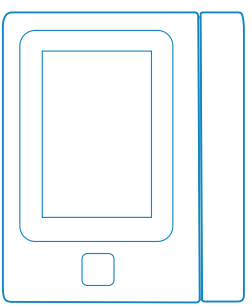
extriCARE®

Operating Manual

extriCARE® 3000

Negative Pressure Wound Therapy System



For Clinicians Use

Online Reference for Clinicians

ALLEVA MEDICAL

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FOR CLINICIAN USE

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 healthcare facilities. Patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, diabetic ulcers, neuropathic ulcers, pressure ulcers, incisional wounds, flaps and grafts may benefit from using the **extriCARE® NPWT** system.

The **extriCARE® 3000 NPWT Pump** is a portable, battery-powered pump with a touchscreen user interface, capable of delivering 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® 3000 NPWT Pump** comes with a sturdy 100cc collection canister provided with solidifying agents to ease disposal and handling. For wounds with larger drainage needs, a 400cc collection canister is also available.

Alleva Medical provides two main type of wound filler dressings to be used in conjunction to an **extriCARE®** pump unit – the **extriCARE® Negative Pressure Wound Therapy Bandage Dressings** and the **extriCARE® Negative Pressure Wound Therapy 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 and are sold separately.

The **extriCARE® 3000 NPWT Pump** allows a user to select a treatment pressure ranging from 20mmHg to 140mmHg. 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 the target pressure for 5 continuous minutes and a lower pressure (20mmHg) for 2 minutes.

The **extriCARE® 3000 NPWT Pump** is meant for continuous use (at least 22 of 24 hours per day). The **extriCARE® 3000 NPWT** Pump is to be used in healthcare facilities.

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

2. Indications for Use

The **extriCARE® 3000 Negative Pressure Wound Therapy System** is intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed.

It 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

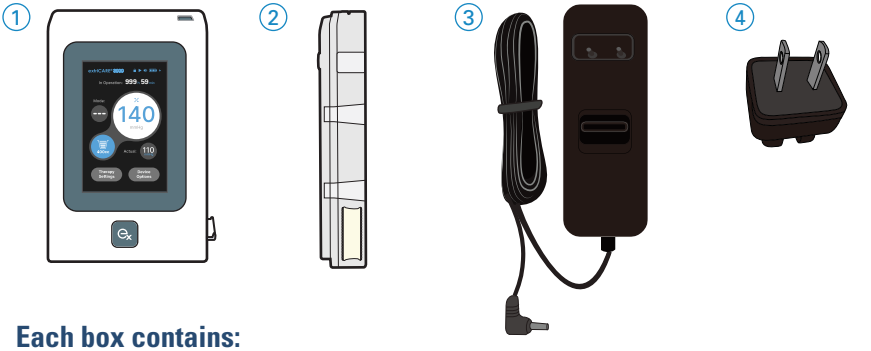
The **extriCARE® 3000** Negative Pressure Wound Therapy System is suitable for use in healthcare facilities.

3. Contraindications for Use

The **extriCARE® 3000 NPWT Pump** 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

4. Package Content



Each box contains:

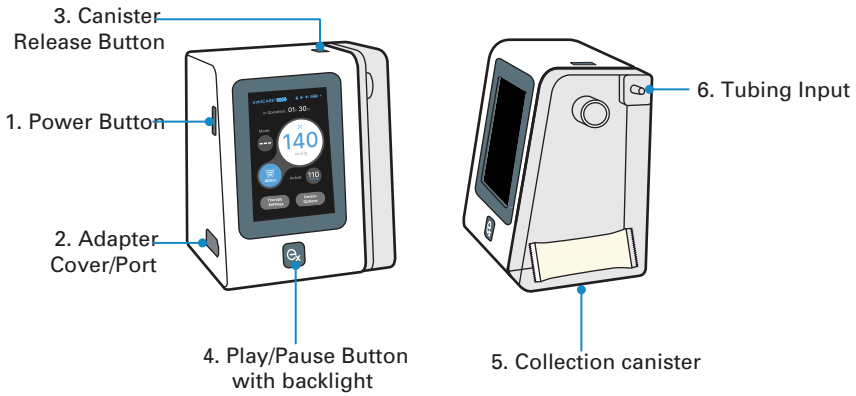
1. An **extriCARE® 3000 Negative Pressure Wound Therapy Pump** unit.
2. An **extriCARE®** 100cc collection canister with solidifying agents.
3. A 12V/2A AC/DC Adapter.
4. An electric plug (of either US, UK, EU variant) for the adapter.

5. Accessories

The following accessories are available for purchase with the **extriCARE® 3000 NPWT pump**. Please contact your local distributor for purchase orders.

1. AC/DC Adapter: Please only use the AC/DC adapter provided in the package.
2. Collection Canister: Available in 100cc and 400cc.
3. Carrying Case: For use to carry the device with the two sizes of collection canister.
4. Wound Dressings: Please contact your local distributor for a complete listing of all currently available dressing options.

6. Features



1. **Power Button:** to turn the device on or off.

2. **Adapter Cover/Port:** the soft adapter cover protects the adapter port from dust and debris. The adapter port receives only the adapter model provided in the package.

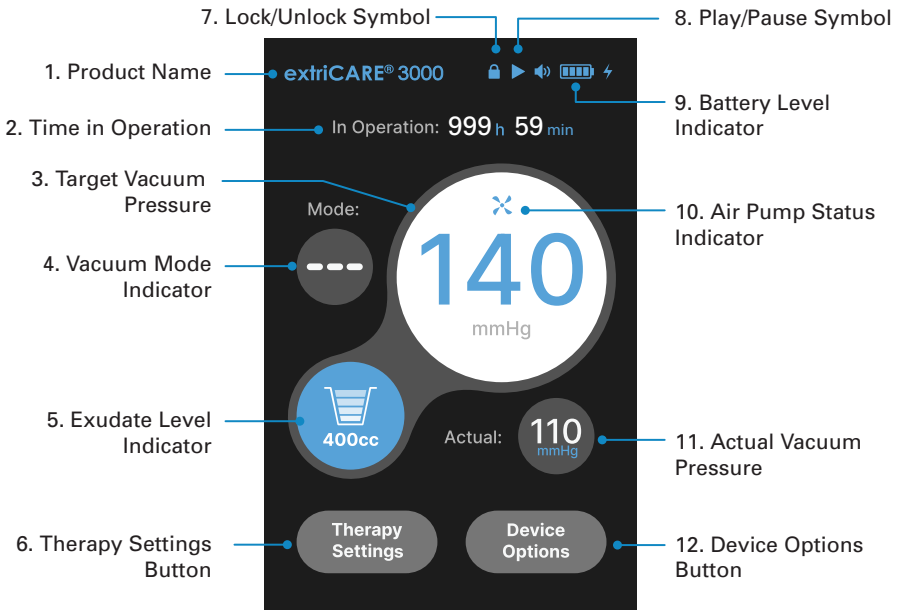
3. **Canister Release Button:** pressing the button will release the collection canister from the device.

4. **Play/Pause Button with backlight:** to start or stop a therapy. The button is also equipped with a red, green and yellow backlight to indicate device status.

5. **Collection canister:** to store exudates removed from the wound.

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

7. User Interface



Certain therapy settings for the **extriCARE® 3000 NPWT** pump shall be adjusted using the device's touchscreen. The resistive touchscreen can be used with surgical gloves and/or through the clean panel of the carrying case.

The Main Page contains the following features:

1. **Product Name:** displays the product name. A white product name indicates the pump is in normal blockage mode, whereas a blue product name indicates the pump is in sensitive mode (see Section 12.5.2)

2. **Time in Operation:** displays how long the pump has been in operating since the last reset (See Section 12.5.1)

3. **Target Vacuum Pressure:** displays the target therapy pressure, in mmHg

7. User Interface (continued)

4. **Vacuum Mode Indicator:** indicates the selected vacuum mode. A straight line denotes continuous mode, and a dashed line denotes intermittent mode

5. **Exudate Level Indicator:** indicates the approximate level of the collection canister and the size of the canister. Pressing this area will generate a log with collection time and level (See Section 12.7)

6. **Therapy Settings Button:** pressing this button will open a new window that allows user to adjust therapy settings (See Section 12.4)

7. **Lock/Unlock Symbol:** indicates whether the device is under locked or unlocked mode (See Section 8 Symbol List)

8. **Play/Pause Symbol:** indicates whether the therapy is in session or on pause (See Section 8 Symbol List)

9. **Battery Level Indicator:** displays the battery level and charging status (See Section 8 Symbol List)

10. **Air Pump Status Indicator:** appears when the air pump is operating.

11. **Actual Vacuum Pressure:** displays the actual target pressure, in mmHg

12. **Device Options Button:** pressing this button will open a new window that allows user to mute alarms and lock device settings (See Section 12.8)

8. Symbol List

	**Battery Level Indicator:** In 5 states (1 to 4 bars, or empty)
	Indicates that the device is charging normally. The battery levels would also alternate.
 Therapy in session  Therapy in pause	**Therapy Symbol:** Indicates whether the device is in therapy or in pause.
 Sound On  Sound Off	**Alarm Indicator:** Indicates if the device alarm is muted or not.
	This symbol appears when the device is under Lock Mode (see Section 10.7 for further details).
	See Section 11 for warnings and error handling.
	Single Use Only
	Date of Manufacture
	Use-by Date
	Type BF applied part
	Atmospheric pressure limitation
	Humidity limitation

8. Symbol List (continued)

	Keep Dry
SN	Serial Number
	Power Switch
	Class II Equipment
ETL CLASSIFIED c ETL us Intertek 5011631	CONFORMS TO AAMI STD ES 60601-1, IEC STD 60601-1-6, AAMI STD HA 60601-1-11.
REF	Catalog / Model Number
	Consult Instructions For Use
IP22	Protection against solid objects of >12.5mm and modest vertical liquid ingress
	Operation temperature Limit (low left number denotes the lower temperature limit and upper right number denotes the upper temperature limit)
	Unsafe
	Protect from heat and radio-active sources
UDI	Unique device identifier
	Information of Manufacturer

9. Device Specifications

DIMENSIONS:	Length: 4.0” (10.2cm) Depth: 3.1” (7.9cm) Height: 5.0” (12.7cm)
WEIGHT:	1.21 lbs (0.55 kg)
BATTERY TYPE:	Lithium Battery, 7.3V, 2450mAh (rechargeable)
AC/DC ADAPTER:	Model Number: UES24LCP1-120200SPA AC Input: 100-240Vac, 50/60Hz, 0.8A DC output: 12V 2A
VACUUM MODES:	Continuous or Intermittent
OPERATING CONDITIONS:	Temperature: +5°C to 40°C (41°F to 104°F) Humidity: 15-93%
PRESSURE OPTIONS:	20mmHg - 140mmHg in increments of 5mmHg
CHARGING TIME:	<4.5 hours
BAROMETRIC PRESSURE:	80kPa-106kPa
STORAGE/TRANSPORTATION CONDITIONS:	Temperature: -20°C to 50°C; Humidity: <93% non-condensing
ALTITUDE RANGE:	<2000m
INGRESS PROTECTION:	IP22
PROTECTION AGAINST ELECTRICAL SHOCK:	Class II
PATIENT PROTECTION:	Type BF
SHELF LIFE:	3 Years
PUMP SERVICE LIFE:	3000 hours

10. Warnings

- Review this manual prior to using the **extriCARE® 3000 NPWT Pump**. If clarification is needed, contact technical personnel or Alleva Medical Devices at 1-877-312-NPWT prior to use. Additional questions can be immediately addressed as well.
- Do not use the **extriCARE® 3000 NPWT Pump** around explosive or flammable material. Do not use the pump in an MRI environment or hyperbaric chamber. Disconnect pump from dressing prior to MRI, hyperbaric chamber, or defibrillation according to dressing instructions found with each dressing kit.
- This device should be used only under the direction of a trained professional, such as a doctor or nurse.
- 400cc 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 14.1) when using the 400cc 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.**

11. Precautions

11.1 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, complete evaluations shall be conducted per the facility's guideline before beginning treatment and special care and monitoring of collected exudate level shall be exercised during treatment; 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. **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.

11. Precautions (continued)

11.1 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 the 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® Negative Pressure Wound Therapy Dressings** next to the vagus nerve to minimize the risk of bradycardia.

11.2 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.
- Insert the plug into the adapter prior to connecting to an electric outlet.

12. Operating Instructions

⚠ **Please consult Section 10 Warnings and Section 11 Precautions before reading this section.**

extriCARE® 3000 Wound Dressings (sold separately) include bandages and foam kits. Follow detailed instructions that come with your **extriCARE® 3000 Wound Dressing** to apply the dressing.

12.1 Canister Installation

The **extriCARE® 3000** pump comes with a pre-installed 100cc canister. To install a fresh canister, engage the canister to the pump at the bottom. Then push the canister against the pump, so a snap can be felt and heard.

12.2 Turning on the Device

To turn on the device, locate the Power Button on the side of the device (See Section 6. Features).

Press down the Power Button for 2 seconds. The color touchscreen shall turn on and display the device model (**extriCARE® 3000**) and current software version.

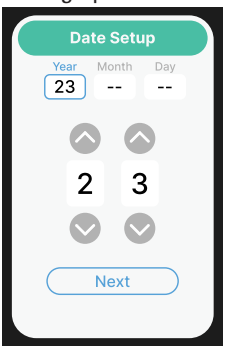
The Main Page shall appear on the screen as the device makes a single chirp sound.

12.3 Setting Up Time/Date

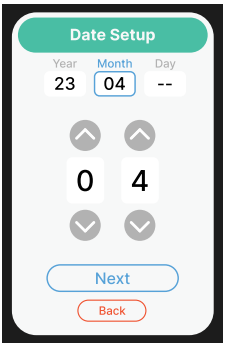
The first time the **extriCARE® 3000 NPWT** pump is turned on, the time/date setup page will appear automatically. The year, hour, month, and time can be setup sequentially via the grey up and down arrow buttons. Press the "Next" button to proceed to the next page, or "Back" to go back to the previous page.

12. Operating Instructions (continued)

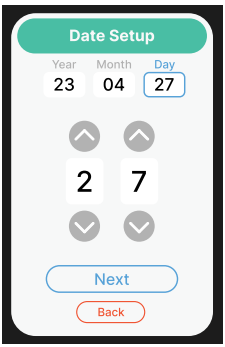
1. Setting up the Year



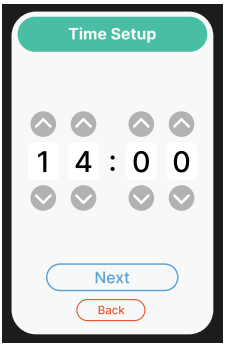
2. Setting up the Month



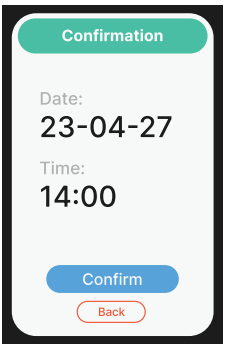
3. Setting up the Day



4. Setting up the Time



5. A confirmation page will appear once all the time and date are set. Pressing the “Confirm” button will enter into the Main Page.



12. Operating Instructions (continued)

12.3.1 Resetting the Date / Time

It is possible to reset the date and time (for example, when the pump is being used in a different time zone). To reset the date and time on the **extriCARE® 3000 NPWT** pump, go to the Main Page, hold down the Play/Pause button and the onscreen Device Options simultaneously for 3 seconds. The same date/time setup pages will appear.

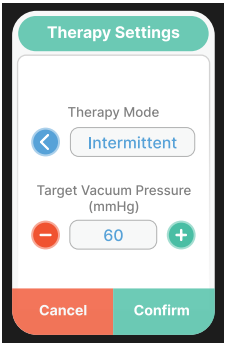
12.3.2 Extended Hiatus

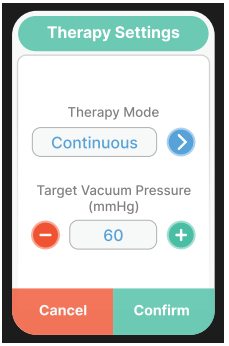
If the **extriCARE® 3000 NPWT** pump is shut off for an extended period (for example, 6 months), it is possible to that the internal battery runs out and the internal timer is interrupted. The device software will recognize the battery outage and will ask for user to confirm the time/date when the device is restarted, as per following figure. Press "Adjust" if user would like to re-adjust the time and date again.

12.4 Adjusting Therapy Settings

On the **extriCARE® 3000 NPWT** pump, the target vacuum pressure and pattern of vacuum delivered to the wound site can adjusted for different clinical situations. Before adjusting either of these therapy settings, please ensure the device is NOT in Locked Mode (See Section 12.8). Settings can be adjusted during a therapy or when the therapy is on pause.

The default factory setting for the **extriCARE® 3000 NPWT** pump is 125mmHg in continuous vacuum mode. To adjust the therapy settings, simply press the Therapy Settings button on the Main Page. A new window will appear:





12.4.1 Changing the Vacuum Mode.

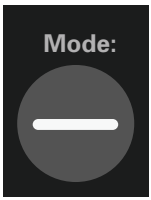
When therapy settings dialog window appears, the current vacuum mode is displayed. To change vacuum mode, press on the blue arrow button next to the

mode name. The mode will toggle between Continuous and Intermittent Mode. (Intermittent mode cycles through the target vacuum for 5 minutes, and then at 20mmHg vacuum for 2 minutes.)

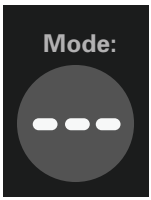
12.4.2 Changing the Target Vacuum Pressure

To change the target vacuum pressure, simply press on the green "+" or red "-" button on the screen. Pressure adjustments is done in 5mmHg increments. The target vacuum pressure can be adjusted between 20 to 140mmHg.Press Confirm to confirm the new therapy settings and to return to the Main Page.On the Main Page, the vacuum mode is indicated on Vacuum Mode Indicator:

Continous Mode



Intermittent Mode



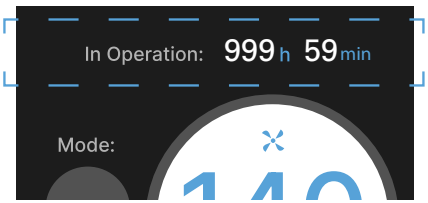
12.5 Running a Treatment

Once the therapy settings are set, therapy can begin by pressing the Play/Pause button. When the therapy begins, the blue backlight will remain lit for the duration of the therapy.

Pressure sensing technology in the pump will ramp up pumping power depending on the amount of air leaks in the dressing and the vacuum level. The actual vacuum level is displayed in real-time on the Main Page.

12.5.1 Usage Counter

The total duration of the current treatment session is displayed above the Target Vacuum Pressure to a maximum of 999 hours and 59 minutes. If the treatment is paused, the usage counter will pause also. The usage counter will resume only when the session is resumed. To reset the usage counter, press down the Power button and the Play/Pause button for 3 seconds.



12. Operating Instructions (continued)

12.5.2 Blockage Alarm

The **extriCARE® 3000 NPWT** pump allows for two blockage modes. Under the normal default mode, blockage alarm will be triggered only after 120 minutes in continuous mode and 140 minutes under intermittent mode. Under sensitive mode, a blockage alarm can be triggered within 20 minutes. To toggle between the two modes, first ensure that the Main Page is shown, then press down on the Therapy Settings on-screen button and the Play/Pause button simultaneously for 2 seconds.

The blockage mode is indicated by the color of the Product Name:

Normal Mode

Sensitive Mode

12.5.3 extriCARE® 3000 NPWT - General Settings:

Please ensure the device is used upright. When using the device in an ambulatory setting, please adjust the shoulder strap of the carrying case to ensure the device is upright and as parallel to the ground as possible.

12.6 Automatic Screen Shut-Off

To maximize battery life, the **extriCARE® 3000 NPWT** pump has an automatic screen shut-off feature. If a therapy is in session and the screen is not touched for 5 minutes, it will automatically shut off. If the device is in standby (i.e. not running a therapy), the screen will automatically shut off after 10 minutes of inactivity. The device will also shut off under standby after 1 hour of inactivity.

- Pressing the Power Button.
- Pressing the Play/Pause button
- Pressing anywhere on the touchscreen

• Plugging the device to the external charger

• An alarm is generated

Note: When the screen is shut-off, a green light will be flashing if treatment is in process, or a greenlight light will be flashing if the device is charging normally.

12.7 Tracking Exudate Level in Collection Canister

extriCARE® 3000 has a proprietary technology to not only monitor exudate level in the collection canister, but also the time to reach these levels. Furthermore, **extriCARE® 3000** has the ability to detect the volume of the canister (100cc or 400cc) connected to the pump.

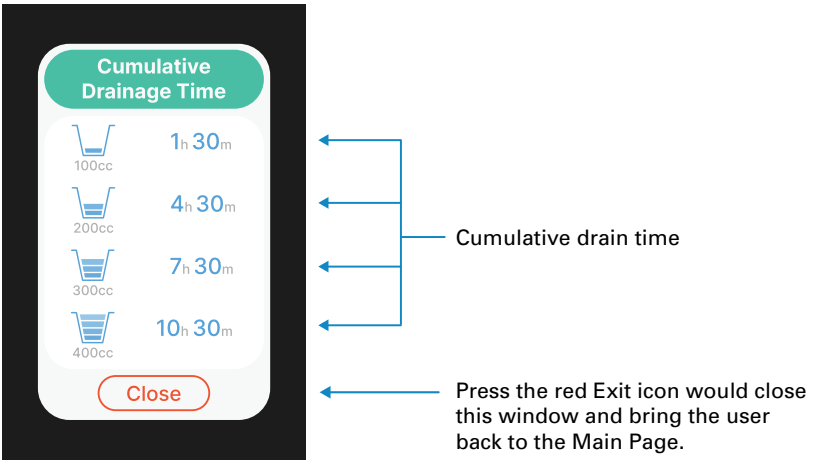
On the main page, the Canister & Fluid Level Indicator would display the approximate level of fluid collected as per below (with a canister).

	Exudate level is < 25% of the canister capacity.
	Exudate level between 25-50% of the canister capacity.
	Exudate level between 50-75% of the canister capacity.
	Exudate level between 75-100% of the canister capacity.
	Canister is full, replacement is needed.

12. Operating Instructions (continued)

12.7 Tracking Exudate Level in Collection Canister (continued)

Pressing the Canister & Fluid Level Indicator would display a new window that list out the cumulative collection time to reach each level. The cumulative drain time allow user to determine whether exudate level collection is accelerating (possible bleeding) or decelerating (increased wound healing).



The **extriCARE® 3000** has an internal algorithm to determine whether a canister has been changed. If a canister is changed, the cumulative collection time would be reset.

12.8 Alarm Sound and Lock Mode Toggles

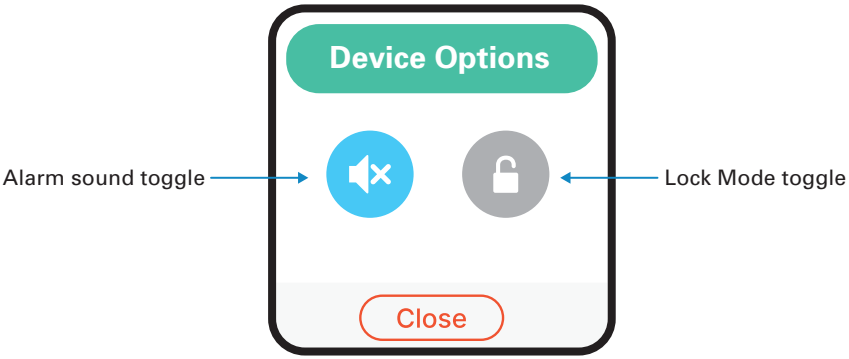
extriCARE® 3000 has two settings options where user can turn on or off:

- Alarm sound: the user has the option of muting the alarm sound (but error message will still display on the screen with the red light on the Play/Pause button)
- Lock mode: in order to avoid accidental adjustment of the treatment parameters, the user has the option of turning the device into Lock Mode, where neither target vacuum pressure, vacuum pattern, nor sound alarm can be changed.

Pressing the Device Options Button, a new window will appear:

12. Operating Instructions (continued)

12.8 Alarm Sound and Lock Mode Toggles (continued)



Alarm sound toggle: the display window shows the current state (mute, in the above example). Pressing the sound symbol will toggle the alarm sound on or off:

	Alarm sound is turned on.
	Alarm sound is muted for 4 hours. Only error message and red warning light will be display to alert user.

Lock Mode toggle: the display window shows the current state (in the above example, the device is in unlocked state). Pressing the lock symbol will turn the device into the Locked Mode. When a therapy starts, the device will also automatically enter into Locked Mode after 3 minutes.

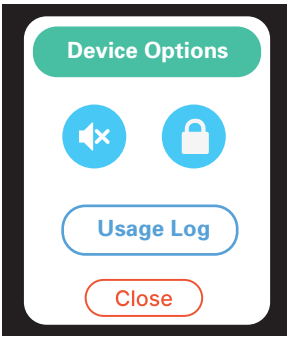
To change from Locked Mode to Unlocked mode, press down on the lock icon for 4 seconds.

	Lock Mode is turned on
	Lock Mode is turned Off.

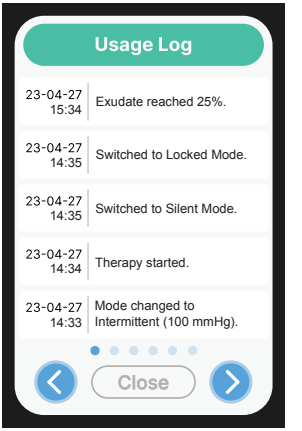
12. Operating Instructions (continued)

12.9 Usage Log

The **extriCARE® 3000 NPWT** pump has the ability to record events encountered during the therapy, including all alarms, the time when the therapy was paused/resumed, exudate level changes, and any therapy settings changes. The Usage Log can be accessed through the Device Options button. An oval button named Usage Log shall appear, as shown in the following diagram:



Pressing on the Usage Log will open another dialog window that displays the events in reverse chronological order. The most recent 30 events are displayed on the Usage Log. Access different pages by pressing the blue "<" or ">" button.



12. Operating Instructions (continued)

12.10 End of Therapy

To shut down the device, locate the Power Button on the side of the device and press down for 2 seconds.

A shutdown page will appear, with a dwindling white bar. Press down on the Power Button until the white bar completely disappears. The device will then shut down automatically after a single chirp sound (if alarm sound is on).

12.11 Canister Removal

To remove the full canister, hold down on the Canister Release button found on the top of the pump. The canister will be ejected. Pull it away from the pump.

12.12 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.

13. Error Messages / Troubleshooting

extriCARE® 3000 has an embedded diagnostic algorithm that detects abnormalities during treatment, some of which may require immediate intervention. Each error message is displayed on an Error Message window similar to the one shown below, and is accompanied by alarm sounds.

13. Error Messages / Troubleshooting (continued)

The following are the list of error messages (in descending priorities) and their mitigative actions:

Error Message	Priority	Alarm Signal	Action to Remove Alarm
SYSTEM HIGH PRESSURE Restart device. If issue persists, contact provider.	High	4 beeps every 5 seconds with 1 red lights on	Stop treatment immediately and restart device. If problem persists, contact your local distributor.
DEVICE ERROR (Code XX) Restart device. If issue persists, contact provider.	High	4 beeps every 5 seconds with 1 red lights on	Code 01 - pump error Code 02 - valve error Code 03 - sensor error In all cases, stop treatment and restart device. If problem persists, contact your local distributor.
SCREEN ERROR Restart device. If issue persists, contact provider	Medium	2 beeps every 10 seconds with 1 yellow lights on	Stop treatment and restart device. If problem persists, contact your local distributor.
UNABLE TO CHARGE Restart device. If issue persists, contact provider.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Stop treatment and restart device. If problem persists, contact your local distributor.
BLOCKAGE Check for kinks or clamped tubing. Contact provider if issue persists.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Check if tubing is kinked or accidentally clamped off. Check if tubing is blocked by wound debris or other foreign materials. Replace dressing and/or tubing if necessary.
SEVERE LEAKAGE Check for damaged canister and tubing. Check dressing for leaks.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Check for any cracks and damage to the canister or any disconnected tubing. Check wound dressing for air leaks by running fingers through the edge of the dressing. If necessary, use additional drapes.
CANISTER ABSENT Install collection canister.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Install a collection canister to the pump
CANISTER FULL Replace canister immediately.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Replace a collection canister to the pump
BATTERY CRITICALLY LOW Charge device with packaged charger immediately.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Treatment could stop anytime. Immediately plug the provided adapter to the pump to the charging port (see Section 4 of the Patient section)
BATTERY LOW Charge device with packaged charger.	Medium	2 beeps every 10 seconds with 1 yellow lights on	Plug the provided adapter to the pump to the charging port (see Section 4 of the Patient section)

14. Maintenance and Cleaning

14.1 Maintenance and Replacement Parts

The **extriCARE® 3000 NPWT Pump** 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 Devices directly.

No modification of the device is allowed.

Power adapter: The **extriCARE® 3000 NPWT Pump** should only be recharged using the AC/DC adapter provided or an equivalent IEC 60601-1 compliant adapter with a DC 12V 2A 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.

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.

14.2 Cleaning

To clean the **extriCARE® 3000 NPWT Pump**, 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 casing. Do not use Isopropyl alcohol or bleach to clean the surface as these may wipe off markings on the pump.

15. Warranty Information

LIMITED WARRANTY

Alleva Medical Devices warrants its **extriCARE® 3000 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 Devices' 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 Devices' 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 DEVICES 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 DEVICES 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 DEVICES SHALL NOT BE LIABLE FOR ANY EXEMPLARY OR PUNITIVE DAMAGES.

16. Electromagnetic Compatibility Tables

Essential Performance. The essential performance of the **extriCARE® 3000** Negative Pressure Wound Therapy unit is to maintain its pressure accuracy delivered to the wound site to an accuracy of ±10mmHg.
The **extriCARE® 3000** is suitable for use in hospitals or clinical settings. 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.

WARNING: Use of **extriCARE® 3000** 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.

WARNING: Use of accessories and cables other than those specified or provided by Alleva Medical may negatively affect EMC performance.

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® 3000** including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. See table below for additional details regarding recommended separation distances between portable and mobile RF communications equipment and the **extriCARE® 3000**

Guidance and manufacturer's declaration – electromagnetic emissions		
The **extriCARE® 3000 NPWT Pump** is in compliance for each EMISSIONS test specified by the standard, e.g. EMISSIONS class and group.		
Emissions	**Compliance**	**Electromagnetic environment-- guidance**
RF emissions CISPR 11	Group 1	The **extriCARE® 3000 NPWT Pump** 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 **extriCARE® 3000 NPWT Pump** is suitable for use in hospitals or clinical settings, including those directly connected to the public low voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

16. Electromagnetic Compatibility Tables – RF Emissions Class B (continued)

Guidance and manufacturer's declaration – electromagnetic immunity		
The **extriCARE® 3000 NPWT Pump** is in compliance for each IMMUNITY test specified by the standard, e.g. IMMUNITY test level.		
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±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 IEC 61000-4-3	10 V/m 80 MHz - 2.7GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency	±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	±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 IEC 61000-4-6	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 IEC 61000-4-11	0% U_T: 0.5 cycle [a] At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚.	0% U_T: 0.5 cycle [a] At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚, and 315˚.
	0% U_T: 1 cycle 70% U_T: 25/30 cycles [b] Single phase: at 0˚	0% U_T: 1 cycle 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 (50/60 Hz) magnetic field IEC 61000-4-8	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.		

16. Electromagnetic Compatibility Tables – RF Emissions Class B (continued)

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment							
Test Frequency (MHz)	**Band (MHz)**	**Service [a]**	**Modulation [b]**	**Max. Power (W)**	**Distance (m)**	**Test Level (V/m)**	**Compliance level**
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430-470	GMRS 460 FRS 460	FM[c] ±5 kHz deviation 1 kHz 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 18 Hz	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® 3000.**

The **extriCARE® 3000** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **extriCARE® 3000** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **extriCARE® 3000** as recommended below, according to the maximum output power of the communications equipment.

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® 3000**.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m)**		
(W)	150 kHz to 80 MHz d = 0.58√P	80 MHz to 800 MHz d = 0.13√P	800 MHz to 2.7 GHz d = 0.25√P
0.01	0.058	0.013	0.025
0.1	0.18	0.041	0.079
1	0.58	0.13	0.25
10	1.8	0.41	0.79
100	5.8	1.3	2.5

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.

17. Contact Infomation


Manufacturer

Manufactured for:
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