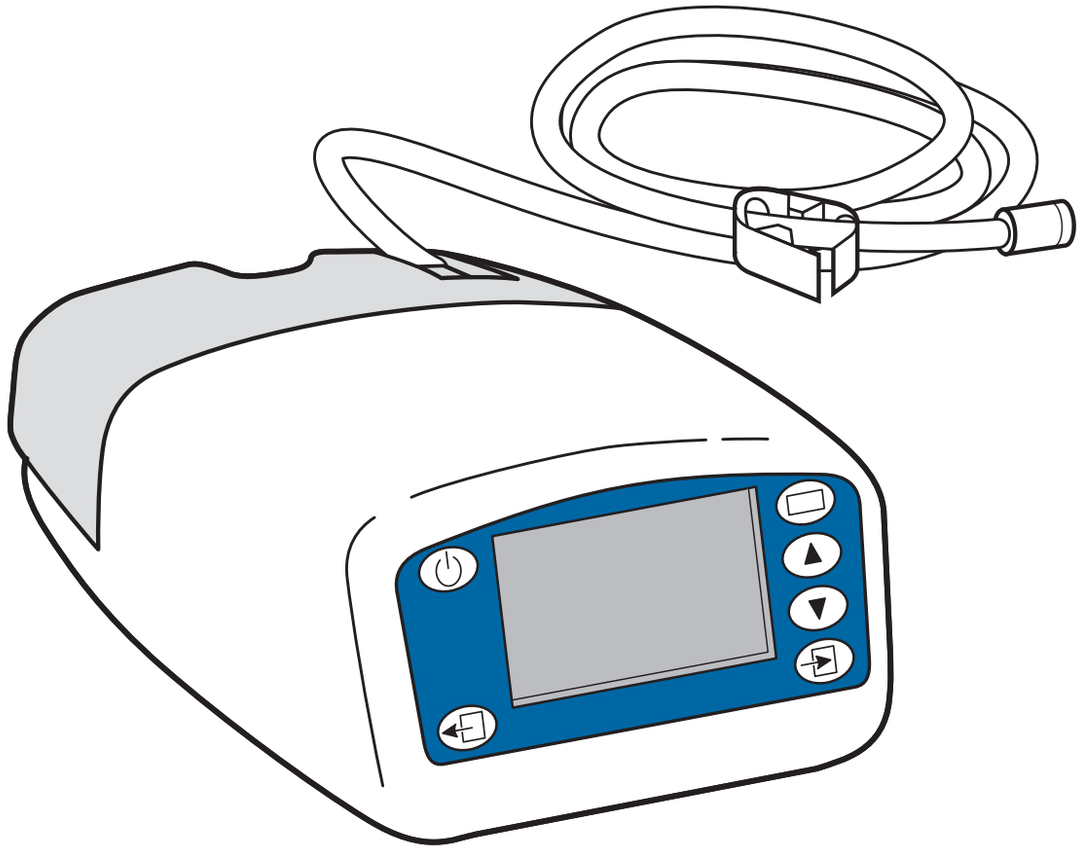
V.A.C. Freedom®

SYSTEM

USER'S GUIDE

320327 Rev B **September 2009**



KCI
The Clinical Advantage®

WARNING

Important Safety Information accompanies this device.

Indications, Contraindications, Warnings, Precautions and other Safety Information are contained in the V.A.C.® Therapy Safety Information Sheet located in the pocket on the top of the V.A.C. Freedom® unit carrying case.

IMPORTANT NOTICE ON UPDATED INFORMATION: THE INFORMATION IN THIS USER'S GUIDE AND THE SAFETY INFORMATION SHEET ACCOMPANYING THIS DEVICE CONTAIN THE MOST RECENT UPDATES TO THIS DEVICE'S INSTRUCTIONS FOR USE AND REPLACES INFORMATION FOUND IN THE ON-SCREEN USER'S GUIDE.

If there are questions or if the V.A.C.® Therapy Safety Information Sheet is missing, immediately contact KCI for a replacement at 1-800-275-4524.

V.A.C.® Therapy Safety Information can also be found on the internet at www.kci1.com.

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IMPORTANT SAFEGUARDS

For medical questions please consult a physician. For additional product information, or specific product questions, please call 1-800-275-4524.

IMPORTANT: **As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions and safety information found in the dressing cartons, top pocket of the carrying case, and KCI's website at www.kci1.com prior to each use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit settings or perform therapy application without directions from/or supervision by your clinical caregiver.**

In order for KCI products to provide safe and proper performance:

- The product must be used in accordance with this User's Guide.
- It is recommended that the V.A.C. Freedom® Therapy Unit always be kept in the carrying case when in use.
- **Please note:** To help provide safe and effective use, V.A.C.® Dressings are only to be used with V.A.C.® Therapy Units.
- All assembly, adjustment, modification, maintenance and/or repair should be carried out by qualified personnel authorized by KCI.
- The electrical installation of the room must comply with the appropriate electrical wiring standards.
- Refer to the **Standard Precautions** section of this user's guide for information on infection control procedures. Refer to the **Care and**

Cleaning section for recommended daily and weekly cleaning for the V.A.C. Freedom® Therapy Unit.

- Never operate this product if it has a damaged power cord, power supply or plug. If the power cord, power supply or plug is worn or damaged, contact KCI at 1-800-275-4524.
- Never drop or insert any object into any opening or tubing of the V.A.C. Freedom® Therapy System.
- Do not use attachments not recommended by KCI.
- Keep the V.A.C. Freedom® Therapy System away from heated surfaces.
- Although the V.A.C. Freedom® Therapy System conforms to 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.

Warning: Liquids 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.

- Avoid spilling fluids on any part of the V.A.C. Freedom® Therapy Unit.
- If spills do occur, unplug the unit immediately if plugged into electrical source and clean the unit with an absorbent cloth. Ensure there is no moisture in or near the power connection and power supply components before reconnecting power. If the V.A.C. Freedom® Therapy Unit is not working properly, contact KCI.

IMPORTANT SAFEGUARDS (CONT.)

- Do not use V.A.C. Freedom® Therapy Unit 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.

INTRODUCTION

The V.A.C. Freedom® Negative Pressure Wound Therapy System provides therapy that creates an environment which promotes wound healing. Controlled, localized subatmospheric pressure is applied to draw the wound edges together.

The V.A.C. Freedom® System is designed specifically for patients who require mobility.

V.A.C.® (or Vacuum Assisted Closure®) brand therapy removes exudate and infectious materials from the wound site.

All disposable components of the V.A.C.® (or Vacuum Assisted Closure®) Therapy System, including the foam dressing (i.e., V.A.C.® GranuFoam®, V.A.C. GranuFoam Silver®, or V.A.C.® WhiteFoam Dressing), tubing, and drape, are packaged sterile. Canisters are supplied with a sterile fluid path. All disposable components are latex free and they are for single use only. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology, physician/clinician preference, and institutional protocol.

To help ensure safe and effective use, the V.A.C.® GranuFoam®, V.A.C. GranuFoam Silver®, and V.A.C.® WhiteFoam dressings are to be used only with V.A.C.® Therapy Units.

WARNING: Review all V.A.C.® Therapy Safety Information in the Safety Information Sheet located in the top pocket of the V.A.C. Freedom® carrying case before initiating V.A.C.® Therapy.

NOTE: *When making adjustments, use the* ***Buttons and Display*** *section of this guide for easier navigation.*

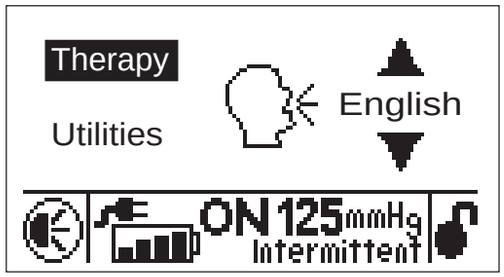
NOTE TO CLINICIANS: *It is recommended that the* ***Therapy Lockout*** *feature be used when patients are left unattended to prevent unintentional changes to therapy settings.*

Carefully read the **Safety Information** located in the top pocket of the V.A.C. Freedom® carrying case as well as the **Important Safeguards** and **Standard Precautions** sections of this guide prior to operating the V.A.C. Freedom® Unit.

1. Verify tubing is connected and both clamps are open.
2. Press the ON/OFF button, shown at right, to activate unit.

The display shows the start-up screen sequence (Button Description) for 15 seconds. After 5 seconds, press any button to bypass the Button Description screen.

The next screen to be displayed is the Home Screen as shown at right.



Home Screen

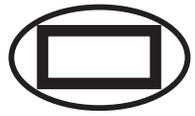
3. Therapy will start automatically.

NOTE: *The unit will default to the last therapy settings used unless buttons are pressed to change settings.*

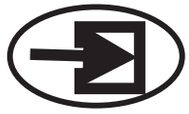
4. To change therapy settings:

a. Press the SELECT button, shown at right, until Therapy is highlighted.

b. Press the ENTER Button, shown at right, to go to the Therapy Menu.



c. Press SELECT Button to highlight the Therapy Option to change (Negative Pressure, Therapy, and/or Intensity).



d. Press the UP/DOWN ARROW buttons, shown at right, to increase or decrease values or to toggle between settings.

Press the SELECT button to highlight the Therapy Option to change, if needed.

If Intermittent Therapy is selected, INTERMITTENT will flash to indicate there is a Sub-Menu. Press the ENTER button to view this Sub-Menu.

Press the UP/DOWN ARROW buttons to set Intermittent Time ON and Time OFF.

Press the EXIT button, shown at right, to return to the Therapy Menu.

e. Press the EXIT button until the Home Screen is displayed.

5. Verify that dressing compresses and there are no leaks in the system.

6. Coil excess tubing and place into tubing pocket of carrying case.

7. Ensure carrying case zipper is securely closed.

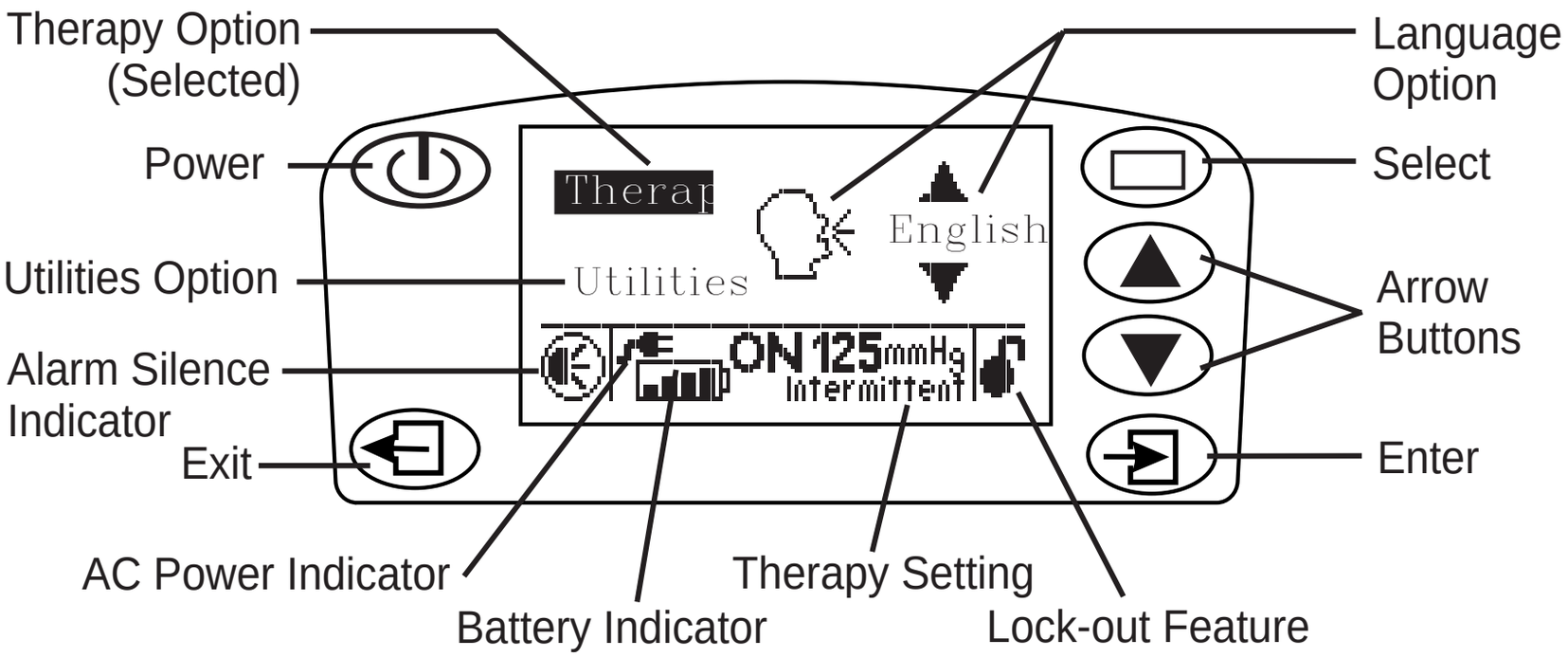
CAUTION: Do not carry or store personal items in the pockets of the carrying case to prevent excess strain on zipper.

8. **For Clinician Use Only:** Press and hold the ENTER and EXIT buttons at the same time to activate/deactivate the lock-out feature and prevent unintentional changes to therapy settings.

CAUTION: Only a physician can prescribe settings. Failure to follow product instructions or

adjusting settings and performing therapy applications without the express direction and/or supervision of your trained caregiver may lead to improper product performance and the potential for serious or fatal injury.

BUTTONS AND DISPLAY



Press to turn unit ON/OFF.

Press to scroll among options.

Press to return to the previous screen.

Press to increase/ decrease numbers or to toggle between settings.

Enters a highlighted option.

CANISTER INSTALLATION

WARNING: Review all V.A.C.® Therapy Safety Information in the Safety Information Sheet located in the top pocket of the V.A.C. Freedom® carrying case before initiating V.A.C.® Therapy.

NOTE: *Unit may remain in carrying case with zipper open during insertion and removal of the canister.*

1. Remove V.A.C.® Canister from packaging.
2. Place back of canister into unit, hooking the middle groove onto the metal bracket. (Fig. 1)

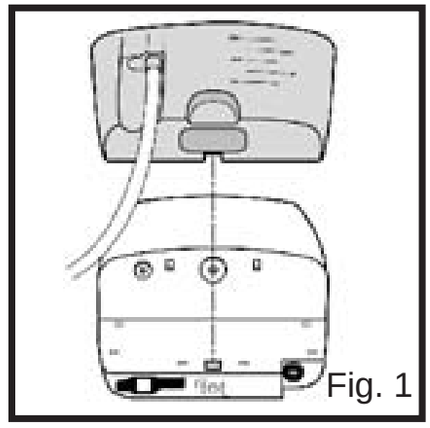


Fig. 1

3. Push front of canister down so that it locks into the unit. (Fig. 2)

   Note: *If the canister is not fully engaged, the V.A.C. Freedom® Therapy Unit will alarm.*

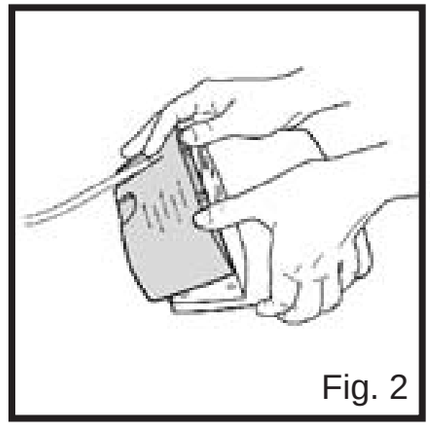


Fig. 2

4. Remove tubing cap from canister if present. Connect T.R.A.C.®/SensaT.R.A.C.® Pad tubing to canister tubing and ensure clamp on each tube is open (Fig. 3). Position clamps away from patient.

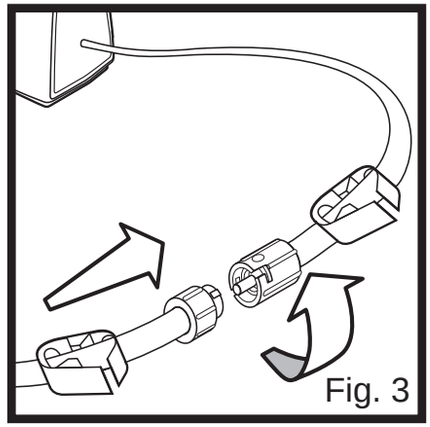


Fig. 3

5. Close zipper on carrying case.
6. Power on V.A.C. Freedom® Therapy Unit to initate V.A.C.® Therapy and select prescribed therapy setting. Refer to the V.A.C® Therapy Clinical Guidelines for specific recommendations.
7. Secure excess tubing in tubing pocket of carrying case to prevent interference with patient mobility.

CANISTER REMOVAL

1. Tighten clamps on canister and dressing tubing.
2. Turn therapy OFF.
3. Twist T.R.A.C.® Connector to disconnect canister tubing from dressing tubing.

4. With the display screen facing you and using both hands, pull the canister in towards the unit to compress seals. (Fig. 4)

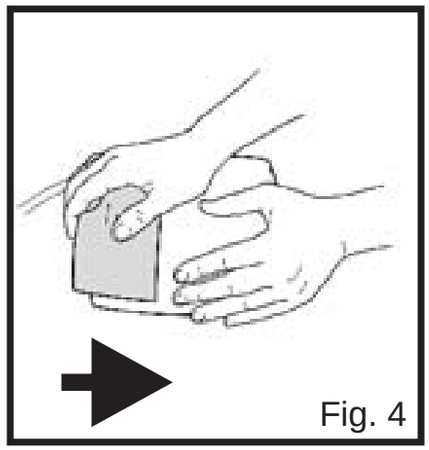


Fig. 4

5. While maintaining the compression of the seals (Step 4), pull up on the far end of the canister, using the finger grip as leverage. (Fig. 5)

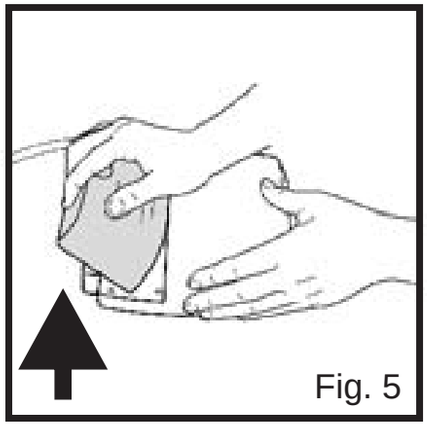


Fig. 5

6. Dispose of canister according to local, state, and federal regulations and institution protocols.


Fig. 6

CANISTER FULL OR TUBING BLOCKED ALARM

1. Stand unit upright to determine the level of exudate in canister. (Fig. 6)

- Canister is full if exudate reaches 300 ml.
- There is a potential blockage in tubing if canister is **not** full.

2. Refer to the Alarm Troubleshooting section of this guide if canister is full or tubing is blocked.

ALARM TYPE	NOTIFICATION	REMEDY
CANISTER FULL OR TUBING BLOCKED Refer to the **Canister Installation and Removal** section of this guide.	Visual message with prompt which cancels after 1 minute if blockage is cleared. After 5 minutes of blockage, therapy is turned off and full alarm is sounded.	Change canister if full and restart therapy. If canister is not full, ensure tubing clamps are open. Check that tubing is not kinked or pinched.
CANISTER MISSING OR TUBING/DRESSING LEAKS	Visual message with audible alarm which cancels after 2 minutes if leak is sealed. After an additional 2 minutes, a full alarm is sounded, and after 5 minutes therapy is turned off.	Pat around drape to check for leaks. If leak is identified, patch the leak with extra drape. Ensure T.R.A.C.® Connector is properly locked. Ensure V.A.C. Freedom® Canister is fully engaged.
THERAPY NOT ACTIVATED	Visual message accompanied by an audible alarm after 15 minutes with therapy OFF.	Ensure alarm conditions are resolved and restart therapy.
BATTERY LOW	Audible alarm accompanied by a visual message before shutdown.	Connect unit to an electrical source to recharge the battery.
INTERNAL DEVICE OR INTERNAL MEMORY ERROR	Visual message accompanied by an audible alarm.	Device is not operable. Disconnect device, remove dressing, and contact KCI at 1-800-275-4524.

NOTE: *In the event of an emergency, please contact your local emergency response number and your treating physician or home health agency.*

WARNING: **Under clinician supervision, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted for more than two hours.**

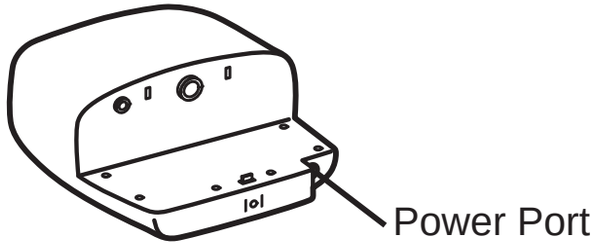
BATTERY OPERATION

NOTE: *The patient need not be removed from the V.A.C. Freedom® unit to recharge the internal battery supply, nor does the unit need to be removed from its carrying case.*

CAUTION: Use only the power supply provided with the V.A.C. Freedom® Therapy Unit. Using any other power supply may damage the V.A.C. Freedom® Therapy Unit.

RECHARGING BATTERY:

1. Plug the detachable Power Cord into the Power Port on the V.A.C. Freedom® Therapy unit as shown at right.



2. Plug the Power Cord into an outlet that is not operated by a light switch to avoid inadvertent power shutoff.

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

When the unit is connected to an AC power supply, the **power cord icon** (shown at right) will appear on the display screen, and the **green LED will light** to indicate battery is charging. The battery indicator icon will also flash in sequence.

When the V.A.C. Freedom® Unit is disconnected from the AC power supply or Power Cord, the unit will automatically revert to internal battery operation. The battery icon (shown at right) will appear on the display screen. **The green LED light will go out.**

AVERAGE BATTERY LIFE: Approximately 12 hours**,** depending on settings and dressing leaks.

AVERAGE TIME TO RECHARGE: Approximately 12 hours to reach full charge.

LOW BATTERY ALARM: An audible alarm will sound when the battery is very low.

AUTOMATIC SHUTDOWN: If the battery charge falls below a critical level, the unit will automatically turn off. To restore power, plug unit into an AC power supply and press the ON/OFF button.

WARNING: Under clinician supervision, replace V.A.C.® Dressing with alternate dressing if therapy is interrupted for more than two hours.

Always follow Standard Precautions.
Standard Precautions are provided for personal protection and 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. Standard Precautions 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.

Hand Washing
Proper hand washing is the most important step in preventing the spread of infection. Follow these steps to properly wash hands:

- Wet hands with warm, running water and apply liquid or clean bar soap. Lather well.
- Rub hands together vigorously for at least 15 seconds.
- Scrub all surfaces, including the backs of hands, wrist, between fingers and under fingernails.
- Rinse well.
- Dry hands with a clean or disposable towel.
- Use a towel to turn off the faucet.

Alcohol based hand sanitizers are a good alternative when soap and water are not available. They have been shown to be more effective than soap and water in decreasing the number of bacteria and viruses. Use only 'alcohol based' products since the hand sanitizers without alcohol do not have the same effect. To properly use an alcohol based sanitizer, follow these steps:

- Apply about ½ teaspoon of the product to the palm of the hand.
- Rub hands together, covering all surfaces of the hands, until they are dry.

If hands are visibly dirty, however, wash with soap and water rather than a sanitizer.

Wash hands before and after direct contact with the patient. When using gloves, wash hands immediately after gloves are removed, between patient contacts and when necessary to avoid transfer of microorganisms to other patients or environments. It may be necessary to wash hands between tasks and procedures on the same patient to prevent cross-contamination of different body sites.

Gloves

Wear medical gloves when touching blood, body fluids, secretions, excretions and contaminated items. Put clean gloves on just before touching moist areas, such as mucous membranes and non-intact skin. Change gloves between tasks and procedures on the same patient when gloves become contaminated or soiled. Remove gloves promptly after use, before touching non-contaminated items and environmental surfaces. Gloves do not provide complete protection against hand contamination. Hands should be washed immediately after completed tasks or procedures to avoid transfer of microorganisms to other people or environments.

Mask, Eye Protection, Face Shield

Wear a mask and eye protection or a face shield to protect the mucous membranes of the eyes, nose and mouth during procedures, and patient care activities that are likely to generate splashes or sprays of blood, body fluids, secretions and excretions.

Gown
Wear a gown (a clean, non-sterile gown is adequate) to protect skin and to prevent soiling of clothing during procedures and patient care activities that are likely to generate splashes or sprays of blood, body fluids, secretions or excretions. Select a gown that is appropriate for the activity and amount of fluid likely to be encountered. Remove a soiled gown as promptly as possible, and wash hands to avoid transfer of microorganisms to other people or environments.

Patient Care Equipment
Handle used patient care equipment soiled with blood, body fluids, secretions and excretions in a manner that prevents skin and mucous membrane exposures, contamination of clothing and transfer of microorganisms to other patients or environments.

Linen
Handle, transport and process used linen soiled with blood, body fluids, secretions and excretions in a manner that prevents skin and mucous membrane exposures and contamination of clothing and that avoids transfer of microorganisms to other people, patients and environments.

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

CARE AND CLEANING

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

CAUTION: To reduce the risk of transmission of bloodborne pathogens, apply standard precautions for infection control to all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. Use gloves, gown and goggles if exposure to body fluid is likely.

NOTE: *The Patient need not be removed from the V.A.C. Freedom® System when performing weekly cleaning procedures.*

Perform a daily visual inspection of the unit. Check for any signs of contamination. Follow weekly care and cleaning anytime signs of contamination are observed.

At least once per week, the V.A.C. Freedom® Unit should be wiped over with either a diluted solution of 5 milliliters bleach to 1 liter warm water (1 teaspoon bleach to 1 quart water) or mild disinfectant. Use a coarse cloth and wring out excess solution until the cloth is damp and not dripping. Other fluids should not be used as they may damage the V.A.C. Freedom® Unit enclosures. Please read Caution on next page.

CAUTION: Avoid spilling liquid on any part of the therapy unit. Liquids remaining on electronic controls can cause corrosion which can cause the electronic components to fail. Component failure may cause the therapy unit to operate erratically, possibly causing a potential hazard to patient or caregiver. Particular care must be taken when handling undiluted disinfectant concentrate or chlorine bleach, including proper shielding of eyes. Always mix by adding concentrated disinfectants or chlorine bleach to the water. NEVER mix disinfectants with each other or with chlorine bleach.

WARNING

Possible Risk of Electric Shock - V.A.C.® Therapy Unit must only be used with KCI-supplied Power Supply that is suitable for your country's voltage. Connect power supply with dry hands to V.A.C.® Therapy Unit first before connecting to main voltage. Use device in dry locations only.

WARNING

Do not remove the protective cover of the serial port, which is located on the back of the V.A.C. Freedom® Unit. This port is to be used only with devices specified by KCI and which comply with applicable IEC standards.

WARNING

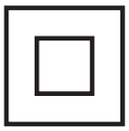
Under no circumstances should a Battery, Charger, or Mains Adapter, other than those supplied with the V.A.C. Freedom® (see list below), be used with the V.A.C. Freedom® System.

- North America: Ault Corp Model MW125KA1803B52
- Europe: Ault Corp Model MW125KA1803M52
- UK: Ault Corp Model MW125KA1803G52
- AU: Ault Corp Model MW125RA1803H02

NOTE: *Failure to use KCI-specified Power Supply will void Electrical Safety Agency Approval and may lead to electrical shock hazard.*

EXPLANATION OF HARDWARE SYMBOLS

HARDWARE



Class II, Internally Powered Equipment

Type B, Applied Part

Caution: Consult Accompanying Documents

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

Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

IPX0

Not protected against harmful effects of water

Alternating Current

Direct Current

Power On/Off

Waste Electrical and Electronic Equipment

EXPLANATION OF DISPOSABLES SYMBOLS

STERILE DISPOSABLES

LOT — Lot/Batch Number

STERILE R — Method of Sterilization – Radiation

 Expiration Date

 Date of Manufacture

 Manufacturer

SN — Serial Number

EC REP — Authorized Representative in the European Community

 Single Use Only

 Keep Dry

Latex Free

CE
0473

Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive.

V.A.C. Freedom® Therapy Unit

Dimensions . . . . . 6.5 x 7.5 x 3.125 inches (16.51 x 19.05 x7.9 cm)

Weight . . . . . 3.2 lbs. (1451.5 g)

Pressure Options . . . . . 50 to 200 mmHg

Modes . . . . . Continuous and Intermittent

Medical Equipment with respect to electric shock, fire, and mechanical hazards only in accordance with UL 2601-1, EN60601-1, and CAN/CSA, C22.2 No. 601.1.

IEC Classification:

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

Battery:

Run Life . . . . . approximately 12 hours, depending on settings

Electrical:

Charger/External Power Supply Input . . . . . 100-240 VAC, 50 / 60 Hz,1 Amp

Charger/External Power Supply Output . . . . . 18 VDC, 2.2 Amp

Patient and Enclosure Leakage Current . . . . . < 100 Microamps

Environmental Conditions:

Storage Conditions

Temperature Range . . . . . -4° (-20°C) to 140° (60°C)

Relative Humidity Range . . . . . 10 to 95% Non-condensing

Atmospheric Pressure Range . . . . . 700 hPa to 1060 hPa

Operating Conditions

Temperature Range . . . . . 50°F (10°C) to 85°F (30°C)

Relative Humidity Range . . . . . 30 to 75%

Atmospheric Pressure Range . . . . . 50kPa to 106kPa

*Specifications subject to change without notice.

CAUTION: United States Federal Law restricts the use of this device to sale by or on the order of a physician.

CLASSIFIED C UL US
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QUESTIONS AND INFORMATION

For additional information concerning the V.A.C. Freedom® Therapy System, contact your local KCI Representative or:

KCI USA, Inc.
San Antonio, Texas 78219, USA
1-800-275-4524
www.kci1.com

EC REP
KCI Medical Products (UK) Ltd.
Wimborne Dorset
BH21 7SH
UK
www.kci-medical.com

In the event of an emergency, please contact your local emergency response number and your treating physician or home health agency.