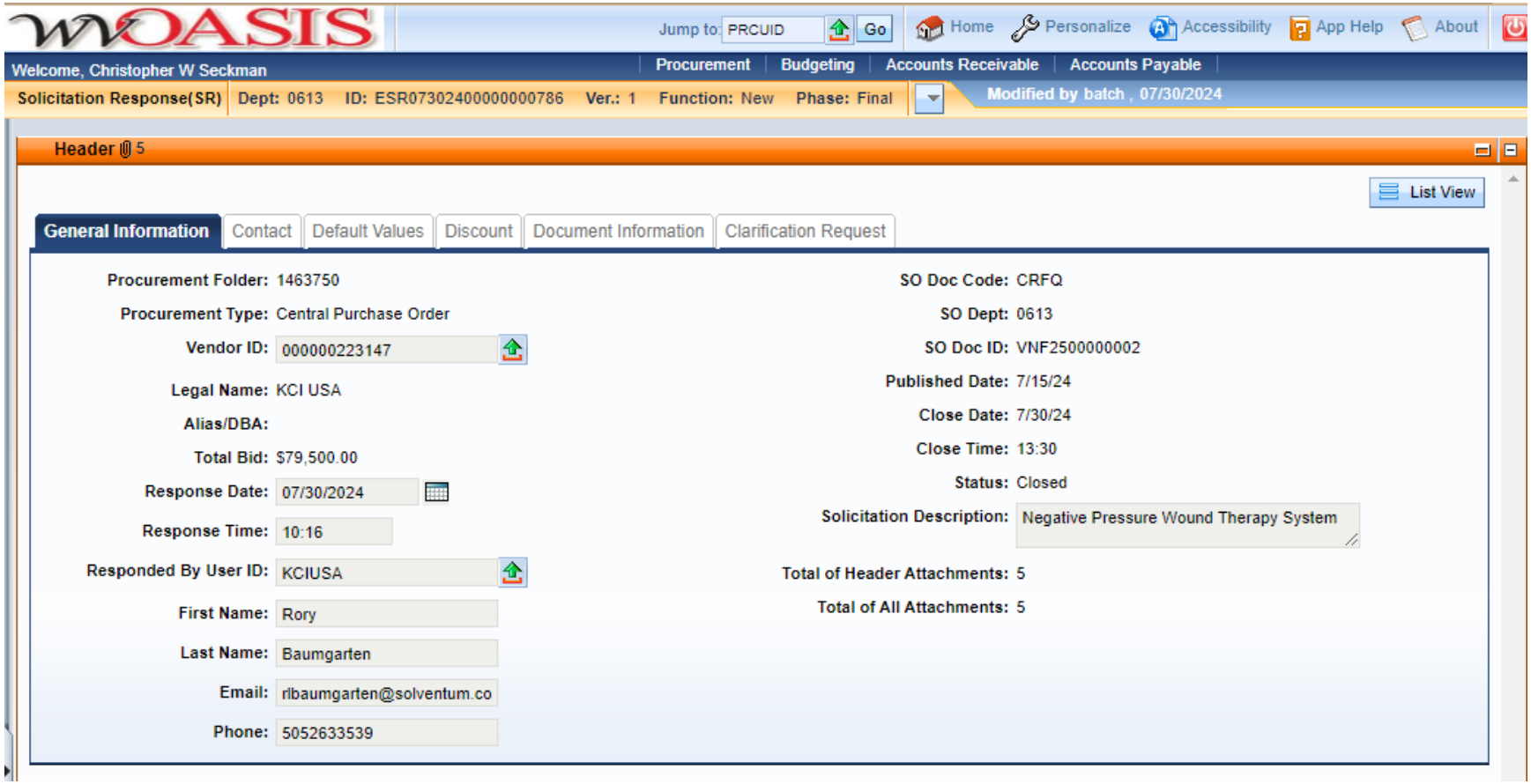
The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.


wvOASIS
Jump to: PRCUID Go
Home Personalize Accessibility App Help About
Welcome, Christopher W Seckman
Procurement Budgeting Accounts Receivable Accounts Payable
Solicitation Response(SR) Dept: 0613 ID: ESR07302400000000786 Ver.: 1 Function: New Phase: Final
Modified by batch , 07/30/2024
Header 5
List View
General Information Contact Default Values Discount Document Information Clarification Request
Procurement Folder: 1463750
Procurement Type: Central Purchase Order
Vendor ID: 000000223147
Legal Name: KCI USA
Alias/DBA:
Total Bid: $79,500.00
Response Date: 07/30/2024
Response Time: 10:16
Responded By User ID: KCIUSA
First Name: Rory
Last Name: Baumgarten
Email: rlbaumgarten@solventum.co
Phone: 5052633539
SO Doc Code: CRFQ
SO Dept: 0613
SO Doc ID: VNF2500000002
Published Date: 7/15/24
Close Date: 7/30/24
Close Time: 13:30
Status: Closed
Solicitation Description: Negative Pressure Wound Therapy System
Total of Header Attachments: 5
Total of All Attachments: 5

Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

State of West Virginia
Solicitation Response

Proc Folder:	1463750
Solicitation Description:	Negative Pressure Wound Therapy System
Proc Type:	Central Purchase Order

Solicitation Closes	Solicitation Response	Version
2024-07-30 13:30	SR 0613 ESR07302400000000786	1

VENDOR

000000223147
KCI USA

Solicitation Number: CRFQ 0613 VNF2500000002

Total Bid: 79500 **Response Date:** 2024-07-30 **Response Time:** 10:16:33

Comments:

FOR INFORMATION CONTACT THE BUYER
David H Pauline
304-558-0067
david.h.pauline@wv.gov

Vendor
Signature X **FEIN#** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Negative Pressure Wound Therapy System	3.00000	EA	26500.000000	79500.00

Comm Code	Manufacturer	Specification	Model #
42191707			

Commodity Line Comments: The V.A.C Freedom is obsolete, therefore KCI USA, Inc. is proposing our most similar, the ActiV.A.C. Therapy Unit

Extended Description:

See Attached Exhibit "A" Pricing Page to input pricing.
Negative Pressure Wound Therapy Systems, KCI 60050 FREEDOM V.A.C unit or equal

3M | V.A.C.® Therapy

Designed for mobile patients

3M™ ActiV.A.C.™ Therapy System

The 3M™ ActiV.A.C.™ Therapy Unit is a portable negative pressure wound therapy device designed for the mobile patient

The features of this ergonomically designed therapy unit include:

For the patient

- Lightweight. Weighs only 1.08Kg
- Small size with a low profile that can be worn close to the body
- Easy-to-use, single-touch therapy on/off operation
- Alarm notifications that are easy to recognize and correct
- Easy, quick release 300ml canister
- 14-hour battery for activities of daily living

For the clinician

3M™ SensaT.R.A.C.™ technology

Only 3M™ V.A.C.® Therapy Systems provide patented SensaT.R.A.C. Technology, a real time pressure feedback system.

- Adjusts pump output to the wound site, compensating for wound distance, wound position, exudate characteristics, and patient movement
- Delivers and maintains programmed negative pressure to support optimal healing outcomes

3M™ Seal Check™ Feature

Designed to help clinicians and patients identify and troubleshoot negative pressure leaks.

- Instant Feedback. Audio and visual cues are delivered in real-time, allowing easy location of dressing leaks
- Enhanced Therapy Confidence. A proper seal helps maintain programmed therapy to support optimal wound healing
- Possible Reduction of Unscheduled Visits. Easier for clinicians to help troubleshoot problems over the phone

Settings guide

Recommended therapy settings and pressure ranges are pre-programmed for indicated wound types:

- Easy Set Up. With pre-programmed settings by wound type, clinicians can initiate therapy quickly and efficiently
- Ease of Use. Intuitive control functions make it easier to use, especially for clinicians who are not as familiar with V.A.C.® Therapy

Therapy history reporting

Document Patient Compliance with V.A.C.® Therapy.

- Monitors therapy usage, settings, durations, and dressing and canister changes to help verify patients are receiving the prescribed course of therapy
- USB port for convenient data downloads

Simplified touch screen

Enhanced, simplified control functions:

- Easy Navigation. With full-color interface with intuitive touch screen controls
- Simplified Patient Mode. Designed to be easy to use and understand

3M™ V.A.C.® Dressing options with 3M™ SensaT.R.A.C.™ Technology

Specially designed dressings, because no two wounds are alike.

3M™ V.A.C.® Simplace™ Dressings

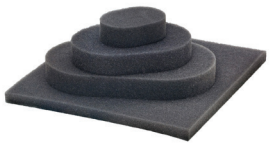
Designed to simplify the V.A.C.® Dressing placement process

- Helps to create an environment that promotes healing by facilitating granulation tissue formation
- Fewer steps, easier and faster application
- Spiral cut foam is simple to size; no scissors necessary
- Design allows for easier bridging

3M™ V.A.C.® Granufoam™ Bridge Dressings

Ideal for use with wounds in pressure sensitive areas that requiring bridging

- Preassembled components specifically designed to simplify dressing application
- Integrated bridge allows for SensaT.R.A.C. Pad placement away from the wound site
- Wicking layers help ensure intact skin stays dry
- Allows V.A.C.® Therapy to be used in conjunction with off-loading therapies



3M™ V.A.C.® Granufoam™ Dressings

Advanced wound dressings to assist granulation tissue formation and enhance exudate removal

- Can be easily trimmed to fit the contours of deep or irregularly shaped wounds
- Can be customized for bridging techniques when treating multiple wounds

3M™ V.A.C.® Granufoam Silver™ Dressings

More than just a silver dressing

- Combines the benefits of V.A.C.® Therapy and silver in one dressing, with no need for adjunct silver layers
- Specifically designed for use with V.A.C.® Therapy Systems

3M™ SensaT.R.A.C.™ Pad

Only SensaT.R.A.C.™ Technology actively measures, monitors, and manages the accurate delivery of the physician's prescribed therapy to the wound site.

- Designed with patient comfort in mind
- Flexible pad material for easy application over body contours
- Discreet, low profile design

3M™ V.A.C. Whitefoam™ Dressings

Comfortable and versatile wound dressings

- May be used over split thickness skin grafts
- Helps bolster flaps and grafts
- Higher tensile strength (than V.A.C.® Granufoam™ Dressing) allows for easy removal from tunnels and undermining
- Recommended in situations where hypergranulation responses are likely

3M™ V.A.C.® Dressings and Accessories Ordering Information

Part Number	Description	Case Quantity
Standard		
M8275051/10	3M™ V.A.C.® Granufoam™ Dressing Kit - Small	10
M8275051/5	3M™ V.A.C.® Granufoam™ Dressing Kit - Small	5
M8275052/10	3M™ V.A.C.® Granufoam™ Dressing Kit - Medium	10
M8275052/5	3M™ V.A.C.® Granufoam™ Dressing Kit - Medium	5
M8275053/10	3M™ V.A.C.® Granufoam™ Dressing Kit - Large	10
M8275053/5	3M™ V.A.C.® Granufoam™ Dressing Kit- Large	5
M8275065/5	3M™ V.A.C.® Granufoam™ Dressing Kit - X-Large	5
Silver		
M8275098/10	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Small	10
M8275098/5	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Small	5
M8275096/10	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Medium	10
M8275096/5	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Medium	5
M8275099/10	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Large	10
M8275099/5	3M™ V.A.C.® Granufoam Silver™ Dressing/Dressing Kit - Large	5
Ease of Use		
M8275045/5	3M™ V.A.C.® Simplace™ EX Dressing Kit - Medium	5
M8275046/5	3M™ V.A.C.® Simplace™ EX Dressing Kit - Small	5
M8275042/10	3M™ V.A.C.® Granufoam™ Bridge Dressing Kit	10
M8275042/5	3M™ V.A.C.® Granufoam™ Bridge Dressing Kit	5
Less-Adherent* *Than 3M™ V.A.C.® Granufoam™ Dressings		
M6275033/10	3M™ V.A.C. Whitefoam™ Dressing, Foam Only - Small	10
M6275034/10	3M™ V.A.C. Whitefoam™ Dressing, Foam Only - Large	10
M8275067/10	3M™ V.A.C. Whitefoam™ Dressing Kit - Large	10
M8275067/5	3M™ V.A.C. Whitefoam™ Dressing Kit - Large	5
M8275068/10	3M™ V.A.C. Whitefoam™ Dressing Kit - Small	10
M8275068/5	3M™ V.A.C. Whitefoam™ Dressing Kit - Small	5
Accessories		
M6275009/10	3M™ V.A.C.® Drape	10
M6275026/10	3M™ V.A.C.® Gel	10
M6275066/10	3M™ V.A.C.® Y-Connector	10
M6275066/5	3M™ V.A.C.® Y-Connector	5
M6275069/10	3M™ V.A.C.® Tubing Cap	10
M6275069/5	3M™ V.A.C.® Tubing Cap	5
3M™ ActiV.A.C.™ Canisters		
M8275058/10	3M™ ActiV.A.C.™ 300ml Canister with Gel	10
M8275058/5	3M™ ActiV.A.C.™ 300ml Canister with Gel	5

APPROVED
AMERICAN PODIATRIC MEDICAL ASSOCIATION

3M™ V.A.C.® Therapy has been awarded the APMA Seal of Acceptance, which recognizes products that have been found to promote quality foot health and be of significant value when used in regular professional treatment.

3M Company
2510 Conway Ave.
St. Paul, MN 55144 U.S.A.

Phone 1-800-275-4524 (NPWT products)
Phone 1-800-228-3957
Web 3M.com/Medical

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. This material is intended for healthcare professionals. Rx Only.

Note: Disposable components of the 3M™ V.A.C.® (Vacuum Assisted Closure®) Therapy System, including the foam dressing (i.e., 3M™ V.A.C.® Granufoam™, 3M™ V.A.C.® Granufoam Silver™, or 3M™ V.A.C. Whitefoam™ Dressing), tubing and drape are packaged sterile and are manufactured without natural rubber latex. 3M™ V.A.C.® Therapy Unit canisters are packaged fluid path sterile and are manufactured without natural rubber latex. All disposable components of the V.A.C.® Therapy System are for single use only. To help ensure safe and effective use, the V.A.C.® Granufoam®, V.A.C.® Granufoam Silver™ and V.A.C. Whitefoam™ Dressings are to be used only with V.A.C.® Therapy Units.

ACTIV.A.C.™ THERAPY SYSTEM

DESIGNED SPECIFICALLY FOR THE AMBULATORY PATIENT

LIGHTWEIGHT, PORTABLE THERAPY UNIT

- Easy to use full color LCD screen with touch-screen controls
- Single-touch therapy on/off
- Intuitive menus simplify therapy programming and operation
- Quick release, multi-orientational 300ml canister
- Discreet carrying case provided for ambulatory use

SENSAT.R.A.C.™ TECHNOLOGY

- Proprietary technology monitors and maintains set negative pressure at the wound site
- Designed to help reduce false alarms and tubing blocks
- Tubing and Pad designed with patient comfort in mind

SEAL CHECK™ FEATURE

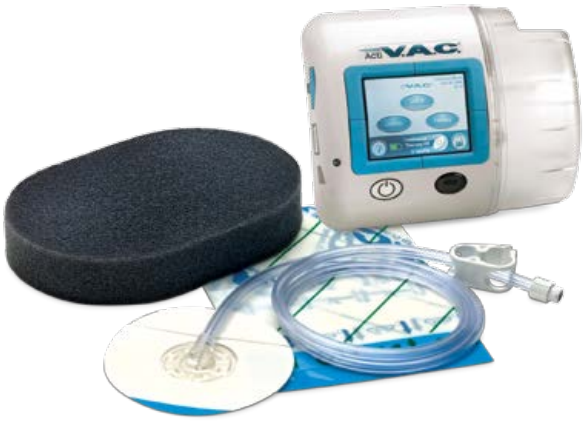
- Provides instant feedback to help identify leaks
- Helps ensure seals
- Easy troubleshooting for patients; can help reduce unscheduled caregiver visits

THERAPY HISTORY REPORT

- Allows clinicians to monitor and track therapy settings, alarm history, therapy dates and times, dressing and canister changes and records the number of pieces of foam used

SETTINGS GUIDE

- Aligned with V.A.C.® Therapy Clinical Guidelines
- Optional preset therapy settings by wound type eases setup
- Step-by-step guide simplifies setup for infrequent users



SPECIFICATIONS:

ACTIV.A.C.™ Negative Pressure Wound Therapy System: P/N 340000

Weight: .....2.4 lbs (1.08 kg) with an empty canister
Dimensions: .....7.6" W x 6" H x 2.5" D (19.3 x 15.2 x 6.4cm)
Battery Type:.....Lithium ion rechargeable battery
Battery Life: .....14 hour average, depending on settings
Recharging Time:.....6 hours max
Canister Size: 300ml
Therapy Delivery Modes: .....Continuous or Intermittent
Intensity Settings: .....Low, Medium, High
Therapy Pressure Options: .....-25mmHg to -200mmHg (-3.3 kPa to -26.6 kPa)

ELECTRICAL DATA

External Power Supply Input:.....100-240 VAC .72 A @ 115 VAC 47-63 Hz
External Power Supply Output: .....12 V, 3.3 A
Patient & Enclosure Leakage Current:.....<100 Microamps

IEC CLASSIFICATION

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

STORAGE CONDITIONS

Temperature Range:.....-4°F (-20°C) to 140°F (60°C)
Relative Humidity Range: .....0-95% non-condensing

OPERATING CONDITIONS

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

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult product instructions for use prior to application. Rx only.

DSL#16-0372.US (Rev. 4/16)

KCI
An Acelity Company

Acelity™

activac®
KCI Healing by design

User Manual

For Patients and Clinicians

KCI®

WARNING

Important Safety Information Accompanies This Device

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

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

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

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

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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

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

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.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not connect this product or its components to devices not recommended by KCI.
- Use only V.A.C.® Dressings with this product.
- Keep this product away from heated surfaces.
- Although this product conforms to the intent of the standard IEC 60601-1-2 in relation to Electromagnetic Compatibility, electrical equipment may produce interference. If interference is suspected, separate the equipment and contact KCI.
- Avoid spilling fluids on any part of this product.

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

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

Notice

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

Patient Table of Contents

PATIENT

Introduction

This Patient information provides operating instructions for the ActiV.A.C.® Therapy Unit. Patient Mode allows the patient to start and stop therapy, find leaks using the Seal Check™ feature, and attend to alerts and alarms, but does not allow changes to therapy settings.

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

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

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

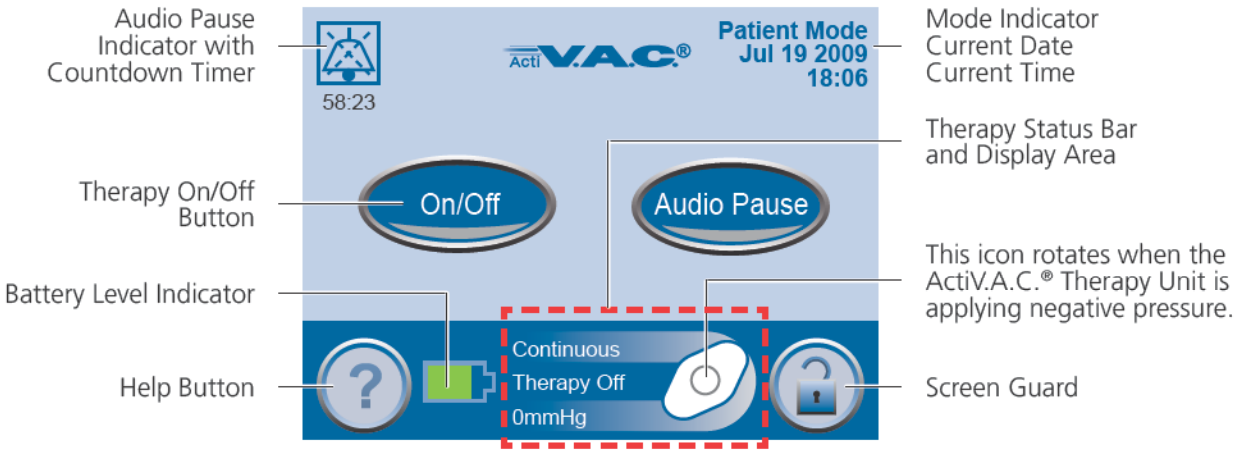
V.A.C.® Therapy is prescribed by a physician or other licensed prescriber. As with any prescription medical device, it is important to follow physician's orders and product instructions. Do not adjust settings or perform therapy application without the express direction and/or supervision of a trained clinical caregiver.

Important product and therapy indications, contraindications, precautions and safety information apply. Please consult your healthcare provider, the accompanying V.A.C.® Therapy System Safety Information Sheet, Quick Reference Guide (located in the pocket on the inside of the front flap of the carrying case) and this User Manual prior to use.

ActiV.A.C.® Therapy Unit

The USB Data Port is to be used with non-powered USB flash drives (memory sticks) only. No AC or battery powered drives, computers, computer equipment or other devices may be used.

Patient Mode Home Screen



A lighted green crescent means the function is on.

An unlit crescent means the function is off.

Common Screen Control Buttons

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

Access *Help* screens when available.

Activate the Screen Guard feature to help prevent unintentional changes. This feature should be used when cleaning the touch screen. To release Screen Guard, press 1 and then 2.

Navigation Buttons

One or more of these buttons may appear on a screen:

Leave the current screen.

Stop action in progress.

Go to the next screen.

Return to the previous screen.

Acknowledge the action is complete and display the next screen.

Audio Pause

Press Audio Pause to silence (for 60 minutes) alerts that do not need immediate attention.

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

Alarms needing immediate attention override the Audio Pause feature. See the *Alerts and Alarms* chapter of this manual (page 18) for details on alarms and how to resolve them.

Battery Charging Instructions

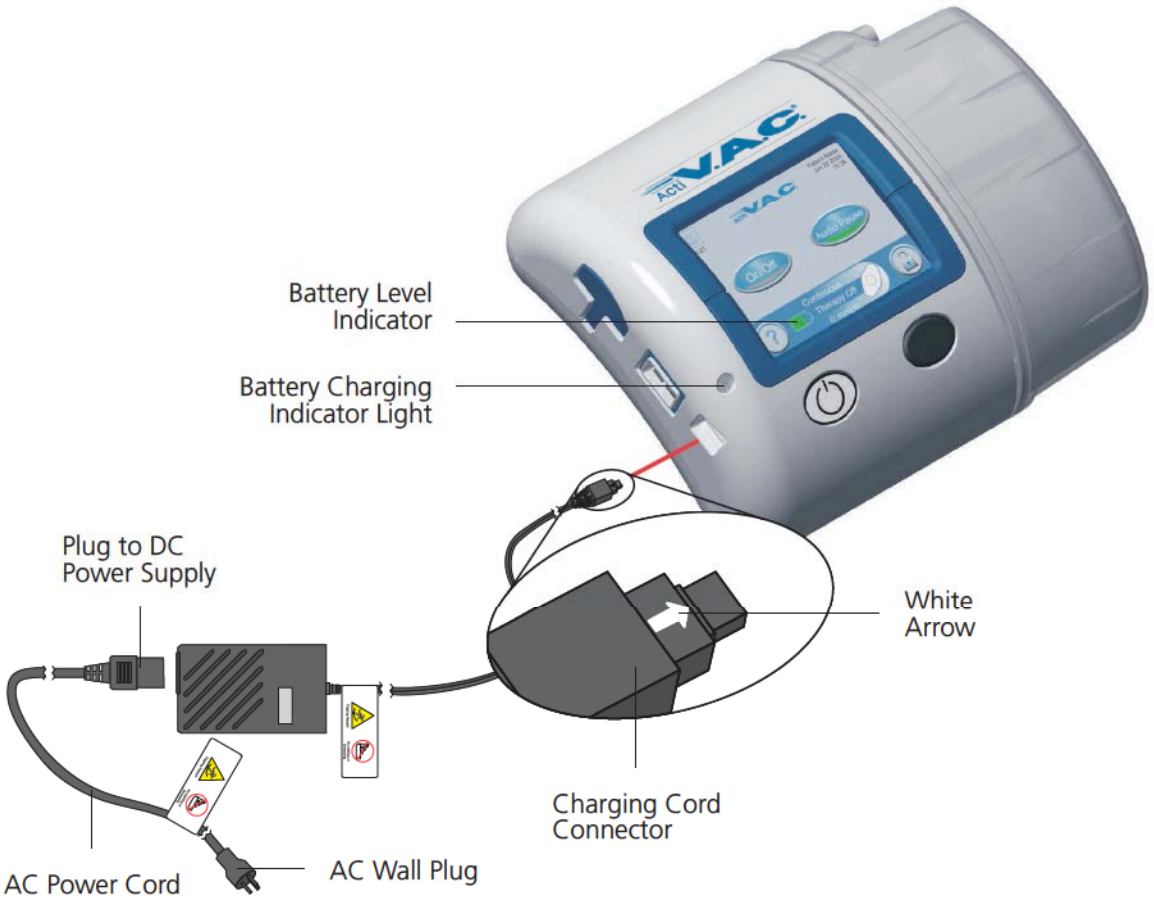
The ActiV.A.C.® Therapy Unit comes with a rechargeable battery. The battery is not user accessible or serviceable. The power supply has a two-part cord; one that plugs into an AC wall outlet and one that plugs into the ActiV.A.C.® Therapy Unit.

Use only the power supply provided with the ActiV.A.C.® Therapy Unit. Using any other power supply may damage the therapy unit.

If environmental conditions (specifically, low humidity) pose a risk of static electricity, take care when handling the therapy unit while it is out of the carrying case and 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.

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

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



To charge the battery:

1. Plug the AC power cord into the DC power supply.
2. Plug the AC wall plug into an AC wall outlet.
3. Locate the arrow on the charging cord connector.
4. Place therapy unit and charging cord so that touch screen (on therapy unit) and arrow (on charging cord connector) both face up.
5. Plug charging cord connector **securely** into therapy unit.

The plug indicator appears on the touch screen while the unit is plugged into a wall outlet.

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

To maximize battery life, keep the unit plugged in whenever possible.

Battery Charging Indicator Light

When the ActiV.A.C.® Therapy Unit is correctly plugged into the ActiV.A.C.® Power Supply, the Battery Charging Indicator Light (page 8) will glow amber as the battery charges. When the battery has reached full charge the light will glow green.

Battery Level Indicator

The battery level is shown on the bottom of the touch screen (page 6).

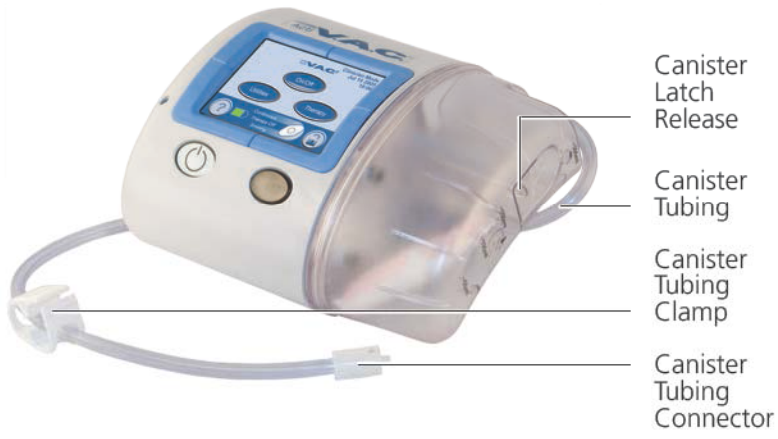
Fully Charged

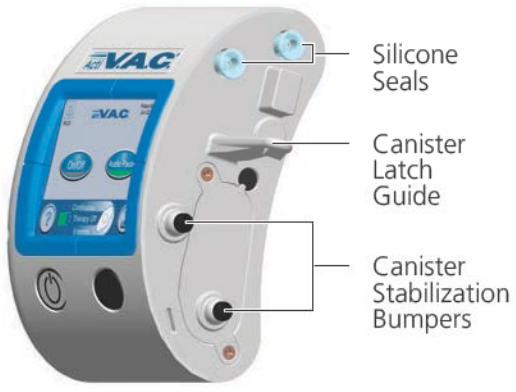
In Use

Battery Low. Charge battery soon.

Battery Critical. **Charge battery immediately.**

Canister





Canister latch guide on the therapy unit may have sharp edges. Do not handle the ActiV.A.C.® Therapy Unit by the canister latch guide.

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

When not in use, always store the ActiV.A.C.® Therapy Unit in the carrying case <u>without</u> a canister in place.

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

Canister Changes

The ActiV.A.C.® Canister should be changed when full (the alarm will sound), or at least once a week to control odor.

V.A.C.® Therapy is stopped when Canister Full Alarm sounds.

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

1. Stop therapy by pressing the Therapy On/Off button on the touch screen (therapy is already off if addressing a Canister Full Alarm). **Do not turn power off to the ActiV.A.C.® Therapy Unit.**


Fig. 1

2. Slide both tubing clamps toward the tubing connector.

3. Tightly close both tubing clamps to prevent spillage of contents in tubing. Several clicks should be heard (Fig. 1).


Fig. 2a


Fig. 2b

4. Compress and then twist the tubing connectors until the locking tabs are disengaged and pull the connector apart to disconnect the dressing tubing from the canister tubing (Fig. 2a and 2b).


Fig. 3

5. Press downward on the canister latch release (Fig. 3).

6. Remove the canister from the therapy unit by pulling it directly away from the unit (Fig. 4).

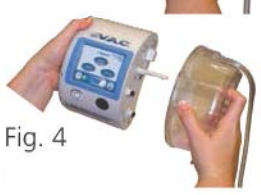


Fig. 4

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

7. Install the new canister onto the therapy unit by sliding the opening in the canister over the canister latch guide. Ensure the canister is installed directly onto the therapy unit. Do not twist or turn the canister as it is being installed. An audible click should be heard when canister is properly installed.


Fig. 5a

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


Fig. 5b

9. Reconnect the new canister tubing to the dressing tubing by pushing the connectors together. Compress and twist until the locking tabs are fully engaged (Fig. 5a and 5b).


Fig. 6

10. Open both tubing clamps (Fig. 6).

11. Press the Therapy On/Off button on the touch screen to restart therapy. Verify the dressing collapses.

Carrying Case

Keep the ActiV.A.C.® Therapy Unit in the upright position. The touch screen should be in a readable, right-side-up orientation or facing up when the therapy unit is laid on a level surface.

It is recommended that the ActiV.A.C.® Therapy Unit always be kept in the carrying case when in use.

Carrying Case Options

The ActiV.A.C.® carrying case has an integrated belt loop and a separate adjustable strap to allow for versatile carrying options.

When worn or carried ensure that the buckles are properly snapped together.

Keep the ActiV.A.C.® Therapy Unit in the upright position. The touch screen should be in a readable, right-side-up orientation or facing up when the therapy unit is laid on a level surface.

It is recommended that the ActiV.A.C.® Therapy Unit always be kept in the carrying case when in use.

Therapy Unit Disconnect

The therapy unit may be disconnected from dressing tubing for short periods of time for such activities as bathing.

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

1. Stop therapy by pressing the Therapy On/Off button on the touch screen.


Fig. 1

2. Turn power off to the ActiV.A.C.® Therapy Unit and uplug it from the electrical outlet.

3. Slide both tubing clamps toward the tubing connector.

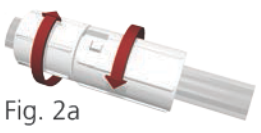


Fig. 2a

4. Tightly close both tubing clamps to prevent spillage of contents in tubing. Several clicks should be heard (Fig. 1).

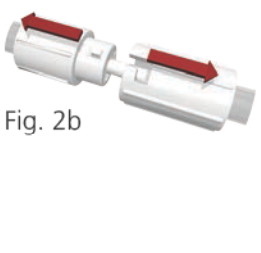


Fig. 2b

5. Compress and then twist the tubing connectors until the locking tabs are disengaged and pull the connector apart to disconnect the dressing tubing from the canister tubing (Fig. 2a and 2b).

6. Cover tubing ends with gauze to collect any spillage from tubing.

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

Power Therapy Unit On or Off

The Power On/Off button is located immediately below and to the left of the touch screen (see page 6 for illustration).

Press and hold the Power On/Off button for approximately two seconds to turn the ActiV.A.C.® Therapy Unit on or off.

The therapy unit will go through a self-check routine and then present a *Warning Message* screen. Press OK to continue to the *Patient Mode* home screen (shown on page 6).

Therapy On or Off

Start or stop V.A.C.® Therapy.

A lighted green crescent means the function is on.

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

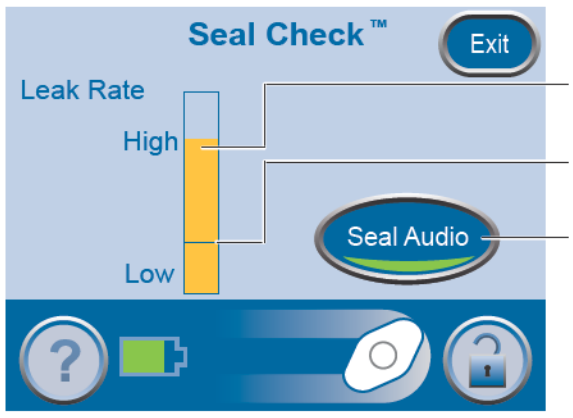
Seal Check™ Leak Detector

When the ActiV.A.C.® Therapy Unit detects a significant leak, the Leak Alarm will activate. See *Alerts And Alarms - Leak Alarm*, page 22.

Flashing Green Oval

Press the Seal Check™ button on the *Leak Alarm* screen to use the Seal Check™ Leak Detector to help find leaks.

The Seal Check™ feature uses an audible tone and bar graph to help find leaks. The frequency of the audible tone and the height of the bar graph will reflect the leak rate. The audible tone slows down and the bar graph decreases in height as the leak is found.



Orange bar graph indicates a significant leak. Green bar graph indicates that the ActiV.A.C.® Therapy System is operating normally.

Line on bar graph is the transition point from green to orange and vice-versa.

Press to turn the Seal Audio tone on or off.

Finding the Leak

Most leaks occur:

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

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

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

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

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

5. When finished, press Exit to return to the *Patient Mode* home screen.

6. If necessary, contact your healthcare provider or KCI for assistance or further information.

Alerts and Alarms

ATTENTION: Important Information about Alerts and Alarms

An ***Alert*** will be displayed on the touch screen when the ActiV.A.C.® Therapy Unit detects a condition that requires patient or caregiver attention.

Alerts will be accompanied by a ***single*** audible tone.

An ***Alarm*** will be displayed on the touch screen when the ActiV.A.C.® Therapy Unit detects a condition that ***requires immediate patient or caregiver attention in order to ensure the prescribed therapy is being delivered.***

Alarms will be accompanied by a ***repeating*** audible tone.

Press Audio Pause to silence the audible tone for two minutes.

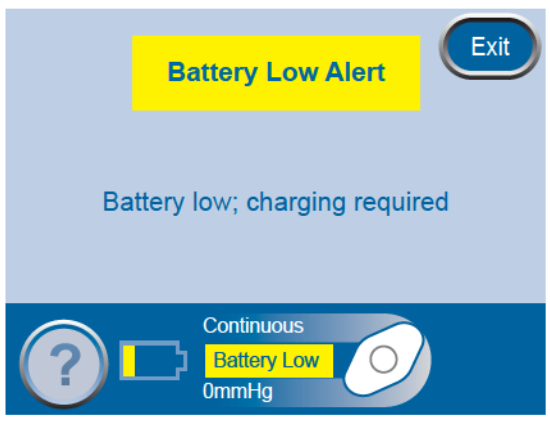
Press Help for more information about the alert or alarm.

If alarm conditions cannot be resolved, contact your caregiver or KCI.

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

Battery Low Alert

This alert screen appears approximately two hours before the battery power runs out. This alert will be accompanied by a *single* audible tone.



To resolve this alert:

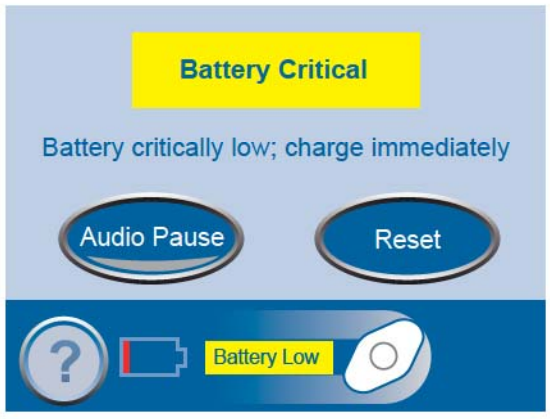
1. Connect the therapy unit to a wall outlet using the ActiV.A.C.® Power Supply to recharge battery. The light next to the bottom-left of the touch screen will glow amber as the battery charges. Refer to the ***Battery Charging Instructions*** chapter of this manual (page 8) for more information.

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

V.A.C.® Therapy continues.

Battery Critical Alarm

This alarm screen appears approximately 30 minutes before the battery power runs out. This alarm will be accompanied by a *repeating* audible tone.



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Connect the therapy unit to a wall outlet using the ActiV.A.C.® Power Supply to recharge battery. The light next to the bottom-left of the touch screen will glow amber as the battery charges. Refer to the ***Battery Charging Instructions*** chapter of this manual (page 8) for more information.

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

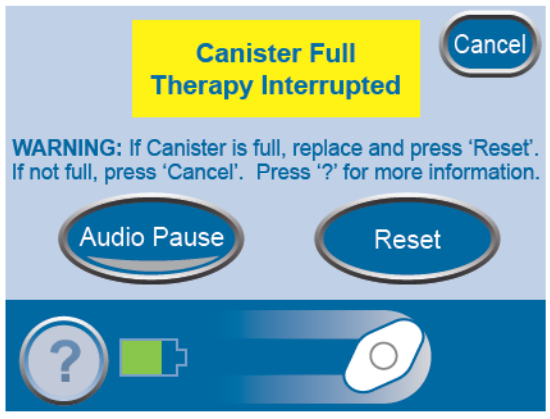
3. Ensure therapy is on by confirming that the green crescent is lit on the Therapy On/Off button. If not, press the Therapy On/Off button to restart therapy.

V.A.C.® Therapy continues; however, if this alarm is not resolved within 30 minutes, therapy will turn off.

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

Canister Full Therapy Interrupted Alarm

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



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Check fluid level of canister by holding the therapy unit so that the graduated marks on the canister are level and parallel to the floor.

A full canister is approximately 300 mL.

2. If canister is not full after checking level, press Cancel.

3. If canister is full, change canister and press Reset to return to the *Patient Mode* home screen. See the ***Canister*** chapter of this manual (page 10) for additional information.

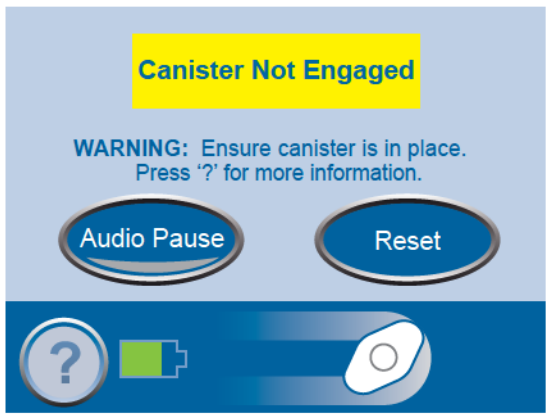
4. Restart therapy by pressing the Therapy On/Off button.

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

To avoid a false alarm, keep the therapy unit as upright as possible. The touch screen should be in a readable, right-side-up orientation or facing up when the unit is laid on a level surface.

Canister Not Engaged Alarm

This alarm screen appears when the canister is not fully seated and not properly latched. This alarm will be accompanied by a *repeating* audible tone.



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Remove the canister by pressing the canister latch release (see page 10 for illustration).
2. Inspect the canister and ActiV.A.C.® Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
3. Ensure both silicone seals and both canister stabilization bumpers are present (see page 10 for illustration). If any are missing or damaged, contact KCI.
4. Re-install the canister and ensure that it is fully engaged and latched. An audible click should be heard when canister is properly installed.

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

6. Restart therapy by pressing the Therapy On/Off button.
7. If this alarm continues to appear, repeat steps 1 through 6 with a new canister. Otherwise, if alarm condition cannot be resolved, contact your caregiver or KCI representative.

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

Leak Alarm

This alarm screen appears when there is a significant negative pressure leak. If this alarm is not resolved in three minutes, therapy will be interrupted. This alarm will be accompanied by a *repeating* audible tone.

Flashing Green Oval

Press Audio Pause to silence the audible tone for two minutes.

If this alarm is resolved within three minutes without using the Seal Check™ Leak Detector, the ActiV.A.C.® Therapy Unit will automatically reset and the *Patient Mode* home screen will be displayed. Press Reset on this screen to return to the *Patient Mode* home screen. Therapy will be off.

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

To resolve this alarm:

1. Ensure connector between dressing tubing and canister tubing is properly locked.
2. Ensure canister is fully engaged (See ***Canister Not Engaged Alarm***, page 21).

3. Press the Seal Check™ button to use the Seal Check™ Leak Detector to help find leaks. Refer to the ***Seal Check™ Leak Detector*** section of this manual (page 16) for details on how to use the Seal Check™ feature.

Refer to the *Application Instructions* provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area.

4. When the leak is resolved, press Exit on the *Seal Check™* screen to return to the *Home* screen.

5. Ensure that therapy is on by observing that the green crescent is lit on the Therapy On/Off button and the icon is rotating on the *Patient Mode* home screen.

Refer to *Leak Alarm Therapy Interrupted* section of this manual (page 23) for procedures to restart therapy.

The patient's only access to the Seal Check™ Leak Detector is through the *Leak Alarm* screen.

Leak Alarm Therapy Interrupted

This alarm screen appears when a leak has not been resolved and therapy has been interrupted. This alarm will be accompanied by a *repeating* audible tone.

Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Fix any leaks as described in the previous section.

2. Press Reset on this screen to return to the *Patient Mode* home screen.

3. Restart therapy by pressing the Therapy On/Off button.

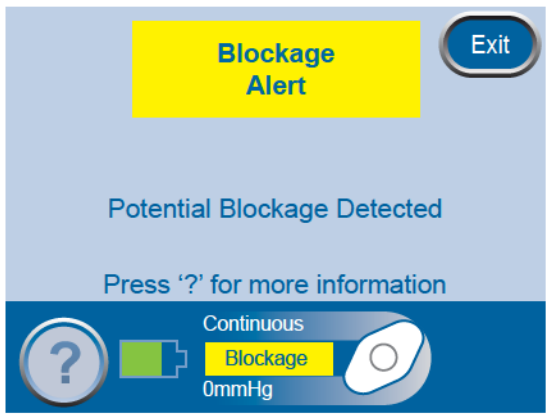
WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.

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

If alarm condition cannot be resolved, contact your caregiver or KCI representative.

Blockage Alert

This alert screen appears when a potential blockage is present. This alert will be accompanied by a *single* audible tone. The ActiV.A.C.® Therapy Unit continues to attempt to apply therapy.



To resolve this alert:

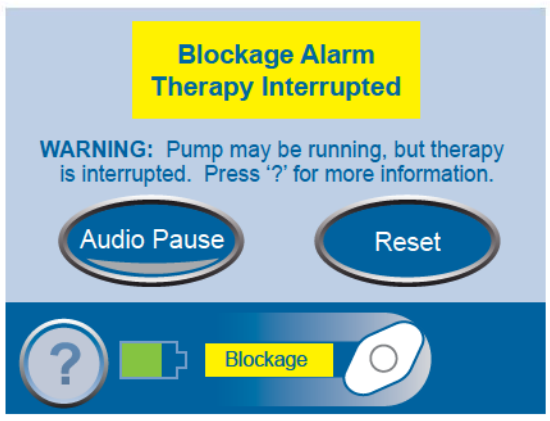
1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

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

Blockage Alarm Therapy Interrupted

This alarm screen appears when a blockage is present. This alarm will be accompanied by a *repeating* audible tone.

WARNING: Therapy unit remains on; however, negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits.



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alarm Therapy Interrupted remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

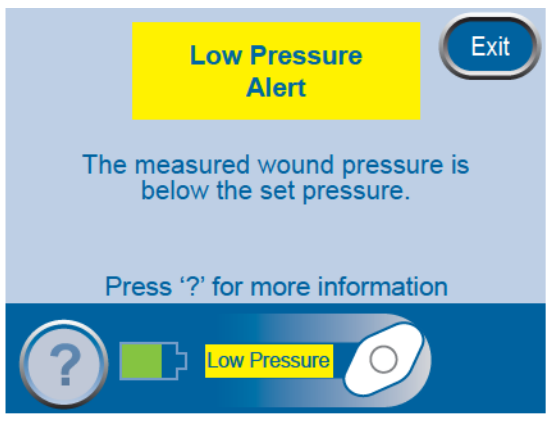
4. Press Reset to return to the *Patient Mode* home screen.

If alarm condition cannot be resolved, contact your caregiver or KCI representative.

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

Low Pressure Alert

This alert screen appears when the selected therapy set pressure has not been reached. This alert will be accompanied by a *single* audible tone. V.A.C.® Therapy is still being applied, but at a lower than selected pressure.



To resolve this alert:

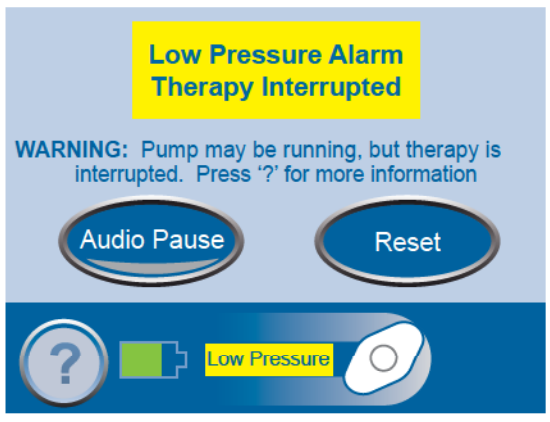
1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

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

Low Pressure Alarm Therapy Interrupted

This alarm screen appears when the selected therapy set pressure has not been reached and negative pressure at the wound may be below set pressure. This alarm will be accompanied by a *repeating* audible tone.

WARNING: Therapy unit remains on; however, negative pressure at the wound may be below set pressure, potentially compromising therapeutic benefits.



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Ensure both clamps on the dressing and canister tubing are open.
2. Ensure that the tubing is not kinked, crimped or blocked in any way.
3. If the Low Pressure Alarm Therapy Interrupted remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site. If the alert is resolved by lowering the unit, normal use may resume.

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

If alarm condition cannot be resolved, contact your caregiver or KCI representative.

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

Therapy Inactive Alarm

This alarm screen appears when therapy has been off for 15 minutes (with the unit powered on) and without using the touch screen. This alarm will be accompanied by a *repeating* audible tone.

Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

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

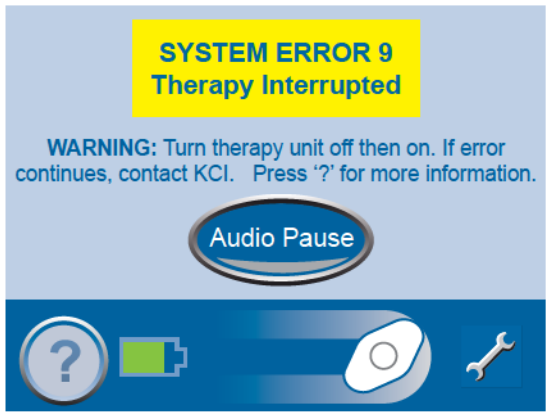
2. Restart therapy by pressing the Therapy On/Off button.

3. If V.A.C.® Therapy is not desired, turn the ActiV.A.C.® Therapy Unit off using the Power On/Off button on the front of the unit.

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

System Error Alarm

This alarm screen appears when there is a technical fault within the ActiV.A.C.® Therapy Unit. Several different types of system errors may occur. A number will appear in the yellow alarm box that represents the diagnostic code of the technical fault. This alarm will be accompanied by a *repeating* audible tone.



Press Audio Pause to silence the audible tone for two minutes.

To resolve this alarm:

1. Record the error number.

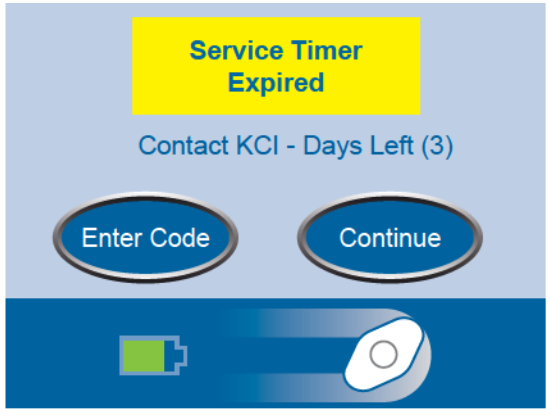
2. Turn the unit off and then on using the Power On/Off button on the front of the unit.

If alarm condition cannot be resolved, contact your caregiver or KCI representative.

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

Service Timer Expired Alert

This alert screen appears when the ActiV.A.C.® Therapy Unit has reached its service time limit. Once the Service Timer has expired, this alert will appear every time the unit is powered up. When Days Left reaches zero, this alert will reappear periodically during therapy.



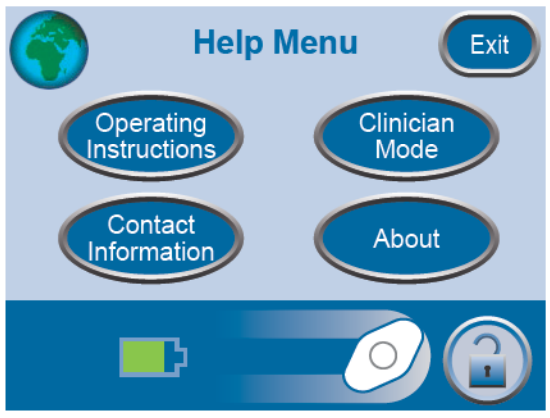
To resolve this alert:

1. Contact KCI to obtain a new Service Timer code.

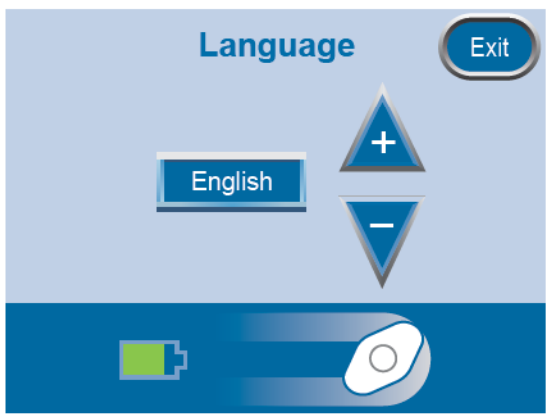
2. Press Enter Code to enter the code obtained from KCI.

Help Menu

Change Languages

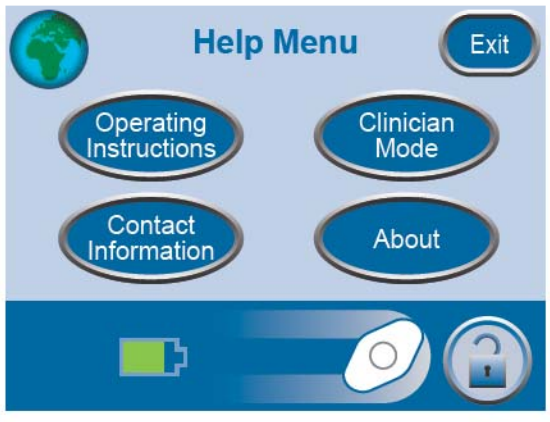


1. Press Help to access the *Help Menu*.
2. Press the Globe (upper left) to access the *Language* screen.



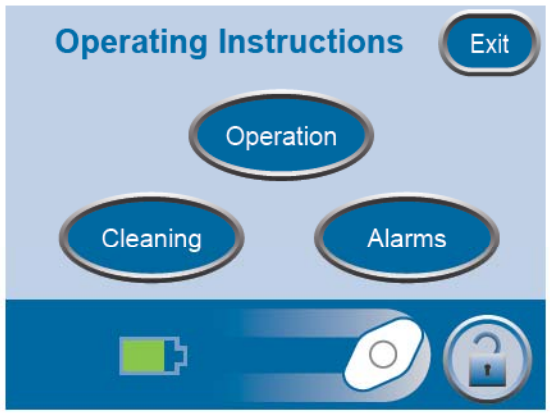
3. Use the + and - buttons to select the desired language.
4. Press Exit when finished.

Onscreen Operating Instructions



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

Onscreen Operating Instructions (cont.)



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

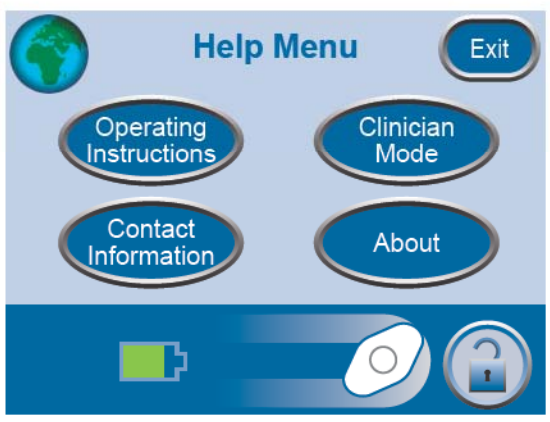
4. Press Exit when finished.

Access basic operating guidelines.

Access basic cleaning guidelines.

Access general information for pausing or silencing alarms.

Clinician Mode



Press Help to access the *Help Menu*.

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

Care and Cleaning

Standard Precautions

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

Always follow Standard Precautions.

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

Waste Disposal

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations.

Cleaning the ActiV.A.C.® Therapy Unit

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

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

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

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

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

Cleaning the Touch Screen

1. Select the Screen Guard button on the *Home* screen (pg. 6) to activate Screen Guard.

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

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

Do not use any liquid to clean the touch screen.

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

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

Frequently Asked Questions

Q: How much does the ActiV.A.C.® Therapy Unit weigh?
A: The ActiV.A.C.® Therapy Unit weighs ~2.4 lbs (~1.08 kg) with an empty canister installed.

Q: How long does it take to charge the battery, and how long will a fully charged battery last?
A: It takes approximately six hours to fully charge the battery. The ActiV.A.C.® battery can maintain a charge up to 14 hours.

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

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

Q: What hapens if the ActiV.A.C.® Therapy Unit alarms?
A: The ActiV.A.C.® Therapy Unit is built with your safety in mind. The ActiV.A.C.® Therapy Unit has alarms that you can see and hear which will alert you to a potential problem. In most situations, the reason for the alarm is easily fixed (see pages 18-27). This is something your healthcare provider can explain in more detail, so you are comfortable with this alarm system.

Q: How do I know if the ActiV.A.C.® Therapy Unit is working properly?
A: The Therapy Status Bar at the bottom of the touch screen displays specific therapy information. The rotating icon, also found in the Therapy Status Bar, indicates the ActiV.A.C.® Therapy Unit is applying negative pressure. The foam dressing will be collapsed indicating negative pressure is being applied. Wound fluid may or may not be seen moving in the tubing.

Q: What if I do not hear an audible click when installing a canister onto the ActiV.A.C.® Therapy Unit?
A: An audible click should be heard when installing a new canister. Occasionally, you may not hear an audible click. If the canister is properly installed, the canister cannot be removed by gently pulling it directly away from the unit.

Q: What steps should I take before bathing?
A: **Do not** take the ActiV.A.C.® Therapy Unit into the shower or tub. Turn therapy and power off, and disconnect canister tubing from dressing tubing. The clear drape is waterproof; you may wash or shower with dressings in place. Care should be taken not to roll the edges of the drape while bathing. Refer to the ***Therapy Unit Disconnect*** chapter of this manual (page 14) for more information.

Q: Is the ActiV.A.C.® Canister compatible with all V.A.C.® Therapy Units?
A: No, the 300 mL canister is to be used only with the ActiV.A.C.® Therapy Unit and InfoV.A.C.® Therapy Unit.

Q: What languages are available in the ActiV.A.C.® Therapy Unit?

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

Q: When should additional SensaT.R.A.C.® Dressings and ActiV.A.C.® Canisters be ordered?

A: Order additional supplies when you have only one case of dressings OR five canisters left. Orders may be placed by calling KCI at least 3-5 business days before the supplies are needed.

Q: Are there any recommendations to note when traveling?

A: Consult your healthcare provider prior to traveling to determine if it is safe for you to travel. **Do not travel without first obtaining medical approval and a complete understanding of all of the risks that may pertain to your medical condition as well as to V.A.C®. Therapy.** Risk of bleeding during travel can have serious and potentially fatal consequences.

Once medical approval is obtained, it is recommended that you have the following items with you during travel:

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

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

Q: Can the ActiV.A.C.® Therapy System be used during diagnostic procedures?

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

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

WARNING: The ActiV.A.C.® Therapy Unit MUST NOT be taken into a Magnetic Resonance Imaging (MRI) suite or Hyperbaric Oxygen Therapy (HBO) chamber. See the V.A.C.® Therapy System Safety Information Sheet that accompanies the ActiV.A.C.® Therapy Unit (located in the front flap pocket of the carrying case) for specific instructions concerning MRI and HBO therapy.

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

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

activac®
KCI Healing by design

For Clinician Use Only

Patients: Refer to Previous Section of This Manual

KCI®

Clinician Table of Contents

See The Following Pages Of The ***Patient Section*** Of This User Manual For Additional Information

Introduction

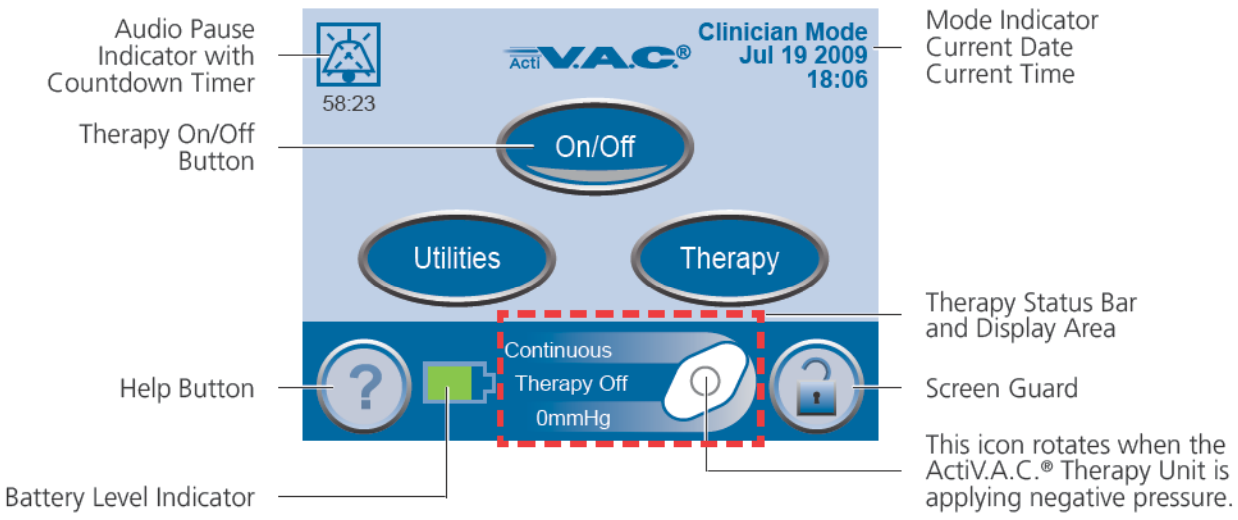
This Clinician information provides operating instructions for the ActiV.A.C.® Therapy Unit to the healthcare professional. Many features described are not available in Patient Mode. Patient Mode allows the patient to start and stop therapy, find leaks using the Seal Check™ feature, and attend to alerts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

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

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

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

Clinician Mode Home Screen



A lighted green crescent means the function is on.

An unlit crescent means the function is off.

Start or stop V.A.C.® Therapy.

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

Access Settings, Seal Check™ Leak Detector, Settings Guide, and History buttons.

The plug indicator appears on the touch screen while the unit is plugged into a wall outlet.

Common Screen Control Buttons

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

Access *Help* screens when available.

Activate the Screen Guard feature to help prevent unintentional changes. This feature should be used when cleaning the touch screen. To release Screen Guard, press 1 and then 2.

Navigation Buttons

One or more of these buttons may appear on a screen:

Leave the current screen.

Stop action in progress.

Go to the next screen.

Return to the previous screen.

Acknowledge the action is complete and display the next screen.

Audio Pause

Press Audio Pause to silence (for 60 minutes) alerts that do not need immediate attention.

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

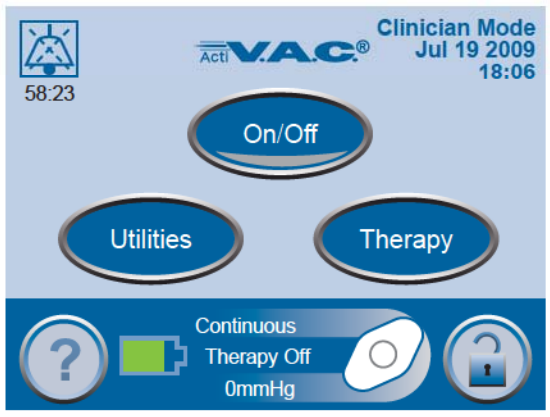
Alarms needing immediate attention override the Audio Pause feature. See the *Alerts and Alarms* chapter of this manual (page 18) for details on alarms and how to resolve them.

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

Power Therapy Unit On or Off

The Power On/Off button is located immediately below and to the left of the touch screen (see page 6 for illustration).

Press and hold the Power On/Off button for approximately two seconds to turn the ActiV.A.C.® Therapy Unit on or off.



The therapy unit will go through a self-check routine and then present a *Warning Message* screen. Press OK to continue to the *Clinician Mode* home screen (shown left).

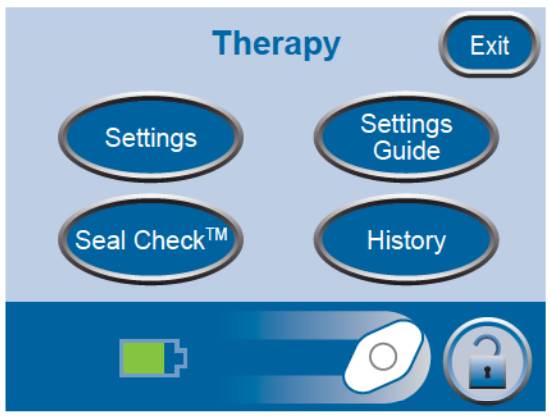
Therapy On or Off

On/Off Start or stop V.A.C.® Therapy.

On/Off A lighted green crescent means the function is on.

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

Access Manual Therapy Settings



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

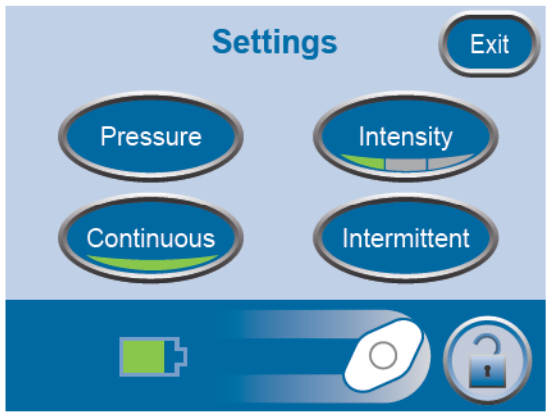
Options available from this *Therapy* screen:

- Settings - Manually set therapy.
- Seal Check™ - Helps in find leaks.
- Settings Guide - Helps select preset therapy settings.
- History - View or export therapy history.

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

Settings

Settings changed manually take immediate effect when therapy is on.



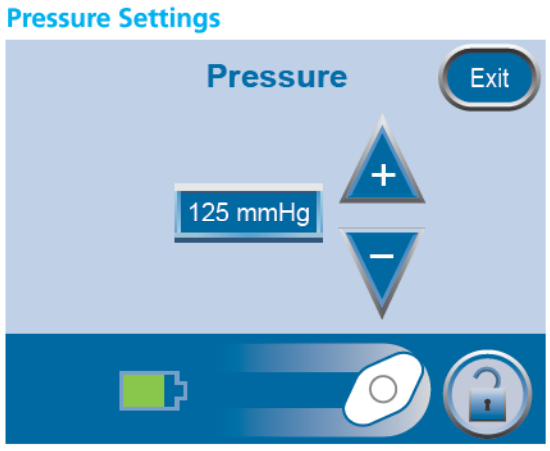
From the *Clinician Mode* home screen, press Therapy, then Next, then Settings to access this screen.

Options available from this *Settings* screen:

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

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

Pressure Settings



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

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

Press Exit to return to the *Settings* screen.

Default setting is 125 mmHg.

Intensity Control

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

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

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

Low

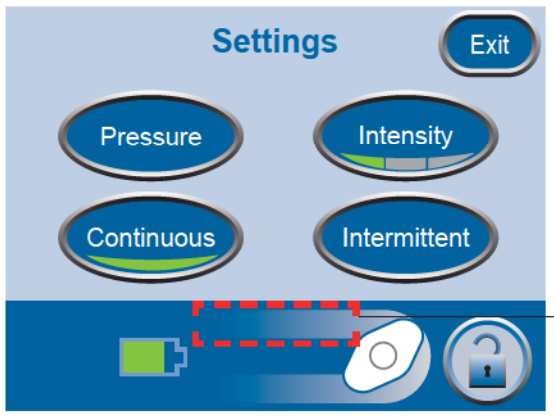
Medium

High

Default setting is Low.

CLINICIAN

Continuous and Intermittent Modes



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

Continuous mode in use when green crescent is lit.

Intermittent mode in use when green crescent is not lit.

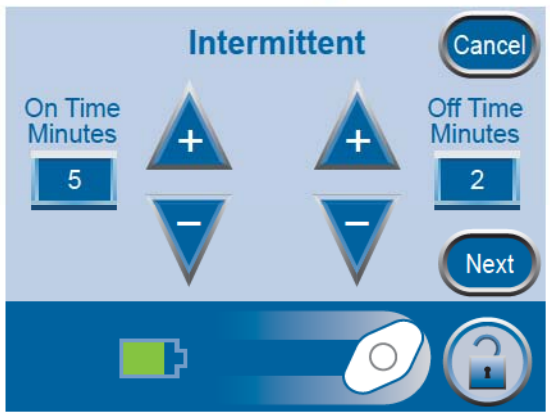
The words *Continuous* or *Intermittent* will appear in this area as modes are switched.

Default setting is Continuous.

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

Intermittent Settings

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



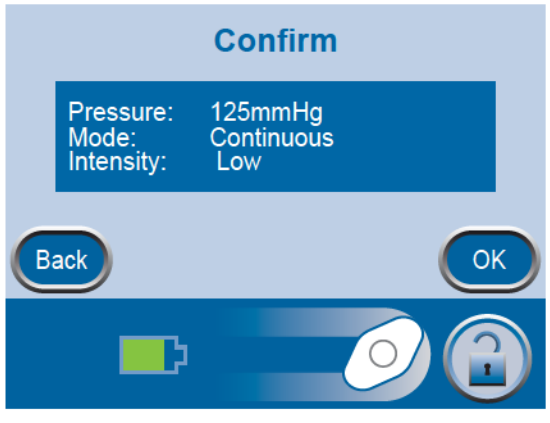
From the *Clinician Mode* home screen, press Therapy, then press Settings, then press Intermittent to access this screen.

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

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

Press Exit to return to the *Settings* screen.

Settings Confirmation



Exit

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

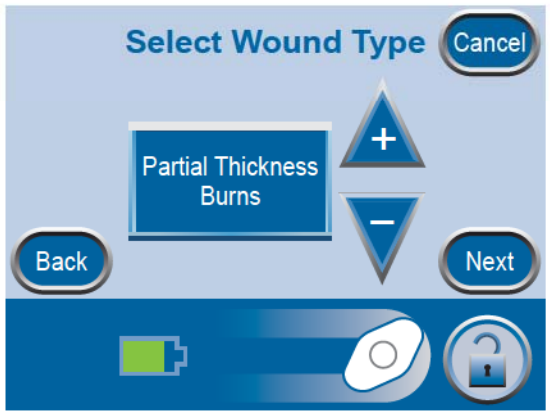
Press OK to continue to the *Clinician Mode* home screen if the displayed settings are as desired, or press Back to change any settings that are incorrect.

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

Settings Guide

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

Should physician orders fall outside the pre-set therapy ranges, select Other in this mode or use the Manual Therapy Settings detailed earlier (page 41).

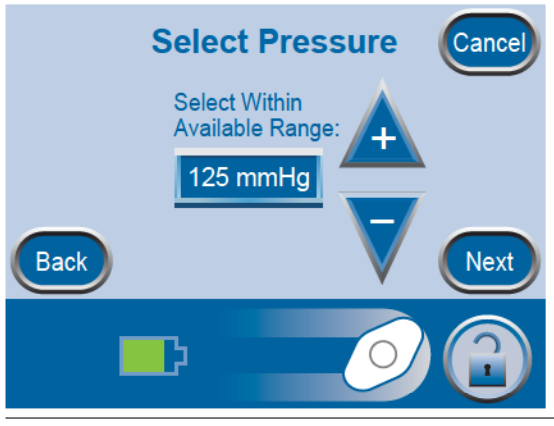


From the *Clinician Mode* home screen, press Therapy, then Next, then Settings Guide, then OK to access the *Select Wound Type* screen.

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

Next

Press Next when finished to continue to the *Select Pressure* screen.



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

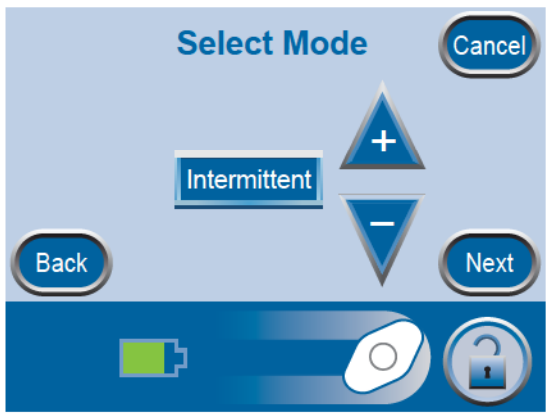
Next

Press Next when finished to continue to the next screen.

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

CLINICIAN

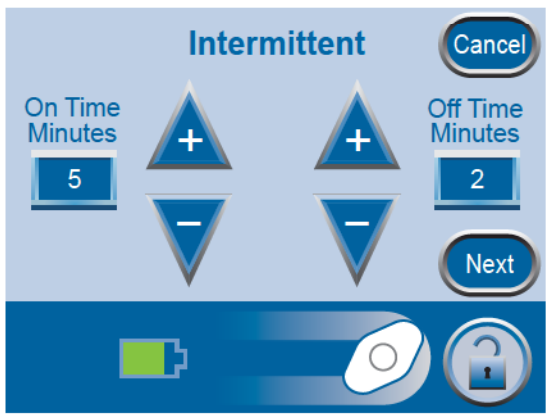
Settings Guide (cont.)



Use the + and - buttons to choose Continuous or Intermittent therapy.

Next

Press Next when finished to continue.



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

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

Next

Press Next when finished to continue to the *Confirm* screen.

Settings Guide Confirmation

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

Press OK to continue to the *Clinician Mode* home screen if the displayed settings are as desired, or press Back to change any settings that are incorrect.

Settings take effect after OK is pressed.

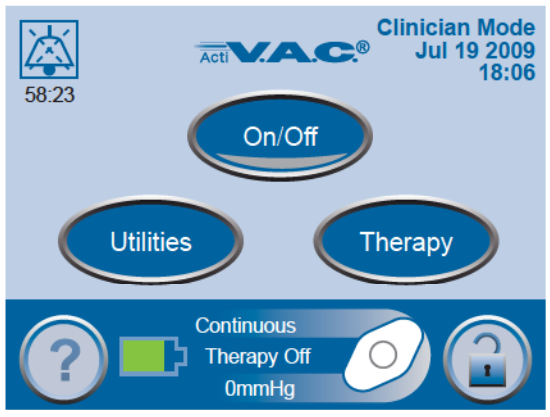
Settings Guide Intensity default is Low. Intensity can only be changed using Manual Therapy Settings (page 41).

CLINICIAN

Starting Therapy

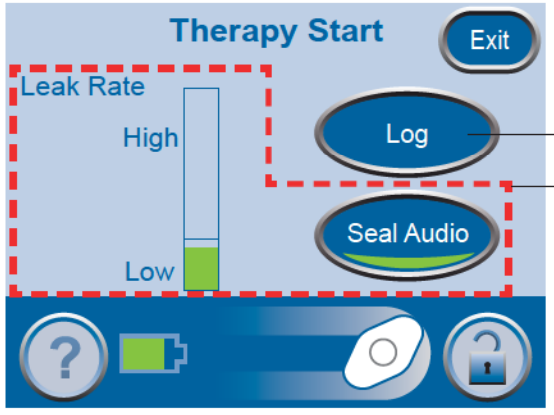
WARNING: Ensure that a new V.A.C.® Dressing has been applied and therapy settings have been selected per physician's orders before starting therapy.

Canister should be properly engaged for therapy to start.



On/Off

Press the Therapy On/Off button to start therapy.



The *Therapy Start* screen will appear.

Log Tool

Seal Check™ Leak Detector

Options available from this screen:

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

Seal Check™ Leak Detector

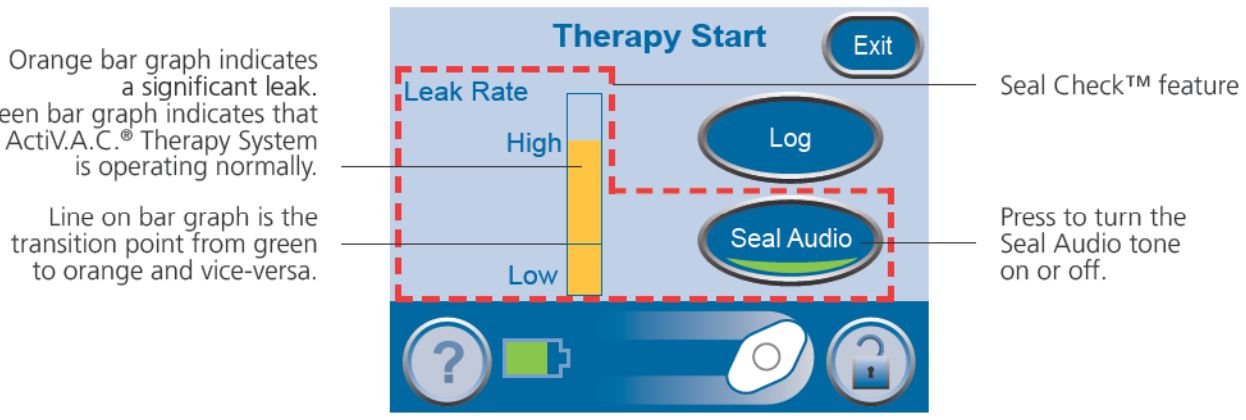
The Seal Check™ feature is used to help find negative pressure leaks and may be accessed three different ways:

- When therapy is started from the *Clinician Mode* home screen.
- When the Seal Check™ button is pressed from the *Therapy* screen.
- When the Seal Check™ button is pressed on the *Leak Alarm* screen after the ActiV.A.C.® Therapy Unit detects a possible leak.

Patients only have access to the Seal Check™ feature through the *Leak Alarm* screen when the ActiV.A.C.® Therapy Unit detects a possible leak.

How to Use the Seal Check™ Leak Detector When Starting Therapy

Press the Therapy On/Off button located on the *Clinician Mode* home screen to immediately display the *Therapy Start* screen.



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

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

Most leaks occur:

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

Finding the Leak Using the Seal Check™ Leak Detector

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

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

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

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

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

Log Tool

The Log Tool can be used to track:

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

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

How to Use the Log Tool When Starting Therapy

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

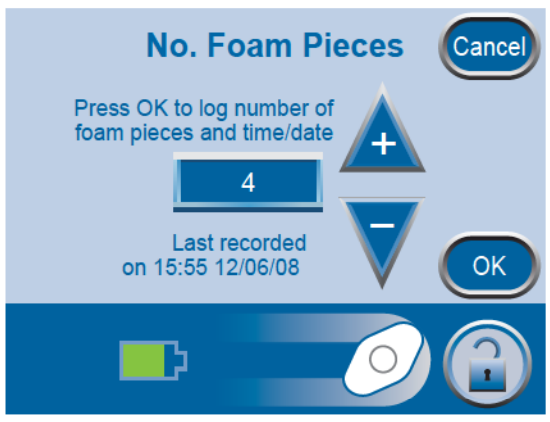
Choose Canister or Dressing.

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

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

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

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



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

Information displayed represents the last logged entry.

\+ / − — Use the + and - buttons to select the number of foam pieces used during the current dressing change.

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

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

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

Logged information will appear in Therapy History as follows:

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

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

View or Export Therapy History

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

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

Starting from the *Clinician Mode* home screen, press Therapy, then Next then History to access the *Therapy History* screen.

The *Therapy History* screen has two options:

- View History - View Therapy History on screen.
- Export History - Access screens where the Therapy History Report can be transferred via USB.

IR feature is no longer available. Use USB only port for data transfer.

View Therapy History

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

Use the + and - buttons to scroll through the Therapy History Report.

Hold the + and - buttons to rapidly scroll through the recorded information.

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

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

Exit

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

Export Therapy History Report

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

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

Export History

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

USB devices should be connected directly and only unpowered USB mass storage devices should be attached to the ActiV.A.C.® Therapy Unit. AC or battery powered drives, computers, computer equipment, other devices or USB extension leads should not be connected to this device.

Export To USB

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

Exit

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

USB Export Issues

USB:

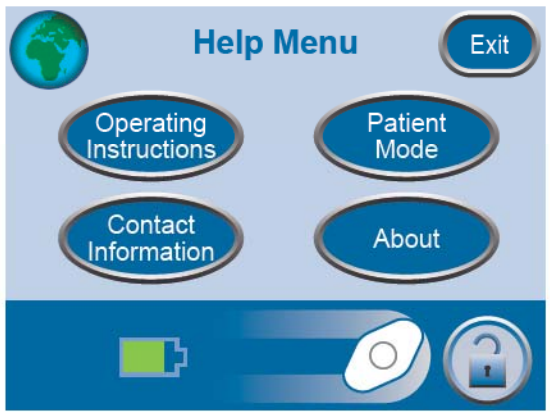
- Ensure that the USB flash drive (memory stick) being used is USB 2.0 compatible.
- Ensure that the flash drive is fully plugged into the therapy unit. It may be necessary to unplug and re-plug the flash drive into the therapy unit.
- Try using a different USB flash drive.
- Remove the flash drive.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

IR feature is no longer available. Use USB port only for data transfer.

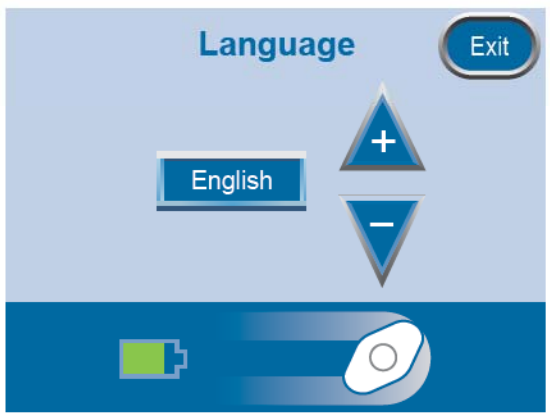
If the above steps do not resolve the problem, contact KCI for further assistance.

Help Menu

Change Languages

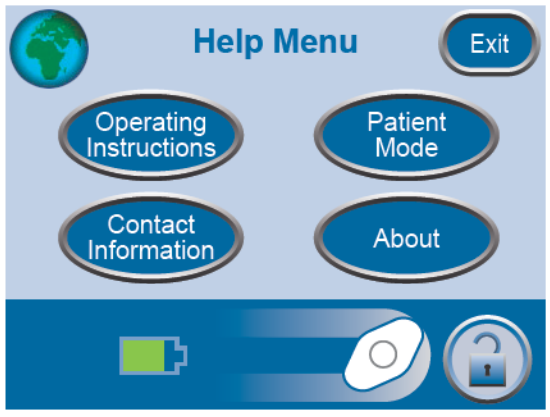


1. Press Help to access the *Help Menu*.
2. Press the Globe (upper left) to access the *Language* screen.



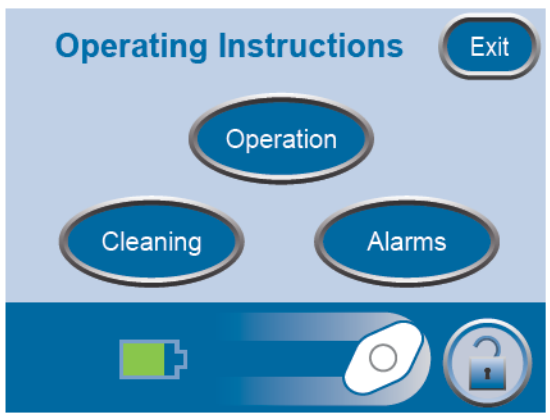
3. Use the + and - buttons to select the desired language.
4. Press Exit when finished.

Onscreen Operating Instructions



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

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



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

4. Press Exit when finished.

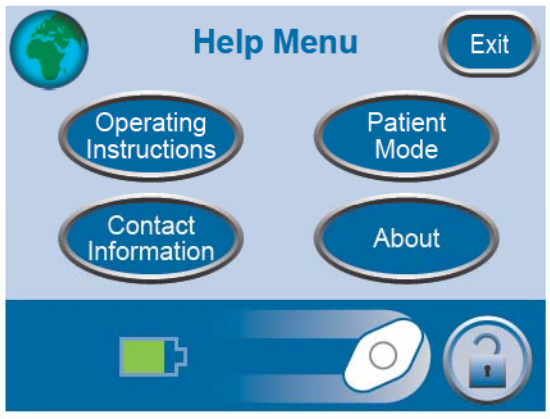
Access basic operating guidelines.

Access basic cleaning guidelines.

Access general information for pausing or silencing alarms.

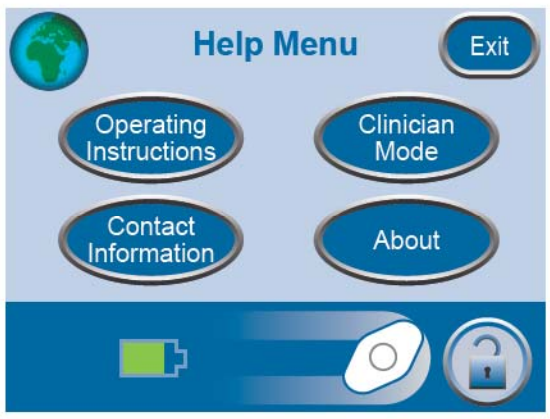
Change to Patient or Clinician Mode

Press Help to access the *Help Menu*.



Patient Mode

Press Patient Mode to change to *Patient Mode*.



Clinician Mode

Press Clinician Mode to change to *Clinician Mode*.

A screen will appear to confirm which mode is set.

Only authorized caregivers should access Clinician Mode. Select Cancel unless authorized.

OK

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

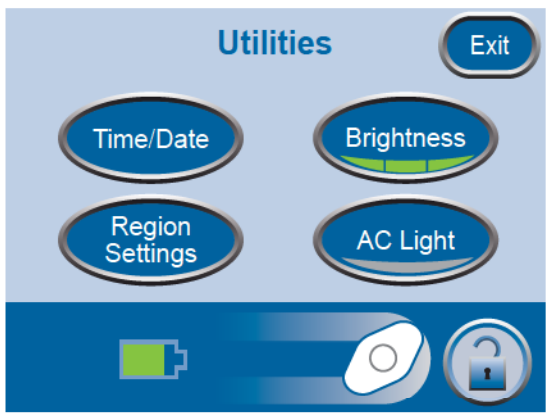
Cancel

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

CLINICIAN

Utilities

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



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

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

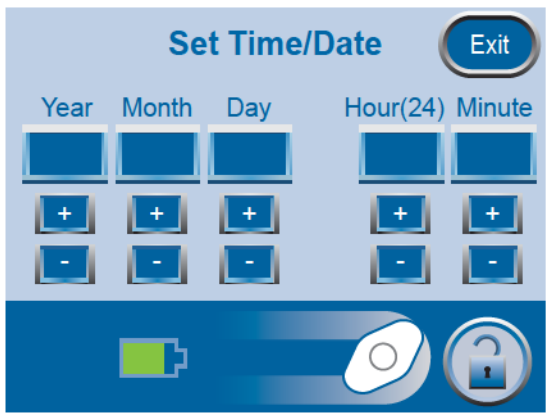
Brightness — Press Brightness to set the display brightness of the touch screen.

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

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

Change Time and Date

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



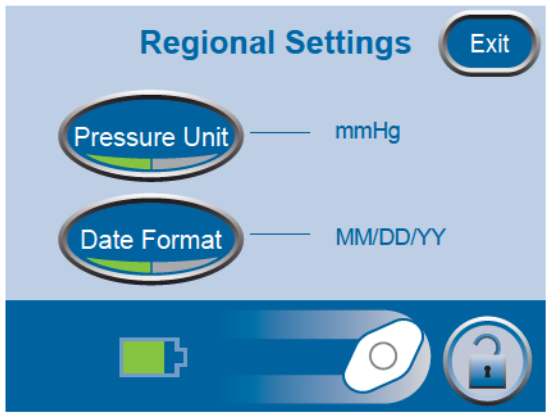
+ - Use the + and - buttons to set current time and calendar date.

Hold the + and - buttons to rapidly scroll through available selections.

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

Change Pressure Units and Date Format

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



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

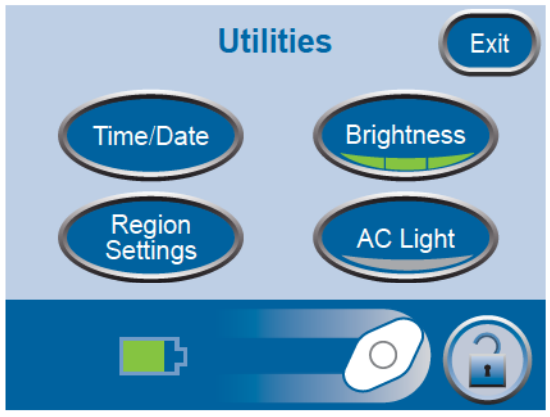
Default settings are mmHg and MM DD YY.

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

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

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

Change Screen Brightness



Press Brightness to switch between three levels of screen brightness.

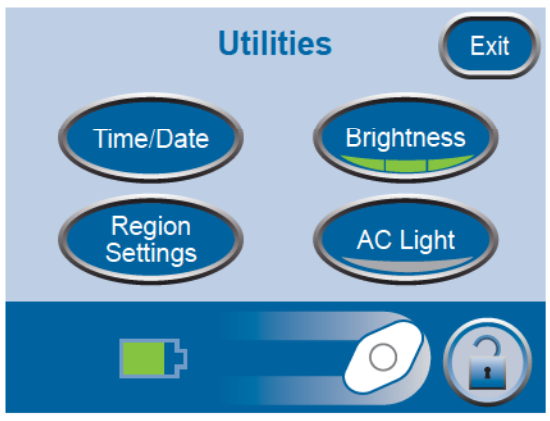
Brightness — High

Brightness — Medium

Brightness — Low

Default setting is High.

Change AC Light



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

AC Light — On

AC Light — Off

Default setting is Off.

Standard Precautions

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

Always follow Standard Precautions.

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

Waste Disposal

Discard all disposable items (all tubing, connectors, clamps, used canister, used dressings, etc.) in accordance with local medical waste disposal regulations.

Cleaning the ActiV.A.C.® Therapy Unit

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

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

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

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

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

Cleaning the Touch Screen

1. Select the Screen Guard button on the *Home* screen (pg. 38) to activate Screen Guard.

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

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

Do not use any liquid to clean the touch screen.

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

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

Explanation of Symbols Used

Refer to ***Explanation of Symbols Used*** if symbols appear on the product or accompanying documentation.


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


Important Operational Information


Caution: Consult Accompanying Documents


WARNING: Consult Accompanying Documents


Consult Instructions For Use


Keep Dry


Tripping Hazard


No Bathing or Showering


Power On / Off

SN

Serial Number


Date of Manufacture


Manufacturer

~

Approximate


Temperature Limitations

EC REP

Authorized Representative in the European Community

IPXO

Ingress Protection

Alternating Current


Direct Current


Class II


Type B, Applied Part


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

CE
0473

Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.
CE Mark on the user manual or safety information sheet is not valid unless there is a CE Mark directly on the product label.


Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards Only in accordance with UL 60601-1 and to CAN/CSA C22.2 No. 601.1 Standards, including JIS amendment by Underwriters Laboratory Inc.


Medical Equipment classified with respect to Electrical Shock, Fire and Mechanical Hazards Only in accordance with UL 60601-1 Standards, including JIS amendment by Underwriters Laboratory Inc.


ETL Listed, Conforms to AAMI ES60601-1 1st edition, CSA C22.2#60601-1 2nd edition and IEC 60601-1 2nd edition

CLINICIAN

Specifications

Specifications subject to change without notice.

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

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

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

IEC Classification
Medical Equipment
Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
Type B, Applied Part
Class II
IPX0

Customer Contact Information

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

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

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

3M | V.A.C.® Therapy

3M™ V.A.C.® Therapy

Scientific and clinical outcomes overview

Contents

Executive summary

Wound healing progression involves removal of barriers to wound healing (such as exudate), adequate perfusion to the wound bed and production of granulation tissue. Successful healing involves addressing wounds that may be stalled in the inflammatory and proliferative phases of wound healing. Many passive and active therapies have been developed to address those barriers of wound healing. This includes Negative Pressure Wound Therapy (NPWT). NPWT is utilized across the continuum of care and has substantial amounts of clinical outcomes data demonstrating efficacy in creating an environment that promotes healing in a wide variety of wounds.

The 3M™ V.A.C.® Therapy System was introduced in 1995 as the first commercial NPWT system. 3M™ has continued to lead the way in the development of new technologies and therapies designed to make wound healing manageable for caregivers and more comfortable for patients around the world. The V.A.C.® Therapy System (3M™ V.A.C.® Therapy) is indicated for patients with chronic, acute, traumatic, sub-acute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts.

Negative Pressure Wound Therapy (NPWT) is defined as the application of sub-atmospheric pressure to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention. NPWT facilitates the continuous removal of exudate and helps prepare the wound bed for closure.

To help promote healing, V.A.C.® Therapy provides mechanical forces at the tissue level to create macrostrain and microstrain. Macrostrain causes the 3M™ Granufoam™ Dressing to contract under a controlled negative pressure setting,[1] drawing the wound edges together, reducing the overall wound area and allowing for granulation tissue to fill in. Microstrain is the transduction of pressure to tissue surfaces, resulting in cell surface deformation as the tissue is being pulled up into the pores (tissue stretch) and the compression of tissue at the struts.[1] Macrostrain and microstrain increase granulation tissue formation. These actions by the application of the V.A.C.® Therapy System are responsible for promoting changes in gene expression, proliferation and protein synthesis, all of which contribute toward the promotion of granulation tissue.[2]

The abundance of clinical evidence for the V.A.C.® Therapy System demonstrates an active, integrated system designed and clinically proven to create an environment that promotes wound healing at the cellular level by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation, promoting perfusion and removing exudate and infectious material. Functions and outcomes of V.A.C.® Therapy are critically linked to the interaction of its component parts. Because other devices use different wound interface materials and do not provide controlled, self-adjusting pressure technology (3M™ SensaT.R.A.C.™ Technology), it cannot be presumed the data from those devices can be pooled and evaluated with V.A.C.® Therapy data, nor can their evidence be construed to represent the same outcomes as V.A.C.® Therapy.

There are numerous studies which have evaluated the cost effectiveness of V.A.C.® Therapy in a variety of settings and indicated wound types. These studies have shown that V.A.C.® Therapy has been associated with fewer hospitalizations[3], fewer complications[4,5], fewer amputations[6,7], fewer dressing changes[8,9], faster time to wound healing[10], shorter hospitalization[6,7], and reduced treatment times[11-13]. By minimizing the factors that contribute to direct and indirect wound care costs, V.A.C.® Therapy has emerged as a cost-effective option for wound management.

This overview document provides both clinical and economic summary of the current peer-reviewed published literature on V.A.C.® Therapy on a wide variety of acute and chronic wound types.

Background

Negative pressure wound therapy (NPWT) has been used for over 25 years across the continuum of care. Its application on a variety of acute and chronic wounds speaks to the versatility of NPWT in wound care. V.A.C.® Therapy was introduced commercially in 1995[13]; since then, the number of competitor products has increased substantially. However, V.A.C.® Therapy has shown its prevalence in the medical community, being the most published of all the commercial systems with a majority of all NPWT publications utilizing V.A.C.® Therapy.

Wound type, size, and severity, as well as treatment cost and patient mobility, have become important considerations when choosing an NPWT system to improve patient's wound healing outcomes. The V.A.C.® Therapy System is an integrated wound management system for use in acute, long-term care and home care settings. It is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material. The integrated system includes a pump to provide 3M™ Dynamic Pressure Control™ Therapy, intermittent or continuous negative pressure monitored by SensaT.R.A.C.™ Technology, a separate collection canister, and proprietary dressings.

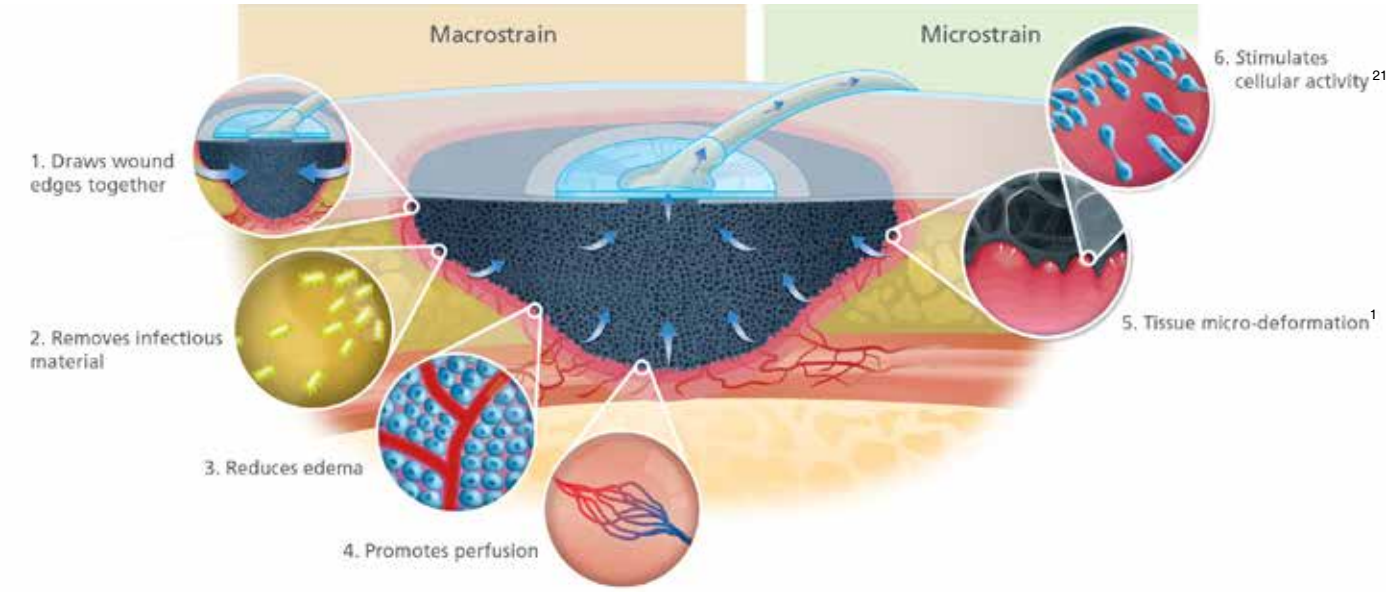
Optimal wound healing occurs when there is:[14,15]

- Effective removal of barriers to wound healing, including exudates, inflammatory mediators (eg, cytokines, proteases) and infectious materials
- Adequate perfusion to the wound bed
- Presence of metabolically active cells to produce granulation tissue
- Protection of the peri-wound tissue

3M™ V.A.C.® Therapy mechanism of action

The integrated V.A.C.® Therapy System has a unique mechanism of action whereby the delivery of negative pressure using the proprietary 3M™ V.A.C.® Granufoam™ Dressing not only maintains a wound environment that promotes healing, but also supports physiologic responses important to wound healing. These responses are observed at the tissue and cellular levels. Macrostrain approximates the tissue edges, minimizing the tissue defect size.[1,19-20] Microstrain stimulates increased cellular proliferation, leading to angiogenesis and granulation tissue formation.[1, 19-20] The adequate delivery of negative pressure can support granulation tissue formation[21], perfusion[22] and removal of wound exudate and infectious materials (**Figure 1**). The scientific foundation for V.A.C.® Therapy forms the basis for the patient outcomes observed in the published clinical literature and supports its use for managing wounds and protecting them from external contamination in all care settings.

Figure 1: Mechanisms of Action



Material matters

Both reticulated open-cell foam (such as V.A.C.® Granufoam™ Dressing) and gauze are currently used with NPWT for the management of wounds. Both dressings create an environment that promotes wound healing by providing a moist wound environment and by removal of exudates. However, due to the differences in dressing interactions, gauze may not offer the same level of granulation tissue formation that is affected through macrostrain and microstrain with V.A.C.® Granufoam™ Dressings.[16, 23-25]

Three bench studies have been published specifically comparing the effect of microstrain on cell proliferation, migration and gene expression. In 2007, McNulty et al.. developed a three-dimensional fibrin matrix to study the effects of negative pressure on fibroblast viability, chemotactic signaling, and proliferation. They found that NPWT utilizing gauze had significant cell death and stimulated less migration and proliferation than V.A.C.® Therapy with V.A.C.® Granufoam™ Dressing treated cells ($p<0.05$).[19] In 2009, Derrick et al.. reported that gene expression profiles for V.A.C.® Therapy with V.A.C.® Granufoam™ Dressing (5,072 genes) were >1.6-fold than moist wound dressings (3,601 genes) and NPWT gauze (3,952 genes).[2] In 2009, McNulty et al. published their finding on the effect of V.A.C.® Therapy with Granufoam Dressing and NPWT gauze on cellular energetics. They found that levels of cytochrome c oxidase, energy charge, and adenosine triphosphate/adenosine diphosphate were significantly increased following the application of V.A.C.® Therapy compared to NPWT gauze ($p<0.05$).[20]

Depending on your goal of therapy such as fluid management and/or fluid management versus granulation tissue formation, 3M has a dressing solution without having to switch between therapy units.

Not all NPWT systems are the same

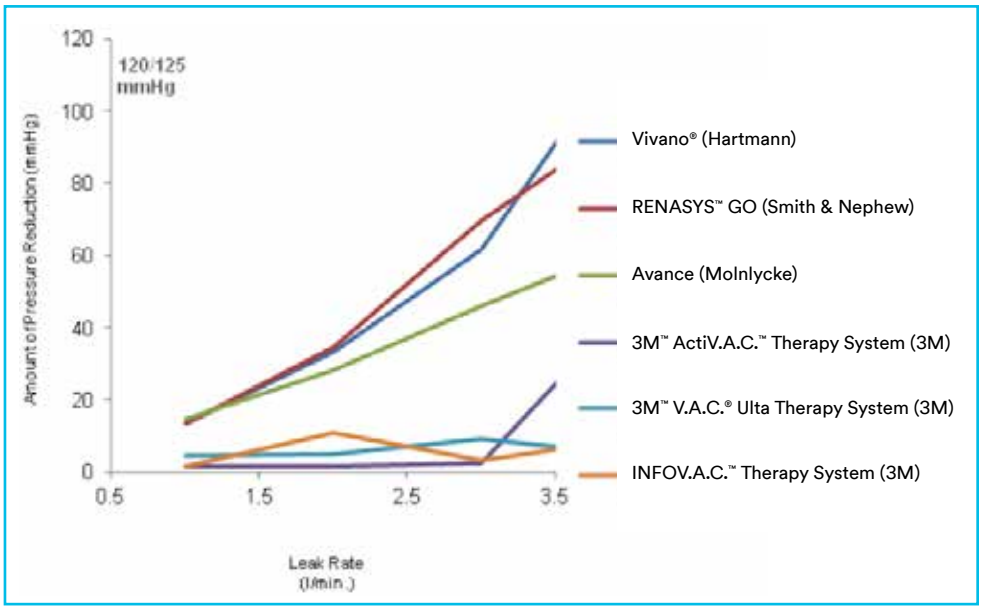
3M™ V.A.C.® Therapy Systems are the only NPWT systems that provide proprietary 3M™ SensaT.R.A.C.™ Technology, a real-time pressure feedback system. This technology continuously monitors, measures, and maintains the set negative pressure at the wound site and adjusts pump output, compensating for wound distance, anatomical wound position, exudates characteristics, and patient movement. The 3M™ SensaT.R.A.C.™ Pad (**Figure 2**) efficiently draws exudates away from the wound through the large inner lumen and independently monitors target pressure at the wound through outer sensing lumens (**Figure 3**). The SensaT.R.A.C. Pad distributes negative pressure to individual sensing lumens and helps reduce tubing blockages and false alarms.

Figure 2: 3M™ SensaT.R.A.C.™ Pad

Figure 3: 3M™ V.A.C.® Tubing

Although the majority of NPWT literature is reported using V.A.C.® Therapy, the number of alternative NPWT systems has increased over the years. Therefore, it is important to understand the differences that may exist among the different NPWT systems. A bench top NPWT study[26], of four cohorts with two units each, compared 3M™ ActiV.A.C.™ Therapy Unit integrated with SensaT.R.A.C. Technology with the RENASYS™ GO Wound Therapy Unit (Smith & Nephew). Therapy units were placed 92cm above dressed simulated wounds with inline canisters for fluid collection 48cm above the simulated wounds. Simulated wound fluid at 30cP viscosity was injected into the dressings, therapy units were started, and wound pressure and fluid volume were measured over 24 hours. Three therapy units per group were tested 3 times each. Under similar test conditions, ActiV.A.C. Therapy maintained a target pressure at the simulated wound site, while RENASYS™ GO was unable to maintain the target negative pressure at the wound site. In addition, it took RENASYS™ GO 24 hours to remove the volume of fluid removed in 15 minutes by ActiV.A.C. Therapy.[26] Correlation of bench results in humans has not been established in specific clinical studies. Similar findings from other bench top studies comparing V.A.C.® Therapy Units with other competitor products have also been reported (**Figure 4**).[27-30] These data demonstrated that the performance of all NPWT systems is not necessarily similar.

Figure 4: Side by side comparative bench test: Tolerance of small-sized air leakage

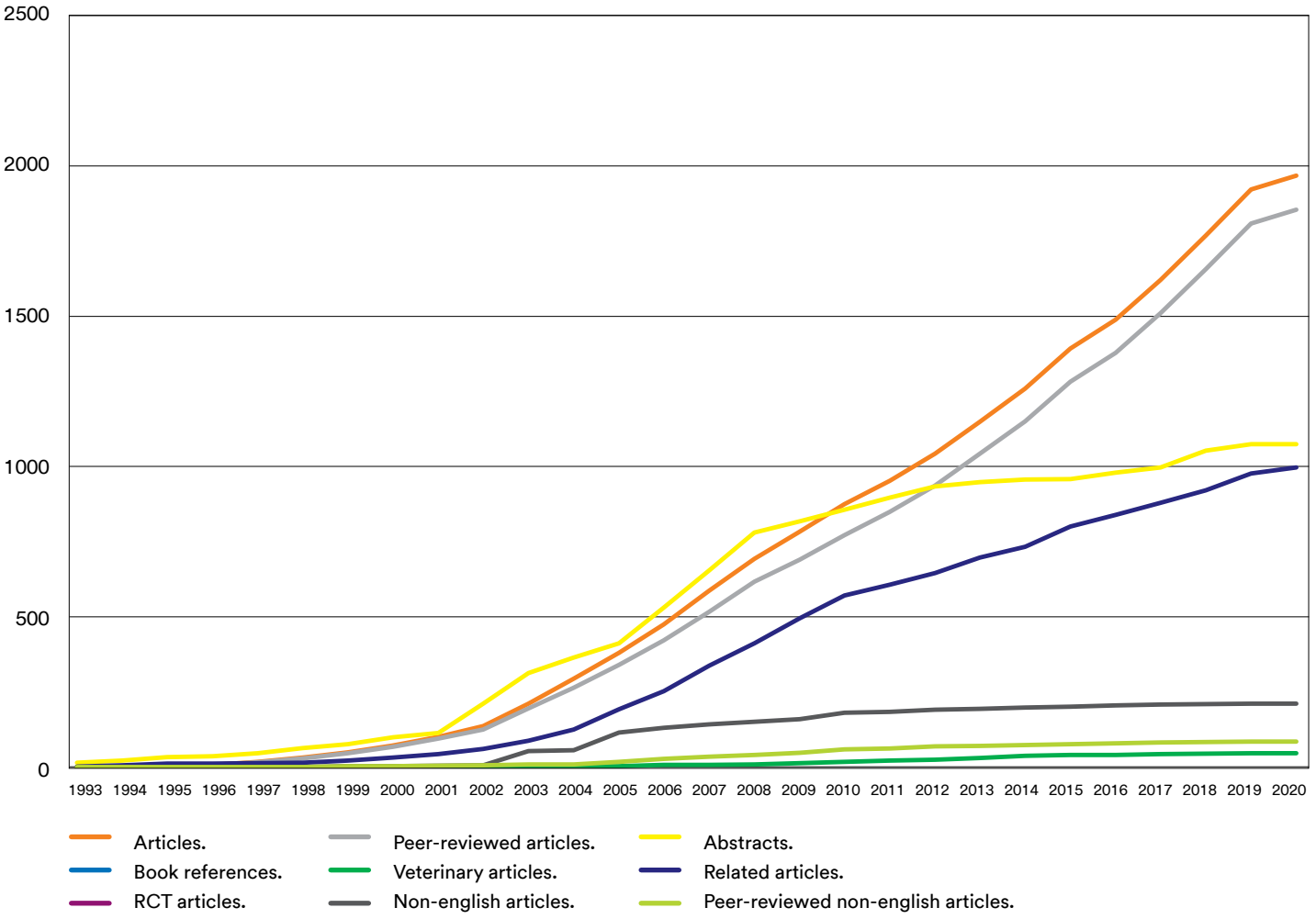


Clinical evidence

Of all the commercialized NPWT products, 3M™ V.A.C.® Therapy has the largest body of evidence to date, including over 1,800 peer-reviewed articles, 97 of which are randomized controlled trials (RCT) (**Figure 5** and **Table 1a-b**).[31] These studies have demonstrated several benefits of NPWT, as well as the effectiveness of V.A.C.® Therapy in helping to manage diabetic foot wounds, chronic wounds (eg, pressure ulcers and lower extremity ulcers), and a variety of acute wounds. Table 2 lists a number of key references by wound type.

Suissa, Danino and Nikolis published a meta-analysis of randomized trials of NPWT vs standard wound care. Their results suggest that NPWT appears to be effective in the management of chronic wounds.[32]

Figure 5: 3M™ V.A.C.® Therapy publication numbers



Clinical evidence (cont.)

Table 1a: 3M™ V.A.C.® Therapy vs. S&N NPWT vs. Other NPWT manufacturers by evidence type

Type of study	3M™ V.A.C.® Therapy	Smith & Nephew NPWT	Other NPWT manufacturers
RCT	97	24	9
PC	186	34	13
CRS	149	16	3
RS	286	13	13
CST	451	58	24
CSE	307	24	12

Study Type: CRS=Comparative Retrospective Study; CSE= Case Series; CST=Case Study; PC=Prospective Cohort;

RCT=Randomized Controlled Trial; RS=Retrospective Study

Data based on results of a search of 3M internal publication database. (Data as of April 2021)

Table 1b: 3M™ V.A.C.® Therapy vs. Other NPWT evidence numbers by wound type

Type of study	3M™ V.A.C.® Therapy	Smith & Nephew NPWT	Other NPWT manufacturers
Acute Wounds			
Surgical Wounds	788	82	24
General Trauma	154	11	13
Grafts	165	15	2
Chronic Wounds			
Pressure Ulcers	56	3	3
Diabetic Foot	94	9	6
Chronic Leg	23	4	1

Data based on results of a search for Levels 1-5 evidence of the appropriate wound types in a 3M internal publication database. (Data as of April 2021)

Clinical evidence (cont.)

The body of literature provides evidence to 3M™ V.A.C.® Therapy's effectiveness in diabetic foot wounds, chronic wounds such as pressure ulcers and lower extremity ulcers, and a wide variety of acute wounds (**Table 2** below) more evidence can be found at https://www.mykci.com/healthcare-professionals/clinical-evidence.

Table 2: Key publications demonstrating the efficacy of 3M™ V.A.C.® Therapy NPWT

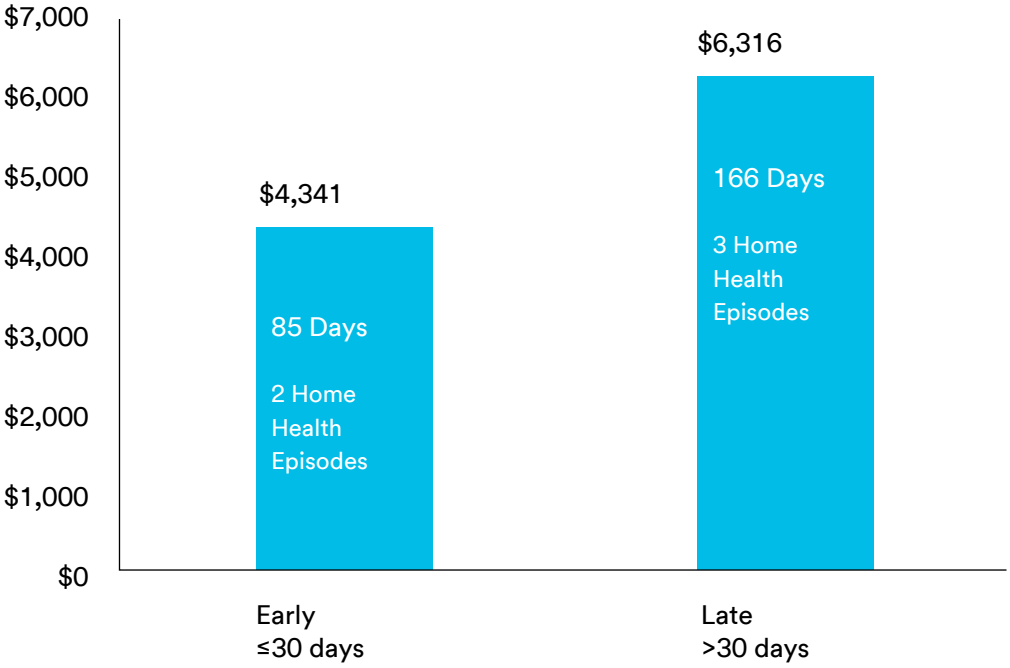
Wound type	Key publications – Acute wounds
Surgical wounds	Zannis et al. 2009 (PCT)[33] Siegel et al. 2007 (CRS)[34] Biter et al. 2014 (RCT)[35] Zenke et al. 2014 (PCT)[36] Seidel et al. 2020 (RCT)[37]
General trauma	Machen et al. 2007 (CSE)[38] Labler et al. 2007 (CST)[39] Raj et al. 2016 (PCT)[40] Maurya et al. 2017 (PC)[41] Burtt et al. 2020 (CRS)[42]
Grafts	Blume et al. 2010 (RS)[43] Ho et al. 2013 (PCT)[44] Eisenhardt et al. 2011(RCT)[45] Joo et al. 2020 (RCT)[46] Vather et al. 2018 (RCT)[47] Halama et al. 2019 (RCT)[48]
Diabetic foot amputations	Lavery et al. 2008 (RS)[49] Armstrong et al. 2005 (RCT)[7] Dalla Paola et al. 2010 (RCT)[12] Eginton et al. 2003 (RCT)[50] De Caridi et al. 2016 (PCT)[51] Sukur et al. 2018 (CRS)[52]

Wound type	Key publications – Chronic wounds
Pressure	Wanner et al. 2003 (RCT)[53] Ford et al. 2002 (RCT)[54] Joseph et al. 2000 (RCT)[55] Wild et al. 2008 (RCT)[56] Fulco et al. 2015 (RCT)[57] Wagstaff et al. 2014 (RCT)[58]
Diabetic foot	Suissa et al. 2011 (Meta Analysis)[32] Blume et al. 2008 (RCT)[6] Cole et al. 2016 (PCT)[59] Skrinjar et al. 2016 (RCT)[60] Maranna et al. 2021 (RCT)[61]
Venous stasis ulcer	Vuerstaek et al. 2006 (RCT)[62] Dini et al. 2011 (RCT)[63] Egemen et al. 2012 (PCT)[64]

Early vs. Late

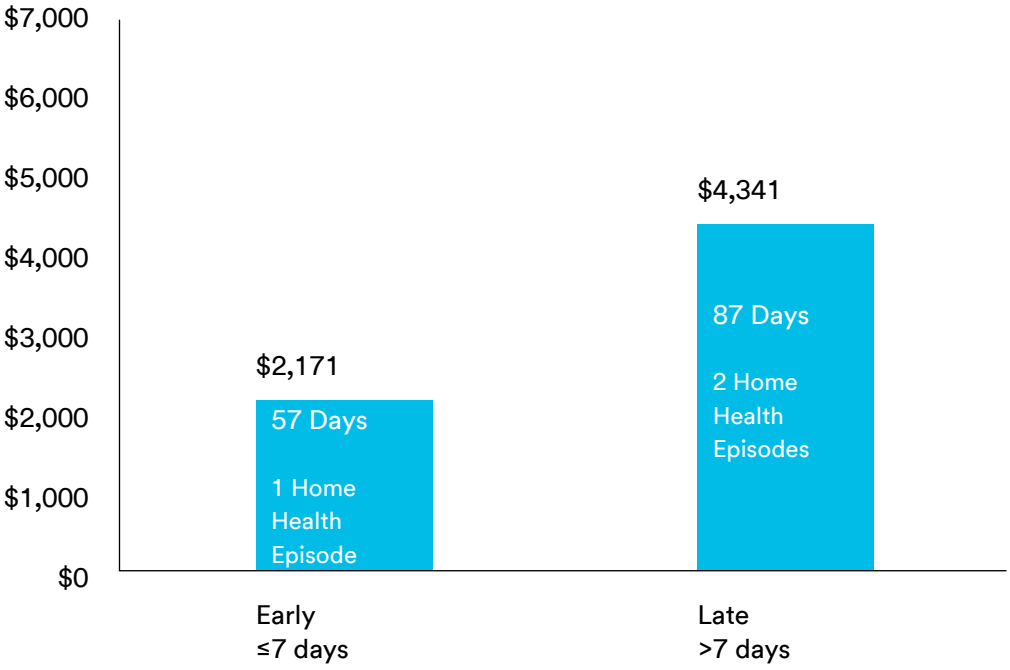
The cost savings associated with the use of 3M™ V.A.C.® Therapy support early initiation of NPWT. A study by Baharestani et al. evaluated how early versus late initiation of NPWT affected the length of stay (LOS) in home healthcare with Stage III or IV pressure ulcers or surgical wounds.[65] The results indicated that early application of NPWT was related to a reduced overall length of home care services (**Figures 6** and **7**). Additionally, higher costs for wound care treatment could result because for each day that NPWT application was delayed, nearly 1 day was added to total LOS.[65] Kaplan et al. further demonstrated the success of early initiation of NPWT for the treatment of traumatic wounds.[66] Records of trauma patients were retrospectively analyzed and divided into two groups: early (Day 1 or 2 of hospital stay) or late group (Day 3 or later). Results showed the early use of NPWT was associated with reduced hospital stays (10.4 vs 20.6 days, $p<0.0001$), ICU stays (5.3 vs 12.4 days, $p<0.0001$), and treatment days, translating into lower total and variable costs. In a third study, de Leon et al. retrospectively investigated the effects of early use of NPWT on LOS in a long-term acute care setting.[67] Records of patients who received NPWT within 14 days of admission (early) or after 15 days of admission (late) were analyzed. Findings from this study favored early initiation of NPWT with a reduction in mean LOS (35.4 vs 56.4 days, $p<0.0001$) and mean time to wound closure (22 vs 34 days, $p=0.0154$) in these patients compared to the late NPWT patients.

Figure 6: Home health comparison of Early vs. Late NPWT on home patients with pressure ulcers[65]



Early vs Late (cont.)

Figure 7: Home health cost comparison of Early vs. Late NPWT on home patients with surgical wounds[65]

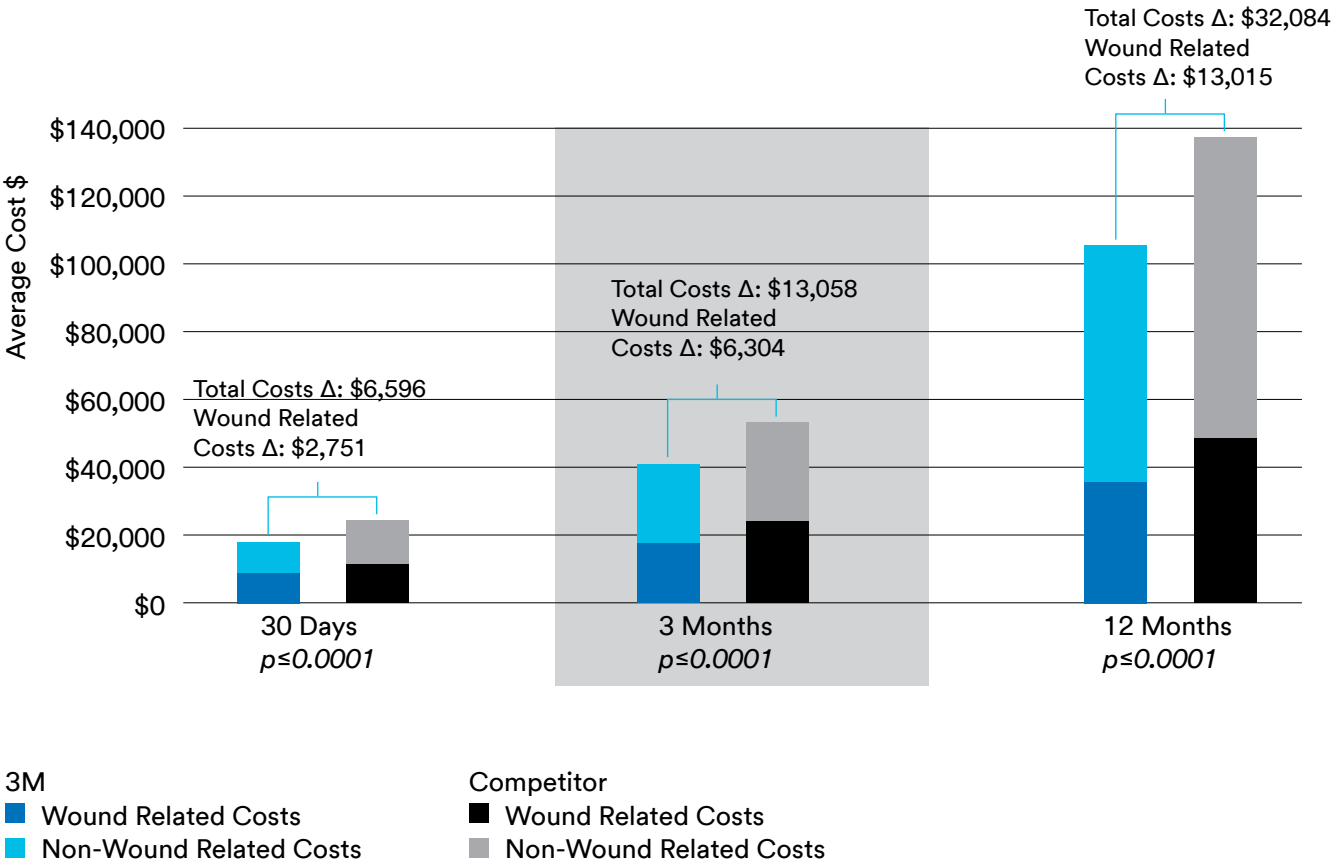


Yao et al. (2014) published findings on their evaluation of the efficacy of negative pressure wound therapy (NPWT) compared to standard of care on wound healing in high-risk patients with multiple significant comorbidities and chronic lower extremity ulcers (LEUs) across the continuum of care setting.[10] This was a retrospective cohort study of 'real-world' high-risk patients conducted using the review of the Boston University Medical Center electronic medical records, along with chart abstraction to capture detailed medical history, comorbidities, healing outcomes and ulcer characteristics. A total of 342 patients (171 NPWT patients with LEUs vs 171 non-NPWT patient matched for age and gender), were included in this cohort from 2002 to 2010. The hazard ratios (HRs) were estimated by COX proportional hazard models after adjusting for potential confounders. The results found that NPWT patients were 2.63 times (95% CI = 1.87-3.70) more likely to achieve wound closure compared to non-NPWT patients. Incidence of wound closure in NPWT patients were increased in diabetic ulcers (HR = 3.26, 95% CI = 2.21-4.83), arterial ulcers (HR = 2.27, CI = 1.56-3.78) and venous ulcers (HR = 6.31, 95% CI = 1.49-26.6) compared to non-NPWT patients. Wound healing appeared to be positively affected by the timing of NPWT application. Compared with later NPWT users (1 year or later after ulcer onset), early NPWT users (within 3 months after ulcer onset) and intermediate NPWT users (4-12 months after ulcer onset) were 3.38 and 2.18 times more likely to achieve wound healing. The authors concluded that despite greater significant comorbidities, patients receiving NPWT experienced a reduced time to healing, and that early use of NPWT demonstrated greater incidence of wound healing. They also determined that the longer the interval before intervention with NPWT, the higher the correlation was to with poor wound healing outcome.

Health economics

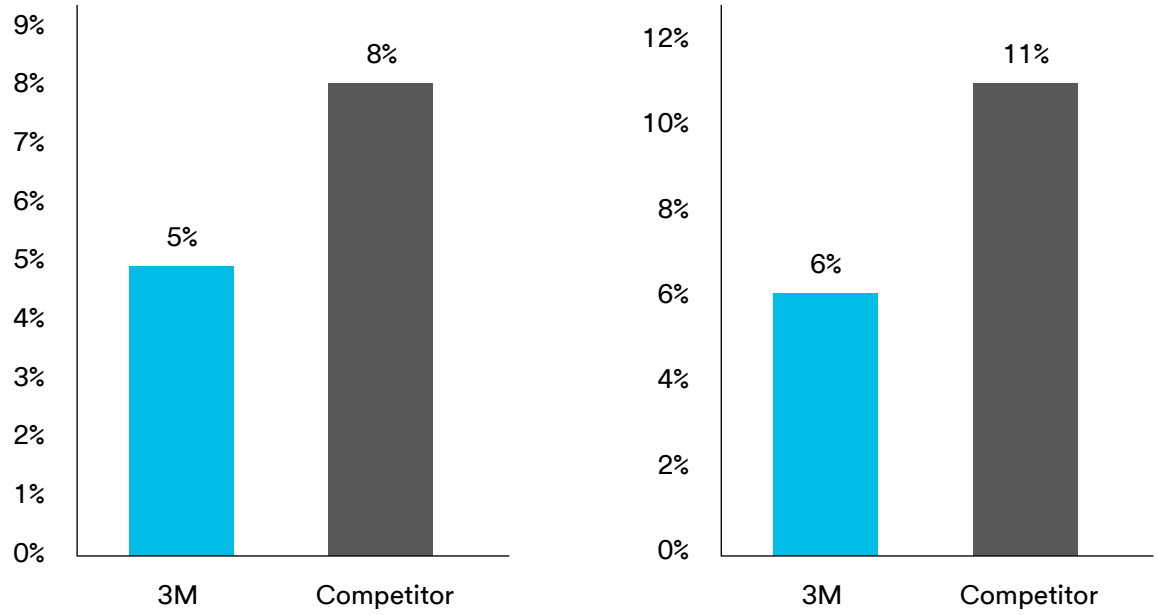
Because not all NPWT systems may be the same and price differences may exist, it is important to understand the comparative effectiveness of these different systems because certain NPWT systems may be associated with potential overall cost savings. Law et al.[68] (2015) analyzed de-identified insurance claim data from a major US insurance company (Optum Life Sciences, Eden Prairie, MN) for patients with chronic wounds who received any type of NPWT model. At 12 months, total costs were significantly lower for 3M™ V.A.C.® Therapy patients (n=7,860) compared to Competitor NPWT patients (n=378) ($80,768 vs $111,212, respectively; p=0.03). A second study by Law et al.[69] retrospectively evaluated a later data set from the same national insurance claims database to assess costs, treatment duration, and multiple sites of care for V.A.C.® Therapy and a case-matched cohort of other NPWT systems. The study found that compared to V.A.C.® Therapy, patients receiving competitor NPWT had a higher cost to treat for all wounds, at all time periods. Compared to V.A.C.® Therapy, competitor NPWT wound-related costs at 30 days were 32% higher ($11,334 vs. $8,583) and total cost to treat at 30 days was 37% higher ($24,405 vs. $17,809). Patients being treated with V.A.C.® Therapy had lower total costs across all time periods, as well as a shorter average length of therapy. These higher competitor costs were driven by statistically significantly higher NPWT, inpatient, home health care, skilled nursing facility, long-term care, and other expenses. The study's findings also reinforce the importance for purchasers and payers to look beyond therapy acquisition price to consider all associated economic outcomes.

Figure 8: Costs at 30 days, 3 months, 12 months: all wounds[69]



Health economics (cont.)

Figure 9: Wound related re-admission rates[70]



A similar analysis was reported by Law and Beach (2014), who performed a retrospective observational database analysis, conducted by Premier Research Services (Charlotte, NC), that identified and followed to discharge hospitalization visits where NPWT was provided to patients.[71] The objective of this study was to assess hospital charges and readmission rates for patients who were treated with 3M™ V.A.C.® Therapy versus other NPWT systems.

De-identified hospital database records of patients treated between 01-Jul-2011 and 30-Jun-2013 with at least one NPWT claim were retrospectively analyzed. The analysis included 18,385 V.A.C.® Therapy discharges and 3,253 other NPWT discharges from 144 and 24 hospitals, respectively. Results showed V.A.C.® Therapy patients had 10% shorter LOS (13.0 vs. 14.5 days, respectively; p<0.0001). V.A.C.® Therapy patients also had lower all-cause 30-day readmission rates of 16.1% vs 17.9% (p=0.0145). Average hospital charges were 11% lower ($14,512) for V.A.C.® Therapy patients versus other NPWT patients ($112,759 vs $127,272, p<0.0001). Estimated length of therapy was lower for V.A.C.® Therapy patients versus other NPWT patients (7.1 vs. 7.5, respectively; p<0.0032), and V.A.C.® Therapy patients received NPWT earlier in their stay than patients in facilities using other NPWT (4.6 vs. 5.5 days, respectively; p<0.0001). Percentage of NPWT patients who required an ER visit within 30 and 60 days post discharge was lower for V.A.C.® Therapy patients versus other NPWT patients (16.6% vs 18.1%, respectively, at 30 days, p=0.0456; 23.4% vs 26.2%, respectively, at 60 days, p=0.0012). Based on this analysis, patients treated with V.A.C.® Therapy had shorter lengths of stay and lower hospital readmission rates than patients treated with other NWPT.

In 2008, Apelqvist et al. published their findings on resource utilization and direct economic cost of care for patients treated with V.A.C.® Therapy compared with standard moist wound therapy (MWT).[71] The analyses were based on the published RCT by Armstrong and Lavery.[7] Apelqvist et al. found that more surgical procedures, including debridement, were required for the MWT group (120 vs 43 V.A.C.® Therapy, p<.001). The dressing change average performed per patient was 118 (range 12-226) for MWT versus 41 (6-140) for V.A.C.® Therapy (p=0.0001). Outpatient treatment visits were 11 (range 0-106) for the MWT group versus 4 (range 0-47) in the NPWT group (p<0.05). The average direct cost per patient treated for 8 weeks or longer (independent of clinical outcome) was $27,270 (V.A.C.® Therapy) and $36,096 (MWT). The average total cost to achieve healing was $25,954 for V.A.C.® Therapy (n=43) compared to $38,806 for MWT group (n=33). The authors concluded that V.A.C.® Therapy treated diabetic patients with post amputation wounds resulted in lower resource utilization and a greater number of patients obtaining wound healing at a lower overall cost of care compared to MWT.[71]

Health economics (cont.)

In 2014, Driver and Blume[72] published their findings on a post-hoc retrospective analysis of patients enrolled in a randomized controlled trial (Blume et al., 2008)[6] to evaluate overall costs of V.A.C.® Therapy (n=169) versus advanced moist wound therapy (AMWT; n=166) in treating grade 2 and 3 diabetic foot wounds during a 12-week therapy course. A total of 324 patient records (NPWT = 162; AMWT = 162) were analyzed. There was a median wound area reduction of 85.0% from baseline 3M™ V.A.C.® Therapy treated patients to 61.8% reduction in those treated with AMWT. Total cost for all patients, regardless of closure, was $1,941,472.07 for V.A.C.® Therapy group compared to $2,196,315.86 for AMWT group. For patients achieving complete wound closure, the mean cost per patient for V.A.C.® Therapy group was $10,172 compared to $9,505 for the AMWT group. The median cost per 1cm^2 of closure was $1,227 for V.A.C.® Therapy and $1,695 for AMWT. In patients not achieving complete wound closure, the mean total wound care cost per patient was $13,262 for V.A.C.® Therapy group, compared to $15,069 for AMWT group. The median cost to close 1cm^2 in non-healing wounds for V.A.C.® Therapy was $1,633, compared to $2,927 for AMWT. They concluded that the results showed a greater cost effectiveness for V.A.C.® Therapy versus AMWT.[72]

In 2008, Flack et al. reported on the cost-effectiveness of V.A.C.® Therapy compared to advanced wound dressings, for the treatment of diabetic foot ulcers in the US.[73] They used a Markov model designed to estimate the cost per amputation avoided and the cost per quality-adjusted life year (QALY) of V.A.C.® Therapy, compared with both traditional and advanced dressings. The Markov model simulated 1,000 patients over a one-year period using transition probabilities obtained from the literature. The model analyzed health states such as: uninfected ulcer; infected ulcer; infected ulcer post-amputation; healed; healed post-amputation; amputation; and death. Simulated patients initially treated with V.A.C.® Therapy switched to the advanced dressing after three months of treatment if their wound remained unhealed. Simulated patients treated with traditional or advanced dressings were assumed to continue with their treatment for the full 12 months if they remained unhealed. The model results demonstrated improved healing rates (61% versus 59%), more QALYs (0.54 versus 0.53) and an overall lower cost of care ($52,830 versus $61,757 per person) for V.A.C.® Therapy simulated patients compared with advanced dressings. V.A.C.® Therapy was reported to be the dominant intervention when compared with traditional dressings. The model results indicated that V.A.C.® Therapy was less costly and more effective than both traditional and advanced dressings. The results were reported to be robust to changes in key parameters, including the transition probabilities, the cost of V.A.C.® Therapy and the utility weights applied to health states.[73]

In the largest RCT on V.A.C.® Therapy (n=539), Seidel et al. explored both the clinical and health economic outcomes for the use of V.A.C.® Therapy in patients with subcutaneous abdominal wound healing impairment (SAWHI) after surgery compared to conventional wound treatment (CWT).[74] The clinical results showed that V.A.C.® Therapy (n=256), compared to CWT (n=251), in the intent-to-treat population, provided: 1) Significantly higher wound closure rate within 42 days ($p<0.001$); 2) Significantly shorter mean time to wound closure ($p<0.001$); and 3) Significantly greater total reduction of wound surface area ($p=0.007$) and wound volume ($p=0.002$) within 42 days. In the per-protocol population, V.A.C.® Therapy (n=157), compared to CWT (n-174), provided: 1) Significantly higher wound closure rate within 42 days ($p<0.001$), and; 2) Significantly shorter mean time to wound closure ($p<0.001$). In comparing the resource utilization of the per-protocol population[75], V.A.C.® Therapy, as compared to CWT, demonstrated: 1) Significantly shorter treatment length (V.A.C.® Therapy 22.8 days vs. CWT 30.6 days, $p=0.001$); Significantly shorter time for dressing changes per patient (V.A.C.® Therapy 196 minutes vs. CWT 278 minutes, $p<0.001$), and; 3) Significantly shorter time for wound-related procedures per patient (V.A.C.® Therapy 167 minutes vs. CWT 266 minutes, $p<0.001$). However, in this study, due to local infrastructure and reimbursement challenges, many V.A.C.® Therapy patients were prevented from transferring out of the hospital setting which resulted in a longer hospitalization time for V.A.C.® Therapy patients (13.9 days) than CWT patients (11.8 days) ($p=0.047$). The results of this study encouraged a change in out of hospital reimbursement policy for NPWT in Germany.

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For more information, contact your local representative.

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

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70-2011-8282-4 PRA-PM-US-03262 (11/21)

3M | V.A.C.® Therapy

Negative pressure wound therapy you can trust

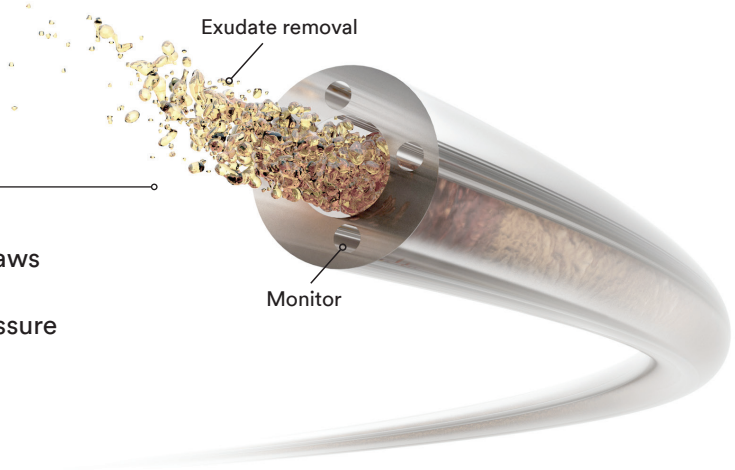
Discover the value of 3M™ V.A.C. Therapy, now with 3M™ Dermatac™ Drape

3M™ V.A.C.® Therapy: Technology you can trust

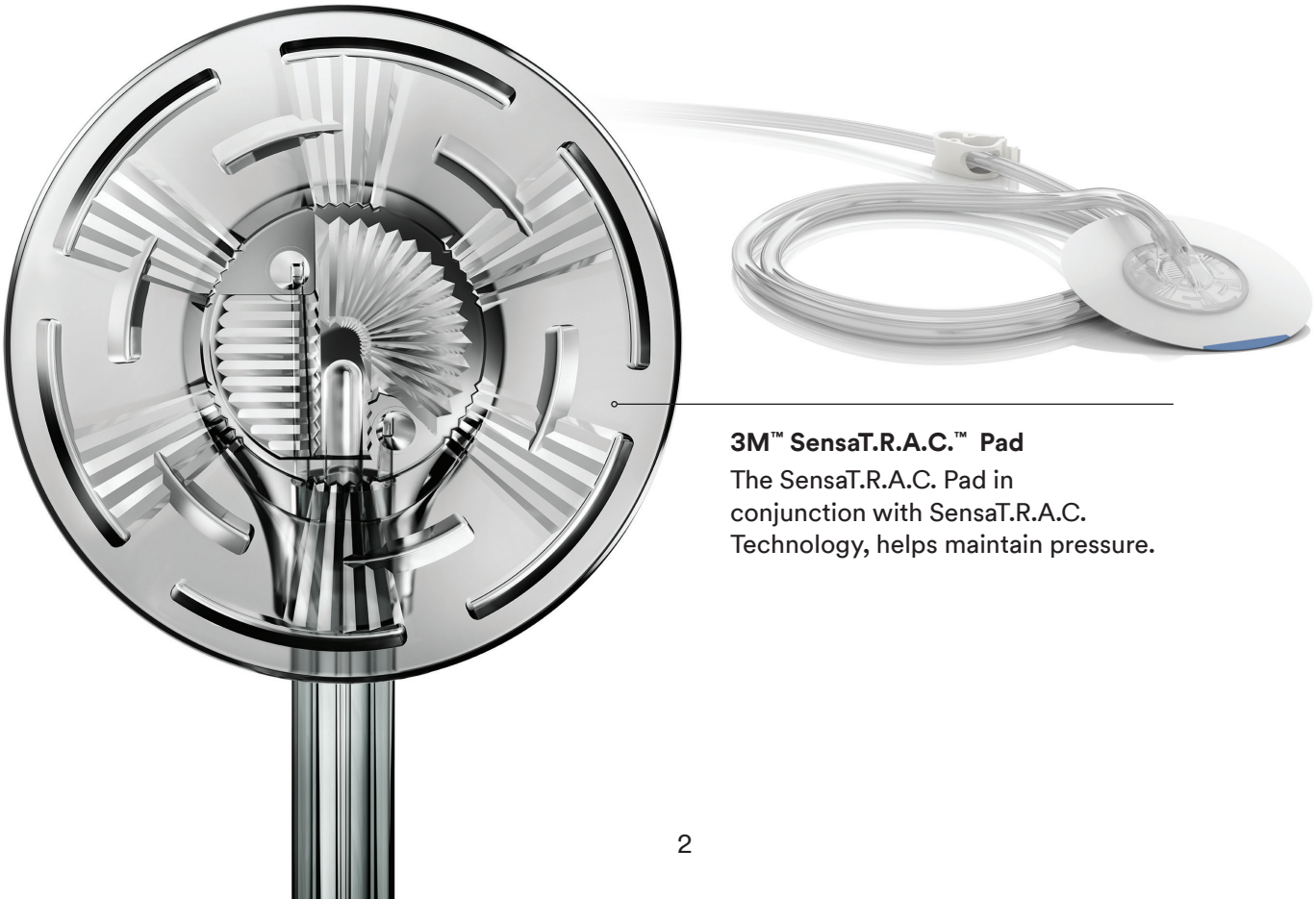
V.A.C.® Therapy is the only negative pressure wound therapy device engineered with 3M™ SensaT.R.A.C.™ Technology, a proprietary technology that maintains and adjusts to deliver set pressure at the wound site. SensaT.R.A.C. Technology helps ensure that the prescribed settings are delivered to the wound.

V.A.C.® Therapy with SensaT.R.A.C. Technology can:

- Sense pressure changes at the wound site.
- Regulate and maintain pressure as conditions change. (e.g., change in head height, patient position, viscosity of exudate, etc.)
- Detect blockages below the canister site and notify clinicians with alarms when target pressure is not achieved.
- Force air into the system to help reduce blockages. (i.e., 3M™ Easyclear Purge™ Technology)



3M™ SensaT.R.A.C.™ Tubing
SensaT.R.A.C. Tubing efficiently draws exudate away from the wound and independently monitors target pressure through multi-lumen tubing.



3M™ SensaT.R.A.C.™ Pad
The SensaT.R.A.C. Pad in conjunction with SensaT.R.A.C. Technology, helps maintain pressure.

3M™ SensaT.R.A.C.™ Technology in action

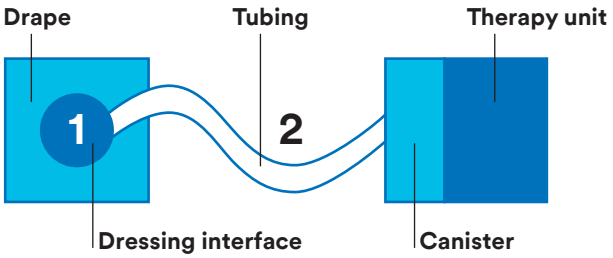
3M™ V.A.C.® Therapy vs. Smith & Nephew RENASYS™ TOUCH[1]

Background: Blockage alarms on Negative Pressure Wound Therapy (NPWT) Systems serve to detect and notify caregivers of existing blockages that could prevent the programmed negative pressure from being delivered to the wound site. Of equal importance is how the NPWT system responds to a blockage being present. If the unit does not alarm to notify the caregiver to clear the blockage or does not clear the blockage by introducing air and/or increasing pressure, the wound may not receive the programmed therapy, which can result in poor outcomes. To better understand the capability of NPWT systems at detecting and responding to blockages, 3M initiated a bench study designed to evaluate the parameters.

Methods: Multiple NPWT units underwent evaluation:

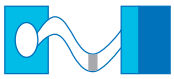
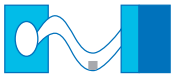
- 3M™ V.A.C.® Ulta Therapy System, INFOV.A.C.™ Therapy System and 3M™ ActiV.A.C.™ Therapy System.
- Smith and Nephew RENASYS™ TOUCH. The various therapy units and their respective foam based dressing kits were set to default parameters of -120/-125mmHg and were evaluated for their ability to trigger blockage alerts or alarms. Blockages* were intentionally created (1) at the dressing interface (3M™ SensaT.R.A.C.™ Pad or RENASYS™ SOFT PORT connector) or (2) in the tubing/connector between the simulated wound and the canister. The units of each type were tested in triplicate for a total of 9 evaluations.

Experimental design set up



*The blockage at site 1 was created by placing a polymeric disc at the simulated wound site directly below the dressing interface (3M™ SensaT.R.A.C.™ Pad or RENASYS™ SOFT PORT connector). The blockage at site 2 was created by controlling airflow into the test set-up using needle valves that were based upon the condition being evaluated, either partially or completely closed.

3M™ V.A.C.® Therapy with 3M™ SensaT.R.A.C.™ Technology vs. Smith & Nephew Renasys™ Therapy System

Location and blockage status		Smith & Nephew RENASYS™ TOUCH Therapy Unit				3M™ V.A.C.® Therapy Units			
Description	**Visual representation**	**Blockage alarm incidence**	**Time(s) to alarm (seconds)**	**NP @ Dressing (mmHg)**	**NP @ Canister (mmHg)**	**Blockage alarm incidence**	**Time(s) to alarm (seconds)**	**NP @ Dressing (mmHg)**	**NP @ Canister (mmHg)**
No blockage		0/9	N/A	-124	-125	0/27	N/A	-120 to -126	-120 to -127
Full blockage at the dressing interface		0/9	>600	~0	-121	27/27	88 - 108	-1	-170 to -196
Full blockage of the dressing tubing		9/9	141	-5	-125	27/27	90 - 106	-6 to -7	-202 to -218
Partial blockage of the dressing tubing		0/9	N/A	-87	-125	0/27	N/A	-116 to -126	-134 to -149

Conclusions

3M™ V.A.C.® Therapy integrated with 3M™ SensaT.R.A.C.™ Technology was shown in bench testing to:

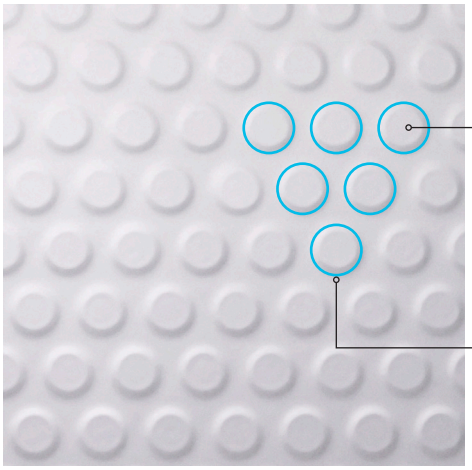
- Demonstrate improved performance in monitoring negative pressure delivery at a simulated wound site and notifying users if blockages exist that could prevent the programmed negative pressure from being delivered to the simulated wound site.
- Attempt to overcome blockages by increasing negative pressure at the canister.

Introducing 3M™ Dermatac™ Drape

3M™ Dermatac™ Drape is the first ever silicone-acrylic hybrid drape for use with 3M™ V.A.C.® Therapy.

The Dermatac Drape hybrid composition unites the necessary properties of soft and skin friendly, with strong, stable adhesion to provide the ideal balance for wound healing support.

Now you can provide wound healing support for V.A.C.® Therapy patients with the dual benefits of adhesive acrylic and forgiving silicone.



Acrylic (inside the circles) helps provide a tight seal to protect wounds on different anatomical locations.

Silicone (outside of the circles) allows for repositioning at initial placement and gentle removal.

Apply with ease

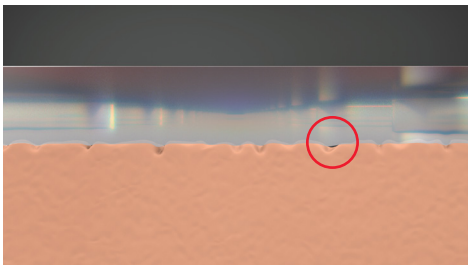


Figure 1. Acrylic is a stiffer adhesive and adhesion builds over time, potentially leaving gaps between drape and skin at initial placement.

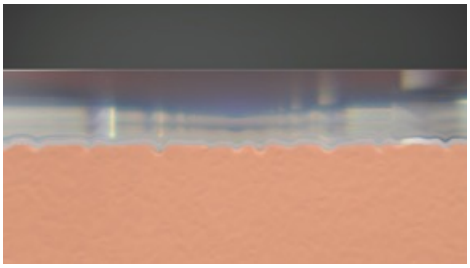


Figure 2. Silicone is a softer adhesive, rapidly filling gaps at placement.

Dermatac Drape introduces a new class of drape by combining both acrylic and silicone adhesive properties to overcome limitations of traditional adhesive drape technology.

1. High tack-acrylic will cure to patient up to 20 min after placement, allowing repositionability in this timeframe.
2. Silicone allows for greater contact with skin, filling any gaps at placement and potentially reducing leaks.

The precise combination of acrylic and silicone allows for an ideal balance for wound healing support, leading to significant benefits related to:

- Sealing and repositionability upon initial placement.
- Less time at dressing changes, improved ease of use, and less waste.
- Kind to patients' skin and minimizes discomfort.

Seal in the heal

With Dermatac Drape you can rely on a strong and effective seal for negative pressure wound therapy.

In a simulated wound model (n=5), Dermatac Drape with 3M™ V.A.C.® Therapy maintained a seal in 100% (5/5) of samples vs. Mölnlycke's Avance® Film with Safetac® technology which failed to maintain a seal in 80% (4/5) of samples[2].

	3M™ Dermatac™ Drape	Other Silicone -based Drape
Seal maintained in a simulated wound model (n=5)[2]	**100%**	**20%**

Remove with kindness

With its low tack adhesive properties Dermatac Drape is strong enough to maintain a seal for V.A.C.® Therapy, yet gentle enough to help take the pain out of dressing changes.

Patients (n=5) observed that V.A.C.® Therapy with Dermatac Drape was more comfortable both when worn and during dressing changes compared to standard drape[3].

Impact of adhesive properties on skin at drape removal

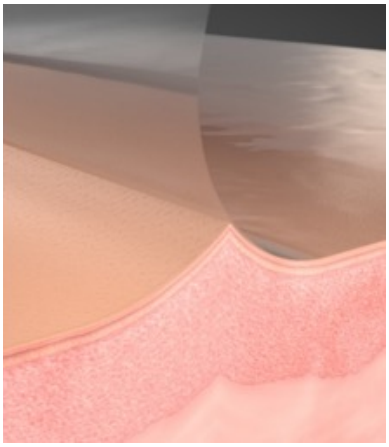


Figure 3. Traditional Acrylic Drape

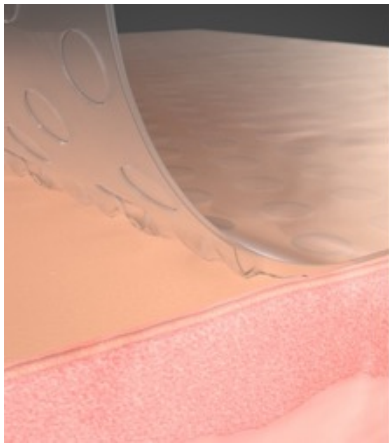


Figure 4. 3M™ Dermatac™ Drape

The full periwound skin contact provided by traditional high-tack acrylic drapes (shown in **Figure 3.**) can deform skin upon removal.

Dermatac Drape has less acrylic contact with periwound skin due to its perforated silicone layer allowing the softer, more flowable silicone to deform at removal instead of the patient's skin.

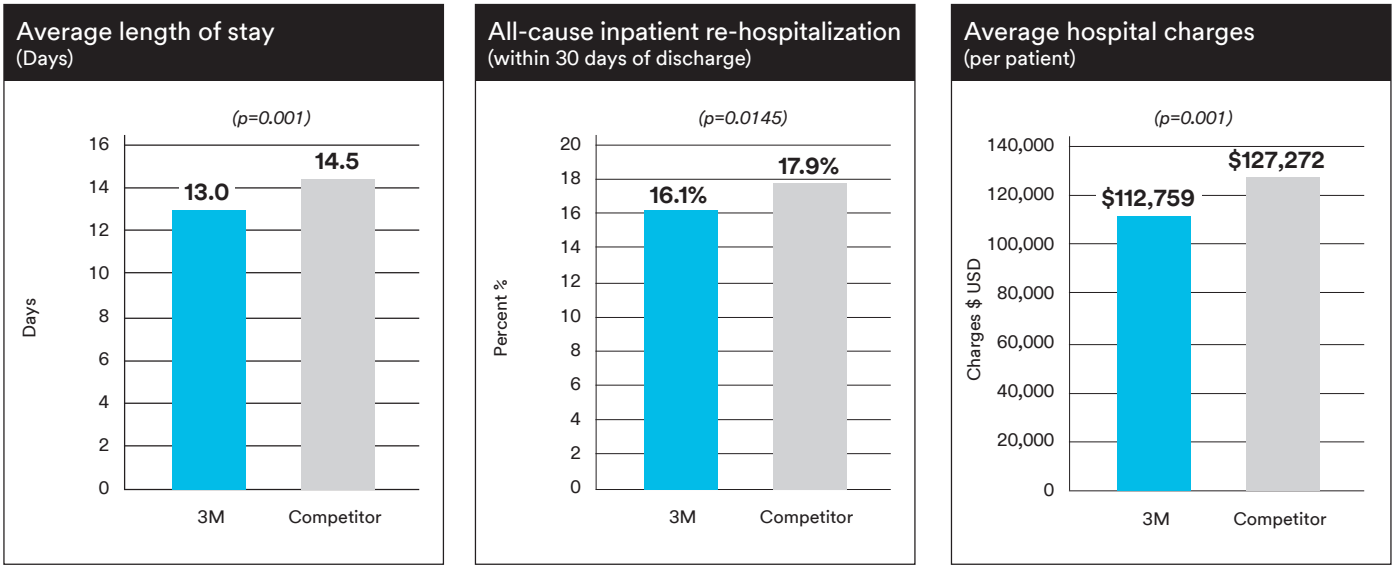
100% (n=17) of patients agreed that Dermatac Drape was painless upon removal[4]

- Dermatac Drape was placed on 17 patients over a 2-week period, with dressing changes every 48 to 72 hours.
- At dressing changes patients were asked how Dermatac Drape felt upon removal.

Failure to heal a wound effectively can lead to higher overall cost of care

Cost savings in the acute setting
A retrospective observational database study of 21,638 patients (3M n=18,385, Competitor n=3,253) was conducted by Premier Research Services (PRS) to evaluate the costs and readmission rates of Negative Pressure Wound Therapy (NPWT) patients* at facilities using 3M NPWT vs. Competitor NPWT Therapies.[5]

Analysis of 3M NPWT vs. Competitor NPWT



*Each patient received at least 1 charge for NPWT. Competitor hospitals include all Non-3M NPWT hospitals.

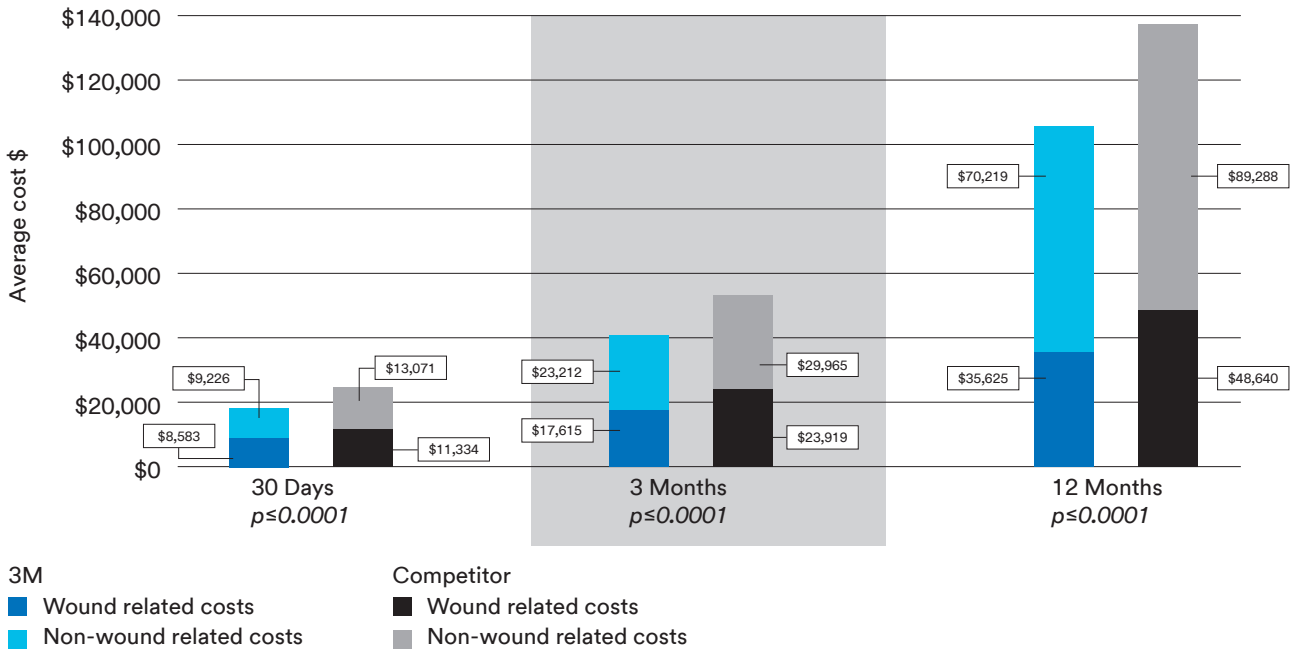
Total cost of care

- Total cost to treat (in addition to wound closure) is important for evaluating cost effectiveness of wound care products and services.
- Failure to heal a wound effectively can lead to overall higher costs to treat.
- In addition to randomized control trials and clinical papers, analysis of real world expenditure data can provide insights into cost effectiveness of wound care therapies.

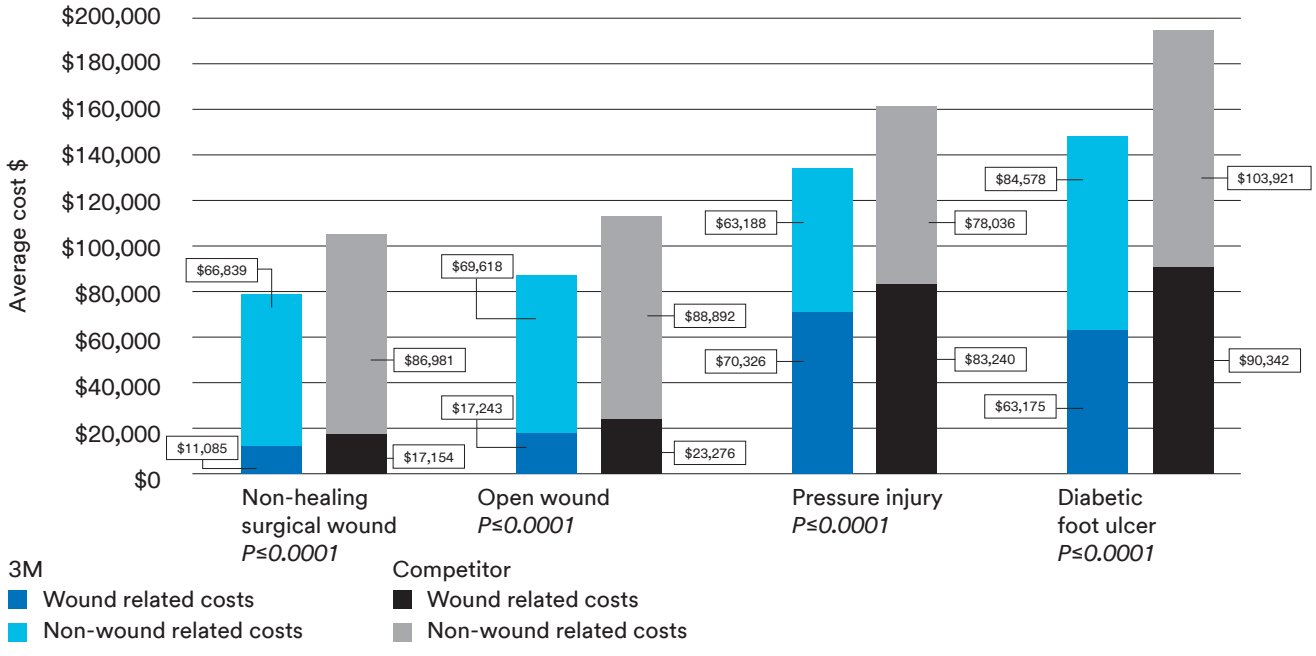
Cost savings in the out-of-hospital setting

Retrospective analysis of U.S. insurance claims database compared total and wound-related costs for 15,180 patients who received 3M™ V.A.C.® Therapy versus competitor NPWT in the outpatient setting between January 2016 and September 2018. Costs were compared across care settings and wound types at 30 days, 3 months, and 12 months after initial claim.[6]

Costs at 30 days, 3 months, 12 months: all wounds



Costs at 12 months: key wound types



- 3M™ V.A.C.® Therapy patients had lower total and wound related costs across all time periods and across all wound types at 12 months.
- V.A.C.® Therapy patients experienced shorter average length of therapy and were less likely to be switched to another supplier.

A world leader in skin and wound care right by your side

As your partner, we're here to help you help your patients. When we combine our science with your expertise, amazing things happen.

Science-based solutions	3M products are trusted in more than 60,000 hospitals, and businesses worldwide. Our comprehensive portfolio of advanced wound care solutions is supported by clinical evidence across new and growing categories—including dressings, disposables, and digital technology and connectivity.
Ongoing support	From ordering to placement and therapy through patient discharge, our clinical and technical support is seamless, efficient, and available when you need it.
World-class education	We act as an extension of your team - empowering you with hands-on training and free, award-winning medical education available live and on demand at: **www.3m.com/3M/en_US/medical-us/3m-medical-education/**
3M reimbursement education hotline	Specialists assist with insurance coding, coverage guidelines, and other reimbursement information. Call: **1-800-668-6812** (Available from 7am - 6pm CST) E-mail: **ReimbursementEducation@mmm.com**

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References:
1. KCI Report: Evaluation of KCI negative pressure wound therapy (NPWT) systems versus RENASYS™ TOUCH with 2nd generation SOFT PORT connectors. Oct 31, 2016. **2.** KCI. Evaluation of Seal Performance for KCI DERMATAC™ Drape and Mölnlycke Avance Safetac Drape on Simulated Wound Model. Nov 20, 2018. **3.** Napolitano, R. Early Use of a Novel Acrylic-Silicone Hybrid Drape With Negative Pressure Wound Therapy in Lower Extremity Wounds. SAWC Fall, Las Vegas NV. October 2019. **4.** Galarza, L. Initial clinical observations using a novel negative pressure wound therapy drape comprised of acrylic and silicone. Poster Presented at the SAWC Spring Meeting, San Antonio, TX. May 2019. **5.** Law, A., Beach, K. Hospital stay costs associated with negative pressure wound therapy. Poster Presented at: Symposium on Advanced Wound Care(SAWC);October 16-18, 2014, Las Vegas, NV. 47(5):547-51. **6.** Law A L. Krebs B. Karnik B. Griffin L. Comparison of Healthcare Costs Associated With PatientsReceiving Traditional Negative Pressure Wound Therapies in the Post Acute Setting. Cureus 12(11):e11790. DOI 10.7759/cureus.11790.

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