GENADYNE

XLR8+

Negative Pressure Wound Therapy System

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Safety Standards

Read All Instructions Prior To Use

When using electrical devices, especially when children are present, basic safety precautions should always be followed, including the following.

DANGER

To reduce the risk of electrocution:

1. ALWAYS unplug this product immediately after using or when charging is completed.
2. DO NOT use while bathing.
3. DO NOT place or store product where it can fall or be pulled into a tub or sink.
4. DO NOT Place or drop into water or other liquid.
5. DO NOT reach for a product that has fallen into water. Unplug immediately.

WARNING

When the Genadyne accessories (Type BF Applied Part) are used, patient leakage current will not exceed limits set for this Device (Class II).

The USB port is blocked by tape. Removing the tape invalidates the Warranty. The use of the USB port is strictly limited to Genadyne Personnel.

WARNING: The Cords and Tubing on this product present a potential strangulation hazard, particularly due to excessive length. Keep cords and tubing out of reach of children.

WARNING: Disregarding the information on safety of this device is considered ABNORMAL USE

Do not wrap carrying case strap or dressing tubing around neck.

To reduce the risk of burns, electrocutions, fire or injury to persons:

1. This product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used near infants or children.
3. Use this product only for its intended use as described in this manual. DO NOT use attachments or kits not recommended by Genadyne.
4. NEVER operate this product if it has a damaged cord or plug, any missing components, is not working properly, has been dropped or damaged or has been dropped into water.
5. Keep the cord away from heated surfaces.
6. Do not use in presence of flammable anesthetics.
7. DO NOT operate where aerosol (spray) products are being used or where oxygen is being administered.
8. The AC ADAPTER should be unplugged from the outlet when not in use. When unit is not going to be used for an extended period of time, store carefully in a cool, dry place.

WARNING: The user SHOULD NOT attempt to service, repair or modify the Negative pressure wound therapy system. Refer all servicing to Genadyne. No user serviceable parts inside.

As with all prescription medical devices, failure to follow product instructions or adjusting settings and performing therapy applications without the express direction and/or supervision of your trained clinical caregiver may lead to improper product performance and the potential for serious fatal injury. For medical questions, please consult a physician. In case of medical emergency, immediately contact your local emergency services provider.

CAUTION: Federal Law (USA) restricts this device to the sale by or on the order of a licensed physician.

Warnings

DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS, CAUTIONS AND INSTRUCTIONS, CONTACT A HEALTHCARE PROFESSIONAL, DEALER OR TECHNICAL PERSONNEL IF APPLICABLE BEFORE ATTEMPTING TO USE THIS EQUIPMENT. OTHERWISE INJURY OR DAMAGE MAY RESULT.

BEFORE PERFORMING ANY MAINTENANCE TO THE CONSOLE, DISCONNECT THE POWER CORD FROM THE WALL OUTLET. REFER SERVICING TO QUALIFIED PERSONNEL ONLY. DO NOT USE THE POWER UNIT IN THE PRESENCE OF FLAMMABLE GASES SUCH AS ANESTHETIC AGENTS.

WARNING/CAUTION NOTICES USED IN THIS MANUAL APPLY TO HAZARDS OR UNSAFE PRACTICES WHICH COULD RESULT IN PERSONAL INJURY OR PROPERTY DAMAGE.

PLEASE MAKE SURE THAT THE POWER ADAPTER IS PLUGGED INTO THE WALL BEFORE PLUGGING INTO THE UNIT. FAILURE TO FOLLOW THIS PRECAUTION MIGHT CAUSES DAMAGE TO THE UNIT.

Power Adapters

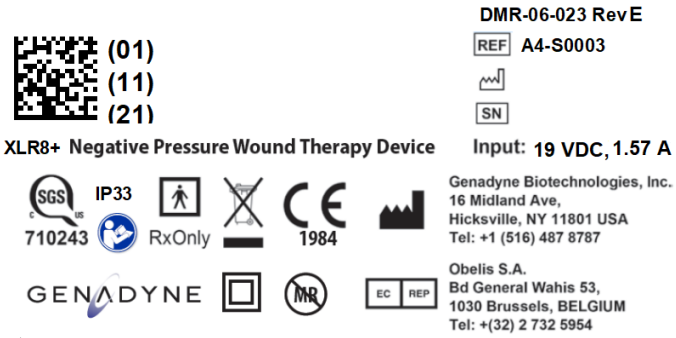
This system is internally powered with battery and externally powered with an approved Class II Power Adapter.

Note: Only this Power Adapter may be used with the device. Use of any other adapter automaticaly voids warranty and may be hazardous to the patient and the operator.

IEC-320 C8 Power Cord
(Model# MPU30B-5)
19 VDC 1.57A 30W

IEC-320 C14 Power Cord
(Model# MPU30B-5)
19 VDC 1.57A 30W

Symbols



XLR8+ NPWT
System Label
Reproduction

Equipment Classification
Isolation Type BF Applied Part

Date of Manufacture

Place of Manufacture

Storage Temperature

Biohazard

Keep Dry

Conforms with the Waste Electrical and Electronic Directive (2002/96/EC). At the end of useful life; dispose of all waste according to local requirements, or contact your local Genadyne subsidiary or agent for advice. This product is designated for separate collection at an appropriate collection point. Do not dispose of in normal waste stream.

Serial Number

Caution:
Read Instructions Before Use

Lot Number

Product Reference Number

Authorized European Representative

XLR8+ Notified Body CE Mark

CSA International Classification

Double Insulated (Class II)

Recognized Component Mark for Canada and the United States (Power adapter)

Certified Body (Power Adapter)

IP33
Protected against solid foreign objects of 2.5 mm and greater.
Protected against spraying water

Rx Only

Caution: Federal (US) law restricts this device to sale/ rental by or on the order of a physician

Keep away from sunlight

Keep Upright

Fragile; Handle with care

MR Unsafe

Intended Use/ Indication for Use

The Genadyne XLR8+ Negative pressure wound therapy system (NPWT) is indicated for use in treating patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

User

The Genadyne XLR8+ NPWT System is designed for use by licensed healthcare professionals only. The keyboard is locked by the professional to prevent the patient from changing the settings prescribed by the physician.

Contraindications

Genadyne XLR8+ Negative Pressure Wound Therapy System is contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis (***NOTE:*** *Refer to Clinical Guide for Osteomyelitis information.)*
- Non-enteric and unexplored fistulas
- Necrotic tissue with eschar present (***NOTE:*** *After debridement of necrotic tissue and complete removal of eschar, Genadyne XLR8+ Negative Pressure Wound Therapy System may be used.)*

CAUTION:

Do not place dressing directly in contact with:

- Exposed blood vessels
- Anastomotic sites
- Organs
- Nerves

NOTE: *Refer to Clinical Guide for additional information concerning bleeding.*

Precautions

Precautions should be taken for patients who are or may be receiving anticoagulant therapy, suffering from difficult hemostasis, untreated for malnutrition and non-compliant or combative.

Standard Precautions

To reduce the risk of transmission of blood borne pathogens, apply standard precautions for infection control with all patients, per institutional protocol, regardless of their diagnosis or presumed infection status. In addition to gloves, use gown and goggles if exposure to body fluid is likely.

The XLR8+ NPWT is intended for use in both a hospital and homecare setting.

Continuous versus Variable Therapy

Continuous, rather than Variable, Genadyne XLR8+ Negative Pressure Wound Therapy System is recommended over unstable structures, such as an unstable chest wall or non-intact fascia, in order to help minimize movement and stabilize the wound bed. Continuous Therapy is also generally recommended for patients at increased risk of bleeding, highly exudating wounds, fresh flaps and grafts and wounds with acute enteric fistulae.

Patient Size and Weight

The size and weight of the patient should be considered when prescribing Genadyne XLR8+ NPWT. Infants, children, certain small adults and elderly patients should be closely monitored for fluid loss and dehydration. Also, patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

Spinal Cord Injury

In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Genadyne XLR8+ Negative Pressure Wound Therapy System to help minimize sensory stimulation and seek immediate medical assistance.

Bradycardia

To minimize the risk of bradycardia, the Genadyne XLR8+ Negative Pressure Wound Therapy System dressing must not be placed in proximity to the vagus nerve.

Enteric Fistulas

Wounds with enteric fistulas require special precautions to optimize Genadyne XLR8+ Negative Pressure Wound Therapy System . In certain circumstances, the Genadyne XLR8+ Negative Pressure

Wound Therapy System may help to promote healing in wounds with an enteric fistula. When the physician orders the Genadyne XLR8+ Negative Pressure Wound Therapy System , it is recommended that support from an expert clinician is sought. Genadyne XLR8+ Negative Pressure Wound Therapy System is **not** recommended or designed for fistula effluent management or containment, but as an aid to wound healing. Genadyne XLR8+ Negative Pressure Wound Therapy System is not recommended if enteric fistula effluent management or containment is the sole goal of this therapy.

Protect Periwound Skin

Consider use of a skin preparation product to protect periwound skin. Do not allow wound filler to overlap onto intact skin. Protect fragile / friable periwound skin with additional hydrocolloid or other transparent film.

- Multiple layers of the transparent film dressing may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the film dressing, wound filler or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the transparent film over the wound filler dressing during film application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.

Circumferential Dressing Application

Avoid use of circumferential dressings except in the presence of anasarca or excessively weeping extremities, where a circumferential film technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of transparent film rather than one continuous piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the film when securing it, but let it attach loosely and stabilize edges with an elastic wrap if necessary. When using circumferential film techniques, it is crucial to systematically and recurrently palpate distal pulses and assess distal circulatory status. If circulatory compromise is suspected, discontinue therapy, remove dressing and contact a physician.

Operating Precautions:

When operating, transporting, repairing or disposing of XLR8+ devices and accessories, the risk of infectious liquids being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed whenever working with potentially contaminated parts or equipment.

As a condition of use, the XLR8+ Negative Pressure Wound Therapy System System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which NPWT is being used.

The XLR8+ Negative Pressure Wound Therapy System should remain on for the duration of the treatment. If the patient must be disconnected, the ends of the tubing should be protected using the tethered cap. The length of time a patient may be disconnected from the XLR8+ Negative Pressure Wound Therapy System is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the location of the wound, the volume of drainage, the integrity of the dressing seal, the assessment of bacterial burden and the patient's risk of infection.

Ensure that tubing and Port Dressing is installed completely and without any kinks to avoid leaks or blockages in the vacuum circuit. Position the XLR8+ Negative Pressure Wound Therapy System and tubing appropriately to avoid the risks of causing a trip hazard. Whenever possible, the device and system tubing should be positioned level with or below the wound.

Physician Orders

As a condition of use, the XLR8+ NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which Negative Pressure Wound Therapy Treatment is being used.

Prior to placement of the Genadyne XLR8+ NPWT device, the medical professional treating the wound must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for Negative Pressure Wound Therapy (NPWT) are met.

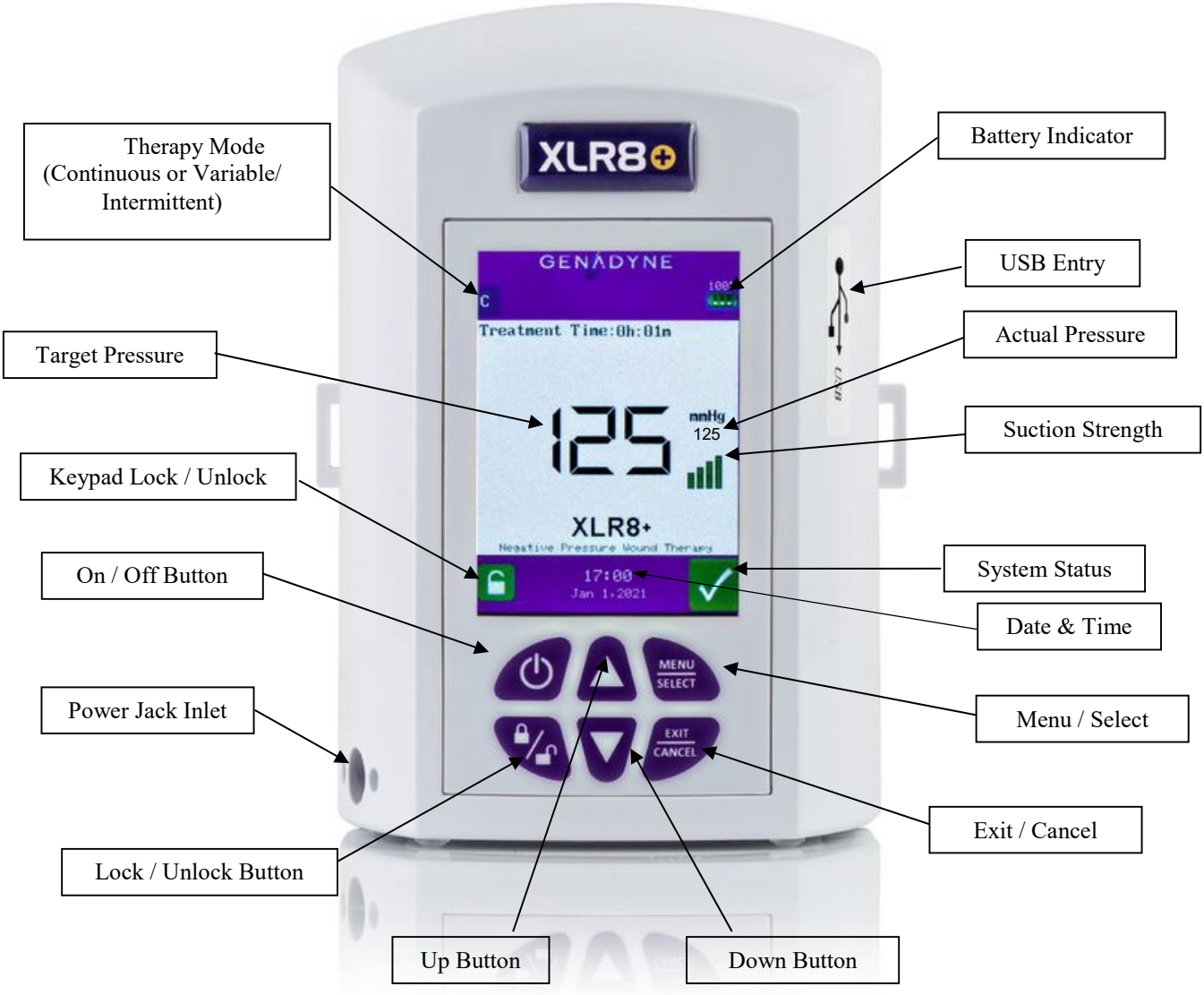
All orders should include:

- Wound location, size and type
- Dressing kit type
- Vacuum settings
- Frequency of dressing changes
- Adjunctive dressings

Introduction

Information provided in this user manual contains important information regarding the safe and effective operation of the Genadyne XLR8+ Negative Pressure Wound Therapy (NPWT) System. Use this manual as a personal reference and also in the training of personnel. Preventive maintenance, cleaning and disposal information are also included.

Features



System Usage

The XLR8+ **must be used ONLY** at these suggested orientations.

YES (KEEP UPRIGHT)

NO

NO

NO

Keypad Feature

Power Button
Turns the device on and off.

Up Button
Increase suction pressure.
Enables user to scroll up in a menu.

Down Button
Decrease suction pressure.
Enables user to scroll down in a menu.

Lock / Unlock
Lock and unlock keypad.

Menu / Select
Brings up the system menu.
Enables user to select the desired function.

Exit / Cancel
Exit from the system menu.
Enables user to cancel from current and selected function.

Operating the Device

Starting Up / Powering Down

Press the Power Button  once. The LCD will light up. The pump will start running. Suction is immediately available.

To Power Down the unit, press the Power Button once. A timer will appear on the main screen and start counting down. If the Power Button was pressed by accident, the user can press the Power Button again to turn on the machine and resume therapy.

The pump will always remember the previous settings before it was powered off.

Therapy Modes

The Genadyne XLR8+ provides the user with 3 therapy modes:

1. Continuous Therapy
2. Variable Therapy
3. Intermittent

Continuous Therapy Mode

If a symbol C is observed on the top left corner of the screen, this means Continuous Therapy is active. The system sets it at Continuous Therapy mode by default. If the symbol V is observed, this means Variable Therapy is in active. If the symbol I is observed, this means Intermittent Therapy is active.

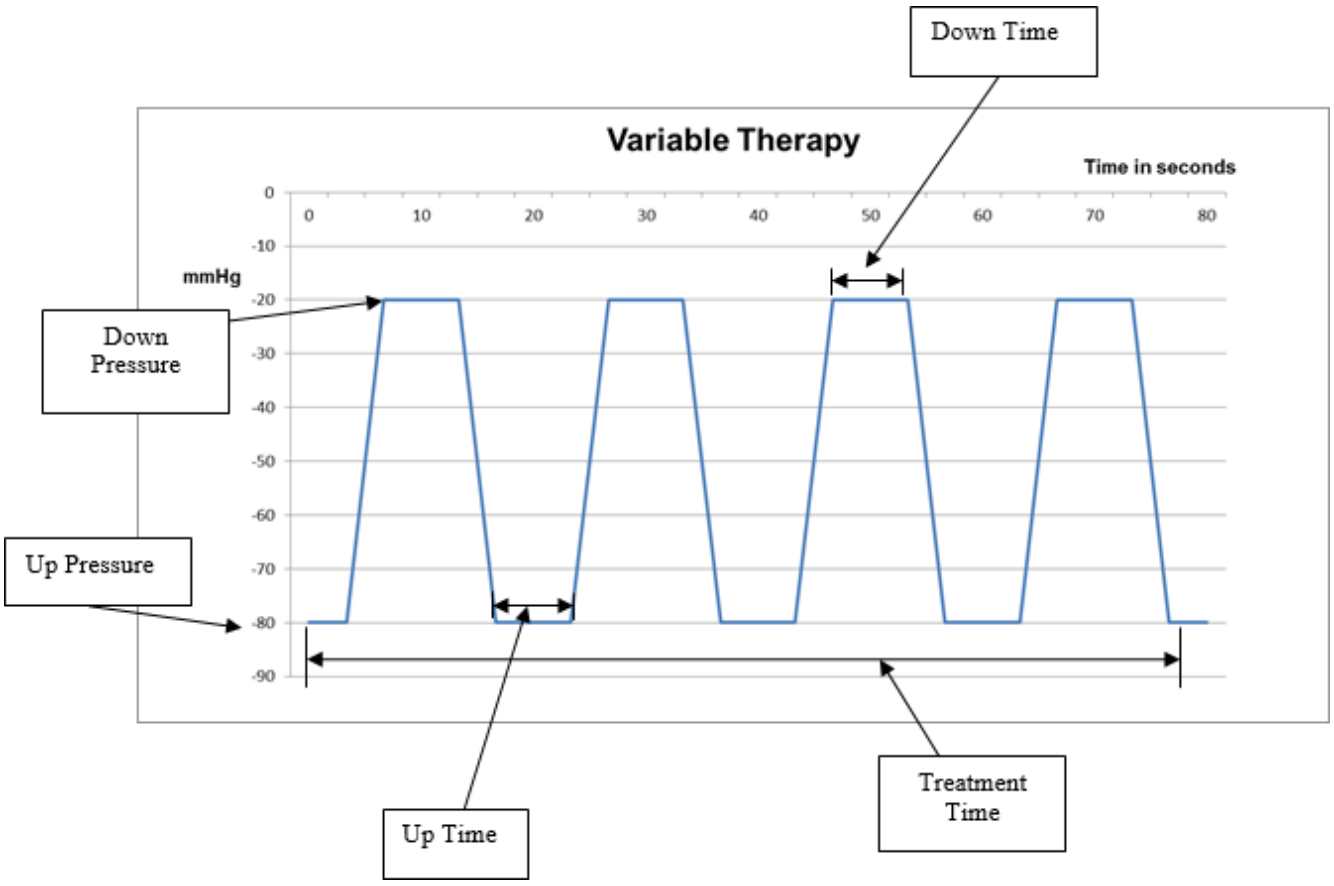
Continuous Therapy Mode

Variable Therapy Mode

Variable Therapy Mode

In Variable Therapy mode, the high pressure time (Up Time) and low pressure time (Down Time) will also be displayed on the main screen. The user will be asked to set 5 parameters when selecting:

1. **Treatment Time.** Treatment time allows the user to set how long they want the patient to be on Variable Therapy mode. Once the treatment time ended, the system will automatically switch back to Continuous Therapy mode.
2. **Up Time.** Up time allows the user to determine how long they want the system to hold at a set high pressure vacuum. When the time is up, it will go down to the set *down pressure* and will remain at that level until the *down time* ends. The whole process will then cycle up and down until the *treatment time* finishes.
3. **Up Pressure.** Up pressure allows the user to determine the high vacuum threshold while the patient is on Variable Therapy.
4. **Down Time.** Down time allows the user to determine how long they want the system to hold at a set low pressure vacuum. When the time is up, it will go up to the set *up pressure* and will remain at that level until the *up time* ends. The whole process will then cycle down and up until the *treatment time* finishes.
5. **Down Pressure.** Down pressure allows the user to determine the low vacuum threshold while the patient is on Variable Therapy.



Therapy Selection

To select which therapy to use at any time:

1. Press the Menu / Select button.
2. Scroll using the Up button or Down button and choose the Treatment Mode function by pressing the Menu / Select button once.
3. Choose either Continuous or Variable Therapy by pressing the Menu / Select button once.
4. For Continuous Therapy selection, after **Step 3**, exit to the main screen by holding on to the Exit / Cancel button for 5 seconds. The user can also press the Exit / Cancel button 2 times or more to exit to the main screen.
5. For Variable Therapy selection, after **Step 3**, press Menu / Select button one more time to enter into the variable setting screen.
    a. Treatment Time. Press the Menu / Select button to enter the desired treatment time. For continuous variable mode, set the treatment time to 0h. Use the Up button or Down button to increase or decrease the desired time. All settings are in hours. Once the treatment time is set, press the Menu / Select button again to confirm selection. It will then bring you back to the Variable Therapy setting screen.
    b. 125/30. 5 Minutes at 125 mmhg, then 3 minutes at 30 mmhg.
    c. 80/30. 5 Minutes at 80 mmhg, then 3 minutes at 30 mmhg.
    d. 125/0. 5 Minutes at 125 mmhg, then 3 minutes at 0 mmhg.
    e. Program. Press the Menu / Select button to define your own variable therapy session.
        i. Up Time. Press the Menu / Select button to enter the desired up time. Use the Up button or Down button to increase or decrease the desired time. All settings are in minutes. Once the Up Time is set, press the Menu / Select button again to confirm selection. It will then bring you back to the Variable Therapy setting screen.
        ii. Up Pressure. Press the Menu / Select button to enter the desired high pressure threshold. Use the Up button or Down button to increase or decrease the desired vacuum pressure. All settings are in mmHg. Once the vacuum pressure is set, press the Menu / Select button to confirm selection. It will then bring you back to the Variable Therapy setting screen.
        iii. Down Time. Press the Menu / Select button to enter the desired down time. Use the Up button or Down button to increase or decrease the desired time. All settings are in minutes. Once the Down Time is set, press the Menu / Select button to confirm selection. It will then bring you back to the Variable Therapy setting screen.
        iv. Down Pressure. Press the Menu / Select button to enter the desired low pressure threshold. Use the Up button or Down button to increase or decrease the desired vacuum pressure. All settings are in mmHg. Once the vacuum pressure is set, press the Menu / Select button to confirm selection. It will then bring you back to the Variable Therapy setting screen.
6. To exit the variable setting screen and return to the main screen, hold on to the Exit / Cancel button for 5 seconds. The user can also press the Exit / Cancel button 3 times or more to exit to the main screen.

Adjusting the Pressure

At any given point in time (except when the keypad is locked), whether the system is On or Off, whether it is on a therapy or not, the user can adjust the pressure by pressing the Up button to increase the vacuum pressure or the Down button to decrease the down pressure.

The adjustment to this pressure setting is displayed by the large digit in the center of the LCD screen.

Each key press corresponds to either a 1 mmHg increment / decrement. By holding down the key, it will gradually change to a 10 mmHg increment / decrement.

Intensity Mode

The Intensity Mode has 3 basic settings. The Intensity Mode is for users to adjust the speed of suction of the XLR8+ device. Setting 1 will run at the lowest speed, while Setting 3 will run at the highest speed.

Alerts

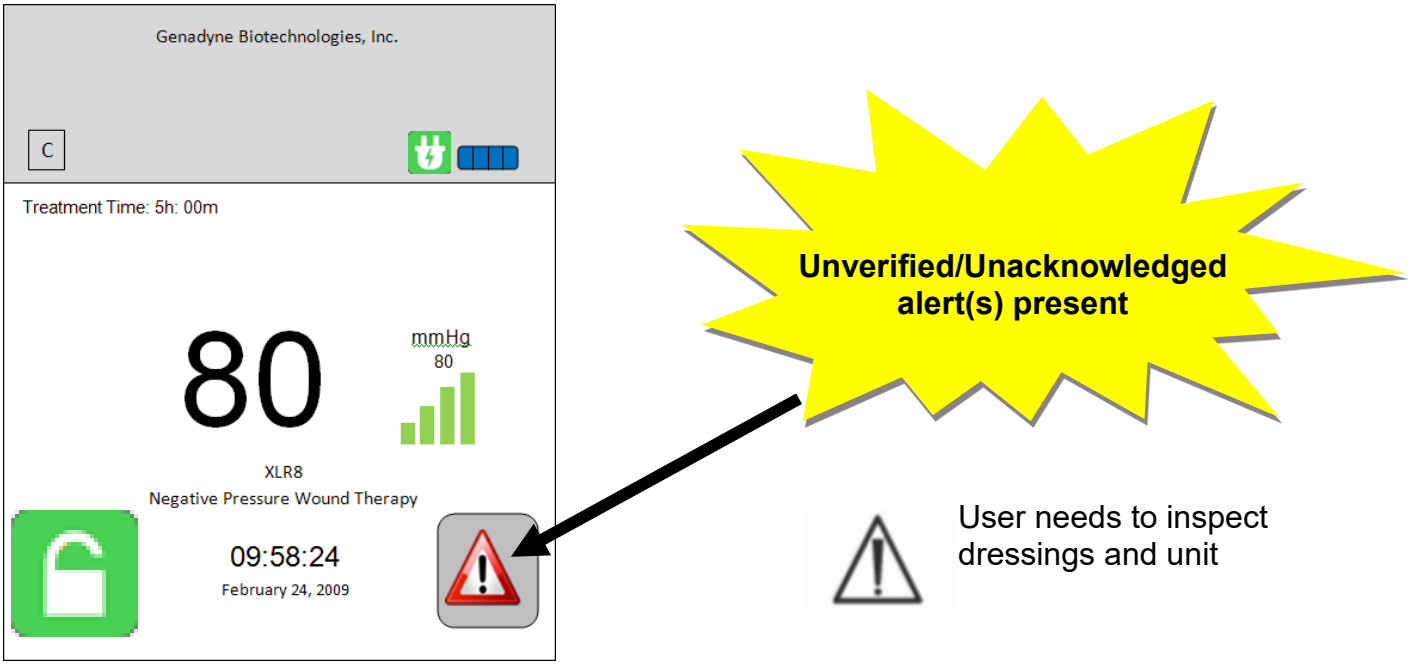
There are 6 Alert Notifications in the XLR8+.

Leak Alert 	Whenever there is a leak in the dressing or the canister, the Leak Alert will occur. The message on the screen will show: ALERT: LEAK OR LOSS OF SUCTION REVIEW DRESSINGS AND CANISTER CONNECTION TO UNIT
Troubleshooting	1. Select MENU to silence the alert during troubleshooting 2. Ensure clamp of XLR8+ canister's tubing is open 3. Ensure canister is fully attached 4. If alert is not triggered, power off the device and contact Genadyne to resolve this problem

Canister Full 	Canister Full Alert occurs when the canister is filled with exudates. The message on the screen will show: **ALERT:CANISTERFULL** **REPLACECANISTER**
Troubleshooting	1. To resolve the issue, turn off the device by pressing the power button 2. Check if the canister is full. This occurs when the fluid reaches the highest graduated marks on the canister. 3. If canister is not full, power off the device and turn it back on 4. If canister full, change the canister. Power off the device and power it on 5. If canister full remains on, contact Genadyne to resolve the problem
Low Battery 	Whenever the battery level is less than 20%, the Low Battery Alert will occur. The message on the screen will show: **ALERT: LOW BATTERY** **PLUG UNIT IN ELECTRICAL SOCKET TO CONTINUE THERAPY**
Troubleshooting	1. Connect the device to electrical socket as soon as the low battery alert appears on the screen
Blockage 	Blockage Alert occurs when there is a blockage in between wound dressing and the canister. The message on the screen will show: **ALERT: BLOCKAGE REVIEW DRESSING AND TUBING ENSURE THAT CLAMPS ARE OPEN**

Troubleshooting	1. Select MENU to silence the alert during troubleshooting 2. Ensure luer connectors of the XLR8+ canister and XLR8+ ports are connected properly 3. Ensure clamps of the XLR8+ canister's tubing are open 4. Ensure tubing is not kinked, crimped, or blocked in any way 5. If the problem persist, contact Genadyne to resolve the problem
Critical Battery 	Critical Battery Alert occurs when the battery level is less than 5% and will require the user to plug in the power adapter to charge the machine and use the machine. **NOTE: MACHINE WILL NOT WORK UNTIL A POWER ADAPTER IS PLUG IN.** The message on the screen will show: **ALERT: CRITICAL BATTERY** **ONLY 5 % OF CHARGE LEFT ON BATTERY** **PLUG UNIT IN ELECTRICAL SOCKET**
Troubleshooting	1. Connect the device to electrical socket otherwise it will power off and stop therapy.
Check Dressing 	In the event of the unit detecting a minor leak the notification icon will FLASH 5 TIMES ON THE LOWER RIGHT CORNER OF THE SCREEN. The buzzer will produce 2 quick beeps and will prompt the user to be aware of their dressing situation when silent mode is off. Silent mode is ON by default.
Troubleshooting	1. Correct the leak by changing dressing

Alert Notification screens will automatically clear if the problem is fixed, but the Alert Log will still show the event.



An unverified alert will repeat itself every 5 minutes after the user press the Menu / Select button to silence it.

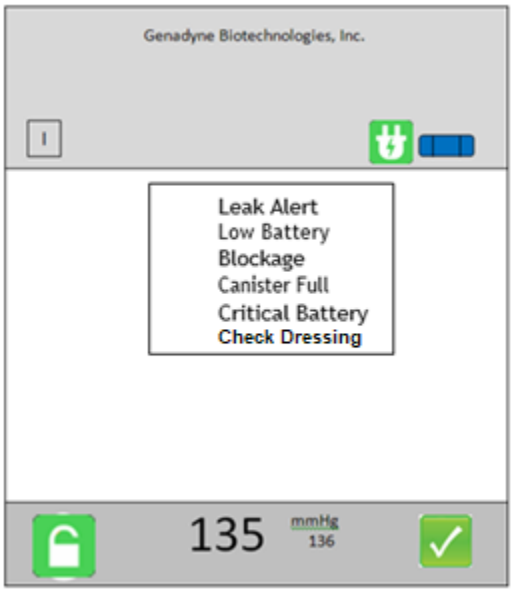
Enable / Disable

The XLR8+ provides the option for the caregiver to enable or disable which Alert Notifications they want to have turned on.

To Enable / Disable the Alert, the caregiver would have to request the special key combination from Genadyne.

Arrows on the side means enabled.

To select the desired Alert, navigate to the desired Alert and press the Menu / Select button once. The arrow will appear on the side.



Disabled (No arrows).

To disable the Alerts, navigate to the desired Alert and press Menu / Select once to have the arrow disappear.

Alert Log

All Alerts are logged and saved in the XLR8+ memory. Only the last 16 alerts are displayed, by which the latest alert will be at the top of the list.

To enter into the Alert Log:

1. Press Menu / Select button.
2. Navigate to Alert Setup by using the Up / Down button and press the Menu / Select button to enter into the Alert Setup function.
3. Navigate to the Alert Log by using the Up / Down button and press the Menu / Select button to enter into the Alert Log screen.
4. All the past 16 Alerts will be shown on the screen.
5. To acknowledge them, scroll to the desired Alert Notification and press the Menu / Select button.
6. The Alert bell will stop once acknowledged.
7. The asterisk (*) on the left side of the notification **WILL NOT** disappear until the problem is fixed.
8. To toggle and show the time and date stamp, please press the Lock / Unlock key.

To exit to the main screen, press and hold on to the Exit / Cancel button for 5 seconds.

The Alert Notification Icon above will appear on the top right corner of the screen whenever an alert event occurs. The number will indicate how many alerts occurred that were unacknowledged so that the caregiver can view a brief history of the alert events.

To clear the Alert Notification Icon:

1. Press Menu / Select button.
2. Navigate to Alert Setup by using the Up / Down button and press the Menu / Select button to enter into the Alert Setup function.
3. Navigate to the Alert Log by using the Up / Down button and press the Menu / Select button to enter into the Alert Log screen.
4. Scroll to the desired Alert Notification and press the Menu / Select button to acknowledge them.
5. The Alert Notification Icon will clear once acknowledged.

Advance Menu

The Advance Menu is for system setups and therefore untrained users should not be navigating into this part of the system unless being authorized to do so.

Preferences

In preferences, there are 2 functions for user to choose from:

Time — This function will enable the user to change the time accordingly to the local time.

To set the time, go to:

1. Menu > Advance Menu > Preference > Time
2. Use the 

(Menu / Select) button to toggle between HH, MM, SS, DD, MM, and YYYY.
3. Use the  (Up) button to increase the value and  (Down) button to decrease the value.
4. After the correct time and date is entered, press the  (Lock / Unlock) button to store the value.
5. Hit the 

(Exit / Cancel) button to exit to the main screen.

Backlight — This function allows the user to set the backlight to either brighter or dimmer according to the user's preference.

System Info

System info provides information about the system.

Software version, serial number and the usage meter is included in this function.

Language Selection

This function allows the user to choose which language to use.

To select the desired language, navigate using the Up / Down button in the Language and press the Menu / Select button.
The words in system will then automatically change to the selected language.

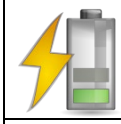
Battery Power

The XLR8+ can run on both battery powered and / or while plugged in with the power adapter.

Please note that every time the power adapter is plugged into the machine, it is charging the battery.

While the machine is plugged in, it does not affect or interfere with the therapy as the XLR8+ machine will still function as it is.

ONLY USE THE POWER ADAPTER THAT CAME IN THE BOX. DO NOT USE AN UNKNOWN POWER ADAPTER.

	Battery life is between 2% to 25%
	Battery life is between 25% to 50%
	Battery life is between 50% to 75%
	Battery life is between 75% to 100%
	Battery life is between 0% to 2% (Alert Notification will occur. User needs to plug in the power adapter to recharge the battery)
	Battery is charging
	Battery is fully charged and system is running on while the power adapter is plugged in

Advance Features

Lock / Unlock Keypad

To lock the keypad

1. Press and hold the  (Lock / Unlock) together with the  (Exit / Cancel) button for a duration of 7 seconds.
2. When the  icon changes  , the keypad is locked.
3. To unlock the keypad, repeat step 1 above.
4. The icon will then change from  to  .

Alert Log Clearing

To clear the Alert Log, the user needs to go to the main screen.

1. Press and hold  (Menu / Select) button.
2. Press the  (Lock / Unlock) and release while holding onto number 1.
3. Press the  (Exit / Cancel) and release while holding onto number 1.
4. Release the  (Menu / Select) button.

Treatment Time Reset (Both Continuous and Variable Therapy)

To reset the treatment time, the user needs to go to the main screen.

1. Press and hold 

(Menu / Select) button.
2. Press and release in sequence, the  (On / Off) button, and the  (Lock / Unlock) button.
3. Release the 

(Menu / Select) button.
4. The Treatment Time will be reset to 00:00:00.

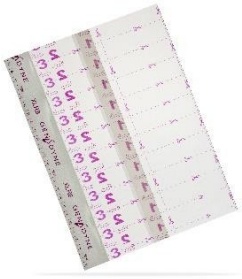
Dressing Application

Step 1 Choose appropriate size of XLR8 foam kit for wound.

Step 2 Clean the wound according to the agency / facility protocol. Protect wound edges with the XLR8 drape if necessary.

Step 3 Cut foam to appropriate size of the wound. Place the foam into the wound. Avoid cutting the foam over the wound. Do not over pack.

Step 4 Cover foam with XLR8 drape. Peel layers 1, 2, and 3. Remove the handlers.



Step 5 Cut a hole on the drape in the middle of the foam approximately 1” in diameter. Remove paper backing (number 1) from the port pad*. Place over the hole. Peel number 2. Remove handlers.

**Actual port pad may be different from the picture. The picture is for illustrative purposes only.*

Step 6 Attach the canister to the back of the machine. Slide in the canister and make sure it is secure and tightly held.

Step 7 Connect the port pad tubing to the canister tubing. Ensure all clamps are unclamped at this time.

Step 8 Initiate therapy at the prescribed pressure by turning the machine on.

Step 9 Foam will collapse down and target pressure will be achieved.

Maintenance

It is mandatory for the product to have scheduled diagnostic maintenance every 12 months or 6000 hours, whichever comes first. Failure to comply will void warranty. Only trained personnel will be able to perform preventative maintenance to the unit. Distributor will only have the preventative maintenance manual.

By following the steps below, the user can determine that the unit is due for maintenance:

1. Press Menu / Select button
2. Navigate to Advanced Menu by using the Up /Down button and press the Menu / Select button
3. Navigate to the System Info by using the Up / Down button and press the Menu / Select button
4. If Preventive Maintenance is required, the below can be found in the System Info Menu
    a. MAINTENANCE REQ. : YES

Product is also recommended to be opened and inspected between patient use by trained personnel to detect any possible issues before returning the device to the field. Please contact Genadyne for a free training on how to perform both the recommended and mandatory preventative maintenance on the device.

The mandatory preventative maintenance consists of full inspection and diagnostics of unit, replacement of internal tubing and battery if necessary, replacement of Double O-rings, replacement of odor patches and cleaning of the inside and outside of the unit. This maintenance insures proper continued performance from the unit, as well as maintaining the indicated battery run time.

Please contact your local distributor or Genadyne regarding the preventative maintenance for the device.

Cleaning

Adherence to facility directives concerning hygiene is of prime importance.

Only use low level diluted form of disinfectants or cleaning agents when cleaning the XLR8+. Use damped cloth to clean the pump.

Be cautious when cleaning because no liquids should enter the power unit. If liquid goes inside of the power unit, it might cause the unit to malfunction or damage the mechanics.

Dry with a separate soft cloth.

Do not use solvents or abrasives.

Do not immerse any part of the XLR8+ in fluid or use an unnecessarily wet cloth.

Please contact your distributor if any liquids penetrated the device.

Returning the Device

For any returns or rental returns, prior to returning the device to your representative, the device must be cleaned in line with the steps laid out under the cleaning section of this manual.

All used canisters have to be disposed.

Disposal of used canisters should follow facility protocols or local ordinances relating to the handling of potentially infected or bio-hazardous materials.

The device will also need to be returned in the original packaging.

Disposing of the Device

Conforms with the Waste Electrical and Electronic Directive (2002/96/EC). At the end of useful life, dispose of all waste according to local requirements, or contact your local Genadyne subsidiary or agent for advice. This product is designated for separate collection at an appropriate collection point. Do not dispose of in normal waste stream.

Limited Warranty

Genadyne Biotechnologies warrants its products, as listed below for one year on the machine.
This warranty does not cover damage or breakdown to Genadyne units due to misuse or improper handling.
The company will repair the system outside of the warranty coverage and shall bill the customer for parts and labor.
Items sent in for repair outside of warranty period that are paid shall have a limited 90-day warranty commencing from the date the product is shipped back to the customer.
Items sent in that are covered under the warranty period shall not have their warranty extended, other than having the time remaining on the warranty continue once the repaired product is shipped back to the customer.
The company also reserves the right to revise the warranty policy from time to time and to issue different warranty policies for different products.
This warranty shall supersede and replace all warranties of merchantability and fitness applicable to the fullest extent allowed under the laws of State of New York.

---- Warranted Products ----

Genadyne XLR8+ Negative Pressure Wound Therapy System

Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

The Genadyne XLR8+ is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne XLR8+ should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Genadyne XLR8+ 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 Genadyne XLR8+ is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

The Genadyne XLR8+ is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne XLR8+ 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	+/- 8 kV contact +/- 15 kV air	+/- 8 kV contact +/- 15 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 homecare and hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+ 1kV differential mode (line-line) + 2kV common mode (line-earth)	Mains power quality should be that of a typical commercial or homecare and hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles h) Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Genadyne XLR8+ be powered from an uninterruptable power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or homecare and hospital environment

Note Ut is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration – electromagnetic immunity			
The Genadyne XLR8+ is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne XLR8+ 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 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Negative Pressure Wound Therapy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	S2AD6b8mW□ 800 MHz S2AD6b8mW□8 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 in meters (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: 
NOTE 1 At 80 MHz and 800 MHz, 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.			

- 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 Genadyne XLR8+ is used exceeds the applicable RF compliance level above, the Genadyne XLR8+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Negative Pressure Wound Therapy System.

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Genadyne XLR8+ is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne XLR8+ should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Negative Pressure Wound Therapy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance y2SAD S2yAD where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment the Negative Pressure Wound Therapy System				
The Genadyne XLR8+ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Genadyne XLR8+ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Genadyne XLR8+ 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)			
	80 to 800 MHz d P	800 MHz to 2.7 GHz d = [7/10 P	710, 745, 780, 5240, 5500, 5785 S2AD	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 S2AD
0.01	0.035	0.070	0.067	0.021
0.1	0.110	0.221	0.211	0.070
1	0.350	0.700	0.667	0.214
10	1.107	2.213	2.108	0.700
100	3.500	7.000	6.670	2.143
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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.				

Technical Specifications

VACUUM PUMP

Service Life	: 3 year
Continuous Mode	: Min Vacuum 40mmHg; Max Vacuum 230mmHg
Variable Mode	: Min Vacuum 30mmHg; Max Vacuum 230mmHg
Intermittent Mode	: Min Vacuum 0mmHg; Max Vacuum 230mmHg
Suction Capacity	: 5.2 Liters per minute (LPM) – 6.4 LPM

DIMENSIONS/WEIGHT

Dimension	: 5.9” (H) x 3.9” (W) x 3.4” (L)
Weight	: 1.65 lbs (748.42 grams)

ELECTRICAL REQUIREMENT

Power	: 19 VDC, 1.57A 30W
Charger Model	: MPU30B-5
Battery Type	: Li-Ion rechargeable batteries
Battery Run Time	: ~ 12 hours, depending on settings
Recharge Time	: ~ 3 Hours

Device will operate with battery and while charging.

ENVIRONMENTAL CONDITIONS

Operating Conditions	: 5°C to 40°C, 41°F to 104°F
Relative Humidity	: 15% to 93%

STORAGE AND SHIPPING CONDITIONS

Ambient Temperature	: -20°C to 60 °C, -4°F to 140°F
Relative Humidity	: 10%-90% Non-Condensing
Atmospheric pressure	: 8.6 psia - 14.3 psia

PATIENT PROTECTION

Class II per EN 60601-1
Applied Part Type BF per EN 60601-1

COMFORMS TO

EN 60601-1
EN 60601-1-2
EN 60601-1-6
EN 60601-1-11
EN 61000-3-2
EN 61000-3-3
ISO 10079-1

IP Class

IP 33

Software Version

Software version are found in each unit under advance menu

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