Quantum

WOUND CARE. ANYWHERE.

Wound Treatment System User's Manual

ITI
Innovative Therapies Inc.
Outcomes Focused Wound Therapy

CAUTION: This Quantum Wound Treatment System User's Manual is not a guarantee or warranty. It is intended only as an operational guide. For additional information and questions, please contact Innovative Therapies, Inc.'s (ITI) Customer Service department at 1-866-484-6798.

In order for the Quantum Wound Treatment System to provide safe, reliable, and proper performance, the following conditions must be met. Failure to comply with these conditions will void all pertinent warranties.

- **There are no user serviceable components in the Quantum. All assembly, operation, adjustment, modification, maintenance, and/or repair must be carried out only by qualified personnel authorized by ITI.**
- **The electrical installation of the room in which the device will be used complies with the appropriate national electrical standards.**
- **The product must be used in accordance with this manual and all associated labeling and the Instructions for Use.**
- **Any device that does not function as expected must be returned to ITI.**

Notice to Users:

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

As with any prescription medical device, failure to follow product instructions or changing settings and performing therapy applications without the express direction and/or supervision of a trained clinical caregiver may lead to improper product performance and the potential for serious or fatal injury.

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1. Introduction

Indications

The Quantum Wound Treatment System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

Contraindications

The Quantum Wound Treatment System is contraindicated for patients with malignancy in the wound, untreated osteomyelitis, non-enteric and unexplored fistulas, or necrotic tissue with eschar present. Do not place the ITI foam dressing over exposed blood vessels or organs.

Precautions

Precautions should be taken for patients with active bleeding, difficult wound hemostasis, or who are on anticoagulants. When placing the ITI foam dressing in close proximity to blood vessels or organs, take care to ensure that they are adequately protected with overlying fascia, tissue or other protective barriers. Exposed tendon, nerves or blood vessels should be protected by moving available muscle or fascia over them or by a layer of synthetic material. Greater care should be taken with respect to weakened, irradiated or sutured blood vessels or organs. Bone fragments or sharp edges could puncture a dressing barrier, vessel or organ. Wounds with enteric fistula require special precautions in order to optimize therapy.

Additional Precautions

- **Defibrillation**: Remove the ITI Dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit electrical current transmission and/or patient resuscitation.
- **Magnetic Resonance Imaging (MRI)**: The Quantum Suction Pump Unit is not MRI-compatible. Do not take into the MRI area.
- **Hyperbaric Oxygen Therapy (HBO)**: **NEVER allow a device—whether on or off—inside a hyperbaric chamber**. The device must be disconnected from the patient prior to HBO treatment. Refer to the Clinical Guidance for the Innovative Therapies Wound Treatment Systems for more information on use with HBO therapy.
- **Large Canisters**: Use of Large Canisters (>500ml) may increase serious risks associated with excessive fluid loss. Monitor patient status continually. **DO NOT USE** for infants or other patients with low fluid volume, nor for patients at high risk of major hemorrhage.
- During Negative Pressure Therapy, the Quantum Suction Pump and ITI Dressing are a closed system and are NOT vented to atmosphere.
- During Therapy, when a canister fills with fluid, it should be replaced immediately as fluids such as wound exudate will not be removed from the dressing once the canister is full.

Safety Tips

The Quantum Wound Treatment System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

KEEP THERAPY ON

The Quantum Wound Treatment System should be operated at least 22 hours out of every 24 hour period. Remove the ITI foam dressing if therapy is terminated or is off for more than 2 hours in a 24 hour period.

DRESSING CHANGES

Clean the wound per physician order prior to dressing application. Routine dressing changes should occur every 48 to 72 hours. Dressing changes for infected wounds should be accomplished more frequently than 48 to 72 hours. Always replace with sterile disposables from unopened packages. Follow established institution protocols regarding clean versus sterile technique.

MONITORING THE WOUND

Inspect the dressing frequently to ensure that the foam is collapsed and that therapy 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 the Quantum Wound Treatment System, infection can lead to many adverse complications including pain, discomfort, fever, gangrene, toxic shock, septic shock, and various other complications. With signs of more serious complications of infection, discontinue the use of the Quantum Wound Treatment System until the serious infection is diagnosed and properly treated.

DISCOMFORT / ADHERENCE

If patient complains of discomfort during dressing change, consider pre-medication, such as use of a non-adherent prior to foam placement or irrigation of a topical anesthetic agent such as 1% Lidocaine prior to dressing removal.

UNSTABLE STRUCTURES

Use the lowest pressure setting on the Quantum Wound Treatment System over unstable body structures such as unstable chest wall or non-intact fascia.

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 the use of the Quantum Wound Treatment System 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 ITI Dressing.

ITI DRESSING USE

The ITI Dressings distributed by Innovative Therapies, Inc. are to be used exclusively with the Quantum Wound Treatment System.

NOTE: *All dressing components of the Quantum Wound Treatment 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 the Quantum Wound Treatment System disposable set are latex free.*

Be sure to comply with all other **CONTRAINDICATIONS** and **PRECAUTIONS** for the Quantum Wound Treatment System.

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

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

Features

Easy-to-use "One-Touch" Operation – Therapy activation and change of pressure settings can be accomplished with the push of a button. Therapy settings can be locked by the caregiver (see "*Therapy Selection Lock/Unlock*"). Lighted LEDs clearly indicate current therapeutic settings.

Renewable Device – The Quantum is the world's first renewable NPWT device. The therapy unit incorporates a service timer that will indicate when to return the device for renewal.

Light Weight/Impact Resistant – The Quantum device weighs only 15 oz. (0.43 Kg) and can be easily carried and transported. The polymer enclosure is impact resistant to help prevent damage from dropping.

Self-limiting Pump – The pump is designed to mechanically self-limit the amount of suction that can be applied to the wound site. Electronic sensors limit the maximum applied suction to -200 mmHg (±10%).

Intermittent Mode – The Quantum Wound Treatment System can be set to operate intermittently (5-minute ON/2-minute OFF cycle). Unit maintains pressure at -25 mmHg during the "OFF" state to prevent loss of dressing seal and increase patient comfort.

NoiseGuard - Unit is virtually silent in its normal operation with a well-sealed dressing increasing patient comfort and compliance.

PowerGuard – An internal battery provides up to 24 hours of operation from a single full-charge. Battery charges while unit is operating with the AC adapter. While running on battery, a low-battery alarm will sound and the front-panel LED display will indicate a low battery alarm condition when remaining capacity of the battery is less than 20%.

TherapyGuard - Automated alarms for leak/low pressure, full canister and low battery. Alarms provide both a visual and audible indication. Alarms will self-reset once a problem is corrected or can be manually reset by turning the therapy unit OFF and ON. Audible alarms can be muted for five minutes by pressing the MUTE button.

SpeedConnect™ – Eight-foot single-lumen tubing set with adhesive flanges facilitate connection to dressing.

Single Patient Use Canisters – 300cc and 500cc canisters for normal and highly exudating wounds.

CAUTION: *Use of large canisters (>500ml) may increase serious risks associated with excessive fluid loss. Monitor patient status continually.* ***DO NOT USE*** *for infants or other patients with low fluid volume, nor for patients at high risk of major hemorrhage.*

2. Care & Cleaning

Introduction

The following instructions are the Innovative Therapies, Inc. (ITI) recommended cleaning and infection control procedures for the Quantum Wound Treatment System. The Caregiver should review this manual in its entirety before attempting to the use the product. Carefully read the **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to perform cleaning procedures on the Quantum Wound Treatment Unit.

Protective Equipment

Universal Safety Precautions should be used to minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes. The protective equipment includes:

- Disposable gloves (latex or latex-free).
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids.
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress).
- Disposable impervious gown (if splashing of blood or bodily fluids is possible).

Disposal

After patient use, all disposable components of the system should be treated as contaminated. These include:

- The ITI Foam Dressing components.
- The exudate collection canister.
- Tubing, connectors and clamps.

Dispose of all disposable components in accordance with local, state, and federal regulations and institution protocols.

NOTE: *Cleaning procedures should not be performed when unit is connected to a patient. Disconnect the unit from the patient and power source before cleaning or servicing.*

Cleaning the Quantum Device

Perform a visual inspection of the device. Check for any sign of contamination and ensure that the device is functioning properly. If the device is not operating properly, refer to the Alarm Troubleshooting guide in the **OPERATING INSTRUCTIONS** section of this manual or contact ITI to replace the device.

To help reduce the risk of infection and contact with contaminated blood and bodily fluids please wear the protective equipment identified above when cleaning the Quantum Wound Treatment device.

NOTE: *Always follow Universal Safety Precautions. Follow established institution protocols regarding clean versus sterile technique.*

The following cleaning procedure must be performed at least once a week and must be completed between patients. The Quantum Wound Treatment device should be wiped with either a diluted solution of 5 milliliters bleach in 1 liter of warm water (approximately 1 teaspoon bleach in 1 quart water) or mild disinfectant. Use a coarse cloth and wring out any excess solution until the cloth is damp and not dripping. Refer to the Clinical Guidance for the Innovative Therapies Wound Treatment Systems for more information on acceptable cleaning solutions and products.

A.C. ADAPTER INSPECTION

The A.C. Adapter should be inspected regularly for damage and/or unusual wear. Replace damaged or worn Power Supplies immediately. A.C. Adapters are available from ITI.

WARNING: The Quantum Wound Treatment device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver.

WARNING: Avoid spilling liquid on any part of the therapy unit. Liquids can cause corrosion when left on electronic controls which can lead to failure. Component failure may cause the therapy unit to operate erratically, possibly causing a potential hazard to the patient or Caregiver.

WARNING: Particular care must be taken when handling undiluted germicide concentrate or chlorine bleach, including proper shielding of eyes. Always mix by adding concentrated germicide or chlorine bleach to the water. NEVER intermix germicides or mix germicides with chlorine bleach.

3. Patient Care

It is recommended that all sections of this manual be reviewed prior to using the product. Carefully read the **INDICATIONS**, **CONTRAINDICATIONS**, **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to perform patient care for a patient with the Quantum Wound Treatment System.

Applying the Dressing

1. Cleanse wound according to institutional protocols or physician order.
2. Debride all necrotic tissue including eschar and hardened slough.
3. Be certain the wound has achieved hemostasis.
4. Visually examine and palpate wound bed to locate any blood vessels or delicate underlying structure in close proximity.
5. Prepare area around wound to permit adhesion of the polyurethane drape.

NOTE: *If peri-wound area is excessively moist or oily, a medical-grade liquid adhesive may improve sealing. For fragile skin, use a skin sealant prior to drape application, or frame the wound with a skin barrier layer, such as Duoderm® or the ITI SensiSkin Drape. Cut the drape to a size large enough to cover the foam and the barrier layer only.*

6. Take measurements of the wound dimensions and note wound type. Select the appropriate foam based on wound assessment. Cut the ITI foam dressing to a size that is appropriate for the wound.

NOTE: *Do not trim the foam dressing over or around the wound site to help prevent debris from the foam dressing from falling into the wound.*

7. Place the ITI foam dressing in the wound site taking care to avoid contact with the peri-wound skin.

WARNING: Do not pack the ITI foam dressings into any areas of the wound. Forcing dressings in a compressed manner into any wound is contrary to approved protocols. Loosely fill all visible and invisible dead space in the wound.

NOTE: *The ITI foam dressing should cover the entire wound margin, including tunneling and undermining. However, the ITI foam dressing should not be in contact with intact skin.*

8. Size and trim the ITI Polyurethane Drape to cover dressing plus a 3-5 cm border of intact skin (extra pieces of drape can be used to seal dressing leaks). Remove the drape's release liner and place over the ITI foam dressing and peri-wound.
9. Pat drape material down around the wound site and over the ITI foam dressing to ensure dressing is properly sealed.
10. Cut a 1 cm diameter hole in the top of the drape at a convenient location over the dressing (see Fig. 1).
11. Peel the backing from one of the SpeedConnect™ flanges and place it above the hole made in Step 10. Using the tips of the fingers, press around the top of the SpeedConnect to ensure a good seal to the dressing (see Fig. 2).

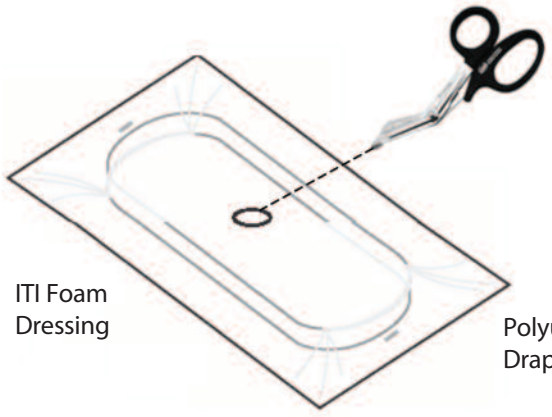


Figure 1

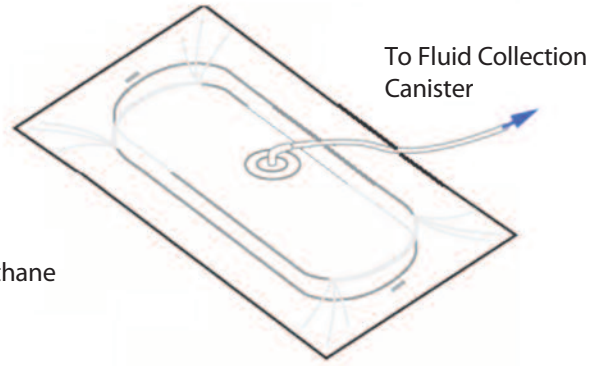


Figure 2

Canister Installation

1. Ensure that an ITI Canister is properly inserted in the receptacle located on the back side of the therapy unit (see Fig 3). The canister should "snap" into place and lock. The canister release button may need to be depressed to permit canister insertion. **NOTE**: *Always use a new canister with a new patient*.

Figure 3

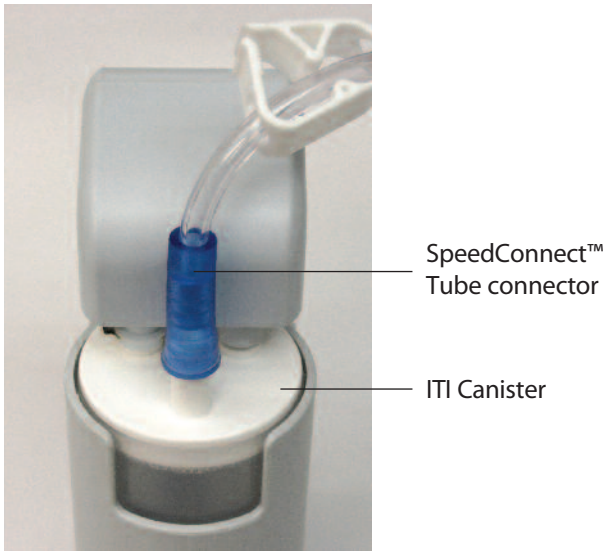


Figure 4

2. Inspect the SpeedConnect Tube flanges to ensure that they are properly connected to the ITI Dressing and that the connections are well sealed.
3. Connect the distal end of the SpeedConnect Tube with the blue tapered connector to the patient port of the Canister (see **Figure 4**). Gently twist and push the connector on just enough to secure and seal it. Also, make sure that the clamp on the SpeedConnect Tube is open (see **Figure 5**).

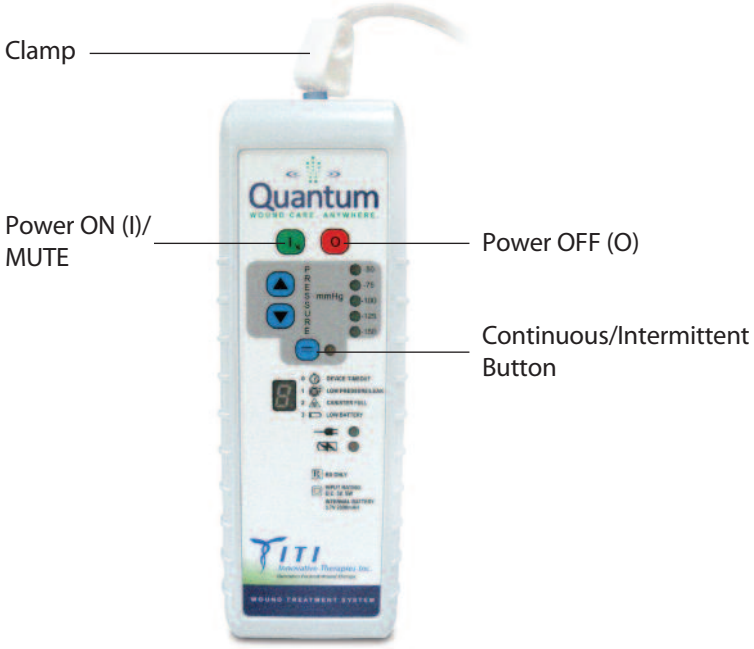


Figure 5

4. Plug the device's A.C. Adapter into a suitable 100-240 VAC, 50-60Hz, outlet. Insert the power plug into the Power Jack on the side of the device (refer to **Figure 5**). The Quantum Device should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient and caregiver.

NOTE: *ITI offers a 12 Volt vehicle adapter that allows the device to operate on external power while traveling.*

5. Verify the dressing application is correct, the tubing is connected, and the ITI Suction Tubing with SpeedConnect clamp is open.
6. Begin therapy (see **OPERATING INSTRUCTIONS**).

Canister Removal

1. Press the OFF button to turn the therapy off.
2. Close suction tubing clamp.
3. Remove tubing connector from top of canister.
4. Press canister release button and withdraw canister from bottom of unit.
5. Dispose of canister according to local, state and federal regulations as well as institutional protocols.

Dressing Removal

Carefully read the **SAFETY TIPS** in the **INTRODUCTION** section of this guide prior to removing the dressing.

NOTE: *Wounds must be carefully monitored at regular intervals. In a non-infected wound, dressings should be changed every 48 to 72 hours; but no less than 3 times per week, with the frequency of dressing change determined by the clinician. Infected wounds must be monitored continuously. For infected wounds, dressings may need to be changed more often than 48-72 hours; the dressing change interval should be based on a clinical evaluation of the wound condition rather than a fixed schedule.*

NOTE: *The canister should be replaced when full (the Full Canister alarm activates) or at least once every week to minimize the potential for contamination and production of odors.*

1. Press the OFF button to turn the therapy off.
2. Close suction tubing clamp.
3. Disconnect SpeedConnect™ suction tube. Twisting the tapered connector will make removing the Suction tube from the canister easier.
4. Slowly pull drape up and away from skin while gently stretching drape.

NOTE: *If the ITI foam dressing adheres to the wound during removal, refer to the **SAFETY TIPS** section of this manual*.

5. Discard disposables in accordance with applicable rules, regulations and infection control protocols, and always follow Universal Safety Precautions.

Disposal of Dressings, Canister and Other Disposables

To minimize the risk of infection and contact with contaminated blood or bodily fluids during the dressing changes or disposal, it is important to protect all exposed skin and mucous membranes. The protective equipment includes:

- Disposable gloves (latex or latex-free)
- Protective eyewear to help prevent splashing of cleaning solutions and/or blood or bodily fluids
- Protective mask (to protect the nose and mouth from inadvertent fluid ingress)
- Disposable impervious gown (if splashing of blood or bodily fluids is possible)

After patient use, all disposable components of the system should be treated as contaminated. These include:

- The ITI foam dressing and ITI Polyurethane Drape
- The exudate collection canister
- SpeedConnect tubing, connectors & clamps

Dispose of all disposable components in accordance with local, state, and federal regulations and institution protocols.

Device Renewal

When the device's service timer indicates it is time to have the therapy unit renewed, please return the device and A.C. power adapter to Innovative Therapies, Inc. or its representative, for servicing. Please ensure the canister is removed from the device before sending it, and never send disposable components/accessories such as the carry bag, canisters, dressings or tubing in the return package.

4. Operating Instructions

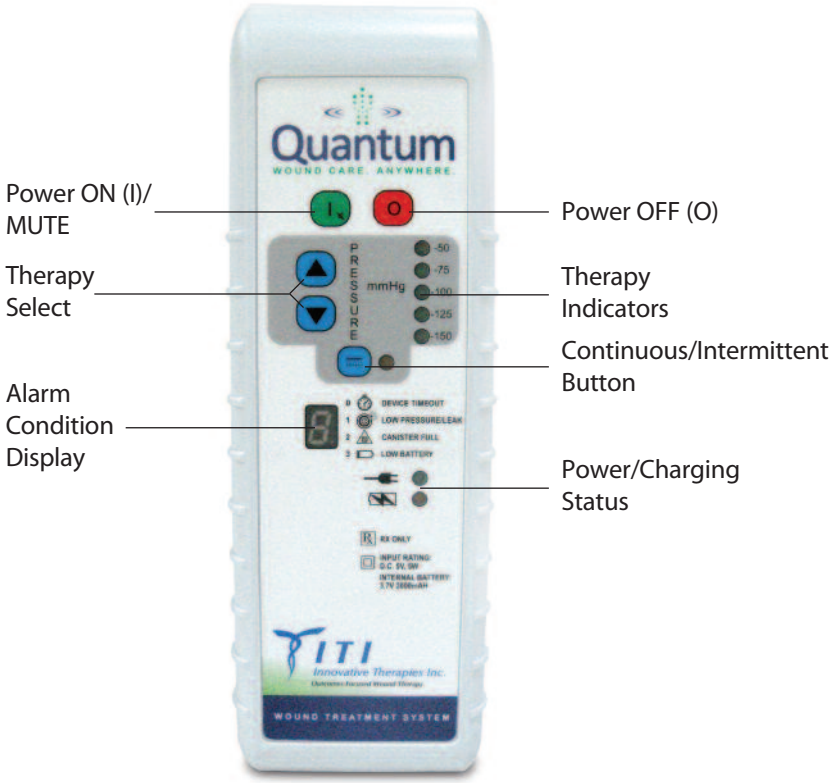
This section contains instructions for setting and adjusting functions of the Quantum Wound Treatment System. The section explains the procedure for activating therapy and explains the major functions that are adjusted from the control panel.

Carefully read the **PRECAUTIONS** and **SAFETY TIPS** in the **INTRODUCTION** section before attempting to operate and adjust the Quantum Wound Treatment System.

WARNING: The Quantum Wound Treatment System should only be used with the supplied A.C. Adapter. Use of an incorrectly rated adapter could create a shock hazard for the patient or caregiver. The part number for the adapters can be found in the REPLACEMENT PARTS section of this manual.

Power On/Off

The ON and OFF buttons are located on the front top of the control panel. The ON and OFF buttons control the application of power to the therapy unit.



Power-Up Procedure

1. Verify the dressing application is correct, the tubing is connected, and the ITI Suction Tubing with SpeedConnect clamp is open.
2. Place the therapy unit in an upright position as level with the wound as possible. The device can be placed on a table, or attached to an I.V. pole using the I.V. Pole adapter.

CAUTION: The I.V. pole clamp should only be used on poles that are in excess of 0.9" (2.2 cm) diameter and are securely attached to a bed frame or suitable stand. To ensure stability of the therapy unit on the I.V. pole, it should be clamped no higher than two times the width of the pole base. The clamp should be tightened to ensure that the therapy unit cannot slide down the pole.

3. Press the ON button. All LED indicators will sequentially illuminate during the power-on self-test.
4. Each time the device is turned on, the front panel LED display will indicate the remaining therapy life of the unit using the following display format: "**d XX**, **h YY**". For example, if the display (for a 30-day device) indicates "d 11 h 22," this means 11 days and 22 hours of therapy remain on the device. This information can also be interpreted as the device has been used for 18 days and 2 hours. This provides the caregiver compliance information.
5. Upon turning on the device, the dressing should slowly collapse indicating the presence of suction. Once dressing integrity is verified, adjust the unit for desired therapy. **NOTE**: *The device must be connected to the A.C. Adapter while attempting to obtain an initial dressing seal*.
6. Carefully check dressing for vacuum leaks, and repair with additional ITI Polyurethane Drape, if necessary.
7. The Quantum Wound Treatment System should be operated at least 22 hours out of every 24-hour period. Remove the ITI Dressing if therapy is terminated or is off for more than 2 hours in a 24 hour period.

Therapy Setting Adjustment

CAUTION: Only a physician can prescribe the proper settings and protocols for the therapy unit. Failure to follow product instructions or adjusting settings and performing therapy application 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.

Negative Pressure Level Adjustment

There are five negative pressure settings that can be selected: -50 mmHg, -75 mmHg, -100 mmHg, -125 mmHg and -150 mmHg. The pressure selection buttons are located on the left side of the control panel. The ▲ button decreases the negative pressure setting and the ▼ button increases the negative pressure setting.

1. When the unit is powered-up, the current setting is selected automatically (unless therapy setting has been locked previously by caregiver, see "Therapy Selection Lock/Unlock" Section).
2. To change the setting, simply press either the ▲ therapy selection button or ▼ therapy selection button until desired therapy selection is indicated by the green LED.
3. The green LED indicator will flash indicating the selection has been made and will continue flashing until the desired negative pressure level has been achieved at which time the LED will remain illuminated. If the green LED indicator begins to flash during therapy, it means the device is unable to maintain the therapeutic setting. This event would most likely be associated with a dressing leak and will require clinician intervention to correct.

Intermittent Mode ON/OFF

The Quantum can operate in an intermittent suction mode with a 5 minute "ON" and 2 minute "OFF" cycle. Press the ▬ button to turn the Intermittent Mode on and off.

During intermittent operation, Quantum will provide target therapy pressure during the "ON" part of the cycle and approximately -25 mmHg during the "off" part of the cycle. By maintaining this lower pressure while the unit is "OFF," the dressing seal is never compromised. This method of applying intermittent pressure also increases patient comfort.

Beeper Volume Adjustment

The volume of the beeper can be adjusted to fit various care settings or patient preferences. To adjust the beeper volume, press and hold the ON button while simultaneously pressing the ▲ button to increase the volume, or the ▼ button to decrease the volume. The LED display will indicate the volume level.

Battery Operation

NOTE: *The Quantum Wound Treatment System is designed to permit use of the product while the internal battery is charging. The therapy unit will continue to operate properly while the battery is charging.*

Battery Life

The specified battery life of the Quantum Wound Treatment System with a fully-charged battery and a well-sealed dressing is up to 24 hours. The actual life is dependent on the integrity of the dressing. A leak in the dressing can reduce overall battery longevity significantly.

Average Time for Recharging

To ensure the battery has been fully charged, the device should be connected to an A.C. supply for approximately 3 hours. After approximately 2 hours of charging, the device will have achieved 80% of total battery capacity.

Low Battery Alarm

While running on battery, a low-battery alarm will activate when remaining capacity of the battery is less than 20% (See "Alarm Operation"). Typically, the unit will continue to operate between 30 minutes and 1 hour after the low-battery alarm is activated.

Low Battery Shutoff

If the battery charge falls below a critical level, the device will shutoff automatically and therapy will be discontinued. At this point, the device must be plugged into an A.C. power source for therapy to resume. Once the A.C. Adapter is plugged in, pressing the ON button will restart the device.

Recharging the Battery

Plug the power cord from the A.C. Adapter into the power receptacle on the side of the therapy unit. Plug the A.C. Adapter into a suitable 120 VAC, 60 Hz wall outlet.

When the device is connected to an AC power source, the green "power" LED on the front of the device will illuminate indicating AC power is present and the amber "charging" LED, located just below the "power" LED, will illuminate when the battery is charging.

Once the battery is fully charged, the amber LED will extinguish indicating the charge cycle is complete.

When the Quantum Wound Treatment System is disconnected from the AC power source, the device will automatically switch over to the internal battery and continue to operate without interruption.

Alarm Operation

Clearing an Alarm Condition

To clear an alarm condition, turn the therapy unit OFF then ON. The alarm will clear when the power is cycled.

Alarm Troubleshooting

Alarm Type	Indication	Corrective Action
FLASHING "**0**" THERAPY TIME-OUT	• Device is ready to be checked and serviced.	• Return device to representative for service
FLASHING "**1**" LOW PRESSURE/ DRESSING LEAK	• LED display flashes "1" accompanied by an intermittent single-tone audible beep. • Unit will continue to alarm until the low pressure/leak condition is corrected or the alarm is cleared.	• Pat around drape to check for leaks. If leak is found, patch with extra drape material. • Check all tubing connections between the therapy unit and dressing. • Check to ensure the canister is fully seated and locked. Check for cracks in the canister or lid separation.
FLASHING "**2**" CANISTER IS FULL	• LED display flashes "2" accompanied by an intermittent two-tone audible beep. • Unit will continue to alarm until the canister is replaced.	• Turn unit off by pressing the OFF button. • Remove canister and replace as necessary. • Press the ON button to resume therapy. • If conditions persist, the problem may be related to the device.
FLASHING "**3**" LOW BATTERY	• The LED display flashes "3" accompanied by a three-tone audible beep. • The unit will continue to alarm until connected to an A.C. power source. • When the charge falls below a critical level, the therapy will be discontinued.	• Utilizing an approved ITI A.C. Adapter, connect device to an A.C. power source to provide operating power and to recharge the internal battery.

NOTE: *Pressing the ON (MUTE) button after an alarm will silence the beeper for 5 minutes.*

NOTE: *In the event of an emergency, please contact your treating physician, caregiver, or your local emergency responders.*

NOTE: *If an Alarm Condition persists and cannot be resolved, please contact ITI for further assistance.*

Therapy Selection Lock/Unlock

The Quantum Wound Treatment System is equipped with a therapy locking feature designed to prevent unauthorized individuals from changing the therapeutic settings inadvertently.

Locking

To lock the unit, press and hold the power ON button for three seconds until three audible beeps are heard. At this point, the unit is locked. The therapeutic setting will be recalled each time the unit is powered OFF and ON, and the unit will remain locked until it is subsequently unlocked.

Unlocking

To unlock the unit, press and hold the power ON button until three audible beeps are heard. At this point the unit is unlocked and therapy settings can be changed. Additionally, when the unit is powered OFF and ON, the unit will remain unlocked.

5. Specifications

Quantum Wound Treatment System

Dimensions ..... 7.6 x 4.3 x 2.75 in. (19.3 x 11.0 x 7.0 cm)
Weight ..... .0.9 Lbs (0.43Kg)
Therapy Settings ..... -50, -75, -100, -125, -150 mmHg
Canister Volume 300cc/500cc
With respect to electric shock, fire, and mechanical hazards, conforms to UL 60601, IEC60601-1, EN60601-1.

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
- IPXO

Battery

Duration (Fully Charged) ..... up to 24 hours

Electrical

External Power Supply Input. ..... 100-240 VAC, 50-60Hz, 200 mA or 12-24 VDC, 850 mA (Optional)
External Power Supply Output. ..... 5 VDC, 1 Amps
Patient & Enclosure leakage Current ..... < 100 Micro amps

Environmental Conditions

Storage Conditions
Temperature Range ..... 10oF (-12oC) to 110oF (43oC)
Relative Humidity Range ..... 20 – 95% Non-condensing
Atmospheric Pressure Range ..... 50 kPa to 110 kPa

Operating Conditions

Temperature Range. ..... 40oF (4oC) to 90oF (32oC)
Relative Humidity Range ..... 20 - 75% Non-condensing
Atmospheric Pressure Range ..... 50 kPa to 110 kPa
Service life of Quantum Wound Treatment System ..... 3 years

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

Explanation of Symbols


Refer to User Instructions


Power ON/MUTE


Power OFF


Adjustment Button, UP


Adjustment Button, DOWN


Continuous/ Intermittent


A.C. Power Status


Battery Charge Status


Device Timeout


Low Pressure/Leak


Canister Full


Low Battery


Class II, Internally Powered Equipment


Type B, Applies Part


Alternating Current

IPX0

Not protected against harmful effects of water


Manufacturer


Date of Manufacture


Expiry Date

LOT

Lot/Batch Number

REF

Catalog Number

SN

Serial Number

Storage Conditions


Keep Dry


Fragile

STERILE EO

Method of Sterilization - Ethylene Oxides


Rx Only


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

EC REP

Authorized Representative in the European Union

ITI Innovative Therapies Inc.
Outcomes Focused Wound Therapy

6. Replacement Parts

Description	Part Number
Therapy Unit	
Quantum Wound Treatment System	6702232
Quantum User's Manual	6702232M
Power Supply	
A. C. Power Adapter	47-9100
Car Adapter	47-9150
Accessories	
I.V. Pole Holder	47-5600
Carrying Bag	47-9600

NOTE: *Part numbers for Canisters, Dressings and Disposable Accessories may be obtained by visiting ITI's website (www.ITIMEDICAL.com).*

NOTE: *In order to assure the highest safety, quality and efficacy of the products, the Quantum Wound Treatment System should only be used with Innovative Therapies, Inc.'s disposables, and ITI Dressings should only be used with the Quantum Wound Treatment System.*

7. Questions & Information

For additional information pertaining to the Quantum Wound Treatment System, please contact your local ITI representative, or:

ITI
Innovative Therapies Inc.
Outcomes Focused Wound Therapy

Innovative Therapies Inc.
12 Meem Avenue, Suite C
Gaithersburg, MD 20877
1-866-484-6798
www.itimedical.com

For questions or comments regarding the content of this User's Manual, please contact Innovative Therapies, Inc. (ITI) at the above address. Please contact ITI Customer Service at 1-866-484-6798 for issues concerning the product and its use.

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