

ACTIV.A.C.™ THERAPY SYSTEM

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.



ACCREDITED

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



IMPORTANT INFORMATION	
Please READ and KEEP this information posted in a handy place.	
YOUR CONTACT INFORMATION	
Your Nurse's Name:	
Your Nurse's Phone Number:	
Your Home Health Agency (HHA) or Wound Care Center:	
Your Doctor's Name:	
Your Doctor's Phone Number:	
KCI CUSTOMER SUPPORT	Call 1-800-275-4524.
In case of emergency:	<ul style="list-style-type: none">• FIRST call 9-1-1 (or your local emergency number)• THEN call your doctor or nurse
INFORMATION FOR YOU TO KNOW	
Your V.A.C.® Therapy Unit model:	
Where can you find information about your specific V.A.C.® Therapy Unit?	Refer to the documents that came with your therapy unit for instructions on how to use it. If you did not receive these items, call KCI at 1-800-275-4524.
Issues with the V.A.C.® Therapy Unit?	Do not attempt to fix the therapy unit. If you have any problems with the unit, call KCI right away at 1-800-275-4524.
Keep your V.A.C.® Therapy Unit ON.	If therapy is off/interrupted for more than two hours, your dressing will need to be changed!
Dressings:	Remember dressings are for single use only! The used dressing must be thrown away after each dressing change.
Who changes the dressings?	Your doctor will decide how and when your dressings will be changed. It could be in the doctor's office, by a home health agency or at a wound care clinic. In some cases, a caregiver, family member or friend may be trained. ONLY THOSE WHO HAVE BEEN PROPERLY TRAINED SHOULD CHANGE THE DRESSINGS.
Ordering Supplies:	Call KCI at 1-800-275-4524.



WHEN TO CALL YOUR DOCTOR OR NURSE	
BLEEDING:	<p>If you see a sudden increase or large amount of blood from your wound in the tubing or canister:</p> <ol style="list-style-type: none">1. TURN OFF the therapy unit right away.2. APPLY pressure over the area.3. DO NOT remove your dressing.4. CALL 9-1-1 (or your local emergency number) and THEN call your doctor or nurse.
DIFFICULTY BREATHING:	<p>If you have DIFFICULTY BREATHING, CALL 9-1-1 (or your local emergency number).</p>
Other Concerns:	<p>Talk with your doctor or nurse if you have any concerns about:</p> <ul style="list-style-type: none">• Wound Infection• Other Serious Infections• Allergic Reactions <p>See page 20 of this Patient Information Guide for more safety information.</p>

How To Use This Book

This Patient Information Guide is designed to be an all in one resource for KCI V.A.C.® Therapy. Please save this guide and all the documents that came with your therapy unit. You may be asked to refer to these items during a KCI service call.

Read and follow all instructions in this guide. Your safety is our first concern. For important safety information, see page 20. Please read this information carefully.

For a description of how V.A.C.® Therapy works and what to expect while you are using it, see page 13.

For information about your benefits and the terms and conditions of use, see page 24. Please read this information carefully. Your signature on the Proof of Home Delivery/Assignment of Benefits (POD/AOB) form is your agreement to these important terms and conditions. This section also includes information about privacy practices and your rights and responsibilities as a patient.

For information specific to the state where you live, see page 41. Check this section to see if your state is included.

Important Safety Information Comes With Your V.A.C.® Therapy Unit

Your therapy unit comes with several documents that include important warnings for your safety. Before using your therapy unit:

- Review the user manual included in this book with your doctor or nurse (see page 59).
- Review the two quick reference guides included in this book. Cut these guides out of the book and keep them with your therapy unit at all times (see page 45 and page 55).
- Review the safety information sheet with your doctor or nurse. Keep this SIS with your therapy unit at all times.
- If there are questions or this information is missing, contact KCI right away at 1-800-275-4524.

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What is V.A.C.® Therapy?

Introduction

This Patient Information Guide provides important information about your treatment with KCI's V.A.C.® Therapy System. If you have questions or need further information call your doctor or nurse, or call KCI at 1-800-275-4524.

Wound healing is a process

Proper wound care management is needed to heal your wound. Your doctor has prescribed a V.A.C.® Therapy System for your care. A doctor or nurse is responsible for directing the use of the system, including therapy application and 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 V.A.C.® Therapy may end.

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.

What is V.A.C.® Therapy?

The V.A.C.® Therapy System is a medical device system that helps wounds heal by delivering negative pressure (a vacuum) to the wound through a special dressing and therapy unit. This creates an environment that promotes the wound healing process. This negative pressure helps:

- Draw wound edges together
- Remove wound fluids and infections materials
- Promote granulation tissue formation (the connective tissue in healing wounds)

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

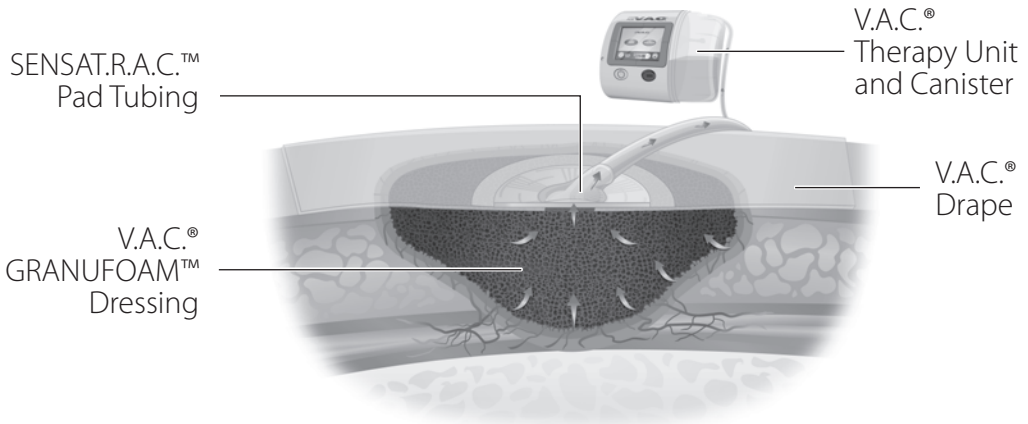
The V.A.C.® Therapy System also helps:

- Provide a moist wound healing environment
- Reduce wound odor
- Reduce the need for daily dressing changes

The V.A.C.® Therapy System

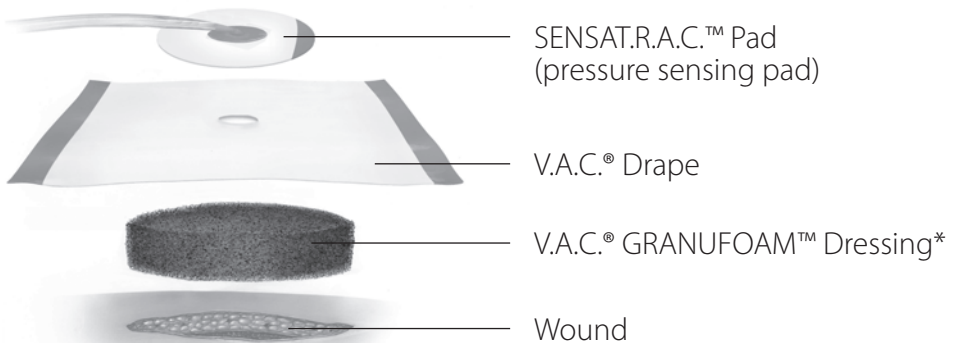
The V.A.C.® Therapy System includes:

- The V.A.C.® Therapy unit that delivers negative pressure
- A specially designed disposable canister to manage wound fluid
- Sterile tubing with a pressure sensing system that connects the therapy unit to the dressing
- Special foam dressings that are placed in the wound
- A clear drape with adhesive that covers the foam dressing



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 V.A.C.® Therapy Unit.



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

V.A.C.® Dressing Changes

The V.A.C.® Therapy System uses special foam dressings with the therapy unit. Only V.A.C.® dressings are to be used with V.A.C.® Therapy units. Wounds treated with the V.A.C.® Therapy System should be checked on a regular basis by your doctor or nurse who is responsible for treatment.

- For a non-infected wound: KCI recommends the dressings be changed every 48 to 72 hours, but no less than 3 times per week.
- For infected wounds: These wounds must be checked often and very closely. Infected wounds dressings 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.

V.A.C.® Therapy Units



V.A.C.® Therapy Units are lightweight portable devices designed for patients who enjoy the freedom of being mobile. Refer to the documents that came with your therapy unit for specific instructions on how to use it.

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



V.A.C.® Therapy Use

Keep V.A.C.® Therapy on (off for no more than two hours).

- If therapy is turned off for more than two hours, the V.A.C.® Dressing must be removed and replaced. Call your doctor or nurse for more information.

- If the unit is off for more than 15 minutes and the power to the unit is on, an alarm will sound. Refer to the documents that came with your therapy unit for instructions on how to manage this alarm.
- 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 into the bathtub or shower.**

V.A.C.® Therapy Settings

Patient compliance with V.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 V.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.

IMPORTANT: DISPOSABLE ITEM RETURN INFORMATION

KCI only accepts the return of unopened and/or unused V.A.C.® Therapy disposables if:

- the product is identified as substandard (defective and less than full quality for the particular item)
- the product is identified as unsuitable (inappropriate for the customer at the time it was sold)
- the product was shipped in error by KCI, in accordance with the Centers for Medicare & Medicaid Services (CMS), Durable Medical Equipment (DME) Prosthetics, Orthotics and Supplies (POS) Supplier Standards

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 return of your V.A.C.® Therapy System. This call stops the billing process and you will not be charged.

Also call your doctor or nurse to arrange a visit to ensure the V.A.C.® Therapy Unit has been properly removed and all necessary precautions are in place to ensure your safe transfer.

Questions and Answers

1. How does V.A.C.® Therapy feel?

Most patients describe V.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 call your doctor.

2. Can you move around while on V.A.C.® Therapy?

Yes. The V.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 V.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. If therapy is off/interrupted for more than two hours, your dressing will need to be changed.**

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

Your doctor may prescribe a V.A.C.® GRANUFOAM™ or V.A.C. WHITEFOAM™ Dressing for your wound type. The V.A.C.® GRANUFOAM™ Dressing will shrink down and wrinkle like a raisin when V.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 V.A.C.® Therapy will change your dressing. If approved by your doctor or nurse, a caregiver, family member or friend may change the dressing **if they have been properly trained.**

The following steps should be followed by you and your caregiver to reduce the risk of infection and the spread of germs:

- Cover your mouth and nose with a tissue when you cough or sneeze or cough or sneeze into your upper sleeve, not your hands. Put your used tissue in a waste basket.
- 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 count the total number of foam pieces put into the wound. They should record this number and the dressing change date on the drape or Foam Quantity Label (if supplied) and in your chart.
- Refer to application instructions provided with the dressing for more information.

6. What if my V.A.C.® Therapy Unit alarms?

Refer to the documents that came with your therapy unit for information on alerts and alarms. If needed, call your doctor, nurse or KCI for assistance.



You can call KCI at 1-800-4524 to troubleshoot in real time over the phone, 24 hours a day. To help in troubleshooting your therapy unit, please keep handy the small white tubing cap that comes on the end of the canister tubing.

7. Who do I call in case of an emergency?

- First, call your local emergency number (i.e., 911).
- After you call local emergency, call your doctor or nurse.
- For all other medical concerns, refer to the Patient Safety Information section of this guide.

8. How can my caregiver be helpful?

A family caregiver or friend can help you by reminding you how important it is to keep your V.A.C.® Therapy Unit on. Also, when directed by your doctor or nurse and only after proper training, your caregiver can assist in:

- changing dressings and canisters
- responding to therapy unit alarms
- monitoring the therapy

9. How do I order supplies?

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

10. What do I do when my V.A.C.® Therapy is completed?

Call KCI at 1-800-275-4524 to arrange for the return of your V.A.C.® Therapy System. This call stops the billing process and you will not be charged.

Patient Safety Information

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

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



Important

For operating instructions and additional safety information, please see the documents included with your therapy unit.

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 approved 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.**



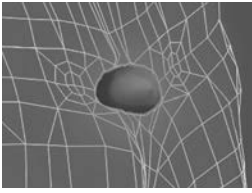
Bleeding

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 V.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) FIRST.**
- **Then call 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 develop or worsen:

- 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

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
- You have a headache
- Your throat is sore
- You have a rash
- You feel confused
- You have a fever over 102°F



V.A.C.®
Disposables

Allergic Reactions

V.A.C.® Dressings, V.A.C.® Drape and V.A.C.® Canisters are delivered sterile and do not contain latex. Use items only from unopened packages, use them 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 symptoms:

- Redness
- Rash or hives
- Swelling
- Severe itching

If you have difficulty breathing, seek immediate emergency medical assistance or call 9-1-1 (or local emergency number).



V.A.C.® Therapy Unit

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

If therapy is interrupted or turned off for more than two hours, call your nurse or doctor right away. The old dressing will need to be removed and the wound irrigated. Never leave a V.A.C.® Dressing in place without active V.A.C.® Therapy for more than two hours.

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



V.A.C.® SIMPLACE™ Dressing

Count Foam Dressing Pieces

Your doctor, nurse, or trained caregiver should always count the total number of foam pieces put into your wound. They should record this number and the dressing change date on the drape or Foam Quantity Label (if supplied) and in your chart. Make sure that the same number of foam pieces is removed during your dressing change.

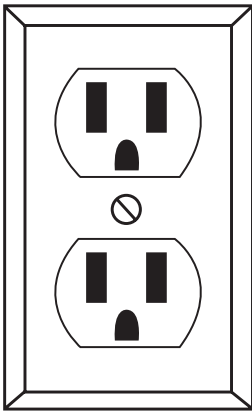
Cover Your Cough

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.

In Case of Evacuation or Immediate Departure

Please call KCI at 1-800- 275-4524 if you are evacuated due to natural disaster or choose to evacuate or immediately depart from your current address. We will need your new or temporary address so we can best support your needs.



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 V.A.C.® Therapy Unit; it must remain dry.

Fall Prevention Tips

Follow these safety tips to help prevent slips or falls while using the V.A.C.® Therapy System:

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

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 301328, Dallas, TX, 75303-1328.
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 Rights and Responsibilities

Patient's Bill of Rights and Responsibilities

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

1. To strengthen consumer confidence that the healthcare system is fair and responsive to consumer needs;
2. To reaffirm the importance of a strong relationship between patients and their healthcare providers; and
3. 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

Notice of Privacy Practices (effective 13 September 2013)

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

Acelity Health Care Compliance Department at 1-210-255-6605.

Purpose of This Notice

This notice will tell you about the ways in which KCI may use and disclose the protected health information (“PHI”) that identifies you. 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 the entire 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 or any KCI affiliate or subsidiary in which work performed on behalf of U.S. operations is subject to the Health Insurance Portability and Accountability Act of 1996.
- KCI USA, Inc. and KCI Medical Puerto Rico, Inc.

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 Acclity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. You have the right to request a readily-producible form in which your PHI may be delivered. 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 Acclity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. 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 Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. 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 Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, TX 78249. 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 Restrict Certain Disclosures to Health Plans. You have the right to restrict certain disclosures of PHI to a health plan when you pay out of pocket in full for health care items or services.

Right to Notice of Breach of Unsecured PHI. You have the right to receive notice in the event that unsecured PHI identifying you has been, or is reasonably believed to have been used, accessed, acquired or disclosed in an unauthorized manner.

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 Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249. 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.acelity.com, under the menu heading "For Patients." To obtain a paper copy of this notice, you must contact the Acelity Health Care Compliance Department at 1-210-255-6605.

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, except that we may not do so without your authorization to the extent that we receive direct or indirect remuneration for such use or disclosure of PHI.

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 KCI USA, 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 we receive reassurance from the requestor that 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. Certain uses and disclosures of PHI, including those uses and disclosures of PHI for marketing purposes, and disclosures that constitute a sale of PHI require your authorization. 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.acelity.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, Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249. **You will not be penalized for filing a complaint.**

Contact

For more information regarding this Notice of Privacy Practices and your rights hereunder, contact: Privacy Officer, Acelity Health Care Compliance Department, 6103 Farinon Drive, San Antonio, Texas, 78249, or by phone at 1-210-255-6605.

Medicare Supplier Standards

Medicare DMEPOS Supplier Standards



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.

State Specific Information

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:

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

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.

Florida Special Needs Registry

The Florida Division of Emergency Management, in coordination with each local emergency management agency in the state, developed a registry to allow residents with special needs to register with their local emergency management agency to receive assistance during a disaster. The statewide registry provides first responders with valuable information to prepare for disasters or other emergencies.

Providing as much information as possible will allow emergency management officials to plan accordingly for future disasters. You will be emailed periodically to verify the information provided is correct and to make any necessary changes. Individual surveys will be archived after one year if not verified.

Why should you register?

- To receive important information from local emergency management officials about evacuation and sheltering options available to you.
- **IT MAY SAVE YOUR LIFE!**

Will my privacy be protected?

The information within the registry will only be used in the planning for and provision of emergency and/or disaster services. Additionally, Florida Statute 252.905 declares any information furnished by a person or business to the Florida Division of Emergency Management for the purpose of being provided assistance with emergency planning is exempt from F.S. 119.07 (1) and s.24 (a), Art. I of the State Constitution. Information provided through the registry is therefore exempt from public records requests made of the Division.

Completing the Florida Special Needs Registry does not automatically qualify the individual for a special needs shelter. Additional information will be provided by your local emergency management agency regarding evacuation and sheltering options available to you. For more information on your local options, please visit <http://www.floridadisaster.org/disability/specialneeds> for contact information. Please select your county to view important information and register.

For registry questions, please contact the Florida Special Needs Registry Help Desk:

Email: FLSNRsupport@deltaone.com

Phone: 800-374-9689

TTY: 800-395-1878

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

Customer Contact Information

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

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

Quality of Care

For Concerns or Questions

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 accrediting organization, the Accreditation Commission for Health Care, Inc., at (919) 785-1214.

ACTIV.A.C.™ Therapy System

Quick Reference Guide For Patient Use

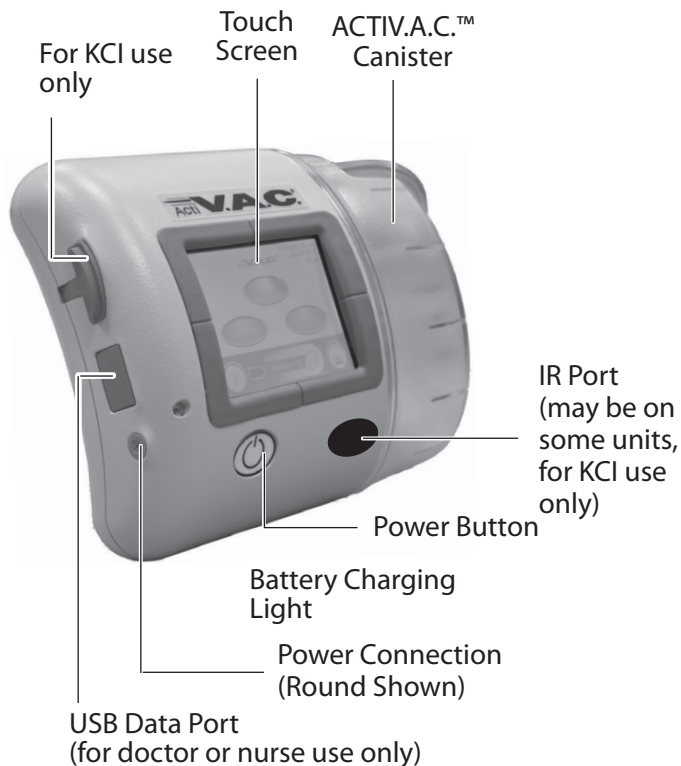
Important Safety Information accompanies this device.

Before using the ACTIV.A.C.™ Therapy System:

- Review the user manual with your doctor or nurse.
- Review this quick reference guide.
- Review the safety information sheet with your doctor or nurse.
- Keep this quick reference guide and the safety information sheet in the pocket on the therapy unit carrying case.

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

ACTIV.A.C.™ Therapy Unit





Power Therapy Unit On or Off



Press and hold the Power button for about two seconds to turn the therapy unit on or off.

Therapy On or Off

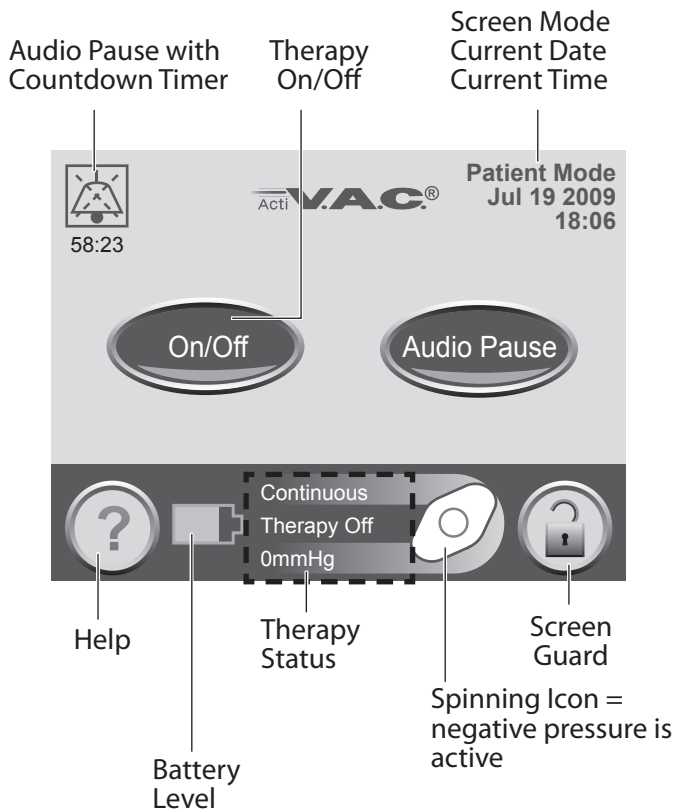


Green = function is on



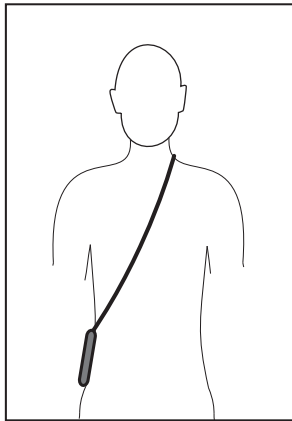
Gray = function is off

Patient Mode Home Screen



Carrying Case

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



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



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

Alerts and Alarms

See the Alerts and Alarms section of the ACTIV.A.C.™ Therapy System User Manual for more details. If necessary, contact your doctor, nurse or KCI for assistance or further information.



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



Alarms needing immediate attention override the Audio Pause feature.



Press Help for more information about the alert or alarm.



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



Alerts

Alerts will be displayed on the touch screen when the therapy unit detects a condition that requires patient or caregiver attention. A single audible tone will sound.

- Battery Low Alert: About two hours of battery power remain. Recharge the battery.
- Blockage Alert: Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.
- Low Pressure Alert: Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.
- Service Timer Expired Alert: Contact KCI for instructions.

Alarms

Alarms will be displayed on the touch screen when the therapy unit detects a condition that **requires immediate patient or caregiver attention**. Repeating audible tones will sound.

- Battery Critical Alarm: About 30 minutes of battery power remain. **Immediately recharge the battery.**
- Blockage Alarm Therapy Interrupted: Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.
- Canister Full Therapy Interrupted Alarm: Change canister and restart therapy.
- Canister Not Engaged Alarm: Ensure canister is properly installed.
- Leak Alarm: Use leak detection procedures and the **SEAL CHECK™** Leak Detector to help find and repair leak.
- Leak Alarm Therapy Interrupted: A leak has been detected and not resolved. Press Reset and restart therapy.
- Low Pressure Alarm Therapy Interrupted: Check tubing for closed clamps, kinks, crimps and blockages. Lower therapy unit and tubing to or below the wound level.
- System Error Alarm: A technical fault has occurred. Turn unit off and then back on. If the fault persists, contact KCI.
- Therapy Inactive Alarm: Therapy has been off for 15 minutes. Restart therapy.

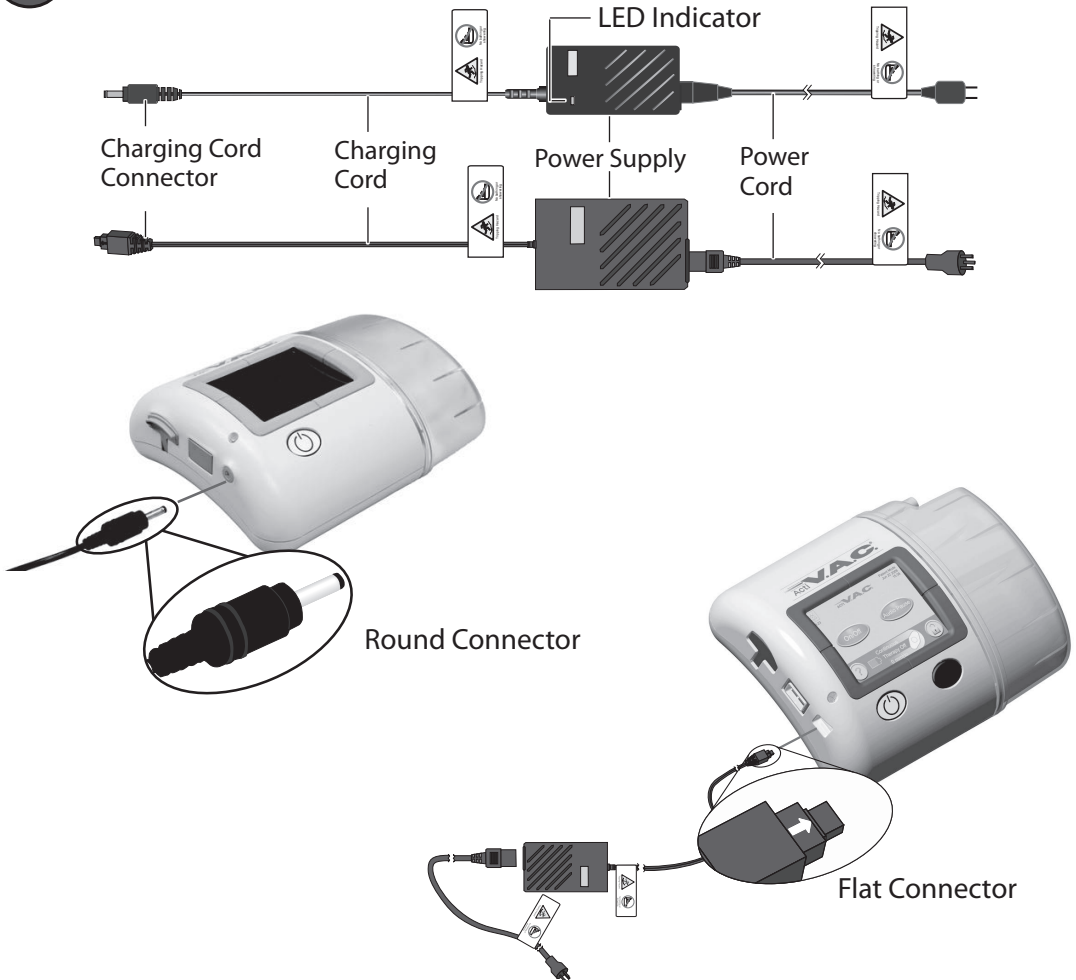


Charge the Battery

1. Plug the power cord into the power supply.
2. Plug the power cord into an AC wall outlet.
3. Plug the charging cord connector into therapy unit.
4. Keep the unit plugged in whenever possible.



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



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

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



Battery Level

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 about six hours to fully charge the battery.

Canister



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

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

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



Canister
Latch
Guide



Canister
Latch
Release



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



Canister Changes



In the US, 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. Outside the US, please contact your local KCI representative.

The canister should be changed when full (the alarm will sound), or at least once a week to control odor.

1. Do not turn the therapy unit off.



2. Press the On / Off button on the touch screen to stop therapy.

3. Slide both tubing clamps toward the tubing connector.

4. Tightly close both tubing clamps to avoid spilling tubing contents.

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

- Push the connectors together.
- Twist the connectors to unlock.
- Pull the connectors apart.



6. To remove the canister:

- Press down on the canister latch release.
- Pull the canister directly away from the therapy unit.



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



7. To install a new canister:

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

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

- Push the connectors together.
- Twist the connectors to lock.



9. Open both tubing clamps.

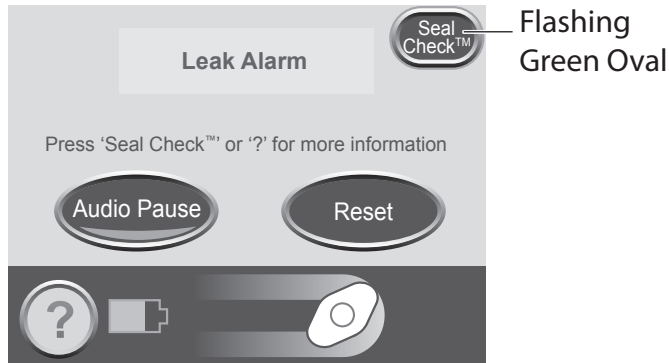


10. Press the On / Off button on the touch screen to restart therapy.

11. Make sure the dressing collapses.

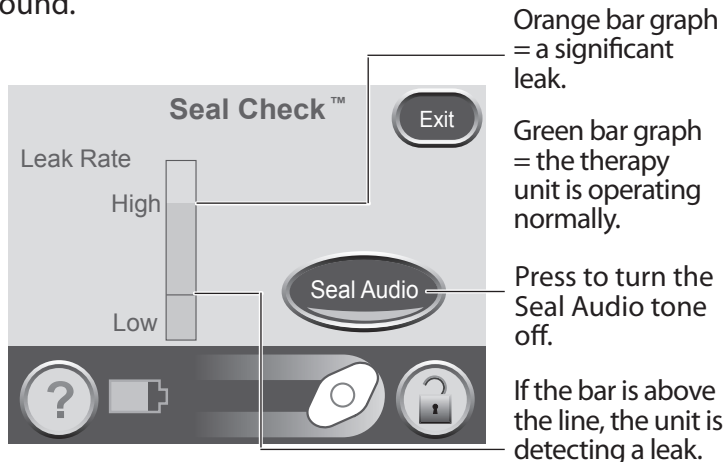
SEAL CHECK™ Leak Detector

If the 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.)



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

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




Most leaks occur:

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



To fix the leak:

1. Check the tubing connectors between the dressing and the canister. Make sure they are properly locked.
2. Make sure the canister is properly installed onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit.
3. Use the SEAL CHECK™ Leak Detector to find the leak at the dressing.
4.  When the leak is fixed, press Exit to return to the Patient Mode *Home* screen.
5. If the leak alarm persists or you cannot find the leak, call your doctor, nurse or KCI.

Questions and Information

For medical questions, please call your doctor or nurse. In case of emergency, call your local emergency service (i.e. 911) immediately.

This quick reference guide is not intended to be a comprehensive manual. For more information about the ACTIV.A.C.™ Therapy System, including detailed operating instructions, please consult the ACTIV.A.C.™ Therapy System User Manual and your doctor, nurse, caregiver or KCI.

Customer Contact Information

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

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

Outside the US visit www.kci-medical.com



Manufactured for:

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

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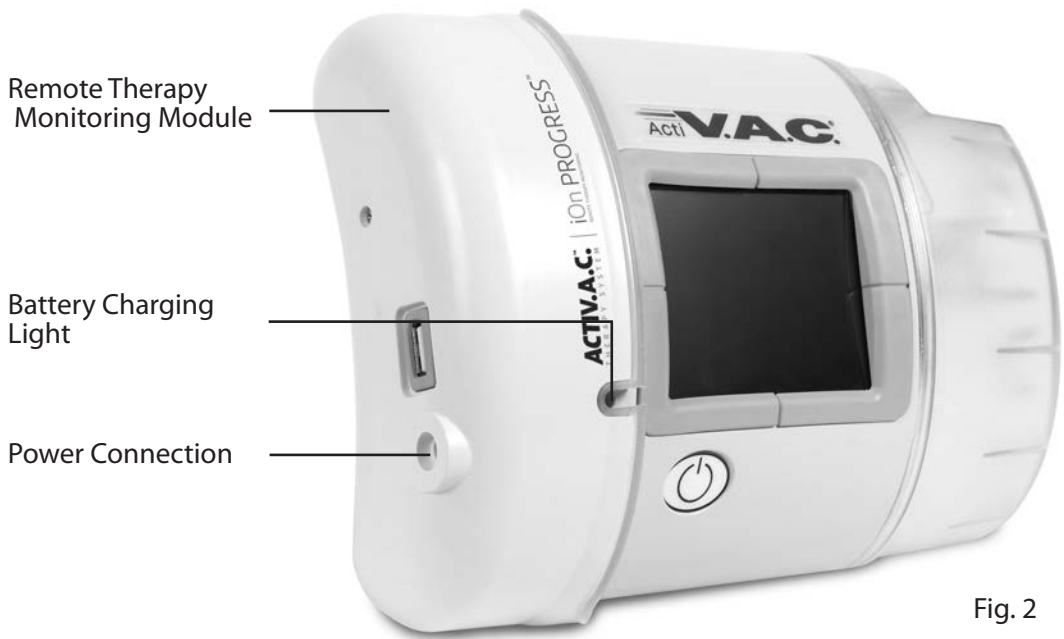
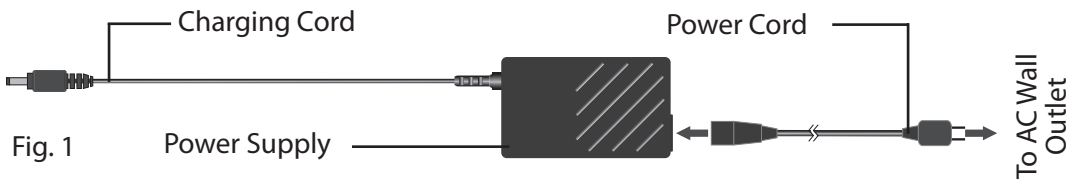


iON PROGRESS™ Remote Therapy Monitoring Quick Reference Guide For Patients

Introduction

Your ACTIV.A.C.™ Therapy System may be equipped with iOn PROGRESS™ Remote Therapy Monitoring. As a result KCI will be able to monitor your ACTIV.A.C.™ Therapy System usage to aid in your recovery. You will not need to do anything as your unit is specially equipped with this capability. You can expect phone calls from a KCI representative to discuss your ACTIV.A.C.™ Therapy System usage.

When your ACTIV.A.C.™ Therapy Unit is equipped with iOn PROGRESS™, it has a different power cord than described in the user manual. Use these instructions to connect your ACTIV.A.C.™ Therapy Unit to the provided power supply.





Charge the Battery

1. Plug the power cord into the power supply (**Fig. 1**).
2. Plug the power cord into an AC wall outlet (**Fig. 1**).
3. Plug the charging cord into therapy unit (**Fig. 2 and 3**).
4. Keep the unit plugged in whenever possible.



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



Fig. 3

The battery charging light will glow amber while unit is charging (**Fig. 2**). The light will change to green when the unit is fully charged.



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



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



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



ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit Carry Case



Keep the therapy unit in the upright position.

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

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

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

Access Flap with Hook
and Loop Fastener

Tubing Storage Straps



Belt Loop



ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit Carry Case (cont)



Use the adjustable strap to wear the carrying case over your shoulder. You can also wear the carrying case on your belt.



Make sure the case buckles are securely snapped together (if equipped).

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

To discontinue this rental product please call KCI at 1-800-275-4525. Failure to contact KCI for product pick-up may result in additional daily charges.

This device may be worn on the hip using the carrying case, or kept 20 cm or greater away from the body.

FCC ID: 2AHDZ-ACTIVAC-RTM

Manufactured For:

KCI USA, Inc.
12930 IH 10 West
San Antonio, TX 78249 USA
1-800-275-4524
www.acelity.com

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ACTIV.A.C.™

THERAPY SYSTEM

User Manual

For Patients and Clinicians



Rx Only

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ACTIV.A.C.™

THERAPY SYSTEM

For Patient Use



Important Safety Information Accompanies this Device



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

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



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

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

Warnings: Important Information for Users

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

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

Small Parts - Choking Hazard

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

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

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

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

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

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

Keep the therapy unit away from heated surfaces.

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

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

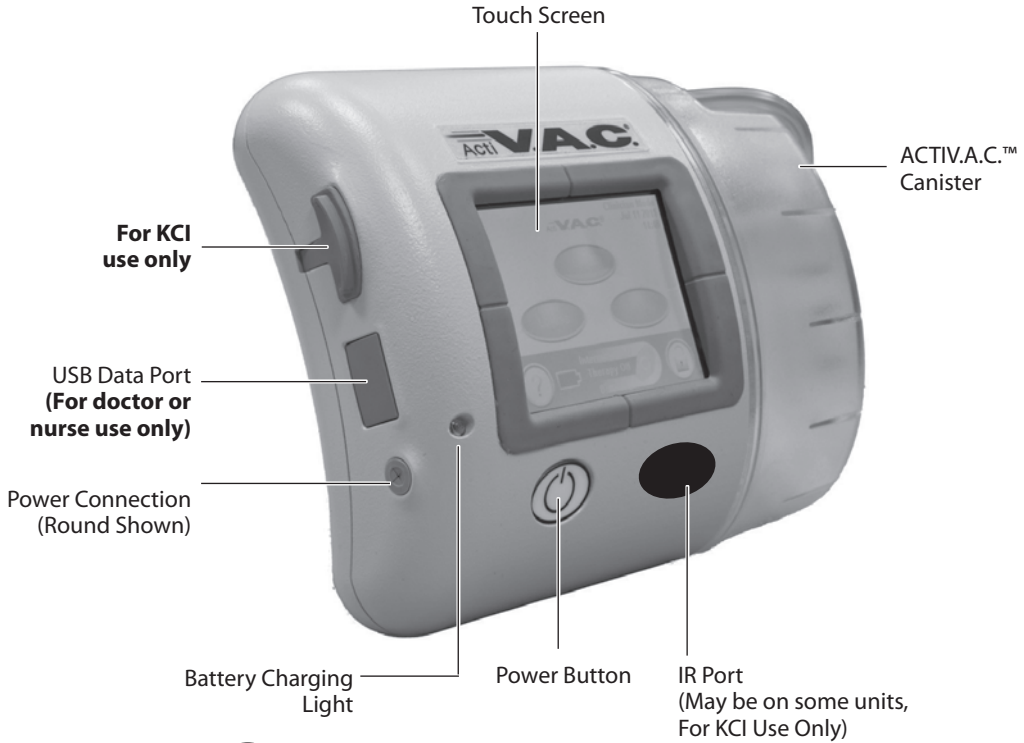
Do not reach for a therapy unit that has fallen into water. Unplug the unit immediately if plugged in. Disconnect the unit from the dressing and call KCI.

Introduction

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

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

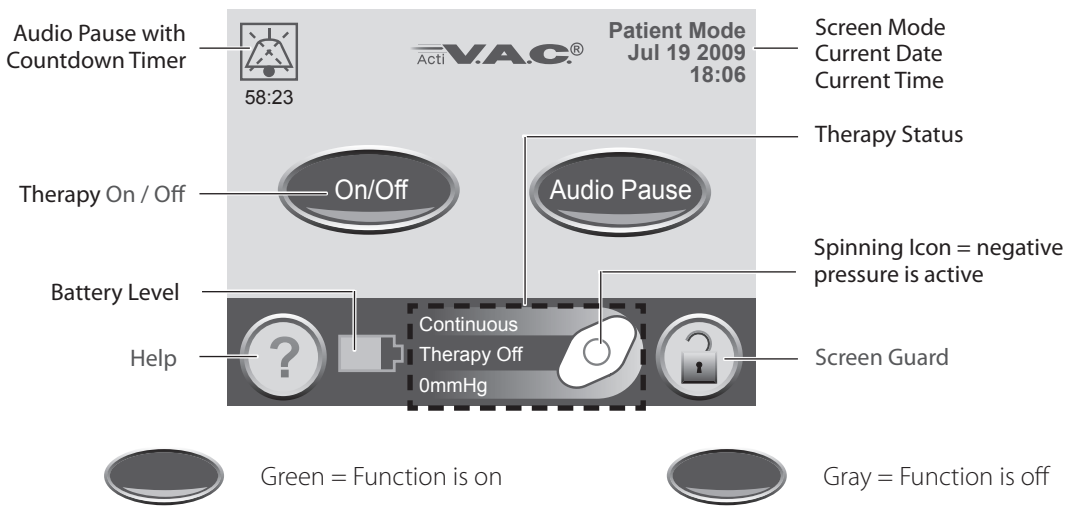
ACTIV.A.C.™ Therapy Unit



The ports on the therapy unit may have a cover.








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

Patient Mode Home Screen



Common Screen Control Buttons

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

-  Help - Access *Help* screens
-  Screen Guard - Turn on Screen Guard to help prevent accidental changes to the unit settings. Use this feature when cleaning the touch screen.
-  Exit - Leave the current screen.
-  Cancel - Stop the action in progress.
-  Next - Go to the next screen.
-  Back - Return to the previous screen.
-  OK - Confirm the selection.

Battery Charging Instructions

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

The battery is not user accessible or serviceable.

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

Static Electricity

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

A static discharge may cause:

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

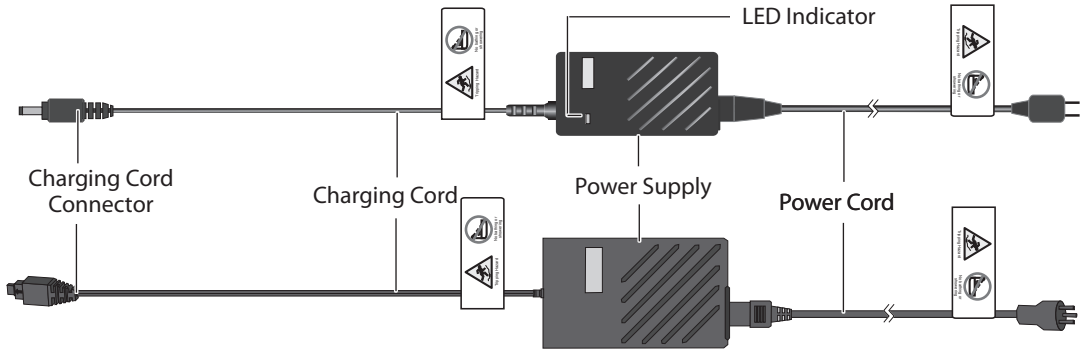


If this happens, turn the unit off then back on. If the unit will not come back on, call KCI.



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

Charge the Battery



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



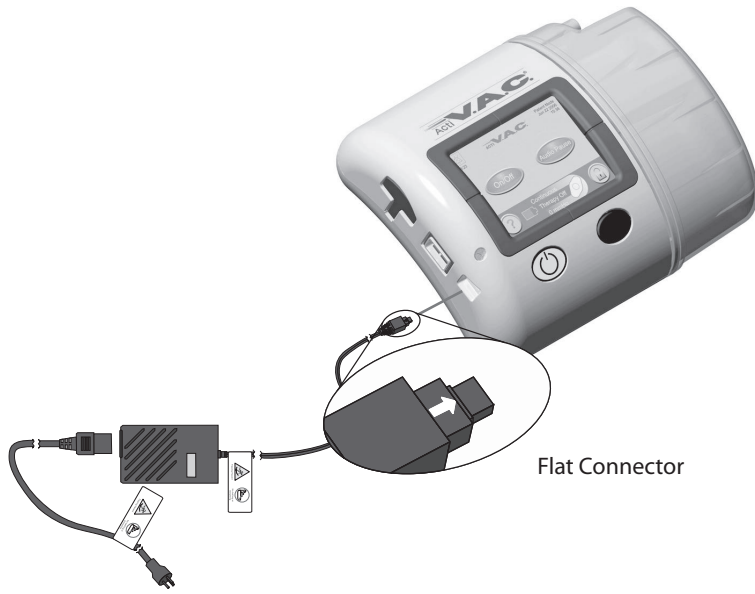
3. Plug the charging cord connector into therapy unit.



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



Round Connector



Flat Connector

4. Keep the unit plugged in whenever possible.



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

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



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



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



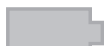
Unplug the power cord from the wall outlet to disconnect the unit from main power.

Battery Charging Light



Battery Level

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



Fully Charged



In Use

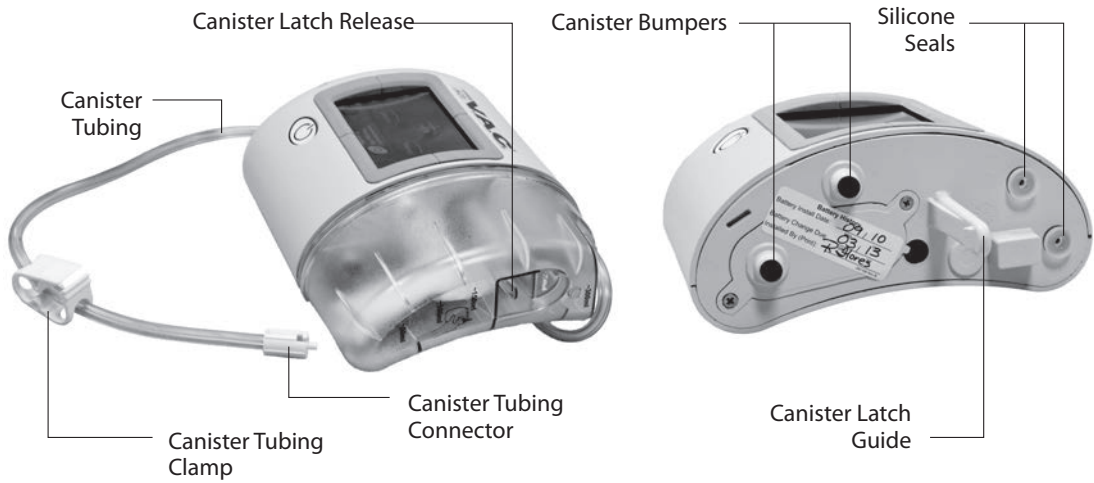


Battery low. Charge battery soon.



Battery critical. **Charge battery immediately.**

Canister



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

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

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



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

Canister Changes

The canister should be changed:

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



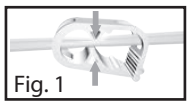
WARNING: If therapy stops or the unit shuts off for any reason, call your doctor or nurse right away. Without active therapy, your dressing will need to be replaced within two hours.



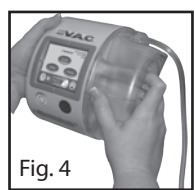
1. Do not turn the therapy unit off.
2. Press On / Off to stop therapy.



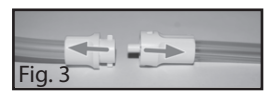
During a Canister Full Alarm, therapy will already be off.



3. Slide both tubing clamps toward the tubing connector.
4. Tightly close both tubing clamps to avoid spilling tubing contents (Fig. 1).



5. To disconnect the dressing tubing from the canister tubing:
 - Push the connectors together.
 - Twist the connectors to unlock (Fig. 2).
 - Pull the connectors apart (Fig. 3).



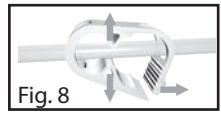
6. To remove the canister:
 - Press down on the canister latch release (Fig. 4).
 - Pull the canister directly away from the therapy unit (Fig. 5).



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

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

8. Connect the new canister tubing to the dressing tubing:
 - Push the connectors together (Fig. 6).
 - Twist the connectors to lock (Fig. 7).



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



10. Press On / Off on the touch screen to restart therapy.
11. Make sure the dressing collapses.

Carrying Case

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



Access Flap with Hook and Loop Fastener



Tubing Storage Straps

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

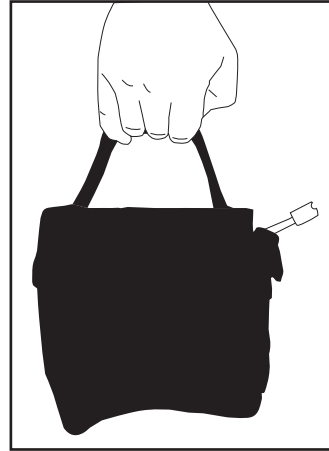
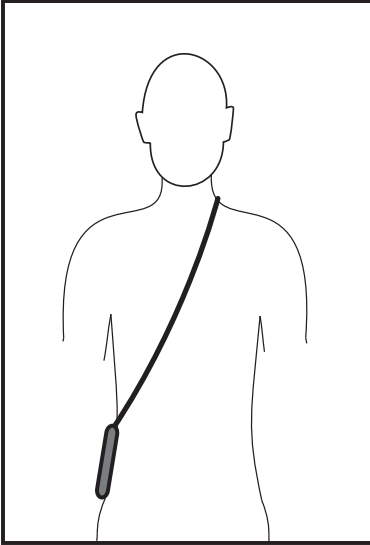


Keep the therapy unit in the upright position.

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

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

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



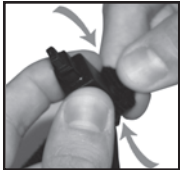
Do not wrap the carrying case strap, power cord or dressing tubing around neck.

Power Supply Retainer Instructions

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



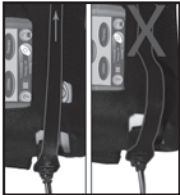
1. Wrap the end tabs of the retainer strap around the charging cord connector.



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



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



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



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



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

Therapy Unit Disconnect

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



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



1. Press On / Off to stop therapy.



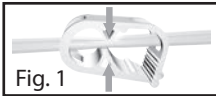
2. Press the Power button to turn the therapy unit off.

3. Unplug the unit if it is plugged in.

4. Slide both tubing clamps toward the tubing connector.

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

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



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

7. Cover the tubing ends with gauze to collect any spillage from tubing.



Operating Instructions



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

Power Therapy Unit On or Off

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



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



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



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

Therapy On or Off

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



Green = function is on



Gray = function is off



Spinning icon = negative pressure is active



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

SEAL CHECK™ Leak Detector

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

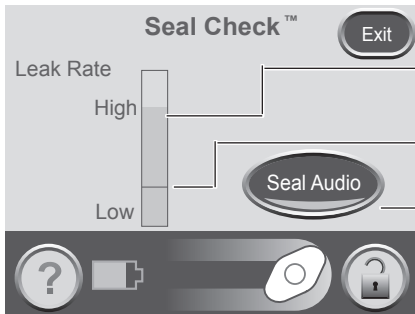


Flashing Green Oval



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

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



Orange bar graph = a significant leak.

Green bar graph = the therapy unit is operating normally.

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

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


Press to turn the Seal Audio tone off.

Find and Fix the Leak

Most leaks occur:

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

To fix the leak:

1. Check the tubing connectors between the dressing and the canister. Make sure they are properly locked.
2. Make sure the canister is properly installed onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit.
3. Use the SEAL CHECK™ Leak Detector to find the leak at the dressing.
 - Make sure therapy is on.
 - Using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad.
 - Watch the bar graph and listen to the audible tone. The bar will get shorter and the frequency of the audible tone will decrease when the leak is found.
4. When the leak is fixed, press  to return to the Patient Mode *Home* screen.
5. If the leak alarm persists or you cannot find the leak, call your doctor, nurse or KCI.

Alerts and Alarms

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

Low Priority Alarm / Alert

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

Medium Priority Alarm

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

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



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



Press Help for more information about the alert or alarm.

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



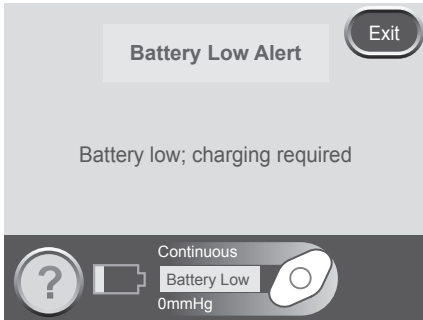
WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Battery Low Alert

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



Therapy will continue during this alert.



This alert is fixed by recharging the battery.

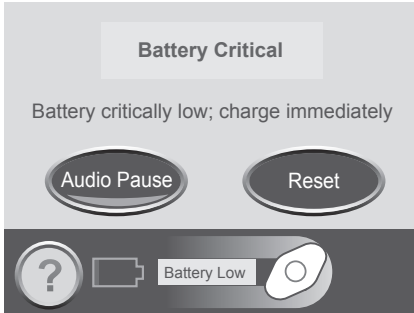
1. Connect the therapy unit to a wall outlet using the power supply. Refer to the **Battery Charging Instructions** section for more information.



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

Battery Critical Alarm

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



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



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

This alarm is fixed by recharging the battery.

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



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



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

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



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

Canister Full Therapy Interrupted Alarm

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



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



Therapy will stop during this alarm.

This alarm is fixed by changing the canister.

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



2. If canister is not full, press Cancel.

3. If the canister is full, change canister (see **Canister Changes** section).



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



5. Restart therapy by pressing On / Off.



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



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



Canister Not Engaged Alarm

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



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



Therapy will stop during this alarm.

This alarm is fixed by reinstalling the canister.

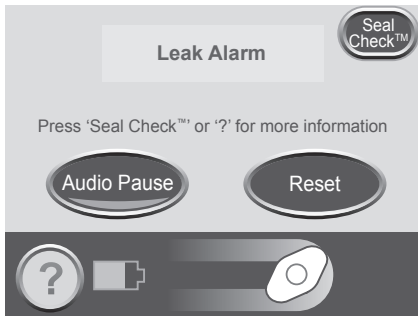
1. Press the canister latch release to remove the canister (see **Canister** section).
 2. Inspect the canister and therapy unit for:
 - Debris between the canister and therapy unit.
 - Two silicone seals (see **Canister** section).
 - Two canister bumpers (see **Canister** section).
 3. If seals or bumpers are missing or damaged, contact KCI.
 4. Reinstall the canister. Make sure that it is fully engaged and latched. An audible click should be heard when the canister is properly installed.
5. Press Reset to return to the Patient Mode *Home* screen.
 6. Press On / Off to restart therapy.
 7. If the alarm continues, install a new canister (see **Canister Changes** section).
 8. If the alarm cannot be fixed, call KCI or your doctor or nurse.



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

Leak Alarm

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



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



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



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

This alarm is fixed by finding and fixing the leak.

Most leaks occur:

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

To fix the leak:

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

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



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

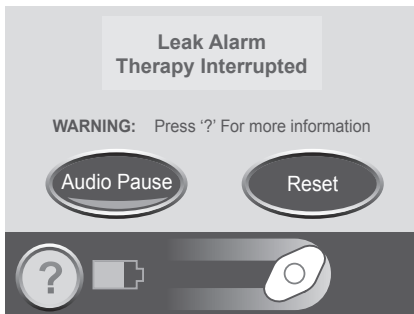
7. If the leak alarm persists or you cannot find the leak, call KCI or your doctor or nurse.

Use the SEAL CHECK™ Leak Detector feature:

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

Leak Alarm Therapy Interrupted

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



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

This alarm is fixed by finding and fixing the leak.

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



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



3. Press On / Off to restart therapy.

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



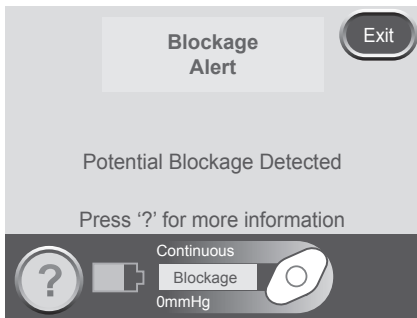
WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.



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

Blockage Alert

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



Therapy will continue during this alert.

This alert is fixed by checking the tubing.

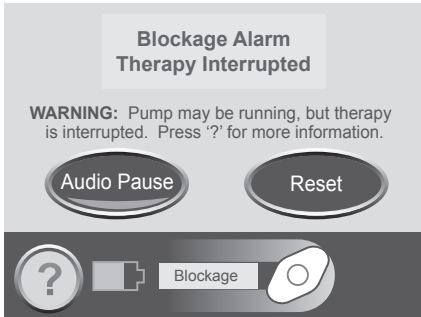
1. Make sure both clamps on the tubing are open.
2. Make sure that the tubing is not kinked, crimped or blocked in any way.
3. If the Blockage Alert remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.



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

Blockage Alarm Therapy Interrupted

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



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



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

This alarm is fixed by checking the tubing.

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



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

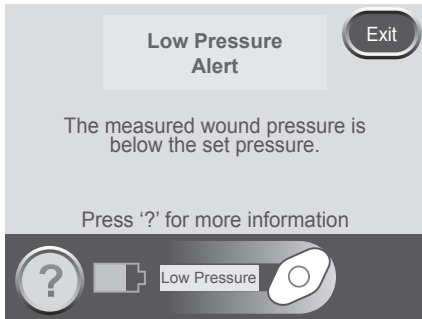
5. If the alarm persists or you cannot find the blockage, call KCI or your doctor or nurse.



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

Low Pressure Alert

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



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

This alert is fixed by checking the tubing.

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



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

Low Pressure Alarm Therapy Interrupted

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



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



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

This alarm is fixed by checking the tubing.

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



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

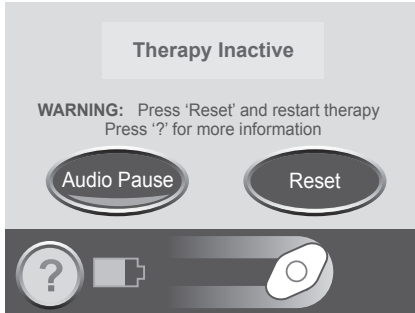
5. If the alarm persists, call KCI or your doctor or nurse.



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

Therapy Inactive Alarm

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



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

This alarm is fixed by restarting therapy.



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



2. Press On / Off to restart therapy.



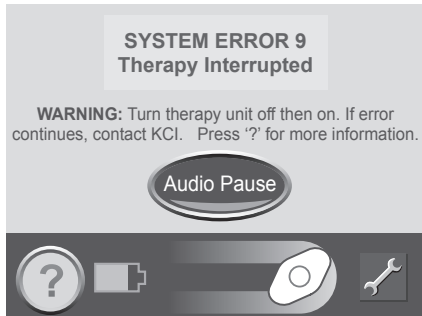
If therapy is not desired, turn the therapy unit off using the Power button on the front of the unit.



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

System Error Alarm

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



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

This alarm is fixed by restarting the therapy unit.

1. Record the error number.



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

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



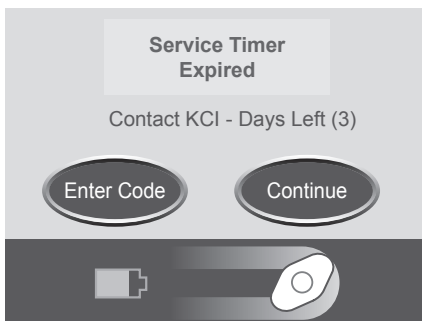
WARNING: If the therapy unit will be off for more than two hours, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced.

Service Timer Expired Alert

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

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

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



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

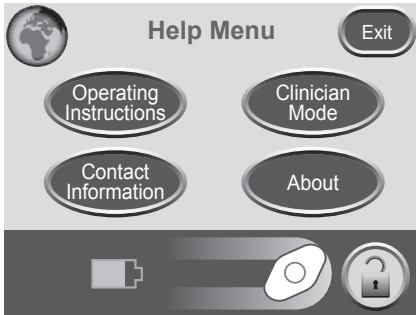
1. Contact KCI for a new service timer code.



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

Help Menu

Change Languages



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



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

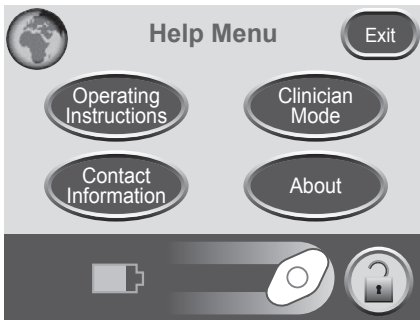


3. Use the + and - buttons to select language.



4. Press Exit when finished.

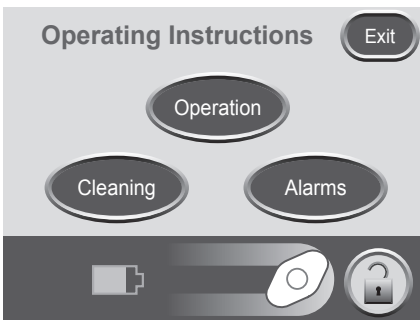
Onscreen Operating Instructions



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



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



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



4. Press Exit when finished.



Operation - Access basic operating guidelines.

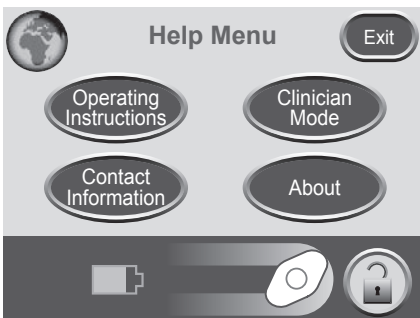


Cleaning - Access basic cleaning guidelines.



Alarms - Access general information for pausing or silencing alarms.

Clinician Mode



Press Help to access the *Help Menu*.



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

Care and Cleaning

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

Disposal

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

Cleaning the Touch Screen



1. Press the Screen Guard button on the *Home* screen (see **Patient Mode Home Screen** section).
2. Use a soft cloth to gently clean the touch screen.
 - Do not use any liquid on the touch screen.
 - Do not press too hard on the touch screen while cleaning.
3. Press the 1 button, then the 2 button on the *Screen Guard* screen to return to the *Home* screen.

Cleaning the Therapy Unit

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

Frequently Asked Questions

Q: How much does the therapy unit weigh?

A: The therapy unit weighs about 2.4 lbs (about 1.08 kg) with an empty canister installed.

Q: How long does it take to charge the battery?

A: It takes about six hours to fully charge the battery.

Q: How long will a fully charged battery last?

A: The battery charge will last up to 14 hours.

Q: The therapy unit is sometimes noisy. Why is this and what can I do about it?

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

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

Q: What happens if the therapy unit alarms?

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

Q: How do I know if the therapy unit is working properly?

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

Q: What if I do not hear an audible click when installing a canister onto the therapy unit?

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

Q: What steps should I take before bathing?

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

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

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

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

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

Q: When should I order more dressings and canisters?

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

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

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

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

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

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

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



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

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

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

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

If you need:

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

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



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



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



ACTIV.A.C.™

THERAPY SYSTEM

For Clinician Use Only

Patients: Refer to Previous Section of This Manual



Important Safety Information Accompanies This Device



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

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

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

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

Warnings: Important Information For Users

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

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



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

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

Notice

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

Introduction

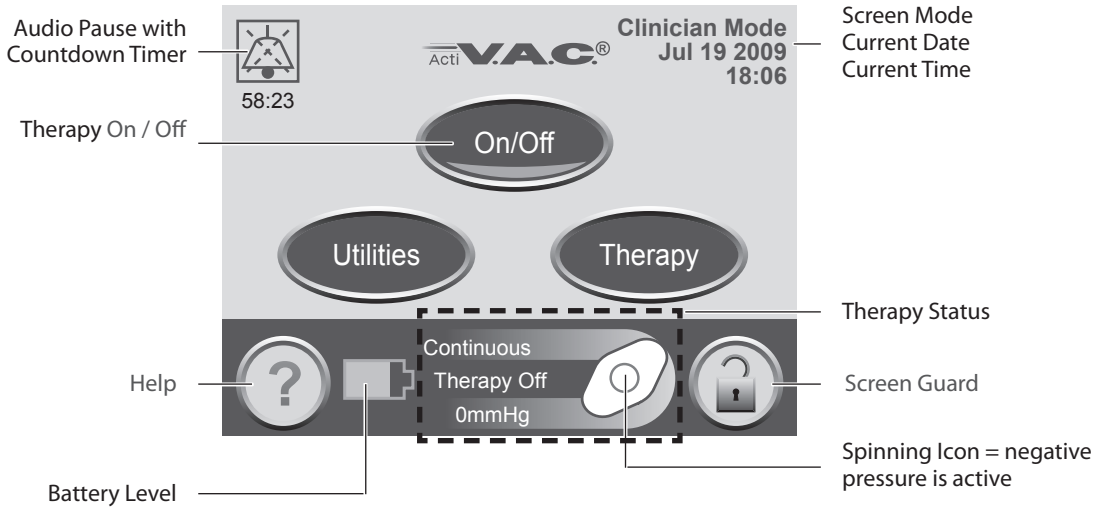
This Clinician information provides operating instructions for the ACTIV.A.C.™ Therapy Unit to the healthcare professional. Many features described are not available in Patient Mode. Patient Mode allows the patient to start and stop therapy, find leaks using the SEAL CHECK™ feature, and attend to alerts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






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

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

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

Clinician Mode Home Screen










-  Green = function is on
-  Gray = function is off
-  On / Off - Start or stop V.A.C.® Therapy.
-  Utilities - Access Region Settings and Time/Date buttons, Screen Brightness and AC Light buttons.
-  Therapy - Access Settings, SEAL CHECK™ Leak Detector, Settings Guide, and History buttons.

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

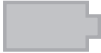



Common Screen Control Buttons

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

-  Help - Access *Help* screens
-  Screen Guard - Turn on Screen Guard to help prevent accidental changes to the unit settings. Use this feature when cleaning the touch screen. To turn off Screen Guard, press 1 and then 2.
-  Exit - Leave the current screen.
-  Cancel - Stop the action in progress.
-  Next - Go to the next screen.
-  Back - Return to the previous screen.
-  OK - Confirm the selection.

Battery Level

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

-  Fully Charged
-  In Use
-  Battery Low. Charge battery soon.
-  Battery Critical. **Charge battery immediately.**

Audio Pause



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



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



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

Operating Instructions



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

Power Therapy Unit On or Off

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



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



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

Therapy On or Off

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



Green = function is on



Gray = function is off



Spinning icon = negative pressure is active



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

Access Manual Therapy Settings



1. From the Clinician Mode *Home* screen, press Therapy, then Next to access this screen.
2. Select desired option from the *Therapy* screen:
 - Settings - Manually set therapy.
 - SEAL CHECK™ - Helps to find leaks.
 - Settings Guide - Helps select preset therapy settings.
 - History - View or export therapy history.

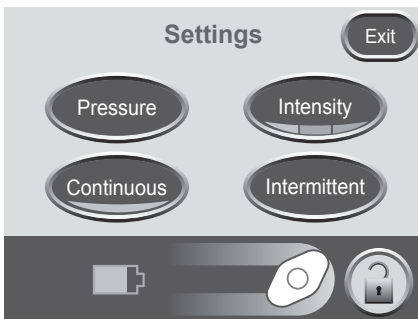


3. Press Exit to return to the Clinician Mode *Home* screen.

Settings



Settings changed manually take immediate effect when therapy is on.

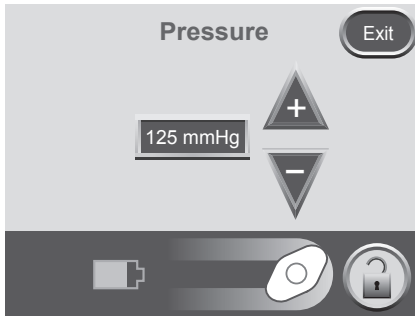


1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings to access this screen.
2. Select desired option from the *Settings* screen:
 - Pressure - Change pressure settings.
 - Intensity - Change Intensity.
 - Continuous - Toggle between Continuous and Intermittent therapy.
 - Intermittent - Set Intermittent therapy times.



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

Pressure Settings



1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings, then Pressure to access this screen.
2. Use the + and - buttons to change the desired pressure. Pressure can be set from 25 to 200 mmHg in increments of 25 mmHg.
3. Press Exit to return to the *Settings* screen.



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

Intensity Control

1. From the Clinician Mode *Home* screen, press Therapy, then Next, then Settings, then Intensity to change intensity level.
 - Intensity is related to the time it takes to reach the target therapy level after the initiation of therapy.
 - The lower the intensity setting, the slower the target therapy level will be reached.
 - It is recommended that new patients begin therapy at the lowest intensity setting as this allows for slower increase of negative pressure once the foam is compressed in the wound.
 - The intensity can remain at the minimum setting throughout the entire length of treatment, if desired.
2. Press to change levels. Green crescent changes with each setting.



Low



Medium

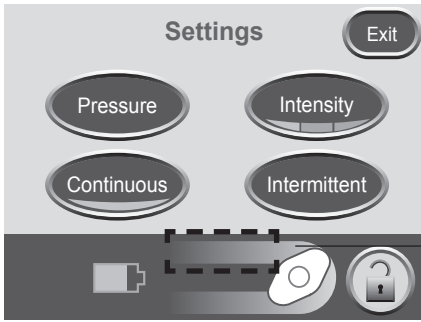


High



Default setting is Low.

Continuous and Intermittent Modes



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



Green = Continuous mode is active.



Gray = Intermittent mode is active.

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



Default setting is Continuous.

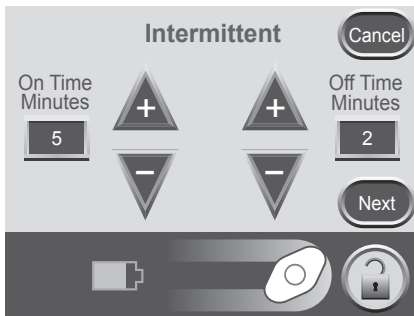


2. Press Exit to continue to the *Confirm* screen.

Intermittent Settings



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



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



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

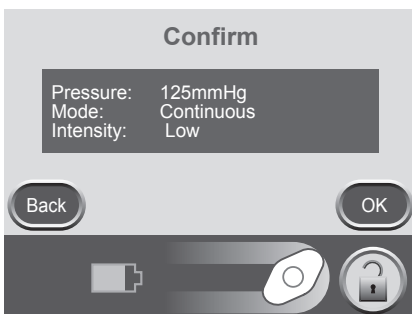


Default setting is On Time = five minutes, Off Time = two minutes.



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

Settings Confirmation



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

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

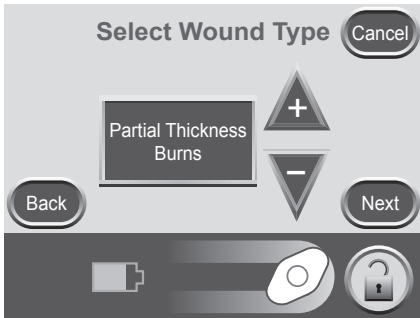


If settings were changed with V.A.C.® Therapy off, press On / Off to start therapy.



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

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



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



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



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



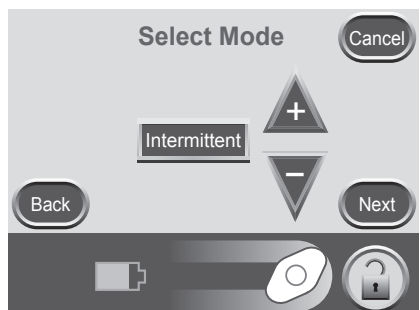
4. Use + and - to scroll through the pressure selections. Pressure selections are in ranges for the wound type selected on the previous screen.



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



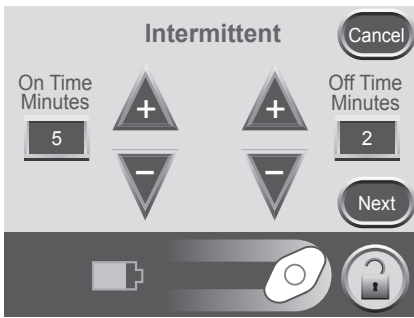
For wound types in which Intermittent is an option, the *Select Mode* screen will appear. If Intermittent is not an option, the *Confirm* screen will appear.



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



7. Press Next to continue.



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

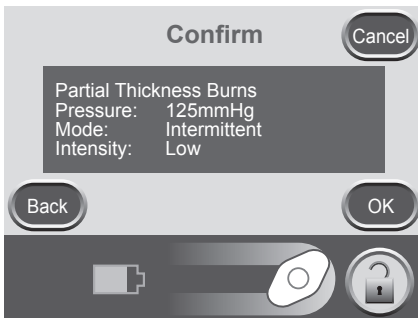


9. Use + and - to change the desired on and off time. Both times can be set from one minute to ten minutes in one minute increments.



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

Settings Guide Confirmation



1. Once the settings are chosen, the *Confirm* screen will appear.
2. Press OK to continue to the Clinician Mode *Home* screen if the displayed settings are as desired, or press Back to change settings.



Settings take effect after OK is pressed.

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

Starting Therapy



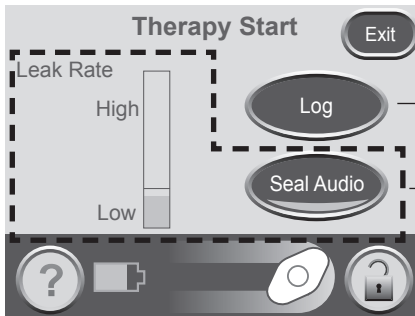
WARNING: Ensure that a new V.A.C.® Dressing has been applied and therapy settings have been selected per physician's orders before starting therapy.



Canister should be properly engaged for therapy to start.



Press On / Off to start therapy.



The *Therapy Start* screen will appear.

Log Tool

SEAL CHECK™ Leak Detector

Options available from this screen:

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

SEAL CHECK™ Leak Detector

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

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



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

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



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

The screenshot shows the 'Therapy Start' screen. On the left, a vertical bar graph is labeled 'Leak Rate' with 'High' and 'Low' markers. A dashed box encloses the 'Log' and 'Seal Audio' buttons. An 'Exit' button is in the top right. At the bottom, there are icons for help, battery, a dial, and a lock.

Orange bar graph = a significant leak.

Green bar graph = the therapy unit is operating normally.

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

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

SEAL CHECK™ feature

Press to turn the Seal Audio tone on or off.

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



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



Most leaks occur:

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

Finding the Leak Using the SEAL CHECK™ Leak Detector

1. Ensure the connector between dressing tubing and canister tubing is properly locked.
2. Ensure the canister is securely installed on the therapy unit. If the canister is properly installed, it cannot be removed by gently pulling it directly away from the unit.
3. While therapy is on and using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad. The bar graph will lower and the frequency of the audible tone (if Seal Audio is on) will decrease when the leak is found.
4. Refer to the instructions for use provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area.
5. When finished press Exit to return to the Clinician Mode *Home* screen.



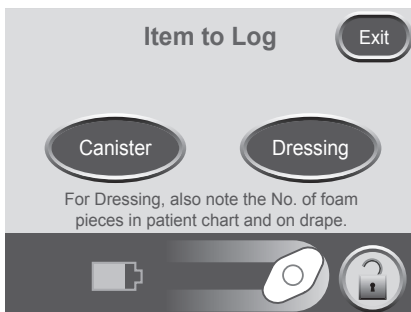
Log Tool

The Log Tool can be used to track:

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

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

How to Use the Log Tool When Starting Therapy



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

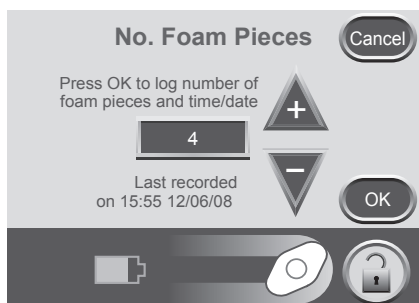
2. Choose Canister or Dressing.



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



1. Press Canister to access the *Canister Replaced* screen.
2. Press OK to log that the canister has been replaced and return to the *Item to Log* screen. The current time and date will be recorded.
3. Press Cancel to return to the *Item to Log* screen without logging an entry.



1. Press Dressing to access the *No. Foam Pieces* screen.
- Information displayed represents the last logged entry.**
2. Use + and - to select the number of foam pieces used during the current dressing change.
 3. Press OK to log the number of foam pieces used and return to the *Item to Log* screen. The current time and date will be recorded.
 4. Press Cancel to return to the *Item to Log* screen without logging an entry.



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



Logged information will appear in Therapy History as follows:

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

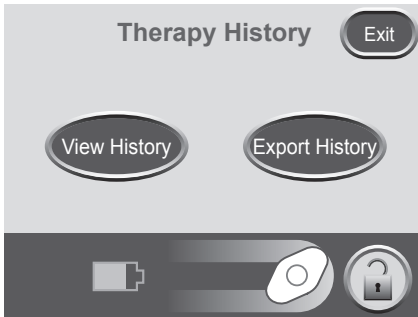
Numeral after Dressing Changed represents the number of foam pieces recorded on the above screen.

View or Export Therapy History



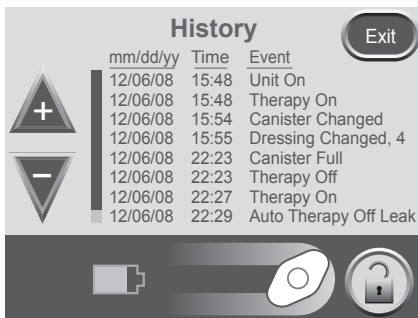
Therapy History is a chronological log of dates and times for therapy starts and stops, therapy settings, unit inactivity that exceeds 15 minutes, alarm occurrences, and manually logged canister / dressing changes.

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



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

View Therapy History



1. Press View History on the *Therapy History* screen to access the on-screen therapy history display.
2. Use + and - to scroll through the Therapy History Report.
3. Hold the + and - buttons to rapidly scroll through the recorded information.

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

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



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

Export Therapy History Report



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

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



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



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



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



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

USB Export Issues

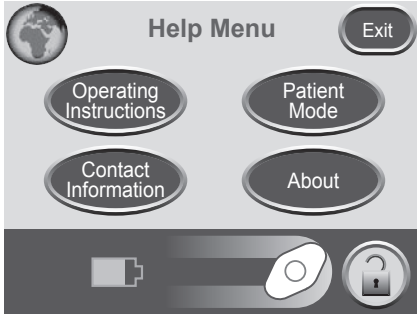
USB:

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

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

Help Menu

Change Languages



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



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

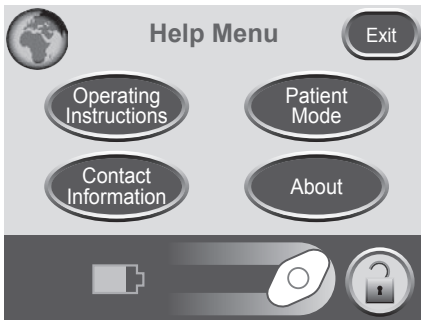


3. Use + and - to select the desired language.

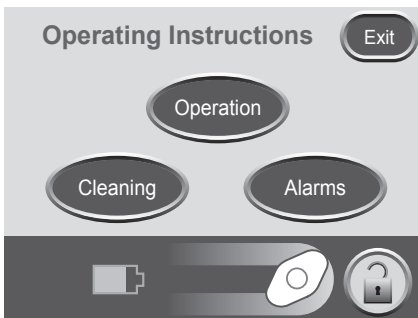


4. Press Exit when finished.

Onscreen Operating Instructions



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



3. Choose from Operation, Cleaning instructions and Alarms for alarm descriptions and suggested resolutions.
4. Press Exit when finished.



Operation - Access basic operating guidelines.



Cleaning - Access basic cleaning guidelines.

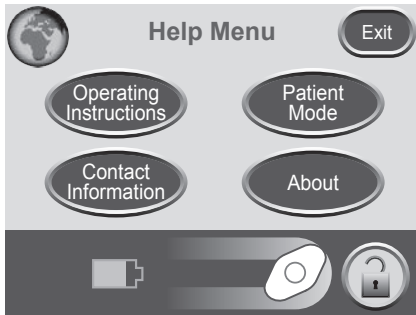


Alarms - Access general information for pausing or silencing alarms.

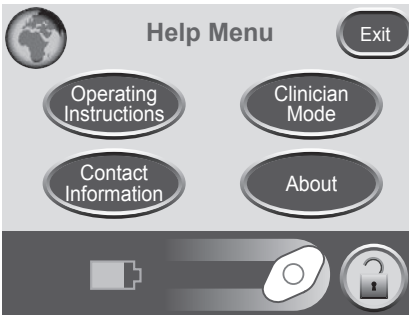
Change to Patient or Clinician Mode



Press Help to access the *Help Menu*.

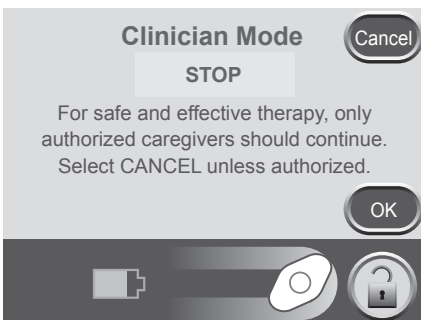


Press Patient Mode to change to *Patient Mode*.



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.



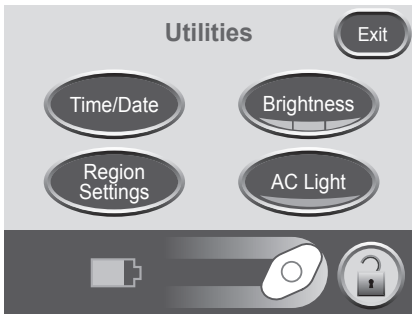
Press OK to return to *Patient Mode*. Press and hold OK for at least 5 seconds to proceed to *Clinician Mode*.



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 Mode *Home* screen.

Change Time and Date

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



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



Hold + and - to rapidly scroll through available selections.

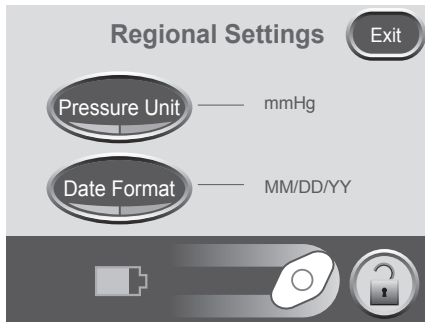


2. Press Exit to return to the *Utilities* screen.

Change Pressure Units and Date Format

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

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



Default settings are mmHg and MM DD YY.



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



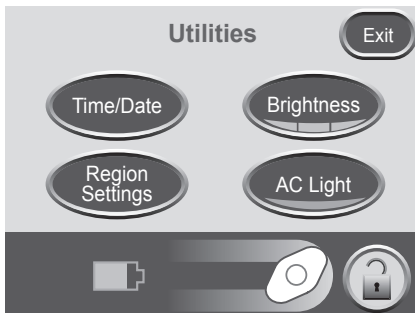
Press Date Format to switch between DD MM YY (Day-Month-Year) and MM DD YY (Month-Day-Year) formats.



Press Exit to return to the *Utilities* screen.

Change Screen Brightness

Press Brightness to switch between three levels of screen brightness.



High



Medium



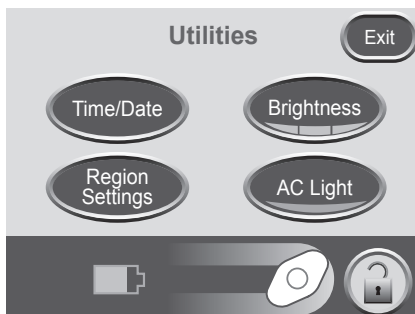
Low



Default setting is High.

Change AC Light

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



On



Off



Default setting is Off.

Care and Cleaning

Standard Precautions

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



Always follow Standard Precautions.

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

Waste Disposal

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

Cleaning the ACTIV.A.C.™ Therapy Unit

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

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



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

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

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

Cleaning the Touch Screen



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



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

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



Do not use any liquid to clean the touch screen.

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

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

Electromagnetic Compatibility (EMC)

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

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



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

- Portable and Mobile RF communications equipment, RFID readers, electronic article surveillance (anti-theft) equipment and metal detectors can affect the performance of the ACTIV.A.C.™ Therapy Unit. Please use the guidelines and recommendations specified in Tables 204 and 206.
- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the ACTIV.A.C.™ Therapy Unit. Care should be used when operating the ACTIV.A.C.™ Therapy Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ACTIV.A.C.™ Therapy Unit and the other equipment should initially be observed to verify normal operation in the configuration in which it will be used.
- The electrical cables, external power supplies and accessories listed or referenced in this manual have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and accessories with the ACTIV.A.C.™ Therapy Unit. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the ACTIV.A.C.™ Therapy Unit and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the ACTIV.A.C.™ Therapy Unit or decreased electromagnetic immunity of the ACTIV.A.C.™ Therapy Unit.

Table 201

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

Table 202

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

Table 204


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

Table 206

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

Included Power Supplies

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



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

Explanation of Symbols Used



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



Important Operational Information



Refer to User Manual



Caution: Consult Accompanying Documents



Keep Dry



Tripping Hazard



No Bathing or Showering



Power On / Off



Manufacturer



Temperature Limitations

Explanation of Symbols Used

IP22 Ingress Protection

IPX0 Ingress Protection



Class II



Type BF, Applied Part



Type B, Applied Part



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

Rx Only

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



Humidity Limitations



MR Unsafe



Serial Number



Catalog Number

Specifications

Specifications subject to change without notice.

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

Electrical:

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

Environmental Conditions (60601 2nd Edition):

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

Environmental Conditions (60601 3rd Edition):

Storage / Transport Conditions
Temperature Range:-13°F (-25°C) to 158°F (70°C)
Relative Humidity Range: 0-93% non-condensing
Operating Conditions
Temperature Range: 41°F (5°C) to 104°F (40°C)
Relative Humidity Range: 15 - 93% non-condensing
Atmospheric Pressure: 1060 hpa to 700 hpa
Expected Service Life..... 3 years

IEC Classification (60601 2nd Edition)

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

IEC Classification (60601 3rd Edition)

Medical Equipment
Equipment not suitable for use in presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
Type BF, Applied Part
Class II
IP22 - Protection against solid objects greater than 12.5 mm and against liquid water falling for short periods of time.

The dressing components of the V.A.C.® Therapy System are considered Applied Parts under IEC 60601-1 Third Edition.

Customer Contact Information

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

In the US call 1-800-275-4524 or visit www.accelity.com.
KCI USA, Inc. 12930 IH10 West San Antonio, TX 78249

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



Manufactured for:

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iON PROGRESS™ Remote Therapy Monitoring Electromagnetic Compatibility (EMC)

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

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



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

- Portable and Mobile RF communications equipment can affect the performance of the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit. Please use the guidelines and recommendations specified in the following tables.
- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit. Care should be used when operating the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit should initially be observed to verify normal operation in the configuration in which it will be used.
- The electrical cables, external power supplies and accessories listed or referenced in this section have been shown to comply with the test requirements listed in the following tables. Care should be taken to use only manufacturer-recommended cables, power supplies and accessories with the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit and they are not listed or referenced in this manual, it is the responsibility of that third-party supplier to determine compliance with the standards and tests in the following tables.
- The use of electrical cables and accessories other than those specified in this manual or referenced documents may result in increased electromagnetic emissions from the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit or decreased electromagnetic immunity of the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit.

Table 1

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

Table 2

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

Table 3


Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the unit should assure it is used in such an environment.			
Immunity Test	EN / IEC 60601 Test Level	Compliance Level	Intended Electromagnetic Environment
Conducted RF EN / IEC 61000-4-6	3Vrms 150kHz to 80MHz	3Vrms 150kHz to 80MHz	Portable and mobile RF communications equipment should be used no closer to any part of the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF EN / IEC 61000-4-3	3V / m 80MHz to 2.5GHz	3V / m 80MHz to 2.5GHz	$d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit.</p> <p>b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V / m.</p>			

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit			
The ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ACTIV.A.C.™ iOn PROGRESS™ Therapy Unit can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the unit as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to frequency of transmitter in meters (m)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80MHz to 800MHz $d = 1.2\sqrt{P}$	800MHz to 2.5GHz $d = 2.3\sqrt{P}$
0.01	.12	.12	.23
0.1	.38	.38	.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

The iOn PROGRESS™ Remote Therapy Monitoring Unit uses cellular radio technology whose radio frequency receiver has the following characteristics:

- Frequency Bands: UMTS (WCDMA) Bands 5 and 2 (869-894 MHz and 1930-1990 MHz)
- Bandwidth within these bands: 5 MHz for each channel

The iOn PROGRESS™ Remote Therapy Monitoring Unit uses cellular radio technology whose radio frequency transmitter has the following characteristics:

- Frequency Bands: Bands 5 and 2 (824-849 MHz and 1850-1910 MHz)
- Modulation: Wideband CDMA
- Effective Radiated Power: 265 mW for 850 MHz, 318 mW for 1850 MHz

Included Power Supplies

Part Number	Description	Manufacturer	Max Length
413708	Cord, ACTIV.A.C.™ International Desktop - External Power Supply	ICC	3.05 m



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

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To learn more about KCI V.A.C.® Therapy Systems, please visit our website at www.acelity.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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