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extriCARE[®]

Negative Pressure Wound
Therapy System

extriCARE[®] 3600

Operating Manual

ENGLISH

IFU38.0012 Rev C 20150317

EN-US



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1. 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.








Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. Symbol List

	<p>Battery: Full  <33%:  <10%: </p>
	<p>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.</p>
	<p>Bell: When an alarm is occurring, the symbol on the right will appear, showing that the alarm 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.</p>
	<p>Alarm: This icon indicates that there is an alarm. Please see the alarm section 9.2 for a full description of all of the alarms.</p>
	<p>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.</p> <p>To change between the modes, press the SET button.</p>
<p>125 mmHg</p>	<p>Real Negative Pressure: This shows the real-time pressure.</p>
<p>125 mmHg</p>	<p>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.</p>
	<p>Pump Running: This icon indicates that the pump is turned on and engaged.</p>
	<p>Error Modes: See section 9.2.</p>
<p>2 </p>	<p>Lock/Unlock: See section 10.2, step 5</p>

2. Symbol List (continued)

	Warning/Caution: See instructions for use for additional guidance
	Single Use Only
	Date Of Manufacture
	Type BF applied part
	Keep Dry
	Serial Number
	Power Switch
	Manufacture Lot Number
	Authorized Representative in the European Community
	Class II Equipment
	Use By

	<p>Conforms to AAMI STD ES.60601-1, HA 60601-1-11 Certified to CSA STD C22.2 No.60601-1, 60601-1-11</p>
	<p>Manufacturer</p>
	<p>Catalog / Model Number</p>
	<p>Sterilized Using Ethylene Oxide</p>
	<p>Refer to instruction manual.</p>
	<p>Protected against foreign objects equal to or greater than 12.5mm and against falling drops of water when enclosure tilted up to 15°.</p>
	<p>Waste Electrical Goods Recycled</p>



3. Device Specifications

DIMENSIONS:	Length: 6.7" (17cm) Depth: 4.3" (11cm) Height: 5.1" (13cm)
WEIGHT:	2.87 lbs (1.3 kg)
BATTERY TYPE:	Lithium Battery, 10.8V, 4400mAh (rechargeable)
AC/DC ADAPTER:	Model Number: GTM91099-6015-T2 AC Input: 100-240V, 1.5A, 50/60Hz DC output: 15V 4A, 60W
VACUUM MODES:	Continuous or Intermittent
OPERATING CONDITIONS:	Temperature: +5°C to 40°C (41°F to 104°F) Humidity: 15-93%
PRESSURE OPTIONS:	40mmHg - 200mmHg (+/- 5mmHg) in increments of 5mmHg
CHARGING TIME:	5h
BAROMETRIC PRESSURE:	800hPa-1060hPa
STORAGE/TRANSPORTATION CONDITIONS:	Temperature: -25°C to 70°C Humidity: < 93% non-condensing
ALTITUDE RANGE:	<2000m
INGRESS PROTECTION:	IP22
PROTECTION AGAINST ELECTRICAL SHOCK:	Class II
PATIENT PROTECTION:	Type BF

4. Accessories

1. AC/DC Adapter: Please only use the AC/DC adapter provided in the package.
2. Tubing Set: 1.55m tubing with a luer-lock connector on one end preattached. A clamp is also attached to the tubing.
3. Canister: Available in 400cc and 1000cc.
4. Dressings: Please reference [extriCARE® Negative Pressure Wound Therapy System Bandages](#) (IFU30.0006) and [Foam Dressings](#) (IFU38.0011) for a complete listing of all current dressing options.
5. Carrying Case: Used to carry the device if desired.

5. Indications for Use

The [extriCARE® 3600 Negative Pressure Wound Therapy System](#) is indicated for wound management via the application of negative pressure to the wound by the removal of wound exudate, infectious materials, and tissue debris from the wound bed. The [extriCARE® 3600 Negative Pressure Wound Therapy System](#) is indicated for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

6. Contraindications for Use

The [extriCARE® 3600 System](#) should **NOT** be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound.
- Fistulas, unexplored or non-enteric.

6. Contraindications for Use (continued)

- Untreated osteomyelitis.
- Malignancy in the wound.
- Excess amount of necrotic tissue with eschar.
- Wounds which are too large or too deep to be accommodated by the dressing.
- Inability to be followed by a medical professional or to keep scheduled appointments.
- Allergy to urethane dressings and adhesives.
- Use of topical products which must be applied more frequently than the dressing change schedule allows.

7. Warnings

- Review this manual prior to using the **extriCARE[®] 3600 Negative Pressure Wound Therapy Pump System**. If clarification is needed, contact technical personnel or Alleva Medical Products at 1-866-446-0092 prior to use. Additional questions can be immediately addressed as well.
- Do not use the **extriCARE[®] 3600 Negative Pressure Wound Therapy Pump** around explosive or flammable material. Do not use the pump in an MRI environment or hyperbaric chamber. Disconnect prior to defibrillation.
- This device should be used only under the direction of a trained professional, such as a doctor or nurse.
- Larger canister sizes (400cc or larger) should only be used in a facility where drainage can be closely monitored due to the increased risk of injury to the patient due to bleeding when using the 400cc canister. Precautionary measures should be taken for patients who have an increased risk of bleeding (Please see Section 8.1 #1) when using larger canisters.
- Negative Pressure Wound Therapy has not been cleared for use on children.
- Use a properly rated charger to charge the lithium battery. Incorrect voltage and/or current can cause fire.
- Do not place this device at temperatures greater than 170°F for more than 2 hours which may cause a battery fire.
- If battery swells, gets hot, or smokes while charging, disconnect the charger immediately. This may cause the battery to leak, and the reaction with air may cause the chemicals to ignite, resulting in fire.
- Battery may need to be replaced after 500 discharge cycles.
- Avoid heat from a fireplace or radiant heater.
- Use the device in a clean environment; one that is free from dirt, dust, pets, hair, etc.
- Do not position the device that makes it difficult to unplug the power cord.
- * There is a risk of strangulation if one gets tangled in the cables or tubing. Keep away from babies and children.

8. Precautions

8.1) 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. These conditions should be factored into the therapy prescription as the attending clinician sees fit.
3. **ENVIRONMENT:**
The **extriCARE®** system should not be used in an magnetic resonance imaging (MRI) environment, in hyperbaric chamber environment (HBO), nor with defibrillation. Please disconnect device and/or remove dressings as instructed by your physician if these situations arise.
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**.
5. **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.

8.1) Be aware for any of the following conditions (continued):

6. **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.
7. **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.
8. **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.
9. **CIRCUMFERENTIAL DRESSING:** Do not use circumferential dressings.
10. **BRADYCARDIA:** Avoid placement of the **extriCARE® 3600 Negative Pressure Wound Therapy Dressings** next to the vagus nerve to minimize the risk of bradycardia.
11. **PERIWOUND SKIN:** Protect periwound skin with additional hydrocolloid, other transparent film, or other skin prep methods. Monitor skin for any signs of irritation or irregularity. If this occurs, stop treatment and consult physician.

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

8.2) 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.

8.3) 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.

8.4) Dressing Management

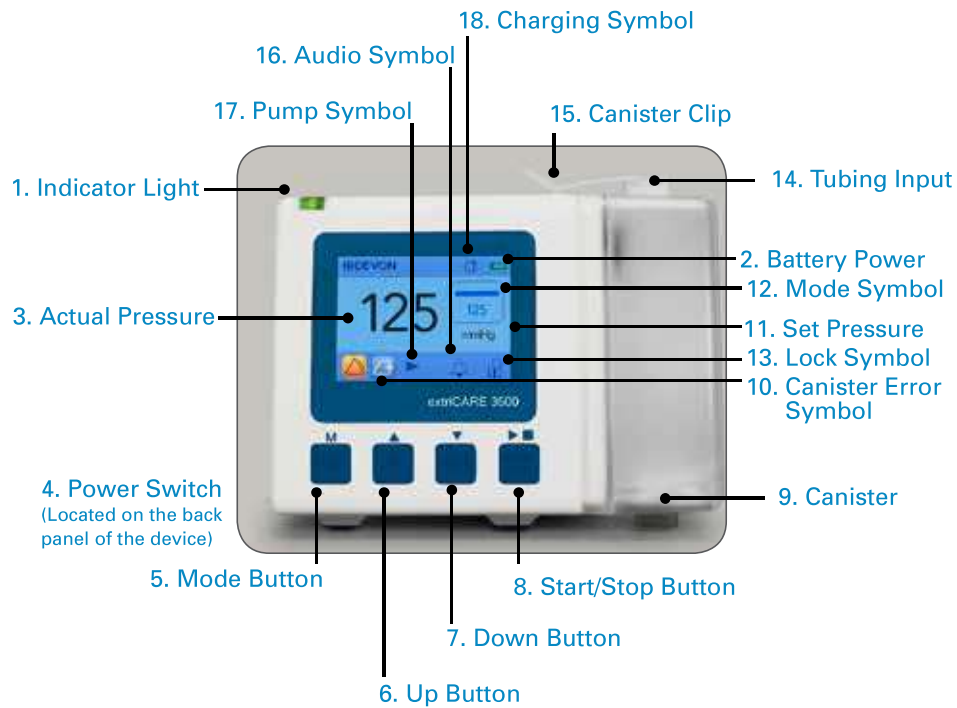
In the event that the **extriCARE®** wound dressings comes apart, all **extriCARE®** wound dressings materials must be removed from the wound prior to further treatment.

Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control. The type of **extriCARE®** wound dressings chosen for use is dependent on the wound type, size, and location. **extriCARE®** wound dressings size and type is labeled on each package.

- Care should be taken to avoid stretching of the dressing.
- Avoid pleating the **extriCARE®** wound dressings. Additional tape and urethane may be applied to secure the **extriCARE®** dressing in place.
- Do not use as a circumferential dressing.
- Additional wrap dressing may be applied over the **extriCARE®** wound dressings to further secure the **extriCARE®** wound dressings and provide additional support.
- If used on anatomically challenging areas or where adhesion is a problem, a thin layer of ostomy paste may be applied.
- Refer to instructions for specific information regarding each **extriCARE®** wound dressings.
- In a non-infected and monitored wound, dressings should be changed no less frequently than every 72 hours. Disconnect the dressing from the drainage tubing and gently peel off to remove.

9. Features

9.1) Defined Features



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.





9. Features

9.1) Defined Features (continued)




6. **Up Button:** This increases the set pressure in increments of 5 mmHg up to a maximum of 200 mmHg.
7. **Down Button:** This decreases the set pressure in increments of 5 mmHg down to a minimum of 40 mmHg.
8. **Start/Stop Button:** Used to engage or disengage the pump.
9. **Canister:** Used to store exudates removed from the wound.
10. **Canister Error Symbol:** Indicates a canister installation error or canister full error.
11. **Set Pressure:** This displays the pressure that the **extriCARE® 3600** is set for.
12. **Mode Symbol:** Indicates pump operating mode (continuous or intermittent).
13. **Lock Symbol:** Indicates if the device is locked or not.
14. **Tubing Input:** This is the connection port used for the **extriCARE® 3600 dressings** to attach to the pump.
15. **Canister Clip:** Clip that connects the canister to the **extriCARE® 3600 device**.
16. **Audio Symbol:** Indicates whether the sound is on or off.
17. **Pump Symbol:** Indicates whether the pump is engaged or not.
18. **Charging Symbol:** Indicates whether the **extriCARE® 3600** is charging or not.

The device can be operated under battery charging condition.

9.2) Alarm Features/Troubleshooting

Error Type	Cause/Description	Audio Alarm Features	Visual Alarm Features	System Status	Suggested Mitigation
Canister Installation Error	The canister is not detected or is installed incorrectly	3 beeps every 20 seconds	 <p>Yellow LED flashing every 2 seconds</p>	Pump remains on	Properly install the canister
High Voltage Error	The extriCARE® 3600 is being used with an adapter that is not recommended; There is a risk of voltage incompatibility if the input voltage is greater than 16V	3 beeps every 20 seconds	 <p>Yellow LED flashing every 2 seconds</p>	Fuse may blowout	Unplug the adapter and use the recommended adapter
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>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>Yellow LED flashes every 2 seconds</p>	Pump will shot off immediately	Install a new canister

9.2) Alarm Features/Troubleshooting (continued)

Error Type	Cause/Description	Audio Alarm Features	Visual Alarm Features	System Status	Suggested Mitigation
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 alarms have been divided into two categories, mild and severe.				
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 -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>	Pump remains on but will shut down after 10 minutes of continuous alarm and without any operation	- if necessary, power off and back on to restart the system after adjustment
Blockage	Tubing or dressing clog or blockage	3 beeps every 20 seconds	 <p>Yellow LED blinks every 2 seconds</p>	Pump remains on	Replace with new dressing and tubing set

10. Instructions for Use

10.1) 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.

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.

10.1) Dressing and Canister Application (continued)

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 applying the **extriCARE**® wound dressings over toes:

- A thin layer of petroleum jelly or other oil based ointment should be applied to nails.
- Additionally, antifungal medication and a small amount of soft dressing material may be applied between each toe.

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.

10.2) Operating the Device

1. **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:



2. **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 pressure the UP or DOWN button, the pressure will change continuously by every 5mmHg.

10.2) Operating the Device (continued)

- 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:



- 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 alarm occurs when the device is locked, the backlight to the screen will turn on and the alarm will display.

Unlocked:



Locked:



10.3) Rail Clamp

Rail clamp (Figure 1) is provided to hang the device in case it is necessary. To use the rail clamp, insert the clamp board firmly into the socket located at the back of the device. Release the screw on the clamp to make space for the hanging media. Snap the clamp onto the hanging medium with the socket opening facing the ground. Tighten the screw, make sure there is a secure clamp (Figure 2).

Note: Do not use the device as a hanger and hang objects on the device, i.e. clothes.



Figure 1



Figure 2

10.4) Disposal

The **extriCARE[®] Negative Pressure Wound Therapy Pump** is powered electromechanically by a battery that should be recycled according to the local regulations governing such products and Waste Electrical and Electronic Equipment (WEEE) Directive.

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

Unplug the power adapter plug when the device is not in use.

10.5) Maintenance and Replacement Parts

The **extriCARE[®]** device contains no user serviceable parts inside: Opening or tampering with this device will void the warranty. In the event the **extriCARE[®]** device requires repairs, it should be returned to the medical equipment company or to Alleva Medical Products directly. No modification of the device is allowed.

Power adapter: The **extriCARE[®]** device should only be recharged using the AC/DC adapter provided or an equivalent IEC 60601-1 compliant adapter with a DC 15V 4A output.

Battery: Do not attempt to open, disassemble, or service the battery pack. Do not crush, puncture, short external contacts, or dispose of in fire or water. Use only a Alleva Medical Products approved battery. If the device will not be in use for an extended period of time, the battery should be maintained by recharging regularly. Battery should be stored in a safe and dry place.

10.6) Cleaning

To clean the **extriCARE[®]** Device, use a medical grade cleanser (such as Envirocide) and follow the directions indicated by the cleanser. The device should not, for any reason, be immersed in water; additionally, water should not be allowed to breach the device's outer shell.

11. Warranty Information:

LIMITED WARRANTY

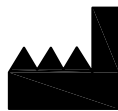
Alleva Medical Products warrants its **extriCARE[®] Negative Pressure Wound Therapy Pump** (“Device”) to be free from defects in workmanship and materials for a period of two (2) year from the date the Device is delivered to the original purchaser (“Warranty Period”). This Limited Warranty is extended only to the original purchaser and is non-transferable. Alleva Medical Products’ sole obligation under this Limited Warranty shall be, at its sole discretion, to repair or replace a Device which is defective in either workmanship or material. This is the sole remedy of the Purchaser. This Limited Warranty excludes the battery, canister, canister clip, power plug, connection tubing, and dressings. In addition, this Limited Warranty does not cover any Device which may have been damaged in transit or has been subject to misuse, neglect, or accident; or has been used in violation of Alleva Medical Products’ instructions, including, without limitation, the instructions contained in the Operation Manual.

THERE ARE NO OTHER WARRANTIES THAN THOSE EXPRESSLY STATED HEREIN.

TO THE EXTENT PERMITTED BY LAW, ALLEVA MEDICAL PRODUCTS DOES NOT MAKE ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS TO ANY PRODUCT OR DEVICE, WHETHER OR NOT THAT PRODUCT OR DEVICE IS COVERED BY ANY EXPRESS WARRANTY CONTAINED HEREIN.

IN NO EVENT SHALL ALLEVA MEDICAL PRODUCTS BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR INDIRECT DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, USE OR TIME INCURRED BY PURCHASER OR END USER). IN ADDITION, ALLEVA MEDICAL PRODUCTS SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

12. Contact Information



Manufactured For

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Appendix 1

Product Classification:

- According to the type of protection against electrical shock, this device is classified as a Class II Equipment, and Type BF Equipment that is powered by an external electrical power source.
- According to the degree of protection against harmful ingress of water this system is classified as Ordinary Equipment (IP22: Protected against foreign objects equal to or greater than 12.5mm and against falling drops of water when enclosure tilted up to 15°.)
- **CAUTION:** This device has been tested and confirmed to comply with the IEC 60601-1-2:2007 and essential requirements of Medical Device Directive 93/42/EEC. However with the proliferation of radio-frequency transmitting equipment, and other sources of electrical noise in a healthcare environment, high levels of interference may induce an abnormal stoppage or other disruption of this device. This device may also cause adverse effects in other nearby equipment. It is strongly recommended that this device be isolated from other electromagnetic equipment when in use.
- This system is classified as Equipment not Suitable for use in the presence of a Flammable Anesthetic Mixture with Air or Oxygen or Nitrous Oxide.
- According to the mode of operation this system is classified as Equipment that can be used for Continuous Operation.
- **CAUTION:** In the USA, Federal Law restricts this device to sale, by or on the order of a physician.
- For reusable medical devices (such as the pump), it will have an estimated useful life of 3 years. For disposable medical devices (such as the dressings and canisters), the shelf life expires at their respective expiration dates, which can be found on the package labeling.
- Unit is packaged for transportation by common carrier.

Appendix 2

Accompanying Documents:

A. Instructions for use

1. **MODEL 3600** needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS;
2. Portable and mobile RF communications equipment can affect **MODEL 3600**.

B. Technical description

1. **MODEL 3600** needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.
2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect **MODEL 3600** and should be kept at least a distance d away from the **MODEL 3600**.
3. Warning that the use of accessories, transducers and cables other than those specified with the exception of transducers and cables sold by the manufacturer of the **MODEL 3600** as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the **MODEL 3600**.
4. Warning that the **MODEL 3600** should not be used adjacent to or stacked with other equipment.
5. Guidance and manufacturer's declaration – electromagnetic emissions

The **MODEL 3600** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 3600** should assure that it is used in such an environment.

Emissions	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The MODEL 3600 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MODEL 3600 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	



Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MODEL 3600 is intended for use in the electromagnetic environment specified below. The customer or the user of the MODEL 3600 should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) and neutral	±1 kV line(s) and neutral	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If a dips or an interruption of mains power occurs, the current of the MODEL 3600 may be dropped off from normal level, it may be necessary to use uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application if the test level.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The **MODEL 3600** is intended for use in the electromagnetic environment specified below. The customer or the user of the **MODEL 3600** should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 Hz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the MODEL 3600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> <p>$d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ 80MHz to 800MHz</p> <p>$d = 2.3\sqrt{P}$ 800MHz to 2.5GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation.</p> <p>Distance is metres (m)</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

NOTE 1: At 80 MHz, the higher the frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **MODEL 3600** is used exceeds the applicable RF compliance level above, the **MODEL 3600** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **MODEL 3600**.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the **MODEL 3600**.

The **MODEL 3600** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **MODEL 3600** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **MODEL 3600** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

References

References available upon request.

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