Kalypto Medical

NPD 1000™ Negative Pressure Wound Care System

Portable Negative Pressure Pump & Dressing

Clinician & Patient Instructions for Use
Important Safety Information accompanies this device. Indications for Use, Contraindications, Warnings, Precautions and other Safety Information are included in these Instructions for Use (IFU). To reduce risk of serious or fatal injury, all caregivers and patients must carefully read and follow all user instructions and safety information that accompany Kalypto Medical products.

If there are questions, please contact Kalypto Medical immediately at (877) 286-3740.

See back cover of this IFU for other Kalypto contact information.
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The NPD 1000 Negative Pressure Wound Therapy System Instructions for Use (IFU) is intended to supply information to both the clinician and patient on the use of the device, application of the wound dressing, expectations for normal operation and troubleshooting system issues. While the system is designed to provide negative pressure wound therapy in a patient’s home, the system should be set up and dressings applied by a qualified wound clinician. The patient should with the use of the IFU be able to competently troubleshoot any problems that appear during the normal course of use and know when it is appropriate to call their medical provider regarding issues with the system. Thus, the IFU is divided into three sections, 1) General information - including indications for use, contraindications, warnings and precautions, 2) Clinician - information needed by the clinician to use the device on a patient with a wound and 3) Patient - information needed by the patient to insure that the device continues to operate appropriately after leaving the direct care of their wound care professional.
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<th>Symbol</th>
<th>Description</th>
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<td>Single use only. Do not reuse.</td>
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**PRODUCT DESCRIPTION**

The NPD 1000 Negative Pressure Wound Therapy System is comprised of a battery-operated system controller, with a portable electromechanical pump and proprietary wound dressing. The pump produces a controlled negative pressure (vacuum) under the wound dressing.

The pump device (depending on the model purchased) can provide negative pressure therapy in two modes, “continuous” and “intermittent”, with pressure ranges from -40 mmHg to -125 mmHg. In “continuous” mode, the pump holds the pressure inside the dressing at the prescribed programmed level while the negative pressure dressing is worn, the pump is connected to the dressing and therapy is turned ON. In intermittent mode, the pump cycles between the programmed pressure and atmospheric pressure by venting the bandage with a solenoid valve. The dressing is held at the therapeutic negative pressure for 5 minutes and vented to atmospheric pressure for 2 minutes. This cycle continues from the time therapy is initiated until the pump is turned OFF.

**Available Models**

The NPD 1000 Negative Pressure Wound Therapy device is available in two configurations utilizing the universal system controller, the NPD 1000i Intermittent Therapy Pump and the NPD 1000c Continuous Negative Pressure Therapy Pump.

**CAUTION:** Both devices are designed to only work with all Kalypto Negative Pressure bandages. They are not compatible with other negative pressure bandage systems.

**The NPD 1000i** is an assembly of the NPD 1000 system controller and the 1000i pump module. It is capable of providing both “intermittent” and “continuous” modes of therapy over the specified pressure range. This assembly can be used by multiple patients.

**The NPD 1000c** is an assembly of the NPD 1000 system controller and the 1000c pump module. It is capable of providing only the “continuous” mode of therapy over the specified pressure range. This assembly should only be used by one patient. **Note:** The system controller can be used by multiple patients but the pump assembly is single patient use only.
INDICATIONS FOR USE & CONTRAINDICATIONS

Indications for Use
The NPD 1000 Negative Pressure Wound Therapy System is a portable, low powered, battery operated, suction pump intended for the application of suction to remove a small amount of fluid from the wound bed, including wound exudate and infectious material, which may promote wound healing.

Contraindications
Do not use the NPD 1000 Negative Pressure Wound Therapy System for -
1. Application to wounds where there is evidence of
   - Exposed arteries or veins in wound
   - Fistula - unexplored
   - Fistula - non enteric
   - Osteomyelitis, untreated
   - Malignancy in the wound
   - Necrotic tissue with eschar

   NOTE: After debridement of necrotic tissue and complete removal of eschar, the NPD 1000 Negative Pressure Wound Therapy System may be used.

2. Emergency Airway Aspiration

3. Pleural, mediastinal or chest tube drainage. These applications require a device that provides specific low suction levels and an underwater seal.

4. Surgical Suction

5. Do not apply the NPD 1000 Wound Dressings directly to exposed blood vessels, organs, or nerves.

6. Sensitivity to silver (NPD 1000 Silver Dressing only).
WARNINGS, CAUTIONS & ADVERSE REACTIONS

Warnings
With or without using NPD 1000 Therapy, certain patients are at high risk of bleeding complications. The following types of patients are at increased risk of bleeding, which, if uncontrolled, could potentially be 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 anastamoses 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 NPD 1000 Therapy 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 NPD 1000 Therapy, or if frank (bright red) blood is seen in the dressing, immediately stop NPD 1000, leave dressing in place, take measures to stop the bleeding. Seek immediate medical assistance.

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 negative pressure wound therapy with the NPD 1000 system.

Always ensure that the negative pressure 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 material, or bio-engineered tissue may be considered as an alternative, if deemed 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.
Cautions

- Wound Dressings are single patient use only and should be disposed of in accordance with local rules and practices regarding infectious waste.
- The device should not be used once the wound is no longer producing exudates.
- Use of clean technique is the responsibility of the healthcare professional directly responsible for patient care.
- Use only alkaline AA batteries.
- If the patient needs to shower or bathe in between dressing changes, steps should be taken to prevent water from coming in contact with the dressing and to disconnect the pump from the dressing. However, it is advisable that as part of the care plan, personal hygiene matters, such as showering and bathing should be done immediately preceding the changing of the dressing, when the device can be detached from the patient until the application of the new dressing.
- The devices are designed to work with 50cc Kalypto Negative Pressure bandage and are not compatible with other negative pressure bandage systems.
- Safe Performance: Even in fault conditions, the NPD 1000 will not exceed 250 mmHg of suction.
- Do not use the NPD 1000 Wound Therapy System in the presence of flammable anesthetics.
- 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 fluids is likely.
- To minimize the risk of bradycardia, the NPD 1000 Negative Pressure Wound Therapy System must not be placed in proximity to the vagus nerve.
- Consider use of a skin preparation product to protect periwound skin.
- If any signs of irritation or sensitivity to the dressing or tubing assembly appear, discontinue use and consult a physician immediately.
- To avoid trauma to the periwound skin, do not pull or stretch the dressing during application.
- Extra caution should be used for patients with neuropathic etiologies or circulatory compromise.
WARNINGS, CAUTIONS & ADVERSE REACTIONS con’t

• When using the NPD 1000 Silver Dressing, do not use topical solutions or agents that may have adverse interactions with silver. Dressing effectiveness may decrease if used with products containing saline, chlorine, potassium, iodine and hydrogen peroxide.

• Do not allow the NPD 1000 Silver Dressing to come in contact with EKG or other electrodes or conductive gels during electronic monitoring, or when taking electronic measurements.

• The NPD 1000 Silver Dressing contains metallic silver that may impair visualization with certain imaging modalities.

• Operation of the NPD 1000 in the presence of high magnetic fields, such as those produced by an MRI (Magnetic Resonance Imager), has not been tested and is not recommended. Incorrect operation could result.

Adverse Reactions

• Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions, is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the Physician of any sudden or abrupt changes in the volume or the color of exudate.
PRODUCT OVERVIEW

Negative Pressure Pump

The NPD Negative Pressure Wound Therapy Pump Device contains a microprocessor-controlled pump and pressure sensor working in feedback fashion to control the pressure under the wound dressing. (Fig. 1).

![Image of Kalypto Negative Pressure Wound Therapy Device & Accessories](image)

Fig. 1. Kalypto Negative Pressure Wound Therapy Device & Accessories

It has a user interface of three buttons to control the treatment mode, pressure setting and turn the device ON/OFF. It is powered by 3 AA alkaline batteries. Additionally, it has 6 ft. of tubing with a pressure fitting between the pump and the dressing.

The pump applies controlled suction, adjustable by the user, in the vacuum range (negative pressure) from 40 mmHg to 125 mmHg. The pump operates in continuous and intermittent modes. For therapy status notification, it has a proprietary leak detection system, a low battery indicator and therapy proceeding indication.
ASSEMBLING THE PUMP

CAUTION: Be careful when assembling device to not pinch your fingers between the two parts.

The NPD 1000 Negative Pressure Pump device consists of two pieces; a system controller and one of two pump housings - continuous (NPD 1000c) or intermittent (NPD 1000i). (See Fig. 2)

Both pump housings can provide continuous therapy. However, the NPD 1000i housing is the only one that can perform intermittent therapy. Neither the system controller nor the pump housings are provided sterile and do not need to be sterilized between subsequent patients.
PRODUCT OVERVIEW - ASSEMBLING THE PUMP

To assemble the two pieces into a functioning negative pressure wound therapy device, fit the two subassemblies together by matching the male and female connector housings and pressing them together. (Fig. 3a)

Fig. 3a  Assembling the control and pump modules
Insert accompanying screws into pump housing, tighten to point of resistance, Fig. 3b. **DO NOT overtighten.**

Fig. 3b: Inserting screws to secure control and pump
This will secure the device and prevent the modules from separating. The system controller automatically recognizes whether a continuous or intermittent pump has been attached.
NPD 1000 Negative Pressure Wound Therapy Dressing

The NPD 1000 Dressing Technology is a state-of-the-art product that delivers the benefits of negative pressure therapy with a disposable fluid absorbing dressing. It is best used on wounds occurring on anatomical surfaces which will allow the dressing to seal appropriately when vacuum is applied. Highly curved surfaces such as those found below the ankle or on the hand may create difficulties in achieving an adequate vacuum seal.

It is comprised (See Fig. 4) of a semi-occlusive outer layer that maintains negative pressure (1), a pressure port (2a) with an in-line hydrophobic, anti-bacterial filter (2b) which attaches the NPD Pump system, a gasket to seal the wound area (3), a super-absorbing non-woven polymer matrix to absorb exudates(4) and a non-adherent silver-coated wound contact layer to provide effective protection against microbial contamination (5). The dressing also has three windows near the pressure port (6) to monitor the level of exudate in the dressing.

Fig. 4: Components of Kalypto Negative Pressure Dressing

Applying the Dressing

Carefully inspect the wound and treat per the order of the patient’s physician and according to the institution’s protocol and standards of practice for wound care. This should include proper hand washing and gloving practices. Appropriate skin prep should be used to preserve the wound margins and prevent epithelial stripping.

1. Prior to application of the cover, ensure that the skin that will be under the dressing is clean, dry and shaven. This will ensure proper adherence and sealing of the thin film dressing.
2. Use of a skin preparation layer may protect peri-wound skin and promote and prolong cover adhesion.
3. Remove the NPD 1000 dressing consumables from the sterile package.
4. Remove the release liner from the dressing exposing the adhesive side of the dressing and the sealing gasket. (Fig. 5)

Fig. 5: Removing the dressing release liner

5. Carefully place the dressing on the wound, taking care to minimize folds and wrinkles. (Fig. 6). Do not force the wound dressing into the wound. The application of negative pressure will cause the dressing to conform to the surface of the wound.

Fig. 6: Applying the dressing over a wound
6. Run your finger along the perimeter of the gasket to secure the gasket material to the skin and increase the dressing seal, Fig. 7.

Fig. 7: Securing sealing gasket to skin

7. Attach provided pigtail tubing to the port on the top of the dressing. (Fig. 8)

Fig. 8 Attach pigtail tubing to dressing

The dressing is now ready for application of negative pressure.
PROGRAMMING THE PUMP

CAUTION: When programming the pump system, make sure that the settings match exactly those specified by the physician. Not following the negative pressure therapy prescription could result in sub-optimal therapeutic results.

Before attaching the pump device to the patient’s dressing, the clinician should set the device to the appropriate treatment settings in the following way:

1. Slide the bottom cover down to expose the programming, labeled “VAC” and “MODE”, buttons, Fig. 9.

![Fig. 9 Negative Pressure Wound Therapy Pump Programming Buttons](image)

2. Depress and hold the “VAC” and “MODE” buttons simultaneously, while also pressing the power button, , for one second.

3. Release the buttons and the device will beep twice and the pressure setting on the screen will blink, indicating the device is in programming mode.

4. Depress the “MODE” button to toggle the device between “continuous” and “intermittent” therapy, according to the placement of the tic mark on the display. For a description of “continuous” and “intermittent” therapy, see the Product Description section of this IFU.

5. Next depress the “VAC” button to set the pressure. The system cycles down 15 mmHg for each button push. The available settings are 40, 50, 65, 80, 95, 110 and 125 mmHg. The default setting of the device is 125 mmHg of vacuum.

6. After setting the device to the prescribed therapy, press the power button, briefly, to exit setup mode.

7. Slide the bottom cover back into place to protect the buttons.
CONNECTING THE PUMP & INITIATING THERAPY

1. Trim pump tubing to appropriate length with a scissors, Fig 10. When determining the tube length, take into consideration where and how the patient will carry the device during mobile use and how the device will be placed during stationary use.

Fig. 10: Trimming pump tubing to length

2. Attach proprietary connector to newly trimmed tubing, black plastic piece with gray button and hose barb. Push the end of the tubing entirely over the hose barb at the end of the connector.

3. Attach the pump to the dressing by mating the connector on the pump tubing to the connector on the dressing tubing, Fig. 11.

Fig. 11: Connecting the pump to the dressing

4. Depress the ON/OFF button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the therapy proceeding icon should appear in the upper left hand corner of the screen.
5. As the air is removed underneath the dressing, the surface of the dressing will contract toward the surface of the wound. When the set therapeutic pressure is reached the pump will shut off.

6. After the pump has shut off, watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon does not appear, The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.

7. The patient can know that the system is operating as needed by looking at the screen and finding the therapy proceeding icon in the upper left hand corner.

8. If the user or clinician notices, either an audible beep from the device or visual indicator on the screen, either the low battery indicator icon or the leak icon, during setup or during therapy, proceed to the troubleshooting section of this IFU.

Wearing the Device

For the ambulatory patient, the pump may be carried in their pocket, purse, or any other convenient location. It does not need to be next to the wound.

For use in the home, pump can sit on a bedside table or any other convenient location within the 6 foot length of the negative pressure tubing.
TROUBLESHOOTING

The following are the alarm states for the NPD 1000 Negative Pressure Wound Therapy Pump signaled by an audible beep from the device or a visual indication on the LCD display.

All LCD Segments Flashing – This condition indicates a system fault indicating either a mechanical issue with the device or that the dressing has reached capacity.

First, check to see if the problem is a full dressing. Check the three window near the vacuum port on the dressing. If they are discolored, indicating the presence of exudate near the vacuum source and the pump is LCD is flashing, the dressing should be changed. Turn off the pump and disconnect the tubing.

If the dressing is not full, turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Interrupt therapy and turn off the device. The clinician should contact their Kalypto Medical sales representative. The patient should call your clinician for guidance.

Leak Balloon Icon (ॉॉॉॉॉ) On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Depending on the source of the leak, the user may or may not be able to fix it. First, verify that the wound site was appropriately prepared; the periwound skin was cleaned and dried and the skin under the dressing was shaved smooth. If this is the case, the most likely source of a system leak is the dressing so troubleshooting should start there.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure. Also, smooth out any wrinkles in the semi-occlusive dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm condition goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.

If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.

Tubing Leaks – First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the quick connect fittings that connect the pump device to the dressing. The connection should be firm enough to withstand a firm tug on the tubing.

No Dressing or Tubing Leak – If after verifying that the tubing connections are good, the leak icon is still present, a existing dressing should be removed and disposed of in accordance with local regulations. Apply a second dressing and attempt to achieve a good seal (follow directions found in the “Applying the Dressing” section of this IFU). If the second dressing has been applied in accordance with the instructions and a leak still exists, it is likely that the leak is in the pump itself. Call your clinician.
for guidance. Clinicians having this problem should call their Kalypto representative for instructions as the device may need servicing that can only be done in the factory.

Low Battery Icon (🔋) On - If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

**NOTE:** If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in the orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode in place when the device was turned off.

**Disabling the Audible Alarm** - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the alarm state still exists.
COURSE OF THERAPY WITH THE NPD 1000

Dressings should be changed per the standard protocol for negative pressure wound therapy. The patient/clinician can monitor the level of fluid in the dressing by examining the three windows in the dressing near the pressure port. If they appear discolored (as in exudate is being absorbed in the pad near the pressure source), the pump and dressing should be monitored for signs that the dressing has reached capacity. These are 1) the pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time, 2) the dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing. If the dressing and/or pump meets the above criteria, the wound care professional should consider changing the dressing.
SERVICE & CLEANING OF THE PUMP DEVICE

SERVICE AND CLEANING OF THE PUMP DEVICE

The NPD 1000 Negative Wound Therapy Pump is designed to have a service life of multiple patients. However, before the device can be given to a new patient, the external case of the pump must be cleaned and disinfected. (Note: the internal plumbing of the pump does not need to be cleaned as it is protected by anti-bacterial and fluid filters on each dressing.)

These devices are tested to an IPX0 rating. Thus, they cannot be immersed in water or subject to large volumes of water spray such as in the shower. The outside case of both the system controller and pump housings can be cleaned using the procedure articulated below. No solvents should be used. Do not open either device housing (except the battery door, as proper operation cannot be assured once this has happened.

SERVICE

1. There are no user serviceable components inside the Kalypto NPD 1000 Wound Therapy System Pump.
2. Contact your Kalypto representative for return/replacement of damaged pumps.
3. Do not open the NPD 1000 pump or attempt to service it yourself.

CLEANING

1. Use cloth dampened with tap water and household dishwashing soap to clean the external surfaces. Wipe down until visibly clean.
2. Wipe the external surfaces again with a cloth dampened with water (no soap) to remove the residual soap. Wipe until no longer “slippery”, then allow to air dry.
3. Wipe external surface with 70% ethyl alcohol and allow to air dry.
4. Visually inspect for cleanliness.

DISPOSAL OF DRESSING AND PUMP

The NPD 1000 dressing is not constructed with any hazardous materials. Subsequently, after use it can be disposed of in the normal medical waste stream for wound care dressings.

The NPD 1000 Negative Pressure Wound Therapy Pump System is an electromechanical device powered by non-integral batteries. The batteries and device should be recycled according the local regulations governing such products.
## PRODUCT SPECIFICATIONS

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<th>Specification</th>
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<tr>
<td><strong>Dimensions:</strong></td>
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<td><strong>Weight:</strong></td>
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<td><strong>Pressure Options:</strong></td>
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<td>-5.3 to -16.6 kPa</td>
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<td><strong>Leakage Current:</strong></td>
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<td>- Class II</td>
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<td>- IPX0</td>
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Specifications subject to change without notice.
Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this user manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

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<th>Compliance</th>
<th>Guidance</th>
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<td>RF Emissions CISPR 11</td>
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<td>The NPD 1000 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.</td>
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<td>RF Emissions CISPR 11</td>
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<td>The NPD 1000 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.</td>
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<td>Harmonic Emissions IEC 61000-3-2</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>
### Electromagnetic Compatibility (Cont'd)

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Guidance</th>
</tr>
</thead>
</table>
| Electrostatic Discharge                    | ±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%.
| IEC 61000-4-2                             |                      |                  |          |
| Electrical Fast Transient/ Burst           | Not Applicable       | Not Applicable   | The NPD 1000 has no connection to Mains |
| IEC 61000-4-4                             |                      |                  |          |
| Surge                                      | Not Applicable       | Not Applicable   | The NPD 1000 has no connection to Mains |
| IEC 61000-4-5                             |                      |                  |          |
| Voltage Dips, Short Interrupts, & Variations on Power Supply Lines | Not Applicable       | Not Applicable   | The NPD 1000 has no connection to Mains |
| IEC 61000-4-11                            |                      |                  |          |
| Power Frequency Magnetic Fields            | 3 A/m                | 3 A/m            | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| IEC 61000-4-8                             |                      |                  |          |
**Guidance and Manufacturer’s Declaration - Electromagnetic Immunity**

The NPD 1000 is intended for use in the electromagnetic environments specified below. The customer or the user of the NPD 1000 should assure it is used in such an environment.

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>IEC 60601 Test Level</th>
<th>Compliance Level</th>
<th>Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the NPD 1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>IEC 61000-4-6</td>
<td></td>
<td></td>
<td>Recommended separation distance</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>3 VRMS 80 MHz to 2.5 GHz</td>
<td>3 V/m</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-4-3</td>
<td></td>
<td></td>
<td>[d = 1.2\sqrt{P}] (80 MHz to 800 MHz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>[d = 2.3\sqrt{P}] (800 MHz to 2.5 GHz)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m).</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Filed strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (c) should be less than the compliance level in each frequency range.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Interference may occur in the vicinity of equipment marked with the following symbol</td>
</tr>
</tbody>
</table>

*con’t next page*
**ELECTROMAGNETIC COMPATIBILITY Con’t**

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NPD 1000 is used exceeds the applicable RF compliance level above, the NPD 1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the NPD 1000.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.
Recommended separation distances between portable and mobile RF communications equipment and the NPD 1000

The NPD 1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NPD 1000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NPD 1000 as recommended below, according to the maximum output power of the communications equipment.

<table>
<thead>
<tr>
<th>Rated maximum output power of transmitter (W)</th>
<th>Separation distance according to frequency of transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150kHz to 80MHz</td>
</tr>
<tr>
<td>0.01</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>0.1</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>1</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>10</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>100</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
Overview of Negative Pressure Wound Therapy
Negative Pressure Wound Therapy (NPWT) is used to promote wound healing for a variety of wounds that are difficult to treat or having difficulty healing with the use of conventional wound dressings. It involves the use of a negative pressure pump (vacuum) and a special pressure sealing dressing. The wound dressing is placed over the wound and connected to the pump with medical tubing. The pump is turned on and the air under the dressing is removed. The removal of the air causes the dressing to exert a small mechanical force on the wound bed. Additionally, the negative pressure helps draw out various fluids produced by the body at the site of the wound. The pump removes these fluids from the tissues and they are stored in the dressing. The Kalypto Medical NPD 1000 Negative Pressure Wound Therapy system is a state-of-the-art medical device designed to deliver negative pressure wound therapy to wounds that may benefit from the application of such treatment.

What to expect during treatment
After your wound care professional has determined that your wound is a candidate for NPWT, the NPD 1000 system was prescribed. The system includes a battery-operated negative pressure pump, a negative pressure wound dressing and medical tubing to connect the pump to the dressing. On the first day, the wound care professional will apply your wound dressing and connect the pump to the dressing and turn on the device. As the air is removed from underneath the dressing, the dressing will shrink and press down on your skin. You should feel a slight mechanical force under the dressing. At this point, barring a battery change or an unlikely mechanical issue, you should not have to adjust the device until you see your wound care professional for a dressing change. Once therapy begins, the wound dressing should be changed every two to three days by your wound care professional. Therapy will proceed in this fashion until the wound care professional determines that the NPWT treatment is no longer necessary.
Operation of the Device

Patient instructions for the operation of the device are as follows:

Negative pressure wound therapy is a 24 hour a day treatment. Once set up and turned “ON” by your healthcare professional, you should not need to adjust the system other than to address an unusual, but possible, alarm or change the batteries. For directions with regards to these issues, see the Alarms and Troubleshooting section in the pages that follow.

For the ambulatory patient, the pump may be carried in their pocket, purse, or any other convenient location. It does not need to be next to the wound.

For use in the home, pump can sit on a bedside table or any other convenient location within the 6 foot length of the negative pressure tubing.

The patient SHOULD NOT change or remove the dressing between visits with their wound care provider. The wound dressing is designed to meet the needs of the patient for the entire time between visits and should not be changed except by the clinician.

Full Dressing

In some cases, it may be possible that the wound is producing so much fluid that the dressing reaches its fluid absorption capacity. The patient can monitor the level of fluid in the dressing by examining the three clear windows in the dressing near the pressure port. If they appear discolored, as wound fluid is being absorbed in the pad near the pressure source, the pump and dressing should be monitored for signs that the dressing has reached capacity. Additionally the other signs of a full dressing are:

1) The pump has not turned on (to maintain the negative pressure in the dressing) for an extended period of time.

2) All of the LCD icons are flashing on the pump screen, the numbers, the low battery icon (■) and the balloon icon (🎈).

3) The dressing does not have the appearance (shriveled and firm to touch) of being under negative pressure as was evident at the application of the dressing.

If the dressing and/or pump meets the above criteria, turn off the pump, and contact your woundcare professional. Do not remove dressing.
PATIENT INFORMATION & INSTRUCTION con’t

Powering “ON” the Device

Note: This should only be necessary for the patient if the device was inadvertently turned OFF for some reason or the batteries needed to be changed.

Depress the ON/OFF button for one second and release. The pump should turn on and the dressing should begin to contract under the application of negative pressure. Additionally the “pump operational” icon should appear in the upper left hand corner of the LCD display indicating the system is working. The device can be shut off by depressing the ON/OFF button again for one second and releasing.

As the device is applying vacuum to the dressing, the dressing should appear to contract against the skin and become firm to the touch. After the dressing has reached the target pressure, the pump will shut off. If it continues to run, beyond 1 or 2 minutes, the seal of the dressing will need to be improved. Watch the device for 2-3 minutes to be certain of the quality of the seal on the dressing. If the leak icon does not appear the seal is good. The pump should only run very briefly every 30 seconds to 5 minutes (depending on the quality of the dressing seal) once the therapy has started. In the RUN mode, the user may not even hear the pump when it is operating.
Maintenance and Care of the system

The patient is not responsible for the maintenance of the device. In fact, the device is designed to be maintenance free, meaning other than changing batteries in the pump, the patient should not have to service the device.

If the device were to get dirty, clean the surface of the pump as follows:

• Do not immerse in water or expose to water sprays, or other liquids
• Use cloth dampened with tap water and household dishwashing soap to clean the external surfaces. Wipe down until visibly clean.
• Wipe the external surfaces again with a cloth dampened with water (no soap) to remove the residual soap. Wipe until no longer “slippery”.

As for caring for the NPD 1000, take the following precautions with the device during use

• Keep away from open flames or high heat
• Be careful to not allow the device to drop onto hard surfaces, such as a floor
• Do not set anything on top of the pump
Alarms and Troubleshooting

The NPD 1000 Negative Pressure Wound Therapy Pump has various alarms to let the user know of any system malfunctions. Some alarms are serviceable by the patient, others may require a call to your clinician. Under no circumstances should a patient try to service the device outside of the instructions provided below. All of the system malfunctions (or momentary problems) are signaled by an audible beep from the device and/or a visual indication on the LCD display. Each section below details the reasons for device alarms, the potential source of the problem and the possible fixes to be tried by the patient or home caregiver.

Audible Beep (alarm) heard – If the user hears an audible beep from the device, he/she should inspect the display on the pump to determine the nature of the problem. The user is notified of all problems with the device by the audible beeping sound. An audible beep will be produced by the device to notify the user of any problem, including LOW BATTERY and DRESSING LEAK.

All LCD Segments Flashing – This condition indicates a system fault. Turn off the device, remove the batteries for 30 seconds, replace and turn the device on again. If the condition is repeated after this process, the device will not function properly. Turn off the device. At this point, the patient should call their clinician for guidance.

Leak Balloon Icon (□) On – If the leak icon is present, the system has a leak in the dressing, the tubing or the device. Additionally, the dressing may feel soft or the pump is running continuously. Depending on the source of the leak, the patient may or may not be able to fix it.

Dressing Leaks – First, run your fingers along the perimeter of the gasket applying gentle pressure, see picture below. Also, smooth out any wrinkles in the dressing outside the gasket. Wait for 2 to 3 minutes to see if the alarm goes away. For a new dressing, the gasket may take a few minutes to seat itself properly to provide a good seal.

If the leak icon does not disappear after two attempts to seat the gasket, then the leak may be in the tubing or the device.
**PATIENT INFORMATION & INSTRUCTION con’t**

**Tubing Leaks** - First, make sure the tubing is securely attached to all of the fittings, including the pressure port on the dressing and the fittings that attach the pump device to the dressing. The connection should be strong enough to withstand a firm tug on the tubing.

**No Dressing or Tubing Leak** - If the leak icon is still present checking for dressing and tubing leaks, turn off the pump, by depressing the ON/OFF button for one second and contact your health care provider. The problem is not serviceable by the patient.

**Low Battery Icon (🔋) On** - If you see the low battery indicator, replace the batteries. First, turn off the device by pressing the ON/OFF button for one second.

**NOTE:** If the batteries are low in the middle of therapy, there is no need to disconnect the pump unit from the bandage.

Remove the battery door, pull upwards on the battery removal strap and remove the batteries. Place new batteries in the battery holder in by following the +/- orientation found in the battery holder. Replace the battery door. Turn on the device by pressing the ON/OFF switch for one second. The device will return to the therapy mode as set when the device was turned off.

**Disabling the Audible Alarm** - The audible alarm warns the user of the presence of a performance problem with the device. These alarms are also displayed on the LCD display. For many reasons, including inconvenient location, church, movie, etc., the user may wish to disable the audible alarm for a few minutes.

The alarm sound can be temporarily disabled by pressing any of the three blue buttons briefly. This will disable the alarm for 5 minutes. After which time, it will sound again if the problem still exists.

**End of Therapy and Returning the NPD 1000 device**

As the negative pressure therapy proceeds, the healing of the wound will progress to a point at which the clinician will determine that the NPD 1000 system is no longer necessary. **DO NOT DISCONTINUE USE OF THE NEGATIVE PRESSURE WOUND THERAPY SYSTEM WITHOUT THE CONSENT OF YOUR WOUND CARE PROFESSIONAL.** Ask your clinician for guidance on the return of the pump. **DO NOT THROW THE PUMP IN THE TRASH.** It is likely that you will be returning the device to the clinician, the hospital or nursing facility or be required to call your home medical equipment provider. Your clinician will be able to tell you what to do once therapy has been terminated.
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