

GENADYNE

XLR8+

Negative Pressure Wound Therapy



H&R

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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

The use of external accessories and cables other than those provided by Genadyne may result in increased Electromagnetic Emissions or decrease in Immunity of the Wound Vacuum System.

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



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

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.

9. The user **SHOULD NOT** attempt to service, repair or modify the Wound Vacuum 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. GROUNDING RELIABILITY DEPENDS UPON A PROPERLY GROUNDED WALL OUTLET. 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 adaptor may be used with the device. Use of any other adaptor automatically voids warranty and may be hazardous to the patient and the operator.











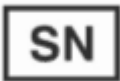









IEC-320 C8 Power Cord
(Model# MPU30B-5)
19 VDC 1.57A 30W



Symbols



XLR8+ NPWT System Label Reproduction

	Equipment Classification Isolation type BF applied part		Single use only
	Date of Manufacture		Place of Manufacture
	Storage Temperature		Biohazard
	Keep Dry		EU: Not for general waste
	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
	Recognized Component Mark for Canada and the United States (Power adapter)		Certified Body (Power adapter)
IPX1	Not evaluated for protection against solid foreign objects and protected from moisture up to vertically dripping water	Rx Only	Caution: Federal (US) law restricts this device to sale/rental by or on the order of a physician

Indication for use

The Genadyne XLR8+ Wound Vacuum System is indicated for use in 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. Patients may be trained to perform some limited functions, but the keyboard is locked by the professional to prevent the patient from changing the settings prescribed by the physician.

Contraindications

Genadyne XLR8+ Therapy 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+ Therapy 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.

Continuous versus Variable Therapy

Continuous, rather than variable, Genadyne XLR8+ Therapy 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+ Therapy. 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+ Therapy to help minimize sensory stimulation and seek immediate medical assistance.

Bradycardia

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

Enteric Fistulas

Wounds with enteric fistulas require special precautions to optimize Genadyne XLR8+ Therapy. In certain circumstances, the Genadyne XLR8+ Therapy may help to promote healing in wounds with an enteric fistula. When the physician orders the Genadyne XLR8+ Therapy, it is recommended that support from an expert clinician is sought. Genadyne XLR8+ Therapy is **not** recommended or designed for fistula effluent management or containment, but as an aid to wound healing. Genadyne XLR8+ Therapy 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+ Wound Care 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+ Wound Care 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+ Wound Care 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+ Wound Care 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+ 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 Treatment is being used.

Prior to placement of the Genadyne XLR8+, 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.

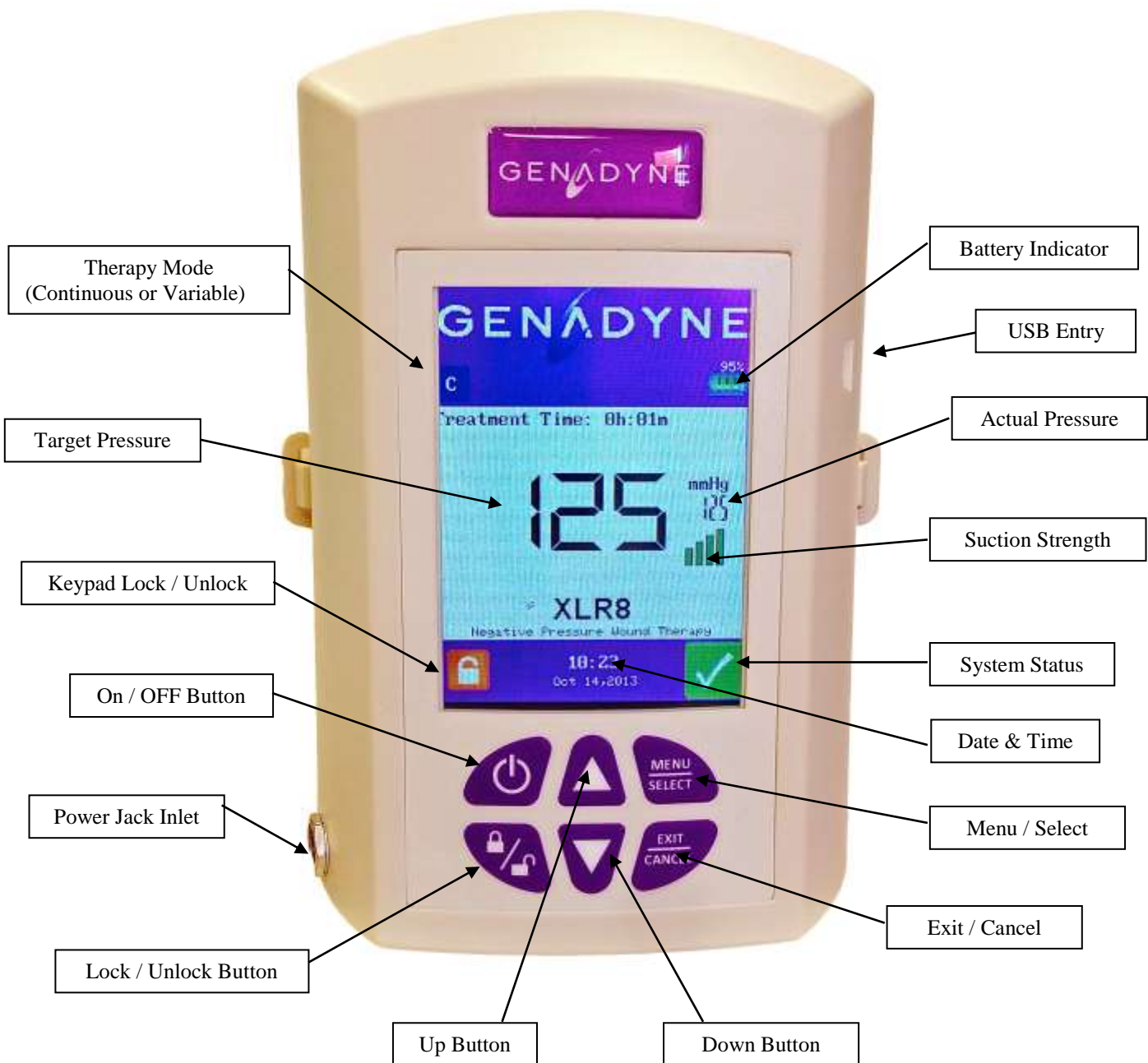
All orders should include:

- 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.
Enable user to scroll up in a menu.



Down Button

Decrease suction pressure.
Enable user to scroll down in a menu.



Lock / Unlock

Lock and unlock keypad.



Menu / Select

Brings up the system menu.
Enable user to select the desired function.




Exit / Cancel

Exit from the system menu.
Enable 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.

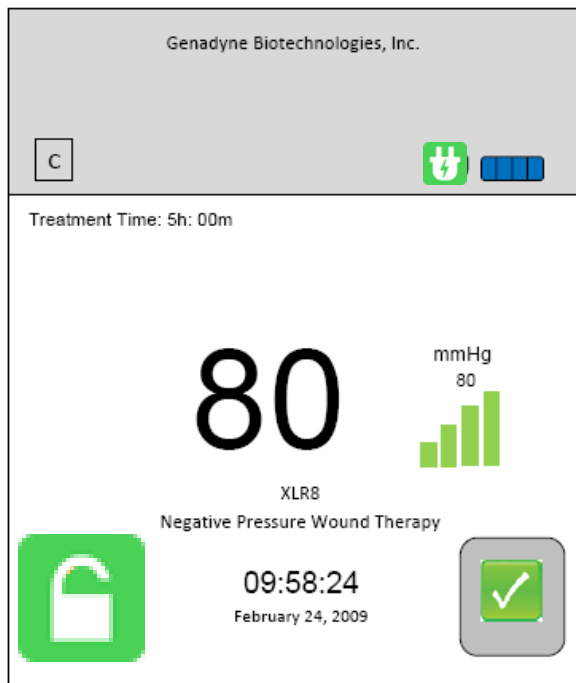
Therapy Modes

The Genadyne XLR8+ provides the user with 2 therapy modes.

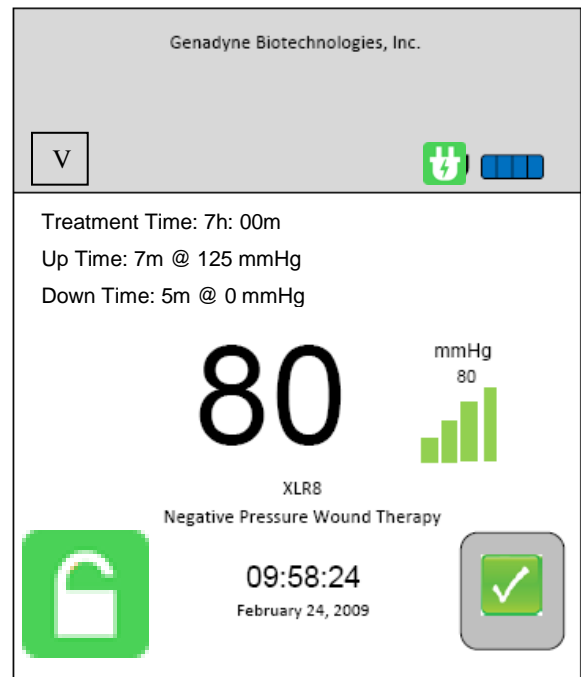
1. Continuous
2. Variable

Continuous Mode

If a symbol  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  is observed, this means variable therapy is in active.



Continuous Mode

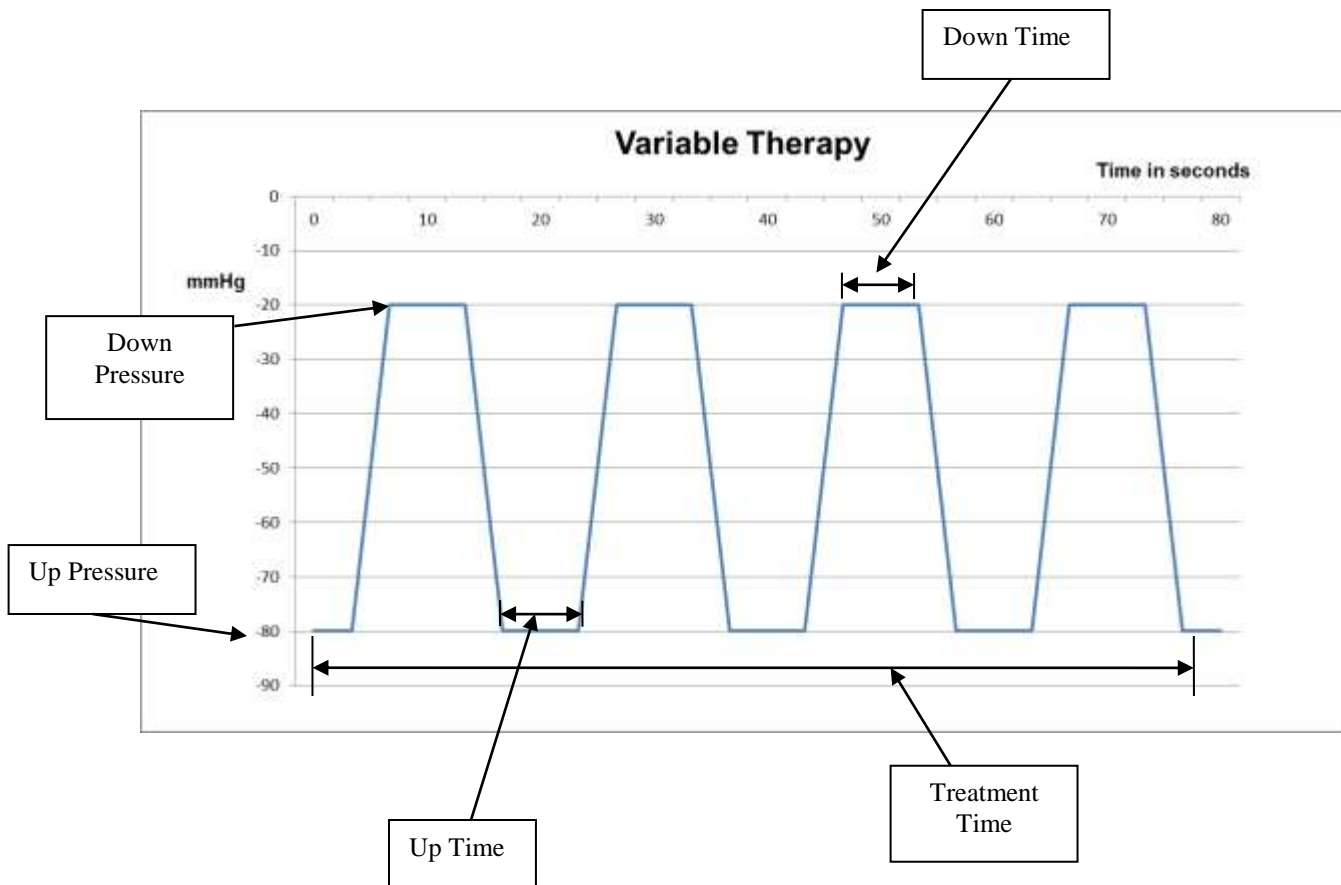


Variable Mode

Variable Mode

In Variable 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 anytime

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 by pressing the Menu / Select button once.
4. For Continuous 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 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 setting screen.
 - b. 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 setting screen.
 - c. 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 setting screen.
 - d. 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 setting screen.
 - e. 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 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 being 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

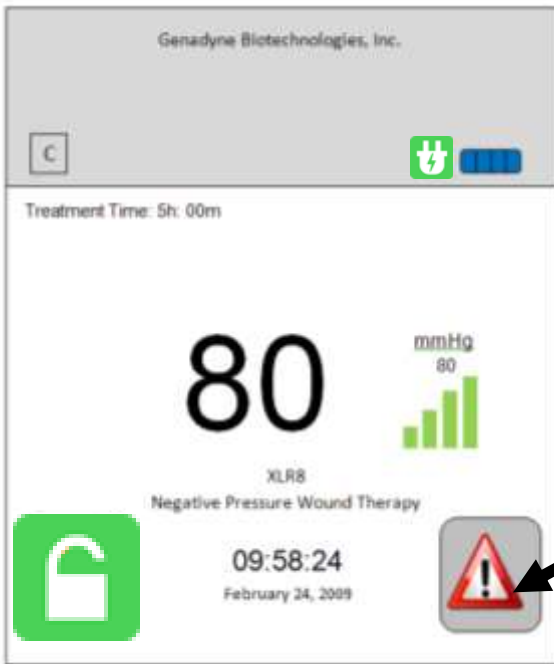
The intensity mode has 3 basic settings. The intensity mode is for users to adjust the speed of suction of the XLR8+ device. Setting 1 will run at the lowest speed while Setting 3 will run at the highest speed.



There are 5 Alert notifications in the XLR8+.

<p>Leak Alert</p> 	<p>Whenever there is a leak in the dressing or the canister, the Leak Alert alert will occur.</p> <p>The Message on the screen will show:-</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>ALERT: LEAK OR LOSS OF SUCTION</p> <p>REVIEW DRESSINGS AND CANISTER CONNECTION TO UNIT</p> <p>ONCE LEAK IS RESOLVED, PRESS MENU BUTTON TO CONTINUE THERAPY</p> </div>
<p>Canister Full</p> 	<p>Canister Full Alert occurs when the canister is filled with exudates.</p> <p>The Message on the screen will show:-</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>ALERT: CANISTER FULL</p> <p>REPLACE CANISTER</p> <p>REMOVE CANISTER FROM UNIT, REPLACE WITH A NEW CANISTER. TURN UNIT OFF. ONCE COMPLETELY OFF, TURN BACK ON AND CONTINUE THERAPY.</p> </div>
<p>Low Battery</p> 	<p>Whenever the battery level is less than 20%, the low battery Alert will occur.</p> <p>The Message on the screen will show:-</p>

	<p style="text-align: center;">ALERT: LOW BATTERY</p> <p style="text-align: center;">PLUG UNIT IN ELECTRICAL SOCKET TO CONTINUE THERAPY</p>
<p>Blockage</p> 	<p>Blockage Alert occurs when there is a blockage in between wound dressing and the canister.</p> <p>The Message on the screen will show:-</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>ALERT: BLOCKAGE</p> <p>REVIEW DRESSING AND TUBING</p> <p>MAKE SURE THAT CLAMPS ARE OPEN</p> <p>PRESS MENU BUTTON TO CONTINUE THE THERAPY</p> </div>
<p>Critical Battery</p> 	<p>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.</p> <p>NOTE: MACHINE WILL NOT WORK UNTIL A POWER ADAPTER IS PLUG IN.</p> <p>The Message on the screen will show:-</p> <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>ALERT: CRITICAL BATTERY</p> <p>ONLY 5 % OF CHARGE LEFT ON BATTERY</p> <p>PLUG UNIT IN ELECTRICAL SOCKET</p> </div>



**Unverified/Unacknowledged
alert(s) present**



User needs to inspect
dressings and unit.

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

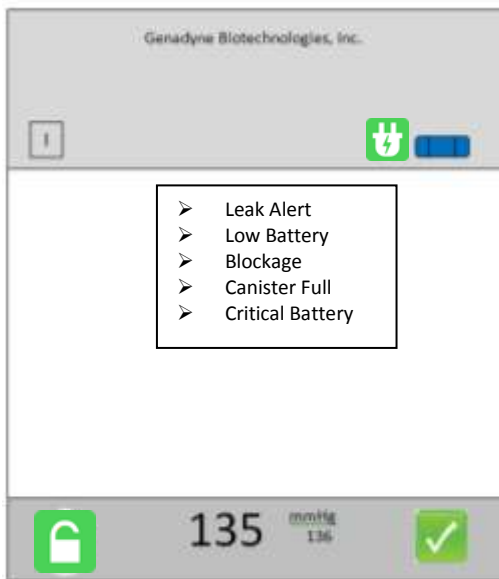
Enable / Disable

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

To Enable / Disable the Alert

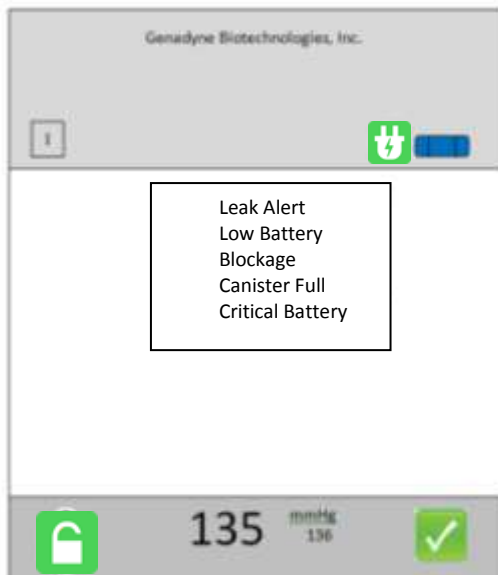
1. Press Menu/Select button, use the Up/Down button to navigate to Alert Setup, press the Menu/Select button again to enter into the Alert Setup function.
2. Press Menu/Select button to select the Enable/Disable function.

3.



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.

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

Alert Log

All Alerts are logged and saved in the XLR8+ memory. Only the last 8 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 8 Alerts will be shown on the screen
5. To acknowledged 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.

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 in to 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

Maintenance

It is mandatory for the product to have scheduled diagnostic maintenance every 6 months or 4000 hours, whichever comes first. Failure to comply will void warranty. Product is also recommended to be opened and inspected between patient use by trained personnel. 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 dampened cloth to clean the pump.

Be cautious when cleaning because no liquids should enter the power unit. If the 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

The device contains batteries. Do not dispose of this device by placing it in the trash. Return the device to Genadyne or use local procedures for battery disposal.

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 <u>XLR8+</u> 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 <u>XLR8+</u> 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)	+/- 6 kV contact	Passed	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2	+/- 8 kV air		
Electrical fast transient / burst	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Below Maximum permissible limit	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-4 Surge	+/- 1 kV line(s) to line(s)	Acceptable Performance	Mains power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 Voltage dips, short interruptions and voltage variations on power supply input lines	+/- 2 kV line(s) to earth < 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	Acceptable Performance	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Genadyne <u>XLR8+</u> be powered from an uninterruptable power supply or a battery.
IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 5 sec		
Power frequency (50/60 Hz) magnetic field	3 A/m	Non Applicable	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment
IEC 61000-4-8			

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

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m

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.

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)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.33 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.33 m

Technical Specifications

VACUUM PUMP

Service Life (est.) : 1 year (Brushless motor)
Continuous Mode : Min Vacuum 50mmHg; Max Vacuum 230mmHg
Variable Mode : Min Vacuum 0mmHg; Max Vacuum 230mmHg

DIMENSIONS/WEIGHT

Dimension : 5.9" (H) x 3.9" (W) x 3.4" (L)
Weight : 1.65 lbs

ELECTRICAL REQUIREMENT

Power : 19 VDC, 1.58A 30W (Min)
: 20 VDC (Max)
Model : MPU30B-5
Battery Type : Li-Ion rechargeable batteries
Recharge Time : ~ 3 Hours

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 : -25°C to 70°C, 0°F to 110°F
Relative Humidity : ≤ 93 % Non-Condensing

PATIENT PROTECTION

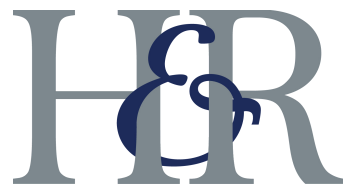
Class II per EN60601-1
Applied part Type BF per EN60601-1

COMPLIANCE

IEC 60601-1, 3rd Edition
IEC 60601-1-2

Contact Information

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