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Wound Healing TECHNOLOGIES

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extriCARE 3600 Operating Manual

Introduction

The **extriCARE® 3600 Negative Pressure Wound Therapy Pump System** is a multi-purpose negative pressure pump and dressing system.

The **extriCARE® 3600 NPWT pump** is a portable, battery powered pump which may promote wound healing through the drainage and removal of wound exudates, infectious material, and tissue debris from the wound bed using continuous and/or intermittent negative pressure.

The **extriCARE® Negative Pressure Wound Therapy Bandages** and the **extriCARE® Negative Pressure Wound Therapy Foam Kits** are both **extriCARE® Wound Dressing** intended to be used with an NPWT device to treat acute and chronic wounds which have failed to heal despite good wound care. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, flaps and grafts may benefit from this system.

The **extriCARE® 3600 Negative Pressure Wound Therapy** pump and **extriCARE®** wound dressings are able to produce a negative pressure environment in either intermittent or continuous mode. This allows the user to program the specific pressure ranging from 40mmHg to 200mmHg. In continuous mode, the pressure is applied to the wound as long as the pump is powered on. In intermittent mode, the pump will alternate between applying pressure for 5 continuous minutes and reducing pressure to 20mmHg for 2 minutes.

The **extriCARE®** device is meant for continuous use (at least 22 of 24 hours per day). The extriCARE 3600 device is not to be used for home use.

Please call Wound Healing Technologies at (718) 871-2800 for questions or technical assistance.

Operating the Device

POWER ON/OFF: To power on the device, flip the POWER SWITCH located on the back panel of the device. The screen will display the starting image and the system will complete a self-check. After the self-check the device will display the STANDBY SCREEN.

Start Screen:



Standby Screen:



1. **PRESSURE CONTROL:** The **extriCARE® 3600** has a default pressure of 125 mmHg. This can be changed by pressing the UP or DOWN buttons. The pressure will change in increments of 5 mmHg with a range of 40 mmHg to 200 mmHg. Long press the UP or DOWN button, the pressure will change continuously by every 5mmHg.
2. **MODE:** The **extriCARE® 3600** can operate in **continuous or intermittent modes**. In continuous mode, the **extriCARE® 3600** will continuously operate at the set pressure. In intermittent mode, the **extriCARE® 3600** will operate for 5 minutes at the set pressure, and then for 2 minutes at 20 mmHg, and then repeat the cycle.

Continuous Mode:



Intermittent Mode:



Mode: Continuous mode: The solid line indicates Continuous mode. In Continuous mode, the device will always maintain the set pressure.

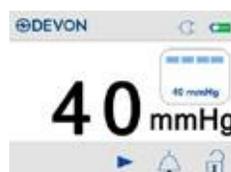
Intermittent mode: The dashed line indicates Intermittent mode. In Intermittent mode, the device will run for 5 minutes at the set pressure, and then increase pressure to negative 20 mmHg for 2 minutes. The device will continuously repeat this cycle while in Intermittent mode.

To change between the modes, press and hold the mode button while therapy is stopped.

START/STOP TREATMENT: To start treatment, press the START/STOP BUTTON for 2 seconds.

LOCK/UNLOCK DEVICE: The **extriCARE® 3600** will lock automatically if there is no button input for 3 minutes. At this time, any button press will illuminate the display with the current settings, but the buttons will not take any input, and the backlight to the screen will turn off. If there is no additional button presses, the backlight will turn off after 6 seconds. To unlock the device, press and hold the MODE and START/STOP buttons for 2 seconds. To manually lock the device, press and hold the MODE and START/STOP buttons for 2 seconds. In the case that an error indication occurs when the device is locked, the backlight to the screen will turn on and the error indication will display.

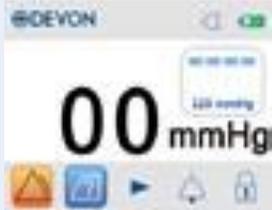
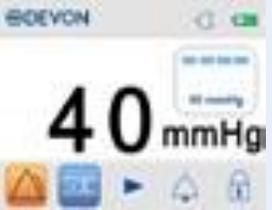
Unlocked:



Locked:



Error Indication: This icon indicates that there is an error indication.

| Error Type | Cause/Description | Audio Indication Features | Visual Indication Features | System Status | Suggested Solution |
|-----------------------------|--|---------------------------|--|--|---|
| Canister Installation Error | The canister is not detected or is installed incorrectly | 3 beeps every 20 seconds |  <p>00 mmHg</p> <p>Yellow LED flashing every 2 seconds</p> | Pump remains on | Properly install the canister |
| Blockage or Obstruction | Tubing or dressing clog or blockage. Hole cut in transparent dressing too small / blocking opening in top-mount disc | 3 beeps every 20 seconds |  <p>40 mmHg</p> <p>Yellow LED flashing every 2 seconds</p> | Pump remains on | Replace with new top mount drain and tubing set |
| Low Battery Error | When the battery contains less than 10% power. This indicates that the system will shutoff soon | 3 beeps every 20 seconds |  <p>40 mmHg</p> <p>Yellow LED flashing every 2 seconds</p> | Pump remains functioning until the battery depletes completely | Plug the extriCARE® 3600 in allowing it to function and charge simultaneously |
| Canister Full Error | The canister is equipped with full sensors that will be triggered either when the canister is full of exudates, or a false fullness is caused by incorrect use of the system | 3 beeps every 20 seconds |  <p>40 mmHg</p> <p>Yellow LED flashes every 2 seconds</p> | Pump will shot off immediately | Install a new canister |

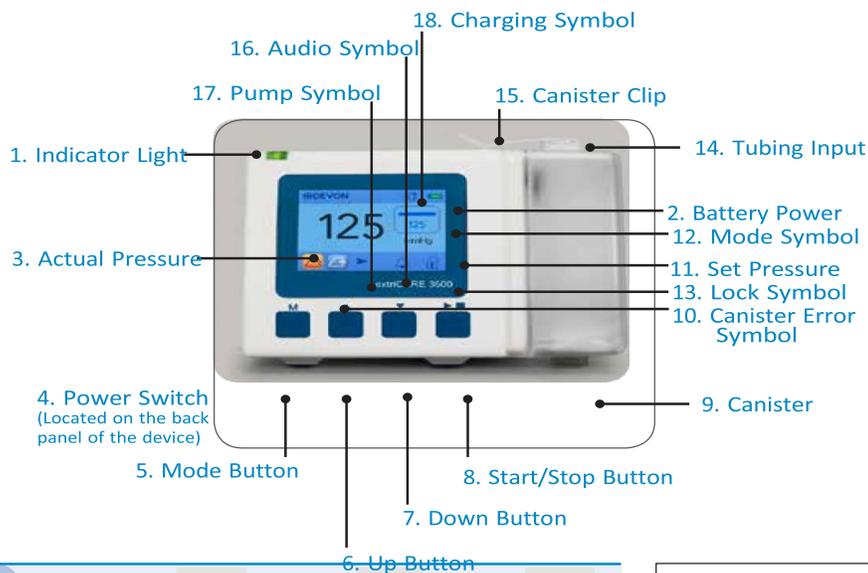
Error Indication: This icon indicates that there is an error indication.

Air Leakage Error

There are many potential sources of leaks (incomplete seal between extriCARE® 3600 dressing and skin, improper connection between tubing, canister leakage, etc.). The error indication have been divided into two categories, mild and severe.

| Error Type | Cause/Description | Audio Indication Features | Visual Indication Features | System Status | Suggested Solution |
|----------------|---|---------------------------|---|---|---|
| Minor Leakage | Pump is unable to reach 80% of the preset pressure after 5 minutes of pump effort | 1 beep every 20 seconds |  <p>Yellow light is on constantly</p> | Pump remains on | Inspect for possible air leaks between: <ul style="list-style-type: none"> -the wound and extriCARE® dressing. Place Coloplast putty at possible areas causing leak; reinforce with transparent dressing. -the extriCARE® dressing and canister -the canister and pump |
| Severe Leakage | Pump unable to reach 50% of the preset pressure after 2 minutes of pump effort | 3 beeps every 20 seconds |  <p>Yellow light flashes every 2 seconds</p> | Device remains on but suction will shut down after 10 minutes of continuous error indication and without any operation. Screen will display 00 and red exclamation point icon | - if necessary, power off and back on to restart the system after adjustment |

Take Note: For a Severe Leakage alarm; device remains on and alarming, but suction will shut down after 10 minutes of continuous error indication and without any operation. The display screen will show 00 and the Severe Leakage Alarm



Battery: Full <33%: <10%:

Power Adapter: When the device is plugged in and turned on, the screen will display the power adapter icon. During this time, the device will be powered by the external power, and the battery will also recharge.

Bell: When an error indication is occurring, the symbol on the right will appear, showing that the error indication is not muted. If the alarm is muted, the symbol on the left will appear. The alarm will automatically un-mute once the alarm is remedied.

Error Indication: This icon indicates that there is an error indication. Please see the error indication section 9.2 for a full description of all of the error indications.

125 mmHg
Mode: Continuous mode: The solid line indicates Continuous mode. In Continuous mode, the device will always maintain the set pressure.
Intermittent mode: The dashed line indicates Intermittent mode. In Intermittent mode, the device will run for 5 minutes at the set pressure, and then increase pressure to negative 20 mmHg for 2 minutes. The device will continuously repeat this cycle while in Intermittent mode. To change between the modes, press and hold the mode button.

125 mmHg
Real Negative Pressure: This shows the real-time pressure.

125 mmHg
Current Setting Pressure: This shows the pressure that the device is set at. Note that during Intermittent mode, you cannot change the 2 minutes of negative 20 mmHg.

Pump Running: This icon indicates that the pump is turned on and engaged.

Error Modes: See ERROR section.

Lock/Unlock

- 1. Indicator Light:** Indicates if the pump is running and functioning properly or not.
- 2. Battery Power:** Indicates how much battery power is left. Icon has 1-4 bars representing 10%, 33%, 66%, and 100% battery power.
- 3. Actual Pressure:** This displays the real-time pressure reading
- 4. Power Switch:** Used to turn the system power on and off. (Located on the back panel of the device)
- 5. Mode Button:** Allows user to set the pump to either continuous or intermittent mode.
- 8. Up Button:** This increases the set pressure in increments of 5 mmHg up to a maximum of 200 mmHg.
- 9. Down Button:** This decreases the set pressure in increments of 5 mmHg down to a minimum of 40 mmHg.
- 10. Start/Stop Button:** Used to engage or disengage the pump.
- 11. Canister:** Used to store exudates removed from the wound.
- 12. Canister Error Symbol:** Indicates a canister installation error or canister full error.
- 13. Set Pressure:** This displays the pressure that the extriCARE® 3600 is set for.
- 14. Mode Symbol:** Indicates pump operating mode (continuous or intermittent).
- 15. Lock Symbol:** Indicates if the device is locked or not.
- 16. Tubing Input:** This is the connection port used for the extriCARE® 3600 dressings to attach to the pump.
- 17. Canister Clip:** Clip that connects the canister to the extriCARE® 3600 device.
- 18. Audio Symbol:** Indicates whether the sound is on or off.
- 19. Pump Symbol:** Indicates whether the pump is engaged or not.
- 20. Charging Symbol:** Indicates whether the extriCARE® 3600 is charging or not.



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Prior to Therapy

- Patient should be assessed and measures should be taken to optimize and stabilize their medical condition. Nutrition, medication, blood glucose, blood pressure, and circulation as well as other medical issues should be addressed.
- The wound should be recently debrided by whatever measure is appropriate and the amount of necrotic tissue should be minimized.
- Issues of infection should be addressed.

Periwound Skin

- Ensure that the skin that will be under the dressing is clean, dry, free of surfactants and oil. Any hair should be clipped.
The periwound area should be cleaned and allowed to air dry. The use of a skin preparation wipe is also recommended.
- A thin film dressing or hydrocolloid may be used as additional protection.
- Monitor skin for signs of irritation or breakdown. Treatment may be discontinued if this occurs and cannot be managed.

Dressing Management

In the event that the **extriCARE** wound dressings comes apart, all **extriCARE** wound dressings materials must be removed from the wound prior to further treatment.

Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control.

Dressing and Canister Application

extriCARE Wound Dressings include bandages and foam kits. Follow detailed instructions that come with your **extriCARE Wound Dressing** to apply the dressing.

The clinician may loosely place extra non occlusive dressing material into areas of undermining and tunneling. The decision type of non-occlusive material used is based on clinician preference. Document the amount of additional packing material used.

extriCARE wound dressings should be changed as needed.

The initial **extriCARE** wound dressings should be changed in 24 - 48 hours or when leaking, whichever comes first. **extriCARE** wound dressings should not be left in place longer than 72 hours.

If the **extriCARE** wound dressings sticks to the wound, moisten with saline or water during removal. Adhesive remover may be used.

Dispose of soiled **extriCARE** wound dressings according to facility protocol.



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Dressing and Canister Application (cont.)

Avoid outside sources wetting the **extriCARE** wound dressings. The **extriCARE** wound dressings should be protected from moisture during bathing or changed prior to reconnecting to the pump. Do not use the **extriCARE 3600 Negative Pressure Wound Therapy Pump** while showering or bathing. Always disconnect and remove pump from areas of moisture (bathing area or tub). Clamp the tubing when pump is disconnected.

To remove a canister, pull up on the canister clip on the top of the device and pull the canister away. To reinstall a canister, line up the notches on the bottom of the canister holes on the bottom of the **extriCARE 3600 device**, and then press the canister clip into place. The clip should click into place and the canister should feel snug.

When using on a venous or other leg ulcer:

- Edema control must continue during wound treatment.
- Consider lower pressures when applied over fragile skin.

When used on the foot, aggressive measures should be taken to protect the foot and divert unnecessary pressure.

If the **extriCARE** wound dressings is applied over a new graft or bioengineered tissue:

- It is recommended that a non-adherent open weave or fenestrated silicone contact layer be applied atop the wound between the graft and the NPWT dressing.
- Heavy petrolatum or similar products cannot be used as negative pressure will not have an impact on the wound surface.
- Additional care should be used during dressing change to prevent dislodging graft.

The **extriCARE** wound dressings, tubing, and canister can be disposed of according to policy for wound care dressings after use.

Precautions

Be aware for any of the following conditions:

There are additional conditions to take into account before using **Negative Pressure Wound Therapy**, such as:

1. **BLEEDING:** There is a risk of bleeding/hemorrhaging with negative pressure wound therapy. If hemostasis cannot be achieved, if the patient is on anticoagulants or platelet aggregation factors, or if the patient has friable blood vessels or infected vascular anastomosis, he or she may have an increased risk of bleeding; accordingly these patients should be treated in an inpatient care facility per their treating physician. If active bleeding develops suddenly or in large amounts during therapy, immediately disconnect the pump, leave the **extriCARE**.

wound dressings in place, and take measures to stop bleeding. Seek medical attention immediately.

2. **VESSEL AND BONE PROTECTION:** Precautionary measures should be taken if any bones, vessels, ligaments or tendons are exposed. Additionally, sharp edges (due to bone fragments) require special attention; these areas should be covered and smoothed wherever possible.



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Precautions

Be aware for any of the following conditions:

These conditions should be factored into the therapy prescription as the attending clinician sees fit.

3. ENVIRONMENT:

- a) Defibrillation: Remove the **extriCARE®** dressing if defibrillation is required in the area of dressing placement. Failure to remove the **extriCARE®** wound dressings may inhibit transmission of electrical energy and/or patient resuscitation.
- b) Magnetic Resonance Imaging (MRI): The **extriCARE®** pump is unsafe in the MR environment. Do not take the **extriCARE®** pump into the MR environment. **extriCARE®** dressings however can typically stay on the patient with minimal risk in an MR environment, assuming that the use of the **extriCARE® Negative Pressure Wound Therapy System** is not interrupted for more than two hours.
- c) Hyperbaric Oxygen Therapy (HBO): Do not take the **extriCARE®** pump into a hyperbaric oxygen chamber. **extriCARE®** pumps are not designed for this environment, and should be considered a fire hazard in such an environment. After disconnecting the **extriCARE®** pump, either (i) replace the **extriCARE®** dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the unclamped end of the **extriCARE®** tubing. For HBO therapy, the **extriCARE®** tubing must not be clamped. Never leave an **extriCARE®** dressing in place without active **extriCARE® Negative Pressure Wound Therapy** for more than two hours.

4. **INFECTION:** Infected wounds and osteomyelitis pose significant risks for **Negative Pressure Wound Therapy**. If untreated osteomyelitis is present, therapy should not be initiated. **Negative Pressure Wound Therapy** should not be used to treat infections, and all infections should be treated and addressed prior to using the **extriCARE® Negative Pressure Wound Therapy System**.

PATIENT SIZE AND WEIGHT: Patient size and weight should be taken into account when prescribing therapy. In addition, small adults, young adults or elderly patients should be closely monitored.

SPINAL CORD INJURY: If a patient experiences autonomic dysreflexia (sudden changes in blood pressure or heart rate because of sympathetic nervous system stimulation) discontinue **extriCARE®** therapy to minimize sensory stimulation and give immediate medical assistance.

MODE: In unstable anatomical structures, continuous rather than intermittent therapy is recommended to help minimize movement and instability. Continuous therapy is also recommended in patients with an increased bleeding risk, profusely exudating wounds, fresh grafts and/or flaps, and wounds with acute enteric fistulae.

ENTERIC FISTULAS: Wounds with enteric fistulas require special consideration to be effective in negative pressure wound therapy. If enteric fistula effluent management or containment is the only goal of such therapy, **extriCARE®** is not recommended.

CIRCUMFERENTIAL DRESSING: Do not use circumferential dressings.

BRADYCARDIA: Avoid placement of the **extriCARE® 3600 Negative Pressure Wound Therapy Dressings** next to the vagus nerve to minimize the risk of bradycardia.

NOTE: If any of this information is not understood, contact the manufacturer before using the device.