

V.A.C. SIMPLICITY™

THERAPY SYSTEM

User Manual

For Patients and Clinicians



Rx Only



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V.A.C. SIMPLICITY™

THERAPY SYSTEM

For Patient Use



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WARNING: Important Safety Information Accompanies This Device



This manual includes important warnings for your safety. Before using the V.A.C. SIMPLICITY™ 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 if you have any questions about the V.A.C. SIMPLICITY™ Therapy System.

Warnings: Important Information for Users

The V.A.C. SIMPLICITY™ Therapy Unit 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.

- 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 modify the therapy unit or dressing. Do not connect this product or its components to other devices that you may be using.
- Keep the therapy unit away from heated surfaces.
- Do not spill fluids on any part of this product. 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 it 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, sink or toilet.
- Do not reach for a therapy unit that has fallen into water. Unplug the unit immediately if plugged in. Disconnect the unit from dressing and call KCI.
- 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 and turn off the therapy unit.

Introduction

The V.A.C. SIMPLICITY™ 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 start and stop therapy.
- How to handle alerts and alarms.

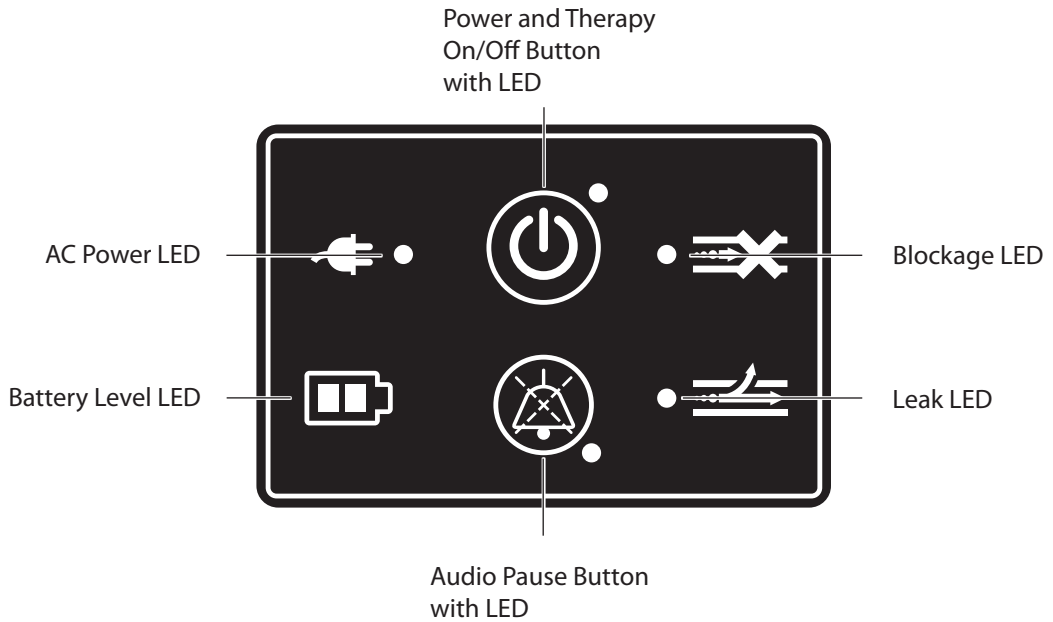


V.A.C.® Therapy is prescribed by a physician or other licensed prescriber. As with any prescription medical device, it is important to follow physician's orders and product instructions. Do not perform therapy application without the express direction and/or supervision of a trained clinical caregiver.

V.A.C. SIMPLICITY™ Therapy Unit



Control Panel



Control Buttons

Power and Therapy On/Off



Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and start therapy. The LED will be solid green. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy. The LED will turn off.

Audio Pause



Press and release **Audio Pause** to silence the audible tone. Do not press and hold. The LED will be solid yellow.

The audible tone will come back on in 60 minutes if the alert has not been fixed.

The audible tone will come back on in two minutes if the alarm has not been fixed.

Battery/Power Icons



The LED will be solid green when the V.A.C. SIMPLICITY™ Therapy Unit is properly connected to AC power.



The LEDs will be green or yellow to show the battery charge status of the V.A.C. SIMPLICITY™ Therapy Unit.

Alarm Icons



The LED will be solid or flash when the therapy unit detects a blockage.

See the *Alerts and Alarms* chapter of this manual (page 21) for details on alarms and how to fix them.



The LED will be solid or flash when the therapy unit detects a leak.

See the *Alerts and Alarms* chapter of this manual (page 21) for details on alarms and how to fix them.

Battery Charging Instructions

The V.A.C. SIMPLICITY™ Therapy Unit contains a rechargeable battery. This battery is charged using the power supply and cord that come 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 the therapy unit shuts off for any reason, call your doctor or nurse right away. Without power to the therapy unit, your dressing will need to be replaced within two hours.*



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. Do not block access to the plug or wall outlet.

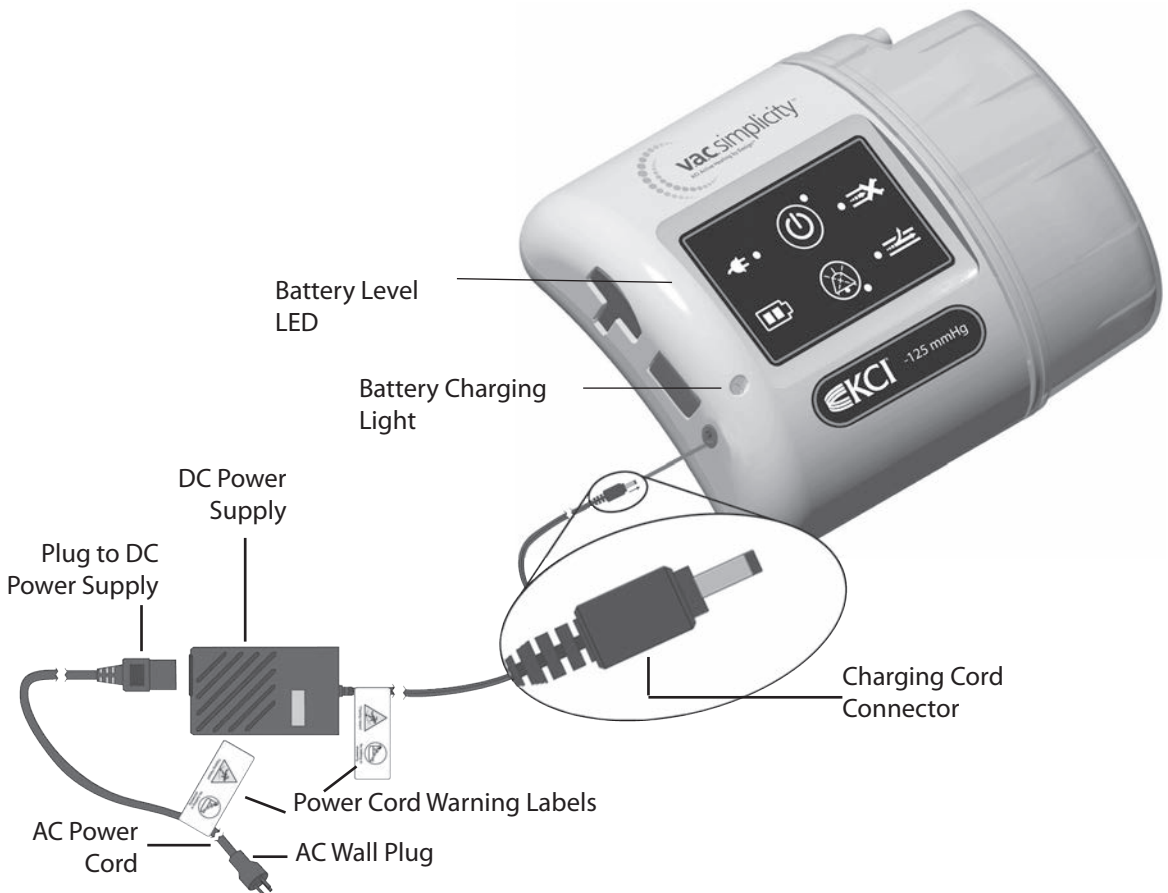
To charge the battery:

1. Plug the power cord into the power supply.
2. Plug the power cord into an AC wall outlet.
3. Plug the charging cord into the therapy unit as shown.
4. Keep the unit plugged in whenever possible to maximize battery life.



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

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



Battery Charging Light

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 left of the control panel (see page 10 or page 13). The battery level is displayed only when the therapy unit is NOT plugged into the power supply.



Fully charged - two green LEDs are lit.



Medium charge - one green LED is lit.

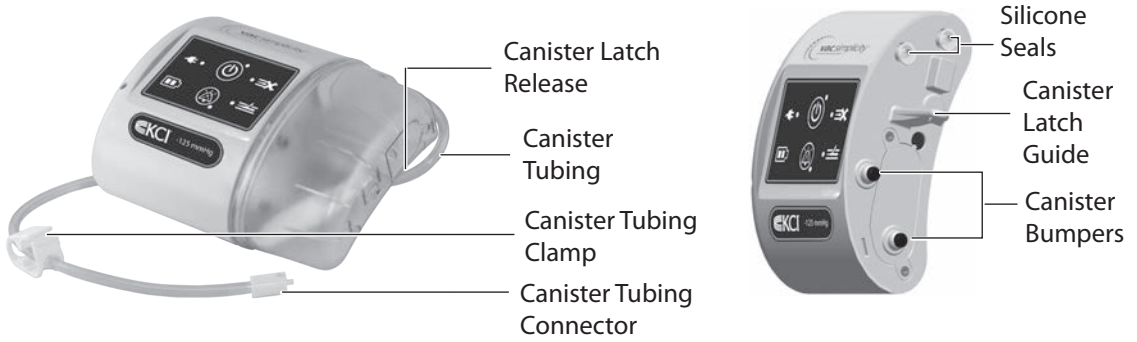


Battery low - one yellow LED is lit. Charge battery soon.



Battery critical - one flashing yellow LED is lit. **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 the canister when installing or removing.

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 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.*

Canister Changes (cont.)



1. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy.

2. Slide both tubing clamps toward the tubing connector.



Fig. 1

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



Fig. 2a

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

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



Fig. 2b

5. To remove the canister:

- Press downward on the canister latch release (Fig. 3).
- Pull the canister directly away from the therapy unit (Fig. 4).



Fig. 3



Fig. 4



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

Canister Changes (cont.)



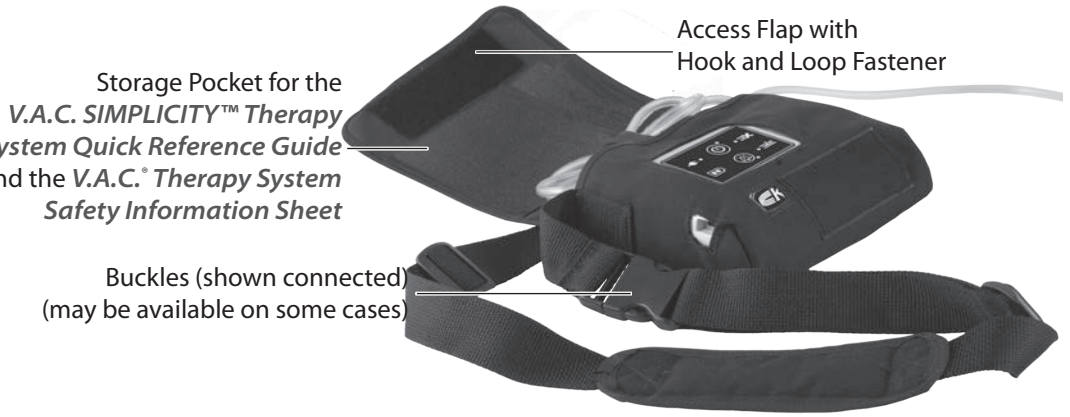
6. To install a new canister:
 - Slide the canister over the canister latch guide.
 - Do not twist or turn the canister as it is being installed.
 - Press the canister firmly onto the therapy unit. When the canister is properly installed, it cannot be removed by gently pulling it away from the unit.
 - An audible click should be heard when canister is properly installed.
7. Connect the new canister tubing to the dressing tubing
 - Push the connectors together.
 - Twist the connectors to lock (Fig. 5a and 5b).
8. Open both tubing clamps (Fig. 6).
9. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and restart therapy.
10. Make sure the dressing collapses.

Carrying Case

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

Buckles (shown connected)
(may be available on some cases)

Access Flap with
Hook and Loop Fastener



Tubing
Storage
Straps

Belt Loop
(may be available on
some cases)



Insert the therapy unit into the carrying case so that the control panel is visible through the cut out window.

Keep the therapy unit in the upright position.

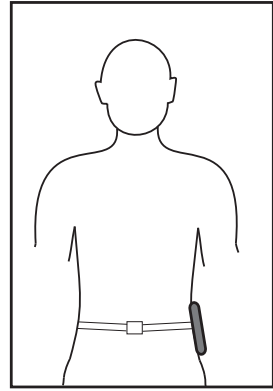
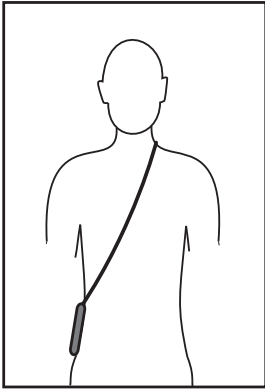


Keep the therapy unit in the carrying case when in use.

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

Carrying Case Options

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



Ensure excess cord and/or tubing do not create a trip hazard.

Therapy Unit Disconnect



You can disconnect the therapy unit from the dressing tubing for short amounts of time for such activities as bathing.



Do not take the therapy unit into the shower or tub. For more information see the *Frequently Asked Questions* on page 30.



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 and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy.

2. Unplug the unit if it is plugged in.



Fig. 1

3. Slide both tubing clamps toward the tubing connector.



Fig. 2a

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. 2a).
- Pull the connector apart (Fig. 2b).



Fig. 2b

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

Turn Therapy Unit On or Off

The **Power and Therapy On/Off** button is located on the top center of the control panel (see page 10 for illustration).

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



2. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on or off and start or stop therapy.



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.*

Alerts and Alarms

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

Low Priority Alert

- Requires patient or caregiver attention.
- Indicated by a ***single*** audible tone and a ***solid yellow LED***.

Medium Priority Alarm

- Requires ***immediate*** attention to ensure your prescribed therapy is being delivered.
- Indicated by a ***repeating*** audible tone and a ***flashing yellow LED***.

See the following pages for instructions on how to fix each alert or alarm.

Audio Pause

Press and release **Audio Pause** to silence the audible tone. Do not press and hold. The LED will be solid yellow.

- The audible tone will come back on in 60 minutes if the alert has not been fixed.
- The audible tone will come back on in two minutes if the alarm has not been fixed.



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



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.

Battery Low Alert (Low Priority)



This alert appears about two hours before the battery power runs out. It is indicated by a ***single*** audible tone and one ***solid yellow LED***.



Therapy will continue during this alert.

To fix this alert, recharge the battery.

Connect the therapy unit to a wall outlet using the power supply. The battery charging light will glow amber as the battery charges. Refer to the ***Battery Charging Instructions*** chapter (page 12) for more information.

Battery Critical Alarm (Medium Priority)

This alarm appears about one hour before the battery power runs out. It is indicated by a ***repeating*** audible tone and one ***flashing yellow LED***.



Press and release **Audio Pause** to silence the audible tone for two minutes. Do not press and hold.



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

To fix this alarm, recharge the battery.

1. Connect the therapy unit to a wall outlet using the power supply. The battery charging light will glow amber as the battery charges. Refer to the ***Battery Charging Instructions*** chapter (page 12) for more information.
2. Make sure therapy is on. The green LED on the power button will be lit.
3. If not, press and hold the **Power and Therapy On/Off** button for three seconds. This will turn the unit on and re-start therapy.



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.

Blockage Alert (Low Priority)

This alert appears when one of three conditions exists:

- Therapy pressure has not been reached. Therapy is still being applied, but at a lower than optimal pressure.
- A blockage may be present. The therapy unit continues to attempt to apply therapy.
- The canister is full and should be replaced



This alert is indicated by a ***single*** audible tone and one ***solid yellow LED***.



Therapy will continue during this alert.

To fix this alert:

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. If the alert is fixed by lowering the unit, normal use may resume.

Blockage Alarm (Medium Priority)

This alarm appears when one of three conditions exists:

- Therapy pressure has not been reached. Therapy is still being applied, but at a lower than optimal pressure.
- A blockage may be present. The therapy unit continues to attempt to apply therapy.
- The canister is full and should be replaced.



This alarm is indicated by a ***repeating*** audible tone and one ***flashing yellow LED***.



Press and release **Audio Pause** to silence the audible tone for two minutes. Do not press and hold.

To fix this alarm:

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 remains after completing steps 1 and 2, lower the therapy unit and tubing to level with or below the wound site.
4. If the alarm is resolved by lowering the unit, normal use may resume.
5. Use the graduated marks on the canister to check the fluid level.



A full canister is approximately 300 ml.

Blockage Alarm (Medium Priority) (cont.)

6. If the canister is not full, make sure the therapy unit is in an upright position. Make sure the control panel is facing up if the therapy unit is laid on a level surface such as a table.



7. If the canister is not full and the alarm continues:

- Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy.
- Wait five seconds and then press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and restart therapy.



8. If canister is full, change the canister (see page 15).



9. After the canister is changed, press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and restart therapy.



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.*



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

Leak Alarm (Medium Priority)

This alarm appears when one of three conditions exist:

- The canister is not properly installed.
- The therapy unit detects a significant leak.
- A dressing leak has not been fixed and therapy is interrupted.



This alarm is indicated by a ***repeating*** audible tone and one ***flashing yellow LED***.



Press and release **Audio Pause** to silence the audible tone for two minutes. Do not press and hold.

To fix this alarm, either:

- Reinstall the canister
- Find and fix the leak.

If this alarm is not fixed within five minutes, therapy will be interrupted.



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.*

Check Canister



1. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy.
2. Press the canister latch release to remove the canister (see page 16).
3. Inspect the canister and therapy unit for:
 - Debris between the canister and therapy unit.
 - Two silicone seals (see page 15 for illustration).
 - Two canister bumpers (see page 15 for illustration).
4. If seals or bumpers are missing or damaged, contact KCI.
5. Reinstall the canister. Make sure that it is fully engaged and latched. An audible click should be heard when the canister is properly installed.
6. Press **Reset** to return to the Patient Mode home screen.



7. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and restart therapy.

8. Verify the dressing collapses.
9. If the alarm continues, install a new canister (see page 17).
10. If the alarm cannot be fixed, call KCI or your doctor or nurse.

Check for Leakage

If this alarm was not the result of a loose or misfit canister, the alarm is because there is a significant negative pressure 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.

To fix the leak:

1. Check the tubing connectors between the dressing and the canister. Make sure they are properly locked.
2. Using light pressure, move your hand and fingers slowly around the edges of the drape and SENSAT.R.A.C.™ Pad. Listen to the pump sound; when the leak is found the pump sound will decrease.
3. Refer to the **Application Instructions** provided with V.A.C.® Dressings for information on using excess V.A.C.® Drape material to seal the leak area. Call your doctor or nurse for assistance if needed.



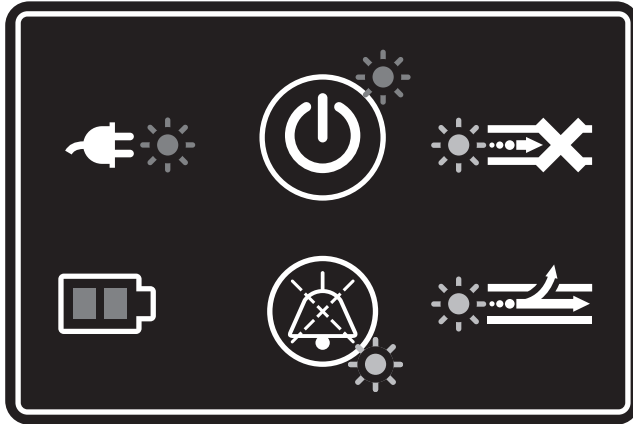
4. To make sure that therapy is on when the leak is resolved, turn the unit off. Wait 15 seconds, then turn the unit back on. Verify the dressing collapses.

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



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.*

System Alarm (Medium Priority)



This alarm appears when the therapy unit detects an internal error. It is indicated by a ***repeating*** audible tone and ***multiple flashing LEDs***.



Press and release **Audio Pause** to silence the audible tone for two minutes. Do not press and hold.

To fix this alarm, restart the unit.



1. Press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit off and stop therapy.
2. Wait 15 seconds and then press and hold the **Power and Therapy On/Off** button for three seconds to turn the unit on and restart therapy.
3. Verify the dressing collapses.
4. If this alarm persists after restarting the unit, call KCI or your doctor or nurse.



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.*

Care and Cleaning

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

1. Unplug the therapy unit.
2. Clean the therapy unit and carrying case as needed 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 2.3 lbs (about 1.04 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 eight 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 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 page 21-27). 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 LED next to the **Power and Therapy On/Off** button will be green. 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* chapter of this manual (page 20) 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: When should I order more dressings and canisters?

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

Q: Can I travel with the V.A.C. SIMPLICITY™ 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 if V.A.C.® Therapy needs to be discontinued.
- A fully charged therapy unit and power cord.
- The V.A.C. SIMPLICITY™ Therapy Unit User Manual and Quick Reference Guide.



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.

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

A: Use the chart below to determine whether 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 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.*



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

Customer Contact Information

For a medical emergency, contact your local emergency services number (911). For medical-related questions regarding your condition, treatment or any other issue, contact your doctor or nurse.

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.

V.A.C. SIMPLICITY™

THERAPY SYSTEM

For Clinician Use Only

Patients: Refer to Previous Section of This Manual



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WARNING: Important Safety Information Accompanies This Device



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

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

As with all prescription medical devices, failure to follow product instructions 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 healthcare provider. 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

The V.A.C. SIMPLICITY™ Therapy Unit 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.

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. Please contact KCI for more information.
- Ensure the electrical installation of the room complies with the appropriate national electrical wiring standards.
- Do not operate this product if it has a damaged power cord, power supply or plug. If these components are worn or damaged, contact KCI.
- Do not drop or insert any object into any opening or tubing of this product.
- Do not modify the therapy unit or dressing. 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.
- 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, sink or toilet. Do not reach for a product that has fallen into water. Unplug the unit immediately if plugged into electrical source. Disconnect the unit from dressing and contact KCI.
- Do not 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.
- 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 patient is sensitive to acrylic adhesives or to silver. The following symptoms may mean indicate an allergic reaction:
 - notice redness
 - notice swelling
 - develop a rash
 - develop hives
 - develop itching
- If patient is short of breath, the allergic reaction may be more serious. Immediately call local emergency services and turn off the therapy unit.

Notice

This product has been configured from the manufacturer to meet specific voltage requirements.

Refer to the product information label for specific voltage.

Introduction

The V.A.C. SIMPLICITY™ 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 wound healing therapy can be readily integrated into the healthcare provider's wound healing practice, helping to optimize patient care and manage costs. This wound healing technology provides microprocessor-controlled therapy units and 24-hour customer service and support.

The patient section of this user manual provides the basic operating instructions for the V.A.C. SIMPLICITY™ Therapy System to the patient, lay caregiver or healthcare professional. Refer to the patient section for information on activating the unit, charging the battery, and resolving alerts and alarms. The patient section also includes frequently asked questions that include troubleshooting information.

This clinician section provides additional information specifically to the healthcare professional including additional warnings, infection control, specifications, EMC precautions and customer contact information.

V.A.C.® (Vacuum Assisted Closure®) Therapy is an integrated wound management system that uses controlled 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 V.A.C. SIMPLICITY™ Therapy Unit is designed to provide a single pressure setting and mode of therapy option – continuous -125 mmHg – which is commonly prescribed by healthcare providers for many types of wounds. Should individual patient conditions or circumstances, in the judgment of the treating physician, require a different pressure setting or mode of therapy options, please contact your supplier to discuss availability of other options that may be appropriate.

Care and Cleaning

The following are the KCI recommended cleaning and infection control procedures for the V.A.C. SIMPLICITY™ Therapy Unit.

Standard Precautions



Always follow Standard Precautions.

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

Waste Disposal

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

Cleaning the V.A.C. SIMPLICITY™ Therapy Unit

Cleaning and disinfection of the V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ Therapy Unit must be cleaned and disinfected:

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
















Ensure that the V.A.C. SIMPLICITY™ Therapy Unit is powered off and disconnected from AC power when using cleaning fluids of any nature.

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

- To help reduce risk of infection and contact with blood and body fluids, use personal protective equipment (PPE) such as medical procedure gloves.
- Clean all organic material (visible soil or body secretions) from the therapy unit prior to disinfection.
- Use hospital-grade cleaners and disinfectants containing quaternary ammonium compounds or other similar disinfectant products.
- 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 control panel edges since alcohol based solutions will easily wick up into small gaps and may cause equipment malfunction.

Explanation of Symbols Used

	Warning or Caution of possible hazard to system, patient or staff	SN	Serial Number
	Important Operational Information		This product is designated for separate collection at an appropriate collection point. Do not dispose of as household waste.
	Refer to User Manual	IP22	Protection level against ingress of solid foreign objects and liquids
	Tripping Hazard		Class II
	No Bathing or Showering		Type BF Applied Part
	Power On/Off		Keep Dry
	Manufacturer	REF	Catalog Number
	Temperature Limitations	Rx Only	CAUTION: Federal (US) law restricts this device to sale/rental by on the order of a physician.
EC REP	Authorized Representative in the European Community		Humidity Limitations

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): about 2.3 lb (about 1.04 kg)
Pressure: -125 mmHg (16.6 kPa)
Therapy Delivery Mode: Continuous
Canister Volume: about 300 ml

Electrical:

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

Environmental Conditions:

Storage 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
Altitude Range: 0 to 14,000 ft (0 to 4267 m)
Optimum Performance: 0 to 8,000 ft (0 to 2438 m)
Atmospheric Pressure 1060hpa to 700hpa

Expected Service Life 3 years

IEC Classification

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.

Electromagnetic Compatibility (EMC)

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

- The V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ Therapy Unit. Please use the guidelines and recommendations specified in Tables 2 and 4.
- Other medical equipment or systems can produce electromagnetic emissions and therefore can interfere with the functionality of the V.A.C. SIMPLICITY™ Therapy Unit. Care should be used when operating the V.A.C. SIMPLICITY™ Therapy Unit adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ Therapy Unit. If a third-party supplier offers cables, external power supplies and electrical accessories for use with the V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ Therapy Unit or decreased electromagnetic immunity of the V.A.C. SIMPLICITY™ Therapy Unit.

Table 1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The V.A.C. SIMPLICITY™ Therapy Unit is intended for use in the electromagnetic environment specified below. The customer or the end user of the V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ 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	Not applicable	
Voltage fluctuations/Flicker Emissions IEC 61000-3-3	Not applicable	

Table 2

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The V.A.C. SIMPLICITY™ 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 home healthcare 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 home healthcare 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 50 Hz or 30 cycles at 60 Hz Single phase: at 0° Interruptions: 0% Ut for 250 cycles at 50 Hz or 300 cycles at 60 Hz	Product has internal battery backup. If the user of the V.A.C. SIMPLICITY™ 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 (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or home healthcare environment.
NOTE: Ut is the AC mains voltage prior to application of the test level.			

Table 3


Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The V.A.C. SIMPLICITY™ 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
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	3Vrms 150 kHz to 80 MHz 6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the V.A.C. SIMPLICITY™ 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 IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	10V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended minimum separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from objects, structures and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the V.A.C. SIMPLICITY™ 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 V.A.C. SIMPLICITY™ Therapy Unit. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.			
Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the V.A.C. SIMPLICITY™ 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 4.			
NOTE: This equipment 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 4

Recommended separation distances between portable and mobile RF communications equipment and the V.A.C. SIMPLICITY™ Therapy Unit			
The V.A.C. SIMPLICITY™ Therapy Unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the V.A.C. SIMPLICITY™ 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)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
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 80MHz and 800MHz, 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
413708	Cord, ACTIVA.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, ACTIVA.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
413626	Cord, V.A.C.® Power, EU-240V	Consolidated Wire	2.05 m



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

Customer Contact Information

For a medical emergency, contact local emergency services. For medical-related questions regarding patient's condition, treatment or any other issue, contact the treating physician.

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.



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