V.A.C.® ATS

USER MANUAL

KCI®
The Clinical Advantage℠

P/N M6252203 REV F 8/12/03

Caution

Federal law restricts this device to sale or rental by or on the order of a physician.

In order for KCI products to provide safe, reliable and proper performance, the following conditions must be adhered too. Failure to comply with these conditions will void any applicable warranties.

- Assembly, operations, extensions, re-adjustments, modifications, or repairs are carried out by qualified personnel authorized by KCI.
- The electrical installation of the room complies with the appropriate national electrical wiring standards.
- The equipment is used in accordance with the accompanying documentation and applicable labelling.
- Technical maintenance for the product is performed by qualified personnel authorized by KCI.

Subject to confidentiality protections, satisfactory to KCI, KCI will make available upon request circuit wiring diagrams, component part lists, descriptions, calibration instructions, or other information which may assist the user's appropriately qualified personnel to repair those parts of the equipment designated by the manufacturer as repairable.

Although this equipment conforms to the intent of the directive 89/336/EEC in relation to Electromagnetic Compatibility, all electrical equipment may produce interference. If interference is suspected, move equipment from sensitive devices or contact the manufacturer.

WARRANTY INFORMATION

IN THE UNLIKELY EVENT OF A DEFECT IN MATERIALS OR WORKMANSHIP, A LOCAL KCI OFFICE, SUBSIDIARY OR AUTHORIZED AGENT WILL REPAIR, REPLACE OR SUPPLY REPLACEMENT PARTS UNDER STANDARD WARRANTY TERMS AND CONDITIONS IN EFFECT AT TIME OF PURCHASE. WARRANTY TERMS AND CONDITIONS ARE SUBJECT TO CHANGE AT ANYTIME WITHOUT NOTICE. WARRANTY TERMS AND CONDITIONS ARE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL KCI BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES AND EXPENSES, INCLUDING DAMAGES TO PROPERTY, DUE IN WHOLE OR IN PART TO THE USE OF THE PRODUCT UNLESS OTHERWISE EXPRESSLY REQUIRED BY LAW.

IN THE EVENT OF DEFECT, REPAIR WORK SHOULD BE COMPLETED BY RETURNING THE THERAPY UNIT TO A LOCAL KCI OFFICE, SUBSIDIARY OR AUTHORIZED AGENT. CONTACT KCI FOR YOUR NEAREST LOCATION.

TABLE OF CONTENTS

V.A.C.® THERAPY CLINICAL APPLICATIONS

Indications:
Indicated for patients who would benefit from a sub atmospheric pressure device particularly as the device may promote wound healing. This includes patients who would benefit from vacuum assisted drainage and removal of infectious material or other fluids from wounds under the influence of continuous and/or intermittent sub atmospheric pressure.

Types of wounds for which V.A.C.® Therapy has been indicated include chronic, acute, traumatic, sub acute and dehisced wounds, partial - thickness burns, diabetic ulcers, pressure ulcers, flaps and grafts.

Contraindications:
Contraindicated for patients with **malignancy** in the wound, untreated **osteomyelitis**, unexplored and non-enteric **fistulas**, or **necrotic** tissue with eschar present. Do not place V.A.C. dressing over **exposed blood vessels or organs**.

Precautions: Always Follow Universal Precautions
Precautions should be taken with patients exhibiting active **bleeding**, difficult wound **hemostasis**, or who are on **anticoagulants**.
When placing the V.A.C. dressing in proximity to **blood vessels or organs**, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers that form a complete barrier between them and the V.A.C. foam dressing. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a barrier, vessel or organ.

Wounds with enteric fistulas may require special precautions in order to optimize V.A.C. Therapy. Refer to the *V.A.C. Therapy Clinical Guidelines* for sample guidelines additional information on clinical applications and therapy considerations. For recommended protocols, please consult the treating physician.

Federal law restricts this device to sale or rental by or on the order of a physician.

V.A.C.® THERAPY CARE AND SAFETY TIPS

KEEP THERAPY ON

Never leave subatmospheric pressure off for more than 2 hours per day. Remove V.A.C.® dressing if subatmospheric pressure is terminated or is off for more than 2 hours per day.

DRESSING CHANGES

Perform aggressive wound cleaning per physician order prior to dressing application. Routine dressing changes should occur every 48 hours. Dressing changes for infected wounds should be accomplished every 12–24 hours. Always replace with sterile disposables from unopened packages. Follow established institution protocols regarding clean versus sterile technique.

Note: All components of the V.A.C. system are packaged sterile. The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology and physician/clinician preference. All components of V.A.C. therapy disposables including the foam, canister, tubing and drape are latex free.

MONITORING THE WOUND

Inspect the dressing frequently to ensure foam is collapsed and negative pressure is being delivered in a consistent manner. Monitor periwound tissue and exudate for signs of infection* or other complications. Extra care and attention should be given if there are any signs of possible infection or related complications. Infection can be serious. With or without V.A.C. therapy, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock and various other complications.

IF DRESSING ADHERES TO WOUND

Instill normal saline into the dressing and let it set for 15–30 minutes, then gently remove the dressing from the wound. Consider placing a single-layer, wide-meshed, non-adherent dressing prior to foam placement.

DISCOMFORT

If patient complains of discomfort **throughout** therapy, consider changing to white PVA Soft-Foam. If patient complains of discomfort during the dressing change, consider pre-medication, use of a non-adherent prior to foam placement or instillation of a topical anesthetic agent such as 1% lidocaine without epinephrine prior to dressing removal.

UNSTABLE STRUCTURES

Over unstable body structures such as unstable chest wall or non-intact fascia, use continuous (not intermittent) therapy to minimize movement and stabilize the wound bed.

SPINAL CORD INJURY

In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system) discontinue V.A.C. therapy to help minimize sensory stimulation.

BODY CAVITY WOUNDS

Underlying structures must be covered by natural tissues or synthetic materials that form a **complete** barrier between the underlying structures and the V.A.C. foam.

V.A.C. DRESSING USE

This and all V.A.C. dressings distributed by KCI are to be used exclusively with the V.A.C. device.

WARNING: Do not pack the foam into any areas of the wound. Forcing foam dressings in a compressed manner into any wound is contrary to KCI recommendations.

*Signs of possible infection may include fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound area, purulent discharge or a strong odor. Nausea, vomiting, diarrhea, headache, sore throat with swelling of the mucous membrane, disorientation, high fever (>102F, 38.8 C), refractory hypotension, orthostatic hypotension, or erythroderma (a sunburn-like rash) may be added signs of more serious complications of infection.

FEATURES

- **T.R.A.C.™ Technology**

T.R.A.C.™ (Therapeutic, Regulated Accurate Care). Ability to accurately sense negative pressure applied at wound site. This feature helps ensure that the target therapy pressure is maintained, even during patient movement.

- **500ml Canister**

A large capacity canister with an integrated hydrophobic and charcoal filter provides bacteriological protection and significantly reduces odor from collected exudate.

- **On-Screen User Guide**

User help screens assist operation.

- **Easy-to-Use Touch Screen**

Allows operator to more easily view and change V.A.C.® ATS therapy settings

- **Removable Power Cord**

Detachable power cord allows greater patient mobility and flexibility.

- **Integrated Battery and Charger**

Provides up to 4 hours battery life. An automatic charging facility switches to battery power when AC/mains power is removed.

- **Extended Pump Life**

Linear, brushless pump with increased life expectancy.

- **Intensity Setting**

The speed at which the target pressure setting is achieved can be varied in accordance with varying wound conditions and pain tolerance as directed by a treating physician.

- **Adjustable Negative Pressure Settings**

Negative pressures can be set between 50 and 200mmHg in increments of 25 mmHg, as directed by a treating physician.

- **Adjustable Therapy**

Application of negative pressure can be selected for continuous or intermittent application, as directed by a treating physician.

- **Therapy Hour Meter**

The total time therapy is applied can be displayed and reset by the caregiver.

- **Integrated IV Pole Clamp**

Allows the therapy unit to be attached to a range of IV poles: 2.2 to 5cm (.9” – 2”)in diameter.

- **Therapy Lockout**

The caregiver can disable the touchscreen controls to prevent unwanted changes.

- **Footboard Hanger**

Extended hanger arm can fit over a range of footboard designs.

Setting up the V.A.C.® ATS Unit

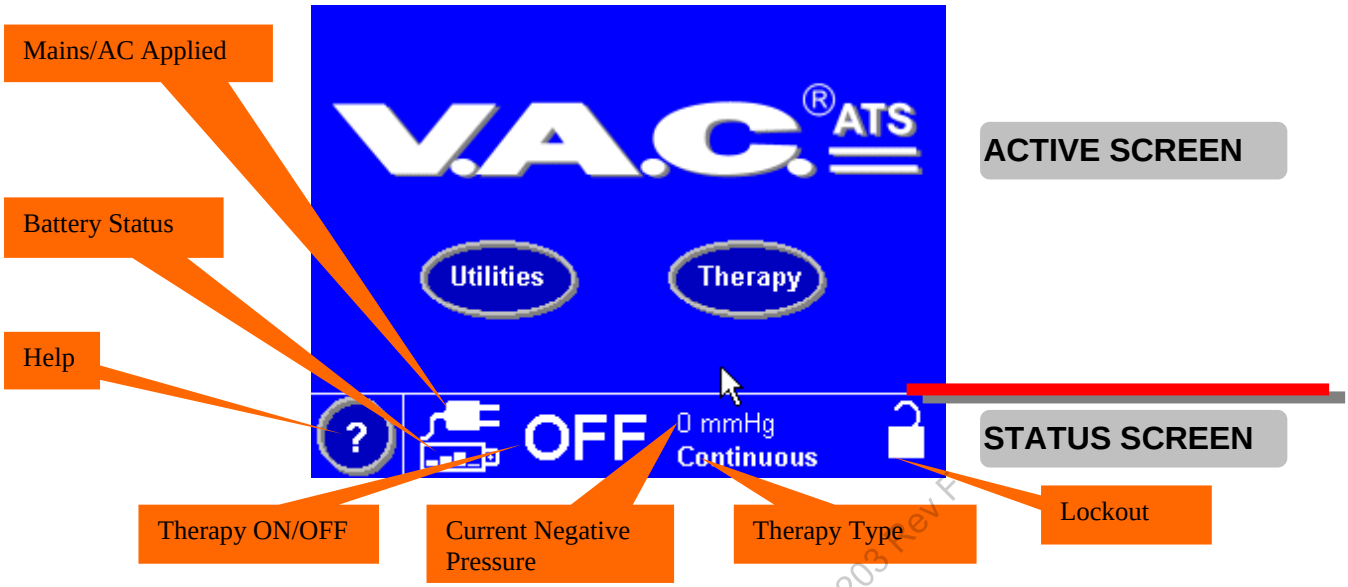
1. **Apply dressing** according to instructions listed on page 8. For canister installation, please refer to page 9.

2. **Place the therapy unit** on the footboard of the bed using the self adjusting hanger which accommodates up to a 7.5cm (3”) thickness footboard. Alternatively the therapy unit can be hung on a suitable IV pole using the integrated IV Pole Clamp located on the rear of the case. Always operate therapy unit in an upright position.

CAUTION:
The IV Pole Clamp should only be used on poles that are in excess of 2.2cm (.9”) diameter and are securely attached to a bed frame or a stable stand. To ensure stability of the therapy unit on the IV pole, it should be clamped no higher than 2 times the width of the pole base. The clamp should be sufficiently tightened to ensure that the therapy unit cannot slide down the pole.

3. **Attach the power cord** to the V.A.C.® ATS unit and connect to a suitable power supply.

4. **Turn on power** to the therapy unit by pressing the green Power ON switch above the power cord.



HOME SCREEN

5. **Press Therapy button** to select Therapy Screen.

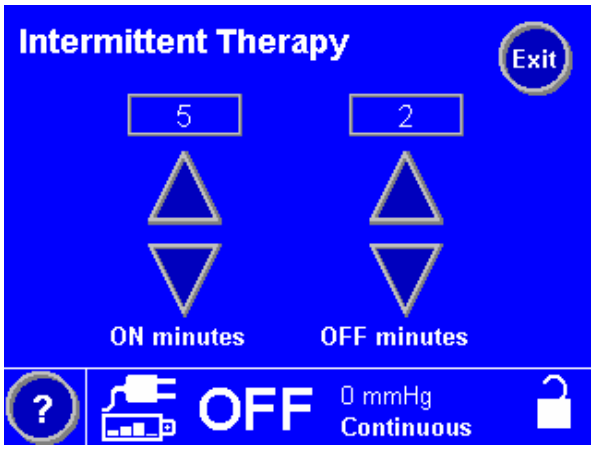
THERAPY SCREEN

6. **Select level of negative pressure:**
   Use arrow keys to increase or decrease therapy levels between 50 and 200mmHg, as per physician order.The therapy unit is set at a standard negative pressure of 125mmHg.

7. Select Continuous or Intermittent therapy:

The standard setting is Continuous therapy. If you select Intermittent, this will take you to the Intermittent Therapy screen.

The standard setting for intermittent therapy is 5 minutes on and 2 minutes off.

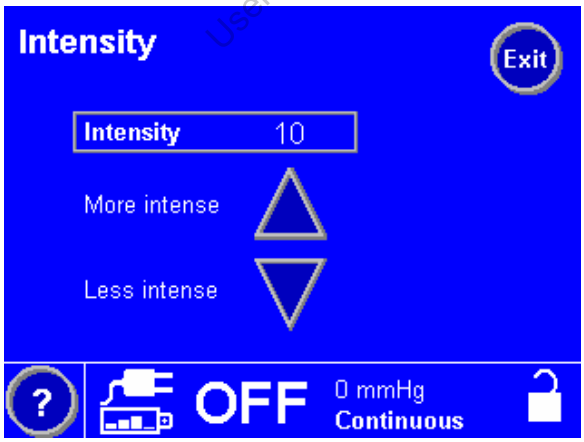


Use the arrow keys to increase or decrease On and Off times between 1 and 10 minutes in accordance with recommended physician guidelines. Press exit to confirm selection and return to Therapy screen.

8. Select Intensity level:

The intensity level is the rate of negative pressure change at the wound site in mmHg per second. The lower the intensity level, the more gradual the negative pressure increases to the desired setting. This option is especially useful for patients who may experience pain and discomfort during initial pull down and release of the foam, especially during intermittent therapy.

The Intensity option ranges from 10 to 50mmHg/sec in increments of 5. The standard setting is 10. It is recommended that new patients start therapy at the standard setting of 10 and increase gradually according to patient tolerance and needs. The intensity can also remain at the minimum setting throughout the entire length of treatment to enhance patient comfort.

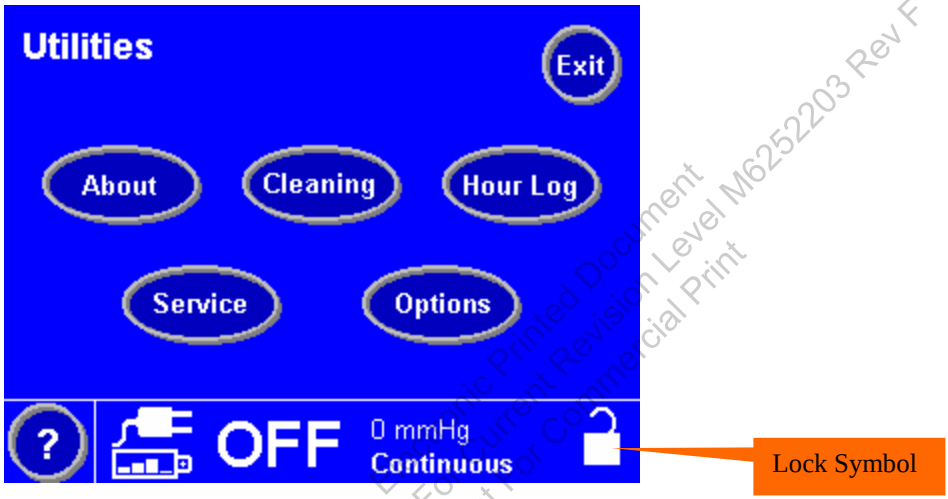


Use the arrow keys to increase or decrease pressure change at the wound site in mmHg per second. This should be adjusted in accordance with varying wound conditions, patient tolerance and at the direction of a physician.

Press Exit to return to the Therapy screen.

Lockout Feature

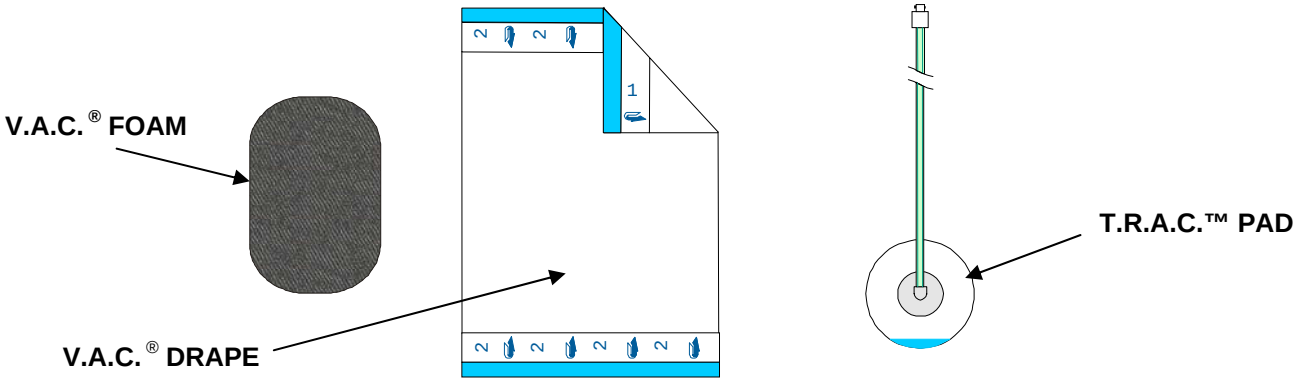
This feature is most useful in preventing individuals from tampering with therapy unit controls or settings. However, it is important that other clinicians in your facility understand how to lock and unlock the screen before the feature is used. The lockout feature is available from all screen menus; example shown is the Utilities Screen.

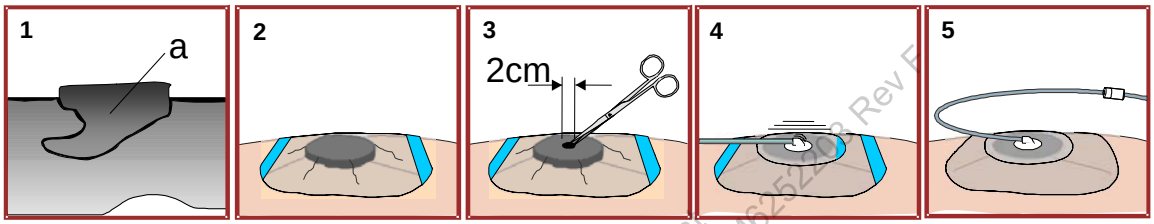


To Lock Touchscreen:
Press the Lock symbol for 3 seconds to disable the touchscreen user controls.
The lock symbol will now be closed to indicate the touchscreen controls are locked.

To Unlock Touchscreen:
To unlock the controls press the lock symbol for 3 seconds.
The lock symbol will now be open to indicate the controls are unlocked.

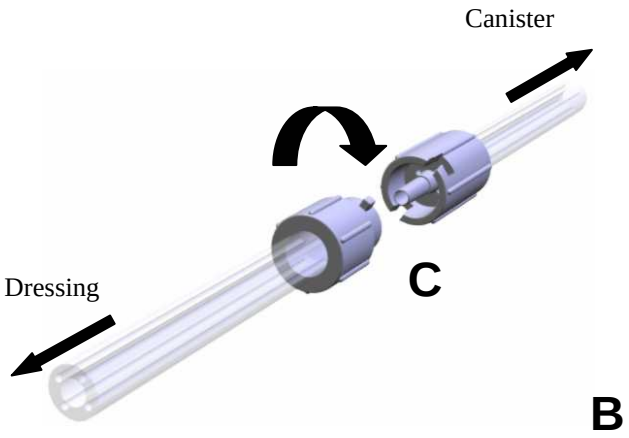
Pouch Contents Identification

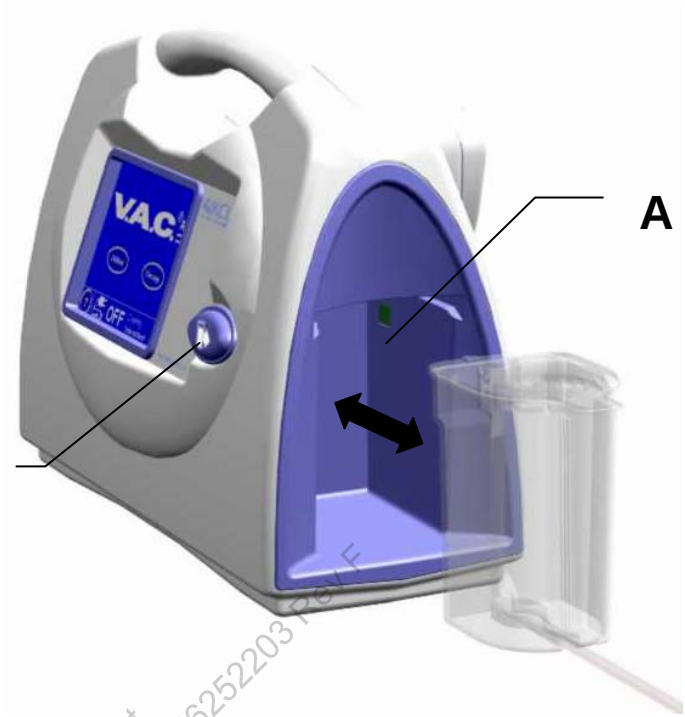




1. Perform aggressive wound care per physician order prior to V.A.C.® Dressing application.
2. Cut the V.A.C.® foam to fit the size and shape of the wound, then place the foam (a) into the wound cavity. Avoid cutting foam directly over wound to prevent particles from entering wound bed.
   Warning: do not pack the foam into any areas of the wound. Forcing foam dressings in a compressed manner into any wound is contrary to KCI recommendations.
3. Size the drape to cover the foam and 3-5 cm of surrounding intact skin. Trim drape if necessary. Remove the white backing liner (labeled **1**) and place drape on foam. Remove top support layer (labeled **2**) and pat around drape to ensure an occlusive seal.
4. Choose a location on the drape where you would like to apply the tubing. At this location, cut a hole through the drape, approximately 2 cm in diameter, leaving the foam mostly intact. An alternative is to cut a 2 cm diameter hole into the drape before you lay it down on the foam. Either process of cutting the drape will work. Note: It is very important to cut a complete hole, not a slit, in the drape, as a slit may not allow fluid passage through the drape, resulting in a blockage alarm.
5. Remove the backing liner (labeled **1**) from the T.R.A.C.™ Pad. Place the T.R.A.C. Pad on the drape, with the hole in the center of the T.R.A.C. Pad elbow directly over the hole in the drape. Gently pat around the T.R.A.C. Pad to ensure complete adhesion. Remove the support layer (labeled **2**).
6. Remove the blue handles from the drape and T.R.A.C. Pad, where applicable. Connect dressing tubing to canister tubing.
7. Refer to page 9 for canister installation.

CANISTER INSTALLATION AND REMOVAL





Canister Installation

1. Slide the canister into the canister port **(A)** until an audible click is heard ensuring that it is fully inserted.
2. Connect the two halves of the T.R.A.C.™ connector **(C)**. Push and twist until it locks in place.
3. Verify that both clamps are open.
4. Turn therapy ON.

Canister Removal

1. Turn therapy off.
2. Close clamps on canister and dressing tubing.
3. Twist T.R.A.C. Connector **(C)** to disconnect canister tubing from dressing tubing.
4. Press canister release button **(B)**, then pull out the canister.
5. Dispose of canister according to hospital protocols.

Additional canisters and dressings are available and can be ordered through your local KCI representative.

Disposal of used V.A.C.® ATS dressings and canisters

After patient use, all disposable parts of the system should be treated as contaminated.

These include:

- All tubing and related connectors and clamps
- Canister
- V.A.C.® ATS dressing, drape and related connector and tubing

Hand and eye protection should be used when handling any body fluids or waste. Properly dispose of all parts according to institutional procedures and local, state and federal regulations. Use universal precautions.

ALARMS

A visual alarm will be indicated on the screen followed by an audible alarm under the following conditions:

ALARM TYPE	NOTIFICATION	REMEDY
CANISTER FULL	Visual message accompanied by audible alarm.	Change canister and restart therapy
TUBING IS BLOCKED	Visual message with audible prompt which cancels after 1 minute if blockage is cleared. After 5 minutes of blockage therapy is turned off and full alarm is sounded.	Ensure tubing clamps are open. Check that tubing is not kinked or pinched.
TUBING AND/OR DRESSING HAS LEAKS	Visual message with audible prompt after 2 minutes which cancels 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. ® ATS canister is fully engaged.
THERAPY IS NOT ACTIVATED	Visual message accompanied by audible alarm after 15 minutes with Therapy Off.	Turn Therapy ON
BATTERY IS LOW	Audible alarm accompanied by a visual message before shut down.	Connect therapy unit to a Mains/ AC power source to recharge the battery.

Silencing the Alarm:
Press the MUTE button on the alarm screen to silence the alarm for two minutes.

After correcting the alarm condition, you can press the CONTINUE button to silence the alarm and return to the HOME screen.

Protection Against Contamination

To help reduce the risk of infection and contact with contaminated blood or body fluids during the dressing change or cleaning of equipment, it is important to protect all exposed skin and mucous membranes.
Protective clothing includes:

- Disposable gloves.
- Disposable impervious gown (if splashing of blood or body fluids is possible).
- Protective eyewear to help protect from splashing of cleaning solution and/or blood or body fluids.
- Protective mask.

Always follow Recommended Safety Precautions and use universal precautions.

Inspect Power Cord Regularly

The power cord should be inspected regularly for damage and wear. Replace damaged or worn power cords, immediately. Power cords are available from KCI.

Cleaning Surface of the Therapy unit

The V.A.C.® ATS unit should be wiped weekly with either a diluted solution of bleach (50ml in 5 liters) or mild disinfectant. The cloth should be damp, not dripping, to avoid getting excess fluid anywhere on the therapy unit. Other chemicals should not be used as they may damage the V.A.C. ATS unit enclosure.
NOTE: ***Patient does not typically need to be removed from the V.A.C. ATS when performing weekly cleaning procedures.***

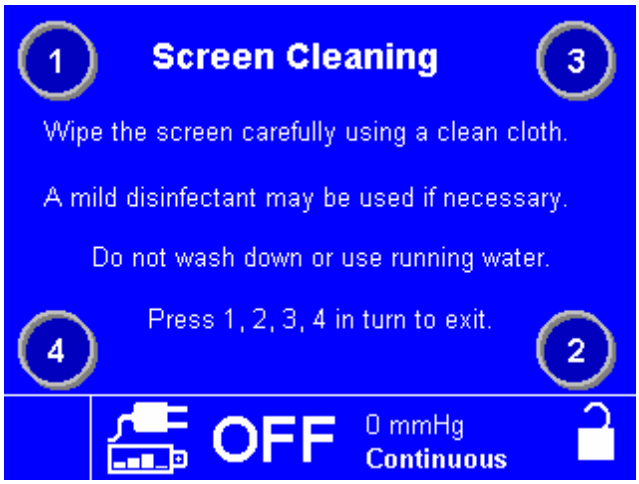
If the therapy unit is being cleaned when therapy is being applied to a patient, it is important to disable the touchscreen to ensure that no inadvertent commands take place.

UTILITIES SCREEN

To disable the touchscreen:

1. Press the Exit button on each screen until the Home Screen is displayed.
2. Press Utilities.
3. Press the button marked Cleaning to enter the Cleaning Screen that automatically disables the main areas of the touchscreen.

CAUTION: The electrical telephone style connector inside the canister housing is for KCI service use only. Care should be taken when cleaning to ensure that no fluid enters this connector.



CLEANING SCREEN

4. Wipe the screen with a clean dry cloth. If necessary, use a slightly damp cloth and wipe dry.

5. Follow the instructions on the screen to exit back to the Home Screen.

Automatic switch to battery power

The V.A.C.® ATS will automatically revert to battery operation if AC/mains power is disconnected. Therapy unit will operate at previous settings. The plug icon will no longer appear on the screen and the battery icon will appear. Once the V.A.C. ATS is plugged back into the wall, AC/mains power is restored and the battery will automatically re-charge while the therapy unit remains plugged in.

- **Average battery time** (after full recharge): approximately 4 hours, depending on the settings.
- **Average time to recharge battery**: approximately 4 hours fast charge to reach 85% capacity; approximately 10 hours to reach full charge.
- **Low battery alarm**: One tick mark within the battery indicator signals approximately 25% of battery time is left. An audible alarm will sound when the battery is very low, then the therapy unit will switch to Therapy OFF. However, the touchscreen will still remain functional at the time of a low battery alarm.
- **Automatic shutdown**: If the battery charge falls below a critical level, the therapy unit will automatically turn off and will remain off even if plugged into AC/mains power. To restore power, turn the therapy unit off then on again using the green power switch.

CLASSIFICATION:

Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.

Type B Equipment.

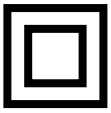
Class II Equipment with internal electrical power source.

PHYSICAL DATA	
Dimensions	14.6” (37cm)W x 11”(28cm)H x 7.1” (18cm)D
Weight	12.3lbs (5.6kg)
ELECTRICAL DATA	
Voltage	100 – 240 V ~
Frequency	50-60Hz
Maximum power consumption	70W
ENVIRONMENTAL DATA	
Storage Conditions	
Temperature range	-4°F (-20°C) to 140°F (60°C)
Relative humidity range	10% to 95% Non Condensing
Atmospheric pressure range	700hPa to 1060hPa
Operating Conditions	
Temperature range	+50°F (+10°C) to +86°F (+30°C)
Relative humidity range	30% to 75%
Atmospheric pressure range	500hPa to 1060hPa

*Specifications subject to change without notice.

EXPLANATION OF SYMBOLS

HARDWARE



Class II Equipment

Type B Equipment

Alternating Current

ON

OFF – part of the equipment **only**

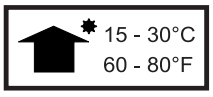
STERILE DISPOSABLES

LOT / BATCH

METHOD OF STERILIZATION - IRRADIATION

EXPIRATION DATE

DATE OF MANUFACTURE



STORAGE CONDITIONS

REFER TO USERS INSTRUCTIONS

FRAGILE

KEEP DRY

SINGLE USE ONLY

The V.A.C.® ATS CONFORMS WITH THE MEDICAL DEVICES DIRECTIVE(93/42/EEC).

EEC DIRECTIVE

The **KCI V.A.C.® ATS** is in conformity with the Medical Device Directive (93/42/EEC) and has been subject to the conformity assurance procedures laid down in the Council Directive.

KCI Medical Products (UK) Ltd. is certified by AMTAC Certification Services Ltd. as an approved medical device manufacturer.

The **KCI V.A.C.® ATS** conforms to the following International standards:
EN 60601-1-1:1990 including A13:1996, CAN/CSA-C22.2 No 601.1-M90, UL2601-1:1994 1st Edition-Amended 1996, EN60601-1-2:1993.

ORDERING INFORMATION AND CONTACT ADDRESSES

Ordering Information:

V.A.C.® ATS 110v Therapy unit	M8259968
V.A.C.® ATS 230v Therapy unit	M8259967
T.R.A.C.™ System Small Black Foam Dressing (10/Carton)	M6275051/10
T.R.A.C.™ System Medium Black Foam Dressing (10/Carton)	M6275052/10
T.R.A.C.™ System Large Black Foam Dressing (10/Carton)	M6275053/10
V.A.C.® ATS T.R.A.C.™ System Canister with Gel (10/Carton)	M6275063/10

Please contact your KCI representative for a full product catalogue.

Contact Addresses:
For location and contact information of KCI operations world wide, visit the KCI website at www.woundvac.com. For additional sales and technical information concerning the V.A.C. ATS, please contact your local KCI representative or:

USA Representative:
KCI USA, Inc.
8023 Vantage Dr.
San Antonio, TX 78230
USA
Phone: 1-888-275-4524 or 1-877-woundvac
Fax: 1-800-275-3417
www.woundvac.com

CANADA Representative:
KCI Medical Canada Inc
7170 Edwards Blvd
Mississauga, Ontario L5S 1ZL
Canada
Phone: 1-905-565-7187
Fax: 1-905-565-7270

Outside USA & Canada:
KCI International, Inc.
8023 Vantage Dr.
San Antonio, TX 78230
USA
Phone: 1-210-255-6460
Fax: 1-210-255-6991
www.woundvac.com

Manufactured For
Corporate Headquarters:
KCI USA, INC.
8023 Vantage Dr.
San Antonio, TX 78230 USA
1-877-WOUNDVAC

Manufactured by and
EU Representative:
KCI Medical Products (UK) Ltd
11 Nimrod Way
Wimborne, Dorset
BH21 7SH
ENGLAND

In case of emergency, contact local emergency number or treating physician.