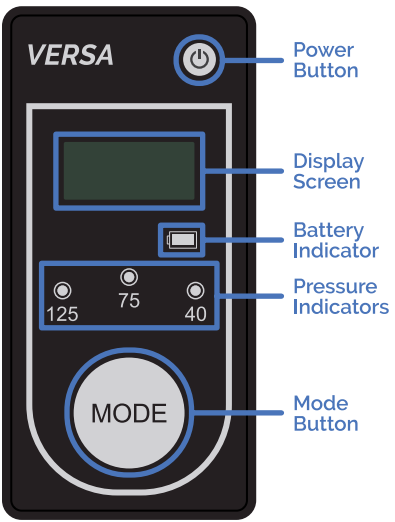
VERSA®

NEGATIVE PRESSURE
WOUND THERAPY SYSTEM

Instructions for Use

Model #: VCMPP-100
v1.0 2024_1114

VERSA NPWT Pump Features



VERSA NPWT System Accessories

- Cork Medical NPWT Wound Dressing Kits
- Cork Medical Canister

Use of Device: Introduction

The VERSA Negative Pressure Wound Therapy System is a prescribed device to be used under the guidance of licensed healthcare professionals. The VERSA Instructions for use provide information regarding safe and effective operation of the VERSA Negative Pressure Wound Therapy System. Disregarding the information on safety and use of this device is considered abnormal use.

Table of Contents

Patient Section

Warnings

- **DO NOT OPERATE THIS EQUIPMENT WITHOUT FIRST READING AND UNDERSTANDING THIS MANUAL. IF YOU ARE UNABLE TO UNDERSTAND THE WARNINGS, CAUTIONS, AND INSTRUCTIONS, CONTACT THE MANUFACTURER IF APPLICABLE BEFORE ATTEMPTING TO USE THIS EQUIPMENT. OTHERWISE, INJURY OR DAMAGE MAY RESULT.**
- **REFER SERVICING TO CORK MEDICAL**
- **DO NOT POWER UNIT IN THE PRESENCE OF FLAMMABLE GASES**
- **RX REQUIRED.**
- **DO NOT USE IN PRESENCE OF AN MRI**
- **WARNING/CAUTION NOTICES APPLY TO HAZARDS OR UNSAFE PRACTICES WHICH COULD RESULT IN PERSONAL INJURY OR PROPERTY DAMAGE.**

Warnings and Safety Standards

Read all instructions prior to use. When using an electrical medical device, basic safety precautions should always be followed. To reduce the risk of burns, electrocution, fire, and/ or injury to persons using this device:

- Review Instructions for Use with your healthcare provider.
- Do not use it while bathing or store product where it can fall into a tub or sink.
- Do not place or drop it into water or other liquid.
- Supervision is recommended when this product is used near infants and children.
- The device should only be used for its intended use as described in this manual.

- Do not operate this device if it has been dropped, damaged, or submerged into water.
- Do not operate the device if drowsy or impaired.
- When not in use, store the device and accessories in a cool, dry place.
- Do not attempt to service or repair the device. Contact your dealer or Cork Medical in these circumstances.
- If bright red blood is visible in the drainage tubing or canister, turn off NPWT, leaving dressing intact, hold pressure on dressing, and contact EMS immediately.

Use of this device adjacent or stacked next to equipment should be avoided because of possible improper operation. If such a scenario is required, observation of equipment is needed to verify normal operation.

The VERSA NPWT pump has been tested and complies with IEC 60601-1 3rd edition Medical Electrical

Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

Magnetic Resonance Imaging (MRI)–MRI Unsafe: Keep away from magnetic resonance imaging (MRI) equipment. Do not take the VERSA NPWT System into the MRI environment. The dressing can typically remain on the patient with minimal risk in an MRI environment.

Hyperbaric Oxygen Therapy (HBO): The VERSA NPWT System is not designed for the HBO environment and should be considered a fire hazard. Disconnect the VERSA NPWT System and replace the wound dressing with another HBO compatible material during the hyperbaric treatment. If dressing is left in place, cover the luer lock end with gauze and leave port unclamped.

If the treatment is longer than 2 hours, wound dressing must be changed.

Portable RF communications equipment: When using the VERSA NPWT System, Portable RF communications equipment (including peripherals such as antenna cables and external antennas should be used no closer than 30 cm (12 inches) to any part of the VERSA NPWT pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Use of Device: Battery

The VERSA NPWT Pump is designed to run on 3 - AA batteries. Batteries shall be replaced when the Critical Battery Alarm is encountered (see section “What Happens When Device Alarms”).

Specifications: Quantity 3 AA batteries 1.5V. Lithium and Alkaline AA battery are both suitable for the device. Lithium AA batteries are recommended.

General Settings

Carrying bag

The VERSA NPWT System Bag should always be utilized. The VERSA NPWT System should remain in the carrying bag unless a canister or battery change is necessary.

Steps:

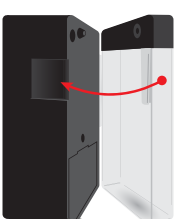
1. Unzip the top of the bag.
2. Place VERSA NPWT System in bag. The top of the pump should be at the top of the zipper area on the bag.
3. Zip the bag once pump is inserted into bag.
4. Double check correct orientation of pump in bag. The button of the VERSA NPWT System should be at the bottom of the bag.
5. Close front flap on bag

Correct Orientation:

Attaching the Drainage Canister to the Pump:

Use only Cork Medical NPWT Canisters with VERSA NPWT System.

1. Canisters are available in only 100 ml size. Attach the canister to the back of the VERSA NPWT System by hooking the canister onto the pump hinge post then rotating to lock the canister into place.
2. The drainage canister is snapped into place and will be secure once properly attached by the user. Gently tug on the canister to ensure it is secured.
3. The canister includes drainage tubing with a luer fitting. Attach the drainage tubing from the canister to the drainage tubing from the wound dressing kit.
4. Once the canister is in place and the drainage tubing is connected to the wound dressing kit, the VERSA NPWT System may then be powered on.
5. Change canister once the canister full alarm triggers or minimally once a week. When the canister is full, an alarm will sound– discard full canister and replace with a new, unused canister.



Device Operations:

1. The VERSA NPWT System has two buttons which are used to control the device. The Power and Mode buttons, shown below:
2. Power on the VERSA NPWT System by pressing the POWER button on the keypad.

   NOTE: When powered on, the pump will run on the default setting of Continuous High Mode at a pressure of 125-mmHg.
3. In the event the pump needs to be powered down, press, and hold the POWER button for 1-3 seconds then release.

What Happens When Device Alarms

The VERSA NPWT pump device provides audible and visual alarms to patients regarding critical battery, pressure leakage, system blockage, and when a collection canister is full. When an alarm condition occurs, a window shall display the specific alarm and alarm icon. The leak, blockage, and canister full alarms request the user to check the device and accessory status, make an adjustment of accessory or turn off the unit if needed.

Alarm Illustrations

Battery Critical Alarm

Alarm Notification	Troubleshooting
	
Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm.	**Battery life is critically low.** **Replace 3 - AA batteries and dispose of them accordingly. Lithium batteries are recommended.**

Canister Full Alarm

Alarm Notification	Troubleshooting
	
Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm.	**Collection canister full.** **Change canister to resolve alarm.**

Leak Alarm

Alarm Notification	Troubleshooting
	
Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm.	**Drainage tubing not connected.** **Wound dressing not completely sealed.** **Canister not latched.**

Press Mode to Snooze Leak Alarm for 5 Minutes

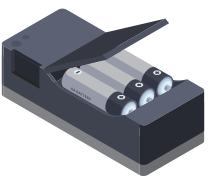
Blockage Alarm

Alarm Notification	Troubleshooting
	
Visual message displayed along with audible alarm. If alarm not corrected, continuous audible alarm.	**Pinch clamps activated.** **Drainage tubing kinked.** **Address blockage to clear alarms.**

Press Mode to Snooze Blockage Alarm for 5 Minutes

Critical Battery Alarm Troubleshooting:

1. When battery life is low the pump will indicate critical battery and user is advised to change the 3 - AA batteries at this time. To access the battery compartment, remove the canister and the battery cover located on the back of the pump.
2. The user will change the 3 - AA batteries. Lithium batteries are recommended and will yield a run time of approximately 6 days. Alkaline batteries can be used with a shorter estimated run time of approximately 4 days.



Leakage Alarm Troubleshooting:

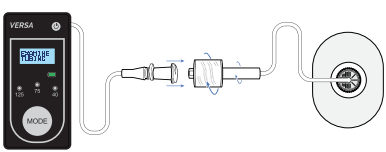
1. Inspect drainage canister to ensure that it has no visible cracks in it.
2. Ensure that port pad tubing is connected to canister tubing at luer lock connection.
3. Press firmly around the port pad to ensure you have a good seal with no leaks between the port pad and wound dressing.
4. Listen for air leak in and around wound dressing and if heard, use transparent film to seal leak.
5. Contact medical provider if the above actions don't rectify alarm.

Blockage Alarm Troubleshooting:

1. Ensure that both clamps are unclamped.
2. Inspect tubing to ensure that there are no kinks in tubing.
3. Ensure that the port pad does not have pressure applied directly on the dome.
4. Contact medical provider if the previous interventions do not resolve the alarm.

Disconnect Canister from dressing tubing

1. Clamp canister tubing
2. Clamp port pad tubing, the tubing that is connected to the wound.
3. Locate the connection point between the canister tubing and port pad tubing.
4. Unscrew counterclockwise.
5. Cover the end of port pad tubing and canister tubing.
6. Perform activities needed.
7. To reconnect, connect the port pad tubing to the canister tubing, and turn luer lock clockwise until snug (Do not overtighten)
8. Unclamp port pad tubing.
9. Unclamp canister tubing.
10. Ensure the foam is compressed as intended.



Malfunction At Pump Troubleshooting:

The VERSA NPWT System should begin running after pressing the POWER button. In the event the pump does not power on, press and hold the POWER button for at least 3 seconds. Attempt to power on again. If the unit still does not power on, it is possible that the batteries need replaced.

If the pump fails to power on, replace the 3 - AA batteries with new batteries and repeat the process above. If the unit still does not power on, contact Cork Medical.

Maintenance

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

Cleaning

General Information:

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

Cleaning:

Take precautions to keep the VERSA NPWT System components free of dirt, dust, lint, and debris. Maintain cleanliness of the system.

The VERSA NPWT should be cleaned on a weekly basis and between each patient's use.

Cleaning Steps:

1. Cork Medical recommends using a bacteriostatic cleaning wipe (e.g., Clorox Wipes)
2. Turn pump off prior to cleaning the device
3. Wipe all external surfaces of the pump with the bacteriostatic cleaning wipe
4. Perform a visible inspection post cleaning and if any dirt, dust, lint and/or debris is present, repeat the cleaning process
5. If any damage is noted, please contact your distributor or medical provider.

Do not submerge the device in any liquid and allow no solution to enter the internal portion of the pump. If any liquid penetrates the internal portion of device, return to your distributor for service.

Disposal of the Device:

After patient use is no longer prescribed, the device shall be disposed of following facility policies and/or local ordinances relating to the handling of potentially infected or bio-hazardous materials.

All used canisters shall be disposed of. Disposal of used canisters should follow facility policies and/or local ordinances relating to the handling of potentially infected or bio-hazardous materials.

Clinician Only Instructions

VERSA NPWT System – Therapy Mode Settings:

Continuous Mode

1. Power on the VERSA NPWT System by pressing the power button. The pump will operate in Continuous High Mode at the pressure of 125mmHg. The target pressure of pump, 125mmHg, is displayed with the white LED on the device. On the screen, "CONT HIGH" will be displayed. Press the mode button to adjust the pressure.

   NOTE: The pressure settings should only be manipulated by the clinician.

2. Pressing the mode button will switch the pump to Continuous Low Mode at the pressure of 75mmHg. On the screen, "CONT LOW" will be displayed

Variable Intermittent Mode

1. In variable intermittent mode, the pump will operate at an up pressure of 125mmHg with the up time of 15 minutes and the down pressure of 40mmHg with the down time of 7 minutes.

   NOTE: The pressure settings should only be manipulated by the clinician.

2. To enter intermittent mode, press and hold the mode button for approximately 10 seconds until the LED flashes quickly between 125 and 40mmHg lights. The screen should show "RELEASE BUTTON", and show "INTERMITTENT".

Indications for Use

The VERSA Negative Pressure Wound Therapy 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.

The Versa Negative Wound Therapy System is only intended to be used with the Cork NPWT Wound Dressing Kit (K132004) and the Versa 100ml Canister.

The VERSA Negative Pressure Wound Therapy System is not intended for home use environments.

Contraindications

The VERSA NPWT System is contraindicated for patients with:

- Malignancy in the wound
- Untreated osteomyelitis
- Enteric and unexplored fistulas
- Necrotic tissue with eschar present

  NOTE: After debridement of necrotic tissue and complete removal of eschar, VERSA NPWT system may be used.

Caution, do not place dressing directly in contact with:

- Exposed blood vessels
- Anastomotic sites
- Organs
- Nerves

Applying NPWT Wound Dressing:

Use only Cork Medical NPWT Wound Dressing Kits and canister with the VERSA NPWT System. Follow instructions for use when applying the wound dressing provided with the kits.

The following types of patients are at an increased risk of bleeding, which if not controlled could be potentially fatal:

- Patients who would have weakened or friable blood vessels or organs in or around the wound because of, but limited to suturing of blood vises, infection, trauma, and 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 active bleeding develops suddenly or large amounts of frank (bright red) blood are seen in the tubing or canister, immediately stop therapy, leave dressing in place, take measures to stop the bleeding, and seek immediate medical assistance. The VERSA NPWT System 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 the VERSA NPWT.

Large Wounds: Caution should be taken when treating large wounds that may hold hidden vessels which may not be readily apparent. The patient should be closely watched for bleeding in a 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. The patient should be closely checked for bleeding in a care setting deemed appropriate by the treating physician.

Hemostasis, Anticoagulants, and Platelet Aggregation Inhibitors: Due to the increased risk for bleeding, consideration should be given to the negative pressure setting and therapy mode used when starting therapy.

These patients should be treated and watched in a care setting deemed appropriate by the treating physician.

Hemostatic Agents Applied at the Wound Site: if disrupted, may increase the risk of bleeding which, if uncontrolled, could be potentially fatal. Consideration should be given to the negative pressure setting and therapy mode used when starting therapy.

Sharp Edges or bone fragments: Must be covered or eliminated from the wound area to prevent them from puncturing blood vessels or organs prior to the application of the VERSA NPWT System. Use caution when removing dressing components from the wound so that the wound tissue is not damaged by unprotected sharp edges.

Vascular Surgical Wounds of the Lower Extremities: Regardless of the treatment, wound complications from peripheral vascular surgery, especially those situated in the groin, are not uncommon and have the potential for severe consequences including significant blood loss.

Infected Wounds: Wound infections should be closely watched and may require more frequent dressing changes. If there are any signs of the onset of systemic infection or advancing infection at the wound site, contact the treating physician immediately to determine if the VERSA NPWT Pump should be discontinued.

Osteomyelitis: VERSA NPWT should not be initiated on a wound with untreated osteomyelitis.

Tendons, Ligaments and Nerves: Protect exposed tendons, ligaments, and nerves with natural tissue, meshed non-adherent material or bio-engineered tissue to help minimize risk.

Dressing Placement: Always use dressings from sterile packages that have not been opened or damaged.

Dressing Removal: Remove entire one-piece dressing. Regardless of treatment, disruption of the new granulation tissue during any dressing change may result in bleeding at the wound site.

Keep VERSA NPWT System turned on: If the VERSA system is off more than two hours, remove entire dressing and place moist dressing in wound.

Defibrillation: If defibrillation is required in dressing placement, remove the dressing immediately, as failure to remove may inhibit transmission of electrical energy and/or patient resuscitation.

Precautions should be taken for patients who are or may be: Receiving anticoagulant therapy, patients with known hemolytic disease, untreated for malnutrition, and who are non-compliant or combative.

Universal Precautions: Hand washing must be performed prior to starting any procedure. Gloves must be donned prior to any direct patient contact. In addition to gloves, use a gown and goggles if exposure to body fluid is likely. Always follow your institutional guidelines on infection control practices.

Patient Size and Weight: The size and weight of the patient should be considered when prescribing negative pressure wound therapy. Patients with highly exudating wounds or large wounds in relation to the patient size and weight should be closely monitored, as they may have a risk of excessive fluid loss and dehydration. When monitoring fluid output, consider the volume of fluid in both the tubing and canister.

Spinal Cord Injury: In the event a patient experiences autonomic hyperreflexia (sudden elevation in blood pressure or heart rate in response to stimulation of the sympathetic nervous system), discontinue therapy immediately and seek immediate medical assistance.

Bradycardia: The dressing should not be placed near the vagus nerve as this may cause bradycardia.

Enteric Fistulas: VERSA NPWT System is not intended for containment of drainage of enteric fistulas. VERSA may be used with enteric fistulas in the aid of promoting wound healing and not the sole purpose of containment of drainage. The physicians ordering the VERSA for enteric fistulas need to closely monitor the patient for any complications that may occur.

Operating Precautions:

When operating, transporting, repairing, or disposing of VERSA NPWT devices and accessories, the risk of infectious liquid being aspirated, or contamination of the device assembly through incorrect use, cannot be eliminated. Universal precautions should be observed when working with potentially contaminated parts or equipment.

In the event materials of the VERSA NPWT System cause skin irritation or an allergic reaction, cease use immediately and contact a physician.

Use of the VERSA NPWT System must be prescribed by a physician per the stated indications for use. As a condition of use, the VERSA NPWT System should only be used by qualified and authorized personnel. The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used.

The VERSA NPWT System should remain on and in use for the duration of the prescribed treatment. If the patient must disconnect the pump from the NPWT wound dressing, the ends of the tubing should be clamped prior to disconnecting. The length of time a patient may be disconnected from the VERSA device is a clinical decision based on individual characteristics of the patient and the wound. Factors to consider include the location of the wound, the volume of drainage, the integrity of the NPWT wound dressing seal, the assessed bacterial burden, and the patient's risk of infection.

Ensure all components of the VERSA NPWT Wound Dressing Kit are installed correctly and that the port pad assembly tubing is not kinked to avoid leakage and blockage during NPWT therapy. Position the VERSA NPWT System and drainage tubing appropriately to avoid the risk of causing a trip hazard. When possible, position the pump device and drainage tubing at or below the level of the wound.

Tubing from the Cork Medical NPWT Wound Dressing Kit and wound drainage canisters are long and represent a possible strangulation hazard.

Ensure the environment where VERSA NPWT System is to be used is clean and free of excessive dirt, lint, dust, and debris. Avoid using or storing VERSA NPWT System in an unclean environment. When not in use, store the device and accessories in a cool, dry place.

Continuous Therapy Versus Variable Intermittent Therapy:

Continuous Therapy is recommended for unstable structures, such as an unstable chest wall or non-intact fascia. Continuous Therapy is also generally recommended for patients at risk of bleeding, highly exudating wounds, fresh flaps and grafts, and wounds with acute enteric fistulae.

Protect Peri wound Skin:

Cork Medical recommends using a skin prep around the wound area prior to placement of one-piece dressing.

Circumferential Dressing Application: VERSA one piece dressing should not be used as a circumferential dressing at any time.

Clinician Orders

Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed clinician.

Use of the VERSA NPWT System must be prescribed by a clinician per the stated indications for use. The VERSA NPWT System is designed for use by licensed healthcare professionals and individual patients. Patient must perform the functions by the instruction manual as prescribed by the clinician.

The user must have the necessary knowledge of the specific medical application for which negative pressure wound therapy is being used. This device should only be prescribed to one patient as it is designed for single-patient use only.

Prior to placement of the VERSA NPWT System, the medical professional treating the patient must assess how to best use the system for an individual wound. It is important to carefully assess the wound and patient to ensure clinical indications for negative pressure wound therapy are met.

Technical Specifications

VERSA NPWT Canister

Shelf Life: 1 year from date of manufacture

Provided Non-Sterile

Cork Medical NPWT Wound Dressing Kit

Expiration: 2 years from date of sterilization

Sterilized via Ethylene Oxide and Gamma

VERSA NPWT Pump

Use life: Pump life is 3 years, shelf life is 3 years, both from date of manufacture

Minimum negative pressure: 40mmHg

Maximum negative pressure: 125mmHg

Suction capacity: 0.7 – 1.5L/min

Pressure settings in either Continuous High at 125 mmHg, Continuous Low at 75 mmHg, or Intermittent modes from 40 mmHg – 125 mmHg. Pressure setpoints are accurate to +/- 10 mmHg.

WARNING:

REFER SERVICING TO QUALIFIED PERSONNEL ONLY. THE DEVICE SHALL NOT BE MODIFIED IN ANY WAY.

Dimensions / Weight

Dimensions: 4.6" (H) x 2.35" (W) x 1.96" (D)

Weight: 0.6 lb.

Environmental Conditions

Operating Temperature: 18°C to 34°C (65°F – 94°F)

Operating Relative Humidity: 10% - 95%

Operating Pressure: 700-hPA – 1060-hPA (10.15-atm – 15.37-atm)

Storage & Shipping Conditions

Storage Temperature: -30°C (-22°F) without relative humidity control to 60°C (140°F) up to 90% relative humidity (non-condensing). The storage and shipping conditions apply to the VERSA NPWT between uses.

Limited Warranty

The VERSA NPWT Pump has Four-Month limited warranty.

Contact Information

Cork Medical
8000 Castleway Drive
Indianapolis, IN 46250

Toll Free: 866.405.6138

Fax: 866.429.5524

Symbols

	Class II, Internally Powered.
	Applied Part, Type BF.
	Read instructions as a mandatory action.
	Do not dispose.
IP22	Ingress protection - protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water.
	Intertek registered certification mark of nationally recognized testing laboratory (NRTL).
	Used canisters are considered biohazardous and should be disposed of accordingly after use.
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.
	MRI Unsafe - keep away from magnetic resonance imaging (MRI) equipment.

Electromagnetic Compatibility

Essential performance

The essential performance of the VERSA Negative Pressure Wound Therapy System is to maintain its pressure accuracy delivered to the wound site to an accuracy of ±10mmHg from set point. The VERSA NPWT System is suitable for use in hospitals , clinical settings. The VERSA NPWT system should not be used in a magnetic resonance imaging (MRI)environment, in hyperbaric chamber environment (HBO), nor with defibrillation. Please disconnect the device and/or remove dressings as instructed by your physician if these situations arise.

WARNING:

Use of the VERSA NPWT System adjacent to or stacked with other electrical equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:

Use of accessories and batteries other than those specified or provided by Cork Medical may negatively affect EMC performance.

WARNING:

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VERSA NPWT System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. See table below for additional details regarding recommended separation distances between portable and mobile RF communications equipment and the VERSA NPWT System. Not approved for use in the device on the motor vehicle or aircraft.

Electromagnetic Emissions

The following electromagnetic emission information is provided for healthcare facilities environments where the use of this device around other devices could result in electromagnetic interference.

Guidance and Manufacturer's Declaration- Electromagnetic Emission		
The VERSA NPWT System complies for each Emissions test specified by the standard, e.g., Emissions class and group.		
Emissions Test	**Compliance**	**Electromagnetic Environment**
F Emissions CISPR 11R	Group 1	The VERSA NPWT uses RF energy only for internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RM Emissions CISPR11	Class B	The VERSA 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	Not Applicable	Battery operated device
Voltage Fluctuations/ Flicker emissions IEC61000-3-3	Not Applicable	

NOTE:

This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2: 2014 4th edition. These limits and test levels are intended to provide reasonable safety with regard to electromagnetic disturbances when the device is used in a typical medical installation.

Electromagnetic Immunity

The following electromagnetic emission information is provided for healthcare facilities where the use of this device around other devices could result in electromagnetic interference.

Guidance and Manufacturer's Declaration- Electromagnetic Emission			
The VERSA NPWT System is intended for use in the electromagnetic environments specified below. The customer or the user of the VERSA NPWT System should assure that it is in such and environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 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%.
Electrostatic fast transient/burst IEC61000-4-4	±2 kV contact For power supply lines ±1 kV For input/output lines	Not Applicable	Battery operated device

Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable	Battery operated device
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5 % U_r (>95 % dip in U_r) for 0.5 cycle 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 cycles	Not Applicable	Battery operated device
Power frequency (50 Hz/60Hz) Magnetic fields IEC61000-4-8	30 A/m	30 /Am 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_r is the a.c. mains voltage prior to application of the test level

Guidance and Manufacturer's Declaration- Electromagnetic Emission			
The VERSA NPWT System is intended for use in the electromagnetic environment specified below. The customer or the user of the VERSA NPWT System should assure that it is in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted RF IEC61000-4-6	3 Vrms 150kHz to 80 Mhz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the VERSA NPWT System than the recommended separation distance calculated from the equation application to the frequency of the transmitter

Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Recommended separation distance $d=0.35\sqrt{P}$ 80 MHz to 800 MHz $d=0.7\sqrt{P}$ 800 MHz to 2.7 GHz 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) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. 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.

Recommended separation distances between portable and mobile RF communications equipment and the VERSA NPWT System			
The VERSA NPWT System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the VERSA NPWT System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VERSA NPWT System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in watts (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.7 GHz $d = 0.7\sqrt{P}$
0.01	.12	.04	.07
0.1	.38	.11	.22
1	1.2	.35	.7
10	3.8	1.1	2.2
100	12	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separate 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 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.

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