XLR8

Negative Pressure Wound Therapy

GENADYNE

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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.

Safety Standards

This system has been designed to comply with the regulatory safety standards including UL 60601-1, CAN/CSA C22.2 No. 601.1-M90, CE 93/42/EEC Class IIa.

This system is internally powered with battery and externally powered with an approved Class II power adapter.

Symbols

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
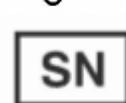
Serial Number

Caution:
See instructions for use

Lot Number

Product Reference Number

Authorized European
Representative

CE Mark

CSA International Classification

Double insulated

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

Certified Body (Power adapter)

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.

Contraindications

Genadyne XLR8 Therapy is contraindicated for patients with:

- o Malignancy in the wound
- o Untreated osteomyelitis (***NOTE:*** *Refer to Clinical Guide for Osteomyelitis information.)*
- o Non-enteric and unexplored fistulas
- o 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:

- o Exposed blood vessels
- o Anastomotic sites
- o Organs
- o 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 Intermittent Therapy

Continuous, rather than intermittent, 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.

Physician Orders

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

NO

NO

NO

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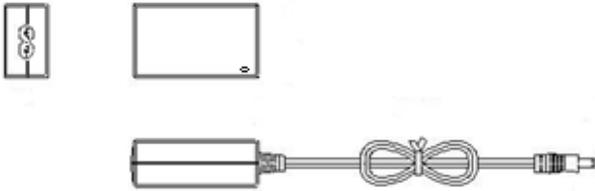
IEC-320 C8 Power Cord
(Model# MPU30B-5)
19 VDC 1.57A 30W

Canisters

Available Canisters:

200 cc Canisters
400 cc Canisters
600 cc Canisters
800 cc Canisters

Accessories

Y connector for multiple wounds

Carrying bag

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

Press the Power Button ![power button] once. The LCD will be lighted up. The pump will start running. Suction is immediately available.

Therapy Modes

The Genadyne XLR8 provides the user with 2 therapy mode.

1. Continuous
2. Intermittent

Continuous Mode

If a symbol $\boxed{C}$ 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 $\boxed{I}$ is observed, this means intermittent therapy is in active.

Continuous Mode screen:
Genadyne Biotechnologies, Inc.
C
Treatment Time: 5h: 00m
80 mmHg 80
XLR8
Negative Pressure Wound Therapy
09:58:24
February 24, 2009

Intermittent Mode screen:
Genadyne Biotechnologies, Inc.
I
Treatment Time: 7h: 00m
Up Time: 7m
Down Time: 5m
80 mmHg 80
XLR8
Negative Pressure Wound Therapy
09:58:24
February 24, 2009

Continuous Mode   Intermittent Mode

Intermittent Mode

In intermittent 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 intermittent:-

1. **Treatment time.** Treatment time allows the user to set how long they want the patient to be on intermittent 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 intermittent 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 intermittent therapy.
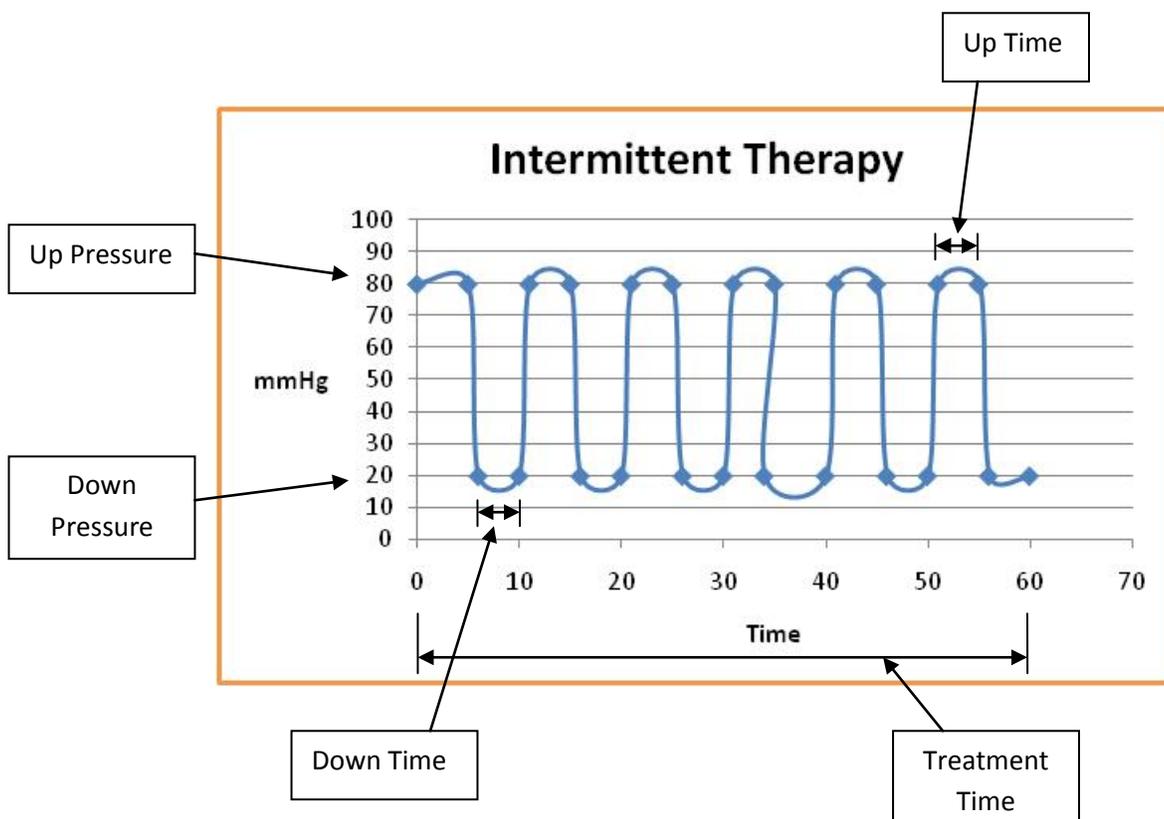
Therapy Selection

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 Intermittent by pressing the Menu / Select button once.
4. For Continuous selection, after **<u>Step 3</u>**, 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 Intermittent selection, after **<u>Step 3</u>**, press Menu / Select button one more time to enter into the intermittent setting screen.
    a. <u>Treatment Time</u>. Press the Menu / Select button to enter the desired treatment time. 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 Intermittent setting screen.
    b. <u>Up Time</u>. 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 Intermittent setting screen.
    c. <u>Up Pressure</u>. 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 Intermittent setting screen.
    d. <u>Down Time</u>. 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 Intermittent setting screen.
    e. <u>Down Pressure</u>. 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 Intermittent setting screen.
6. To exit the intermittent 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.

Alarms

There are 4 alarm notifications in the XLR8.

Target Timeout (Leakage)

Whenever there is a leak in the dressing or the canister, the Target Timeout alarm will occur.

Low Battery

Whenever the battery level is less than 2%, which typically it will have less than 30 minutes of operating time, the low battery alarm will occur.

Blockage

Blockage alarm occurs when there is a blockage in between wound dressing and the canister.

Canister Full

Canister Full alarm occurs when the canister is filled with exudates.

Unverified/Unacknowledged alarm(s) present
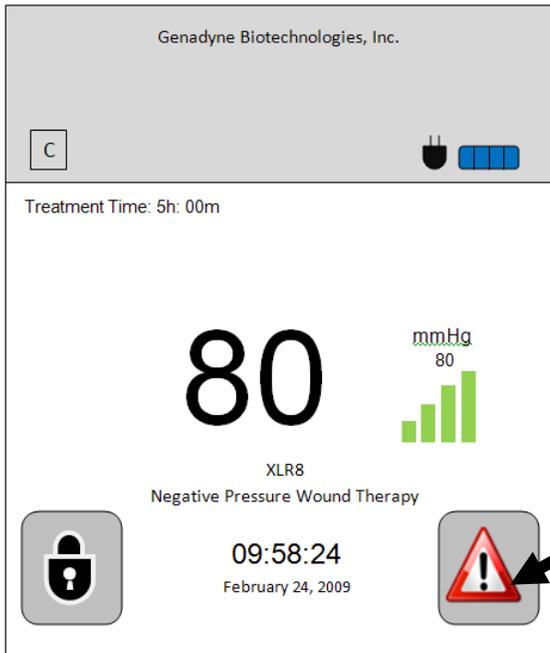
User needs to refer to <u>Alarm Log</u> verify the problem.

The alarm bell will not stop until the user acknowledges the notification by pressing the Menu/Select button when the alarm log screen is up. In the event when the alarm screen is not present, please follow the instructions on how to find the alarm log in this manual.

Enable / Disable

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

To Enable / Disable the Alarm

1. Press Menu/Select button, use the Up/Down button to navigate to Alarm Setup, press the Menu/Select button again to enter into the Alarm Setup function.
2. Press Menu/Select button to select the Enable/Disable function.
3.
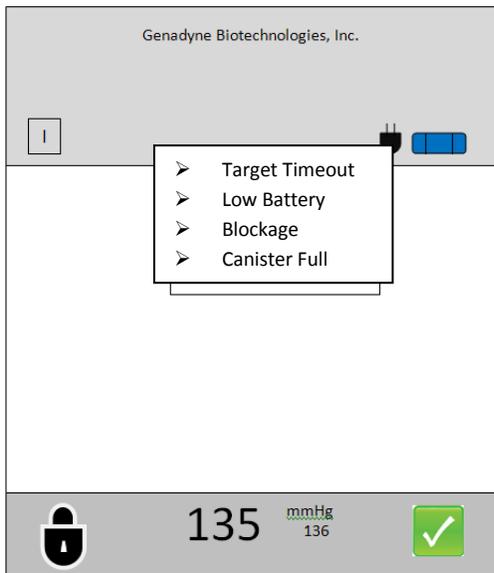
Arrows on the side means enabled.

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

Disabled (No arrows).

To disable the alarms, navigate to the desired alarm and press Menu/Select once to have the arrow disappear.
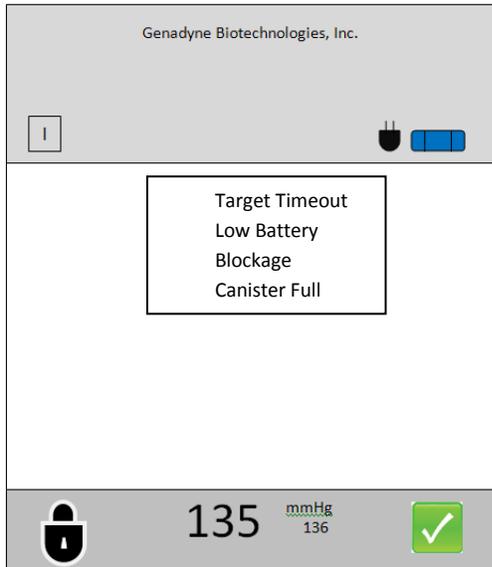
4. To exit to the main screen, press and hold the Exit/Cancel button for 5 seconds.

Target Timeout

The target timeout function is to enable the user to determine how soon after should the device start alarming to notify the user of a leakage event occurring.

For example, if the target timeout is set at 30 seconds, this means that in the event of a target timeout, it will have to last for at least 30 seconds continuously before the system starts alarming.

Use the Up/Down button to increase or decrease the desired time limit and press the Menu/Select button to confirm setting.

Alarm Log

All alarms are logged and saved in the XLR8 memory.

To enter into the alarm log

1. Press Menu/Select button
2. Navigate to Alarm Setup by using the Up/Down button and press the Menu/Select button to enter into the Alarm Setup function
3. Navigate to the Alarm Log by using the Up/Down button and press the Menu/Select button to enter into the Alarm Log screen
4. All the past alarms will be shown on the screen
5. To acknowledged them scroll to the desired alarm notification and press the Menu/Select button
6. The alarm bell will stop once acknowledged.
7. The asterisk (*) on the left side of the notification **WILL NOT** disappear until the problem is fixed.

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] (menu/select) button to toggle between HH, MM, SS, DD, MM, and YYYY.

3. Use the [up button] (up) button to increase the value and [down button] (down) button to decrease the value.

4. After the correct time and date is entered, press the [lock/unlock button] (lock/unlock) button to store the vale.

5. Hit the [EXIT/CANCEL button] (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.

⚠️ 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% (Alarm 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

There are no serviceable parts in the device. Do not attempt to open the enclosure. Contact your distributor if service is required.

Before each usage, inspect the device for visible signs of damage. Please contact your distributor if visible signs of abuse and damage have been observed.

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 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.

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	+/- 6 kV contact +/- 8 kV air	Passed	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 +/- 1 kV for input / output lines	Below Maximum permissible limit	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Acceptable Performance	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 5 sec	Acceptable Performance	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	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

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

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 A4 Negative Pressure Wound Therapy System

Genadyne XLR8 Negative Pressure Wound Therapy System

Technical Specifications

VACUUM PUMP

Service Life (est.)	: Unlimited (Brushless motor)
Minimum Vacuum	: 50mmHg
Maximum Vacuum	: 230mmHg
Suction capacity	: ~4 Liters per Minute

DIMENSIONS/WEIGHT

Dimension	: 5.9" (L) x 3.9" (W) x 2.1" (H) (150 mm x 99 mm x 53 mm)
Weight	: 1.5 lbs (0.68 kg)

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
Safety	: EN55011 Class B
	: UL/cUL 60601-1
	: TUV/GS EN60601-1
	: CE Mark (LVD)

ENVIRONMENTAL CONDITIONS

Operating Conditions	: 18°C to 34°C, 65°F to 94°F
Relative Humidity	: 10% to 95%

STORAGE AND SHIPPING CONDITIONS

Ambient Temperature	: 0°F to 110°F, -18°C to 43°C
Relative Humidity	: 10% to 95 %

PATIENT PROTECTION

Type BF

COMPLIANCE

UL 60601-1
IEC 60601-1
IEC 60601-1-2 CAN/CSA C22.2 No. 601.1

Contact Information

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www.genadyne.ca	www.genadyne.eu	www.obelis.net

GENADYNE

Distributed by
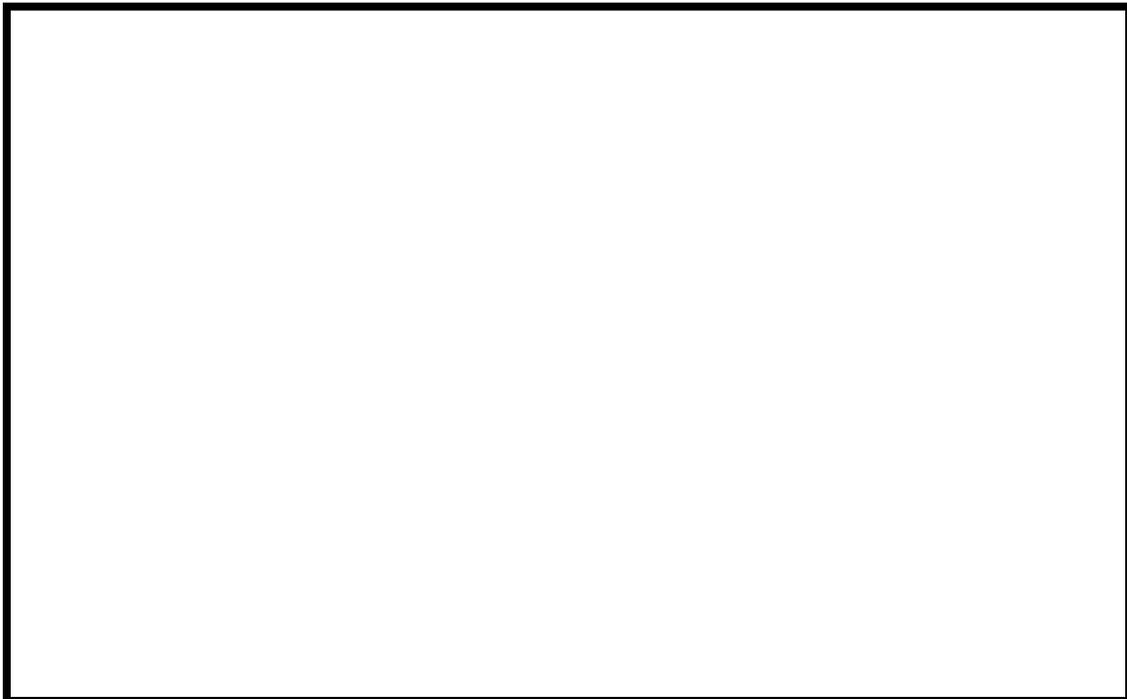
Advance Features

Lock / Unlock Keypad

To lock the keypad

1. Press and hold the ___ (menu / select) button, press a sequence of buttons ___ (Up),

    (down) and ___ (lock / unlock), then release ___ (menu / select).

2. When the ___ icon changes to ___, the keypad is locked.
3. To unlock the keypad, repeat step 1 above.

4. The icon will then change from ___ to ___.

Alarm Log Clearing

To clear the alarm 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.

Genadyne Biotechnologies, Inc.

C

Treatment Time: 5h: 00m

80

mmHg
80

XLR8
Negative Pressure Wound Therapy

09:58:24
February 24, 2009

Treatment Time Reset (Both Continuous and Intermittent)

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

1. Press and hold ![MENU SELECT button] (menu / select) button.

2. Press and release in sequence, the ![on/off button] (on / off) button, and the ![lock/unlock button] (lock / unlock) button.

3. Release the ![MENU SELECT button] (menu / select) button.

4. The treatment time will be reset to 00:00:00.