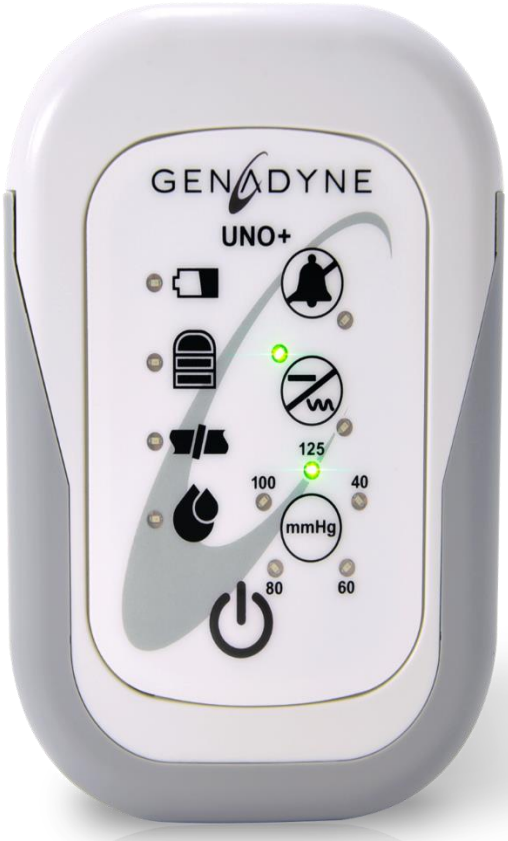
UNO+

Negative Pressure Wound Therapy



Contents

Safety Standards

This system is designed to comply with the regulatory safety standards including IEC 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. No modification of this equipment is allowed.

WARNING: Please do not use this device in oxygen rich environments or flammable anesthetic mixture environments.

WARNING: Radio frequency interference could affect the device performance. If the pump malfunctions, contact your healthcare professional to replace the system.

WARNING: Keep body parts away from the device if the device gets hot during charging.

Description

The Genadyne UNO+ Negative Pressure Wound Therapy (NPWT) (Ref # UP-S01) is a multi-patient use, rechargeable negative pressure wound therapy unit, designed for moderate to low severity wounds. The UNO+ NPWT features an interface panel which provides 5 alerts for the user, selectable therapy modes (Continuous Mode and Variable Mode) and multi-pressure options (40mmHg, 60mmHg, 80mmHg, 100mmHg or 125mmHg). Included in the UNO+ NPWT box is a universal charger, USB cable, a User Manual and a User Carry Bag. The Dressing Kit includes the Transparent Film Dressings, a choice of wound filler (i.e., XLR8 Green Foam) and the XLR8 Port Pad. The UNO+ NPWT is designed to be used with a canister collection system. There are two canister sizes available, 200cc and 300cc. Frequency of dressing changes will be dependent upon factors such as clinical practice, wound type, wound size, rate or volume of exudate, or environmental conditions.

All the dressings and canisters are single use disposable items. To help ensure safe and effective use, the UNO+ NPWT is to be used only with Genadyne supplied dressings and canisters.

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

Indications for Use

The Genadyne UNO+ NPWT 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.

Appropriate wound type include:

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

Contraindications

Genadyne UNO+ NPWT 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 UNO+ NPWT may be used)*
- Exposed arteries, veins, organs or nerves.
- Anastomotic sites

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 units 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. (***NOTE***: *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 fragments 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 and 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 Genadyne Foam 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: Genadyne Foam Dressings are not bio-absorbable. Always count the total number of dressings used to ensure the same number of 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 the 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 remove 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 can be considered expected. However, patients with increased risk of bleeding, as described in the ***Bleeding*** section above, have a potential for more serious bleeding from the wound site. If significant bleeding develops, immediately discontinue the use of the Genadyne UNO+ NPWT 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 Genadyne UNO+ NPWT system until adequate hemostasis has been achieved and the patient is not at risk for continued bleeding.

Keep Genadyne UNO+ NPWT On: Never leave a Genadyne Foam Dressing in place without active Genadyne UNO+ NPWT for more than two hours. If therapy is off for more than two hours, remove the old dressing and irrigate the wound. Apply a new Genadyne Foam Dressing from an unopened sterile package and restart Genadyne UNO+ NPWT,

Acrylic Adhesive: The Genadyne Transparent Film 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 an allergic reaction or hypersensitivity develops, such as redness, swelling, rash, urticarial or significant pruritus, discontinue use and consult a physician immediately. If bronchospasms or more serious signs of allergic reaction appear, seek immediate medical assistance.

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

Magnetic Resonance Imaging (MRI) – NPWT Unit: The Genadyne UNO+ NPWT Device is **MRI Unsafe**. Do not take the Genadyne UNO+ NPWT Device into the MRI environment.

Magnetic Resonance Imaging (MRI) – Genadyne Foam Dressing: Genadyne Foam Dressing can typically remain on the patient with minimal risk in an MRI environment, assuming that use of the Genadyne UNO+ NPWT is not interrupted for more than two hours. (***Refer*** *to the* ***Keep Genadyne UNO+ NPWT On*** *section 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 Genadyne Foam Dressing with another HBO compatible material during the hyperbaric treatment; or, (ii) cover the tubing of the Genadyne Foam Dressing with moist cotton gauze. For HBO therapy, the tubing **must not be clamped.** Never leave an Genadyne Foam Dressing in place without active Genadyne UNO+ NPWT for more than two hours. (*Refer to the* ***Keep Genadyne UNO+ NPWT On*** *section above****)***

Electrical Shock Hazard: Do not take the UNO+ NPWT device apart.

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 Mode, 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 Mode 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 a barrier skin protector to protect periwound skin. Protect fragile/friable periwound skin with additional Film Strip.

- Multiple layers of the film strip may decrease the moisture vapor transmission rate, which may increase the risk of maceration.
- If any signs of irritation or sensitivity to the film 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 film strip over the dressing during 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 strip technique may be necessary to establish and maintain a seal. Consider using multiple small pieces of film strips rather than one piece to minimize the risk of decreased distal circulation. Extreme care should be taken not to stretch or pull the film strip when securing it, but let it attach loosely and stabilize the edges if necessary. When using circumferential film 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

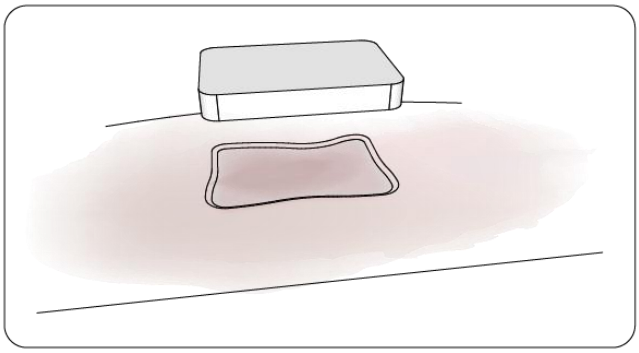
The Genadyne UNO+ NPWT is intended to be operated by qualified clinical caregivers in acute or extended settings. In-service and training programs for use of the Genadyne UNO+ NPWT are available. Patients are not expected to apply or change Genadyne Genadyne Foam Dressings or adjust therapy settings.

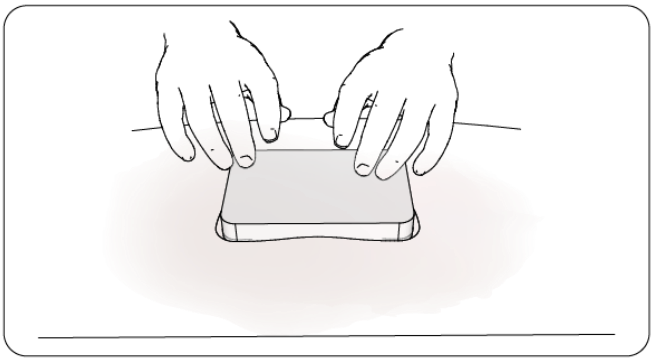
Instructions for Use

a. Application

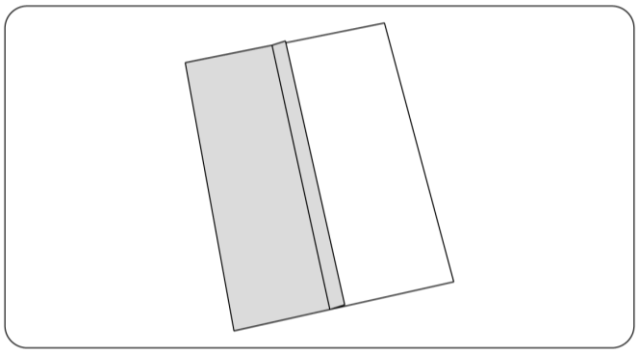
1. If necessary, irrigate the wound with sterile saline and pat the wound dry. Protect wound edges with the Transparent Film/ Film Strip if necessary. Allow the skin to dry.
2. Choose appropriate size of green foam for wound.

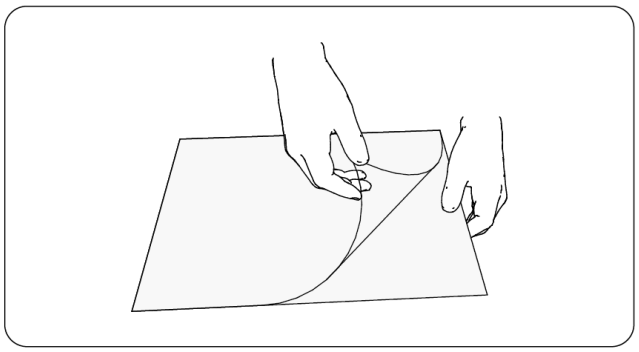
3. Cut foam to appropriate size of the wound. Place the foam on/into the wound. Avoid cutting the foam over the wound. Do not over pack.

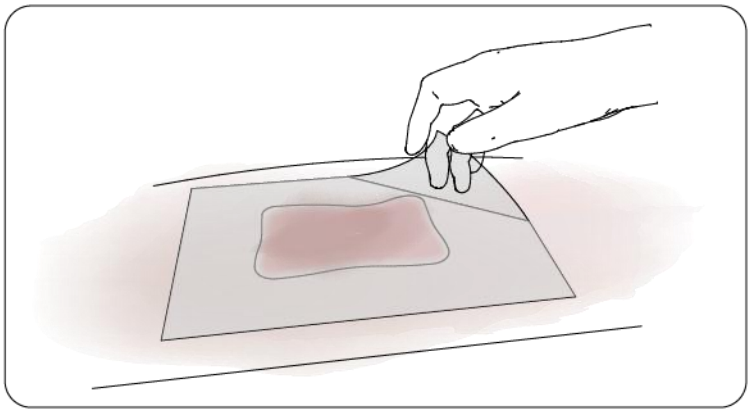




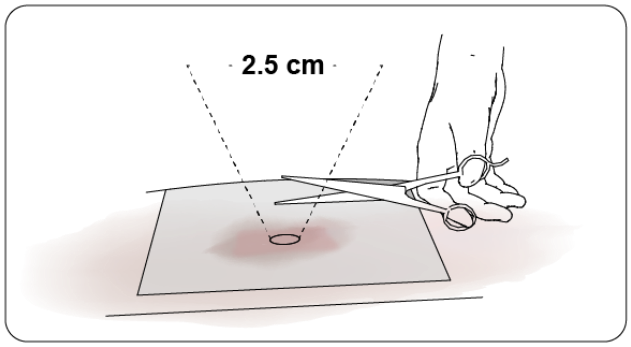
4. Cover the foam with Transparent Film. Peel layers 1, 2 and 3. Remove the handlers.

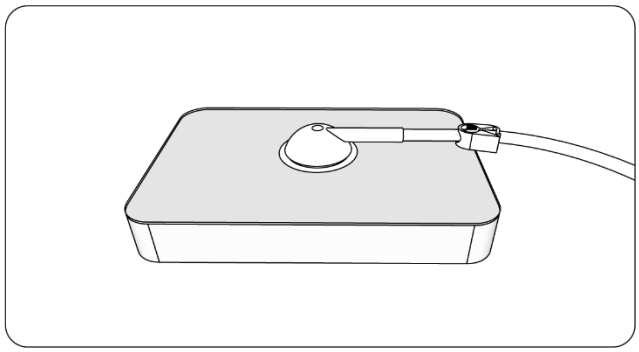




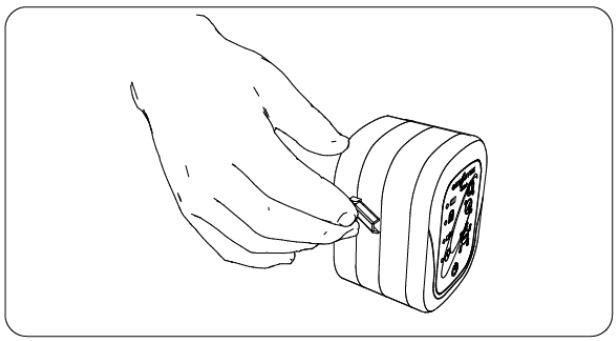


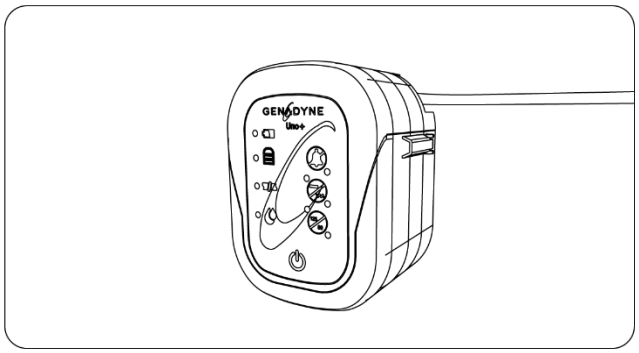
5. Cut a hole in the middle of the Transparent Film approximately 1” in diameter after placing on the foam. Remove paper backing (number 1) from the Port Pad. Place over the hole. Remove handlers.



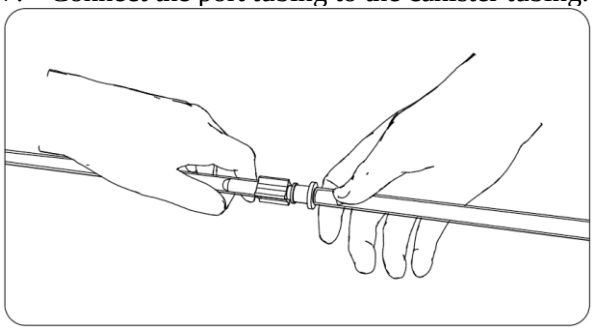


6. Attach the canister to the back of the machine. Slide in the canister and make sure it clicks to confirm the canister is secure and tightly held.





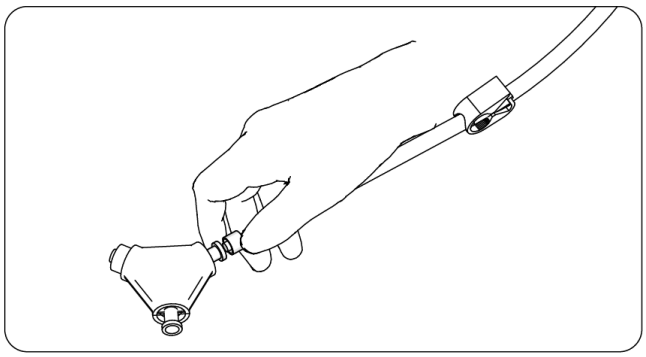
7. Connect the port tubing to the canister tubing. Ensure all clamps are unclamped at this time.



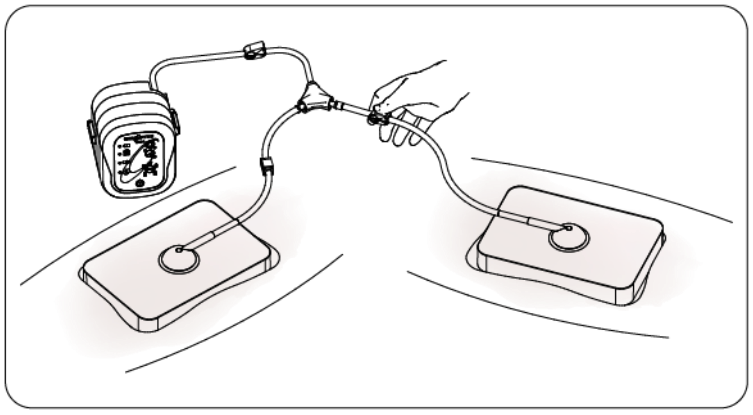
8. Initiate the therapy at the prescribed pressure by pressing the power button to start the application of negative pressure.

b. Application of Y connector

1. For the application of the Y connector, connect the canister tubing to the top part of the Y connector.

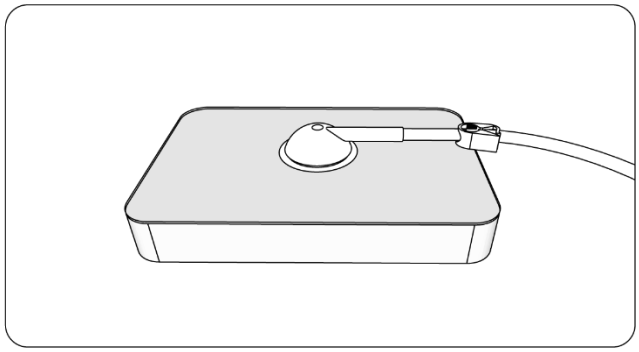


2. Connect the port tubing from the two wound dressing to the luer connection of the Y connector. Twist the tubing connector until it locks in place.

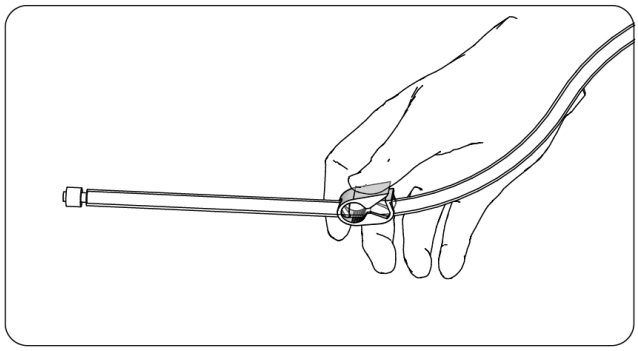


3. Prior beginning therapy, clamp the port tubing of one of the wounds. **Note: this is an important step to achieve the desired therapy**

4. Turn on the pump to begin negative pressure therapy in the wound without port clamped. Finished dressing should be firm to the touch.



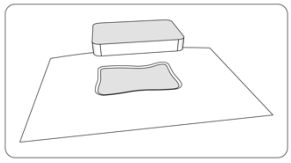
5. Once the pressure is achieved in the wound, clamp the port tubing. This enables hold the pressure in the wound while we begin negative pressure therapy in the second wound.
6. Unclamp the port tubing of the second wound to begin suction.



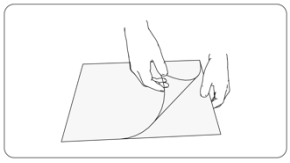
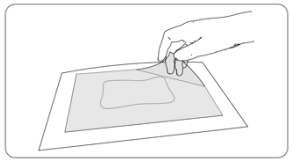
7. Once the desired pressure is achieving, the dressing should be firm to the touch.
8. Unclamp all port tubing to begin negative pressure therapy in both wounds

c. Application of Bridge dressing

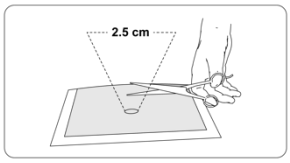
1. For the application, Cut the foam dressing to fit the size and shape of the wound and place into the wound cavity. Foam should fill the wound cavity and it may be necessary to stack pieces of foam in deep wounds. A non-adherent dressing may be applied to the wound prior to placing the foam into the wound bed if required.



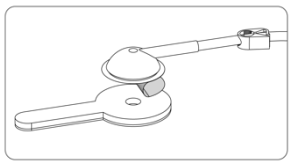
2. Cover foam with transparent film. Film should extend at least 5.1cm beyond wound margin to facilitate adequate seal.
   • Film should be securely anchored to periwound area to maintain an air tight seal.

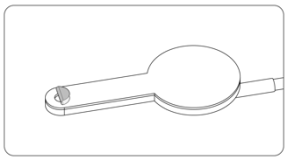
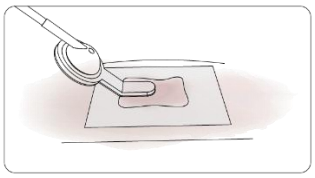
3. Punch a small hole (with a diameter of 2.5mm) in the center of film over the foam.



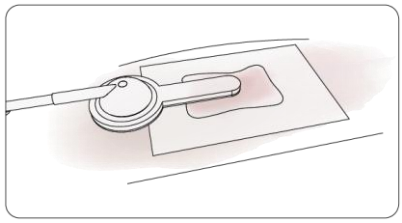
4. Apply the port tubing on top of the GENADYNE XLR8 Bridge Foam Dressing hole.



5. Apply the GENADYNE XLR8 Bridge Foam Dressing on top of the hole.

6.
7. Turn on the pump and check that the seal is secure around the drain. Finished dressing should be firm to the touch. If there is concern of the tube creating pressure on the wound margins, utilize bridging technique.



8. Note that the bridge dressing cannot be used along with the Y connector.

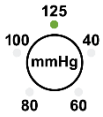
NOTE: To prevent accidental change of settings, each button has to be held down (pressed) for 3 seconds in order for the settings to be changed. The unit goes into sleep/power saving mode after 2 minutes of inactivity. Press and hold any button for 1 second after which the unit will no longer be in the power saving mode. Press the desired button to change the therapy settings.

9. LED light on the front panel indicates what Pressure/Mode is currently selected. If the LED light on the left side is ON, the device is in Continuous Mode. If the LED on the right side is ON, the device is in Variable Mode:

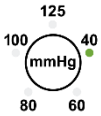
Device is in Continuous Mode

 Device is in Variable Mode

10. Select therapy pressure of 40 mmHg, 60mmHg, 80mmHg, 100mmHg or 125 mmHg by pressing mmHg button. The green LED light next to the button will indicate the selected pressure:

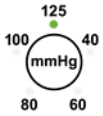


Device is on 125mmHg



Device is on 40mmHg

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

Available therapies at Variable mode is:

- Variable at 125 mmHg - Pressure will cycle between 30 mmHg and 125mmHg every 3 minutes.
- Variable at 100 mmHg - Pressure will cycle between 30 mmHg and 100mmHg every 3 minutes.
- Variable at 80mmHg - Pressure will cycle between 30 mmHg and 80mmHg every 3 minutes.

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

13. If there is any evidence of non-integrity, check the dressing seals, tubing connection, canister connection and ensure clamp is open.

14. If there is any evidence of a leak, refer to the **Correcting a Leak Condition** section below.

15. Secure excess tubing to prevent interferences with patient mobility.

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.**

d. 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 remove the XLR8 film. Do not peel vertically.
3. Gently remove the green foam from the wound.
4. Clean any residual adhesive with alcohol swab.

NOTE: The dressing should be disposed of as clinical waste according to institution and local environmental regulations. Additionally, if the dressing's packaging is damaged or open, do not use it. Instead, dispose of it according to institution and local environmental regulations and use a new dressing.

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.

e. 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 port 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+ NPWT device.
6. Install new canister.
7. Reattach dressing tubing to canister tubing port.
8. Return UNO+ NPWT device to carrying case if desired.
9. Release tubing clamp.
10. Turn on the UNO+ NPWT device.

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

f. Alerts

Blockage

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

-  Blockage icon

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

Canister Full

If the canister is found to be full, please change to a new canister following the canister removal and replacement instructions in this manual.

-  Canister icon

Leak

When the UNO+ NPWT device detects a significant leak, a visual and an audible alert will activate.

Leakage icon

When the UNO+ NPWT device detects a small leak (check dressing alert), the LED on the leak alert icon will be flashing, and the audible alert will beep every 1-minute interval and will clear itself when the leak is corrected.

Correcting a Leak Condition

1. Slowly run hand and fingers around the edge of the 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 UNO+ Transparent Film to ensure seal integrity.
2. Ensure canister is securely locked onto the therapy unit. When canister is installed securely, a distinct click will be heard indicating it has been properly installed. Canister should be flush with the UNO+ NPWT 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 UNO+ NPWT unit senses the correction and silences the alert.

Low Battery Alert

When the battery level is low, a flashing orange LED light on the battery level icon will turn on with an audible alert sound.

When the batteries are fully charged, it is expected to last for up to 40 hours of operation time per charge when the integrity of the dressing is good[1].

Battery Icon

UNO+ NPWT Ended

Once the UNO+ NPWT is complete, the unit should be removed by your healthcare professional. Do not discard these items with household trash. This could violate local laws regarding hazardous waste. Dispose of used canister according to institution and local environmental regulations.

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 .

[1] Usage is based on integrity of the dressing. If the dressing or film is not applied properly, then the pump will require more cycles to provide the wound with required pressure. This will shorten the pump life. If the dressing has a leakage free application, then the pump will last longer.

Blockage/Kink Tubing

It is advisable to periodically check the dressing integrity on the wound. If you see that the dressing is flat and not wrinkled but the UNO+ NPWT unit 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.

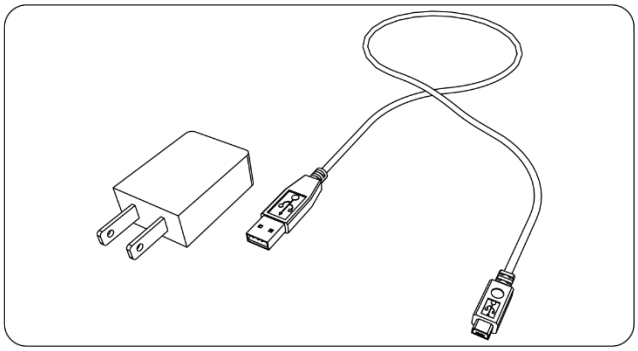
WARNING: Patients having an increased risk of bleeding complications should be treated and monitored in a care setting deemed appropriate by the treating physician.

Device Disposal

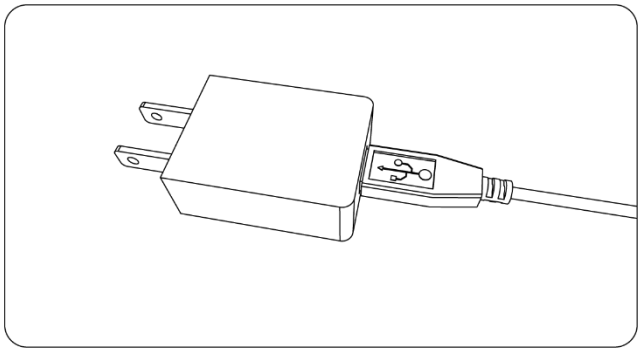
Confirms with the Waste Electrical and Electronic Directive (2002/96/EC). At the end of useful life: dispose of all waste according to local requirements, or contact your local Genadyne subsidiary or agent for advice. This product is designated for separate collection at an appropriate collection point.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

g. Battery Recharging Procedure

1. The USB charger and USB cable shown below are provided in the Genadyne UNO+ NPWT Kit.

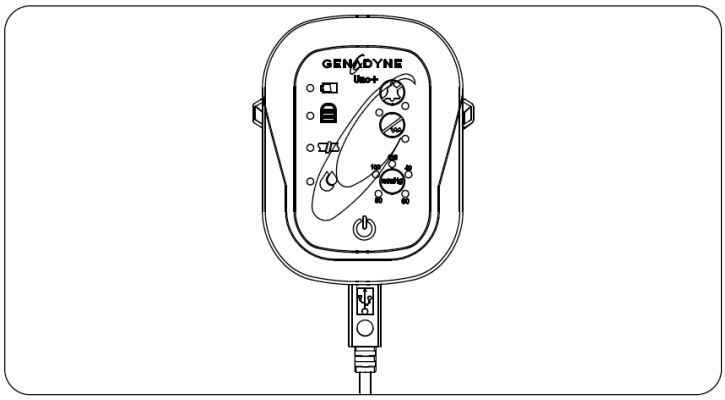


2. Connect the USB cable into the charger head. Make sure you have connected the USB cable all the way in as shown in the image below:

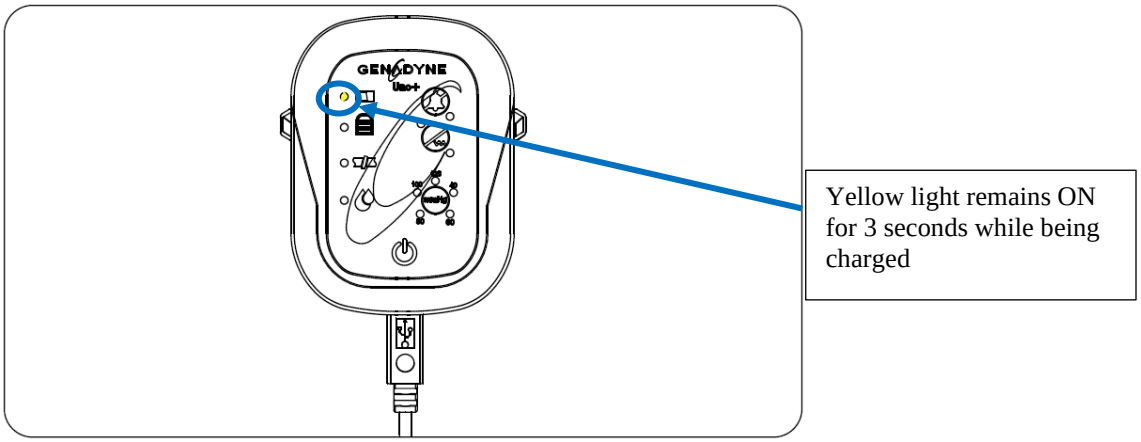


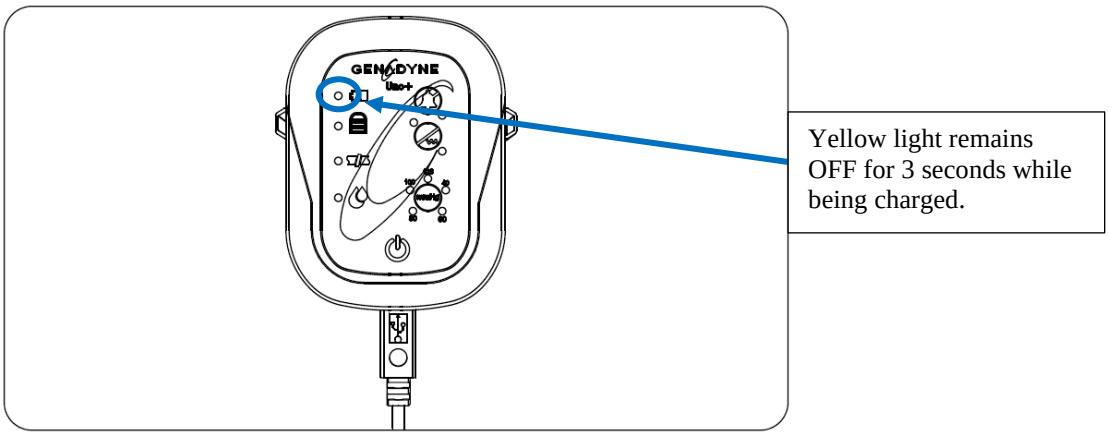
3. Connect the USB charger to a nearby outlet.

4. Plug the USB cable into the lower part of the Genadyne UNO+ NPWT unit (slot below the power button).

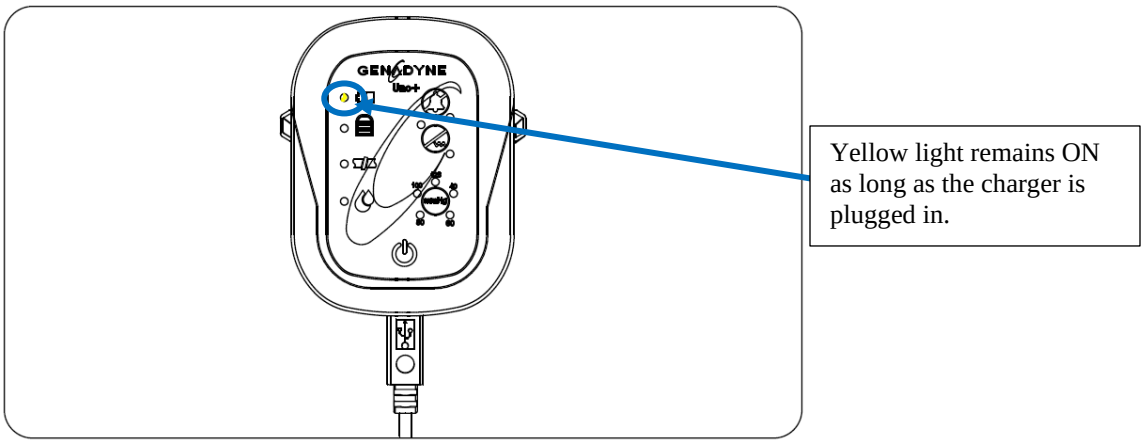


5. Let the unit charge for approximately 5 hours. The LED will blink every 3 seconds (LED will be ON for 3 seconds and OFF for 3 seconds) which indicates that the unit is being charged.





6. After 5 hours of charging time, the battery will be fully charged. The LED near the battery symbol will remain steady ON as long as the charger is plugged in. Once the charger is disconnected from the unit/device, the LED will turn OFF.



7. Unplug the charger from the outlet.

NOTE: The UNO+ NPWT is fully operational while charging.

WARNING: It is unsafe to use any other USB charger and USB cable other than the ones provided in the Genadyne UNO+ NPWT Kit. This could potentially lead to product malfunctioning and will negate the product warranty.

CAUTION: Do not place the device in its carrying case during battery charging.

h. Lock and Unlock Keypad

The UNO+ NPWT device can lock and unlock the keypad by press and hold the SILENCE  button for 5 seconds any time during therapy.

Maintenance

It is mandatory for the product to have scheduled diagnostic Preventive Maintenance every 12 months. Failure to comply will void the warranty. When the unit surpasses the maintenance hours, the keypad will blink all its LED's for 5 seconds when turning on the unit.

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

The mandatory Preventative Maintenance consists of a full inspection and diagnostics of the unit, replacement of internal tubing and battery, if necessary, and cleaning of the inside and outside of the unit with FDA approved cleaning agents.

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 a low level, diluted form of disinfectant or cleaning agent when cleaning the Genadyne UNO+ NPWT unit. Use a damp cloth to clean the pump.

Do not use solvents or abrasives.

Dry with a separate soft cloth.

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

Do not immerse any part of the Genadyne UNO+NPWT unit in fluid or use an unnecessarily wet cloth.

Please contact your distributor if any liquids penetrate the unit.

Returning the Device

For any returns or rental returns, prior to sending the unit back to your representative, the unit must be cleaned as per the steps laid out under the Cleaning section of this manual (above).

The device should be returned in the original packaging.

Disposing of the Device and Canisters

Device

The device contains li-ion batteries. Do not dispose of this device by placing it in the trash. Return the device to Genadyne or your distributor/caregiver or use local procedures for proper disposal.

Canisters

All used canisters have to be disposed of according to local protocols.

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

Symbols

Equipment Classification
Isolation Type BF Applied Part

Date of Manufacture

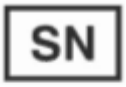
Place of Manufacture

Storage Temperature

Biohazard

Keep Dry

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



Serial Number

Caution:
Read Instructions Before Use

Lot Number

Product Reference Number

Authorized European Representative

Notified Body CE Mark

CSA International Classification

Double Insulated (Class II)

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

Keep away from sunlight

Fragile; Handle with care

Keep Upright

MR Unsafe

Rx Only

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

Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Genadyne UNO+ NPWT is intended for use in the electromagnetic environment specified below. The customer or the user of the Genadyne UNO+ NPWT 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+ NPWT does not intentionally generate any RF energy. Its parasitic emissions are kept to minimum via circuit design therefore the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions *CISPR 11*	Class B	Genadyne UNO+ NPWT 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	Compliant	

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

Immunity Test	**IEC 60601 Test level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/-2kV, ± 4kV, ± 8 kV, ± 15kV air	+/- 8 kV contact +/- +/-2kV, ± 4kV, ±8 kV ± 15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 41%.
Electrical fast transient / burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 2 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
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	30 A/m	Compliant	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

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 Vrms 50 MHz to 54 MHz 10.0 V/m 80 MHz to 2700 MHz	Compliant 10.0 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+ NPWT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Genadyne UNO+ NPWT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Genadyne UNO+ NPWT 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	4 3/8 ” x 3 ” x 1 5/8”
Weight	0.49 lbs (220g)
Operating/Running Time	~ 40 hours of usage time per charge[2] ~15 hours with pump ON all the time
Battery Type	3.6V, 1700mAh, Rechargeable Lithium Ion Batteries
Power Adaptor/Charger	Input: 100 V AC-240V AC, 50-60Hz Output: 5V DC, 2A, 10W
Recharge Time	~ 5 hours
Ingress Protection	IP 22
Maximum Vacuum	125 mmHg
Mode of Operation	Continuous or Variable
Patient Protection	Type BF
Storage/Transport	-20°C to 60°C, 10 – 90% RH 8.6 psia – 14.3 psia atmospheric pressure
Operating Environment	+5°C to +40°C, 15 – 93% relative humidity, non-condensing; 700 to 1060 mbar atmospheric pressure
Compliance	IEC 60601-1 3rd Edition ES 60601-1 1st Edition CSA C22.2#60601-1 IEC 60601-1-2 IEC 60601-1-11 EN/ISO 14791 EN/ISO 10993 EN/ISO 11135-1 EN/ISO 11737-1

[2] Usage is based on dressing integrity. If the dressing or film is not applied properly, then the pump will require more cycles to provide the wound with required pressure. This will shorten the pump life. If the dressing has a leakage free application, then the pump will last longer.

Contact Information

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