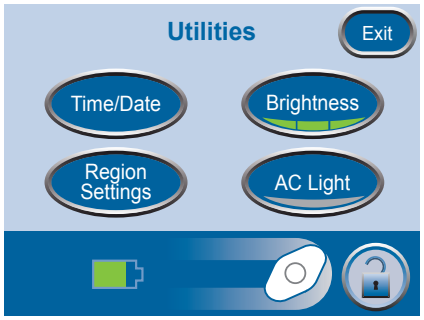
Press Pressure Unit to switch between mmHg (millimeters of mercury) and kPa (kilo-pascals) units of measurement.

Press Date Format to switch between DD MM YY (Day-Month-Year) and MM DD YY (Month-Day-Year) formats.

Press Exit to return to the *Utilities* screen.

Change Screen Brightness

Press Brightness to switch between three levels of screen brightness.



High

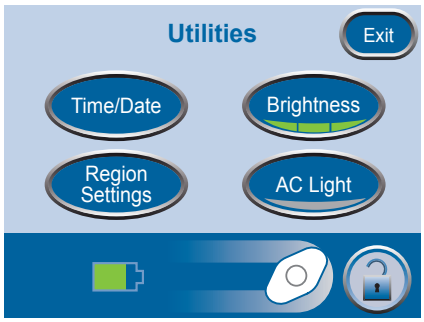
Medium

Low

Default setting is High.

Change AC Light

Press AC Light to force the touch screen backlight to remain bright when the unit is connected to the ACTIV.A.C.™ Power Supply.



On

Off

Default setting is Off.

Care and Cleaning

Standard Precautions

The following are the KCI recommended daily and weekly cleaning and infection control procedures for the ACTIV.A.C.™ Therapy Unit.

Always follow Standard Precautions.

Standard Precautions are designed to reduce the risk of transmission of microorganisms from both known and unknown sources of infection. These precautions can be applied to all patients, regardless of their diagnosis or presumed infection status, and should be used when contact is anticipated with blood and all body fluids. This also includes secretions and excretions (except sweat) regardless of whether blood is visible or not, non-intact skin (i.e., open wounds) and mucous membranes.

Waste Disposal

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations. Improper disposal may run the risk of regulatory non-compliance.

Cleaning the ACTIV.A.C.™ Therapy Unit

Cleaning and disinfection of the ACTIV.A.C.™ Therapy Unit includes wipedown of all hard surface components. Follow your institutional procedures used for cleaning and disinfection of other hard surface durable electronic medical equipment. The ACTIV.A.C.™ Therapy Unit must be cleaned and disinfected:

- If it becomes soiled during patient use.
- At least weekly.

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.

KCI recommends the following regarding cleaning and disinfecting KCI V.A.C.® Therapy devices:

- To help reduce risk of infection and contact with blood and body fluids, use personal protective equipment (PPE) such as medical procedure gloves.
- Clean all organic material (visible soil or body secretions) from the therapy unit prior to disinfection.
- Use hospital-grade cleaners and disinfectants.
- Do not immerse or saturate the therapy unit with fluids to avoid damage to the electronics in the device.
- Do not use alcohol based solutions around the touch screen edges or near gasket and power switches since alcohol based solutions will easily wick up into the screen and may cause equipment malfunction.

Cleaning the Touch Screen

1. Select Screen Guard on the *Home* screen (see ***Clinician Mode Home Screen*** section) to activate Screen Guard.

Lock button icon will close. The next screen displayed will be the screen guard screen.

2. Use a soft, non-abrasive cloth to gently clean the touch screen.

Do not use any liquid to clean the touch screen.

Do not use excessive force to clean the touch screen. Pressing too hard may cause damage.

3. To unlock the touch screen, select 1, then 2 on the *Screen Guard* screen to return to the *Home* screen.

Electromagnetic Compatibility (EMC)

The following are guidance and manufacturer's declarations regarding EMC for the ACTIV.A.C.™ Therapy Unit.

- The ACTIV.A.C.™ Therapy Unit needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following pages.

This equipment is intended for use by healthcare professionals only. As with all electrical medical equipment, this equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orienting or relocating the ACTIV.A.C.™ Therapy Unit or shielding the location.

- Portable and Mobile RF communications equipment, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the ACTIV.A.C.™ Therapy Unit. Please use the guidelines and recommendations specified in Tables 204 and 206.

- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the ACTIV.A.C.™ Therapy Unit. Care should be used when operating the ACTIV.A.C.™ Therapy Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ACTIV.A.C.™ Therapy Unit and the other equipment should initially be observed to verify normal operation in the configuration in which it will be used.

- The electrical cables, external power supplies and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and accessories with the ACTIV.A.C.™ Therapy Unit. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the ACTIV.A.C.™ Therapy Unit and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.

- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the ACTIV.A.C.™ Therapy Unit or decreased electromagnetic immunity of the ACTIV.A.C.™ Therapy Unit.

Table 201

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The ACTIV.A.C.™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the ACTIV.A.C.™ Therapy Unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF Emissions - CISPR 11 (Radiated & Conducted)	Group 1	The ACTIV.A.C.™ Therapy Unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions - CISPR 11 (Radiated & Conducted)	Class B	The ACTIV.A.C.™ Therapy Unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Table 202

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ACTIV.A.C.™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used only in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Intended Electromagnetic Environment**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 8kV contact ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input / output lines	± 2kV for power supply lines 100 kHz repetition frequency ± 1kV for input / output lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	± 1kV differential mode (line-line) ± 2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 seconds	Dips: 0% Ut for 1 cycle 70% Ut for 25 cycles at 50Hz or 30 cycles at 60Hz Single phase: at 0° Interruptions: 0% Ut for 250 cycles at 50Hz or 300 cycles at 60Hz	Product has internal battery backup. If the user of the ACTIV.A.C.™ Therapy Unit requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A / m	30 A/m 50 Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: Ut is the A.C. mains voltage prior to application of the test level.			

Table 204

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ACTIV.A.C.™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Intended Electromagnetic Environment**
			Portable and mobile RF communications equipment should be used no closer to any part of the ACTIV.A.C.™ Therapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz 6Vrms in ISM and amateur radio bands between 150kHZ and 80MHz 80% AM at 1kHz	Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3V / m 80MHz to 2.5GHz	10V / m 80MHz to 2.7GHz 80% AM at 1kHz	$d = 0.35\sqrt{P}$ 80MHz to 800 MHz $d = 0.7\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ACTIV.A.C.™ Therapy Unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ACTIV.A.C.™ Therapy Unit. [b] Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V / m.			
Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ACTIV.A.C.™ Therapy Unit including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. More precisely, the minimum recommended separation distance should be calculated from the equation applicable to the frequency of the transmitter, as noted in Table 206.			
NOTE: This equipment (60601 3rd Edition device only) has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2014 4th edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.			

Table 206

Recommended separation distances between portable and mobile RF communications equipment and the ACTIV.A.C.™ Therapy Unit			
The ACTIV.A.C.™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ACTIV.A.C.™ Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 0.35\sqrt{P}$	800MHz to 2.5GHz $d = 0.7\sqrt{P}$
0.01	.12	.04	.07
0.1	.38	.11	.22
1	1.2	.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7.0
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Included Power Supplies

Part Number	Description	Manufacturer	Max Length
340226	Power Supply	ICC	3.05 m
340225	Elec / Con-US Cordset - ACTIV.A.C.™	Electri-Cord Mfg. Co.	2.03 m
M4268883	Elec / Con-Australia Cordset - INFOV.A.C.™ / ACTIV.A.C.™	Electri-Cord Mfg. Co.	2.05 m
M4268880	Elec / Con-UK Cordset - INFOV.A.C.™ / ACTIV.A.C.™	Electri-Cord Mfg. Co.	2.05 m
M4268881	Elec / Con-EU Cordset - INFOV.A.C.™ / ACTIV.A.C.™	Electri-Cord Mfg. Co.	2.05 m
4103865	Cord, ACTIV.A.C.™ China Power	Electri-Cord Mfg. Co.	2.51 m
4103847	ACTIV.A.C.™ Cord, Power, India	Electri-Cord Mfg. Co.	2.54 m
4103887	ACTIV.A.C.™ Cord, Power, Brazil	Electri-Cord Mfg. Co.	2.05 m
413708	Cord, ACTIV.A.C.™ International Desktop - External Power Supply	ICC	3.05 m
413625	Cord, V.A.C.® Power, UK-240V	Consolidated Wire	2.05 m
413992	Cord, V.A.C.® Power, CH	Consolidated Wire	2.05 m
413628	Cord, V.A.C.® Power, US	Consolidated Wire	2.05 m
413627	Cord, V.A.C.® Power, AZ / NZ 240V	Consolidated Wire	2.05 m
419084	Cord, V.A.C.® Power, EU-240V	Consolidated Wire	2.05 m
414165	Cord, V.A.C.® Power, China	Consolidated Wire	2.05 m
414655	Assy, Power Cord, ACTIV.A.C.™ Japan	Consolidated Wire	1 m
414961	Cord, V.A.C.® Power, South Africa	Consolidated Wire	2.09 m
415569	Cord, V.A.C.® Power, KR-240V	Consolidated Wire	2.09 m
415572	Cord, INFOV.A.C.™ / ACTIV.A.C.™ TW Grounded	Consolidated Wire	2.06 m

The use of cables other than those listed above may cause increased electromagnetic emissions or decrease electromagnetic immunity.

Explanation of Symbols Used

Warning or Caution of possible hazard to system, patient or staff

Important Operational Information

Refer to User Manual

Caution: Consult Accompanying Documents

Keep Dry

Tripping Hazard

No Bathing or Showering

Power On / Off

Manufacturer

Temperature Limitations

Explanation of Symbols Used

IP22	Ingress Protection
IPXO	Ingress Protection
	Class II
	Type BF, Applied Part
	Type B, Applied Part
	This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
Rx Only	**CAUTION:** Federal (US) law restricts this device to sale / rental by or on the order of a physician
	Humidity Limitations
	MR Unsafe
	Serial Number
	Catalog Number

Specifications

Specifications subject to change without notice.

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

Electrical:
Battery Run Life:..... ~14 hours, depending on settings
Battery Charge Time: .....~6 hours from a fully discharged state
External Power Supply Input: .....100-240VAC 0.8A 50 - 60 Hz
External Power Supply Output:.....12V, 3.3 A
Patient & Enclosure Leakage Current: .....<100 Microamps

Environmental Conditions (60601 2nd Edition):
Storage / Transport Conditions
Temperature Range: .....-4°F (-20°C) to 140°F (60°C)
Relative Humidity Range: ..... 0-95% non-condensing
Operating Conditions
Temperature Range: .....41°F (5°C) to 104°F (40°C)
Relative Humidity Range: .....15 - 95% non-condensing
Atmospheric Pressure: ..... 1060 hpa to 700 hpa

Environmental Conditions (60601 3rd Edition):
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 (60601 2nd Edition)
Medical Equipment
Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
Type B, Applied Part
Class I
IPX0

IEC Classification (60601 3rd Edition)
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.

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.acelity.com.
KCI USA, Inc. 12930 IH10 West San Antonio, TX 78249

Outside the US visit www.kci-medical.com.

CLINICIAN

Manufactured for:
KCI USA, Inc.
12930 IH10 West
San Antonio, Texas 78249 USA
www.acelity.com

All trademarks designated herein are property of KCI Licensing, Inc., its affiliates, and / or licensors.
Copyright 2018 KCI Licensing, Inc. All rights reserved. 418443Rev A 2/2018