



USER MANUAL For Clinicians

Do not discard. Please retain this user manual for future reference. For additional copies, in the US, visit www.acelity.com, www.veraflo.com and www.vaculta.com or contact KCI at 1-800-275-4524.

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



Important Safety Information Accompanies This Device



Indications, Contraindications, Warnings, Precautions and other Safety Information are contained in the V.A.C.ULTA™ Negative Pressure Wound Therapy System (V.A.C.ULTA™ Therapy System) Safety Information. This safety information booklet is provided with the therapy unit and also included in V.A.C. VERAFLO™ Dressing cartons. Please consult this V.A.C.ULTA™ Therapy System User Manual and the safety information before applying V.A.C.® Therapy or V.A.C. VERAFLO™ Therapy. Before applying PREVENA™ Therapy or ABTHERA™ Therapy, consult the safety information and instructions for use provided in PREVENA™ and ABTHERA™ Dressing cartons. If there are questions, or if the safety information is missing, immediately contact your local KCI representative.

Additional product information can be found at www.acelity.com, www.veraflo.com or www.vaculta.com (US), www.kci-medical.com (OUS).

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.

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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 (V.A.C.® GRANUFOAM™ Dressings, V.A.C.® GRANUFOAM SILVER™
 Dressings, V.A.C. WHITEFOAM™ Dressings, V.A.C. VERAFLO™ Dressings), PREVENA™ Dressings or
 ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressings and associated disposables with this product.
- · Keep this product away from heated surfaces.
- Although this product conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- · Avoid spilling fluids on any part of this product.

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

- Do not use this product while bathing / showering or where it can fall or be pulled into a tub, shower or sink.
- Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Disconnect the unit from dressing and contact KCI.
- Do not use this product in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous
 oxide, or an oxygen enriched environment.
- Do not take this product into an MR environment. This product is MR Unsafe.

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

Colors Used in this Manual





ABTHERA™ Therapy - Items and information that relate specifically to **ABTHERA™ Therapy**.



PREVENA™ Therapy - Items and information that relate specifically to PREVENA™ Therapy.



System - Items and information that relate specifically to the **V.A.C.ULTA™ Therapy Unit**.

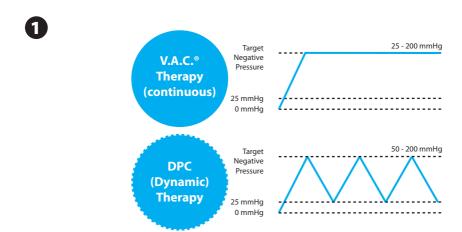
Introduction

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is an integrated wound management system that provides:

- V.A.C.® Negative Pressure Wound Therapy (1)
- V.A.C. VERAFLO™ Instillation Therapy (2)
- PREVENA™ Incision Management Therapy (3)
- ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Therapy (4).

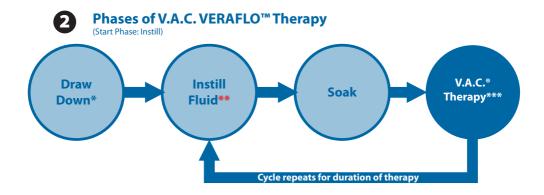
Refer to the V.A.C.ULTA $^{\text{M}}$ Negative Pressure Wound Therapy System (V.A.C.ULTA $^{\text{M}}$ Therapy System) Safety Information that accompanies the V.A.C.ULTA $^{\text{M}}$ Therapy Unit for complete Indications for Use for each of these therapies and safety and use information.

V.A.C.® Negative Pressure Wound Therapy (with two negative pressure modes):



The V.A.C.® GRANUFOAM™, V.A.C.® GRANUFOAM SILVER™ and, V.A.C. WHITEFOAM™ Dressings are available for use with the V.A.C.® Therapy option by the V.A.C.ULTA™ Therapy System. Additional dressings specific to V.A.C. VERAFLO™ Therapy are also available.

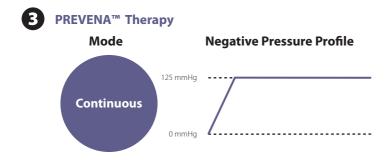
V.A.C. VERAFLO™ Instillation Therapy:



^{*} SEAL CHECK™ Leak Detector

The V.A.C. VERAFLO™, V.A.C. VERAFLO CLEANSE™ and V.A.C. VERAFLO CLEANSE CHOICE™ Dressings are available for use with the V.A.C. VERAFLO™ Therapy option provided by the V.A.C. ULTA™ Therapy System.

PREVENA™ Incision Management Therapy:

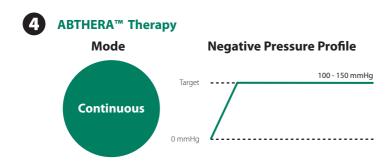


The PREVENA™ PEEL & PLACE™ and PREVENA™ CUSTOMIZABLE™ Dressings are available for use with the PREVENA™ Therapy option provided by the V.A.C.ULTA™ Therapy System.

^{**} Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VERAFLO™Therapy.

^{***} Continuous and DPC Therapy negative pressure modes are available with V.A.C. VERAFLO™ Therapy.

ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Therapy:



The ABTHERATM SENSAT.R.A.C.TM Open Abdomen Dressing is available for use with the **ABTHERA** Therapy option provided by the V.A.C.ULTATM Therapy System.

The V.A.C.ULTA™ Negative Pressure Wound Therapy System is intended to be operated by qualified clinical caregivers in the acute care setting. In-service and training programs for use of V.A.C.® Therapy, V.A.C. VERAFLO™ Therapy, PREVENA™ Therapy and ABTHERA™ Therapy are available. Therapy unit information signals should be monitored by the clinical caregiver. Patients are not expected to apply or change dressings or adjust therapy unit settings.

Therapy Selection - Allows user to select V.A.C. VERAFLO™, V.A.C.®, PREVENA™ or ABTHERA™ Therapies.

Fill Assist (V.A.C. VERAFLO™ Therapy)- Allows the user to monitor the initial wound fill by manually starting and stopping instillation to determine the appropriate instill volume after the dressing is applied. Once determined, this volume will be the set point for each future instill phase of **V.A.C. VERAFLO™ Therapy**.

Benefits:

- Removes the guesswork related to volume setting
- Helps reduce leaks caused by wound overfilling

Volumetric Delivery with Solution Dwell Time (V.A.C. VERAFLO™ Therapy) - The V.A.C. ULTA™ Therapy Unit provides unique and patented volumetric fluid delivery utilizing a pump.

Benefits:

- Delivers fluid reliably and uniformly across wound bed.
- Allows time for solubilizing infectious materials and wound debris.

Automated and Cyclic Wound Cleansing (V.A.C. VERAFLO™ Therapy) - **V.A.C. VERAFLO™ Therapy** is 100% automated after set-up, providing hands-free, repeating wound cleansing cycles through instillation of topical wound solutions.

Benefits:

- · Delivers automatic and repetitive topical wound cleansing without dressing removal.
- Eliminates need for manual wound cleansing between dressing changes.

 $V.A.C. VERALINK^m Cassette (V.A.C. VERAFLO^m Therapy)$ - This disposable component connects the V.A.C. ULTA m Therapy Unit to the solution bag / bottle and dressing tubing.

Benefits:

It provides convenient solution storage and delivery.

Dressing Soak (V.A.C.® Therapy) and **V.A.C. VERAFLO™ Therapy)**-This tool allows the clinician to soak the dressing and the wound with instillation solution in preparation for a dressing change.

Benefits:

- · Provides ability to help "float" the dressing by increasing instillation volume and soak time.
- Moistens and softens the dressing for easier removal and patient comfort.

Additional Features

Touch Screen User Interface: The touch screen user interface allows for easy navigation through operational and help menus. A screen guard is available to help prevent unintentional changes. A settings lock is available to prevent patient access to therapy settings.

Adjustable Negative Pressure Settings and Therapy Modes: Settings can be selected from a range of 25 mmHg to 200 mmHg in increments of 25 mmHg depending on settings available for selected therapy. In addition, V.A.C. **Therapy* and V.A.C. **VERAFLO*** Therapy* can be set for continuous negative pressure or Dynamic Pressure Control** (DPC) Therapy.

SEAL CHECK™ Leak Detector: This tool assists the user in finding negative pressure leaks in the system through the use of audible tones and on-screen visual aids during the troubleshooting process.

History Reports: The V.A.C.ULTA™ Therapy System provides three possible reports: 1. Alarm History, 2. Therapy History, and 3. Patient History. These chronologically logged reports include the date and times for therapy starts / stops, therapy settings, alarm occurrences, and disposable component changes. They can be reviewed on-screen or transferred electronically from the V.A.C.ULTA™ Therapy Unit via a non-powered USB flash memory stick or SD memory card.

SENSAT.R.A.C.™ System: The SENSAT.R.A.C.™ System (also incorporated in the V.A.C. VERAT.R.A.C.™ Pad, V.A.C. VERAT.R.A.C. DUO™ Tube Set, PREVENA PLUS™ Incision Management System, and ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Dressing System) monitors and maintains target pressure at the wound site, helping to deliver consistent therapy. This system includes therapy unit hardware and software, wound exudate collection canister, canister detection method, multi-lumen tubing, connector and SENSAT.R.A.C.™ Pad.



Not available with the PREVENA™ Dressing without SENSAT.RA.C.™ Pad.

In-Line Tubing Connectors: The system incorporates an in-line dressing connector and tubing clamps to conveniently allow the wound dressing to be temporarily disconnected from the therapy unit.

Canisters: The V.A.C.ULTA[™] Therapy Unit is optimized for use with 300 mL, 500 mL or 1000 mL canisters. These are the same canisters used with INFOV.A.C.[™] Therapy Unit. Canisters are single use, manufactured without natural rubber latex, sterile components.

Canister Release Button: The canister release button is illuminated and will flash when the canister is full.

Intensity Setting: Intensity is related to the time it takes to reach the target negative pressure therapy level after the initiation of therapy. The lower the intensity setting, the longer it will take to reach the target negative pressure.

Wound Image Analysis: Digital wound images can be uploaded from a digital camera into the V.A.C.ULTA™ Therapy Unit. When the wound perimeter is traced on-screen with the provided stylus, wound image surface area and volume can be calculated and trended by the therapy unit. A chronological graphical history of the wound (with wound image area trend chart) can be viewed on-screen or this information can be transferred from the V.A.C.ULTA™ Therapy Unit electronically. This information is intended to be used by the treating clinician as a mechanism for providing a record of wound healing progress; it is not intended for use in the diagnosis and treatment of wounds.

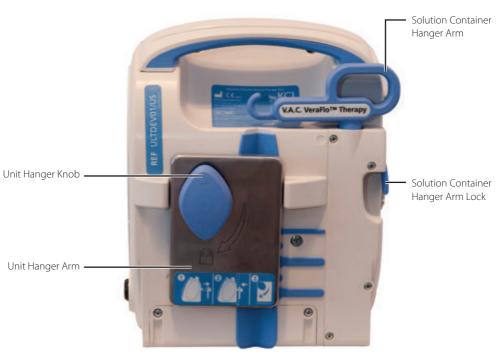
Hanger Mechanism: The therapy unit can be securely mounted to an I.V. pole, a bed footboard or a wheelchair.

Battery Operation: In order to facilitate patient transfer, battery operation is available with the V.A.C.ULTA™ Therapy Unit. During typical usage, the battery may provide up to six hours of operation before needing to be recharged.

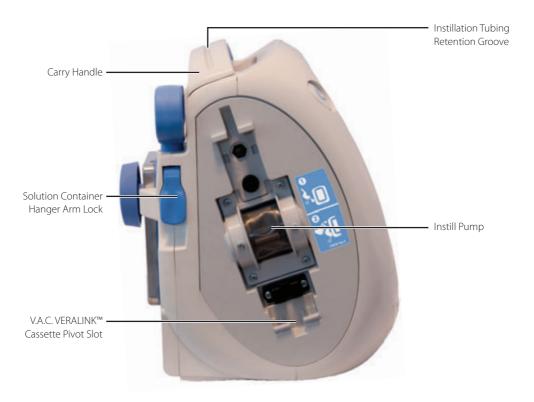
V.A.C.ULTA™ Therapy Unit Component Identification



V.A.C.ULTA™ Therapy Unit - Front



V.A.C.ULTA™ Therapy Unit - Back



V.A.C.ULTA™ Therapy Unit - Left



V.A.C.ULTA™ Therapy Unit - Right

Alert / Alarm	V.A.C. VERAFLO™ Therapy	V.A.C.° Therapy	PREVENA™ Therapy	ABTHERA™ Therapy
Blockage	ALERT	ALERT	ALERT	ALERT
Blockage (Therapy Interrupted)	ALARM	ALARM	ALERT	ALERT
Canister Full	ALARM	ALARM	ALERT	ALERT
Canister Not Engaged	ALARM	ALARM	ALERT	ALERT
Therapy Inactive	ALARM	ALARM	ALERT	ALERT
Leak	ALARM	ALARM	ALERT	ALERT
Leak (Therapy Interrupted)	ALARM	ALARM		
Low Pressure	ALARM	ALARM		
V.A.C. VERALINK™ Not Engaged	ALERT	ALERT		
Solution Bag / Bottle Empty	ALERT	ALERT		
V.A.C. VERAFLO™ Fill Assist Inactive	ALERT			
V.A.C. VERAFLO™ Pressure Deviation	ALARM	ALARM		
V.A.C. VERAFLO™ Instill Tube Blockage (Therapy Interrupted)	ALERT	ALERT		

Alert / Alarm Symbol	V.A.C. VERAFLO™ Therapy	V.A.C.® Therapy	PREVENA™ Therapy	ABTHERA™ Therapy
Battery Low	ALERT	ALERT	ALERT	ALERT
Battery Critical	ALARM	ALARM	ALERT	ALERT
Battery Exhausted	ALARM	ALARM	ALERT	ALERT
Internal Temperature	ALERT	ALERT	ALERT	ALERT
System Error	ALARM	ALARM	ALERT	ALERT

Preparation for Use

Charge Battery

The V.A.C.ULTA $^{\text{M}}$ Therapy Unit comes with its own power supply and a rechargeable battery. The battery is not user accessible or serviceable. The power supply has a two-part cord, one that plugs into an AC wall outlet and one that plugs into the V.A.C.ULTA $^{\text{M}}$ Therapy Unit.



Use only the power supply provided with the V.A.C.ULTA™ Therapy Unit (part number: 4103730). Using any other power supply may damage the V.A.C.ULTA™ Therapy Unit.



If environmental conditions (specifically, low humidity) pose a risk of static electricity, take care when handling the V.A.C.ULTA™ Therapy Unit while it is plugged into an AC wall outlet. In rare instances, discharge of static electricity when in contact with the therapy unit may cause the touch screen to darken, or the therapy unit to reset or turn off. If therapy does not restart by powering the unit off and then on, immediately contact KCI.



To isolate the therapy unit from supply mains, unplug the AC power cord from the wall outlet. Do not block access to the plug or wall outlet.



Power cords may present a tripping hazard. Ensure that all cords are out of areas where people may walk.

1. Plug the AC power cord into the DC power supply.

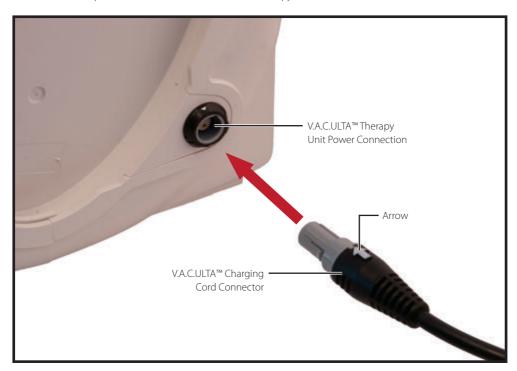


2. Plug the AC wall plug into an AC wall outlet.



DC power supply must remain accessible at all times to allow for immediate disconnect from power source, if necessary.

3. Locate the arrow on the charging cord connector. The arrow should face up as the connector is plugged into the power connection on the V.A.C.ULTA™Therapy Unit.



4. A plug indicator appears on screen while the unit is plugged into a wall outlet.





It should take approximately four hours to fully recharge the battery. To maximize battery life, keep the unit plugged in whenever possible.

When the V.A.C.ULTA™ Therapy Unit is correctly plugged into the V.A.C.ULTA™ Power Supply, the battery charging indicator light on the front of the unit (page 18) will glow amber while the battery is charging. When the battery has reached full charge the battery charging indicator light will glow green.

Therapy Unit Placement

The V.A.C.ULTA™ Therapy Unit can be attached to an I.V. pole or the footboard of a hospital bed. If required, it can be placed on a solid, level surface where it does not cause an obstruction. The V.A.C.ULTA™ Therapy Unit should be placed where cables and tubes cannot be caught on passing objects.



Power cords and tubing may present a tripping hazard. Ensure that all cords and tubing are out of areas where people may walk.

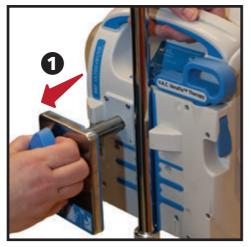


The V.A.C.ULTA $^{\text{TM}}$ Therapy Unit is not to be carried or worn by an ambulatory patient. Consult your physician and contact KCI for V.A.C. $^{\circ}$ Therapy Units designed for ambulatory patient use. The V.A.C.ULTA $^{\text{TM}}$ Therapy Unit can be placed on an I.V. pole, bed frame or wheelchair during patient transport.

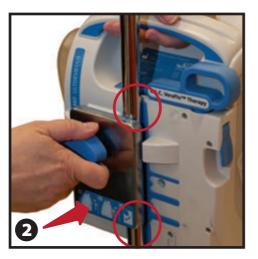
Attaching the Therapy Unit to an I.V. Pole

- 1. Hold the V.A.C.ULTA™ Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out (1).
- 3. Turn the hanger knob to lock the hanger arm in place (3). When the arrow symbol on the hanger knob aligns with the lock symbol, the hanger arm is locked.







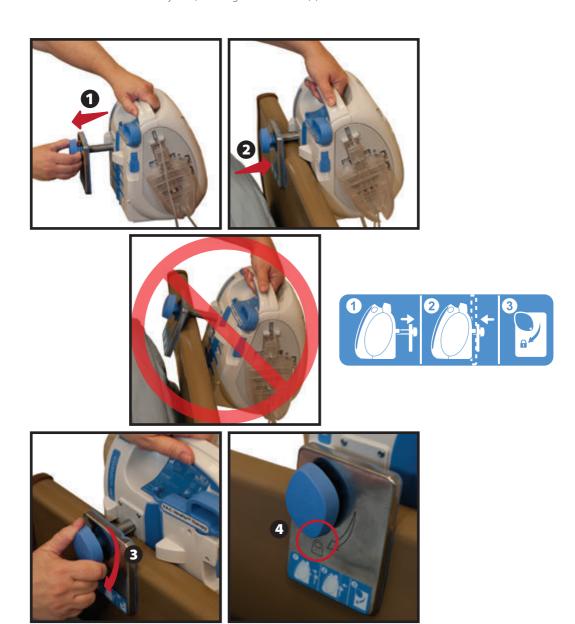




4. Reverse procedure to remove therapy unit.

Attaching the Therapy Unit to a Bed Footboard

- 1. Hold the V.A.C.ULTA™ Therapy Unit by the carry handle, grip the hanger knob and pull the hanger arm out (1).
- 2. Place the hanger over the footboard. Allow the hanger to close, pulling the unit onto the footboard (2).
- 3. Turn the hanger knob to lock the hanger arm in place (3). When the arrow symbol on the hanger knob aligns with the lock symbol, the hanger arm is locked (4).



4. Reverse procedure to remove therapy unit.



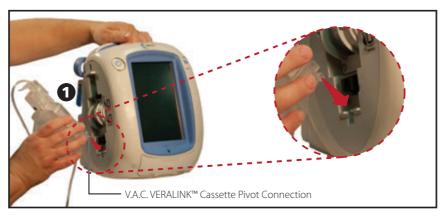
For use only with the V.A.C. $^{\circ}$ Therapy when using the Dressing Soak Feature or V.A.C. VERAFLOTM Therapy.



- Remove the V.A.C. VERALINK™ Cassette from packaging and insert the pivot connection of the V.A.C. VERALINK™ Cassette (1) into the pivot slot on the V.A.C.ULTA™ Therapy Unit.
- Pivot the V.A.C. VERALINK™ Cassette Release Tab toward the unit (2) and press firmly until it clicks into place (3).



The V.A.C. VERALINK $^{\text{TM}}$ Cassette is designed to fit tight to the therapy unit. Apply very firm pressure to ensure the cassette is properly installed.













For use only with the V.A.C.® Therapy when using the Dressing Soak Feature or V.A.C. VERAFLO™ Therapy

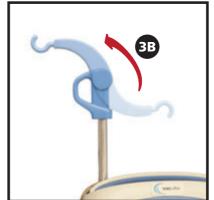
Extend Solution Container Hanger Arm:

- 1. Fully lift the solution container hanger arm lock (1).
- 2. Raise solution container hanger arm (2). Depending on unit, either rotate the handle 180 degrees (3A) or flip the handle up (3B).
- 3. Fully push the solution container hanger arm lock down (4) to lock solution container hanger arm in place.







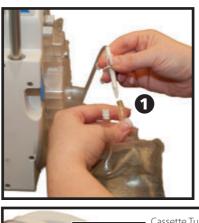




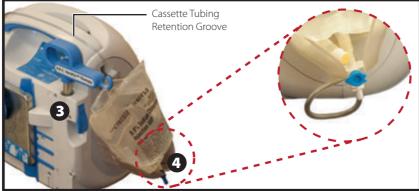


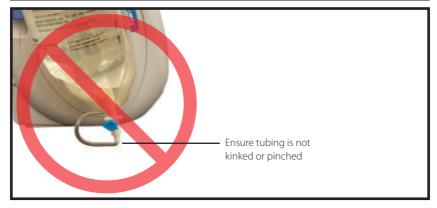
For use only with the V.A.C.® Therapy Dressing Soak Feature or V.A.C. VERAFLO™ Therapy.

- 1. Ensure cassette tubing is routed in the retention groove on the unit handle by applying pressure to push tubing into the groove.
- 2. Spike solution bag / bottle according to manufacturer's instructions using the V.A.C. VERALINK™ Cassette's tubing spike (1).
- 3. Hang the solution bag / bottle from the therapy unit's solution container hanger arm (2).
- 4. Adjust the solution container hanger arm (3) while manipulating the bag / bottle to ensure that the spike is held inside the slot in the V.A.C. VERALINK™ Cassette Basket (4).







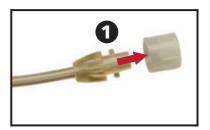


For use only with the V.A.C.® Therapy Dressing Soak Feature or V.A.C. VERAFLO™ Therapy.

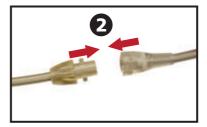


Refer to the appropriate dressing Instructions for Use for safety information and procedures to apply and change the dressing.

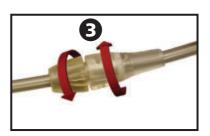
Remove the cap from the end of the V.A.C. VERALINK™
 Cassette tubing (1).



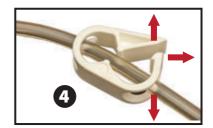
 Connect the V.A.C. VERALINK™ Cassette tubing to the instillation line of the V.A.C. VERAT.R.A.C.™ Pad / V.A.C. VERAT.R.A.C. DUO™ Tube Set by pushing the connectors together (2).



3. Twist connectors until the locking tabs are fully engaged (3).



4. Open all tubing clamps (4).





When selecting canister size (300 mL, 500 mL, 1000 mL), consider the amount of wound exudate and selected therapy. If delivering V.A.C. VERAFLO™ Therapy, also consider the amount of wound instillation fluid and frequency of instillation.



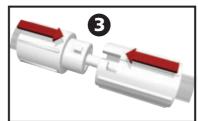
If delivering PREVENA™ Therapy, consider using the smallest available canister for the V.A.C.ULTA™ Therapy Unit.

- 1. Slide the canister into the side of the V.A.C.ULTA™ Therapy Unit (1)
- 2. Push the canister (500 mL shown) firmly into place on the V.A.C.ULTA™Therapy Unit (2). An audible click indicates the canister is fully seated. Ensure the canister is installed directly onto the therapy unit. Do not twist or turn the canister as it is being installed.



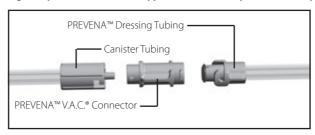


3. Connect the canister tubing to the dressing tubing by pushing the connectors together (3).

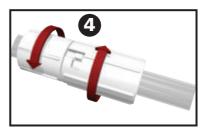




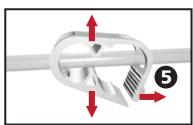
A PREVENA™ V.A.C.® Connector will be needed to connect the PREVENA™ Dressing to the V.A.C.ULTA™ Therapy Unit Canister. This connector, which is available in the PREVENA™ Dressing package, must be used for negative pressure wound therapy to work effectively and accurately.



4. Twist connectors until the locking tabs are fully engaged (4).



5. Open all tubing clamps (**5**).



Changing the Canister

A canister may be changed under routine conditions or under alarm conditions. Under routine conditions the canister release button will NOT be flashing. When changing the canister **DO NOT** power off the V.A.C.ULTA™ Therapy Unit.

Under Canister Full Alarm conditions, the canister release button (page 18) will be flashing, an alert / alarm screen (pages 56, 90, 116 and 134) will be displayed and therapy will be off (unit power remains on).



When delivering PREVENA™ Therapy, a canister change should not be required. Contact the treating physician immediately if a Canister Full Alarm occurs during PREVENA™ Therapy.



The canister used for V.A.C. ° Therapy, V.A.C. VERAFLO™Therapy and ABTHERA™ Therapy should be changed when full (the alarm will sound), or at least once a week to control odor.



If a Canister Full Alarm has occurred, pump will be OFF. Proceed to Step 2.

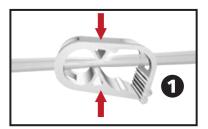


. V.A.C.® Therapy, PREVENA™ Therapy, ABTHERA™ Therapy - Stop therapy by selecting Start / Stop on the touch screen. Do not turn power off to the V.A.C.ULTA™ Therapy Unit.

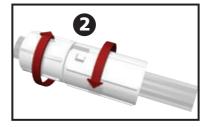


V.A.C. VERAFLOTM **Therapy** - Stop therapy by selecting **Pause / Resume** on the touch screen. Do not turn power off to the V.A.C.ULTA TM Therapy Unit.

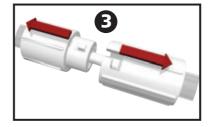
- 2. Slide both tubing clamps toward the tubing connector.
- 3. Tightly close both tubing clamps (1) to prevent spillage of contents in tubing. Several clicks should be heard.



4. Twist the tubing connectors until the locking tabs are disengaged (2).



5. Pull the connector apart (3) to disconnect the dressing tubing from the canister tubing.





6. Press the Canister Release Button.



If the 300 mL ACTIV.A.C.™ Canister is used, it is NOT held in place by the cradle of the V.A.C.ULTA™ Therapy Unit. When removing the 300 mL ACTIV.A.C.™ Canister from the V.A.C.ULTA™ Therapy Unit, hold the canister FIRMLY before pressing the canister release button.

7. Remove the canister from the therapy unit by lifting and pulling the canister away from the unit (4).





Dispose of the used canister according to institution and / or local environmental regulations.

8. Install the new canister and reconnect tubing as described in the **Canister Installation** section (page 32) of this user manual.



 V.A.C.° Therapy, PREVENA™ Therapy, ABTHERA™ Therapy - Select Start / Stop on the touch screen to restart therapy.



V.A.C. VERAFLO™ Therapy - Select Pause / Resume on the touch screen to restart therapy.

Operation

This chapter contains instructions for setting and adjusting functions of the V.A.C.ULTA™Therapy Unit.

Review all sections of this manual prior to product use. Carefully read the Indications, Contraindications, Warnings, and Precautions included with the unit prior to operating the V.A.C.ULTA $^{\text{m}}$ Therapy Unit.

Touch Screen

The display on the front of the unit is touch sensitive. The user interface screens will be shown on this display. These screens will display information on current system operations and settings based on the tab selected (**Therapy, History** or **Utilities**).

The operation of the touch screen is detailed in the following pages.

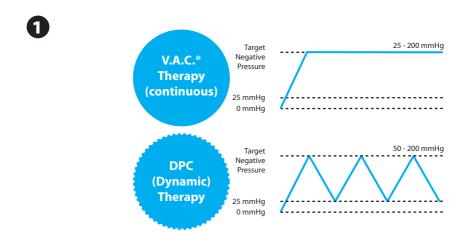


The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen.

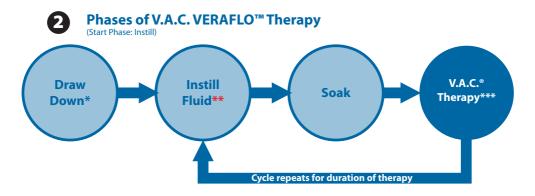
V.A.C.ULTA™ Therapy System - Therapy Options

The V.A.C.ULTA™ Therapy System can be used with four different therapies depending on physician orders:

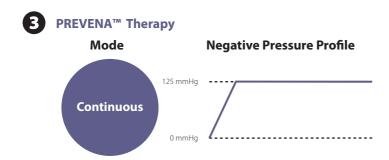
V.A.C.® Negative Pressure Wound Therapy (1):



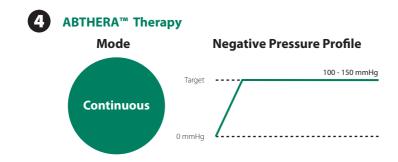
V.A.C. VERAFLO™ Instillation Therapy (2):



- * SEAL CHECK™ Leak Detector
- ** Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VERAFLO™Therapy.
- *** Continuous and DPC Therapy negative pressure modes are available with V.A.C. VERAFLO™ Therapy.

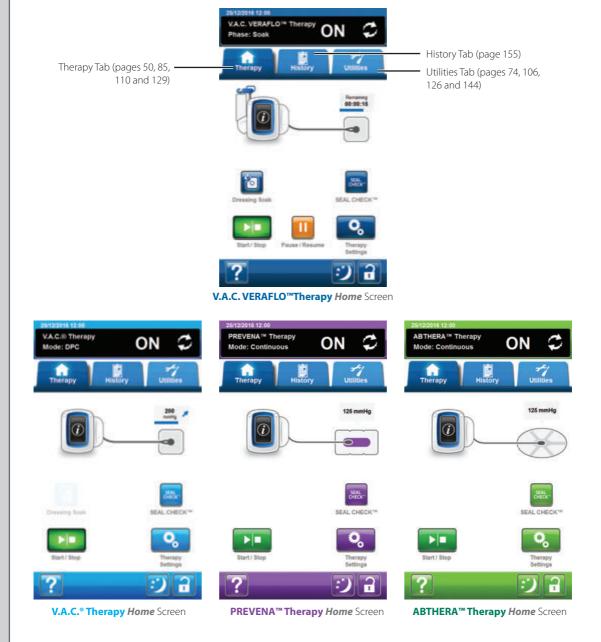


ABTHERA™ SENSAT.R.A.C.™ Open Abdomen Therapy (4):



Touch Screen - Tabs

The touch screen is divided into three sections, each marked by a separate tab. These tabs allow access to the different areas of the V.A.C.ULTA™Therapy Unit's software.



Therapy Tab - (pages 50, 85, 110 and 129) Use to access the *Home* screen, therapy settings, features and active therapy summary information. Use the Therapy Settings button on the Therapy Tab to select prescribed therapy (V.A.C. VERAFLO™ Therapy, V.A.C. Therapy, PREVENA™ Therapy or ABTHERA™ Therapy).

History Tab - (page 155) Use to access to all therapy history for the patient.

Utilities Tab - (pages 74, 106, 126, 144) Use to access therapy related features and to set system preferences including language, unit of measure, date, screen brightness, etc. KCI contact information and software version can also be viewed.

Common Touch Screen Buttons

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



Help - Access Help screens



Screen Guard / Settings Lock- Activate the **Screen Guard** feature to prevent unintentional changes. This feature should be used when cleaning the touch screen (page 192). Select and hold for more than five seconds to activate or deactivate **Settings Lock**. Settings Lock prevents patient access to therapy settings.



Night Mode - Activate Night Mode feature to darken the touch screen. When Night Mode is active, the display will turn on at lowest brightness setting when the touchscreen is touched. To cancel Night Mode, select **Night Mode** to return to previous brightness setting.



OK - Confirm selection



Exit - Close pop-up screen



Cancel - Cancel operation



Back - Return to previous screen



Forward - Advance to next screen





+ or - - Use + / - to adjust above or below values shown.



Information - Select to view Therapy Summary and Current Settings screens for the active therapy.



Start / Stop - Select to restart therapy (V.A.C.® Therapy, PREVENA™ Therapy, ABTHERA™ Therapy).



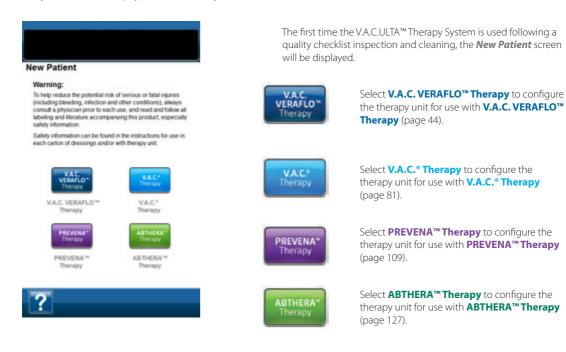
Pause / Resume - Select to restart therapy (V.A.C. VERAFLO™ Therapy).

Power the V.A.C.ULTA™ Therapy Unit On or Off



The **Power** button is located in the upper left hand corner on the front of the unit (page 18). Press and hold the **Power** button until the light comes on to turn the V.A.C.ULTA™ Therapy Unit on. The unit will go through a self-check routine and then present the *Startup* screen. Press and hold the **Power** button until the display turns off to turn the V.A.C.ULTA™ Therapy Unit off.

The **Startup** screen will be displayed one of two ways:





A new therapy mode can not be selected until the current therapy mode is stopped. The selection button for the inactive therapies will not be available.



Startup

Warning:

To help reduce the potential risk of serious or fatal injuries (including bleeding, infection and other conditions), always consult a physician prior to each use, and read and follow all labeling and filerature accompanying this product, especially safety information.

Safety information can be found in the instructions for use in each carton of dressings and/or with therapy unit.





Continue Therapy - Select to accept **Warning** and return to previously used therapy *Home* screen (pages 50, 85, 110 and 129).

If the V.A.C.ULTA[™] Therapy Unit has been previously set up and the unit is power cycled (turned off then back on), the *Startup* Screen

will display Continue Therapy and QC Checklist.



QC Checklist - Select to accept the **Warning** and proceed to Quality Checklist inspection process.

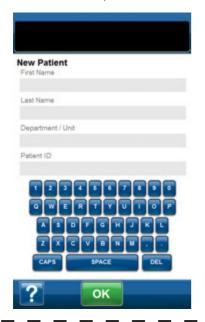


Accompanying Service Documentation is required to use QC Checklist functions. Please contact KCI for more information.



New Patient Screen

Use this screen to enter the patient's information into the V.A.C.ULTA™ Therapy Unit. Patient information is encrypted.





Therapy configuration may not display this

Use the onscreen keyboard to enter the following:

- Patient's First Name
- Patient's Last Name
- Patient's Department / Unit
- Patient's (Identification) ID



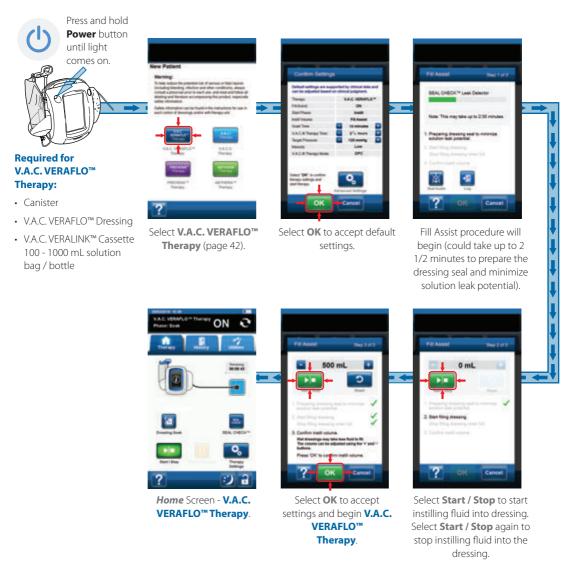
Once this information has been entered, select **OK** to continue to the **Choose Therapy** screen.



At least one character must be entered into each entry row.

V.A.C. VERAFLO™ Therapy Configuration - Default Settings Overview

The following flow chart shows the basic steps required to configure **V.A.C. VERAFLO™ Therapy** using the **Default** settings. Refer to the pages listed for detailed information about individual screens and options.





Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.



Settings displayed will vary depending on settings defined by user.

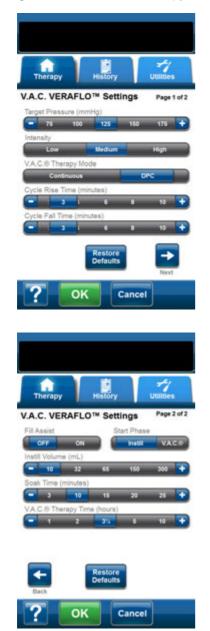
V.A.C. VERAFLO™ Therapy Configuration - Advanced User Defined Settings Overview

The following flow chart shows the basic steps required to configure **V.A.C. VERAFLO™ Therapy** with User defined settings including turning Fill Assist OFF. Refer to the following pages for detailed information about individual screens and options.



Home screen - V.A.C VeraFlo™ Therapy defined by user.

Configure V.A.C. VERAFLO™ Therapy - Advanced User Defined Settings



These screens are used to configure the V.A.C.ULTA™ Therapy Unit to deliver V.A.C. VERAFLO™ Therapy:

- Target Pressure (mmHg) (Default = 125 mmHg)
 Prescribed negative pressure level for V.A.C.® Therapy
 phase. Target Pressure can be set from 50 200 mmHg
 in 25 mmHg increments.
- Intensity (Default = Medium) Related to the time it takes to reach the target pressure after the initiation of therapy. The lower the intensity setting, the slower the target pressure 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.
- V.A.C. Therapy Mode (Default = Continuous)
 Available modes include Continuous and DPC.
 Continuous provides constant negative pressure at selected Target Pressure. DPC provides negative pressure between preset low pressure (25 mmHg) and selected Target Pressure.
- Cycle Rise Time (Default = 3 minutes) Time used to transition from the preset low pressure (25 mmHg) to the selected target pressure while using DPC. Cycle Rise Time can be set from one minute to 10 minutes in one minute increments.
- Cycle Fall Time (Default = 3 minutes) Time used to transition from the selected target pressure to the preset low pressure (25 mmHg) while using DPC. Cycle Fall Time can be set from one minute to 10 minutes in one minute increments.





- Select desired value by selecting or sliding finger / stylus along bar. Use + / - to adjust above or below values shown.
- Fill Assist (Default = ON) Fill Assist allows the user to monitor initial wound fill by manually starting and stopping instillation to determine correct instill volume after dressing is applied. Once determined, this volume will be the set point for each subsequent instill phase of V.A.C. VERAFLO™ Therapy (page 48).
- Start Phase (Default = Instill) (Default = 10 mL if Fill Assist is Off). Sets first phase of V.A.C. VERAFLO™ Therapy (pages 14 and 38).
- Soak Time (minutes) (Default = 10 minutes)
 Duration of time instilled solution will remain in wound during each soak phase of V.A.C. VERAFLO™ Therapy.
 Soak Time can be set from 1 second to 30 minutes with varying increments.
- V.A.C.® Therapy Time (hours) (Default = 3 1/2 hours) Duration of time that negative pressure will be applied during each V.A.C.® Therapy phase of V.A.C. VERAFLO™ Therapy. V.A.C.® Therapy Time can be set from 3 minutes to 12 hours with varying increments.



 Select Next to continue to the V.A.C. VERAFLO™ Settings (page 2 of 2) screen.



Select **Restore Defaults** to return all therapy settings to their defaults.



 Once all settings have been entered or defaults restored, select OK to continue to the Confirm Settings screen. This screen allows the user to review the therapy settings that were selected on the V.A.C. VERAFLO™ Settings screen.



Confirm Settings

FilAssist

Instill Volume:

Soak Time:

V.A.C.® Therapy Mode:

OK

VA.C.® Therapy Time:

Target Pressure:

Select "OK" to confirm therapy settings and start therapy

Start Phase:

Default settings are supported by clinical data and can be adjusted based on clinical judgment.

VA.C. VERAFLO™

ON

Instill

Fill Assist

10 minutes

5% hours

125 mmHg

Low

DPC

Cancel



4. Use + / - to adjust above or below values shown.



Select **Advanced Settings** to return to the **V.A.C. VERAFLO™ Therapy Settings** screen to make any required adjustments.



 Select **OK** to initiate therapy and continue to the **SEAL CHECK™ Leak Detector** screen.

OR



6. Select **Cancel** to return to the **New Patient** screen.



Fill Assist Screens

These screens will display the status of the Fill Assist sequence.





Drawdown can take up to two minutes and thirty seconds to prepare the dressing seal to minimize solution leak potential. During this drawdown, observe the dressing for leaks. The SEAL CHECK $^{\text{TM}}$ Leak Detector time is designed to help minimize the potential for leaks by pulling the drape against the skin and allowing the adhesive time to cure.

Fill Assist (1) will begin to draw down the dressing to prepare the dressing seal to minimize solution leak
potential. Once the V.A.C.ULTA™ Therapy Unit has reached target pressure and determined that the dressing
air leaks are small enough to continue V.A.C. VERAFLO™ Therapy, the therapy unit will continue to the Fill
Assist screen.



Seal Audio - (**Default = OFF**) Audible tone used to find and repair leaks. Select to turn seal audio tone on or off.



Log - Used to record disposable component change (page 150).



. Select **Start / Stop** on the *Fill Assist* screen to begin delivering solution to the wound (2).



During the use of Fill Assist it is possible to exceed the soak time for a solution. Consider elapsed time in comparison to the selected soak time while using this tool.

3. Monitor the wound as it fills with solution.



4. Select **Start / Stop** again to stop solution delivery when suitable fill volume has been delivered to the wound bed.



Overfilling wound may compromise dressing seals.



5. Use +/- to adjust the fluid volume if required.



5. Select **OK** (**3**) to confirm the determined fluid volume as displayed on the *Fill Assist* screen and return to the *Home* screen (page 50). The therapy unit will then begin the soak phase.



If OK is not selected within 15 minutes of starting Fill Assist or within 15 minutes of stopping Fill Assist, the V.A.C.ULTA™ Therapy Unit will transition to V.A.C.® Therapy phase and the Fill Assist volume will not be recorded.



If wound has been over-filled, solution needs to be removed, or Fill Assist needs to be restarted, select Reset to remove solution from the wound and return to the Fill Assist screen.

Home Screen - V.A.C. VERAFLO™ Therapy

This *Home* screen is the main screen displayed by the V.A.C.ULTA™ Therapy Unit during **V.A.C. VERAFLO™ Therapy**. It is used to access important information about the Therapy Status.



Therapy phase and status (**ON**, **OFF** or **PAUSED**) will be displayed in the status bar at the top of the screen. The current therapy phase will also appear under the icon of the therapy unit or above the dressing.

The following options are available from the *Home* screen:

Therapy Settings - Use to change current therapy settings.

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Information - Use to view a summary of therapy history and current therapy settings (page 51).

Start / Stop - Use to start or stop therapy.

Pause / Resume - Use to pause or resume therapy.

Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

Leak Detection - If the therapy unit detects a leak in the system temporarily above the Leak Alarm threshold, the *Home* screen for **V.A.C. VERAFLO™ Therapy** will display a yellow box around the dressing. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.

Refer to page 41 for a list of **Common Touch Screen Buttons** not described here.

Information Screens - V.A.C. VERAFLO™ Therapy

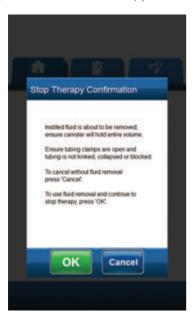
These screens will display the current therapy settings and a summary of therapy applied to the patient.





- Select Information from the Home screen to continue to the Therapy Summary tab. Use this tab to
 review the Therapy Start Date, Therapy Time, V.A.C.* Time, Soak Time, Therapy Cycles and Instilled Volume. If
 the Log feature is used, the date and time for Canister Last Changed, Cassette Last Changed, Dressing Last
 Changed and Solution Last Changed will also be displayed.
- Select Current Settings to continue to the Current Settings screen. Use this tab to review the current therapy settings.
- 3. Select Change Settings to continue to the Confirm Settings screen (page 47).
- 4. Select *Exit* to return to the *Home* screen for **V.A.C. VERAFLO™ Therapy**.

Stop V.A.C. VERAFLO™ Therapy Confirmation





 If therapy is being provided, select Start / Stop from the Home screen to continue to the Stop Therapy Confirmation screen.

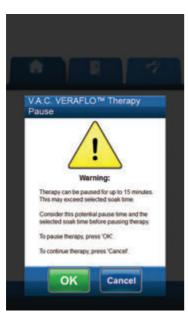


Select **OK** to stop therapy. Select **Cancel** to return to the **Home** screen without stopping therapy.



Instilled fluid will be removed; ensure canister can hold the entire volume. Ensure tubing clamps are open and tubing is not kinked, collapsed or blocked.

V.A.C. VERAFLO™ Therapy Paused





If therapy is being provided, select
 Pause / Resume from the Home screen
 to continue to the V.A.C. VERAFLO™
 Therapy Pause screen.



 Select OK to pause therapy. Select Cancel to return to the *Home* screen for V.A.C. VERAFLO™ Therapy without pausing therapy.



Therapy can be paused for up to 15 minutes. This may exceed selected soak time. Consider this pause time and the selected soak time before pausing therapy.

V.A.C. VERAFLO™ Therapy Alerts and Alarms

The following alerts and alarms may appear on the touch screen during **V.A.C. VERAFLO™ Therapy**.

Alerts and alarms are accompanied by a repeating audible tone.

Following initiation of therapy, if an audible tone is not heard when SEAL CHECK™ Leak Detector is displayed and Seal Audio tone is turned ON, the alarms may not be working properly. Contact KCl for more information. Alarms are intended to be heard when facing the therapy unit at a maximum of one meter away. If two or more alarm conditions are present, only the highest priority alarm will be displayed.

Low Priority Alert Condition - Displayed on the touch screen when the V.A.C.ULTA $^{\mathsf{M}}$ Therapy Unit detects a condition that requires attention. Alerts will be accompanied by a repeating audible tone approximately every 20 seconds (two beeps).

Medium Priority <u>Alarm</u> Condition - Displayed on the touch screen when the V.A.C.ULTA™ Therapy Unit detects a condition that requires prompt attention in order to ensure the prescribed therapy is being delivered. Alarms will be accompanied by a repeating audible tone approximately every two seconds (three beeps) and a flashing screen title.



Select **Seal Audio** to turn the audible tone ON.



Select **Help** for more information regarding alarm resolution.



If alert or alarm conditions cannot be resolved, contact KCI.

V.A.C. VERAFLO™ Therapy Blockage Alert

Low Priority Alert - This alert screen appears when the V.A.C.ULTA™ Therapy Unit has detected a potential blockage in the V.A.C.® Therapy line. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the *V.A.C.* * *Therapy Blockage Alert* remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



5. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



If alarm condition cannot be resolved, contact KCI.

V.A.C. VERAFLO™ Therapy Blockage Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a blockage is present in the V.A.C.® Therapy line. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- If the V.A.C.° Therapy Blockage Alarm (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



If alarm condition cannot be resolved, contact



V.A.C. VERAFLO™ Therapy Canister Full Alarm (Therapy Interrupted)

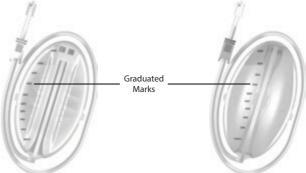
Medium Priority Alarm - This alarm screen appears when the canister is full and should be replaced. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Check if canister is full by comparing the level of fluid to the graduated marks on the canister.





A full canister is approximately 300 mL, 500 mL or 1000 mL depending on canister used. Canister release button will be flashing.



- 3. If canister is not full, select **Reset** to return to the *Home* screen.
- If canister is full, change canister and select Reset on this screen to return to the *Home* screen. See the **Changing** the Canister section of this manual (page 34) for additional information.



5. Select **Pause / Resume** to restart therapy.



V.A.C. VERAFLO™ Therapy Canister Not Engaged Alarm

Medium Priority Alarm - This alarm screen appears when the canister is not fully inserted and / or properly latched. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



 Select Audio Pause to silence alarm for two minutes during troubleshooting.



- Remove the canister by pressing the Canister Release button (page 18) on the unit.
- 3. Inspect the canister and V.A.C.ULTA™Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
- 4. Ensure both seals are present and seated completely (page 19). If seals are missing or damaged, contact KCI.
- 5. Re-attach the canister to the V.A.C.ULTA™ Therapy Unit ensuring that the canister is fully engaged and latched (page 32). An audible click indicates that the canister is properly installed.



6. Select **Reset** to return to the **Home** screen.



- 7. Select **Pause / Resume** to restart therapy.
- 8. If this alarm continues to appear, repeat steps 2 7 with a new canister.



If alarm condition cannot be resolved, contact KCI.

V.A.C. VERAFLO™ Therapy Therapy Inactive Alarm

Medium Priority Alarm - This alarm screen appears when therapy (**V.A.C. VERAFLO™ Therapy**) has been off or paused for more than 15 minutes (with the unit powered on). This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.



2. Select **Reset** to return to the **Home** screen



3. Select **Start / Stop** to restart therapy.



 If therapy is not desired, turn the V.A.C.ULTA™Therapy Unit off by using the Power button on the front of the unit.



V.A.C. VERAFLO™ Therapy Leak Alarm

Medium Priority Alarm - This alarm screen appears when a significant negative pressure leak has been detected. If this alarm is not resolved in three minutes, therapy will be interrupted. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing is properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alarm, page 57).



- Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the V.A.C. VERAFLO™ Therapy Leak
 Alarm screen.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the Status Bar (page 50). If not, select **Start / Stop** to restart therapy.



If this alarm is not resolved within three minutes, the V.A.C. VERAFLO™ Therapy Leak Alarm (Therapy Interrupted) will appear and therapy will stop.

Refer to V.A.C. VERAFLO™ Therapy Leak Alarm (Therapy Interrupted) section of this manual (page 60) for procedures to restart therapy.

V.A.C. VERAFLO™ Therapy Leak Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a detected negative pressure leak has not been resolved and therapy has been interrupted. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing is properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alarm, page 57).



 Select **Reset** to return to the **Home** screen.



5. Restart therapy by selecting **Start / Stop**.



- 6. Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the Home screen.



If the leak condition is not resolved, an alarm screen will reappear after several minutes.

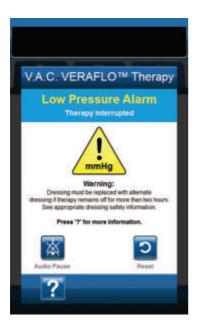


If alarm condition cannot be resolved, contact KCI.



V.A.C. VERAFLO™ Therapy Low Pressure Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the V.A.C.ULTA™ Therapy Unit has not reached the target therapy negative pressure setting and negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits. This alarm is accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- If the V.A.C. Therapy Low Pressure Alarm (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.



5. Select **Reset** to return to the **Home Screen**.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



If alert condition cannot be resolved, contact KCI.



V.A.C. VERAFLO™ Therapy V.A.C. VERALINK™ Not Engaged Alert

Low Priority Alert - This alert screen appears when the V.A.C. VERALINK $^{\text{TM}}$ Cassette is not fully seated and / or properly latched. This alert will be accompanied by a repeating audible tone.



During V.A.C. VERAFLOTM Therapy the V.A.C.ULTATM Therapy Unit will transition to the Soak Phase upon initiation of this alert and will continue to the V.A.C. $^{\circ}$ Therapy Phase before repeating the cycle. If V.A.C. VERALINKTM Cassette is correctly engaged prior to the completion of the V.A.C. $^{\circ}$ Therapy Phase, the V.A.C. VERAFLOTM Therapy cycle will not be interrupted.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Remove the V.A.C. VERALINK™ Cassette from the unit by pushing down on the cassette latch release tab (page 28).
- Inspect the V.A.C. VERALINK™ Cassette and the V.A.C.ULTA™
 Therapy Unit to ensure no foreign objects or debris interfere with the cassette and the therapy unit connection points.
- 4. Ensure the cassette's pivot connection (on the end with the tubing spike) is securely engaged within the pivot slot on the therapy unit (page 28).
- Re-attach the V.A.C. VERALINK™ Cassette to the therapy unit ensuring that the cassette is fully engaged and latched (page 28). An audible click indicates that the cassette is properly installed.



Once the V.A.C. VERALINK™ Cassette is properly installed, the V.A.C. VERALINK™ Not Engaged Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



- Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.
- If this alert condition continues to appear, repeat steps 2 - 7 with a new V.A.C. VERALINK™ Cassette.



If alert condition cannot be resolved, contact

V.A.C. VERAFLO™ Therapy Solution Bag / Bottle Empty Alert

Low Priority Alert -This alert screen appears when there is no instillation fluid in the solution bag / bottle. This alert will be accompanied by a repeating audible tone.



During V.A.C. VERAFLOTM Therapy the V.A.C.ULTATM Therapy Unit will transition to the Soak Phase upon initiation of this alert and will continue to the V.A.C. $^{\circ}$ Therapy Phase before repeating the cycle. If solution bag / bottle is changed prior to the completion of the V.A.C. $^{\circ}$ Therapy Phase, the V.A.C. VERAFLOTM Therapy cycle will not be interrupted.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Remove empty solution bag / bottle from V.A.C. VERALINK™
 Cassette.
- Attach new solution bag / bottle. Refer to Hang Solution Container Bag / Bottle section of this manual (page 30) for more information.
- 4. Place new bag / bottle on the adjustable solution container hanger arm (page 30).



 Select Log to enter the solution bag / bottle change. Refer to the Log screen section (page 150) for more information.



6. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.

V.A.C. VERAFLO™ Therapy Fill Assist Inactive Alert

Low Priority Alert - This alert screen appears if the Fill Assist volume has not been accepted within 15 minutes of using Fill Assist. This alert will be accompanied by a repeating audible tone



To resolve this alert:



 Select **Audio Pause** to silence alert for two minutes during troubleshooting.



- 2. Select **Reset** to return to the **Home** screen.
- 3. Select **Therapy Settings** on the *Home* screen (page 50).
- 4. Reconfigure therapy (page 46).



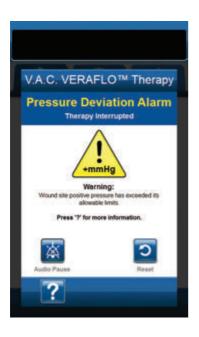
If alert condition cannot be resolved, contact KCI.

V.A.C. VERAFLO™ Therapy Pressure Deviation Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the wound site positive pressure has exceeded its allowable limits. This alarm will be accompanied by a repeating audible tone.



During V.A.C. VERAFLOTM Therapy the V.A.C.ULTATM Therapy Unit will transition to the Soak Phase upon initiation of this alarm and will continue to the V.A.C. $^{\circ}$ Therapy Phase before repeating the cycle. If pressure deviation condition is resolved prior to completion of the V.A.C. $^{\circ}$ Therapy Phase, the V.A.C. VERAFLOTM Therapy cycle will not be interrupted.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C. VERAT.R.A.C.™ Pad or the V.A.C. VERAT.R.A.C. DUO™ Tube Set and V.A.C. VERALINK™ Cassette tubing are open.
- 3. Ensure that the tubing is not kinked, crimped or blocked in any way.
- If the V.A.C. VERAFLO™ Therapy Pressure Deviation Alarm (Therapy Interrupted) remains after completing steps 2 and 3, check patient positioning or any external compression devices that may impede flow. Remove external compression device.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



If alarm condition cannot be resolved, contact KCI.



V.A.C. VERAFLO™ Therapy Instill Tube Blockage Alert (Therapy Interrupted)

Low Priority Alert - This alert screen appears when a blockage is present in the instillation line of the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™Tube Set. This alert will be accompanied by a repeating audible tone.



During V.A.C. VERAFLOTM Therapy the V.A.C.ULTATM Therapy Unit will transition to the Soak Phase upon initiation of this alert and will continue to the V.A.C. $^{\circ}$ Therapy Phase before repeating the cycle. If blockage is resolved prior to completion of the V.A.C. $^{\circ}$ Therapy Phase, the V.A.C. VERAFLOTM Therapy cycle will not be interrupted.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set and V.A.C. VERALINK™ Cassette are open.
- 3. Ensure that the tubing is not kinked, crimped, or blocked in any way.
- Ensure the V.A.C. VERALINK™ Cassette is fully engaged and latched. See the Attaching the V.A.C. VERALINK™ Cassette to the V.A.C.ULTA™ Therapy Unit section (page 28) of this manual for more information.
- Ensure that the instillation solution in the V.A.C. VERALINK™
 Cassette tubing is still liquid and flows freely. If the solution
 has degraded to a thicker consistency, change any or all of
 the following:
 - V.A.C. VERALINK™ Cassette
 - V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set
 - · Solution bag / bottle
- If the V.A.C. VERAFLO™ Therapy Instill Tube Blockage
 Alert remains after completing steps 2 5, check patient
 positioning or any external compression devices that may
 impede flow. If applicable, remove external compression
 device.



7. Select **Reset** to return to the **Home** screen.



Alert screen will clear when the blockage is corrected.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



If alarm condition cannot be resolved, contact KCI.



V.A.C. VERAFLO™ Therapy Battery Low Alert

Low Priority Alert - This alert screen appears approximately two hours before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Connect the therapy unit to a wall outlet using the KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicate the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA $^{\intercal}$ Therapy Unit is plugged into a wall outlet, the Battery Low Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



Therapy continues.

V.A.C. VERAFLO™ Therapy Battery Critical Alarm

Medium Priority Alarm - This alarm screen appears approximately 30 minutes before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- 1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- Connect the therapy unit to a wall outlet using KCl supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.
- 0

Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Critical Alarm screen will automatically clear.



 If the Battery Critical Alarm screen does not automatically clear, select Reset to return to the Home screen.



V.A.C.° Therapy continues and V.A.C. VERAFLO™ Therapy transitions to V.A.C.° Therapy phase after approximately five minutes; however, if this alarm is not resolved within approximately thirty minutes, therapy will be interrupted.



 Ensure therapy is ON by checking the status bar (page 50). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy must be plugged into a wall outlet in order to continue therapy.

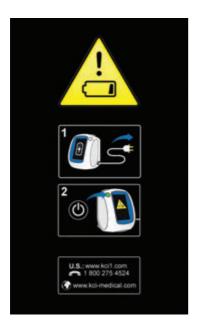


Alarm logs and settings are not lost in the case of a total power loss or if the unit is power cycled (turned off then back on).



Battery Exhausted Alarm

Medium Priority Alarm - This alarm screen appears when the battery power level is too low to power on the V.A.C.ULTA™ Therapy Unit.



To resolve this alarm:

- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.
- Power the V.A.C.ULTA™ Therapy Unit on and initiate therapy. Refer to the **Power the V.A.C.ULTA™ Therapy Unit On or Off** section of this manual (page 42) for more information.

V.A.C. VERAFLO™ Therapy Internal Temperature Alert

Low Priority Alert - This alert screen appears when the internal temperature of the V.A.C.ULTA™ Therapy Unit is outside its specified limits. This alert will be accompanied by a repeating audible tone.





Therapy will continue while this alert is active. The touch screen will be turned off after five minutes of inactivity. The screen will illuminate when touched. Battery charging is stopped.

To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Move the therapy unit to an environment with an operational temperature range as detailed in the **Specifications** section of this manual (page 194).



It may take up to two hours for the therapy unit to return to operating temperatures.



Select **Reset** to return to the **Home** screen.



Therapy continues.



If alarm condition cannot be resolved, contact KCI.



V.A.C. VERAFLO™ Therapy System Error Alarm (Therapy Interrupted) (after Power On)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit after it has been powered on. Several different types of system errors may occur. A number will appear next to **Error Code** that represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Record the Error Code number.



 Power the unit off and then on using the Power button on the front of the unit (page 18).



If alarm condition cannot be resolved, contact KCI.



System Error Alarm (at Power On)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit while the unit is powering on. "00000001" represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:

1. Record the Error Code number (00000001).



 Power the unit off and then on using the Power button on the front of the unit (page 18).

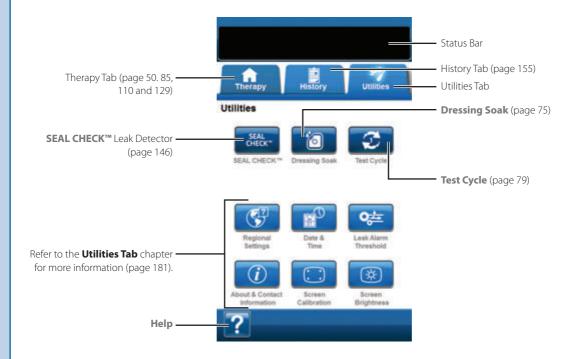


If alarm condition cannot be resolved, contact KCI.



Utilities Tab - V.A.C. VERAFLO™ Therapy

Use the *Utilities Tab* screen to set preferences for the V.A.C.,ULTA[™] Therapy Unit. Certain selections are available no matter what therapy is active. Those selections are discussed in the **Utilities Tab** chapter. Selections that are unique to the selected therapy are detailed below.



The following options are available from the *Utilities Tab* Home screen:

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 146).

Dressing Soak - Use to soak the dressing with solution in preparation for a dressing change (page 75).

Test Cycle - Use to complete an abbreviated V.A.C. VERAFLO™ Therapy cycle. Each phase of the cycle will be tested to ensure system is set up and functioning correctly (page 79).

Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

Dressing Soak

Use to soak the dressing with solution in preparation for a dressing change.



If the Dressing Soak tool is available for selection, the Dressing Soak icon on the Home screen or Utilities Tab (V.A.C. VERAFLO™ Therapy and V.A.C. Therapy only) will be blue.





Dressing Soak selected while therapy is idle:

- 1. Ensure that both the V.A.C.® canister tubing and instillation line are properly connected.
- 2. Ensure that all four tubing clamps are open.
- 3. Ensure that the V.A.C. VERALINK™ Cassette is properly installed (page 28).
- 4. Ensure that the canister has adequate capacity remaining for the dressing change.



- Select **Dressing Soak** from the **Home** screen or **Utilities Tab** to continue to the **Dressing Soak** screen.
- 6. Select the target **Dressing Soak Volume (mL)**.
- 7. Select the target **Dressing Soak Time (minutes)**.

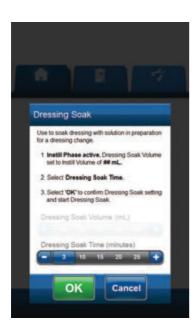


- 8. Select **OK** to confirm settings and return to the *Home* screen or *Utilities Tab*.
- The V.A.C.ULTA™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy phase will be displayed in the status bar (page 50) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the **Instill** phase) remaining.
- 10. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.



11. Select **Exit** to return to the **Home** screen or **Utilities Tab**.







Dressing Soak selected during Instill Phase:



- Select **Dressing Soak** from the **Home** screen or **Utilities Tab** to continue to the **Dressing Soak** screen.
- 2. Ensure that both the V.A.C.® canister tubing and instillation line are properly connected.
- 3. Ensure that all four tubing clamps are open.
- 4. Ensure that the canister has adequate capacity remaining for the dressing change.
- 5. Select the target **Dressing Soak Time (minutes)**.



- 6. Select **OK** to confirm settings and return to the *Home* screen or *Utilities Tab*.
- The V.A.C.ULTA™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy will be displayed in the status bar (page 50) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the **Instill** phase) remaining.
- 8. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.



 Select Exit to return to the Home screen or Utilities Tab.



Dressing Soak selected during Soak Phase:



- Select **Dressing Soak** from the **Home** screen or **Utilities Tab** to begin Dressing Soak.
- 2. Ensure that both the V.A.C.® canister tubing and instillation line are properly connected.
- 3. Ensure that all four tubing clamps are open.
- 4. Ensure that the canister has adequate capacity remaining for the dressing change.
- 5. The V.A.C.ULTA™Therapy Unit will complete the Soak and fluid removal phases. Therapy will be displayed in the status bar (page 50) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the **Instill** phase) remaining.
- 6. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.



7. Select **Exit** to return to the **Home** screen or **Utilities Tab**.









Dressing Soak selected during V.A.C.® Therapy Phase:

- 1. Ensure that the instillation line is properly connected.
- 2. Ensure that all four tubing clamps are open.
- 3. Ensure that the V.A.C. VERALINK™ Cassette is properly installed (page 28).
- 4. Ensure that the canister has adequate capacity remaining for the dressing change.



- Select **Dressing Soak** from the **Home** screen or **Utilities Tab** to continue to the **Dressing Soak** screen.
- 6. Select the target **Dressing Soak Volume (mL)**.
- 7. Select the target **Dressing Soak Time (minutes)**.



- 8. Select **OK** to confirm settings and return to the *Home* screen or *Utilities Tab*.
- The V.A.C.ULTA™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy phase will be displayed in the status bar (page 50) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the **Instill** phase) remaining.
- 10. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.



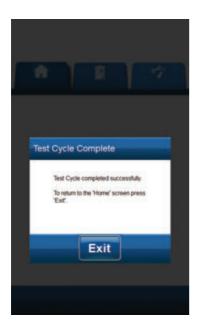
 Select Exit to return to the Home screen or Utilities Tab.



Test Cycle

Use to complete an abbreviated **V.A.C. VERAFLO™ Therapy** cycle. Each phase of the cycle will be tested to ensure system is set up and functioning correctly.





- 1. Ensure that both the V.A.C.* Canister tubing and instillation line are properly connected (page 31).
- 2. Ensure that all four tubing clamps are open (pages 31 and 33)
- 3. Ensure the V.A.C. VERALINK™ Cassette is properly installed (page 28).
- 4. Ensure that the canister is properly installed (page 32).
- 5. Ensure solution bag / bottle is properly installed (page 29).
- If unit has never been configured for V.A.C. VERAFLO™
 Therapy, configure unit as described in the V.A.C.
 VERAFLO™ Therapy Configuration Overview section (pages 44 47).



Test Cycle is only available while configured for $V.A.C.\ VERAFLO^{\mathsf{TM}}$ Therapy.



If the user does not select any therapy settings, the V.A.C.ULTA™ Therapy Unit will default to factory settings.



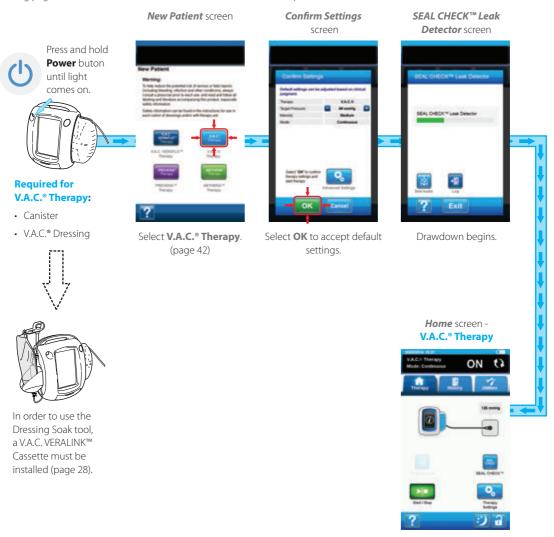
 Select **Test Cycle** from *Utilities* screen (page 74).



8. Once Test Cycle is complete, select **EXIT** to go to the V.A.C.® Therapy phase.

V.A.C.® Therapy Configuration - Default Settings Overview

The following flow chart shows the basic steps required to configure **V.A.C.**° **Therapy** using the default settings. Refer to the following pages for detailed information about individual screens and options.





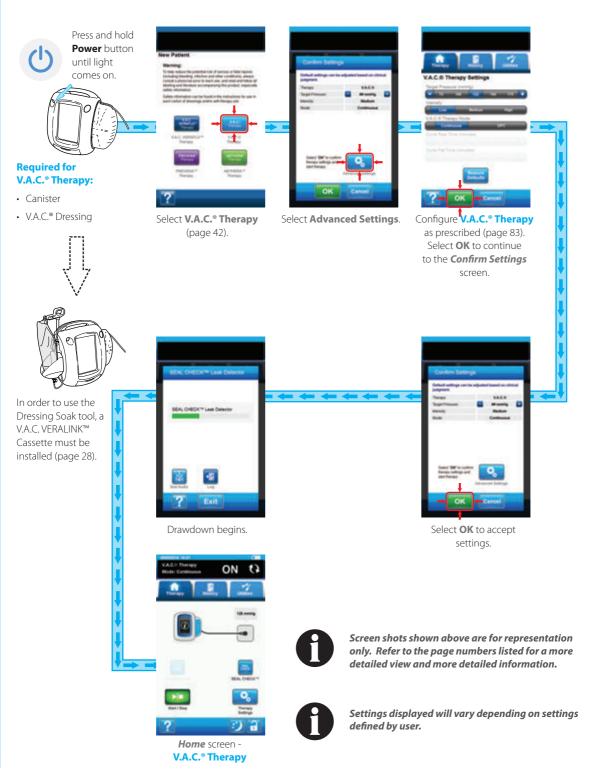
Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.



Settings displayed will vary depending on settings defined by user.

V.A.C.® Therapy Configuration - Advanced User Defined Settings Overview

The following flow chart shows the basic steps required to configure **V.A.C.**° **Therapy** with User defined settings. Refer to the following pages for detailed information about individual screens and options.



V.A.C.® Therapy Settings Screen



This screen allows the user to configure the V.A.C.ULTA™ Therapy Unit to deliver V.A.C.® Therapy:

- Target Pressure (mmHg) (Default = 125 mmHg)
 Prescribed negative pressure level for V.A.C.° Therapy.
 Target Pressure can be set from 25 200 mmHg in 25 mmHg increments.
- Intensity (Default = Low) Related to the time it takes to reach the target pressure after the initiation of therapy. The lower the intensity setting, the slower the target pressure 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.
- V.A.C.® Therapy Mode (Default = Continuous) Available modes include Continuous and DPC. Continuous provides constant negative pressure at selected Target Pressure. DPC provides negative pressure between preset low pressure (25 mmHg) and selected Target Pressure.
- Cycle Rise Time (Default = 3 minutes) Time used to transition from the preset low pressure (25 mmHg) to the selected target pressure while using DPC. Cycle Rise Time can be set from one minute to 10 minutes in one minute increments.
- Cycle Fall Time (Default = 3 minutes) Time used to transition from the selected target pressure to the preset low pressure (25 mmHg) while using DPC. Cycle Fall Time can be set from one minute to 10 minutes in one minute increments.





 Select desired value by selecting or sliding finger / stylus along bar. Use + / - to adjust above or below values shown.



Select **Restore Defaults** to reset therapy settings to the default values.





 Once all settings have been entered, select OK to continue to the Confirm Settings screen. This screen allows the user to review the therapy settings that were selected on the V.A.C. Therapy Settings screen.



 Use + / - to adjust above or below values shown.



Select **Advanced Settings** to return to the **V.A.C.**° **Therapy Settings** screen to make any required adjustments.



 Select **OK** to initiate therapy and continue to the **SEAL CHECK™ Leak Detector** screen for **V.A.C.® Therapy.**

OR



5. Select **Cancel** to return to the **Choose Therapy** screen.

Home Screen - V.A.C.® Therapy

This *Home* screen is the main screen displayed by the V.A.C.ULTA™Therapy Unit during **V.A.C.**° **Therapy**. It is used to access important information about the status of therapy.



Therapy mode and status (**ON** or **OFF**) will be displayed in the status bar at the top of the screen. The current therapy pressure will also appear above the icon of the dressing.

The following options are available from the *Home* screen for **V.A.C.** * Therapy:

Therapy Settings - Use to change current therapy settings.

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Information - Use to view a summary of therapy history and current therapy settings (page 86).

Start / Stop - Use to start or stop therapy.

Help - Use to access to the V.A.C.ULTA™Therapy Unit's on-screen help features.

Leak Detection - If the therapy unit detects a leak in the system temporarily above the Leak Alarm threshold, the *Home* screen for **V.A.C.***Therapy will display a yellow box around the dressing. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.

Refer to page 41 for a list of **Common Touch Screen Buttons** not described here.

Information Screens - V.A.C.® Therapy

These screens will display the current therapy settings and a summary of therapy applied to the patient.





- Select Information from the Home screen to continue to the Therapy Summary tab. Use this tab to review the Therapy Start Date and Therapy Time. If the Log feature is used, the date and time for Canister Last Changed, Cassette Last Changed, Dressing Last Changed and Solution Last Changed will also be displayed.
- Select Current Settings to continue to the Current Settings screen. Use this tab to review the current therapy settings.
- 3. Select **Change Settings** to continue to the **Confirm Settings** screen (page 84).
- 4. Select *Exit* to return to the *Home* screen for **V.A.C.**® **Therapy**.

V.A.C.® Therapy Alerts and Alarms

The following alerts and alarms may appear on the touch screen during **V.A.C.**® **Therapy**.

Alerts and alarms are accompanied by a repeating audible tone.

Following initiation of therapy, if an audible tone is not heard when SEAL CHECK™ Leak Detector is displayed and Seal Audio tone is turned ON, the alarms may not be working properly. Contact KCl for more information. Alarms are intended to be heard when facing the therapy unit at a maximum of one meter away. If two or more alarm conditions are present, only the highest priority alarm will be displayed.

Low Priority Alert Condition - Displayed on the touch screen when the V.A.C.ULTA $^{\mathsf{M}}$ Therapy Unit detects a condition that requires attention. Alerts will be accompanied by a repeating audible tone approximately every 20 seconds (two beeps).

Medium Priority <u>Alarm</u> Condition - Displayed on the touch screen when the V.A.C.ULTA™ Therapy Unit detects a condition that requires prompt attention in order to ensure the prescribed therapy is being delivered. Alarms will be accompanied by a repeating audible tone approximately every two seconds (three beeps) and a flashing screen title.



Select **Seal Audio** to turn the audible tone ON.



Select **Help** for more information regarding alarm resolution.



If alarm conditions cannot be resolved, contact KCI.

V.A.C.® Therapy Blockage Alert

Low Priority Alert - This alert screen appears when the V.A.C.ULTA™ Therapy Unit has detected a potential blockage. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the SENSAT.R.A.C.™ Pad and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the *V.A.C.* * *Therapy Blockage Alert* remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.



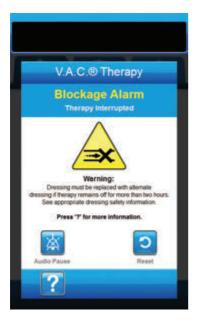
The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



If alarm condition cannot be resolved, contact KCI.

V.A.C.® Therapy Blockage Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a blockage is present in the V.A.C.® Therapy line. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the SENSAT.R.A.C.™ Pad and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- If the V.A.C.® Therapy Blockage Alarm (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



If alarm condition cannot be resolved, contact



V.A.C.® Therapy Canister Full Alarm (Therapy Interrupted)

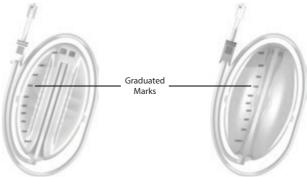
Medium Priority Alarm - This alarm screen appears when the canister is full and should be replaced. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Check if canister is full by comparing the level of fluid to the graduated marks on the canister.





A full canister is approximately 300 mL, 500 mL or 1000 mL depending on canister used. Canister release button will be flashing.



- 3. If canister is not full, select **Reset** to return to the **Home** screen.
- If canister is full, change canister and select Reset on this screen to return to the *Home* screen. See the **Changing** the Canister section of this manual (page 34) for additional information.

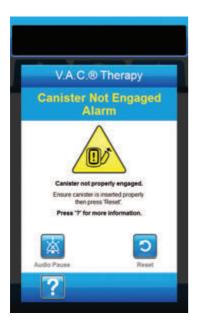


5. Select **Start / Stop** to restart therapy.



V.A.C.® Therapy Canister Not Engaged Alarm

Medium Priority Alarm - This alarm screen appears when the canister is not fully inserted and / or properly latched. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



1. Select **Audio Pause** to silence alarm for two minutes during troubleshooting.



- Remove the canister by pressing the Canister Release button (page 18) on the unit.
- 3. Inspect the canister and V.A.C.ULTA™Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
- 4. Ensure both seals are present and seated completely (page 19). If seals are missing or damaged, contact KCI.
- Re-attach the canister to the V.A.C.ULTA™ Therapy Unit ensuring that the canister is fully engaged and latched (page 32). An audible click indicates that the canister is properly installed.



6. Select **Reset** to return to the **Home** screen.



- Select Start / Stop to restart therapy.
- 8. If this alarm continues to appear, repeat steps 2 7 with a new canister.



If alarm condition cannot be resolved, contact KCI.

V.A.C.® Therapy Therapy Inactive Alarm

Medium Priority Alarm - This alarm screen appears when therapy (**V.A.C.**° **Therapy**) has been off or paused for more than 15 minutes (with the unit powered on). This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



 Select Audio Pause to silence alarm for two minutes during troubleshooting.



Select **Reset** to return to the **Home** screen.



3. Select **Start / Stop** to restart therapy.



 If therapy is not desired, turn the V.A.C.ULTA™Therapy Unit off by using the Power button on the front of the unit.



V.A.C.® Therapy Leak Alarm

Medium Priority Alarm - This alarm screen appears when a significant negative pressure leak has been detected. If this alarm is not resolved in three minutes, therapy will be interrupted. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing is properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alarm, page 91).



- Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the V.A.C.® Therapy Leak Alarm screen.



6. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the Status Bar (page 85). If not, select **Start / Stop** to restart therapy.



If this alarm is not resolved within three minutes, the V.A.C.® Therapy Leak Alarm (Therapy Interrupted) will appear and therapy will stop.

Refer to V.A.C.® Therapy Leak Alarm (Therapy Interrupted) section of this manual (page 94) for procedures to restart therapy.

V.A.C.® Therapy Leak Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when a detected negative pressure leak has not been resolved and therapy has been interrupted. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select **Audio Pause** to silence alarm for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing is properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alarm, page 91).



4. Select **Reset** to return to the **Home**



5. Restart therapy by selecting **Start / Stop**.



- 6. Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the Home screen.



If the leak condition is not resolved, an alarm screen will reappear after several minutes.



If alarm condition cannot be resolved, contact KCI.



V.A.C.® Therapy Low Pressure Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the V.A.C.ULTA™ Therapy Unit has not reached the target therapy negative pressure setting and negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits. This alarm is accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C.® Therapy tubing on the SENSAT.R.A.C.™ Pad and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- If the V.A.C.® Therapy Low Pressure Alarm (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alarm is resolved by lowering the unit, normal use may resume.



Select Reset to return to the Home Screen.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



If alarm condition cannot be resolved, contact KCI.



V.A.C.® Therapy V.A.C. VERALINK™ Not Engaged Alert

Low Priority Alert - This alert screen appears when the V.A.C. VERALINK $^{\text{TM}}$ Cassette is not fully seated and / or properly latched. This alert will be accompanied by a repeating audible tone.



The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



To resolve this alert:



- Select Audio Pause to silence alert for two minutes during troubleshooting.
- Remove the V.A.C. VERALINK™ Cassette from the unit by pushing down on the cassette latch release tab (page 28).
- Inspect the V.A.C. VERALINK™ Cassette and the V.A.C. ULTA™
 Therapy Unit to ensure no foreign objects or debris interfere with the cassette and the therapy unit connection points.
- 4. Ensure the cassette's pivot connection (on the end with the tubing spike) is securely engaged within the pivot slot on the therapy unit (page 28).
- Re-attach the V.A.C. VERALINK™ Cassette to the therapy unit ensuring that the cassette is fully engaged and latched (page 28). An audible click indicates that the cassette is properly installed.



Once the V.A.C. VERALINK™ Cassette is properly installed, the V.A.C. VERALINK™ Not Engaged Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



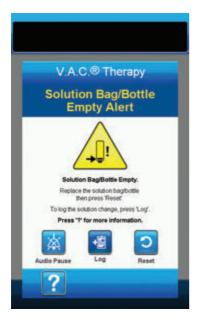
- Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.
- If this alert condition continues to appear, repeat steps 2 - 7 with a new V.A.C. VERALINK™ Cassette.



lf alert condition cannot be resolved, contact

V.A.C.® Therapy Solution Bag / Bottle Empty Alert

Low Priority Alert -This alert screen appears when there is no instillation fluid in the solution bag / bottle. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Remove empty solution bag / bottle from V.A.C. VERALINK™
 Cassette.
- Attach new solution bag / bottle. Refer to Hang Solution Container Bag / Bottle section of this manual (page 30) for more information.
- 4. Place new bag / bottle on the adjustable solution container hanger arm (page 30).



 Select Log to enter the solution bag / bottle change. Refer to the Log screen section (page 151) for more information.



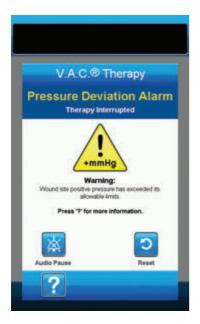
6. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.

V.A.C.® Therapy Pressure Deviation Alarm (Therapy Interrupted)

Medium Priority Alarm - This alarm screen appears when the wound site positive pressure has exceeded its allowable limits. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C. VERAT.R.A.C.™ Pad or the V.A.C. VERAT.R.A.C. DUO™ Tube Set and V.A.C. VERALINK™ Cassette tubing are open.
- 3. Ensure that the tubing is not kinked, crimped or blocked in any way.
- 4. If the V.A.C.® Therapy Pressure Deviation Alarm (Therapy Interrupted) remains after completing steps 2 and 3, check patient positioning or any external compression devices that may impede flow. Remove external compression device.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.



If alarm condition cannot be resolved, contact



V.A.C.® Therapy Instill Tube Blockage Alert (Therapy Interrupted)

Low Priority Alert - This alert screen appears when a blockage is present in the instillation line of the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™Tube Set. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select Audio Pause to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set and V.A.C. VERALINK™ Cassette are open.
- 3. Ensure that the tubing is not kinked, crimped, or blocked in any way.
- Ensure the V.A.C. VERALINK™ Cassette is fully engaged and latched. See the Attaching the V.A.C. VERALINK™ Cassette to the V.A.C.ULTA™ Therapy Unit section (page 28) of this manual for more information.
- 5. Ensure that the instillation solution in the V.A.C. VERALINK™ Cassette tubing is still liquid and flows freely. If the solution has degraded to a thicker consistency, change any or all of the following:
 - V.A.C. VERALINK™ Cassette
 - V.A.C. VERAT.R.A.C.™ Pad or V.A.C. VERAT.R.A.C. DUO™ Tube Set
 - Solution bag / bottle
- If the V.A.C.* Therapy Instill Tube Blockage Alert remains after completing steps 2 - 5, check patient positioning or any external compression devices that may impede flow. If applicable, remove external compression device.



7. Select **Reset** to return to the **Home** screen.



Alert screen will clear when the blockage is corrected.

V.A.C.® Therapy Battery Low Alert

Low Priority Alert - This alert screen appears approximately two hours before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Connect the therapy unit to a wall outlet using the KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicate the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Low Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



Therapy continues.

V.A.C.® Therapy Battery Critical Alarm

Medium Priority Alarm - This alarm screen appears approximately 30 minutes before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Critical Alarm screen will automatically clear.



 If the Battery Critical Alarm screen does not automatically clear, select Reset to return to the Home screen.



V.A.C.® Therapy continues, however, if this alarm is not resolved within approximately thirty minutes, therapy will be interrupted.



 Ensure therapy is ON by checking the status bar (page 85). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy must be plugged into a wall outlet in order to continue therapy.



Alarm logs and settings are not lost in the case of a total power loss or if the unit is power cycled (turned off then back on).



Battery Exhausted

Medium Priority Alarm - This alarm screen appears when the battery power level is too low to power on the V.A.C.ULTA™ Therapy Unit.

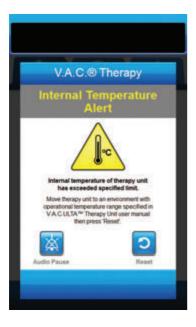


To resolve this alarm:

- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.
- Power the V.A.C.ULTA™ Therapy Unit on and initiate therapy. Refer to the **Power the V.A.C.ULTA™ Therapy Unit On or Off** section of this manual (page 42) for more information.

V.A.C.® Therapy Internal Temperature Alert

Low Priority Alert - This alert screen appears when the internal temperature of the V.A.C.ULTA™ Therapy Unit is outside its specified limits. This alert will be accompanied by a repeating audible tone.





Therapy will continue while this alert is active. The touch screen will be turned off after five minutes of inactivity. The screen will illuminate when touched. Battery charging is stopped.

To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Move the therapy unit to an environment with an operational temperature range as detailed in the **Specifications** section of this manual (page 194).



It may take up to two hours for the therapy unit to return to operating temperatures.



Select **Reset** to return to the **Home** screen.



Therapy continues.



If alarm condition cannot be resolved, contact KCI.



V.A.C.® Therapy System Error Alarm (Therapy Interrupted) (after Power On)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit after it has been powered on. Several different types of system errors may occur. A number will appear next to **Error Code** that represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Record the Error Code number.



 Power the unit off and then on using the Power button on the front of the unit (page 18).



If alarm condition cannot be resolved, contact KCI.



System Error Alarm (at Power On)

Medium Priority Alarm - This alarm screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit while the unit is powering on. "00000001" represents the diagnostic code of the system fault. This alarm will be accompanied by a repeating audible tone.



To resolve this alarm:

1. Record the Error Code number (00000001).



 Power the unit off and then on using the Power button on the front of the unit (page 18).

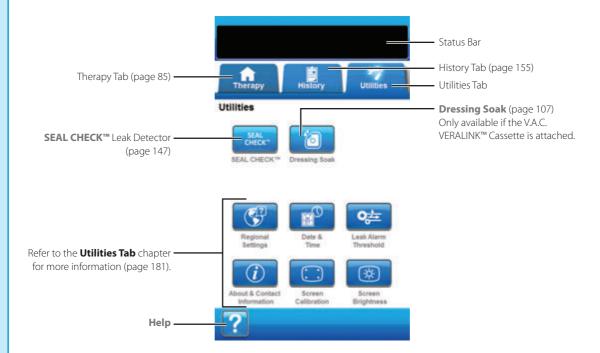


If alarm condition cannot be resolved, contact KCI.



Utilities Tab - V.A.C.® Therapy

Use the *Utilities Tab* screen to set preferences for the V.A.C.ULTA[™] Therapy Unit. Certain selections are available no matter what therapy is active. Those selections are discussed in the **Utilities Tab** chapter. Selections that are unique to the selected therapy are detailed below.



The following options are available from the *Utilities Tab* Home screen:

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Dressing Soak - Use to soak the dressing with solution in preparation for a dressing change (page 107).



The V.A.C. VERALINK™ Cassette (page 28) must be installed for the Dressing Soak tool to be available.

Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

Dressing Soak

Use Dressing Soak to soak the dressing with solution in preparation for a dressing change.



The V.A.C. VERALINK™ Cassette (page 28) must be installed for the Dressing Soak tool to be available.





- 1. Ensure that the instillation line is properly connected.
- 2. Ensure that all four tubing clamps are open.
- 3. Ensure that the V.A.C. VERALINK™ Cassette is properly installed (page 28).
- 4. Ensure that the canister has adequate capacity remaining for the dressing change.



- Select **Dressing Soak** from the **Home** screen to continue to the **Dressing Soak** screen.
- 6. Select the target **Dressing Soak Volume (mL)**.
- 7. Select the target **Dressing Soak Time (minutes)**.



- 8. Select **OK** to confirm settings and return to the *Home* screen.
- The V.A.C.ULTA™ Therapy Unit will complete the Instill, Soak, and fluid removal phases. Therapy phase will be displayed in the status bar (page 85) at the top of the screen. The current therapy status will also appear under the icon of the therapy unit along with time or fluid amount (during the **Instill** phase) remaining.
- 10. Once the Dressing Soak fluid removal phase is complete, the dressing can be removed.

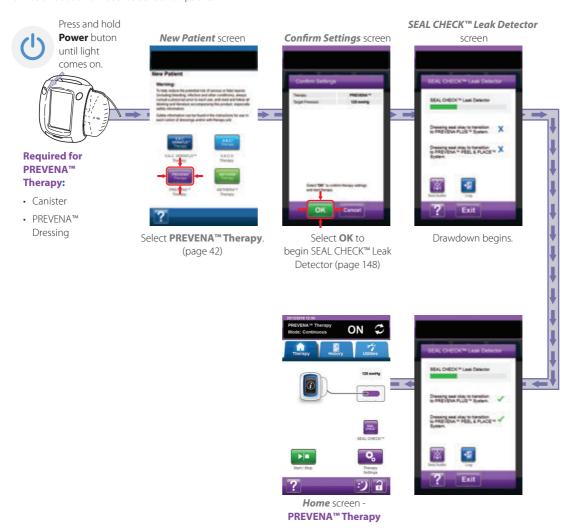


11. Select **Exit** to return to the *Home* screen.



PREVENA™ Therapy Configuration - Overview

The following flow chart shows the basic steps required to configure **PREVENA™ Therapy**. Refer to the following pages for detailed information about individual screens and options.





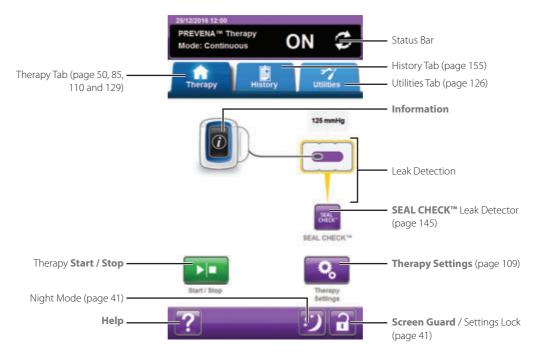
Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.



Settings displayed will vary depending on settings defined by user.

Home Screen - PREVENA™ Therapy

This *Home* screen is the main screen displayed by the V.A.C.ULTA^m Therapy Unit during **PREVENA^m Therapy**. It is used to access important information about the status of therapy.



Therapy phase and status (ON or OFF) will be displayed in the status bar at the top of the screen. The current therapy pressure will also appear above the icon of the dressing.

The following selections are available from the *Home* screen for **PREVENA™ Therapy**:

Therapy Settings - Use to view current therapy settings.

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Information - Use to view a summary of therapy history and current therapy settings (page 111).

Start / Stop - Use to start or stop therapy.

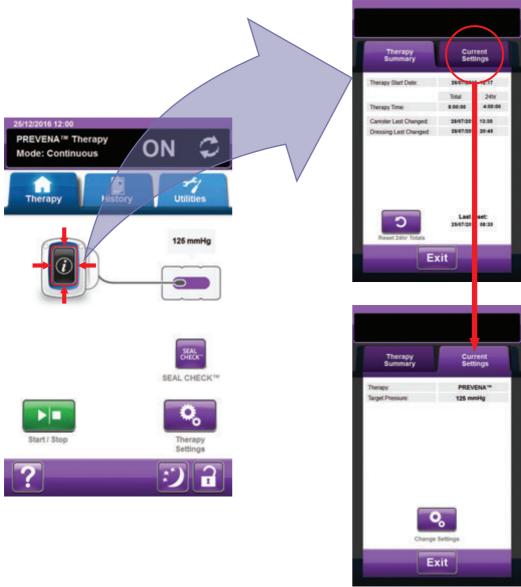
Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

Leak Detection - If the therapy unit detects a leak in the system temporarily above the Leak Alarm threshold, the **Home** screen for **PREVENA™ Therapy** will display a yellow box around the dressing. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.

Refer to page 41 for a list of ${\bf Common\,Touch\,Screen\,Buttons}$ not described here.

Information Screens - PREVENA™ Therapy

These screens will display the current therapy settings and a summary of therapy applied to the patient.





- . Select **Information** from the *Home* screen to continue to the *Therapy Summary* tab. Use this tab to review the Therapy Start Date and Therapy Time. If the Log feature is used, the date and time for Canister Last Changed and Dressing Last Changed will also be displayed.
- Select Current Settings to continue to the Current Settings screen. Use this tab to review the current therapy settings.
- 3. Select **Change Settings** to continue to the **Confirm Settings** screen (page 109).
- 4. Select *Cancel* to return to the *Home* screen for PREVENA™ Therapy.

PREVENA™ Therapy Alerts

The following alerts may appear on the touch screen during **PREVENA™ Therapy**.

Alerts are accompanied by a repeating audible tone.

Following initiation of therapy, if an audible tone is not heard when SEAL CHECK™ Leak Detector is displayed and Seal Audio tone is turned ON, the alerts may not be working properly. Contact KCl for more information. Alerts are intended to be heard when facing the therapy unit at a maximum of one meter away. If two or more alert conditions are present, only the highest priority alert will be displayed.

Low Priority <u>Alert</u> Condition - Displayed on the touch screen when the V.A.C.ULTA™ Therapy Unit detects a condition that requires attention. Alerts will be accompanied by a repeating audible tone approximately every 20 seconds (two beeps).



Select **Seal Audio** to turn the audible tone ON.



Select **Help** for more information regarding alert resolution.



PREVENA™ Therapy Blockage Alert

Low Priority Alert - This alert screen appears when the V.A.C.ULTA™ Therapy Unit has detected a potential blockage. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the dressing tubing and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the PREVENA™ Therapy Blockage Alert remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 110). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA $^{\mathsf{TM}}$ Therapy Unit will continue to attempt to apply therapy during this alert.



PREVENA™ Therapy Blockage Alert (Therapy Interrupted)

Low Priority Alert - This alert screen appears when a blockage is present. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the dressing tubing and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the PREVENA™ Therapy Blockage Alert (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



5. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 110). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



PREVENA™ Therapy Canister Full Alert

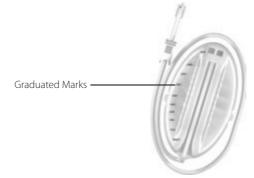
Low Priority Alert - This alert screen appears when the canister is full and should be replaced. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Check if canister is full by comparing the level of fluid to the graduated marks on the canister.





A full canister is approximately 300 mL or 500 mL depending on canister used. Canister release button will be flashing.



- 3. If canister is not full, select **Reset** to return to the **Home** screen.
- 4. If canister is full or near full **call the treating physician immediately** for additional instructions.



5. Select **Reset** to return to the **Home** screen.



6. Select **Start / Stop** to restart therapy.

PREVENA™ Therapy Canister Not Engaged Alert

Low Priority Alert - This alert screen appears when the canister is not fully inserted and / or properly latched. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



 Select **Audio Pause** to silence alert for two minutes during troubleshooting.



- Remove the canister by pressing the
 Canister Release button (page 18) on
 the unit.
- 3. Inspect the canister and V.A.C.ULTA™ Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
- 4. Ensure both seals are present and seated completely (page 19). If seals are missing or damaged, contact KCI.
- Re-attach the canister to the V.A.C.ULTA™ Therapy Unit ensuring that the canister is fully engaged and latched (page 32). An audible click indicates that the canister is properly installed.



6. Select **Reset** to return to the **Home** screen.



- 7. Select **Start / Stop** to restart therapy.
- 8. If this alert continues to appear, repeat steps 2 7 with a new canister.



PREVENA™ Therapy Therapy Inactive Alert

Low Priority Alert - This alert screen appears when therapy (**PREVENA™ Therapy**) has been off or paused for more than 15 minutes (with the unit powered on). This alert will be accompanied by a repeating audible tone.



To resolve this alert:



 Select **Audio Pause** to silence alert for two minutes during troubleshooting.



2. Select **Reset** to return to the **Home** screen.



3. Select **Start / Stop** to restart therapy.



 If therapy is not desired, turn the V.A.C.ULTA™ Therapy Unit off by using the Power button on the front of the unit.

PREVENA™ Therapy Leak Alert

Low Priority Alert - This alert screen appears when a significant negative pressure leak has been detected. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing are properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alert, page 117).



- Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the PREVENA™ Therapy Leak Alert
 screen.



6. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the Status Bar (page 110). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



PREVENA™ Therapy Battery Low Alert

Low Priority Alert - This alert screen appears approximately two hours before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Connect the therapy unit to a wall outlet using the KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicate the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Low Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



Therapy continues.

PREVENA™ Therapy Battery Critical Alert

Low Priority Alert - This alert screen appears approximately 30 minutes before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select Audio Pause to silence alert for two minutes during troubleshooting.
- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Critical Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



PREVENA™ Therapy continues, however, if this alert is not resolved within approximately thirty minutes, therapy will be interrupted.



 Ensure therapy is ON by checking the status bar (page 110). If not, select **Start / Stop** to restart therapy.



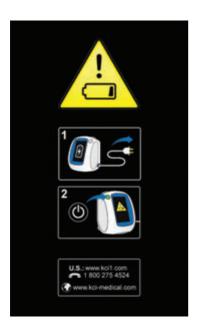
The V.A.C.ULTA™ Therapy must be plugged into a wall outlet in order to continue therapy.



Alert logs and settings are not lost in the case of a total power loss or if the unit is power cycled (turned off then back on).

Battery Exhausted

Low Priority Alert - This alert screen appears when the battery power level is too low to power on the V.A.C.ULTA™ Therapy Unit.



To resolve this alert:

- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.
- Power the V.A.C.ULTA™ Therapy Unit on and initiate therapy. Refer to the **Power the V.A.C.ULTA™ Therapy Unit On or Off** section of this manual (page 42) for more information.

PREVENA™ Therapy Internal Temperature Alert

Low Priority Alert - This alert screen appears when the internal temperature of the V.A.C.ULTA™ Therapy Unit is outside its specified limits. This alert will be accompanied by a repeating audible tone.





Therapy will continue while this alert is active. The touch screen will be turned off after five minutes of inactivity. The screen will illuminate when touched. Battery charging is stopped.

To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Move the therapy unit to an environment with an operational temperature range as detailed in the **Specifications** section of this manual (page 194).



It may take up to two hours for the therapy unit to return to operating temperatures.



Select **Reset** to return to the **Home** screen.



Therapy continues.



PREVENA™ Therapy System Error Alert (Therapy Interrupted) (after Power On)

Low Priority Alert - This alert screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit after it has been powered on. Several different types of system errors may occur. A number will appear next to Error Code: that represents the diagnostic code of the system fault. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select Audio Pause to silence alert for two minutes during troubleshooting.
- 2. Record the Error Code number.



 Power the unit off and then on using the Power button on the front of the unit (page 18).



System Error Alert (at Power On)

Low Priority Alert - This alert screen appears when there is a system fault within the V.A.C.ULTA™Therapy Unit while the unit is powering on. "00000001" represents the diagnostic code of the system fault. This alert will be accompanied by a repeating audible tone.



To resolve this alert:

1. Record the Error Code number (00000001).

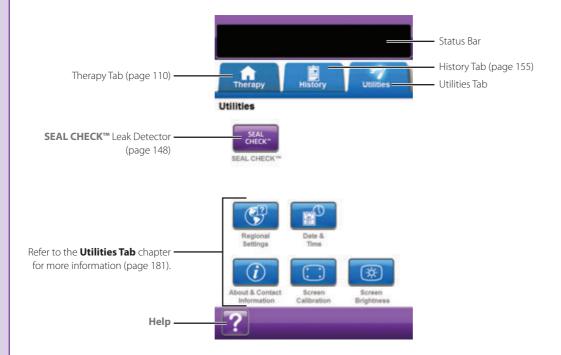


 Power the unit off and then on using the Power button on the front of the unit (page 18).



Utilities Tab - PREVENA™ Therapy

Use the *Utilities Tab* screen to set preferences for the V.A.C.ULTA[™] Therapy Unit. Certain selections are available no matter what therapy is active. Those selections are discussed in the **Utilities Tab** chapter. Selections that are unique to the selected therapy are detailed below.



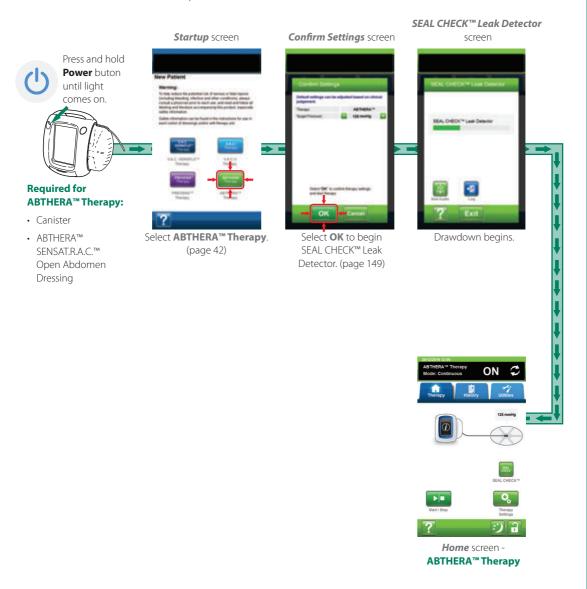
The following options are available from the *Utilities Tab* Home screen:

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

ABTHERA™ Therapy Overview

The following flow chart shows the basic steps required to configure **ABTHERA™ Therapy**. Refer to the following pages for detailed information about individual screens and options.





 $Screen shots shown above are for representation only. \ Refer to the page numbers listed for a more detailed view and more detailed information.$



Settings displayed will vary depending on settings defined by user.

Confirm Settings Screen - ABTHERA™ Therapy



This screen allows the user to adjust the Target Pressure the V.A.C.ULTA™Therapy Unit will deliver during **ABTHERA™ Therapy**:

- Target Pressure (mmHg) (Default = 125 mmHg)
 Prescribed negative pressure level for ABTHERA™ Therapy.
 Target Pressure can be set to 100, 125 or 150 mmHg.
- 1. Use + / to select desired value for **ABTHERA™ Therapy**.



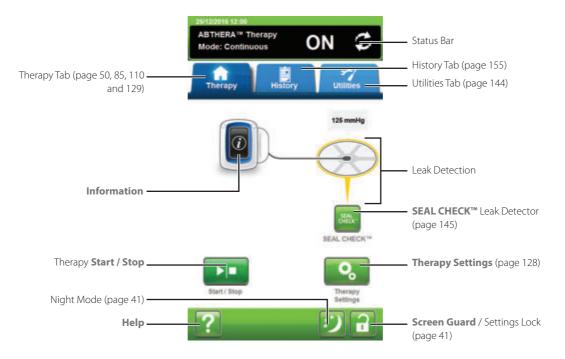
 Once Target Pressure has been entered, select OK to initiate therapy and continue to the SEAL CHECK™ Leak Detector screen for ABTHERA™ Therapy.



3. Select **Cancel** to return to the **Choose Therapy** screen.

Home Screen - ABTHERA™ Therapy

This *Home* screen is the main screen displayed by the V.A.C.ULTA^{\dagger} Therapy Unit during **ABTHERA^{\dagger} Therapy**. It is used to access important information about the status of therapy.



Therapy mode and status (**ON** or **OFF**) will be displayed in the status bar at the top of the screen. The current therapy pressure will also appear above the icon of dressing.

The following options are available from the *Home* screen for **ABTHERA™ Therapy**:

Therapy Settings - Use to change current therapy settings.

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Information - Use to view a summary of therapy history and current therapy settings (page 130).

Start / Stop - Use to start or stop therapy.

Help - Use to access to the V.A.C.ULTA™Therapy Unit's on-screen help features.

Leak Detection - If the therapy unit detects a leak in the system temporarily above the Leak Alarm threshold, the **Home** screen for **ABTHERA™ Therapy** will display a yellow box around the dressing. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.

Refer to page 41 for a list of **Common Touch Screen Buttons** not described here.

Information Screens - ABTHERA™ Therapy

These screens will display the current therapy settings and a summary of therapy applied to the patient.





- Select Information from the Home screen to continue to the Therapy Summary tab. Use this tab to review the Therapy Start Date and Therapy Time. If the Log feature is used, the date and time for Canister Last Changed and Dressing Last Changed will also be displayed.
- 2. Select **Current Settings** to continue to the **Current Settings** screen. Use this tab to review the current therapy settings.
- 3. Select **Change Settings** to continue to the **Confirm Settings** screen (page 128).
- 4. Select **Cancel** on the **Confirm Settings** screen to return to the **Home** screen for **ABTHERA™ Therapy**.

ABTHERA™ Therapy Alerts

The following alerts may appear on the touch screen during **ABTHERA™ Therapy**.

Alerts are accompanied by a repeating audible tone.

Following initiation of therapy, if an audible tone is not heard when SEAL CHECK™ Leak Detector is displayed and Seal Audio tone is turned ON, the alerts may not be working properly. Contact KCl for more information. Alerts are intended to be heard when facing the therapy unit at a maximum of one meter away. If two or more alert conditions are present, only the highest priority alert will be displayed.

Low Priority <u>Alert</u> Condition - Displayed on the touch screen when the V.A.C.ULTA™ Therapy Unit detects a condition that requires attention. Alerts will be accompanied by a repeating audible tone approximately every 20 seconds (two beeps).



Select **Seal Audio** to turn audible tone ON.



Select **Help** for more information regarding alert resolution.



ABTHERA™ Therapy Blockage Alert

Low Priority Alert - This alert screen appears when the V.A.C.ULTA™ Therapy Unit has detected a potential blockage. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the tubing on the SENSAT.R.A.C.™ Pad and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the ABTHERA™ Therapy Blockage Alert remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 129). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



ABTHERA™ Therapy Blockage Alert (Therapy Interrupted)

Low Priority Alert - This alert screen appears when a blockage is present. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure clamps on the tubing on the SENSAT.R.A.C.™ Pad and canister tubing are open.
- 3. Ensure tubing is not kinked, crimped, or blocked in any way.
- 4. If the ABTHERA™ Therapy Blockage Alert (Therapy Interrupted) remains after completing steps 2 and 3, lower the therapy unit and tubing to be level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.



Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the status bar (page 129). If not, select **Start / Stop** to restart therapy.



Therapy unit remains on; however, negative pressure at the wound site may be below therapeutic value.



If alert condition cannot be resolved, contact



ABTHERA™ Therapy Canister Full Alert

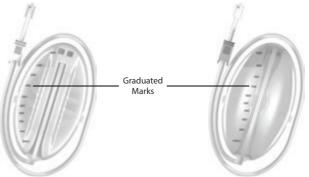
Low Priority Alert - This alert screen appears when the canister is full and should be replaced. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Check if canister is full by comparing the level of fluid to the graduated marks on the canister.





A full canister is approximately 300 mL, 500 mL or 1000 mL depending on canister used. Canister release button will be flashing.



- 3. If canister is not full, select **Reset** to return to the **Home** screen.
- If canister is full, change canister and select Reset on this screen to return to the *Home* screen. See the **Changing** the Canister section of this manual (page 34) for additional information.



5. Select **Start / Stop** to restart therapy.



ABTHERA™ Therapy Canister Not Engaged Alert

Low Priority Alert - This alert screen appears when the canister is not fully inserted and / or properly latched. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



 Select **Audio Pause** to silence alert for two minutes during troubleshooting.



- Remove the canister by pressing the Canister Release button (page 18) on the unit.
- 3. Inspect the canister and V.A.C.ULTA™ Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
- 4. Ensure both seals are present and seated completely (page 19). If seals are missing or damaged, contact KCI.
- Re-attach the canister to the V.A.C.ULTA™ Therapy Unit ensuring that the canister is fully engaged and latched (page 32). An audible click indicates that the canister is properly installed.



6. Select **Reset** to return to the **Home** screen.



- 7. Select **Start / Stop** to restart therapy.
- 8. If this alert continues to appear, repeat steps 2 7 with a new canister.



ABTHERA™ Therapy Therapy Inactive Alert

Low Priority Alert - This alert screen appears when therapy (**ABTHERA™ Therapy**) has been off or paused for more than 15 minutes (with the unit powered on). This alert will be accompanied by a repeating audible tone.



To resolve this alert:



 Select **Audio Pause** to silence alert for two minutes during troubleshooting.



Select **Reset** to return to the **Home** screen.



3. Select **Start / Stop** to restart therapy.



 If therapy is not desired, turn the V.A.C.ULTA™Therapy Unit off by using the Power button on the front of the unit.



ABTHERA™ Therapy Leak Alert

Low Priority Alert - This alert screen appears when a significant negative pressure leak has been detected. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- 2. Ensure connector between dressing tubing and canister tubing is properly locked.
- Ensure canister is fully engaged. (See Canister Not Engaged Alert, page 135).



- Select SEAL CHECK™ to access the SEAL CHECK™ Leak Detector. Refer to the SEAL CHECK™ Leak Detector section (page 145) of this manual for details on how to use the SEAL CHECK™ Leak Detector and how to repair leaks.
- Once the leak is resolved using the SEAL CHECK™ Leak
 Detector, select Exit on the SEAL CHECK™ Leak Detector
 screen to return to the ABTHERA™Therapy Leak Alert
 screen.



6. Select **Reset** to return to the **Home** screen.



 Ensure therapy is ON by checking the Status Bar (page 129). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy Unit will continue to attempt to apply therapy during this alert.



ABTHERA™ Therapy Battery Low Alert

Low Priority Alert - This alert screen appears approximately two hours before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- 1. Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Connect the therapy unit to a wall outlet using the KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicate the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Low Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



Therapy continues.

ABTHERA™ Therapy Battery Critical Alert

Low Priority Alert - This alert screen appears approximately 30 minutes before the battery power level is too low to support continued operation of the V.A.C.ULTA™ Therapy Unit. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.



Once the V.A.C.ULTA™ Therapy Unit is plugged into a wall outlet, the Battery Critical Alert screen will automatically clear.

OR



Select **Reset** to return to the **Home** screen.



ABTHERA™ Therapy continues, however, if this alert is not resolved within approximately thirty minutes, therapy will be interrupted.



 Ensure therapy is ON by checking the status bar (page 129). If not, select **Start / Stop** to restart therapy.



The V.A.C.ULTA™ Therapy must be plugged into a wall outlet in order to continue therapy.



Alert logs and settings are not lost in the case of a total power loss or if the unit is power cycled (turned off then back on).



Battery Exhausted

Low Priority Alert - This alert screen appears when the battery power level is too low to power on the V.A.C.ULTA™ Therapy Unit.



To resolve this alert:

- Connect the therapy unit to a wall outlet using KCI supplied power supply to recharge battery. An amber light at the bottom of the touch screen and a battery charge icon indicates the unit is charging. Refer to the **Charge Battery** section of this manual (page 23) for more information.
- Power the V.A.C.ULTA™ Therapy Unit on and initiate therapy. Refer to the **Power the V.A.C.ULTA™ Therapy Unit On or Off** section of this manual (page 42) for more information.

ABTHERA™ Therapy Internal Temperature Alert

Low Priority Alert - This alert screen appears when the internal temperature of the V.A.C.ULTA™ Therapy Unit is outside its specified limits. This alert will be accompanied by a repeating audible tone.





Therapy will continue while this alert is active. The touch screen will be turned off after five minutes of inactivity. The screen will illuminate when touched. Battery charging is stopped.

To resolve this alert:



- Select **Audio Pause** to silence alert for two minutes during troubleshooting.
- Move the therapy unit to an environment with an operational temperature range as detailed in the **Specifications** section of this manual (page 194).



It may take up to two hours for the therapy unit to return to operating temperatures.



Select **Reset** to return to the **Home** screen.



Therapy continues.



If alert condition cannot be resolved, contact KCI.



ABTHERA™ Therapy System Error Alert (Therapy Interrupted) (after Power On)

Low Priority Alert - This alert screen appears when there is a system fault within the V.A.C.ULTA™ Therapy Unit after it has been powered on. Several different types of system errors may occur. A number will appear next to Error Code: that represents the diagnostic code of the system fault. This alert will be accompanied by a repeating audible tone.



To resolve this alert:



- Select Audio Pause to silence alarm for two minutes during troubleshooting.
- 2. Record the Error Code number.



 Power the unit off and then on using the Power button on the front of the unit (page 18).



If alert condition cannot be resolved, contact KCI.



System Error Alert (at Power On)

Low Priority Alert - This alert screen appears when there is a system fault within the V.A.C.ULTA™Therapy Unit while the unit is powering on. "00000001" represents the diagnostic code of the system fault. This alert will be accompanied by a repeating audible tone.



To resolve this alert:

1. Record the Error Code number (00000001).



 Power the unit off and then on using the Power button on the front of the unit (page 18).

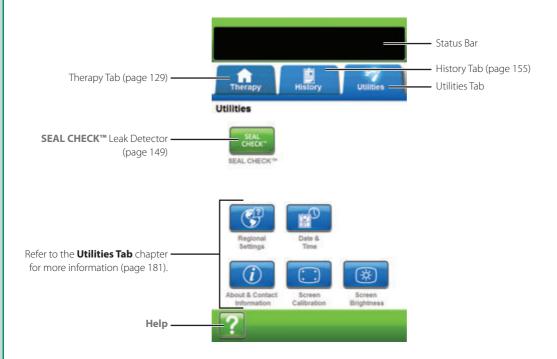


If alert condition cannot be resolved, contact KCI.



Utilities Tab - ABTHERA™ Therapy

Use the *Utilities Tab* screen to set preferences for the V.A.C.ULTA[™] Therapy Unit. Certain selections are available no matter what therapy is active. Those selections are discussed in the **Utilities Tab** chapter. Selections that are unique to the selected therapy are detailed below.



The following options are available from the *Utilities Tab* Home screen:

SEAL CHECK™ Leak Detector - An on-screen bar graph will indicate leak level and an audible tone will sound if unit detects a significant leak (page 145).

Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

SEAL CHECK™ Leak Detector Overview

The SEAL CHECK™ Leak Detector is used to help find negative pressure leaks.







Access the SEAL CHECK $^{\text{m}}$ Leak Detector from the **Home** screen. The SEAL CHECK $^{\text{m}}$ Leak Detector will also automatically run during the initial Drawdown phase once therapy has been initiated.

Most leaks occur:

- where the drape meets the skin.
- where the V.A.C. VERAT.R.A.C.™ Pad, V.A.C. VERAT.R.A.C. DUO™ Tube Set pads or SENSAT.R.A.C.™ Pad is
 attached to the drape, if applicable.
- at tubing connections.
- if canister is not fully seated to therapy unit.



Seal Audio default is set to OFF.

SEAL CHECK™ Leak Detector - V.A.C. VERAFLO™ Therapy





- 1. Ensure that both the V.A.C.® Canister tubing and instillation line are properly connected.
- 2. Ensure that all four tubing clamps are open.
- Ensure the V.A.C. VERALINK™ Cassette is properly installed (page 28), if applicable.
- 4. Ensure that the canister is properly installed (page 32).



 Once therapy has been initiated, select SEAL CHECK™ Leak Detector.

The SEAL CHECK™ Leak Detector uses an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and length of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in length as the leak is found.

The bar graph will be yellow if a significant leak is detected. A green bar graph indicates the V.A.C.ULTA™ Therapy Unit is operating normally. The line on the bar graph is the transition point from yellow to green.



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



- Select Seal Audio to turn seal audio tone on or off. Seal Audio default is set to OFF
- 7. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and tubing pads. The bar graph will decrease and change from yellow to green and the frequency of the audible tone (if Seal Audio is on) will decrease when a leak is found and repaired.
- 8. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.



9. Select **Exit** to return to the *Home* screen.

SEAL CHECK™ Leak Detector - V.A.C.® Therapy





- 1. Ensure that the V.A.C.® Canister tubing is properly connected.
- 2. Ensure that both tubing clamps are open.
- 3. Ensure that the canister is properly installed (page 32).



 Once therapy has been initiated, select SEAL CHECK™ Leak Detector.

The SEAL CHECK™ Leak Detector uses an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and length of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in length as the leak is found.

The bar graph will be yellow if a significant leak is detected. A green bar graph indicates the V.A.C.ULTA™ Therapy Unit is operating normally. The line on the bar graph is the transition point from yellow to green.



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



- Select Seal Audio to turn seal audio tone on or off. Seal Audio default is set to OFF.
- 6. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and tubing pad. The bar graph will decrease and change from yellow to green and the frequency of the audible tone (if Seal Audio is on) will decrease when a leak is found and repaired.
- Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.



Select **Exit** to return to the *Home* screen.

SEAL CHECK™ Leak Detector - PREVENA™ Therapy





- 1. Ensure that the V.A.C.® Canister tubing is properly connected.
- 2. Ensure that both tubing clamps are open.
- 3. Ensure that the canister is properly installed (page 32).



 Once therapy has been initiated, select SEAL CHECK™ Leak Detector.

The SEAL CHECK™ Leak Detector uses an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and length of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in length as the leak is palpated.

The bar graph will be yellow if a significant leak is detected. A green bar graph indicates the V.A.C.ULTA $^{\rm M}$ Therapy Unit is operating normally. The line on the bar graph is the transition point from yellow to green.

If the patient will be transitioned to a PREVENA™ Therapy Unit:

- The **SEAL CHECK™ Leak Detector** screen will display an **X** if the dressing seal is not adequate for use with the associated **PREVENA™ Therapy Unit**. The **PREVENA™ Therapy Unit** may sound a Leak Alarm when connected.
- The **SEAL CHECK™ Leak Detector** screen will display a **Check Mark** if the dressing seal is adequate for use with the associated **PREVENA™ Therapy Unit**. The **PREVENA™ Therapy Unit**
 should not sound a Leak Alarm when connected.



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



- Select Seal Audio to turn seal audio tone on or off. Seal Audio default is set to OFF.
- 6. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the dressing and drape. The bar graph will decrease and change from yellow to green and the frequency of the audible tone (if Seal Audio is on) will decrease when a leak is found and repaired.
- 7. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.



3. Select **Exit** to return to the **Home** screen.

SEAL CHECK™ Leak Detector - ABTHERA™ Therapy





- 1. Ensure that the V.A.C.® Canister tubing is properly connected.
- 2. Ensure that both tubing clamps are open.
- 3. Ensure that the canister is properly installed (page 32).



4. Once therapy has been initiated, select **SEAL CHECK™** Leak Detector.

The SEAL CHECK™ Leak Detector uses an audible tone and bar graph to assist in finding leaks. The frequency of the audible tone and length of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in length as the leak is found.

The bar graph will be yellow if a significant leak is detected. A green bar graph indicates the V.A.C.ULTA™ Therapy Unit is operating normally. The line on the bar graph is the transition point from yellow to green.



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



- Select Seal Audio to turn seal audio tone on or off. Seal Audio default is set to OFF.
- 6. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and tubing pad. The bar graph will decrease and change from yellow to green and the frequency of the audible tone (if Seal Audio is on) will decrease when a leak is found and repaired.
- 7. Refer to the instructions for use provided with the dressings for information on using excess drape material to seal any leak areas.



8. Select Exit to return to the Home screen.

Log - V.A.C. VERAFLO™ Therapy

Use this tool to record important information about dressing and component application / changes. The information will be recorded in the Therapy History Report (page 177).



Number of Foam Pieces - Select the number of foam pieces used in the wound at dressing application or dressing change. Use + / - , as applicable to adjust above or below the values shown.

Canister Changed (mL) - Select which canister (300 mL, 500 mL or 1000 mL) was installed or changed.

Solution Changed (mL) - Select the size (100 to 1000 mL) of solution bag / bottle that was installed. Use +/-, as applicable to adjust above or below the values shown.

V.A.C. VERALINK™ Changed - Select Yes or No to indicate whether or not a V.A.C. VERALINK™ Cassette was installed or changed.

Log - V.A.C.® Therapy

Use this tool to record important information about dressing and component application / changes. The information will be recorded in the Therapy History Report (page 177).



Number of Foam Pieces - Select the number of foam pieces used in the wound at dressing application or dressing change. Use + / - , as applicable to adjust above or below the values shown.

Canister Changed (mL) - Select which canister (300 mL, 500 mL or 1000 mL) was installed or changed.

Solution Changed (mL) - Select the size (100 to 1000 mL) of solution bag / bottle that was installed. Use +/-, as applicable to adjust above or below the values shown.

V.A.C. VERALINK™ Changed - Select Yes or No to indicate whether or not a V.A.C. VERALINK™ Cassette was installed or changed.

Log - PREVENA™ Therapy

Use this tool to record important information about dressing and component application / changes. The information will be recorded in the Therapy History Report (page 177).



Number of Foam Pieces - Select the number of foam pieces used in the wound at dressing application or dressing change. Use + / - , as applicable to adjust above or below the values shown.

Canister Changed (mL) - Select which canister (300 mL, 500 mL or 1000 mL) was installed or changed.

Log - ABTHERA™ Therapy

Use this tool to record important information about dressing and component application / changes. The information will be recorded in the Therapy History Report (page 177).

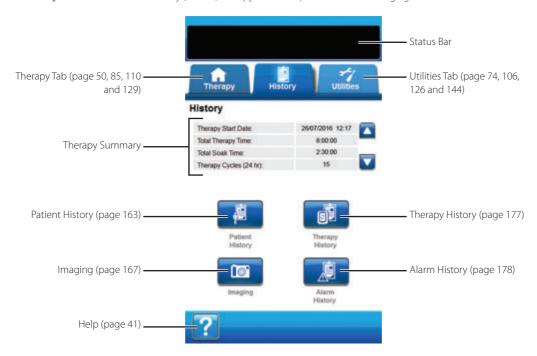


Number of Foam Pieces - Select the number of foam pieces used in the wound at dressing application or dressing change. Use + / - , as applicable to adjust above or below the values shown.

Canister Changed (mL) - Select which canister (300 mL, 500 mL or 1000 mL) was installed or changed.

History Tab Screen

Use the *History Tab* screen to access History (Patient, Therapy and Alarm) and the Wound Imaging Tool.



The following options are available from the *History Tab* screen:

Patient History - The Patient History screen displays the patient's information in date, time and event columns. The date is in descending order and time is displayed using the twenty-four hour clock format.

Imaging - The Wound Imaging feature aids in recording the wound healing process. Use to upload digital wound images for onscreen viewing or surface area and volume trending.

Therapy History - The Therapy History screen displays the patient's therapy information in date, time and event columns. The date is in descending order and time is displayed using the twenty-four hour clock format.

Alarm History - The Alarm History screen displays the alarm information from the V.A.C.ULTA $^{\mathrm{m}}$ Therapy Unit in date, time and event columns. The date is in descending order and time is displayed using the twenty-four hour clock format.

 $\textbf{Help} \text{ - Use to access the V.A.C.ULTA} \\ \text{The rapy Unit's on-screen help features}.$

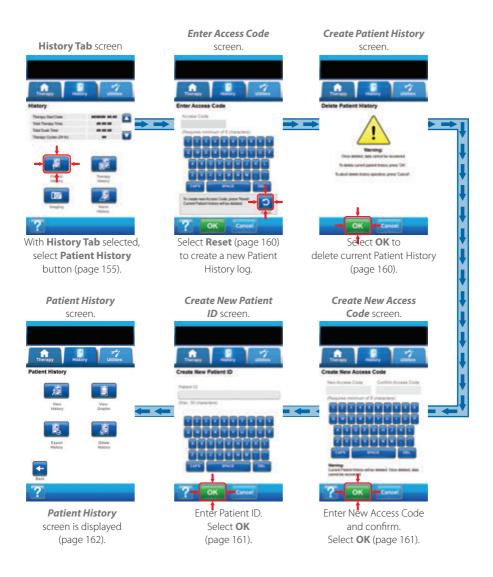
Patient History or Imaging Configuration (First Time Use) - Overview

The following flow charts show the basic steps required to establish an access code and start a new patient history log. Refer to the following pages for more detailed information about individual screens and options.





Screen shots shown above are for representation only. Refer to the page numbers listed for a more detailed view and more detailed information.



Patient History

Use the Patient History screens to create a new access code and start a new patient history log, view patient history, delete patient history, export patient history, and view a wound image area graph.

Create New Patient History





- 1. Select the **History** tab (page 155).
- Select Patient History from the History Tab screen (page 155) to continue to the Create New Access Code screen.
- Select the New Access Code field and use the on-screen keyboard to enter an access code. The access code must be at least six characters long.



Record the access code. It will be needed each time patient history is accessed.

 Select the Confirm Access Code field and re-enter the access code entered in the New Access Code field.



- 5. Select **OK** to continue to the **Create New Patient ID** screen.
- Select the **Patient ID** field and use the on-screen keyboard to enter the patient's identification (ID). The patient's ID must be 30 characters or less.



7. Select **OK** to continue to the **Patient History** screen (page 162).



For security purposes, the V.A.C.ULTA™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.



All information will be automatically deleted when the unit is returned to KCI.

Access Patient History

Once an access code is created, it must be entered to access Patient History.



- 1. Select the **History** tab (page 155).
- Select Patient History from the History Tab screen (page 155) to continue to the Enter Access Code screen.
- 3. Select the **Access Code** field and use the on-screen keyboard to enter the Patient History access code.



4. Select **OK** to continue to the *Patient History* screen (page 162).



For security purposes, the V.A.C.ULTA™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.



All information will be automatically deleted when the unit is returned to KCI.

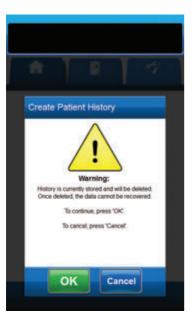


For security purposes, if an incorrect access code is entered 12 times, access to Patient History will be disabled. If this happens, contact KCI.

Create New Access Code

In order to create a second patient history log, a new access code must be created. When a second access code is created, all previously recorded patient history will be deleted.





- 1. Select the **History** tab (page 155).
- Select Patient History from the History Tab screen (page 155) to continue to the Enter Access Code screen.



3. Select **Reset** to create a new access code.



For security purposes, the V.A.C.ULTA™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.

 Select **OK** on the *Create Patient History* warning screen to continue to the *Create New Access Code* screen and delete the currently stored history.



Create New Access Code



Warning: Current Patient History will be deleted. Once deleted, data cannot be recovered.





Create New Patient ID







 Select the New Access Code field and use the on-screen keyboard to enter an access code. The access code must be at least six characters long.



Record the access code. It will be needed each time patient history is accessed.

 Select the Confirm Access Code field and re-enter the access code entered in the New Access Code field.



- 7. Select **OK** to continue to the **Create New Patient ID** screen.
- 8. Select the **Patient ID** field and use the on-screen keyboard to enter the patient's identification (ID). The patient's ID must be 30 characters or less.



9. Select **OK** to continue to the *Patient History* screen (page 162).



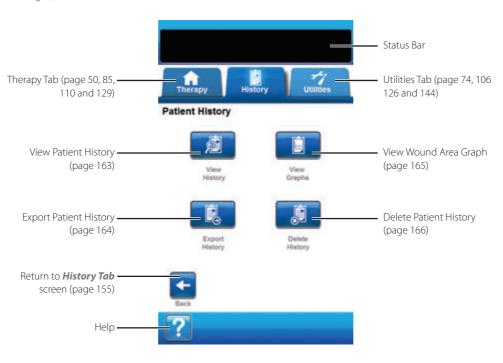
For security purposes, the V.A.C.ULTA™ Therapy Unit will only allow one patient record at a time to be active. If a new access code is entered, the current access code is overwritten and all patient history associated with it is deleted.



All information will be automatically deleted when the unit is returned to KCI.

Patient History Screen

Use the Patient History Screen to view, export, or delete a Patient History log (e.g. wound imaging information and disposable component changes).



The following options are available from the **Patient History** screen:

View History - Use to view patient history and add short notes about the patient's treatment. For a new patient history log, this screen will not have any event entries.

Export History - Use to export all patient history to a USB Drive or SD Card.

View Graph - Use to view a graph of the measured wound area over time.

Delete History - Use to delete the patient history data from the V.A.C.ULTA™ Therapy Unit's memory.

View Patient History Screen

Use the *View Patient History* screen to view and add short notes about the patient's treatment. For a new patient history log, this screen will not have any event entries.





- Select View History from the Patient History screen (page 162) to continue to the View Patient History screen.
- Use the **Up** and **Down** arrows to scroll through the patient's history.



- Select Add Note to continue to the Add Note screen.
- 4. Use the on-screen keyboard to add notes about the patient's history. The note has a maximum of 90 characters.







Cancel

Select **Back** to return to the **Patient History** screen.



Each Instillation cycle is not recorded in the history log. Only the initial settings selected during set up are recorded.

Export Patient History Screen

Use the **Export Patient History** screen to export patient history to a USB Drive or SD Card.







- Select Export History from the Patient History screen (page 162) to continue to the Export Patient History screen.
- Insert the desired memory device (USB Drive or SD Card) into the proper port on the front of the V.A.C.ULTA™Therapy Unit (page 18).



Use only non-powered USB devices.

3. On the *Export Patient History* screen, select the memory device being used, **USB** or **SD Card**.





- Select OK to begin exporting patient history to the memory device or select Cancel to return to the Patient History screen without exporting patient history.
- 5. The V.A.C.ULTA™ Therapy Unit will begin exporting patient history. A bar graph will display transfer progress.



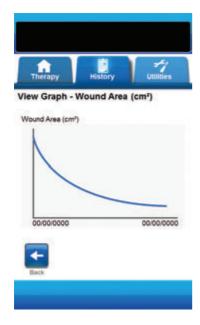
If the V.A.C.ULTA™ Therapy Unit detects an error during transfer, the Export Transfer Error screen will appear. Refer to the Data Transfer Errors section (page 180) of this manual for information about resolving this error.



 Once all patient history is successfully transferred to the memory device, select Exit on the Export Successful screen to return to the Patient History screen.

View Graph - Wound Area (cm²) Screen

Use the View Graph - Wound Area (cm²) screen to view a graph of the measured wound area over time.



 Select View Graph from the Patient History screen (page 162) to continue to the View Graph - Wound Area (cm²) screen.



A graph cannot be constructed if the patient history file has been deleted.



A graph cannot be constructed unless measurements of the wound area have been previously saved in the patient's history. At least two measurements from different days are required (area of the image against time) for a graph to be constructed. Refer to the Wound Imaging section (page 167) of this manual for complete details about entering this information in the patient's history.

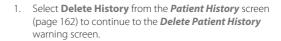


2. Select **Back** to return to the **Patient History** screen.

Delete Patient History Screen

Use the *Delete Patient History* screen to delete patient history data from the V.A.C.ULTA™ Therapy Unit's memory.







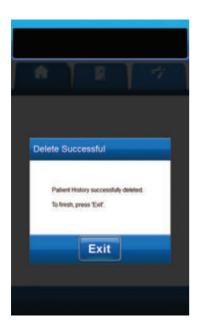
Cancel

 Select **OK** to confirm deletion or **Cancel** to return to the **Patient History** screen without deleting patient history.



3. Once the deletion is complete, select **Exit** on the *Delete Successful* screen to return to the *Patient History* screen.





Wound Imaging

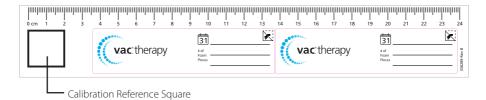
Use the Wound Imaging feature to aid in recording the wound healing process.



Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.

Accessories required to use this feature include:

- Digital camera with at least two megapixel resolution and that uses an SD Memory Card
- An SD Memory Card
- Calibration Reference Square located on the ruler in the dressing kit. This reference square is needed for the V.A.C.ULTA™ Therapy Unit to calculate wound measurements.



Stylus - located inside the door on the front of the V.A.C.ULTA™ Therapy Unit (page 18).



The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.

For optimal operation of the Wound Imaging feature, it is recommended that:

- A new sterile Calibration Reference Square be placed in the same location on the wound each time an image is taken.
- All images be taken directly above the wound.
- The wound and Calibration Reference Square fill as much of the image as possible.
- The image be taken in good lighting conditions.
- Image files must be in a JPEG (.jpg) format.



Using a camera that has a date and time function will allow for easier tracking of images.

Imaging Screen

Use the *Imaging* screen to upload images for calculating wound area and volume and to delete images from the V.A.C.ULTA™Therapy Unit.



Uploading Images

- From the *History Tab* screen (page 155), select *Imaging* to continue to the *Imaging* screen.
- 2. Enter Patient History access code (page 159).



A Patient History Log must be created prior to using the Imaging feature. Refer to the Create New Patient History section (page 158) of this manual for more information.

3. Insert memory device into the proper slot on front of the V.A.C.ULTA™ Therapy Unit (page 18).



Use only non-powered USB devices.



- Select Select Image & Analyze to continue to the *Upload Image* screen.
- Select the memory device that contains the images from the *Upload Images* screen. Select USB, SD Card, or Unit Memory.



There will be short delay while the images are accessed from the V.A.C.ULTA $^{\mathrm{TM}}$ Therapy Unit's memory or the memory card.



When selecting unit memory, the Select Image screen will be blank unless images have been previously uploaded and saved in unit memory.





 Select OK to continue to the Select Image screen. Select Cancel to return to the Imaging screen.



 Use the **Up** and **Down** arrows to display the desired folder or image in the window.



 If the desired image is in a folder, display the available folders with the **Up** and **Down** arrows and select the desired **Folder**. Use the **Up** and **Down** arrows to display the desired image.



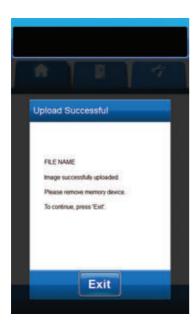
Select Back to back out of the folder.



- When the desired image is displayed, select OK to load the image into the V.A.C.ULTA™ Therapy Unit's memory.
- The V.A.C.ULTA™ Therapy Unit will begin uploading the image. A bar graph will display transfer progress.



If the V.A.C.ULTA™ Therapy Unit detects an error during transfer, the Upload Transfer Error screen will appear. Refer to the Data Transfer Errors section (page 180) of this manual for information about resolving this error.



11. Once image is successfully transferred, remove the memory device.



 Select Exit on the Upload Successful screen to continue to the Touch Corners of Reference Square screen.

Analyzing Images - Touch Corners of Reference Square



Use the supplied stylus to touch each corner of the reference square displayed in the image window on the **Touch Corners of Reference Square** screen.

When the last corner of the reference square is touched, the corner points will be joined by a highlighted line.



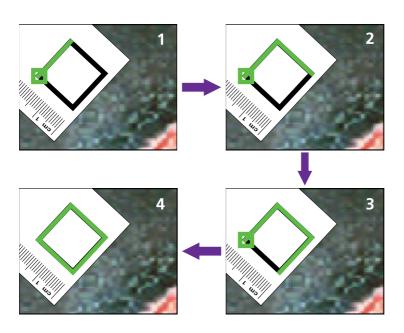
The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.



It is important to select corners in either a clockwise or counter-clockwise manner. Incorrect sequence will lead to a calibration error.



 Once all the corners of the reference square have been touched, select **OK** to continue to the *Trace Wound Perimeter* screen.



Analyzing Images - Trace Wound Perimeter



 Use the supplied stylus to trace a line around the wound area to be analyzed in the image window on the *Trace Wound Perimeter* screen.

If an error is made during tracing, select **Reset** to trace the wound area again.

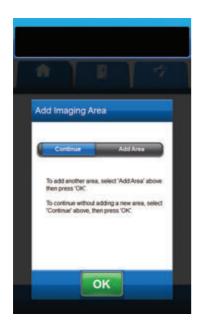


The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.



A square will appear at the start of the trace. The trace is completed when the end of the line returns to the start point.







- Once the wound area has been traced, select OK to continue to the Add Imaging Area screen.
- Select Add Area to continue back to the Trace Wound
 Perimeter screen if there is an additional wound area to be traced.

OR

4. Select **Continue** if all wound area(s) have been traced.



5. Select **OK** to continue to the *Image Area Depth* screen.

Analyzing Images - Image Area Depth



 Select the approximate depth of each wound area traced. Use + / -, as applicable to adjust above and below values shown.



2. Select **Back** to return to the **Add Imaging Area** screen.



3. Select **OK** to save wound imaging data to the patient's history.



4. Select **Cancel** to return to the **Upload Image** screen.

Delete Images



Imaging

Warning:

Wound imaging area and volume calculation features are not intended to be exact measurements and are not intended for use in the diagnosis and treatment of wounds.







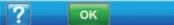




Select Image for Deletion







- From the *History Tab* screen (page 155), select *Imaging* to continue to the *Imaging* screen.
- 2. Enter Patient History access code.



A Patient History Log must be created prior to using the Imaging feature. Refer to the Create New Patient History section (page 158) of this manual for more information.



 Select Manage Saved Images to continue to the Select Image for Deletion screen.



There will be short delay while the images are accessed from the V.A.C.ULTA™ Therapy Unit's memory.

4. Use the **Up** and **Down** arrows to display the desired image in the window.



 When the desired image is displayed, select OK to continue to the Confirm Delete screen.

OR



6. Select **Back** to return to the *Imaging* screen.





7. Select **OK** to delete the image from the V.A.C.ULTA™ Therapy Unit's memory.

OR



8. Select **Cancel** to return to the **Select** *Image for Deletion* screen.



- Once the image is successfully deleted, the Select Image for Deletion screen will be displayed. Select another image to delete, or select Back to return to the Imaging screen.
- 10. Select the **History** Tab to return to the **History Tab** screen.

Therapy History Screen

The *View Therapy History* screen displays the patient's therapy information in date, time and event columns (e.g. therapy starts / stops, therapy settings and disposable component changes). The date is in descending order and time is displayed using the twenty-four hour clock format.



- From the History Tab screen (page 155), select Therapy History to continue to the View Therapy History screen.
- 2. Use the **Up** and **Down** arrows to scroll through the therapy history.



3. Select **Back** to return to the *History Tab* screen.



 Select Export Therapy History to continue to the Export History screen (page 179).

Alarm History Screen

The *View Alarm History* screen displays alarm information for the V.A.C.ULTA™ Therapy Unit in date, time and event columns (e.g. alarms and disposable component changes). The date is in descending order and time is displayed using the twenty-four hour clock format.



- From the *History Tab* screen (page 155), select Alarm
 History to continue to the *View Alarm History* screen.
- 2. Use the **Up** and **Down** arrows to scroll through the alarm history.



3. Select **Back** to return to the *History Tab* screen.



 Select Export Alarm History to continue to the Export History screen (page 179).

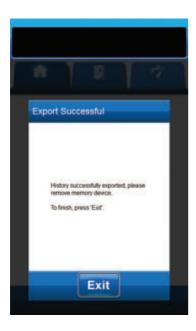
Export History Screen

Use the *Export History* screen to export therapy and alarm history to a memory device (USB or SD Card).









1. Insert the desired memory device (USB or SD Card) into the proper port on the front of the V.A.C.ULTA™ Therapy Unit (page 18).



Use only non-powered USB devices.

2. From the *History Tab* screen (page 155), select **Therapy History** to continue to the *View Therapy History* screen.



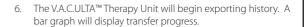
3. Select Export Therapy History to continue to the **Export History** screen.

5. Select **OK** to begin exporting history to

4. On the **Export History** screen, select the memory device being used, USB or SD Card.



the memory device or select Cancel to return to the View Therapy or Alarm *History* screen without exporting history. Cancel





If the V.A.C.ULTA™ Therapy Unit detects an error during transfer, the Export Transfer Error screen will appear. Refer to the Data Transfer Errors section (page 180) of this manual for information about resolving this error.



7. Once all history is successfully transferred to the memory device, select **Exit** on the Export Successful screen to return to the History Tab screen.

Data Transfer Errors

If the V.A.C.ULTA™ Therapy Unit detects an error during data transfer, the unit will display a Transfer Error screen.



The V.A.C.ULTA™ Therapy Unit is not compatible with USB Drives or SD Cards which have U3 software pre-installed. U3 software must be uninstalled prior to use.



If the **Export Transfer Error** screen appears, the possible reasons for transfer errors are:

- SD Card / USB Drive not inserted properly.
- Incorrect SD card / USB drive format.
- · Incorrect type of device connected.



1. Select **Reset** to return to try the export again.



2. Select **Exit** to cancel the export or to select a different destination device.



If the *Upload Transfer Error* screen appears, the possible reasons for transfer errors are:

- SD Card / USB Drive not inserted properly.
- Incorrect SD card / USB drive format.
- · Incorrect type of device connected.
- V.A.C.ULTA™ Therapy Unit's memory is full.



If therapy unit's memory is full, delete any unused photos to free memory. Refer to Delete Images section (page 175) for information on deleting images.



1. Select **Reset** to return to try the upload again.

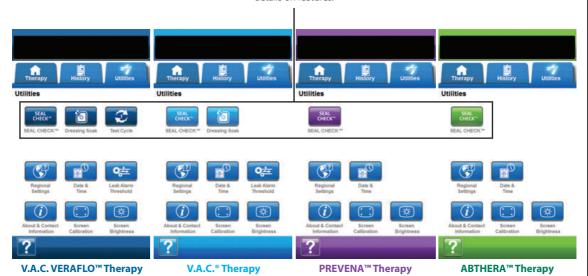


2. Select **Exit** to select a different image (page 168) or to exit Imaging.

Utilities Tab

Use the *Utilities Tab* screen to set preferences for the V.A.C.ULTA™ Therapy Unit.

Refer to pages 74, 106, 126 and 144 for details on features.



The following options are available from any therapy mode on the *Utilities Tab* Home screen:

Regional Settings - Use to set the language, units of measure, number format and date format displayed by the V.A.C.ULTA™ Therapy Unit.

Screen Calibration - Use to calibrate the V.A.C.ULTA™ Therapy Unit's touch screen.

About and Contact Information - Use to access information about the V.A.C.ULTA™ Therapy Unit, including the software version and KCI contact information.

Date and Time - Use to set the current date and time.

Screen Brightness - Use to adjust the brightness of the V.A.C.ULTA™ Therapy Unit's touch screen.

Leak Alarm Threshold - Use to set the leak rate threshold that triggers the Leak Alarm (V.A.C. ** Therapy and V.A.C. VERAFLO™ Therapy only).

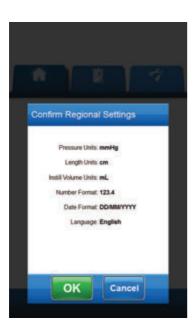
Help - Use to access the V.A.C.ULTA™ Therapy Unit's on-screen help features.

Regional Settings Screen

Use the **Regional Settings** screen to set the language, unit of measure, number format and date format displayed by the V.A.C.ULTA $^{\text{TM}}$ Therapy Unit.







- 1. Select the **Utilities** tab (page 181).
- Select Regional Settings from the Utilities Tab screen (page 181) to continue to the Regional Settings screen.
- 3. Set the following options:
 - Pressure Units Select between mmHg (millimeters of mercury) or kPa (kilo-Pascals).
 - Length Units Select between cm (centimeters) or inch (inches).
 - Instill Volume Units Select between mL (milliliters) or cc (cubic centimeters).
 - Number Format Select decimal separator "" or "" (123.4 or 123.4).
 - Date Format Select between DD/MM/YYYY or MM/ DD/YYYY.
 - **Language** Select the display language for the V.A.C.ULTA™ Therapy Unit.



 Once all options have been selected, select OK to continue to the Confirm Regional Settings screen.





 Select **OK** to confirm settings and return to the *Utilities Tab* screen. Select **Cancel** to return to the *Regional Settings* screen to make any required adjustments.

About and Contact Information Screen

Use the **About** and **Contact Information** screen to access information about the V.A.C.ULTA™ Therapy Unit, including the software version and KCI contact information.



- 1. Select the **Utilities** tab (page 181).
- Select About & Contact Information from the *Utilities Tab* screen (page 181) to continue to the *About* and *Contact Information* screen.
 - About Shows current software version information
 - Contact Information Shows KCI contact information



3. Select **Back** to return to the **Utilities Tab** screen.

Screen Calibration Screen

Use the **Screen Calibration** screen to calibrate the V.A.C.ULTA $^{\text{M}}$ Therapy Unit's touch screen. If screen inputs are not correctly recognized, it may be necessary to calibrate the touch screen.

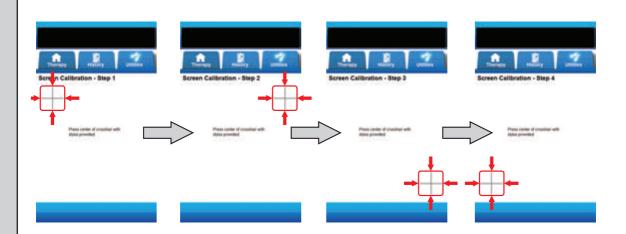


- 1. Select the **Utilities** tab (page 181).
- 2. Select **Screen Calibration** from the *Utilities Tab* screen (page 181) to continue to the *Screen Calibration* screen.



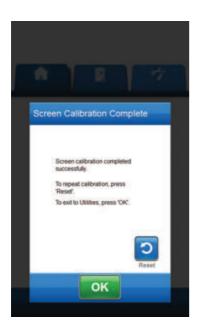
- 3. Select **OK** to begin calibrating the touch screen.
- 4. Using the supplied stylus, touch and hold the center of each cross as it is displayed on the touch screen.



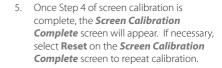




The touch screen should only be operated by finger or the supplied stylus. Using pens or other pointing devices will damage the screen and may affect correct device function.







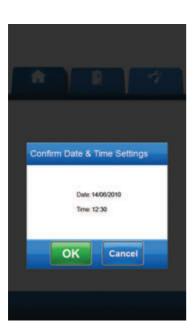


6. Select **OK** to return to the *Utilities Tab* screen.

Date & Time Settings Screen

Use the Date & Time Settings screen to set the current date and time.





- 1. Select the **Utilities** tab (page 181).
- Select Date & Time from the Utilities Tab screen (page 181) to continue to the Date & Time Settings screen.
- 3. Set the following options:
 - Day Select the current day. Use + / to adjust above and below values shown.
 - Month Select the current month. Use + / to adjust above and below values shown.
 - Year Select the current year. Use + / to adjust above and below values shown.
 - Hour Select the current hour of the current time. Use +
 / to adjust above and below values shown.
 - Minute Select the current minute of the current time. Use + / - to adjust above and below values shown.



 Once all options have been selected, select OK to continue to the Confirm Date & Time Settings screen.





 Select OK to confirm settings and return to the *Utilities Tab* screen. Select Cancel to return to the *Utilities Tab* screen without making any adjustments to the date and time.

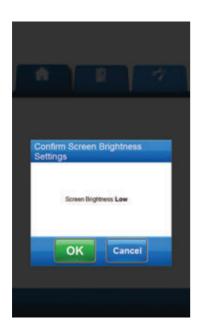
Screen Brightness Screen

Use the **Screen Brightness** screen to adjust the brightness of the V.A.C.ULTA™ Therapy Unit's touch screen.









- 1. Select the **Utilities** tab (page 181).
- Select Screen Brightness from the Utilities Tab screen (page 181) to continue to the Screen Brightness screen.
- Select the desired screen brightness Low, Medium, or High.



 Once the desired screen brightness has been selected, select OK to continue to the Confirm Screen Brightness Settings screen.

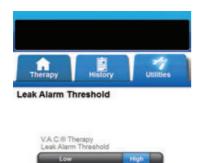




5. Select **OK** to confirm settings and return to the *Utilities Tab* screen. Select **Cancel** to return to the *Utilities Tab* screen without making any adjustments to the screen brightness.

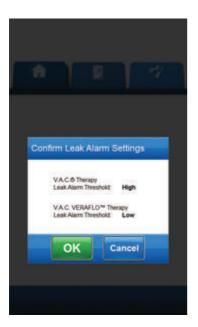
Leak Alarm Threshold Screen

Use the *Leak Alarm Threshold* screen to set the leak rate threshold that triggers the Leak Alarm. This option is available in the V.A.C. VERAFLO™ Therapy and V.A.C.® Therapy modes only.









- 1. Select the **Utilities** tab (page 181).
- Select Leak Alarm Threshold from the Utilities Tab screen (page 181) to continue to the Leak Alarm Threshold screen.
- Select the desired negative pressure leak alarm threshold for V.A.C.® Therapy and V.A.C. VERAFLO™ Therapy. Threshold options are **Low** or **High**. Low is approximately equal to one liter per minute. High is approximately equal to two liters per minute.



 Once the desired negative pressure leak alarm thresholds have been selected, select OK to continue to the Confirm Leak Alarm Settings screen.





 Select **OK** to confirm settings and return to the *Utilities Tab* screen. Select **Cancel** to return to the *Utilities Tab* screen without making any adjustments to the negative pressure leak alarm thresholds.

Confirm Serial Number

This screen appears when the V.A.C.ULTA $^{\text{m}}$ Therapy Unit is powered on and the serial number stored in the unit's memory is corrupt or missing.



To resolve:

- Compare serial number on unit's serial number label (page 18) to displayed serial number.
- 2. If serial number is incorrect, use the on-screen keyboard to re-enter the unit's serial number label.
- 3. Select **OK** to continue to the *Startup* screen.

Care and Cleaning

Standard Precautions

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

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

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



Ensure that the V.A.C.ULTA™ Therapy Unit is powered off and disconnected from 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 touchscreen 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



- Select Lock on the Home screen (page 50, 85, 110 and 129) to activate Screen Guard. The Lock icon will close.
- 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.

4. Select the 1, then the 2 on the Screen

3. To unlock the touch screen, touch the screen to display the **Screen Guard** screen.



Guard screen to return to the **Home** screen.

Explanation of Symbols Used



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

Rx Only

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



Important Operational Information



Manufacturer



Refer to User Manual



Catalog Number



No protection against ingress of solid forcing objects. Protected against ingress of vertically dripping water.



Authorized Representative in the European Community



Conforms with the Waste Electrical and Electronic Equipment Directive (2002/96/EC). At the end of useful life, dispose of all waste according to local requirements, or contact your local KCI subsidiary or agent for advice. This product is designated for separate collection at an appropriate collection point. Do not dispose of in normal waste stream.



ETL Listed, Conforms to AAMI ES60601-1 1st edition, CSA C22.2#60601-1 3rd edition and IEC 60601-1 3rd edition



Type BF Applied Part



MR Unsafe - Keep the V.A.C.ULTA™ Therapy Unit away from magnetic resonance imaging (MRI) equipment

Specifications

Specifications subject to change without notice.

Classification

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

V.A.C.ULTA™ Therapy Unit

Continuous Operation Type BF Applied Part Class I equipment IPX1

Power Supply

Class I Equipment Ordinary Equipment

V.A.C.ULTA™ Therapy Unit

Electrical Data (Power Supply)

External Power Supply Input: 100 - 240 VAC, 1.6A, 50Hz - 60Hz
External Power Supply Output. 15V, 4.8A

Alarm Volume

Minimum of 72 dBA at 1 meter in maximum volume orientation.

Environmental Conditions

Instill Pump Volumetric Accuracy

6 - 10 ml ± 2 ml

12 - 50 ml ± 20%

55 - 500 ml ± 15%

Accuracy Testing performed under the following conditions

 $The \ disposable \ components \ of the \ V.A.C. ULTA \ ^{\mathtt{m}} The \ rapy \ System \ are \ considered \ Applied \ Parts \ under \ IEC \ 60601-1 \ Third \ Edition.$

Electromagnetic Compatibility

Electromagnetic Interference - Although this equipment conforms with the intent of the directive 2004/108/EC in relation to Electromagnetic Compatibility (EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.

Portable and mobile RF communications equipment can effect medical electrical equipment.

Radios, cell phones and similar devices may affect this equipment and should be kept at least 6.5 feet (2 meters) away from the equipment.

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.

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

The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the electromagnetic environment in which the V.A.C.ULTA™Therapy Unit should be used in a clinical environment.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions					
The V.A.C.ULTA™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.ULTA™ Therapy Unit should assure that it is used in such an environment.					
Emission Test	Compliance	Electromagnetic environment			
RF emissions CISPR 11	Group 1 Class A	The V.A.C.ULTA™ 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			
Conducted emissions CISPR 11	Group 1 Class A				
Harmonic emissions IEC 61000-3-2	Class A				
Voltage fluctuations / flicker emissions IEC 61000-3-3	Yes				

Guidance and Manufacturer's Declaration - Electromagnetic Immunity						
The V.A.C.ULTA™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or user of the V.A.C.ULTA™ Therapy Unit should assure that it is used in such an environment.						
Immunity Test	IEC 60601 Test Level	Compliance level	Electromagnetic Environment Guidance			
Electrostatic discharge (ESD) IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	In accordance with IEC 60601-1-2: 2007, floors are covered with synthetic material, the relative humidity should be at least (30)%.			
Electrical fast transient / burst IEC 61000-4-4	±1kV Cables ±2kV Power	±1kV Cables ±2kV Power				
Surge IEC 61000-4-5	1kV line(s) to line(s) 2kV line(s) to earth	1kV line(s) to line(s) 2kV line(s) to earth				
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% half cycle 40% 5 cycles 70% 25 cycles 5% for 5 seconds	5% half cycle 40% 5 cycles 70% 25 cycles 5% for 5 seconds				
Power frequency (50Hz / 60Hz) magnetic field IEC 61000-4-8	3A/M	3A/M	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.			

Recommended separation distances between portable and mobile RF communications equipment and the V.A.C.ULTA™ Therapy Unit

The V.A.C.ULTA™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the V.A.C.ULTA™ Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V.A.C.ULTA™ Therapy Unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter meters			
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz	
w	d = 1.2 \sqrt{P}	d = 1.2 \sqrt{P}	d = 2.3 \sqrt{P}	
0.01	0.12	0.12	0.23	
0.1	0.38	0.37	0.74	
1	1.2	1.2	2.3	
10	3.8	3.7	7.4	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separate 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 surfaces, objects and people.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The V.A.C.ULTA™ Therapy Unit is intended for use in an electromagnetic environment specified below. The customer or user of the V.A.C.ULTA™ Therapy Unit should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the V.A.C.ULTA™Therapy Unit, including cables, than the recommended separation distance calculated from the equation application to the frequency of the transmitter.	
			Recommended Separation Distance	
6 1 1 105	21/	21/	Battery Operated Device	
Conducted RF IEC 61000-4-6	3Vrms 150K - 80 MHz	3Vrms 150K - 80 MHz	$d = 1.2 \sqrt{P}$	
Radiated RF IEC 61000-4-3	3V/meter 80 MHz - 2.5 GHz	3V/meter 80 MHz - 2.5 GHz	d = 1.2 \sqrt{P} 80 MHz to 800 MHz	
			d = 2.3 \sqrt{P} 800 MHz to 2.5 GHz	
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey 1, should be less than the compliance level in each frequency range. 2 Interference may occur in the vicinity of equipment marked with the following symbol:	

NOTE 1: At 80 MHz and 800 MHz, 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.

¹ 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 asses 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 V.A.C.ULTA™Therapy Unit is used exceeds the applicable RF compliance level above, the V.A.C.ULTA™Therapy 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 V.A.C.ULTA™Therapy Unit.

² Over the frequency range 150kHz, field strengths should be less than 3V/m.

Power Cord	Description	Cord Specifications	Max Length (inches)	
350084	Cord, VAC Ulta AC Power	3 x 18 AWG, SJT, 10A / 125V	78.74	
360080	Cord, VAC Via Power, IT-220V	H05VVF-3G, 10A / 250V	79.00	
360074	Cord, VAC Via Power, EU-220V	H05VVF-3G, 10A / 250V	79.00	
350753	Cord, VAC Ulta Power, UK-240V	H05VVF-3G, 10A / 250V	78.74	
350758	Cord, VAC Ulta Power, DK-220V	H05VVF-3G, 10A / 250V	78.74	
360081	Cord, VAC Via Power, CH-220V	H05VVF-3G, 10A / 250V	79.00	
360122	Cord, VACVia Power South Africa / India	H05VVF-3G, 10A / 250V	79.00	
360076	Cord, VAC Via Power, AU / NZ-240V	H05VVF-3G, 10A / 250V	79.00	
4103887	Cord, Power Brazil	H05VVF-3G, 10A / 250V	79.00	



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 V.A.C.ULTA™ Therapy Unit or decreased electromagnetic immunity of the V.A.C.ULTA™ Therapy Unit.

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, www.veraflo.com or www.vaculta.com KCI USA, Inc. 12930 IH 10 West, San Antonio, TX 78249

Outside the US visit www.kci-medical.com



KCI USA, Inc. 12930 IH 10 West San Antonio, TX 78249 USA 1-800-275-4524 www.acelity.com www.veraflo.com www.vaculta.com

EC REP

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