GENADYNE

H&R HEALTHCARE

UNO

Single Use Negative Pressure Wound Therapy

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Contents

UNO Safety Information

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, EC 93/42/EEC Class IIa.

Important: As with any prescription medical device, failure to consult a physician and carefully read and follow all therapy unit and dressing instructions and safety information prior to each use may lead to improper product performance and the potential for serious or fatal injury. Do not adjust therapy unit setting or perform therapy application without directions from/or supervision by the clinical caregiver.

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

Description

The Genadyne UNO is a single use Negative Pressure Wound Therapy (NPWT) Unit designed for moderate to low severity wounds. The Genadyne UNO NPWT Unit has a pre-determined lifespan. The unit features an interface panel which provides alert and information signals and selectable therapy options. This unit provides negative pressure at either 80 mmHg or 125 mmHg, and offers selections of Continuous Mode at 80mmHg / 30mmHg or 125mmHg / 30mmHg in Variable Mode. The Genadyne UNO Therapy Kits include a therapy unit, AA batteries, 70 ml canisters, and sterile dressing kits. Dressing kits and canisters for the Genadyne UNO could be provided separately. The dressing is intended to be used for a maximum of 3 days. Therapy duration of the dressing may be less than indicated if clinical practice or other factors such as wound type, wound size, rate or volume of exudate, orientation of the dressing or environmental conditions, result in more frequent dressing changes.

Disposable components of the Genadyne UNO, including the foam dressing and drape, are packaged sterile (Ethylene Oxide) and not made with natural rubber latex. All disposable components of the Genadyne UNO are for single use only. To help ensure safe and effective use, the Genadyne UNO dressings are to be used only with the UNO Negative Pressure Therapy Unit.

The decision to use clean versus sterile/aseptic technique is dependent upon wound pathophysiology, physician/clinician preference and institutional protocol.

Indications for Use

Genadyne UNO 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 low to moderate exudates and infectious material.

Appropriate wound types include:

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

It is a single patient use device.

Contraindications

- Do not place foam dressings of the Genadyne UNO NPWT system directly in contact with exposed blood vessels, anastomotic sites, organs, or nerves.
  NOTE: *Refer to Warnings section for additional information concerning bleeding.*
- The Genadyne UNO NPWT is contraindicated for patients with:
  - Malignancy in the wound
  - Untreated osteomyelitis

  NOTE: *Refer to Warnings section 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 UNO NPWT may be used.*
  - Exposed arteries, veins, nerves or organs
  - Anastomotic sites
  - Emergency airway aspiration
  - Pleural, mediastinal or chest tube drainage
  - Surgical suction

Warnings

Bleeding: With or without using the Genadyne UNO NPWT, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding which, if uncontrolled, could be potentially fatal.

- Patients who have weakened or friable blood vessels or organs in or around the wound as a result of, but not limited to:
    - Suturing of the blood vessel (native anastomoses or grafts)/organ
    - Infection
    - Trauma
    - Radiation
- Patients without adequate wound hemostasis.
- Patients who have been administered anticoagulants or platelet aggregation inhibitors.
- Patients who do not have adequate tissue coverage over vascular structures.

If the Genadyne UNO NPWT is prescribed for patients who have an increased risk of bleeding complications, they should be treated and monitored in a care setting deemed appropriate by the treating physician.

If active bleeding develops suddenly or in large amounts during wound therapy, or if frank (bright red) blood is seen in the tubing or in the canister, immediately stop the Genadyne UNO NPWT, leave dressing in place, take measures to stop the bleeding and seek immediate medical assistance. The Genadyne UNO NPWT Unit and dressings should not be used to prevent, minimize or stop vascular bleeding.

Protect Vessels and Organs: All exposed or superficial vessels and organs in or around the wound must be completely covered and protected prior to the administration of Genadyne UNO NPWT.

Always ensure that the dressing does not come in direct contact with vessels or organs. Use of a thick layer of natural tissue should provide the most effective protection. If a thick layer of natural tissue is not available or is not surgically possible, multiple layers of fine-meshed, non-adherent materials or bio-engineered tissue may be considered as an alternative, if deemed necessary by the treating physician, to provide a complete protective barrier. If using non-adherent materials, ensure that they are secured in a manner as to maintain their protective position throughout therapy.

Consideration should also be given to the negative pressure setting and therapy mode used when initiating therapy.

Caution should be taken when treating large wounds that may contain hidden vessels, which may not be readily apparent. The patient should be closely monitored for bleeding in a care setting deemed appropriate by the treating physician.

Infected Blood Vessels: Infection may erode blood vessels and weaken the vascular wall which may increase susceptibility to vessel damage through abrasion or manipulation. Infected blood vessels are at risk of complications, including bleeding which, if uncontrolled, could be potentially fatal. Extreme caution should be used when Genadyne UNO NPWT is applied in close proximity to infected or potentially infected blood vessels. *(Refer to **Protect Vessels and Organs** section above)*

Hemostasis, Anticoagulants and Platelet Aggregation Inhibitors: Patients without adequate wound hemostasis have an increased risk of bleeding which, if uncontrolled, could be potentially fatal. These patients should be treated and monitored in a care setting deemed appropriate by the treating physician.

Caution should be used in treating patients on doses of anticoagulants or platelet aggregation inhibitors thought to increase their risk for bleeding (relative to the type and complexity of the wound). Consideration should be given to the negative pressure setting and therapy mode used when initiating therapy.

Hemostatic Agents Applied at the Wound Site: Non-sutured hemostatic agents (for example, bone wax, absorbable gelatin sponge or spray wound sealant) may, if disrupted, increase the risk of bleeding which, if uncontrolled, could be potentially fatal. Protect against dislodging such agents.

Sharp Edges: Bone fragment or sharp edges could puncture protective barriers, vessels or organs causing injury. Any injury could cause bleeding which, if uncontrolled, could be potentially fatal. Beware of possible shifting in the relative position of tissues, vessels, or organs within the wound that might increase the possibility of contact with sharp edges. Sharp edges or bone fragments must be eliminated from the wound area or covered to prevent them from puncturing blood vessels or organs before the application of Genadyne UNO NPWT. Where possible, completely smooth and cover any residual edges to decrease the risk of serious or fatal injury should shifting of structures occur. Use caution when removing dressing components from the wound so that wound tissue is not damaged by unprotected sharp edges.

Infected Wounds: Infected wounds should be monitored closely and may require more frequent dressing changes than non-infected wounds, dependent upon factors such as wound conditions and treatment goals. Refer to dressing application instructions for details regarding dressing change frequency. As with any wound treatment, clinicians and patients/caregivers should frequently monitor the patient's wound, periwound tissue and exudate for signs of infection, worsening infection, or other complications. Some signs of infection are fever, tenderness, redness, swelling, itching, rash, increased warmth in the wound or periwound area, purulent discharge, or strong odor. Infection can be serious and can lead to complications such as pain, discomfort, fever, gangrene, toxic shock, septic shock and/or fatal injury. Some signs or complications of systemic infection are nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucus membranes, disorientation, high fever, refractory and/or orthostatic hypotension, or erythroderma (a sunburn-like rash). If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact a physician immediately to determine if Genadyne UNO NPWT should be discontinued. For wound infections relating to blood vessels, please also refer to the section titled Infected Blood Vessels.

Osteomyelitis: The Genadyne UNO NPWT system should NOT be initiated on a wound with untreated osteomyelitis. Consideration should be given to thorough debridement of all necrotic, non-viable tissue, including infected bone (if necessary), and appropriate antibiotic therapy.

Protect Tendons, Ligaments and Nerves: Tendons, ligaments and nerves should be protected to avoid direct contact with UNO dressings. These structures may be covered with natural tissue, meshed non-adherent material, or bio-engineered tissue to help minimize risk of desiccation or injury.

Foam Removal: UNO dressings are not bio-absorbable. Always count the total number dressings used to ensure the same number dressings are removed. Dressings retained in the wound for greater than the recommended time period may foster ingrowth of tissue into the wound, create difficulty in removing foam from the wound, or lead to infection or other adverse events. If dressing adheres to the wound, consider introducing sterile water or normal saline into the dressing, waiting 15-30 minutes, then gently removing the dressing from the wound. Regardless of treatment modality, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site. Minor bleeding may be observed and considered expected. However, patients with increased risk of bleeding, as described in the Bleeding section, have a potential for more serious bleeding from the wound site. If significant bleeding develops, immediately discontinue the use of the UNO Therapy System, take measures to stop the bleeding, and do not remove the foam dressing until the treating physician or surgeon is consulted. Do not resume the use of the UNO Therapy System until adequate hemostasis has been achieved and the patient is not at risk for continued bleeding.

Keep Genadyne UNO NPWT On: Never leave an UNO dressing in place without active Genadyne UNO NPWT for more than 2 hours. If therapy is off for more than 2 hours, remove the old dressing and irrigate the wound. Either apply a new UNO dressing from an unopened sterile package and restart Genadyne UNO NPWT, or apply an alternative dressing at the direction of the treating clinician.

Acrylic Adhesive: The Genadyne UNO strip has an acrylic adhesive coating, which may present a risk of an adverse reaction in patients who are allergic or hypersensitive to acrylic adhesives. If a patient has a known allergy or hypersensitivity to such adhesives, do not use the Genadyne UNO NPWT system. If any signs of allergic reaction or hypersensitivity develop, such as redness, swelling, rash, urticarial, or significant pruritus, discontinue use and consult a physician immediately. If bronchospasm or more serious signs of allergic reaction appear, seek immediate medical assistance.

Defibrillation: Remove the UNO dressing if defibrillation is required in the area of dressing placement. Failure to remove the dressing may inhibit transmission of electrical energy and/or patient resuscitation.

Magnetic Resonance Imaging (MRI) – Therapy Unit: The Genadyne UNO NPWT Device is MR unsafe. Do not take the Genadyne UNO NPWT Device into the MR environment.

Magnetic Resonance Imaging (MRI) UNO Dressing: UNO dressing can typically remain on the patient with minimal risk in an MR environment, assuming that use of the Genadyne UNO NPWT is not interrupted for more than 2 hours (refer to Keep Genadyne UNO NPWT On above).

Hyperbaric Oxygen Therapy (HBO): Do not take the Genadyne UNO NPWT Device into a hyperbaric oxygen hazard. After disconnecting the Genadyne UNO NPWT Device, either (i) replace the UNO dressing with another HBO compatible material during the hyperbaric treatment, or (ii) cover the tubing of the UNO dressing with moist cotton gauze. For HBO therapy, the tubing must not be clamped. Never leave an UNO dressing in place without an active Genadyne UNO NPWT Device for more than 2 hours (please refer to the Keep Genadyne UNO NPWT On section above).

Precautions

Standard Precautions: To reduce the risk of transmission of bloodborne 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 googles if exposure to body fluids is likely.

Continuous Mode versus Variable Mode: Continuous, rather than Variable Mode, 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 UNO 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 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 dysreflexia (sudden changes in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue Genadyne UNO NPWT to help minimize sensory stimulation and seek immediate medical assistance.

Bradycardia: To minimize the risk of bradycardia, Genadyne UNO NPWT must not be placed in proximity to the vagus nerve.

Protect Periwound Skin: Consider use of barrier skin protector to protect periwound skin. Protect fragile/friable periwound skin with additional UNO strip, hydrocolloid, or other transparent film.

- Multiple layers of the UNO strip may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the strip, dressing, or tubing assembly appear, discontinue use and consult a physician.
- To avoid trauma to the periwound skin, do not pull or stretch the strip over the dressing during strip 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 strip technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of strips rather than one piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the strip when securing it, but let it attach loosely and stabilize the edges with an elastic wrap, if necessary. When using circumferential strip applications, 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.

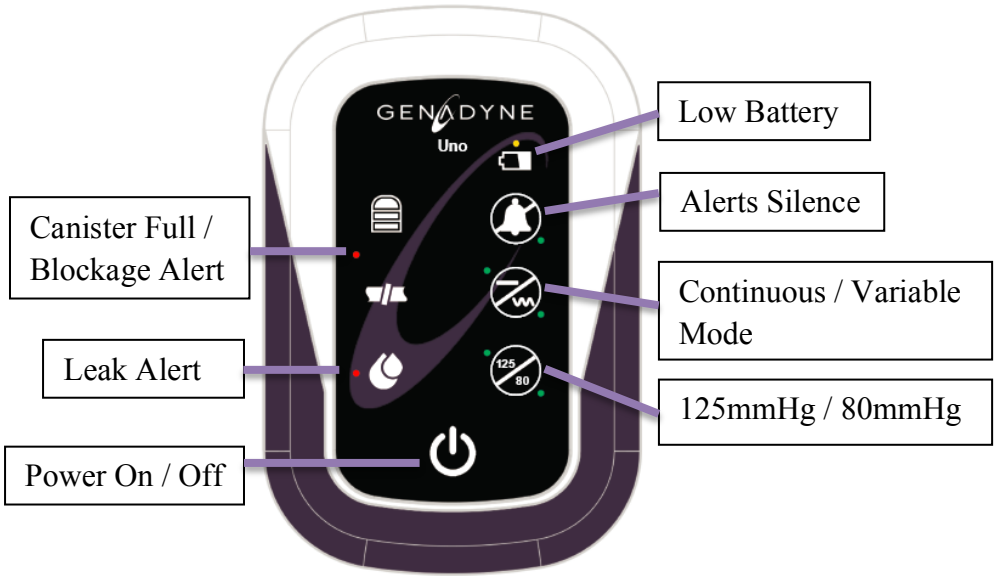
User

The Genadyne UNO is intended to be operated by qualified clinical caregivers in acute or extended settings. In-service and training programs for use of the Genadyne UNO are available. Patients are not expected to apply or change the Genadyne UNO dressings or adjust therapy unit settings.

Instructions for Use

a. Genadyne UNO NPWT

The Genadyne UNO NPWT Device is a single use NPWT device designed for moderate to low severity wounds. The Genadyne UNO has a pre-determined lifespan. The therapy unit features an interface panel which provides alerts and information signals and selectable therapy options. This unit provides negative pressure at either 80 mmHg or 125 mmHg in Continuous Mode and 80mmHg / 30mmHg or 125mmHg / 30mmHg in Variable Mode. The Genadyne UNO Therapy Kits includes a therapy unit, 70 ml canisters, dressing kits and AA batteries.



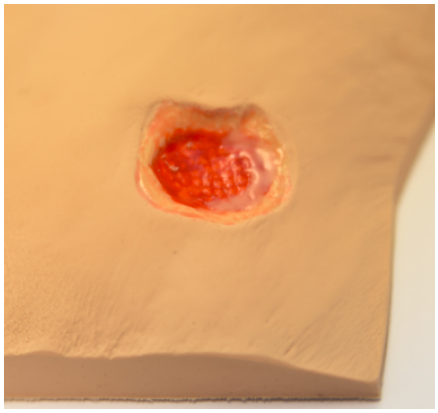
CAUTION: Once therapy is on for 30 minutes continuously, the lifespan counter begins and continues even if unit is turned off.

WARNING: The Genadyne UNO NPWT Device has no serviceable parts and should not be opened, disassembled, or otherwise modified by the user and should be replaced as a device. All assembly, operations, adjustments, modifications, maintenance and repairs must be carried out by qualified personnel authorized by Genadyne.

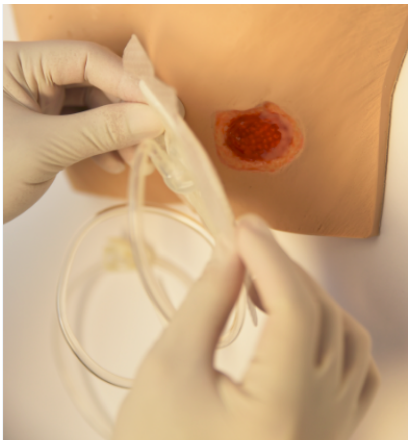
Electric Shock Hazard: Do not take the therapy device apart.

b. Application

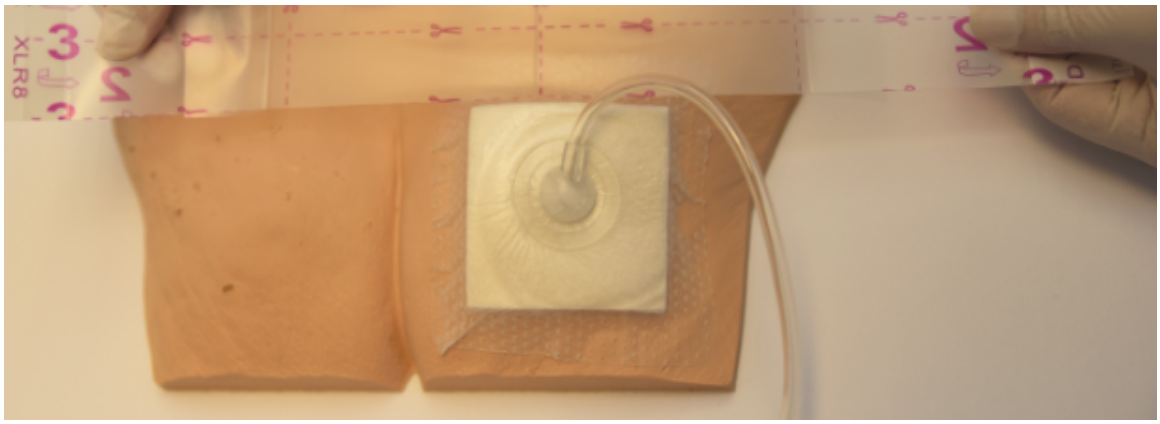
1. If necessary, irrigate the wound with sterile saline and pat the wound dry.



2. Using a clean technique, peel off the release liner and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the port. The port should be uppermost from the wound (depending on the patient's primary position), placed on intact skin and not extending over the wound to prevent fluid pooling around the port and blocking the negative pressure. Remove the other liner and flatten the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.



3. If using skin prep prior to application of the fixation strips, wipe the area surrounding the dressing and allow skin to dry.
4. Apply the fixation strips to each of the four sides of the dressing if the clinician feels it is necessary. Remove top carrier on the strip after each one has been applied. These strips maintain the seal over the wear time of the dressing. In awkward areas, it may be useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps the dressing border by approximately 1cm (2/5 inch). Ensure tubing is not twisted or trapped between clothing. Please note that if at any time the fixation strips are removed, the dressing should also be replaced.



5. Once the dressing is in place, take the device and batteries out of the box. Take off the battery cover and insert the batteries. Replace the cover.

6. Take one of the canisters from the box and slide the canister onto the back of the device. Make sure it clicks.

7. Join the pump to the dressing by pushing the tubing connector into the canister connector and twist until locked. Press the Power button  to start the application of negative pressure.

   NOTE: To prevent accidental change of settings, each button press will have to be held down for 2 seconds in order for the settings to be changed. The keypad can be locked by holding the Power and Mute buttons for 2 seconds. To unlock, press and hold the Power and Mute buttons for 2 seconds.

8. LED on the front panel indicates what pressure/mode is currently selected. If the LED on the left side is on, the device is on Continuous Mode. If the LED on the right side is on, the device is on Variable Mode:

    Device is on Continuous Mode

    Device is on Variable Mode

9. Select therapy pressure of 80 mmHg or 125 mmHg by pressing 125/80 button. The green LED next to the button will indicate the selected pressure:

   Device is on 125mmHg

   Device is on 80mmHg

10. Select Continuous or Variable Mode by pressing -/~ button. Continuous Mode maintains the selected therapy at a constant pressure. Variable Mode cycles the selected therapy as follows:

- Variable 80 mmHg – Pressure will cycle between 30 mmHg and 80 mmHg every 3 minutes.

- Variable 125 mmHg – Pressure will cycle between 30 mmHg and 125 mmHg every 3 minutes.

11. Assess dressing to ensure seal integrity. The dressing should be collapsed and should have a wrinkled appearance. There should be no hissing sounds.

12. If there is any evidence of non-integrity, check the dressing seals, tubing connection, canister connection and ensure clamp is open.
13. If there is any evidence of a leak, refer to the **Correcting a Leak Condition** section in this manual.
14. Secure excess tubing to prevent interference with patient mobility.
15. If desired, place the therapy device into the carrying case. Ensure display is visible through the opening in the carrying case.

16. The carrying case comes with both an adjustable strap and belt clip for carrying. The belt clip and additional clips on each side and at the bottom of the carrying case provide a place where excess tubing may be wrapped and stored to help prevent/minimize tripping.

CAUTION: Do not wear strap around neck.

Duration of Therapy

When the therapy begins, all LEDs will flash to indicate that the unit has been turned on. After which, the subsequent LED actions before the unit turns on will indicate the remaining life time of the device. Each static LED refers to 7 day period and each LED flash refers to a 1 day period. The addition of each static and flashing LEDs equals the remaining life time of the device. Examples are below:

Static LED	Flashing LED	Remaining Life Time
4	2	30 Days remaining
3	4	25 Days remaining
2	5	19 Days remaining
2	1	15 Days remaining
1	6	13 Days remaining
1	2	09 Days remaining
0	3	03 Days remaining
0	1	01 Days remaining

At the end of therapy, the therapy device must be replaced with a new therapy unit or alternative therapy must be used. Patients should be instructed to contact the treating physician or caregiver if therapy device turns off and cannot be restarted before therapy is scheduled to end.

NOTE: *Once therapy is on for 30 minutes continuously, the device's lifespan counter begins and continues even if unit is turned off.*

c. Dressing Removal

NOTE: *If dressing is lifted to observe wound, do not re-adhere the same dressing. A new dressing must be applied.*

1. Turn therapy unit off by pressing the power button.
2. Gently stretch the strips horizontally to release the adhesive from the skin.
3. Do not peel vertically. Gently remove the drape from the wound.
4. Clean any residual adhesive with alcohol swab.

NOTE: *The dressing should be disposed of as clinical waste.*

If a new dressing is to be applied:

1. Ensure that area is clean, using an alcohol swab or antiseptic wipe.
2. Allow skin to dry completely before applying.
3. Follow Application instructions in Section 6 in this manual.

d. Canister Removal and Replacement

1. Turn therapy off.
2. Slide the dressing tubing clamp close to where tubing connects into canister. Close clamp.
3. Disconnect the tubing from canister.
4. Remove therapy unit from carrying case, if in use.
5. Depress tab on the two sides of canister to remove used canister from UNO.
6. Install new canister (see Step 6 of the Application section in this manual).
7. Reattach dressing tubing to canister tubing port.
8. Return UNO to carrying case if desired.
9. Release tubing clamp.
10. Turn on the UNO.

NOTE: *Dispose of used canister according to institution and local environmental regulations.*

e. Alerts

Canister Full / Blockage

When there is an obstruction of air flow, a visual and audible alert will activate:

Ensure that tubing and dressing are installed completely and without any kinks to avoid leaks or blockages in the vacuum circuit.

If the canister is found to be full, please change to a new canister by following the Canister Removal and Replacement instructions section in this manual.

Leak

When the UNO detects a significant leak, a visual and audible alert will activate:

Correcting a Leak Condition:

1. Slowly run hand and fingers around edge of dressing pressing down firmly to ensure good contact between adhesive and skin to verify a good seal. If a leak source is identified, patch with additional strip to ensure seal integrity.
2. Ensure canister is securely locked onto the therapy unit. When canister is installed, a distinct click will be heard indicating it has been properly installed. Canister should be flush with the therapy unit with no space between the two components.
3. Check dressing tubing connector at canister.
4. When leak condition has been corrected, audible alerts will stop and visual alert will turn off.

NOTE: *Upon correcting a leak condition, a small delay will occur before the therapy unit senses the correction and silences the alert.*

Low Battery Level Alert

When the battery level is low (approximately 2 hours of therapy remain), a flashing orange LED on the battery level icon will turn on with audible alert sound.

With a brand new set of batteries, it is expected to last for up to 3 days per pair when the integrity of the dressing is good.

Please remove the battery cover, change to a new set of batteries and place the cover back onto the device.

Therapy Ended

If the device has completed its lifespan and has timed out, when an attempt is made to turn on the device, all LEDs will flash once and the device will sound an audible alert once and then shut off.

Alerts

Audible Alerts: All audible alerts will beep and repeat until the issue is fixed.

Alerts Silence Button: Press the Alert Silence button during an alert condition to silence the audible alert. The alert will reoccur every 2 minutes.

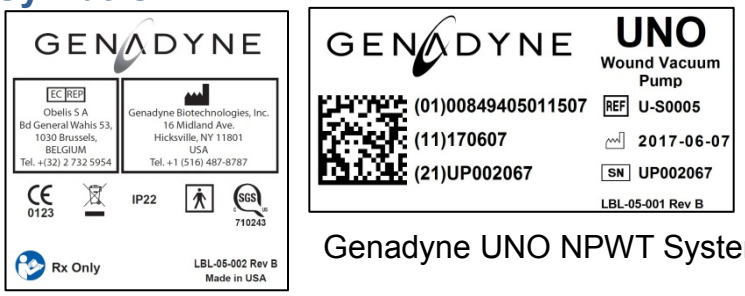
Blockage / Kink in theTubing

Periodically, it is advisable to check the dressing integrity on the wound. If you see that the wound is puffed up but the UNO is not alerting a leak, please check if there is a kink in the tubing, or a clamp that has not been unclamped. Also, check if there is any blockage along the tubing of the dressing and the canister.

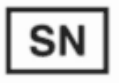
Device Disposal

At the end of therapy, follow local institutional protocols for infection control and waste disposal procedures for dressings and canisters. Local protocols for the disposal of the Genadyne UNO NPWT device should be based on the applicable federal, state and/or local government environmental regulations for recycling electronic devices.

Symbols



Genadyne UNO 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		Notified Body CE Mark
IP22	Protected against solid foreign object of 12.5 mm Ø and greater. Protected against dripping water when tilted up to 15°	**Rx Only**	**Caution:** Federal (US) Law restricts this device to sale/rental by or on the order of a physician
	SGS Listed, Conforms to AAMI ES 60601-1 1st edition, CSA C22.2#60601-1 3rd edition and IEC 60601-1 3rd edition.		**Caution:** MR Unsafe

Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The Genadyne UNO is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne UNO should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Genadyne UNO 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 RF emissions characteristic of the Genadyne UNO makes it suitable for use in hospital, transport and home-use environments.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input / output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Not Applicable	Not Applicable
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	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	50 A/m	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 UNO is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne UNO should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	Not Applicable 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 UNO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Genadyne UNO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Genadyne UNO 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	Not Applicable	0.12 m	0.23 m
0.1	Not Applicable	0.37 m	0.74 m
1	Not Applicable	1.17 m	2.34 m
10	Not Applicable	3.70 m	7.40 m
100	Not Applicable	11.70 m	23.40 m

Specifications

Maximum Dimensions	3" × 4 3/8" × 2 1/4" (76 × 111 × 57 mm)
Weight (including batteries & empty canister)	0.5 lb. (0.45 kg)
Battery Type	AA battery
Power	3V DC
Ingress Protection	IP22
Maximum Vacuum	125 mmHg
Mode of Operation	Continuous or Variable
Patient Protection	Type BF
Storage/Transport	5°C to 40°C, 0 – 95% RH 700 to 1060 mbar atmospheric pressure
Operating Environment	5°C to 40°C, 10 – 95% RH 700 to 1060 mbar atmospheric pressure
Compliance	IEC 60601-1 3rd Edition AAMI ES 60601-1 1st Edition CSA C22.2#60601-1 3rd Edition IEC 60601-1-2:2014 IEC 60601-1-11:2010 1st Edition EN/ISO 14791:2012 EN/ISO 10993:2009 EN/ISO 11135-1:2007 EN/ISO 11737-1:2006/AC:2009

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