extriCARE®

Negative Pressure Wound Therapy System

extriCARE® 2400

Operating Manual

ENGLISH

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1. Introduction

The **extriCARE® 2400 Negative Pressure Wound Therapy Pump System** is a portable, battery-powered pump intended to generate negative pressure or suction to remove wound exudates, infectious material, and tissue debris from the wound bed which may promote wound healing. The **extriCARE® 2400 System** consists of one AC power cable and one 100CC canister. **extriCARE®** wound dressings, additional canisters, carrying cases, and other accessories are sold separately. The **extriCARE® Negative Pressure Wound Therapy Pump**, when used with the proprietary **extriCARE®** wound dressing, creates a negative pressure environment.

The **extriCARE® 2400 Negative Pressure Wound Therapy** pump and **extriCARE®** wound dressing 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 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 pressure for 5 continuous minutes and releasing pressure for 2 minutes.

Clinically suggested wound types that can be treated using **Negative Pressure Wound Therapy** technology are:

- Chronic wounds
- Traumatic wounds
- Partial-thickness burns
- Flaps and grafts
- Acute wounds
- Subacute and dehisced wounds
- Ulcers (such as diabetic or pressure)

The **extriCARE® device** is meant for continuous use (at least 22 of 24 hours per day).

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2. Symbol List

	**Warning/Caution:** See instructions for use
	Single Use Only
	Date Of Manufacture
	Type B. Applied Part. Internally powered electrical device
	Keep Dry
	Serial Number
	Prescription Use Only
	Power Switch
	Manufacture Lot Number
	Biohazard
	Class II Equipment
	Waste Electrical Goods Recycled

2. Symbol List (continued)

EC REP	Authorized Representative in the European Community
CE 0123	Conforms with the Medical Device Directive (93/42/EEC) and has been subject to the conformity procedures laid down in the council directive
ETL CLASSIFIED Intertek	ETL Listed, Conforms to UL Std. 60601-1
	Manufacturer
REF	Catalog / Model Number
STERILE EO	Sterilized Using Ethylene Oxide
	Use By

3. Device Specifications

DIMENSIONS:	Length: 3.35″ (8.5cm) Height: 5.67″ (14.4cm) Width: 1.46″ (3.7cm)
WEIGHT:	8.6 oz.
MOBILITY:	Portable. Carrying case available.
BATTERY TYPE:	Lithium (rechargeable), 3.7V
AC/DC ADAPTER:	Input: 100-240 V, 50/60 Hz, 0.4A; Output: 5V, 1.5A
VACUUM MODES:	Continuous or Intermittent
OPERATING CONDITIONS:	Temperature: +5°C to 40°C (41°F to 104°F) Humidity: 15% to 85% non-condensing
PRESSURE OPTIONS:	40mmHg - 140mmHg
FUSE:	1.5A
CHARGING TIME:	< 3.5 hours
BAROMETRIC PRESSURE:	800hPa – 1060hPa
STORAGE TEMPERATURE:	-10°C to +45°C (14°F to 113°F)
ALTITUDE RANGE:	< 2000 m
INGRESS PROTECTION:	IPX0
PROTECTION AGAINST ELECTRICAL SHOCK:	CLASS II
PATIENT PROTECTION:	Type B

4. Accessories

1. AC/DC Adapter: Input: 100 – 240V, 50/60Hz, 0.4A. Output: 5.0V, 1.5A.
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 100 and 400cc configurations.
4. Dressings: Please reference **extriCARE® 2400 Negative Pressure Wound Therapy (NPWT) System** Dressings (LB30.0004) for a complete listing of all current dressing options.
5. Carrying case: Now available for 100cc and 400cc canister.

5. Indications for Use

The **extriCARE® 2400 Negative Pressure Wound Therapy Pump System** is indicated for wound management via the application of negative pressure to the wound by removal of wound exudate, infectious materials, and tissue debris from the wound bed. The **extriCARE® 2400 Negative Pressure Wound Therapy Pump 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® 2400 System** should **NOT** be used in the following conditions:

- Exposed vessels, organs, or nerves.
- Anastomotic sites.
- Exposed arteries or veins in a wound. All exposed vessels and organs in and around the wound must be completely covered prior to initiation of NPWT. **Note:** A thick layer of natural tissue is preferred. Several layers of fine meshed non-adherent material or bio-engineered tissue may be an alternative. Ensure that protective materials will maintain their position throughout therapy.

6. Contraindications for Use (continued)

- 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.

7. Warnings

- Review this manual prior to using the **extriCARE® 2400 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® 2400 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.
- The 400cc canister 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 the 400cc canister.
- 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, as it 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.

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

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

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.

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® 2400 Negative Pressure Wound Therapy Dressings next to the vagus nerve to minimize the risk of bradycardia.

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

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

The extriCARE® dressing is a one piece all inclusive dressing and should be removed in one piece. 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.

9. Features

9.1) Defined Features

1. **LCD SCREEN:** Indicates the pump operating pressure and displays symbols (also features a blue backlight).

2. **CONNECTION TUBING:** Tubing which connects canister to drainage tubing.

3. **BATTERY POWER:** Indicates how much battery power is left. Icon has 1-4 bars representing 25%, 50%, 75%, and 100% battery power.

4. **CANISTER CLIP:** Clip that connects the canister to the NPWT device.

5. **MODE SYMBOL:** Indicates pump operating mode (continuous or intermittent).

6. **MODE BUTTON:** Allows user to set the pump to either continuous or intermittent mode.

7. **POWER PLUG:** Enables user to charge device.

8. **PUMP BUTTON:** Used to turn pump on or off. Also can be used to exit a setting.

9. **SET BUTTON:** Used to program desired pressure.

10. **POWER SWITCH:** Used to turn the system power on and off.

9.2) Alarm Features/Troubleshooting

In order to assure proper patient compliance, the extriCARE® 2400 system is equipped with both audio and visual alarms for all the errors listed in the chart below.

To disengage the alarms:

1. Audio alarms can be muted by pressing any button on the device front plate.
2. Visual alarms, which include the LED and screen symbols, need to be disengaged by pressing the "PUMP" button. If the screen is locked, it needs to be unlocked first before the visual alarm can be disengaged. For instructions on how to unlock the screen please refer to section 10.2.5.

Error Code	Error Type	Cause	Audio Alarm Features	Visual Alarm Features	System Status	Suggested Mitigation
E01	Canister Full Error	The canister is equipped with full sensors that will be triggered either when a canister is full of exudates or a false fullness caused by incorrect use of the system	3 beeps every 20 seconds	Alarm symbol and "E01" flashing on LCD screen Yellow LED flashing every 2 seconds	Pump will shut off immedi-ately	Install a new canister
E03	Tilt Error	The extriCARE® System is tilted at an angle greater than 95 degrees with respect to the upright position for more than 10 seconds	3 beeps every 20 seconds	Alarm symbol and "E03" flashing on LCD screen. Yellow LED flashing every 2 seconds	Pump re-mains on	Place the device back to an upright position
E04	Low Battery Error	Less than 25% power remaining indicat-ing that extriCARE® System will power off soon	3 beeps every 20 seconds	Battery, alarm symbol and "E04" flashing on LCD screen Yellow LED flashing every 2 seconds	Pump remains in function until the battery depletes	Plug the extriCARE® System in, allowing it to function and charge simultane-ously
E05	High Voltage Error	The extriCARE® Sys-tem being used with an adapter that is not recommended; There is a risk of volt-age incompatibility if the input voltage is greater than 6V	3 beeps every 20 seconds	Alarm symbol and "E05" flashing on LCD screen Yellow LED flashing every 2 seconds	System is shut off	Unplug the adapter and use the rec-ommended adapter

9.2) Alarm Features/Troubleshooting (continued)

Error Code	Error Type	Cause	Audio Alarm Features	Visual Alarm Features	System Status	Suggested Mitigation
E06	Canister Installation Error	The canister is not detected or is installed incorrectly	3 beeps every 20 seconds	Alarm symbol and "E06" flashing on LCD screen Yellow LED flashing every 2 seconds	Pump will not run	Properly install the canister in place
E07	Blockage	Tubing or dressing clog or blockage	1 beep every 20 seconds	Alarm symbol and "E07" flashing on LCD screen. Yellow LED always on	Pump remains on	Replace the dressing and tubing set with a new set
Air Leakage Error		There are many potential sources of leaks (incomplete seal between extriCARE® dressing and skin, improper connection between tubing, canister leakage, etc.) The alarms have been divided into two categories:				
E02	a) Major Leak Error	Pump unable to reach 50% of the preset pressure after 1 minute of pumping effort	3 beeps every 20 seconds	Alarm symbol and "E02" flashing on LCD screen Yellow LED flashing every 2 seconds	System will shut down after 5 minutes	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
E08	b) Minor Leak Error	Pump unable to reach 80% of the preset pressure after 1 minute of pumping effort	1 beep every 20 seconds	Alarm symbol and "E08" flashing on LCD screen, yellow LED remains illuminated	System will shut down after 20 minutes	

10. Instructions for Use

10.1) Dressing and Canister Application

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® 2400 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 notch on the bottom of the canister with the hole for it on the extriCARE® pump, 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

LCD Display

1. **POWER ON/OFF**: To Power on the device, push the POWER SWITCH on the right side of the device downward. The device should then turn on. Push the POWER SWITCH upward to turn device off.

2. **CONTROL PRESSURE**: Holding down the SET key for two seconds will initiate the procedure for setting the pressure. The screen will display a flashing pressure reading at this time. Press SET once to increase pressure by 20mmHg. In order to obtain a lower pressure, scroll through by pressing SET button. The pressure will increase until 140mmHg, and then will start at 40mmHg again. When desired pressure is reached, press the PUMP button to confirm and exit pressure settings.

3. **SET MODE**: Hold down MODE button for two seconds to select the mode (continuous or intermittent). A dotted line at the top right of the LCD Screen indicates intermittent treatment while a straight line indicates a continuous treatment. To change current mode, press the MODE button. To exit Mode Settings, press the PUMP button.

4. **START/STOP TREATMENT**: To start treatment, hold the PUMP button for two seconds. Do the same to stop treatment.

5. **LOCK**: The locking feature prevents the settings from being changed. If no buttons on the device are pressed for more than 60 seconds, the lock will automatically turn on. If the Lock is on and buttons are accidentally pressed, nothing will be changed. Press the SET and MODE button simultaneously for 2 seconds to turn the lock on manually. Repeat for 3 seconds in order to unlock. The backlight should turn off when the device is locked and turn back on when it is unlocked.

10.3) 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.

10.4) 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

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 +5V 1.5A 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.

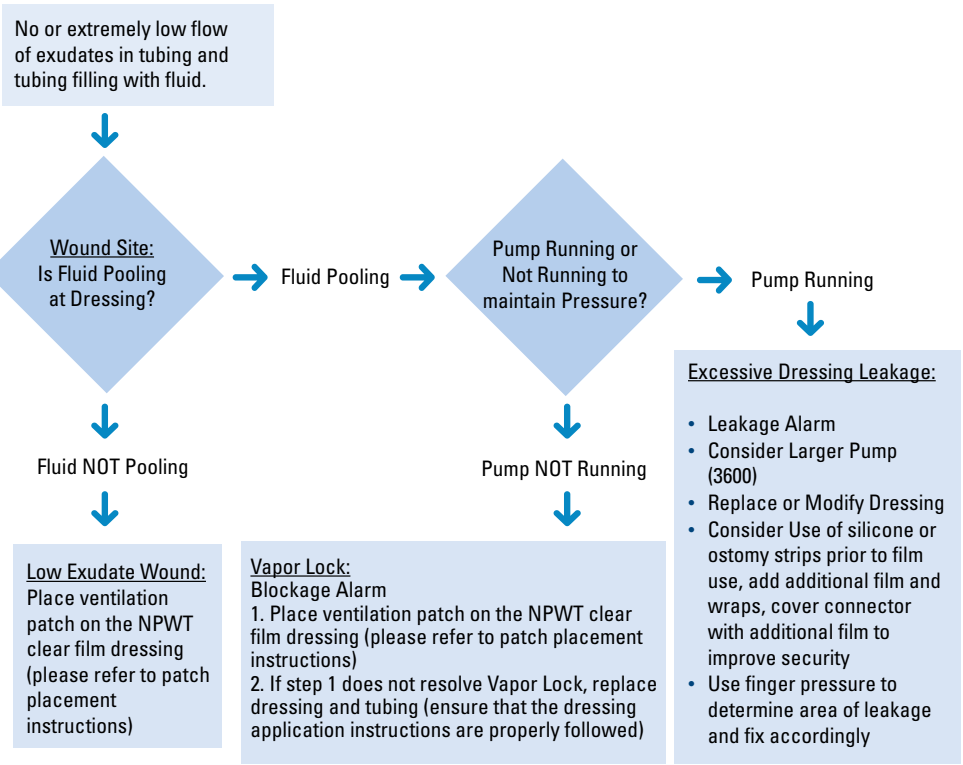
10.5) Cleaning

To clean the extriCARE® Device, follow normal protocol for cleaning medical devices. If additional information is required, please contact your local representative or the manufacturer.

10.6) Pump Operation Tips

1. Fluid Stagnation in Tubing (aka, "Vapor Lock"): This rare condition may occur when an exceptionally tight seal of the wound dressing facilitates a situation which interferes with fluid flow, preventing the proper removal of exudates from the wound site. This phenomenon is caused by a loss of differential pressure between the wound site and pump, which drives the motion of fluid removal. Another contributing cause of this problem is if the pump is placed too high above the wound site.

The potential adverse consequences of fluid stagnation are: 1) pooling of exudates at the wound site, and 2) the potential of exudate backflow from the tubing into the wound. Should fluid stagnation occur, the step by step guide below should be followed to resolve this issue:



- To avoid the gravitational burden that could amplify or cause fluid stagnation, the extriCARE® 2400 device should be placed no higher than 1 meter above the dressing/wound location.
- To avoid differential pressure related stagnation, a ventilation patch should be used over the existing NPWT dressing to supply the pressure difference required to effectively remove the exudates from the wound site.

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 one (1) 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

Alleva Medical
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1 On Kwan St. Shek Mun, Shatin, N.T., Hong Kong
Tel: +852 3166 7200 Fax: +852 2355 7663
info@allevamedical.com

12. Contact Information (continued)

EC REP

Obelis s.a
Bd. Général Wahis 53
1030 Brussels, BELGIUM
Tel: +32.2. 732.59.54

Appendix 1

Product Classification:

- According to the type of protection against electrical shock, this device is classified as a Class II Equipment, and Type B 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 (IPXO: without protection against ingress of water)

- **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.

- Unit is packaged for transportation by common carrier.

Appendix 2

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The model extriCARE® 2400 is intended for use in the electromagnetic environment specified below. The customer or the user of the model extriCARE® 2400 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 dip or an interruption of mains power occurs, the current of the model extriCARE® 2400 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	Not applicable	Not applicable

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

The model extriCARE® 2400 is intended for use in the electromagnetic environment specified below. The customer or the user of the model extriCARE® 2400 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	Portable and mobile RF communications equipment should be used no closer to any part of the model extriCARE® 2400, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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. Distance is metres (m) 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 extriCARE® 2400 is used exceeds the applicable RF compliance level above, the model extriCARE® 2400 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 extriCARE® 2400.

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 extriCARE® 2400**.

The **model extriCARE® 2400** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **model extriCARE® 2400** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **model extriCARE® 2400** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m)**		
(W)	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 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.

extriCARE®

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