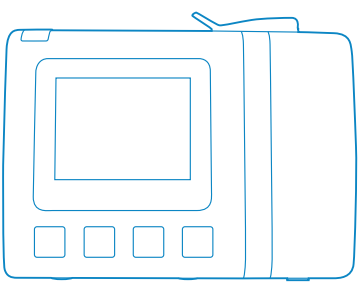
extriCARE®

Operating Manual

extriCARE® 3600

Negative Pressure Wound Therapy System



ALLEVA MEDICAL

www.allevamedical.com

ENGLISH VERSION - US
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1. Introduction

Alleva Medical's **extriCARE® Negative Pressure Wound Therapy (NPWT)** products consist of a family of negative pressure pumps and dressings intended to promote wound healing on patients in either hospital and community settings. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, flaps and grafts may benefit from using the **extriCARE® NPWT** system.

The **extriCARE® 3600 NPWT** is a portable, battery-powered pump capable of delivering bespoke continuous and/or intermittent negative pressure intended to promote wound healing through the drainage and removal of wound exudates, infectious material, and tissue debris from the wound bed. Each **extriCARE® 3600 NPWT pump** comes with a sturdy 400cc collection canister provided with solidifying agents to ease disposal and handling. For wounds with larger drainage needs, a 1000cc collection canister is also available.

Alleva Medical provides two main type of wound filler dressings to be used in conjunction to the **extriCARE® pump units** – the **extriCARE® Negative Pressure Wound Therapy Anatomical Bandages** and the **extriCARE® Negative Pressure Wound Therapy Open-Cell Foam Kits.** Both types of wound dressing are designed to provide an air-tight environment to the wound bed while allowing absorption and drainage of wound fluids into the collection canister.

The **extriCARE® 3600 Negative Pressure Wound Therapy** pump allows a 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® pump** is meant for continuous use (at least 22 of 24 hours per day). The **extriCARE® 3600 pump unit** is to be used in hospital or community settings but not for home use. For home use, the **extriCARE® 2400 pump** is recommended.

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

2. Package Content

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Each box contains:

1. An **extriCARE® Negative Pressure Wound Therapy** pump unit
2. An **extriCARE®** 400cc collection canister with solidifying agents
3. A roller stand clamp
4. A 15V/4A AC/DC Adapter with US Plug

3. Defined Features

1. **Indicator Light:** Indicates if the pump is running and functioning properly or an error is detected.

2. **Power Switch (Located on the back panel of the device):** Used to turn the system power on and off.

3. **Mode Button:** Allows user to set the pump to either continuous or intermittent mode.

4. **Up Button:** This increases the set pressure in increments of 5 mmHg up to a maximum of 200 mmHg.

5. **Down Button:** This decreases the set pressure in increments of 5 mmHg down to a minimum of 40 mmHg.

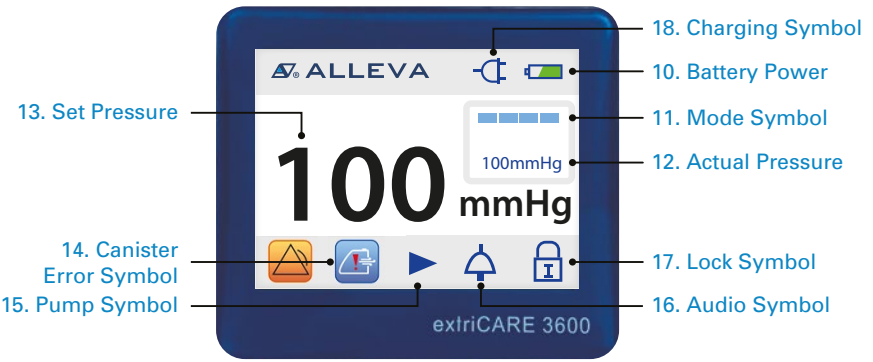
6. **Start/Stop Button:** Used to start or stop a therapy.

7. **Canister:** Used to store exudates removed from the wound.

8. **Canister Clip:** Clip that connects and secures the canister to the extriCARE® 3600 pump unit.

9. **Tubing Input:** This is the connection port used for attaching the extriCARE® 3600 dressings to attach to the collection canister.

3. Defined Features (continued)



10. **Battery Power:** Indicates how much battery power is left. Icon has 1-4 bars representing 10%, 33%, 66%, and 100% battery power, respectively.

11. **Mode Symbol:** Indicates the current operating mode (continuous or intermittent).

12. **Actual Pressure:** This displays the real-time pressure reading.

13. **Set Pressure:** This displays the pressure that the extriCARE® 3600 is set for.

14. **Canister Error Symbol:** Indicates a canister installation error or canister full error.

15. **Pump Symbol:** Indicates whether the pump is engaged or not.

16. **Audio Symbol:** Indicates whether the sound is on or off.

17. **Lock Symbol:** Indicates if the device is locked or not.

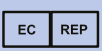
18. **Charging Symbol:** Indicates whether the extriCARE® 3600 is charging or not.

The device can be operated under battery charging condition.

4. Symbol List

	**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 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.
	**Alarm:** This icon indicates that there is an alarm. Please see the alarm section 11 for a full description of all of the alarms.
 	**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 the SET button.
125 mmHg	**Current Set 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.
125 mmHg	**Actual Negative Pressure:** This shows the real-time actual pressure.
	**Pump Running:** This icon indicates that the pump is turned on and engaged.
	**Error Modes:** See section 11.
	**Lock/Unlock:** See section 12.2, step 5

4. 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

ETL CLASSIFIED C ETL LISTED US Intertek 5011631	Conforms to AAMI STD ES.60601-1, HA 60601-1-11 Certified to CSA STD C22.2 No.60601-1, 60601-1-11
	Manufacturer
REF	Catalog / Model Number
STERILE EO	Sterilized Using Ethylene Oxide
	Refer to instruction Manual
IP21	Protected against solid foreign objects of 12.5mm andgreater and vertically falling water drops.
	Waste Electrical Goods Recycled

5. 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, 11.1V, 5200mAh (rechargeable)
AC/DC ADAPTER:	Model Number: GTM91099-6 015-T 2 AC Input: 100-240Vac, 50/60Hz, 1A, 49W Max DC output: 15V 4A, 40W
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 in increments of 5mmHg
CHARGING TIME:	5 hours
BAROMETRIC PRESSURE:	800hPa-1060hPa
STORAGE/TRANSPORTATION CONDITIONS:	Temperature: -25°C to 70°C; Humidity: < 93% non-condensing
ALTITUDE RANGE:	<2000m
INGRESS PROTECTION:	IP21
PROTECTION AGAINST ELECTRICAL SHOCK:	Class II
PATIENT PROTECTION:	Type BF

6. 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 contact your local distributor for a complete listing of all current dressing options.
5. Carrying Case: For use to carry the device if desired.

7. 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 for the following wound types: chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

8. 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.
- 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.

9. 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 1-877-312-NPWT 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 10.1 #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.**

10. Precautions

10.1) 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 im-aging (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.

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

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

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.

10.2) 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.

10.3) 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.

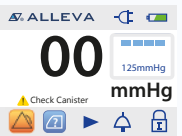
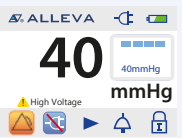
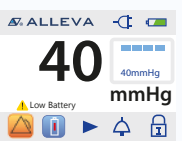
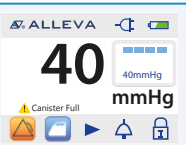
10.4) Dressing Management

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.

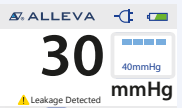
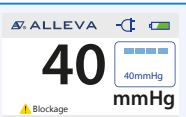
Clean and debride the wound as necessary. Any bleeding should be controlled. Follow facility protocol for wound prep and infection control. The type of extriCARE® wound dressings chosen for use is dependent on the wound type, size, and location. extriCARE® wound dressings size and type is labeled on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

11. 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 **"Check Canister"**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	Pump will not run	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 **"High Voltage "**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	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 **"Low Battery "**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	Pump remains funtioning 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 **"Canister Full "**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	Pump will shot off immediately	Install a new canister

11. 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 **"Leakage Detected"**	1 beeps every 20 seconds	 Yellow light is on constantly	Pump remains on	Inspect for possible air leaks between: -the wound and extriCARE® dressing -the extriCARE® dressing and canister -the canister and pump - if necessary, power off and back on to restart the system after adjustment
Severe Leakage	Pump unable to reach 50% of the preset pressure after 2 minutes of pump effort **"Severe Leakage"**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	Pump remains on but will shut down after 10 minutes of continuous alarm and without any operation	
Blockage	Tubing or dressing clog or blockage **"Blockage Leakage"**	3 beeps every 20 seconds	 Yellow LED flashing every 2 seconds	Pump remians on	Replace with new dressing and tubing set

12. Instructions for Use

12.1) 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 the 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 pump unit, 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 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.

12.1) Dressing and Canister Application (continued)

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:

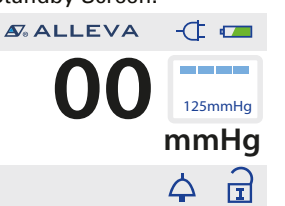
- It is recommended that a non-adherent open weave or fenestrated silicone contact layer be applied atop the wound between the graft and the NPWT dressing.
- Heavy petrolatum or similar products cannot be used as negative pressure will not have an impact on the wound surface.
- Additional care should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

12.2) 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:



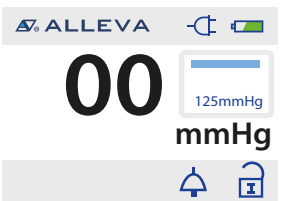
2. **PRESSURE CONTROL**: The extriCARE® 3600 has a default pressure of 125 mmHg. This can be changed by pressing the UP or DOWN buttons. The pressure will change in increments of 5 mmHg with a range of 40 mmHg to 200 mmHg. Long pressure the UP or DOWN button, the pressure will change continuously by every 5mmHg.

12.2) Operating the Device (continued)

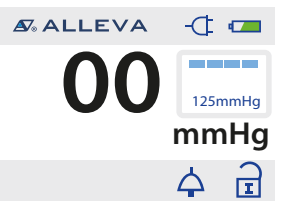
3. **MODE:** The extriCARE® 3600 can operate in continuous or intermittent modes. In continuous mode, the extriCARE® 3600 will continuously operate at the set pressure. In intermittent mode, the extriCARE® 3600 will operate for 5 minutes at the set pressure, and then for 2 minutes at 20 mmHg, and then repeat the cycle.

   To interchange between two modes, ensure the device is in 'unlock state'. Then press the 'M' Mode button for at least two seconds, until the mode symbol changes on the display.

Continuous Mode:



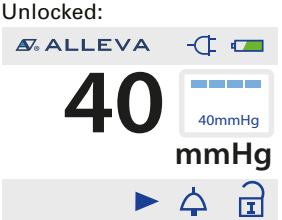
Intermittent Mode:



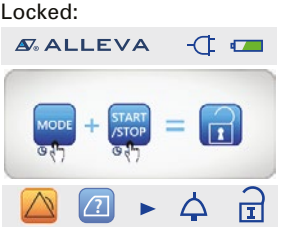
4. **START/STOP TREATMENT:** To start treatment, press the START/STOP BUTTON for 2 seconds.

5. **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:



12.3) 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

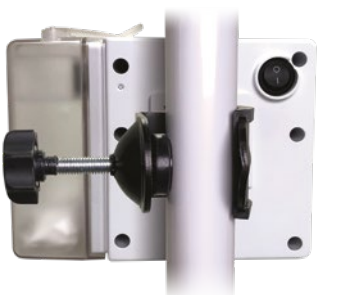


Figure 2

12.4) 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.

12.5) 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 your durable medical equipment company (DME) or local distributor, 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.

12.6) 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.

13. 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.

14. Contact Information

Manufactured by
ALLEVA MEDICAL
Suite M-Q, 12th Floor, Kings Wing Plaza 2
1 On Kwan St., Shek Mun, Shatin, N.T., Hong Kong
www.allevamedical.com
Made in China

Instructions for use

a) A statement of the environments for which extriCARE® 3600 is suitable. Relevant exclusions, as determined by RISK ANALYSIS, shall also be listed, e.g. hospitals except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.

b) The performance of the extriCARE® 3600 that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTRUBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

c) A warning statement to the effect that "WARNING: Use of extriCARE® 3600 adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally." The MANUFACTURER of extriCARE® 3600 may provide a description or list of equipment with which extriCARE® 3600 has been tested in a stacked or adjacent configuration and with which stacked or adjacent use resulted in normal operation.

d) A list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of extriCARE® 3600 with the equirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and MODEL OR TYPE REFERENCE). Transducers and cables specified by the MANUFACTURER of extriCARE® 3600 as replacement parts for internal components need not be listed.

e) A warning statement to the effect that "WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of extriCARE® 3600 cold result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

f) A warning statement to the effect that: " WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the extriCARE® 3600 including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If extriCARE® 3600 is classified class A according to CISPR 11, the instructions for use shall include the following note:
NOTE: The emissions characteristics of extriCARE® 3600 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) extriCARE® 3600 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Technical description

1. The technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES. The technical description shall include the following information:

a) The compliance for each EMISSIONS and IMMUNITY standard or test specified by the standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL; (Table 1, Table 2 and Table 3 as for example)

b) Any deviations from the standard used;

c) All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The extriCARE® 3600 is compliance for each EMISSIONS test specified by the standard, e.g.EMISSIONS class and group.		
Emissions	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR11	Group 1	The extriCARE® 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 near by electronic equipment.
RF emissions CISPR11	Class B	The extriCARE® 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 IEC61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity		
The extriCARE® 3600 is compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.		
Immunity test	**Compliance level**	**IEC 60601-1-2 test level**
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Radiated RF EM fields IEC61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80MHz-2.7GHz 80% AM at 1kHz
Electrical fast transient / burst IEC61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV,±1 kV line-to-line; ±0.5 kV,±1 kV and ±2 kV line-to-ground;	±0.5 kV,±1 kV line-to-line; ±0.5 kV,±1 kV and ±2 kV line-to-ground;
Conducted disturbances induced by RF fields IEC61000-4-6	3V 0.15 MHz - 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3V 0.15 MHz - 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% U_T: 0.5 cycle[a] At0°, 45°, 90°,135°,180°, 225°, 270°, and 315°.	0% U_T: 0.5 cycle[a] At0°, 45°, 90°,135°,180°, 225°, 270°, and 315°.
	0% U_T: 1cycle 70% U_T: 25/30 cycles[b] Single phase: at 0°	0% U_T: 1cycle 70% U_T: 25/30 cycles[b] Single phase: at 0°
	0% U_T: 250/300 cycles[b]	0% U_T: 250/300 cycles[b]
Power frequency (50/60Hz) magnetic field IEC61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz
NOTE: a) U_T is the a.c. mains voltage prior to application of the test level; b) E.g. 25/30 means 25 periods at 50 Hz or 30 periods at 60 Hz.		

Table3 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service[a)]	Modulation[b)]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level
385	380 - 390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27	27
450	430 - 470	GMRS 460 FRS 460	FMc) ±5 kHz deviation 1kHz sine	2	0.3	28	28
710	704 - 787	LTE-Band 13,17	Pulse Modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 - 960	GSM 800/900, TETRA 800, Iden 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0.3	28	28
870							
930							
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

NOTE: a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distances between portable and mobile RF communications equipment and the extriCARE® 3600. The extriCARE® 3600 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the extriCARE® 3600 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the extriCARE® 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√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√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 distanced 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 avaliable upon request.

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