



ActiV.A.C.® Therapy Information Guide

Proven Therapies. Healing at Home with KCI.

Note to Clinicians:

Please review this guide with your patient, and refer to the Clinician section of the User Manual for detailed instructions on operating the ActiV.A.C.® Therapy Unit.

A Joint Commission
Accredited Organization



If you have questions about the KCI ActiV.A.C.® Therapy System, please call 1-800-275-4524.

Important Patient Information

Your Nurse's Name: _____

Nurse's Telephone Number: _____

Home Health Agency (HHA) Name: _____

Your Doctor's Name: _____

Your Doctor's Telephone Number: _____

In case of emergency

- contact your local emergency number (i.e., 9-1-1)
- contact your doctor or nurse

Read and follow all instructions and safety information. Your safety is our first priority.

Do not attempt to service or repair the ActiV.A.C.® Therapy Unit. If you have any problems with the unit, call KCI immediately at 1-800-275-4524.

For additional safety information turn to page 18 of this guide.

Important information regarding your benefits, as well as terms and conditions of use are located in the Patient Financial Responsibility - Assignment of Benefits section of this guide (page 23). Please read these carefully. Your acknowledgement on the delivery receipt indicates your agreement to these important terms and conditions of use.

Important Safety Information accompanies this device.

Review with your doctor or nurse prior to use.

Indications, Contraindications, Warnings, Precautions and other important Safety Information are contained in the V.A.C.® Therapy Safety Information Sheet which is found and should always be kept in the pocket inside the front flap of the carrying case. If there are questions or if this information is missing, immediately contact KCI at 1-800-275-4524.



How To Use This Book

This Information Guide is designed to be a comprehensive resource for using KCI ActiV.A.C.® Therapy. Please save all pages of this guide, as you may be asked to refer to it during a KCI service call. Your doctor or nurse may also need to see certain sections for specific information regarding the therapy unit. This book is divided into five sections, each with a specific purpose:

What is ActiV.A.C.® Therapy? (page 9) / Patient Safety Information (page 18)

The What is ActiV.A.C.® Therapy? section includes descriptions of how ActiV.A.C.® Therapy works, what to expect while you are using it, **important patient safety information**, and how to order additional supplies.

Patient Financial Responsibility (page 21)

The Patient Financial Responsibility section contains information regarding your benefits, rights and responsibilities as a patient, privacy practices, and how to return your ActiV.A.C.® Therapy Unit.

Quick Reference (page 39)

The Quick Reference section provides basic operating information for the ActiV.A.C.® Therapy Unit, including how turn the unit on and off, how to start therapy, how to fix a pressure leak, and how to resolve common alarms. These pages may be cut out and folded so they will fit into the pocket on the ActiV.A.C.® carrying case, or posted in a convenient location for reference by you and your doctor or nurse.

ActiV.A.C.® Patient (page 53) and Clinician User Manual (page 87)

The ActiV.A.C.® User Manual will be used by both you and your doctor or nurse as a guide to all the settings and functions of the ActiV.A.C.® Therapy Unit. It describes all the buttons and screens you will see while using the therapy unit. It explains all the alarms that may occur with the ActiV.A.C.® Therapy Unit and how to resolve them. Also included is a list of frequently asked questions, and information on how to care for the therapy unit. Review this manual with your doctor or nurse at the beginning of therapy.

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What is ActiV.A.C.[®] Therapy?



Introduction

This Information Guide provides important information related to your treatment with KCI's ActiV.A.C.[®] Therapy System and is a valuable reference. For additional questions or information contact your doctor or nurse, or KCI at 1-800-275-4524.

Wound healing is a process

Proper wound care management is important to heal your wound and your doctor has prescribed the ActiV.A.C.[®] Therapy System for your care. A doctor or nurse is responsible for directing the use of the ActiV.A.C.[®] Therapy System including application and periodic dressing changes.

How long will it take to heal my wound?

The length of time to heal a wound is different for every patient. General conditions, size and location of the wound, and nutritional status can affect the time it takes for a wound to heal. Your doctor or nurse will discuss when and why ActiV.A.C.[®] Therapy may end.

What is ActiV.A.C.[®] Therapy?

ActiV.A.C.[®] Therapy is KCI's V.A.C.[®] Negative Pressure Wound Therapy that is provided by the ActiV.A.C.[®] Therapy Unit.

Why V.A.C.[®] Therapy?

V.A.C.[®] Negative Pressure Wound Therapy has helped to promote wound healing for millions of patients worldwide. Doctors, nurses, and hospitals all rely on V.A.C.[®] Therapy as an advanced wound therapy to help their patients heal.

The ActiV.A.C.® Therapy System

What is ActiV.A.C.® Therapy?

ActiV.A.C.® Therapy System is a medical device system that helps wounds heal by delivering negative pressure (a vacuum) to the wound through a patented dressing and therapy unit.

Unlike gauze bandages that merely cover a wound, ActiV.A.C.® Therapy actively works to help the wound healing process.

The ActiV.A.C.® Therapy System helps wounds to heal by:

- Promoting the formation of new granulation tissue
- Providing a moist wound healing environment
- Drawing wound edges together
- Removing fluid and infectious materials

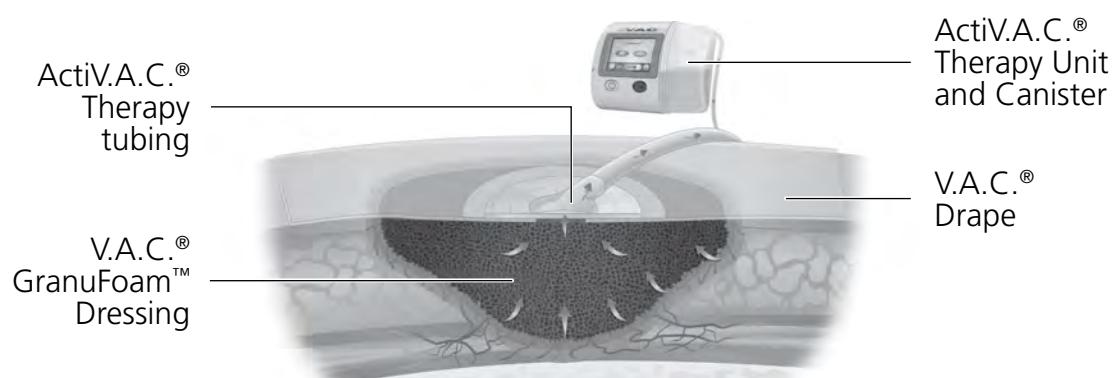
The ActiV.A.C.® Therapy System also helps to:

- Reduce wound odor
- Reduce the need for daily dressing changes

How Does ActiV.A.C.® Therapy Work?

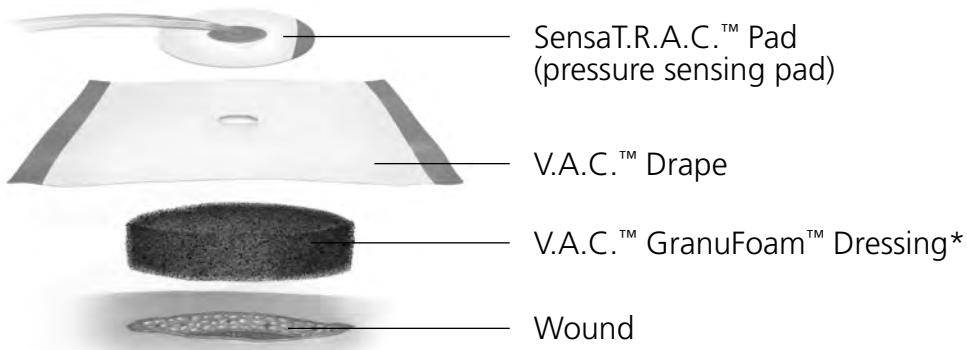
The ActiV.A.C.® Therapy System is an advanced wound therapy system consisting of:

- The ActiV.A.C.® Therapy unit that delivers negative pressure
- A specially designed disposable canister to conveniently manage wound fluid
- Sterile plastic tubing with a pressure sensing system that connects the therapy unit to the dressing
- Special foam dressings (V.A.C.® GranuFoam™ and V.A.C.® WhiteFoam Dressings) that are placed in the wound,
- A clear drape with adhesive (V.A.C.® Drape) that covers the foam dressing(s)



V.A.C.® Dressing Placement

The V.A.C.® Dressing goes inside the wound. The wound area is sealed with the clear V.A.C.® Drape that helps maintain negative pressure over the wound. One end of the tubing connects to the dressing, the other end connects to the canister that fits into the ActiV.A.C.® Therapy Unit.



**If used, V.A.C.® WhiteFoam is typically recommended for placement under V.A.C.® GranuFoam™ Dressing.*

Changing the V.A.C.® Dressing

The ActiV.A.C.® Therapy System uses proprietary foam dressings (V.A.C.® GranuFoam™ and/or WhiteFoam) with the therapy unit. Only V.A.C.® dressings are to be used with the ActiV.A.C.® Therapy units. Wounds treated with the ActiV.A.C.® Therapy System should be monitored on a regular basis by your doctor or nurse who is responsible for treatment.

- For a non-infected wound: KCI recommends the V.A.C.® Dressings be changed every 48 to 72 hours, but no less than 3 times per week.
- For infected wounds: These wounds must be monitored often and very closely. Infected wounds dressing changes may need to be changed more often than 48 to 72 hours. Dressing change intervals should be based on continuing evaluation of your wound condition by your doctor or nurse.

ActiV.A.C.® Therapy Unit



The ActiV.A.C.® Therapy Unit is a lightweight portable device designed for patients who enjoy the freedom of being mobile. The picture shows the important features of the unit.

- A. Power On/Off Button
- B. Touch Screen User Interface
- C. Power Cord Connection
- D. ActiV.A.C.® Canister

ActiV.A.C.® Therapy Use

KCI recommends the ActiV.A.C.® Therapy System remain ON at least 22 out of 24 hours per day.

- If therapy is turned off for more than two hours a day, the V.A.C.® Dressing must be removed and replaced with a traditional dressing. Call your nurse or caregiver to perform this procedure.
- If the unit is off for more than 15 minutes and the power to the unit is on, an alarm will sound.
- If you need more time, press the **AUDIO PAUSE** button on the touch screen. The system will allow 60 minutes before it will alarm again.
- The clear V.A.C.® Drape is waterproof. You can wash or shower with the dressings in place and with the tube clamped (closed off). Turn off the unit and unplug it from the electrical outlet. **Warning: do not take the therapy unit in the bathtub or shower.**

ActiV.A.C.® Therapy Settings

Patient compliance with ActiV.A.C.® Therapy is important for proper healing. Your doctor will determine the negative pressure settings for your unit. **Please do not change any of the settings on the ActiV.A.C.® Therapy System or remove the dressing unless told to do so by your doctor or nurse.**

Ordering Additional Supplies

- When you are down to one case of dressings OR five canisters, it is time to order new supplies.
- To order new supplies, call KCI at 1-800-275-4524. Please allow at least 3-5 business days for delivery.

Hospital Admission

Please notify KCI if you are admitted to a hospital or inpatient facility. Call KCI at 1-800-275-4524 to arrange for the pick-up of your ActiV.A.C.® Therapy System. **This call stops the billing process and you will not be charged.**

Please contact your doctor or nurse to arrange a visit to ensure the ActiV.A.C.® Therapy Unit has been properly removed and all necessary precautions have been taken to ensure your safe transfer to the inpatient facility.

Questions and Answers

1. How does ActiV.A.C.[®] Therapy feel?

Most patients describe ActiV.A.C.[®] Therapy as a non-painful, mild pulling sensation that, in most cases, is not noticeable after a few minutes. Wound comfort may vary by individual person. The wound may become tender or itch as it heals; this is usually a good sign. If itching or discomfort persists, please contact your doctor.

2. Can you move around while on ActiV.A.C.[®] Therapy?

Yes. The ActiV.A.C.[®] Therapy System is lightweight and was specifically designed to provide flexibility and freedom of mobility. Your ability to move around depends on your condition, the wound location and the treatment your doctor has prescribed. The ActiV.A.C.[®] Therapy System may be disconnected so you can take a shower. **Therapy may not be off any longer than two hours per day.**

3. What does the foam dressing look like when ActiV.A.C.[®] Therapy is on?

Your doctor may prescribe a V.A.C.[®] GranuFoamTM or V.A.C.[®] WhiteFoam Dressing for your wound type. The V.A.C.[®] GranuFoamTM Dressing will shrink down and wrinkle like a raisin when ActiV.A.C.[®] Therapy is working. The V.A.C.[®] WhiteFoam Dressing may only have a few wrinkles.

4. Does changing the V.A.C.[®] Dressing hurt?

Some people do experience discomfort during dressing changes depending on the wound type, location and patient condition. The discomfort is similar to other dressings and wound care treatments for the same wound type. Your doctor or nurse can give you advice about pain relief.

5. Who should change my dressing, and how?

Usually a nurse from your doctor's office, home health agency or wound care clinic trained in ActiV.A.C.® Therapy, will change your dressing. If deemed appropriate by your doctor or nurse, a caregiver, family member or friend may change the dressing if they have been properly trained. To help stop the spread of germs and infection, cover your mouth and nose with a tissue when you cough or sneeze and put your used tissue in a waste basket, or cough or sneeze into your upper sleeve, not your hands. The following steps should be followed by you and/or your caregiver to reduce the risk of infection:

- Caregiver should wash hands with soap and warm water for 20 seconds or clean hands with an alcohol-based hand cleaner, before and after each patient contact or procedure.
- Caregiver should always wear gloves and protective clothing and eyewear when handling blood or body fluid, or when in contact with mucous membranes or open cuts.
- Any caregiver with an open cut or skin condition should not care for the patient until the condition has been cleared.
- Caregiver should dispose of soiled dressing according to hospital or institution protocols. **Do not reuse dressing.**
- Caregiver should always note the total number of pieces of foam used in the wound and document on the Foam Quantity Label (if supplied) and in the patient's chart.
- Refer to application instructions provided with the dressing.

6. Who do I contact in case of an emergency?

- First, call 9-1-1 (or your local emergency number).
- After you call local emergency, call your doctor or nurse.
- For all other medical concerns, refer to Patient Safety Information.

8. How can my caregiver be helpful?

A family caregiver or friend can support you by reminding you of the importance of using ActiV.A.C.® Therapy for at least 22 hours each day. In addition, when directed by your doctor or nurse and only after proper training, your caregiver can assist in changing dressings and canisters, responding to alarms and monitoring the therapy.

9. How do I order supplies?

- When you are down to one case of dressings OR five canisters, a new order must be called into KCI at 1-800-275-4524. Please allow at least 3-5 business days for delivery.
- If you are a Medicare patient and you will run out of supplies before the monthly recertification date, your nurse or doctor must complete a Letter of Medical Necessity for Excessive Supplies.

10. What do I do when my ActiV.A.C.[®] Therapy is completed?

- Call KCI at 1-800-275-4524.
- KCI will provide you instructions on how to return the ActiV.A.C.[®] Therapy Unit.
- Billing will continue until this call is completed.

Patient Safety Information

At KCI, your safety is our first priority. If you have questions or concerns regarding product delivery, set up or any product related issues, call KCI US Customer Support at 1-800-275-4524.

- Most issues can be resolved over the phone.
- If the issue cannot be resolved over the phone, US Customer Support can provide additional assistance.



Important

Your doctor or nurse has more information about your wound. Ask your doctor or nurse for any additional information you may need before using this product.

Do not change the settings on the therapy unit without your doctor or nurse giving you specific direction.

If deemed appropriate by your nurse or doctor, a caregiver, family member or friend may change the dressing **if they have been trained by a doctor or nurse.**



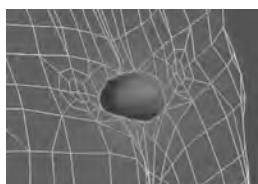
Bleeding

Warning – Some Patients May Have A Risk Of Bleeding

If you have recently had heart surgery, or surgery on blood vessels, or are on blood thinners, you may have a higher risk of bleeding, whether you are using ActiV.A.C.® Therapy or not.

If you see a sudden increase or a large amount of blood from your wound in the tubing or canister:

- **Turn OFF the therapy unit right away.**
- **Apply pressure over the area.**
- **Do not remove your dressing.**
- **Call 9-1-1 (or local emergency number) and then notify your doctor or nurse.**



Wound Infections

Wound Infection

If you have an infected wound, your doctor or nurse will decide the right treatment for you. Your dressing should be changed more frequently.

Call your doctor or nurse right away if you think your wound is infected or if the following symptoms worsen or develop:

- You have a fever
- Your wound is sore, red or swollen
- Your skin itches or you have a rash or redness around the wound
- The area in or around the wound feels very warm
- You have pus or a bad smell coming from the wound



Serious Infections

V.A.C.®
DisposablesActiV.A.C.®
Therapy UnitV.A.C.® Simplace™
Dressing

Serious Infection

Sometimes a wound infection can spread throughout the rest of the body. Call your doctor or nurse right away if you have any of the following symptoms:

- You are sick to your stomach or throwing up
- You are dizzy or feel faint when you stand up
- You have diarrhea
- Your throat is sore
- You feel confused
- You have a headache
- You have a rash
- You have a fever over 102°F

Allergic Reactions

V.A.C.® Dressings, V.A.C.® Drape and V.A.C.® Canisters are latex-free and delivered sterile. Use dressings only from unopened packages, use only once and then throw them away. The V.A.C.® Drape (dressing cover) has a coating that may cause an allergic reaction if you are allergic or sensitive to some glues. Call your doctor or nurse right away if you have any of the following signs:

- Redness
- Swelling
- Rash or hives
- Severe itching

If you have difficulty breathing, seek immediate Emergency Medical Assistance, call 9-1-1 (or local emergency number).

Keep Therapy On For 22 Hours in 24 (Off No More Than Two Hours)

Never leave a V.A.C.® Dressing in place without active ActiV.A.C.® Therapy for more than two hours. If therapy is off for more than two hours, contact your nurse or caregiver to have the old dressing removed and the wound irrigated.

A new V.A.C.® Dressing from an unopened sterile package should be applied and ActiV.A.C.® Therapy started again, or an alternative dressing should be applied at the direction of the treating nurse or doctor. Call your nurse or caregiver to have this done.

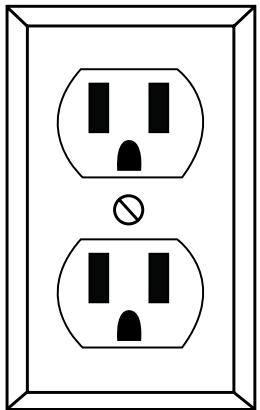
Count Foam Dressing Pieces

Your doctor, nurse, or trained caregiver should count the number of foam pieces put into your wound, and document the foam quantity and dressing change date on the drape or Foam Quantity Label if available, and in your chart. Make sure that the same number of foam pieces are removed during your dressing change.

Cover Your Cough

Cover your mouth and nose with a tissue when you cough or sneeze, or cough or sneeze into your upper sleeve, not into your hands. Put your used tissue in the waste basket.

Clean your hands after coughing or sneezing. Wash hands with soap and warm water for 20 seconds, or clean with alcohol-based cleaner.



Electrical Requirements

A three-pronged electrical outlet is recommended for use with this product. If you do not have a three-pronged outlet, use a three-pronged adapter. For safe use of the adapter, secure the ground wire to the center screw of the outlet cover plate.

- Extension cords are not recommended for use with this product.
- Do not overload your electrical outlets.
- Keep electrical cords out of traffic areas.
- Do not spill liquids on the ActiV.A.C.® Therapy Unit; it must remain dry.

Fall Prevention Tips

The following safety tips should be used to help prevent a patient falling or slipping while using the ActiV.A.C.® Therapy Unit:

- Know your surroundings and avoid possible tripping hazards, such as throw rugs, extension cords, and uneven floors.
- Position the ActiV.A.C.® Therapy Unit electrical cord so that it is not a tripping hazard. When not using the electrical cord (therapy is off or in battery mode) make sure the electrical cord is unplugged and put away.
- Safely store excess electrical cord and any extra tubing and secure it to prevent tripping (See the therapy unit user manual on how to properly secure tubing).
- Be cautious of door knobs and other household objects that could catch on exposed tubing.
- Be careful when getting into and out of bed. When practical, have a caregiver or a capable family member present to provide assistance.
- For hospital bed use: if there is a hospital bed in your home, consult the bed manufacturer's instructions for use and your doctor or nurse about keeping the bed in the lowest practical position. Also, if your doctor has ordered the use of hospital bed rails in your home, it is recommended that you have them fully raised when a nurse or family caregiver is not present.

For operating instructions and safety information, please refer to the:

- ActiV.A.C.® Therapy System Quick Reference document (located in this guide)
- ActiV.A.C.® Therapy System User Manual (located at the back of this guide)
- V.A.C.® Therapy Safety Information Sheet (located in the carrying case pocket; see illustration on page 64)

If you have a concern regarding safety or the quality of services you are receiving from KCI, you may file a complaint by calling 1-800-275-4524. If you believe that your concern was not adequately addressed you can contact KCI's accreditation organization, The Joint Commission at 1-800-994-6610.



Patient Financial Responsibility



Assignment of Benefits (AOB)

The following is a copy of the Assignment of Benefits (AOB) you received with your V.A.C.® Therapy Unit. This form allows KCI to work directly with your insurance company, eliminating any inconveniences. Without a signed AOB, KCI cannot bill your insurance company, which may result in direct patient billing.

I give KCI USA, Inc. ("KCI") the right to bill for and receive insurance payments for my medical care and I direct my insurance company, Medicare, Medicaid, and any other entity paying for my medical care ("my insurer") to pay KCI directly for the equipment and supplies provided to me.

1. I understand that ownership of the equipment shall at all times remain the property of KCI USA, Inc, unless I qualify for and agree to purchase the equipment. KCI shall have the right to inspect the equipment wherever the same may be and that I may be responsible for the replacement value of the KCI rental product in the event it is lost, damaged, or stolen while in my possession or control.
2. I understand that my insurer may need information about my medical condition to make a decision about making payments to KCI. This information may be maintained by my physician, home healthcare agency, medical facility, employer, or other entities. I authorize any holder of medical information about conditions for which I am being treated to release that information to KCI and insurer.
3. I understand that I am responsible for reading, signing, and returning the Assignment of Benefits form to KCI USA, Inc.; if not returned, I assume full responsibility of all financial charges associated to my therapy treatment provided by KCI USA, Inc.
4. I understand that KCI, my insurer, healthcare provider and other entities involved in my medical care may need certain individually identifiable financial or health information to assist in my care. I agree that such information may be used and disclosed by KCI, my insurer, healthcare providers, and other entities for purposes of treatment, payment, healthcare operations or as otherwise permitted by law. I understand that additional information on types of uses and disclosures that may be made are contained in KCI's Notice of Privacy Practices. I understand that I may revoke my consent at any time if I do so in writing, except to the extent such consent has already been relied upon.
5. For Medicare/Medicaid Beneficiaries: I understand that I am responsible for any and all deductibles or co-payments established by Medicare or Medicaid. This information has been explained to me.

6. For all other insurance coverage: I understand that I am responsible for all deductibles, co-payments, or other amounts established by my insurance company, as well as all charges for non-covered services provided to me by KCI. This information has been explained to me.
7. I have received a copy of the Patient Information Guide (which includes KCI's Notice of Privacy Practices, Supplier Standards [for Medicare] and product information and instructions).
8. I understand the care and utilization of this product and know that I can contact KCI USA, Inc. at 1-800-275-4524 for additional information.
9. In the event that my insurer pays me directly, I agree to forward all payments to KCI USA, Inc., P.O. Box 203084, Houston, TX, 77216-3084.
10. I understand: (i) KCI has the option to provide new or used equipment; (ii) that I shall not modify or alter the equipment; (iii) that I will notify KCI immediately of any equipment problems; (iv) that the equipment is only to be used upon the order and direction of my doctor; (v) that the equipment is only to be used with KCI authorized disposables (i.e., dressings).
11. I understand that the equipment rental charges will continue until the date I call KCI USA, Inc. at 1-800-275-4524 to pick up the rental product.

Additional Terms Governing Use, Return, and Payment:

- i. In the event of patient's default in payment, or the default of patient's insurer, health benefit plan or other third party payor, KCI shall be entitled to recover the equipment and shall not be liable to the patient or to the patient's representatives or heirs for any injury or damage resulting from the discontinuation of treatment with the equipment.
- ii. KCI shall be entitled to all expenses, court costs, and reasonable attorney fees for the collection of any patient responsibility amounts that are past due and to enforcement of this AOB. All past amounts shall bear interest at the lesser of 1.5% per month or at the highest rate permitted by law.
- iii. This AOB and any dispute arising out of the goods and services provided shall be governed and construed according to the laws of the State of Texas without regard to its conflict of laws provision, and venue shall lie exclusively with a court of proper jurisdiction in Texas. Any dispute arising out of this Agreement shall be resolved by binding arbitration in accordance with the rules of the Judicial Arbitration and Mediation Services (JAMS).

Patient's Bill of Rights and Responsibilities

The Patients' Bill of Rights and Responsibilities has three goals:

3. to strengthen consumer confidence that the healthcare system is fair and responsive to consumer needs;
4. to reaffirm the importance of a strong relationship between patients and their healthcare providers; and
5. to reaffirm the critical role consumers play in safeguarding their own health.

Your Rights

As a patient you have certain rights including but not limited to the following:

- **Information.** Patients have the right to receive accurate, easily understood information to assist them in making informed choices.
- **Choice.** Patients have the right to a choice of health care providers.
- **Access to Emergency Services.** Patients have the right to access emergency health services when and where the need arises.
- **Being a Full Partner in Health Care Decisions.** Patients have the right to fully participate in all decisions related to their health care.
- **Care Without Discrimination.** Patients have the right to considerate, respectful care from all members of the healthcare industry at all times and under all circumstances.
- **Privacy.** Patients have the right to communicate with healthcare providers in confidence and to have the confidentiality of their individually identifiable health care information protected.
- **Speedy Complaint Resolution.** Patients have the right to a fair and efficient process for resolving differences.

Your Responsibilities

As a patient you have certain responsibilities including, but not limited to the following:

- **Provide information** - give accurate and complete health information concerning your past illnesses, hospital stays, medications, allergies and other pertinent items. You are also responsible for providing documentation required by your insurance company.
- **Ask questions** - when you do not understand medical conditions, equipment instructions, and/or medical terminology.
- **Follow instructions** - adhere to your developed/updated treatment plans.
- **Accept consequences** - for not following the treatment plan instructions of your doctor and nurse.

- **Understand your benefits** - for what your insurance company will or will not authorize for durable medical equipment (DME) benefits.
- **Product responsibilities** - your doctor has prescribed this medical device for the treatment and care of your wound. This is a rental device and cannot be resold. Prompt return of this device is required once therapy is completed.
- **Show respect and consideration** - to those who are assisting you in your treatment plan.
- **Meet financial commitments** - you are responsible for any applicable co-insurance, co-payments, or private pay amounts not covered by your insurance provider.
- **Take on new responsibilities** - In a healthcare system that affords patients rights and protections, patients must also take greater responsibility for maintaining good health.

Notice of Privacy Practices

THIS NOTICE DESCRIBES HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

If you have any questions about this notice, please contact KCI Healthcare Compliance Office at 1-800-275-4524 (Ext. 54477)

Purpose Of This Notice

This notice will tell you about the ways in which KCI may use and disclose your health information that identifies you ("PHI"). We also describe your rights and certain obligations we have regarding the use and disclosure of PHI.

Our Pledge Regarding Protected Health Information:

We understand that health information about you and your health is personal. We are committed to protecting health information about you. We create a record of the products and services that we provide to you. We need this record to provide you with quality products and services used in your care and to comply with certain legal requirements. This notice applies to all of the PHI we use and disclose related to the products and services used in your care. Your personal doctor, healthcare provider and other entities providing products or services to you may have different policies or notices regarding their use and disclosure of your PHI.

Our Legal Requirements

We are required by law to:

- make sure that health information that identifies you is kept private;
- give you this notice of our legal duties and privacy practices with respect to PHI about you;

- notify you if we are unable to agree to a requested restriction on how your information is used or disclosed;
- accommodate reasonable requests that you may make to communicate PHI by alternative means or at alternative locations;
- obtain your written authorization to use or disclose your PHI for purposes other than those listed below and permitted under law; and
- follow the terms of the notice that currently is in effect.

Who Will Follow Our Privacy Practices

This notice describes KCI's practices and that of all KCI employees, staff and other company personnel for U.S. operations, and KCI USA, Inc.

All these entities, sites and locations follow the terms of this notice. In addition, these entities, sites and locations may share PHI with each other for treatment, payment or health care operations purposes described in this notice.

Your Rights Regarding Protected Health Information About You.

You have the following rights regarding PHI we maintain about you:

Right to Inspect and Copy. You have the right to inspect and copy PHI that may be used to make decisions about your care. Usually, this includes medical and billing records. To inspect and copy PHI that may be used to make decisions about you, you must submit a request in writing to the KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. If you request a copy of the information, we will charge a fee for the costs of copying, mailing or other supplies associated with your request. We may deny your request to inspect and copy in certain circumstances. If you are denied access to PHI, you may request that the denial be reviewed. Another person chosen by us will review your request and the denial. We will comply with the outcome of that review.

Right to Amend. If you feel that PHI we have about you is incorrect or incomplete, you may ask us to amend the information. You have the right to request an amendment for as long as the information is kept by or for us. To request an amendment, a request must be made in writing to the KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. In addition, you must provide a reason that supports your request. We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- Was not created by us, unless the person or entity that created the information is no longer available to make the amendment;
- Is not part of the PHI kept by or for us;
- Is not part of the information which you would be permitted to inspect and copy; or
- Is accurate and complete.

Right to an Accounting of Disclosures. You have the right to request an “accounting of disclosures.” This accounting is a list of the disclosures we made of PHI about you. KCI will provide an accounting of all but the following disclosures:

- Those made for treatment, payment and health care operations;
- Those made to you about your own PHI;
- Those made to persons involved in your care or other notification purposes;
- Those made pursuant to an authorization signed by you disclosing specific uses and disclosures;
- Where the disclosures are part of a Limited Data Set;
- Where the disclosures are incidental to an otherwise permissible disclosure;
- For national security or intelligence purposes; and
- To correctional institutions or law enforcement custodial situations.

To request this list or accounting of disclosures, you must submit a request in writing to the KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. Your request must state a time period that may not be longer than six years from the date of service and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (i.e., paper or electronic). The first list you request within a 12-month period will be free. For additional lists, we will charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

Right to Request Restrictions. You have the right to request a restriction or limitation on the PHI we use or disclose about you for treatment, payment or health care operations. You also have the right to request a limit on the PHI we disclose about you to someone who is involved in your care or the payment for your care, like a family member or friend. We are not required to agree to your request. If we do agree, we will comply with your request unless the information is needed to provide you emergency treatment. To request restrictions, you must make a request in writing to the KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. In your request, you must tell us (i) what information you want to limit; (ii) whether you want to limit our use, disclosure or both; and (iii) to whom you want the limits to apply, for example, disclosures to your spouse.

Right to Request Confidential Communications. You have the right to request that we communicate with you about medical matters in a certain way or at a certain location. For example, you can ask that we only contact you at work or by mail. To request confidential communications, you must make your request in writing to the KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. We will not ask you the reason for your request. We will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

Right to Revoke Authorization. You have the right, in those instances where written authorization is required, to revoke such authorization to use or disclose PHI except to the extent action has already been taken. Such revocation must be in writing.

Right to a Paper Copy of This Notice. You have the right to a paper copy of this notice. You may ask us to give you a copy of this notice at any time. Even if you have agreed to receive this notice electronically, you are still entitled to a paper copy of this notice. You may obtain an additional copy of this notice at our website, www.kci1.com. To obtain a paper copy of this notice, you must contact the KCI Healthcare Compliance Office at 1-800-275-4524 (Ext. 54477).

How We May Use And Disclose Protected Health Information About You
The following categories describe different ways that we are permitted to use and disclose PHI as a health care provider. Certain of these categories may not apply to our business and we may not actually use or disclose your PHI for such purposes. Not every use or disclosure in a category will be listed. However, all of the ways we are permitted or required to use and disclose PHI, without your authorization, will fall within one of the categories.

For Treatment. We may use or disclose PHI about you to assist healthcare professionals and providers provide you with medical treatment or services. For example, we may provide PHI related to your use of our products or services to your home health agency or clinic for purposes of documenting your wound progress or we may provide PHI to a discharge planner in the hospital you were treated at to help them arrange for continued care in your home or another facility to which you are being discharged.

For Payment. We may use and disclose PHI about you so that the products and services we provide you may be billed to and payment may be collected from you, an insurance company or a third party. For example, we may need to receive from or disclose to your health plan, Medicare or the medical facility you resided in information about the products and services we provided to you so they or another responsible payor can pay us and so they can seek payment or reimbursement for the products and services provided to you or another payor. This may specifically include information required for the Initial Statement of Ordering Physician, Assignment of Benefits, wound progress notes, and discharge information. We may also tell your health care provider or plan about a product or service you are going to receive to obtain prior approval or to determine whether your provider or plan will cover that product or service.

For Health Care Operations. We may use and disclose PHI about you for our health care operations and we may use and disclose PHI about you to other health care providers involved in your care for certain health care operations they have to undertake. These uses and disclosures are necessary to run our company and make sure that users of our products receive the most cost effective and therapeutic products possible. Examples of health care operations activities by KCI include but are not limited to delivery, pick-up and service functions, collection efforts, internal auditing, business planning (including analysis of

product length of stay, utility, or development/ improvement of reimbursement methods or policy), assessing the quality of care and outcomes in your case and similar cases, and quality assurance/improvement activities. We may also combine PHI about many patients to decide what additional products and services we should offer, what products and services are not needed, and to justify how effective our products are in the care of individuals such as you. We may also disclose information to medical facilities and independent researchers for review and learning purposes. We may remove information that identifies you from this set of PHI so others may use it to study health care and health care delivery without learning who the specific patients are.

Notices/Reminders. We may use and disclose PHI to contact you or arrange for your health care provider to contact you regarding product delivery, maintenance, in-service or pick-up.

Product Alternatives. We may use and disclose PHI to tell you or your health care provider about possible product alternatives that may be of interest to you.

Individuals Involved in Your Care or Payment for Your Care. We may disclose to a family member, other relative, close personal friend of yours or any other person identified by you PHI directly relevant to such person's involvement with your care or payment for your health care when you are present for, or otherwise available prior to, a disclosure and you are able to make health care decisions, if: (i) we obtain your agreement; (ii) we provide you with the opportunity to object to the disclosure and you fail to do so; or (iii) we infer from the circumstances, based upon professional judgment, that you do not object to the disclosure. We may obtain your oral agreement or disagreement to a disclosure. However, if you are not present, or the opportunity to agree or object to the disclosure cannot practicably be provided because of your incapacity or an emergency circumstance, we may, in the exercise of professional judgment, determine whether the disclosure is in your best interests, and, if so, disclose only PHI that is directly relevant to the person's involvement with your health care.

Research. Under certain circumstances, we may use and disclose PHI about you for research purposes. For example, a research project may involve comparing the health and recovery of all patients who received one product or service to those who received another, for the same condition. Also, a research project may involve the gathering of treatment data for certain patients and conditions in order to support the clinical efficacy or new product indications for products that we provide. Most research projects, however, are subject to a special approval process. This process evaluates a proposed research project and its use of PHI, trying to balance the research needs with patients' need for privacy of their PHI. We may, however, disclose PHI about you to people preparing to conduct a research project, for example, to help them look for patients with specific medical needs, so long as the PHI they review does not leave our premises. We will in most circumstances ask for your specific authorization if the researcher will have access to your name, address or other direct identifying information that reveals who you are.

As Required By Law. We will disclose PHI about you when required to do so by federal, state or local law. For example, we may disclose information for judicial and administrative proceedings pursuant to legal authority; to report information related to victims of abuse, neglect or domestic violence; or to assist law enforcement officials in their law enforcement duties.

Government Functions. We may use and disclose PHI about you as required for specialized government functions such as protection of public officials, reporting to various branches of the armed services or national security activities authorized by law.

To Avert a Serious Threat to Health or Safety. We may use and disclose PHI about you when necessary to prevent a serious threat to your health and safety or the health and safety of the public or another person. Any disclosure, however, would only be to someone able to help prevent the threat.

Business Transfers. There may arise in the course of business the acquisition or sale of our business assets (Business Transfers). Such Business Transfers may involve the sale or purchase of PHI. Also, in the event that Kinetic Concepts, Inc. or one of the other entities listed on page one of this notice are acquired or substantially all of its assets are acquired, PHI likely will be one of the transferred assets.

Workers' Compensation. We may release PHI about you for workers' compensation or similar programs. These programs provide benefits for work-related injuries or illness.

Public Health Activities. We may use or disclose your PHI for public health activities such as assisting public health authorities or other legal authorities to prevent or control disease, injury or disability. This may also include reporting required by the Food and Drug Administration or other agencies whose jurisdiction we and our products are subject to.

Health Oversight Activities. We may disclose PHI to a health oversight agency for activities authorized by law. These oversight activities include, for example, audits, investigations, inspections, and licensure. These activities are necessary for the government to monitor the health care system, government programs, and compliance with civil rights laws.

Lawsuits and Disputes. If you are involved in a lawsuit or a dispute, we may disclose PHI about you in response to a court or administrative order. We may also disclose PHI about you in response to a subpoena, discovery request, or other lawful process by someone else involved in the dispute, but only if efforts have been made to tell you about the request and obtain your written authorization or to obtain an order protecting the information requested.

Coroners, Medical Examiners and Funeral Directors. We may release PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death.

Organ / Tissue Donation. We may use or disclose your PHI for cadaveric organ, eye or tissue donation purposes.

Other Uses Of Protected Health Information

Other uses and disclosures of PHI not covered by this notice or otherwise permitted by the laws that apply to us will be made only with your written authorization. Your authorization will not be required if KCI uses or discloses health information, for purposes other than as covered by this notice or permitted by law if KCI removes any information that individually identifies you before disclosing the remaining information. If you provide us authorization to use or disclose PHI about you, you may revoke that permission, in writing, at any time. If you revoke your permission, we will no longer use or disclose PHI about you for the reasons covered by your written authorization. You understand that we are unable to take back any disclosures we have already made with your permission, and that we are required to retain our records of the products and services that we provided to you.

Changes To This Notice

We reserve the right to change our information practices and to make the new provisions effective for all PHI we maintain. We also reserve the right to change this notice at anytime. We reserve the right to make the revised or changed notice effective for PHI we already have about you as well as any information we receive in the future. We will post a copy of the current notice on our website at www.kci1.com. The notice will contain on the first page, in the top right-hand corner, the effective date.

Complaints

If you believe your privacy rights have been violated, you may file a complaint with us or with the Secretary of the Department of Health and Human Services. To file a complaint with us, you must submit it in writing to the following individual: Privacy Officer, KCI Healthcare Compliance Office, 8023 Vantage Drive, San Antonio, Texas, 78230. You will not be penalized for filing a complaint.



Note: This is an abbreviated version of the supplier standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, are listed in 42 C.F.R. 424.57(c).

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.

11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date - October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.

25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date- May 4, 2009
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

Contact Us: Call 1-800-275-4524

We offer 24-hour, 7-day-a-week customer service. Please contact KCI at 1-800-275-4524.

Who is KCI

Mission Statement: We are a dedicated team committed to achieving leadership in wound, pulmonary, bariatric and vascular patient care across healthcare settings throughout the United States and in select international markets.

We provide, measure and support clinically proven therapies which improve patient outcomes at a lower cost of care.

We deliver therapies and services through the rental and sale of specialty surfaces, devices and programs which exceed customer expectations, define industry standards and maximize shareholder value.

We apply integrity, honesty and high ethical standards in everything we do.

We are the Clinical Advantage!

Florida and Tennessee - State-Specific Addendum Sheet

There are specific state requirements for patient information for Home Medical Providers and Home Medical Equipment in Florida and Tennessee. All information outlined below has been supplied via other documents or within this manual. These specific requirements or information are listed by state below:

Florida Home Medical Equipment Provider Standards and Guidelines

http://www.fdhc.state.fl.us/Inside_AHCA/index.shtml

Toll free phone number for Florida's Central Abuse Registry

- As your provider, KCI must inform you or your immediate family of the right to report abusive, neglectful, or exploitative practices.
- To report abuse, neglect, or exploitation, please call toll free 1-800-962-2873 or you may call AHCA at 1-888-419-3456.

Emergency Services:

- KCI can be contacted and services can be made available 24 hours per day, 7 days per week via KCI's Advantage Center at 1-800-275-4524.
- KCI's servicing locations maintain an on-call professional to supply services in emergency situations.

Tennessee Standards for Home Care Organizations providing HME

www.state.tn.us/sos/rules/1200/1200-08/1200-08-29.pdf

Basic Functions

- KCI will supply written guidelines relating to patient and/or caregiver training and education that include at a minimum:
 - Financial responsibilities
 - Equipment use and maintenance
 - Patient rights and responsibilities
 - Troubleshooting procedures
 - How to contact the agency during regular business and after-hours

Maryland – State Specific Addendum Sheet

As described in this guide, KCI offers a fair and efficient process for resolving differences without fear of retribution or disruption in services. Patients may submit complaints directly to the State of Maryland at the below address and phone number:

Barbara Fagan, Program Manager
Office of Health Care Quality
Spring Grove Center
55 Wade Avenue
Catonsville, Maryland 21228
1-800-492-6005

Rented Product Delivery and Return

Delivery of Equipment

The ActiV.A.C.® Therapy Unit is rented by you for the duration of your therapy and will be returned to KCI.

STEP 1: LOOK - at the delivery receipt and make sure the equipment or supplies listed on the delivery receipt match the contents in the delivery box. Call KCI immediately at 1-800-275-4524 if anything is incorrect.

- Damaged Equipment/Supplies - Notify KCI at 1-800-275-4524 of any damaged equipment or supplies and arrangements will be made for a service call.

STEP 2: SIGN - the delivery receipt and Assignment of Benefits (AOB) letter.

Inside the delivery box is the Assignment of Benefits (AOB) letter. It is your responsibility to sign and return the letter to KCI. A copy of the AOB is located at the front of this guide.

STEP 3: KEEP - the cardboard delivery box, plastic shipping container and the foam packing inserts. The ActiV.A.C.® Therapy System is delivered to you in a hard plastic shipping container located inside a cardboard box. Keep these materials and use them to ship the ActiV.A.C.® Therapy Unit back to KCI when therapy is discontinued.

Return of Rental Product

When you and your medical provider have decided ActiV.A.C.® Therapy is no longer required, please call KCI at 1-800-275-4524 within 24 hours to start the product return process.



NOTE: Returning your rental product is critical. The return of your rental product will prompt KCI's systems to flag your therapy as complete and stop billing charges to your account.

You will be provided with two convenient UPS options for return:

1. UPS standard pick-up. A KCI representative will work with you to set up the most convenient time for UPS to pick up your rental product as well as provide directions in the boxing and labeling for return.
2. Drop-off at UPS Store. A KCI representative will assist you in identifying one of the more than 4,000 UPS Store locations. (The chances are there is one near you.) Additionally, they will provide directions in the boxing and labeling of your rental product for return

Please be prepared to tell the KCI representative the following information:

- Your name and phone number
- The date ActiV.A.C.® Therapy ended
- The need to arrange pick-up of the ActiV.A.C.® Therapy Unit.



Quick Reference



Important Safety Information accompanies this device.

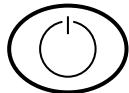
Review with your doctor or nurse prior to use.

Indications, Contraindications, Warnings, Precautions and other important Safety Information are contained in the V.A.C.® Therapy Safety Information Sheet which should always be kept in the pocket inside the front flap of the carrying case. If there are questions or if this information is missing, immediately contact KCI at 1-800-275-4524.

Patient Feature Identification



Power Therapy Unit On or Off



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

Therapy On or Off



Start or stop V.A.C.® Therapy.



A lighted green crescent means the function is on.

Audio Pause

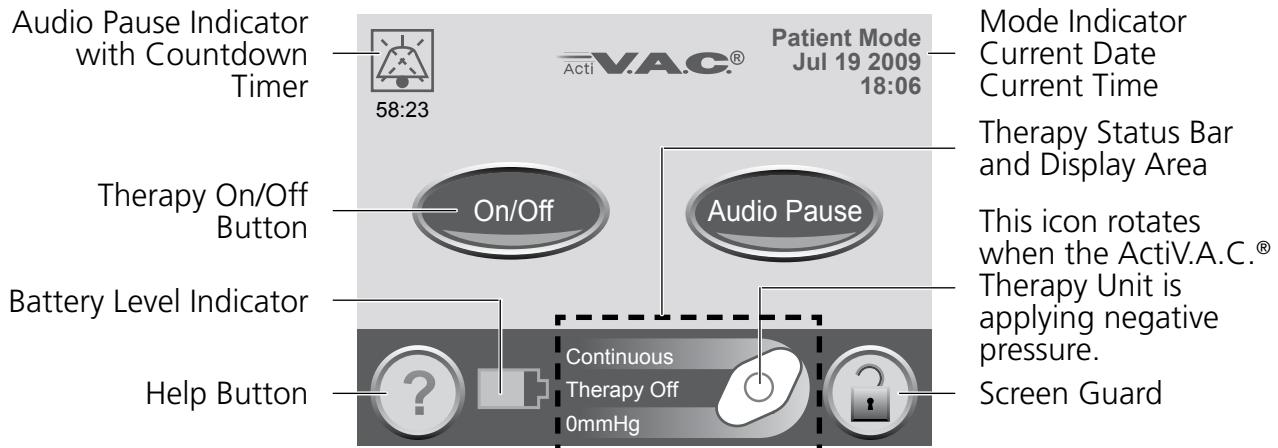


Press Audio Pause to silence (for 60 minutes) alerts that do not need immediate attention.



Alarms needing immediate attention override the Audio Pause feature.

Patient Mode Home Screen



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.



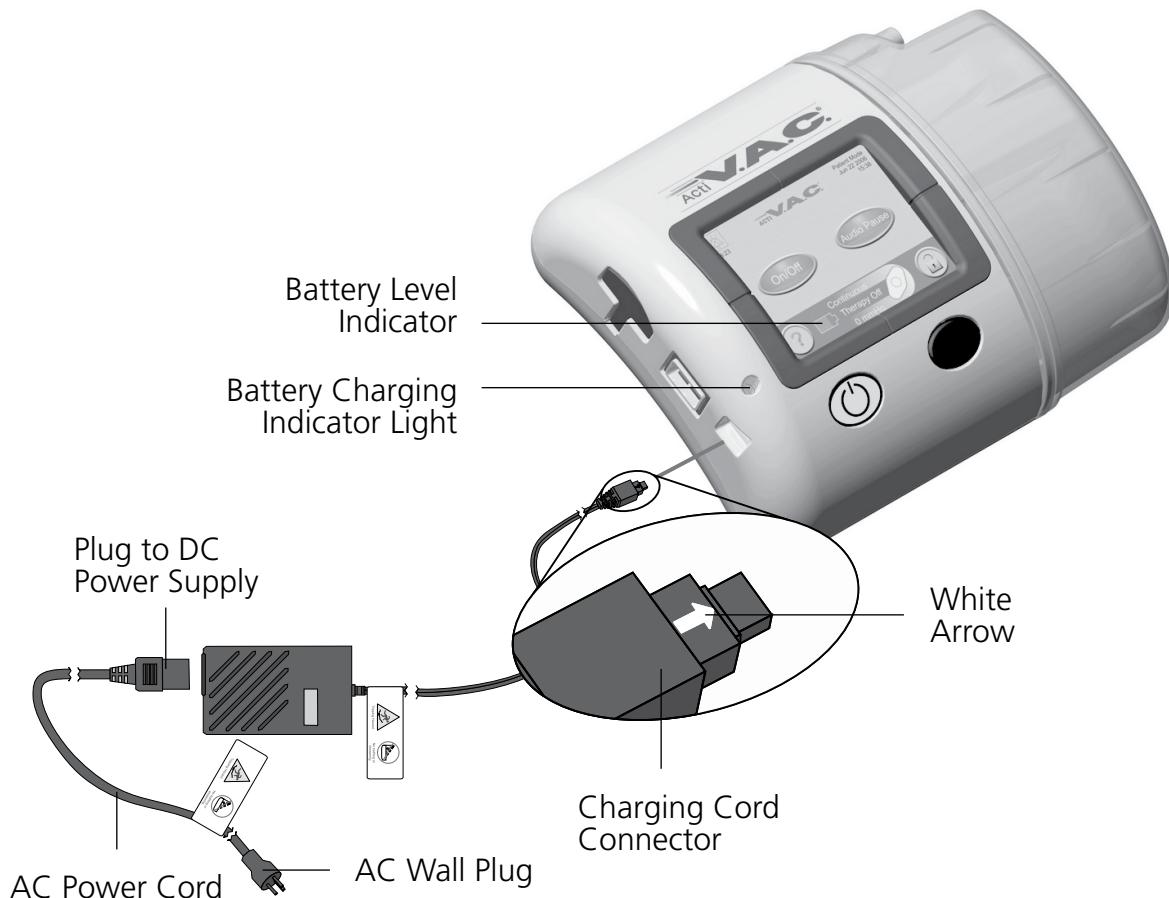
Keep the ActiV.A.C.® Therapy Unit in the upright position. The touch screen should be in a readable, right-side-up orientation or facing up when the therapy unit is laid on a level surface.

Battery Charging Instructions



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.

When the unit is correctly plugged into the power supply, the Battery Charging Indicator Light 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.



Fully Charged



In Use



Battery Low. Charge battery soon.



Battery Critical. **Charge battery immediately.**



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

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 without a canister in place.**



Additional dressings and canisters may be ordered by calling KCI at 1-800-275-4524. Please allow at least 3-5 business days for delivery.

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



1. Stop therapy by pressing the Therapy On/Off button on the touch screen. **Do not turn power off to the ActiV.A.C.® Therapy Unit.**



Fig. 1



Fig. 2a



Fig. 2b



Fig. 3



Fig. 4



Fig. 5a



Fig. 5b



Fig. 6

2. Slide both tubing clamps toward the tubing connector.

3. Close both clamps tightly. Several clicks should be heard. (Fig. 1).

4. Compress and then twist to separate tubing connectors (Fig. 2a and 2b).

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

6. Remove the canister from the therapy unit (Fig. 4).



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

7. Install the new canister onto the therapy unit. An audible click should be heard when the canister is properly installed.

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.

9. Compress and then twist to reconnect tubing connectors (Fig. 5a and 5b).

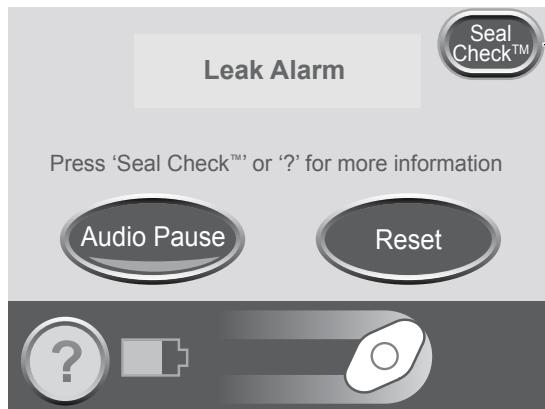
10. Open both tubing clamps (Fig. 6).

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



Seal Check™ Leak Detector

When the ActiV.A.C.® Therapy Unit detects a significant leak, the Leak Alarm will activate. See *Alerts and Alarms* section of the user manual for more details on this alarm.

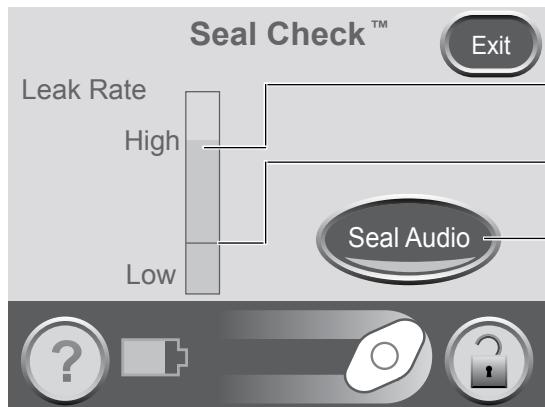


— Flashing Green Oval



Press the Seal Check™ button 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.

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





Detecting and Resolving Common ActiV.A.C.[®] Therapy Alerts and Alarms

The ActiV.A.C.[®] Therapy System has been designed to deliver the proven benefits of ActiV.A.C.[®] Therapy in an easy-to-use system that fits patients' active lifestyles. Understanding its functions and being able to identify and resolve potential problems is essential to providing effective therapy.

The following table is meant to be used in conjunction with the Alerts and Alarms section of the ActiV.A.C.[®] Therapy System User Manual. If necessary, contact your doctor or nurse or KCI for assistance or further information. Customers needing technical assistance, please call KCI at 1-800-275-4524 to troubleshoot in real-time over the phone 24 hours a day.



Please keep the small white tubing cap, which is attached to the end of the canister tubing, as it will assist in troubleshooting the unit.

Alerts

Alerts will be displayed on the touch screen when the ActiV.A.C.[®] Therapy Unit detects a condition that requires patient or caregiver attention. A single audible tone will sound.

System Alert	Alert Condition	Action/Resolution	User Tips
Battery Low Alert	About two hours of battery power remain.	Recharge the battery.	To maximize battery life, keep the unit plugged in whenever possible.
Blockage Alert	Unit has determined that a potential blockage is present.	Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.	If alert condition cannot be resolved, contact your caregiver or KCI representative.
Low Pressure Alert	Selected therapy set pressure has not been reached.	Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.	If alert condition is not resolved, ActiV.A.C. [®] Therapy is still being applied, but at a lower than selected pressure.
Service Timer Expired Alert	Unit has reached its service time limit.	Contact KCI for instructions.	Once the Service Timer has expired, this alert will appear every time the unit is powered up and periodically during therapy.

Alarms

Alarms will be displayed on the touch screen when the ActiV.A.C.® Therapy Unit detects a condition that **requires immediate patient or caregiver attention**. Repeating audible tones will sound.

System Alert	Alert Condition	Action/Resolution	User Tips
Battery Critical Alarm	About 30 minutes of battery power remain.	Immediately recharge the battery. Ensure power cord is securely connected to therapy unit.	Charge ActiV.A.C.® Therapy Unit at least twice a day. Address dressing leak alarms as quickly as possible to avoid a drain on the unit's battery.
Blockage Alarm Therapy Interrupted WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.	Unit has determined that blockage is present.	Check tubing for closed clamps, kinks, crimps or blockages. Inspect to ensure a quarter-sized (2.5cm) hole has been cut in the drape. Inspect to ensure dressing and drape have not shifted and blocked SensaT.R.A.C.™ Pad outer lumens.	Ensure a 2.5cm hole has been cut in the drape. A smaller hole, an "x" or a slit may cause blockage, pressure fluctuations and other functionality issues. Ensure pad is located in a flat area of the body, avoiding a skin fold. Avoid the additional use and application of adhesive tape on or over SensaT.R.A.C.™ Pad.
Canister Full Alarm WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.	Unit has detected the canister is full and should be replaced despite minimal amounts of fluid in canister.	Change canister and restart therapy.	Unit should be worn or hung so that touchscreen is visible in window. Avoid placing therapy unit upside down (with touchscreen facing down) for prolonged periods of time.

System Alert	Alert Condition	Action/Resolution	User Tips
Canister Not Engaged Alarm	<p>WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.</p>	The canister is not fully seated and not properly latched.	Ensure canister is properly installed. If the canister is properly installed, an audible click should be heard, and it cannot be removed by gently pulling it directly away from the unit.
Leak Alarm	Unit has detected a significant negative pressure leak which has not been resolved. If this alarm is not resolved within 3 minutes, therapy will stop.	Use leak detection procedures and the Seal Check™ leak detector to help find and repair leak.	For larger, highly exuding wounds, adjust intensity level to highest level to ensure a faster draw down. Default setting is low intensity.
Leak Alarm Therapy Interrupted	<p>WARNING: According to clinician instructions, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted or off for more than two hours.</p>	A leak has been detected and not resolved, and therapy has been interrupted.	Press Reset and restart therapy. If alarm condition cannot be resolved, contact your caregiver or KCI representative.
Low Pressure Alarm Therapy Interrupted	Unit indicates negative pressure at wound may be below set pressure, potentially compromising therapeutic benefits.	Check tubing for closed clamps, kinks, crimps and blockages. Ensure dressing and drape have not shifted and blocked SensaT.R.A.C.™ Pad outer lumens. Lower therapy unit and tubing to or below wound level.	Ensure a quarter-sized (2.5cm) hole has been cut in the dressing where the SensaT.R.A.C.™ Pad is placed. A smaller hole, an "x" or a slit may cause blockage, pressure fluctuations and other functionality issues.
System Error Alarm	A technical fault has occurred.	Turn unit off and then back on.	If the fault persists, contact KCI.

System Alert	Alert Condition	Action/Resolution	User Tips
Therapy Inactive Alarm 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 has been off for 15 minutes (with the unit powered on) and without using the touch screen.	Restart therapy.	If therapy is not desired, turn the Activ.A.C.® Therapy Unit off using the Power On/Off button on the front of the unit.

Other alarms and features exist. Always read and follow (if patient, discuss with your doctor or nurse) detailed Instructions for Use along with important safety information provided with the Activ.A.C.® Unit and disposables.

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.



User Manual

For Patients and Clinicians



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

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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.

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.

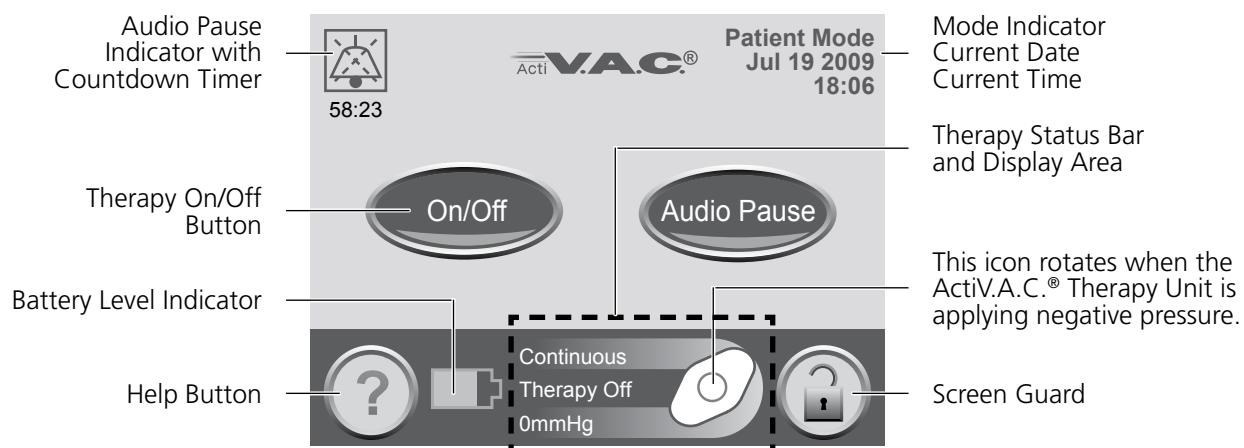
Important product and therapy indications, contraindications, precautions and safety information apply. Please consult your healthcare provider, the accompanying V.A.C.® Therapy System Safety Information Sheet, Quick Reference Guide (located in the pocket on the inside of the front flap of the carrying 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.
58:23



Alarms needing immediate attention override the Audio Pause feature. See the *Alerts and Alarms* chapter of this manual (page 70) 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.



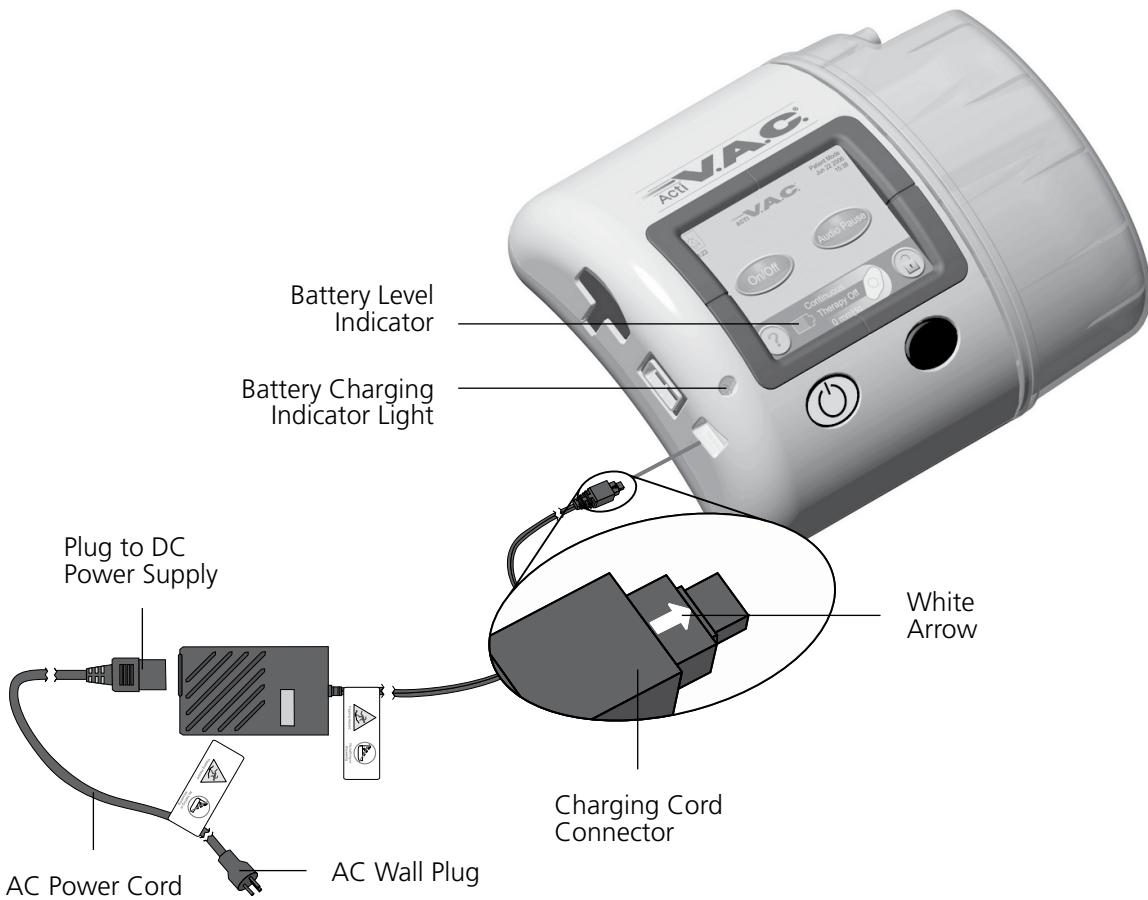
Use only the power supply provided with the ActiV.A.C.[®] Therapy Unit. Using any other power supply may damage the therapy unit.

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 60) 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 58).



Fully Charged



In Use

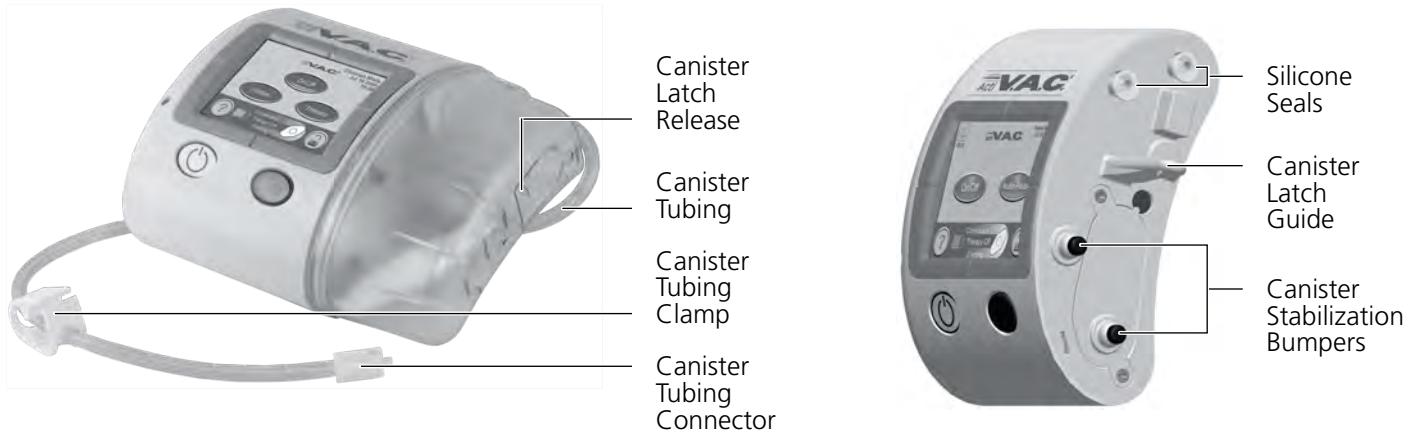


Battery Low. Charge battery soon.



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 without 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



Fig. 2a



Fig. 2b



Fig. 3



Fig. 4



Fig. 5a



Fig. 5b



Fig. 6



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).
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).
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).
- i** **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.
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.
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).
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.



Fig. 1



Fig. 2a



Fig. 2b

1. Stop therapy by pressing the Therapy On/Off button on the touch screen.
2. Turn power off to the ActiV.A.C.® Therapy Unit and unplug it from the electrical outlet.
3. Slide both tubing clamps toward the tubing connector.
4. Tightly close both tubing clamps to prevent spillage of contents in tubing. Several clicks should be heard (Fig. 1).
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.

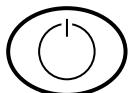
Operating Instructions



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

Power Therapy Unit On or Off

The Power On/Off button is located immediately below and to the left of the touch screen (see page 58 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 58).

Therapy On or Off



Start or stop V.A.C.® Therapy.



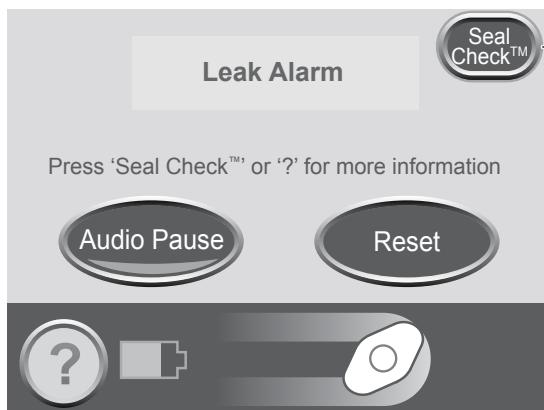
A lighted green crescent means the function is on.



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 74.

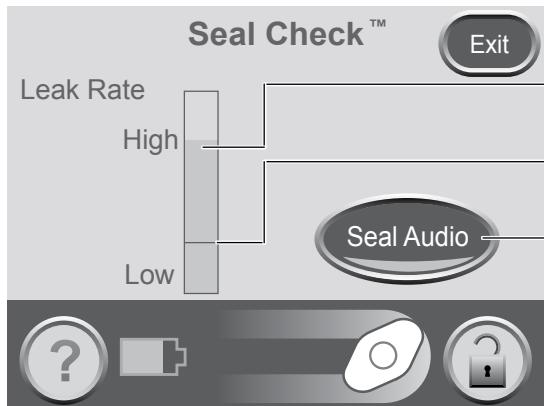


— Flashing Green Oval



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.

Exit

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.



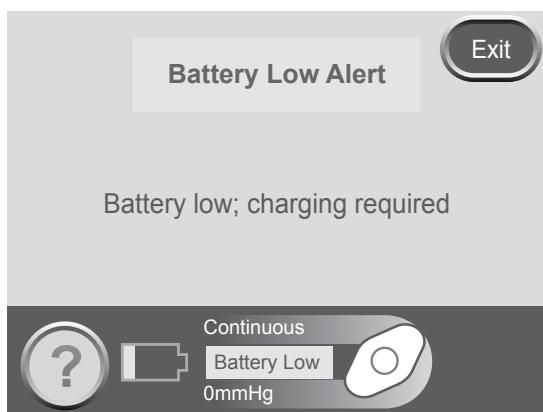
If alarm conditions cannot be resolved, contact your caregiver or KCI.



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.

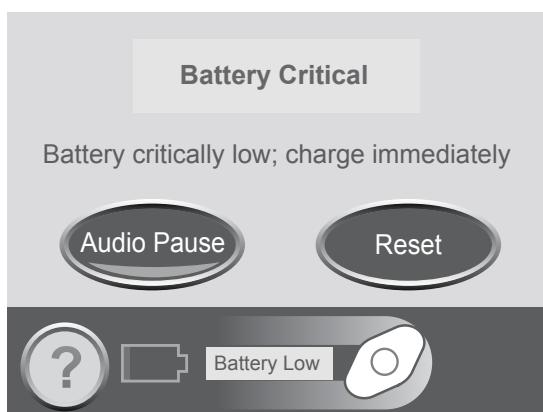


To resolve this alert:

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 60) for more information.
 2. Press Exit to return to the *Patient Mode* home screen.
- i** 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 60) 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.



WARNING: If Canister is full, replace and press 'Reset'. If not full, press 'Cancel'. Press '?' for more information.



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.



Graduated Marks



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 62) 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:

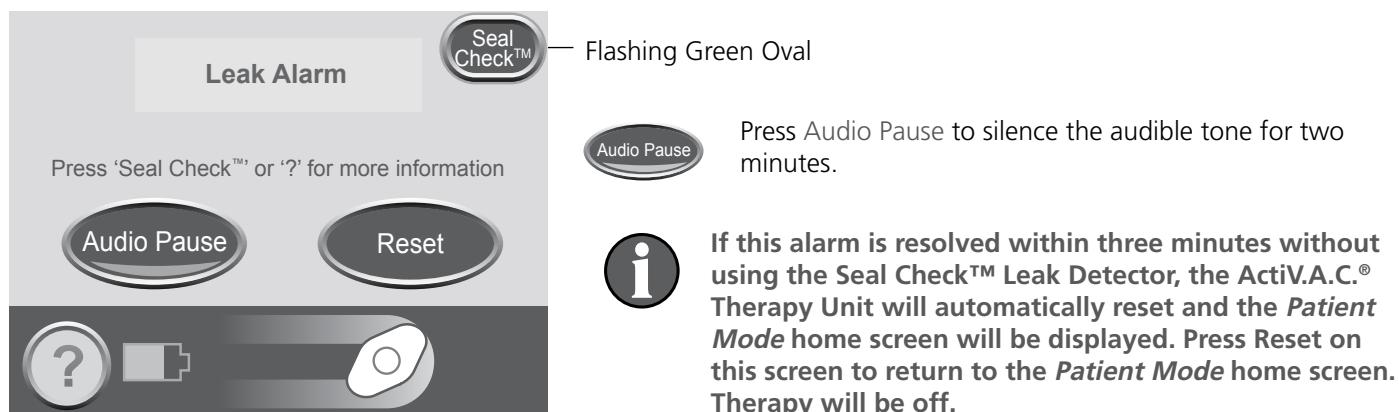
1. Remove the canister by pressing the canister latch release (see page 62 for illustration).
2. Inspect the canister and ActiV.A.C.® Therapy Unit to ensure no foreign objects or debris interfere with the canister and therapy unit's mating surfaces.
3. Ensure both silicone seals and both canister stabilization bumpers are present (see page 62 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.



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 73).
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 68) 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.

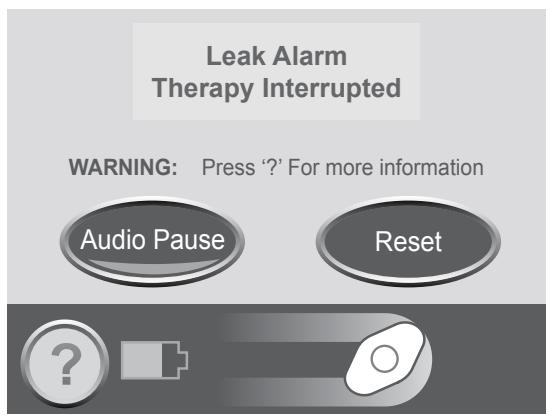


Refer to **Leak Alarm Therapy Interrupted** section of this manual (page 75) for procedures to restart therapy.

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.

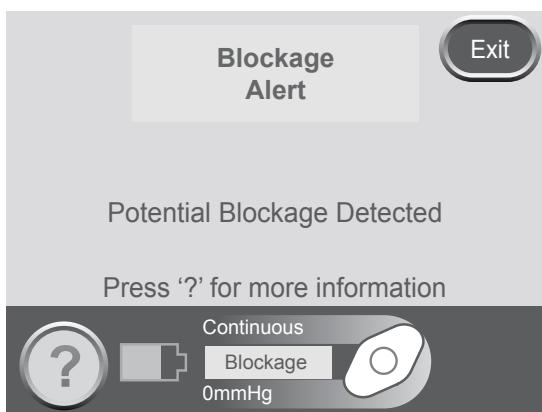


If the leak condition is not resolved, the Leak Alarm will reappear. Continue troubleshooting the leak as described in the previous section.

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.

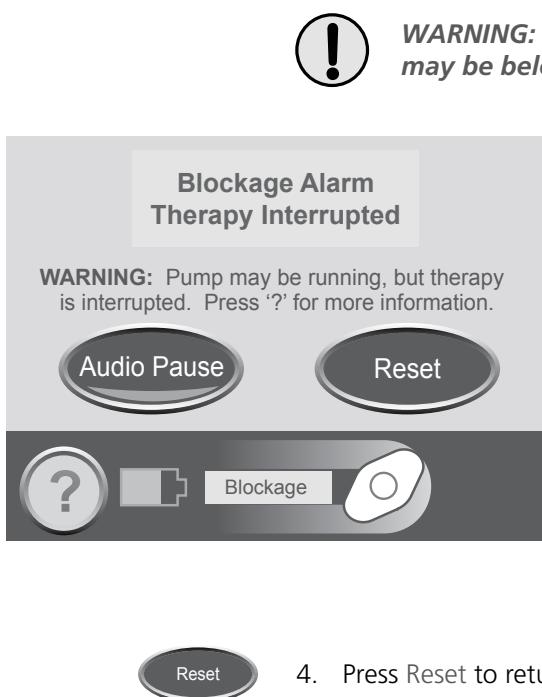


To resolve this alert:

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.



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.



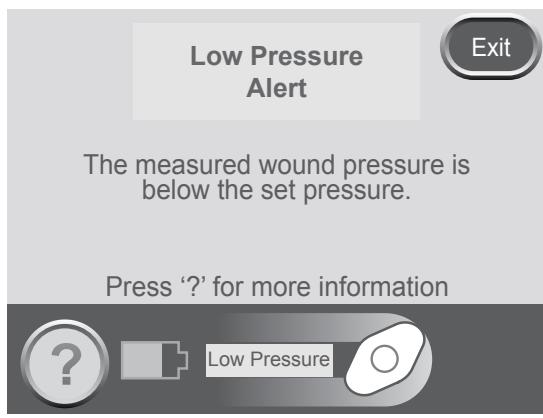
If alarm condition cannot be resolved, contact your caregiver or KCI representative.



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.

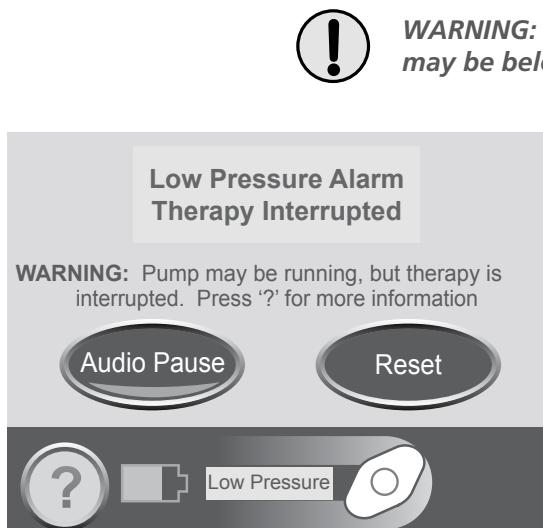


To resolve this alert:

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.



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.



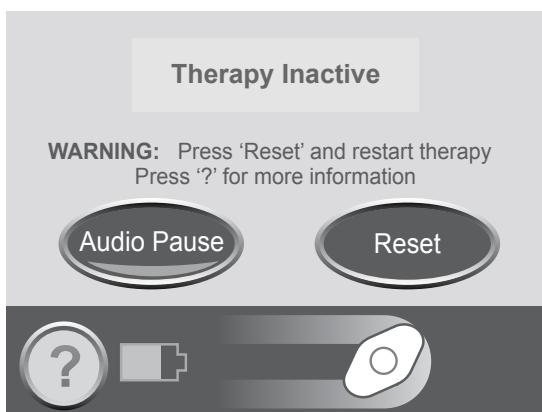
If alarm condition cannot be resolved, contact your caregiver or KCI representative.



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.



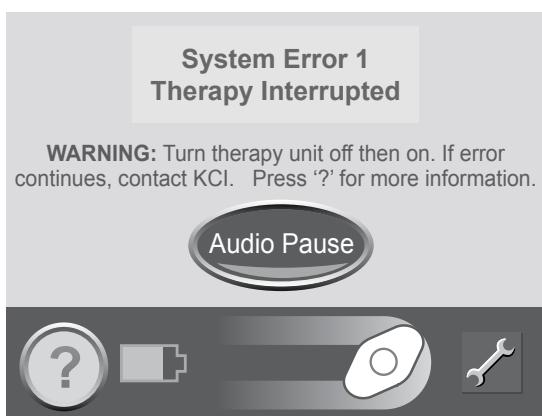
3. If V.A.C.® Therapy is not desired, turn the ActiV.A.C.® Therapy Unit off using the Power On/Off button on the front of the unit.



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.



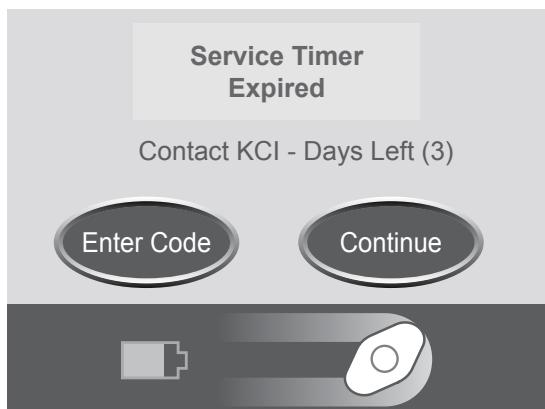
If alarm condition cannot be resolved, contact your caregiver or KCI representative.



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.

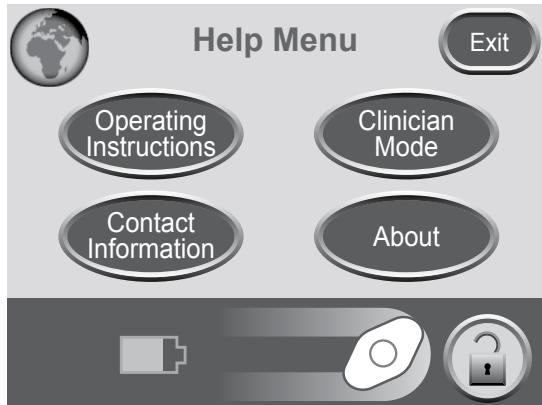


To resolve this alert:

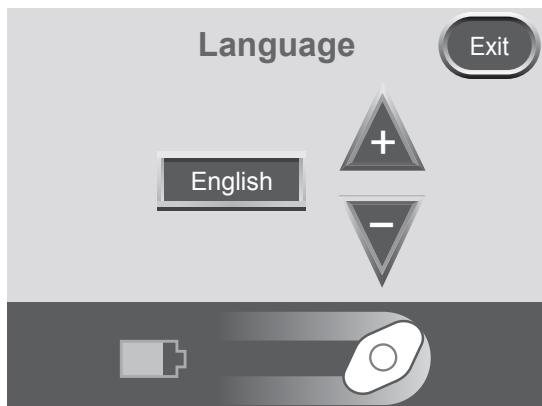
1. Contact KCI to obtain a new Service Timer code.
2. Press Enter Code to enter the code obtained from KCI.

Help Menu

Change Languages



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



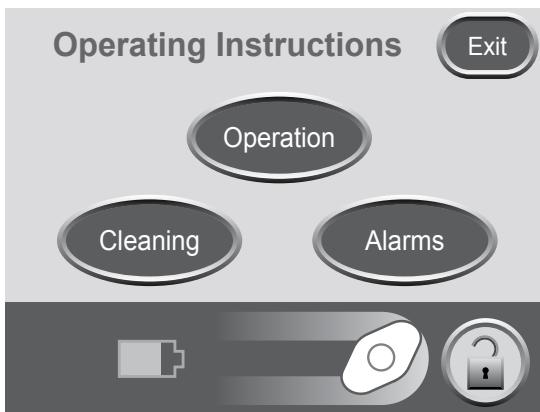
3. Use the + and - buttons to select the desired language.
4. Press Exit when finished.

Onscreen Operating Instructions



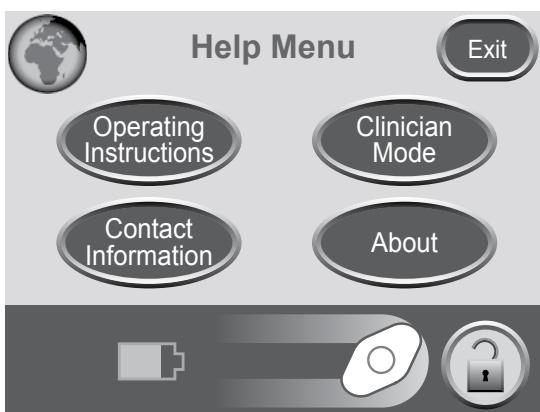
1. Press Help to access the *Help Menu*.
2. Press Operating Instructions to access the *Operating Instructions* selection screen and browse the various available *Help* screens.

Onscreen Operating Instructions (cont.)



3. Choose from Operation, Cleaning instructions and Alarms for alarm descriptions and suggested resolutions.
 4. Press Exit when finished.
- Exit** Access basic operating guidelines.
- Operation** Access basic cleaning guidelines.
- Cleaning** Access general information for pausing or silencing alarms.
- 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. 58) 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 happens 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 70-79). 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 66) 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 practitioner 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.



For Clinician Use Only
Patients: Refer to Previous Section of This Manual



Introduction

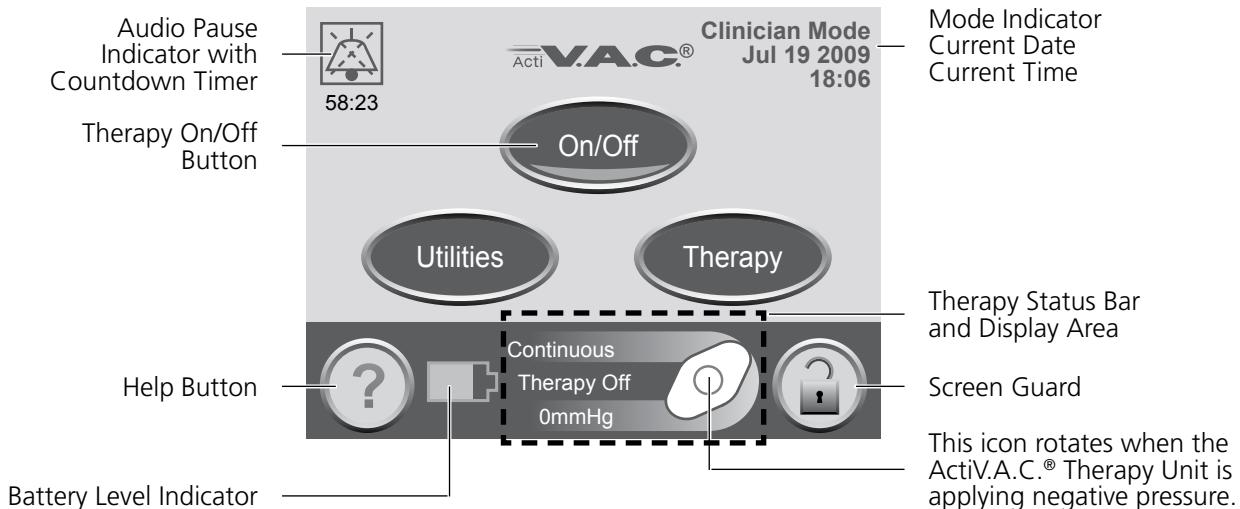
This Clinician information provides operating instructions for the ActiV.A.C.® Therapy Unit to the healthcare professional. Many features described are not available in Patient Mode. Patient Mode allows the patient to start and stop therapy, find leaks using the Seal Check™ feature, and attend to alerts 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 70) for details on alarms and how to resolve them.

Operating Instructions



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

Power Therapy Unit On or Off

The Power On/Off button is located immediately below and to the left of the touch screen (see page 58 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



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.

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 find leaks.
- Settings Guide - Helps select preset therapy settings.
- History - View or export therapy history.

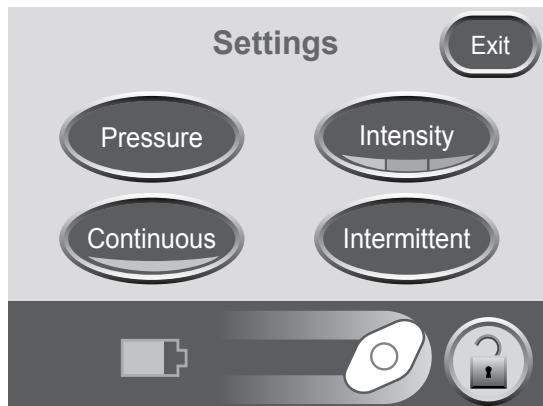


Press Exit to return to the *Clinician Mode* home screen.

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:

- Pressure - 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



Intensity

Medium



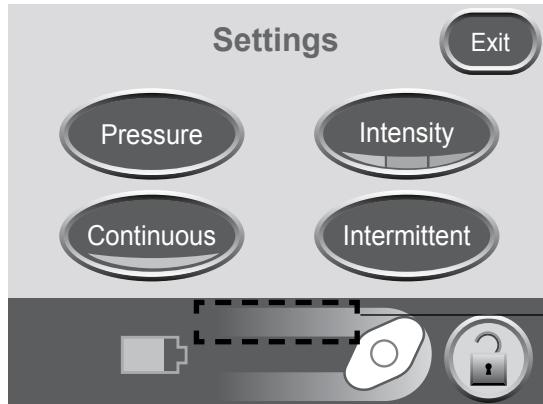
Intensity

High



Default setting is Low.

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.

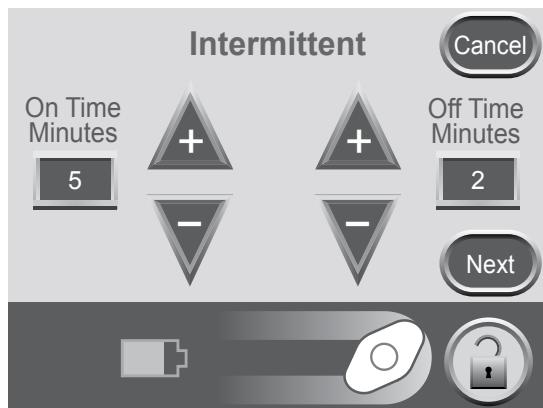


Press Exit when finished with the *Settings* screen and go to the *Confirm* screen.

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



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.



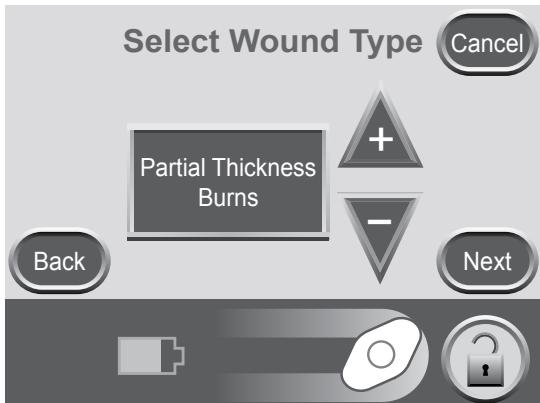
If settings were changed with V.A.C.® Therapy off, press the Therapy On/Off button to start therapy.

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 91).



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.



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.

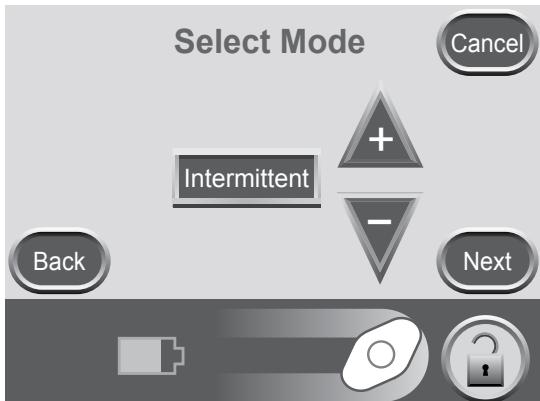


Press Next when finished to continue to the next screen.



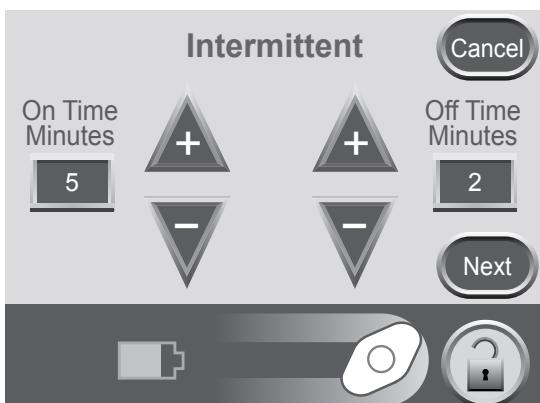
For wound types in which Intermittent is an option, the *Select Mode* screen will appear. If Intermittent is not an option, the *Confirm* screen will appear.

Settings Guide (cont.)



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

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.



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 91).

Starting Therapy



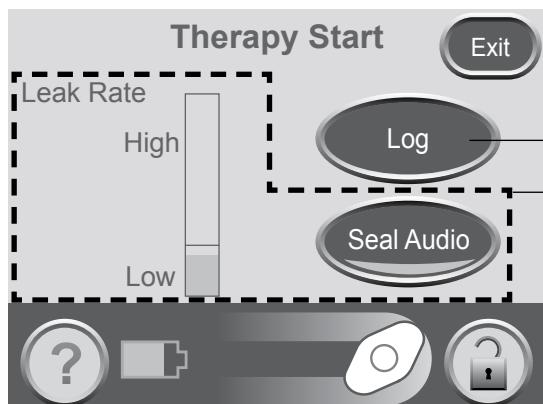
WARNING: Ensure that a new V.A.C.® Dressing has been applied and therapy settings have been selected per physician's orders before starting therapy.



Canister should be properly engaged for therapy to start.



Press 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.

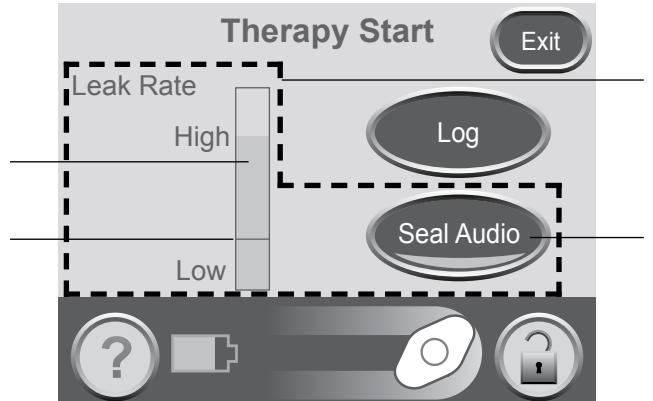
How to Use the Seal Check™ Leak Detector When Starting Therapy



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

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.



Seal Check™ feature

Press to turn the Seal Audio tone on or off.

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.

Exit

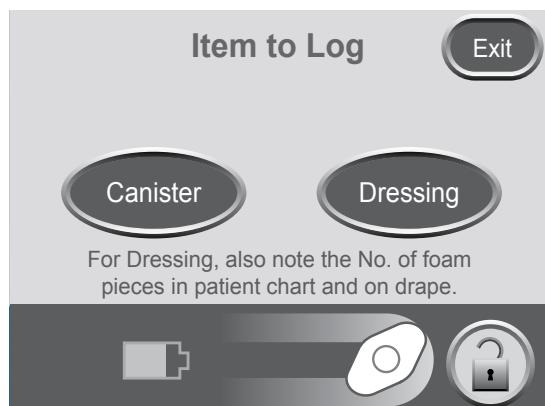
Log Tool

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.

How to Use the Log Tool When Starting Therapy (cont.)

Canister Replaced

Press OK to log that the canister has been changed
(Will use the current time and date)

Press Canister to access the *Canister Replaced* screen.



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.



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

No. Foam Pieces

Press OK to log number of foam pieces and time/date
Last recorded on 15:55 12/06/08



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.



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.



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.

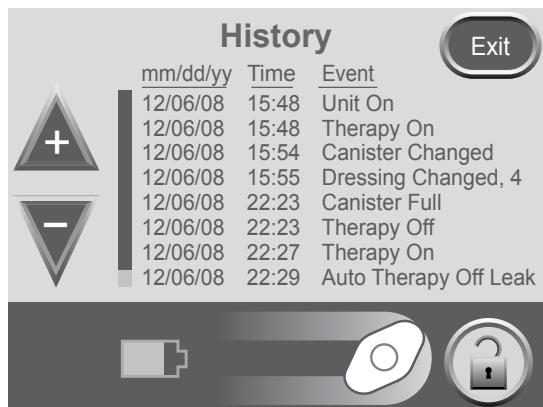
The *Therapy History* screen has two options:

- 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 port only 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



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.



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.



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



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



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.

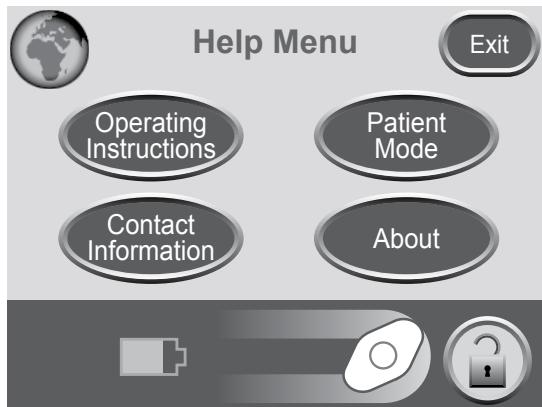


IR feature is no longer available. Use USB port only for data transfer.

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

Help Menu

Change Languages

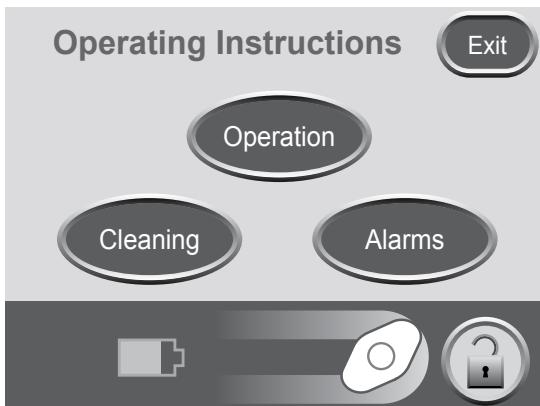
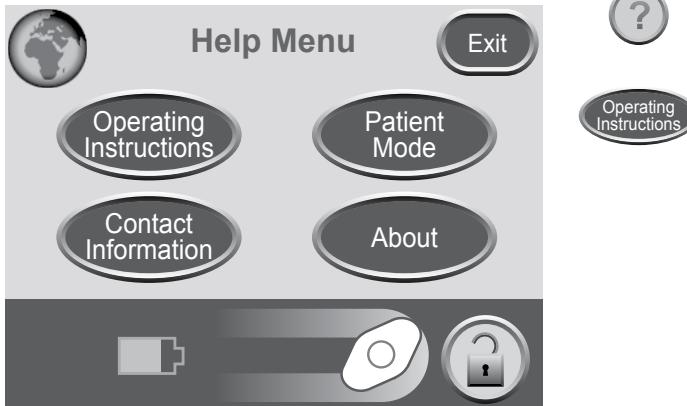


1. Press Help to access the *Help Menu*.
2. Press the Globe (upper left) to access the *Language* screen.



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.

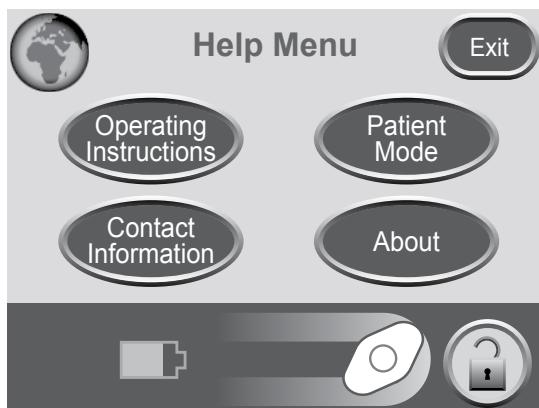
 Access basic cleaning guidelines.

 Access general information for pausing or silencing alarms.

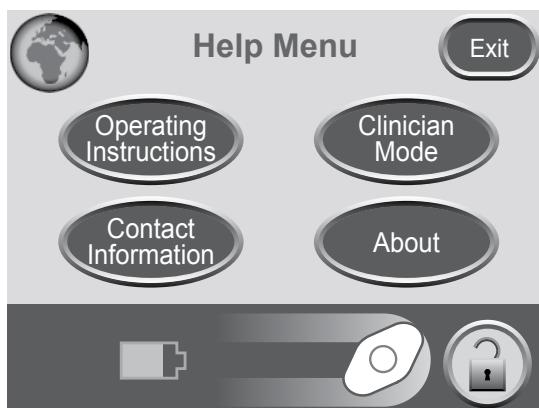
Change to Patient or Clinician Mode



Press Help to access the *Help Menu*.

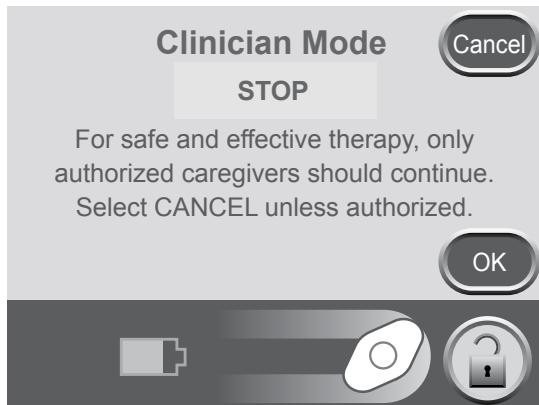


Press Patient Mode to change to *Patient Mode*.



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.



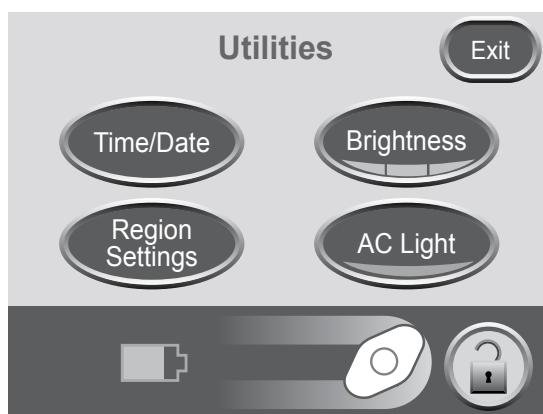
Press OK to return to *Patient Mode*. Press and hold OK for at least 5 seconds to proceed to *Clinician Mode*.



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

Utilities

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



- Press Time/Date to set the current time and calendar date.
- Press Region Settings to set the displayed Pressure Unit and Date Formats.
- Press Brightness to set the display brightness of the touch screen.
- Press AC Light to turn the AC Light on and off.
- Press Exit to return to the *Clinician Home* screen.

Change Time and Date

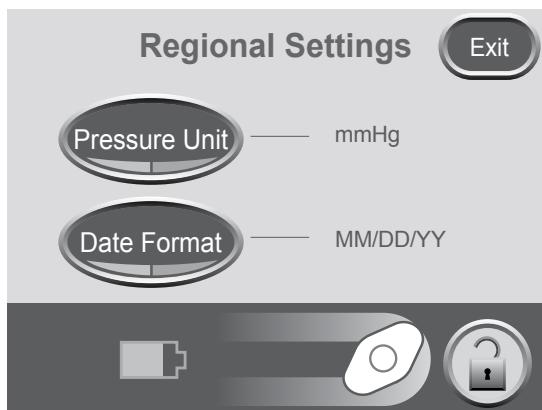
From the *Clinician Mode* Home screen, press Utilities then Time/Date to access this screen.



- Use the + and - buttons to set current time and calendar date.
- Hold the + and - buttons to rapidly scroll through available selections.
- Press Exit to return to the *Utilities* screen.

Change Pressure Units and Date Format

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



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



Default settings are mmHg and MM/DD/YY.



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

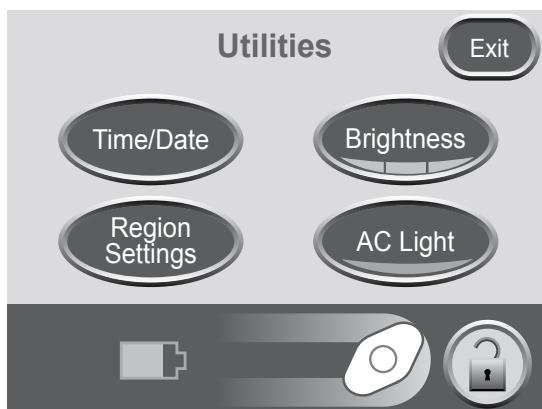


Press Date Format to switch between DD/MM/YY (Day-Month-Year) and MM/DD/YY (Month-Day-Year) formats.



Press Exit to return to the *Utilities* screen.

Change Screen Brightness



Press Brightness to switch between three levels of screen brightness.



High



Medium

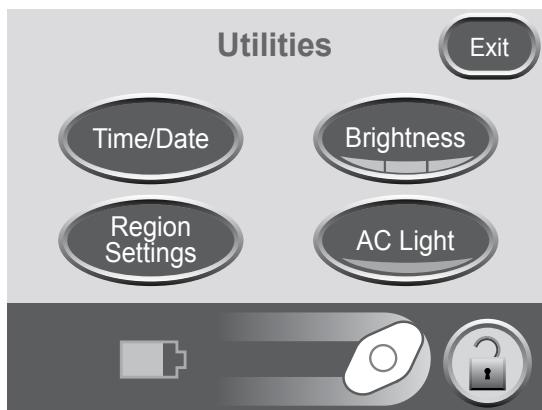


Low



Default setting is High.

Change AC Light



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



On



Off



Default setting is Off.

Care And Cleaning

Standard Precautions

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



Always follow Standard Precautions.

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

Waste Disposal

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

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. 88) 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		IPXO Not protected against harmful effects of water
	Important Operational Information		Alternating Current
	Caution: Consult Accompanying Documents		Direct Current
	WARNING: Consult Accompanying Documents		Class II
	Consult Instructions For Use		Type B, Applied Part
	Keep Dry		This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
	Tripping Hazard		Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.
	No Bathing or Showering		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.
	Power On/Off		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.
SN	Serial Number		
	Date of Manufacture		
	Manufacturer		
	Approximate symbol		
	Temperature Limits Symbol		
	Authorized Representative in the European Community		

Specifications*

Dimensions:	7.6" W x 6" H x 2.5" D (19.3 x 15.2 x 6.4 cm)
Weight (with empty canister attached):	~2.4 lbs (~1.08 kg)
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:	-240VAC .72A @ 115VAC 47-63 Hz
External Power Supply Output:	12V, 3.3 A
Patient & 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
Altitude Range:	0 to 14,000 feet (0 to 4267 m)
Optimum Performance:	0 to 8,000 feet (0 to 2438 m)

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

*Specifications subject to change without notice.

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.



KCI USA, Inc.
San Antonio, Texas 78219 USA
www.kci1.com



KCI Medical Products (UK), Ltd.
Wimborne, Dorset
BH21 7SH
United Kingdom
www.kci-medical.com

For questions, or when product use is discontinued,
please call KCI at 1-800-275-4524 for product pick-up.



Certified Sourcing

www.sfiprogram.org

Cover contains 10% PCW (Post Consumer Waste)
Printed with Soy inks

To learn more about the KCI ActiV.A.C.® Therapy System,
please visit our website at www.kci1.com or call us at
1-800-275-4524.



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

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