Vaporox with VHT™

VHT-200
Wound Treatment System
User Manual



⚠ IMPORTANT ⚠

Caution: Federal law restricts this device to be used by or on the order of a physician. Before using the VHT-200, read this manual and follow the operating instructions carefully.

Some photos in the user's manual may vary depending on the use of the machine.

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Operator Requirements

Operators shall be knowledgeable in the intended use of the system and trained in the clinical environment. In addition, operators of the VHT-200 must be trained to provide treatment at the direction of a medical provider and the operator should be:

- Proficient in healthcare procedures regarding aseptic techniques
- Thoroughly understanding of the contents of this manual
- Fully trained and qualified to operate this system

Vaporox, Inc. Contact Information

The Vaporox model VHT-200 Wound Treatment System and accessories are manufactured by Vaporox, Inc. in Centennial, Colorado. For further information regarding the operation, repair, parts, maintenance or technical support of the VHT-200 System, please contact:



Manufactured for:

VAPOROX, Inc.
(303) 558-5145
9110 E Nichols Ave., Suite 150
Centennial, CO 80112
www.vaporox.com

Updates to this User Manual are available for download at:
www.vaporox.com/usermanual/

Glossary

VHT-200 – Multi-modality wound treatment system.

SYSTEM – Defined as the VHT-200 Equipment, Basin, Pole, Vaporizer and Treatment Chamber Kit.

EQUIPMENT – Primary module of the VHT 200 system, including software, which is located and latched to the top of the Basin

DISPLAY – User interface including touchscreen and switches of the VHT-200 control panel

BASIN – The bottom module, or base, of the VHT 200 system which latches to the Equipment.

POLE – Component of the VHT-200 System that suspends the Treatment Chamber.

VAPORIZER – Component of the VHT-200 System which provides adiabatic ultrasonic formed vapor.

TREATMENT KIT – Component of the VHT-200 System which is a single-use, disposable used to contain the treatment environment around the patient's wound. There are two options offered an Extremity Treatment Kit or Universal Treatment Kit.

TREATMENT – The application and usage of the VHT-200.

CYCLE – Segment of treatment consisting of a pre-defined function and duration set by the physician providing the VHT-200 treatment.

FUNCTION – Any one of the VHT-200 multi-modalities.

HYPEROXIA – Oxygen concentration greater than local environment.

MEDICAL PROVIDER – Prescribing physician of the VHT-200.

OXYGEN – Hyperoxia Treatment.

VHT™– Vaporous Hyperoxia therapy.

TREATMENT SOLUTION – Sterile water for irrigation *

* Note – The VHT-200 System has been validated using a solution of Sterile water for irrigation.

Safety & General Symbols

THE PURPOSE OF SAFETY SYMBOLS IS TO ATTRACT YOUR ATTENTION TO POSSIBLE DANGERS. THE SAFETY SYMBOLS, AND THE EXPLANATIONS WITH THEM, DESERVE CAREFUL ATTENTION AND UNDERSTANDING.

The purpose of general symbols is to attract your attention to key labeling information.

	**Safety Alert** – Indicates danger, warning, or caution.
	**Universal No Smoking Sign**
	**Shock Hazard** – Indicates the presence of electric shock hazards.
	**Consult electronic instructions for use/User Manuel**
	**WARNING:** Read the User's Manual with the Wound Treatment System. Failure to follow operating instructions and safety precautions in User's Manual can result in injury.
	**Federal law restricts this device to be used by or on the order of a physician.**
	**Catalog Number / Part Number**
	**Manufacturer**
	**Date of Manufacture**
	**Do Not Reuse. Dispose of all Contents after one use.**
	**Lot Number/Batch Code**
	**Type B applied part**

Safety & General Symbols

	**DANGER** – May cause or intensify fire. An oxidizing material may or may not burn itself, but will release oxygen or another oxidizing substance, and thereby causes or contributes to the combustion of another material. If a fire or spark is detected, immediately turn the on/off switch to the off position, if possible, unplug the equipment from the outlet and evacuate the area.
	**NOTE:** Notes are advisory comments or recommendations regarding practices and procedures.
	**WARNING:** Guard against electric shock hazards. The power cord protective grounding connector must be connected to ground.
	**TIP HAZARD:** A hazard warning refers to a risk of injury or machine damage due to improper handling of equipment.
	**OVERBALANCE HAZARD:** Do not push against the front or back of the system when transporting.
	**WARNING:** A.) Place any electrical appliance at least five feet from the patient. B.) Move equipment or personal items likely to produce static discharges at least five feet from the patient

User Interface Symbols

	**Back –** Return to Previous Screen/Item
	**Cellular –** Cellular Connection
	**Decrease** – Decrease Parameter
	**Enter/Accept –** Enter; Accept Entry
	**Increase** – Increase Parameter
	**Maintenance** – Access System Maintenance/Info
	**Oxygen** – Indicates Oxygen

User Interface Symbols

	**Pause** – Pause Treatment
	**Proceed** – Proceed with Treatment/Selection
	**Reset** – Reset/Return to Default
	**Signal –** Indicates Signal Strength
	**Start/Resume** – Start/Resume Treatment
	**Stop/End/Cancel** – Stop/End/Cancel Treatment
	**Treatment Parameters –** Configure Treatment Parameters
	**User Manual –** Access Digital User Manual
	**Vapor** – Indicates Vapor
	**Volume/Sound** – Adjust System Volume/Sound
	**Warning** – Warning Message

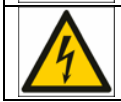
Warnings

	**WARNING!** For treatment of wounds, this device should be used under close supervision and direction of a medical provider.
	**WARNING!** The device is not intended for any use other than indicated.
	**WARNING!** Use of this equipment adjacent to or stacked with other 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!** The treatment chamber kits must be disposed of in a sanitary manner. The treatment kit (treatment bag, bag support, hose and hose connectors) is single use only and must be disposed of after treatment is completed. Improper disposal may lead to cross contamination
	**WARNING!** Unattended use of the VHT-200 by children or incapacitated persons may be dangerous.

Warnings

	**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 VHT-200 Wound Treatment System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result
	**WARNING!** Spills and leaks may pose a slip-and-fall hazard. Be cautious about patient slip hazards during patient set up
	**WARNING!** Failure to install, operate, and maintain this equipment according to Manufacturer's instructions may cause injury.
	**WARNING!** Be careful not to tip the machine when rolling over uneven surfaces. Do not roll machine when filled and in use. Do not push or lean against the machine when wheels are locked
	**WARNING!** Set wheel locks when system is in use or stored or parked
	**WARNING!** Do not Lift the System with the Basin and Equipment portion connected using the handles. Such handling may cause damage
	**WARNING!** Do not lift the Equipment and Basin units together. Detach latches before lifting
	**WARNING!** Two person lift required for Equipment
	**WARNING!** The Equipment must be latched to the Basin during use and before moving
	**WARNING!** Do not position the system so that it is difficult to unplug the system's power cord
	**WARNING!** Remove all highly combustible material from the treatment room
	**WARNING!** There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do not use the device or accessories near sparks or open flames.
	**WARNING!** Use only water-based lotions or salves that are oxygen-compatible before and during treatment. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns
	**WARNING!** Do not lubricate fittings, connections, hose, or other accessories of the device to avoid the risk of fire and burns
	**WARNING!** No user serviceable parts inside. Enclosure should only be opened by an authorized service provider
	**WARNING!** Use only spare parts recommended by the manufacturer to ensure proper function and to avoid the risk of fire and burns.
	**WARNING!** No modification of the equipment is allowed.

Warnings

	**WARNING!** Oxygen makes it easier for a fire to start and spread. Do not leave the treatment chamber components on bed coverings or chair cushions. If the device is turned on, but not in use; the oxygen will make the materials more flammable. Turn the device off when not in use to prevent oxygen enrichment.
	**WARNING!** Not for use with Flammable anesthetics.
	**WARNING!** Do not smoke or operate this machine near open flames.
	**WARNING!** Smoking during oxygen therapy is dangerous and is likely to result in burns or death. Do not allow smoking or open flames within the same room as the device or any oxygen-carrying accessories.
	**WARNING!** Open flames during oxygen therapy are dangerous and are likely to result in fire or death. Do not allow open flames within 2 m of the device or any oxygen-carrying accessories.
	**WARNING!** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
	**WARNING!** This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference.
	**WARNING!** Greater than 22mm Hg of mercury oxygen pressure in chamber may occlude arterial circulation, which may lead to a decrease in local tissue circulation.
	**WARNING!** The electrical source with a hospital grade receptacle with protective earth and ground fault interrupter. Failure may result in electrical shock or burn to the operator or patient.
	**WARNING!** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VHT-200 Wound Treatment System or shielding the location.
	**WARNING!** Do not use an alternate power cord with system as it could affect device safety, specifically electric shock being introduced, or affect compliance with electromagnetic emissions and immunity. A risk of increased emissions or decreased immunity may result if any additional cables are attached.
	**WARNING!** Move equipment or personal items (e.g., clothing, jewelry) likely to produce static discharges at least five feet from the patient in order to prevent potential ignition of the oxygen rich treatment chamber
	**SHOCK HAZARD!** To avoid risk of electric shock, replace fuses only with the same type and rating.
	**SHOCK HAZARD!** To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	**WARNING!** Place any electrical appliance (e.g., television) at least five (5) feet from the patient in order to prevent potential ignition of the oxygen rich treatment chamber.

Warnings



DANGER! VHT-200 may cause or intensify fire. An oxidizing material may or may not burn itself, but will release oxygen or another oxidizing substance, thereby may cause or contribute to the combustion of another material. If a fire or spark is detected, immediately turn the on/off switch to the off position, if possible, unplug the equipment from the outlet and evacuate the area.

General Description

The Wound Treatment System (**VHT-200**) is a prescription medical device. This system is designed for most topical injuries that can benefit from the properties of oxygen and moisture therapy treatments. The VHT-200 operates by generating vapor/mist using non-contact, low-frequency ultrasonic crystals. Concentrated oxygen is generated using a pump compressor and oxygen concentrator. All the benefits of oxygen and moisture modalities are self-contained into one system and applied without the need of switching applications. The VHT-200 is made for clinical office use. The VHT-200 is designed for the medical provider to add oxygen flow rate and frequency of the treatments based on experience and professional assessment of the individual patient's medical need.

The System includes Equipment (a top unit) with a touchscreen user interface, a lower Basin unit, a Vaporizer, a Pole that attaches in the back of the basin unit and provides support for either Treatment Kit and the connecting hose from the vaporizer to the Treatment Bag to fill with oxygen and vapor. The **VHT-200** is made for clinical use only. The maximum duration for a single treatment is 56 minutes total time, including both oxygen and vapor.

Note: This device cannot, nor is it implied, that the VHT-200 Wound Treatment System, is capable of preventing or curing any disease. This device does not have essential performance and should be considered a part of adjunct therapy for wound treatment.

℞ Only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Intended Use

VHT-200 is intended to provide ultrasonically generated mist and concentrated oxygen to open, acute and chronic wounds as an adjunct therapy in wound management and treatment.

The VHT-200 System is intended for the following kinds of wounds:

- Skin ulcerations due to diabetes, venous stasis, and post-surgical infections
- Gangrenous lesions
- Decubitus ulcers
- Amputations / infected stumps
- Skin grafts
- Burns
- Frostbite

Contraindications

Contraindications for the VHT-200 System include:

- Patients with active infections of cellulitis or osteomyelitis in the treated limb
- Patients with diagnosed malignant ulcers in the treated limb
- Not for respiratory use

Accessories

The VHT-200 System includes a primary module, the Equipment, and the following accessories, which are needed to run a treatment:

- Basin
- Vaporizer
- Pole (with hose hangers)
- Treatment Kit(s) (includes treatment chamber bag, bag support, hose connectors, and treatment hose) which is single use only
- Power Cord
- Sterile Water for Irrigation

System Technical Description

The VHT-200 Equipment uses a commercially available, off-the-shelf oxygen concentrator to provide the concentrated oxygen used in the treatment process. The oxygen concentrator used in the VHT-200 incorporates industry standard Pressure Swing Absorption (PSA) Technology. The PSA process separates out oxygen from other gases contained in ambient air using an absorbent material named Zeolite, which is contained within the oxygen concentrator.

Federal Communication Commission Interference Statement: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio

communications.. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own response.

FCC Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter module must not be co-located or operating in conjunction with any other antenna or transmitter. This End equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

Classification & Specifications

VHT-200 System Unit	
Type	**Specification**
Size (approx.)	16” (D) x 48” (H) x 28” (W)
Weight	130 pounds
Oxygen System Flow Rate	Up to 5 L/minute @ > 85% at STDP (standard temperature and pressure, dry)
Transport and Storage Conditions	-20°C to 60°C (-4°F to 140°F) and Humidity: 0% - 85% (non-condensing)
Operating Conditions	18°C to 29°C (65 °F to 85) °F and Humidity: 0% - 80% (non-condensing) Altitude above sea level: 0 - 3000 meters
Operating Pressure	69 kPa - 101 kPa
Power Supply	120 VAC 60Hz 10A
Display	Touchscreen
Modes of Operation	Continuous
Protection against electric shock	Type: Safety Class I Degree: Type B
Ingress Rating	IPX0 (Not protected)
Fuses	F 10AL 250V

VHT-200 System Unit	
Type	**Specification**
Wireless Communications	FCC ID: 2AEMI-BRN402 Operating Frequency: Cellular 698MHz - 2690MHz (Radiated power 1.15mW) Specification: B SoM LTE CAT-M1

VHT-200 Disposable Treatment Chamber Kits	
Type	**Specification**
Size (approx.)	2” (D) x 12” (H) x 18” (W)
Weight	1 pound
Transport and Storage Conditions	-20°C to 60°C (-4°F to 140°F) and Humidity: 0% - 85% (non-condensing)
Operating Conditions	18°C to 29°C (65 °F to 85 °F) and Humidity: 0% - 80% (non-condensing) Altitude above sea level: 0 - 3000 meters
Operating Pressure	69 kPa - 101 kPa

System Environment Requirements

Operation, transport, and storage of the VHT-200 System should be in an environment that meets the following requirements.

Environmental Conditions for Storage and Transport

VHT-200 System (Equipment, Basin, Pole and Vaporizer)

Store indoors or store and transport in an enclosed weatherproof and non-condensing environment.

VHT-200 Treatment Kits

Store indoors or store and transport in an enclosed weatherproof and non-condensing environment. Do not open Treatment Kit pouch until ready to use. There are two options for Treatment Kit: (1) Extremity Treatment Kit, or (2) Universal Treatment Kit.

Environmental Conditions for Operation

The VHT-200 is not weatherproof. Operate indoors or in an enclosed and non-condensing environment. Provide sufficient ventilation to prevent the accumulation of low oxygen concentration gas in the surrounding space, such as a room that has airflow (as provided by a typical building HVAC system). Preferred operation conditions include a controlled and dry environment.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The VHT-200 Wound Treatment System is intended for use in the electromagnetic environment specified below. The customer or the user of the VHT-200 Wound Treatment System should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The VHT-200 Wound Treatment System 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></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The VHT-200 Wound Treatment System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the VHT-200 Wound Treatment System or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Not applicable as the device is only powered at 120V 60Hz</td></tr>
<tr><td>Voltage Fluctuations
IEC 61000-3-3</td><td>Not applicable as the device is only powered at 120V 60Hz</td></tr>
</table>

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The VHT-200 Wound Treatment System is intended for use in the electromagnetic environment specified below. The customer or the user of the VHT-200 Wound Treatment System should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td>±8kV contact
±15kV air</td><td>±8kV contact
±15kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
</table>

Electrical fast transient/burst IEC 610004-4	±2kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line(s) to line ±2kV line(s) to earth	±1kV line(s) to line ±2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles h) Single phase: at 0° 0 % *U*T; 250/300 cycle	0 % *U*T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % *U*T; 1 cycle and 70 % *U*T; 25/30 cycles h) Single phase: at 0° 0 % *U*T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VHT-200 Wound Treat-ment System requires continued operation dur-ing power mains inter-ruptions, it is recom-mended that the VHT-200 Wound Treatment System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be a levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

<table>
<tr><td colspan="4">The VHT-200 Wound Treatment System is intended for use in the electromagnetic environment specified below. The customer or the user of the VHT-200 Wound Treatment System should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
0,15 MHz – 80 MHz

6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz
80 % AM at 1 kHz</td><td>3 Vrms
0,15 MHz – 80 MHz

6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz
80 % AM at 1 kHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the VHT-200 Wound Treatment System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

d = [3.5/3] √P 80 MHz to 800 MHz
d = [7/3] √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 recom-mended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m
80 MHz to 2.7 GHz</td></tr>
<tr><td colspan="4">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.</td></tr>
</table>

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 VHT-200 Wound Treatment System is used exceeds the applicable RF compliance level above, the VHT-200 Wound Treatment System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the VHT-200 Wound Treatment System.

Guidance and manufacturer's declaration – electromagnetic immunity

The VHT-200 Wound Treatment System is intended for use in the electromagnetic environment specified below. The customer or the user of the VHT-200 Wound Treatment System should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
IMMUNITY to proximity fields from RF wireless communications equipment	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	MHz – Modulation – Field Strength 385 - 18 Hz - 27 V/m 450 - 18 Hz - 28 V/m 710 - 217 Hz - 9 V/m 745 - 217 Hz - 9 V/m 780 - 217 Hz - 9 V/m 810 - 18 Hz - 28 V/m 870 - 18 Hz - 28 V/m 930 - 18 Hz - 28 V/m 1720 - 217 Hz - 28 V/m 1845 - 217 Hz - 28 V/m 1970 - 217 Hz - 28 V/m 2450 - 217 Hz - 28 V/m 5240 - 217 Hz - 9 V/m 5500 - 217 Hz - 9 V/m 5785 - 217 Hz - 9 V/m	Portable and mobile RF commun-ications equipment should be used no closer to any part of the VHT-200 Wound Treatment System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an

			electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE: 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 as well as RF wireless communications equipment the VHT-200 Wound Treatment System.

The VHT-200 Wound Treatment System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the VHT-200 Wound Treatment System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the VHT-200 Wound Treatment System 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)			
	80 to 800 MHz $d = [3.5/3]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9]\sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28]\sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

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.

NOTE: *This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.*

Cellular Connection

The VHT-200 can connect, via encrypted connection, to a mobile app for system monitoring and diagnostic data. The data monitored is limited to VHT-200 System data and does not contain any patient or provider data. To maintain cybersecurity, do not to attempt to connect the VHT-200 System to any wifi networks, computers, or remote connections.

Precautions

- Exercise special care for the safe and effective use of this device.
- Read the manufacturer's directions before use.
- Misuse of this device can lead to adverse events.
- Exercise caution when handling.
- In case of emergency turn off device, disconnect power cord from wall outlet to isolate the system from mains power and follow facility emergency protocol.
- Approach bumps perpendicularly when moving device.
- When setting up the VHT-200, make sure the power cord is out of the way and not under feet. Do not tangle cords.
- During patient set-up, exercise special care to avoid patient slip hazards.

Potential Risks and Benefits

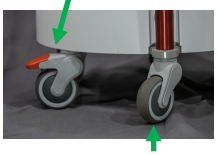
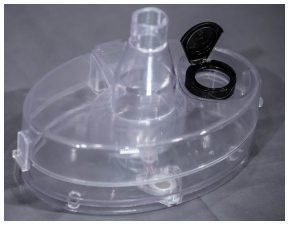
The potential risks to health associated with the device are: delayed wound treatment, inflammation/foreign body response, infection, and electrical shock. Oxygen can be delivered to any part of the body at low pressure that is enclosed in a compartment with complete safety, as long as blood flow to and from the area is not compromised by too tight an application of the restricting element used. Any likelihood of injury is minimal. To prevent any such injury, ensure that all directions have been read and followed correctly and that the patient is in a clear state of mind to stop the treatment in the event of experienced pain during the treatment.
The benefits of the VHT-200 are: temporary increase in local blood circulation and oxygenation where applied. The benefits outweigh the risks and accelerated wound treatment should be realized shortly after the treatments are started.

Patient Sensitivities

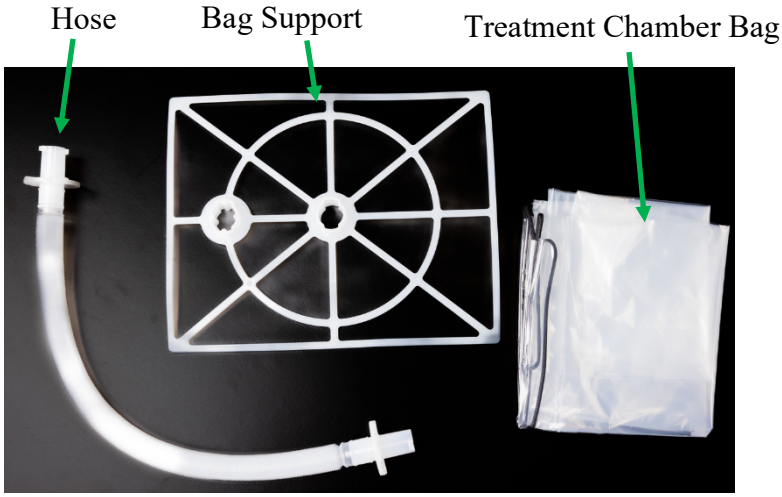
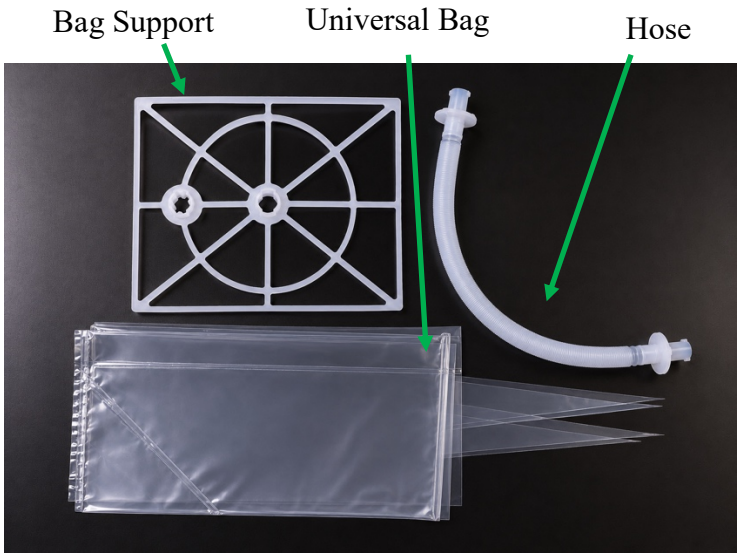
No components in the Disposable Treatment Chamber Kit of the VHT-200 System are made with natural rubber latex.

System Overview

The VHT-200 System is designed for the medical provider to determine the number of cycles and vapor output of the treatments based on his/her experience and professional assessment of the individual patient's medical need.
It consists of:

Basin with six (6) wheels and four (4) are lockable wheels	 
Equipment with two (2) Handles and power cord	 
Vaporizer	

Control Panel	
Extendable Pole	

Treatment Kits	Shown: Extremity Treatment Kit  Shown: Universal Treatment Kit 

System Description

The VHT-200 system is an FDA Class II medical device that provides humidified oxygen to open, acute and chronic wounds as an *adjunct* therapy in wound treatment management. The VHT-200 is designed in modules that can be assembled and disassembled for module replacement. The system is mobile but stationary for patient treatment.

The system's primary module is called the Equipment, which includes a control panel and removable power cord. The Equipment is then combined and assembled with its accessories (the Basin, Pole, and Vaporizer) and this full assembly is called the VHT-200 System. The system is used in conjunction with a single-use disposable, either of the Treatment Kits (Universal Treatment Kit or Extremity Treatment Kit), which attaches to the Vaporizer. The treatment kit is comprised of several Low-Density Poly Ethelene (LDPE) components, the Treatment Hose, Treatment Bag, and Bag Support. Once fully assembled, the disposable kit creates a tent like enclosure containing the treatment environment without producing any positive pressure differential by allowing for flow of the air, vapor, and/or oxygen around the wound and then to exit.

When setting the system up for treatment, the bag is placed over or around the patient's wound. The treatment chamber bag is designed to NOT be in contact with the wound being treated, whereas the only contact would be incidental during setup or removal. The only intended patient contact occurs where the chamber is gathered around a healthy, non-wound portion of the patient's skin or limb.

Once the system and patient have been set up for treatment, the system will deliver several cycles of alternating therapy conditions once treatment has started. Each cycle consists of first applying water vapor to the wound and then switching to deliver oxygen to the wound. The exact amount of water vapor absorbed by the patient's wound and the rise in oxygen level concentration are dependent on many variables such as the patient size, age, weight, wound grade, position of wound, size of wound, age of wound, local environment, and treatment settings. Therefore, the performance of the device has been predicated on simply improving the wound environment to be greater than the local environment in a way that the performance is proportional to all these variables.

System Control Panel

The control panel is located at the top of the VHT-200 Equipment. It consists of a touchscreen display that allows providers to control the operation of the system. The display includes the default settings whereas the operator can choose to set treatment parameters and monitor treatment.

Once the control panel is turned on via the power switch on the left side of the control panel, a Select Treatment Cycles screen is displayed on the touchscreen with the default treatment settings.

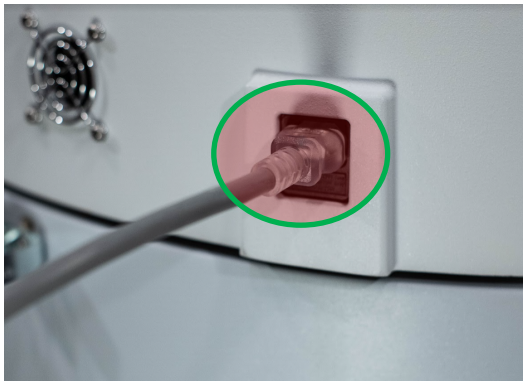


	**WARNING:** No operator serviceable parts inside. Enclosure should only be opened by an authorized service provider.
	WARNING! This unit has been designed and tested to meet the requirements of electromagnetic, electrostatic, and radio frequency interference standards. However, the possibility of electromagnetic or other interference may still exist. Relocating the device may help to eliminate the interference

System Power Connection

The power cord connects on the top Equipment of the VHT-200. This plugs into an A/C outlet.





The power switch is on the left-hand side of the control panel (B). Power is switched ON/OFF by pressing the switch to “-“ or “o”



WARNING! Do not use an alternate power cord with system as it could affect device safety, specifically electric shock being introduced, or affect compliance with electromagnetic emissions and immunity. A risk of increased emissions or decreased immunity may result if any additional cables are attached.

Initial System Set-up

To set-up the VHT-200 System the components need to be unboxed, unpackaged and set-up using the detailed steps that follow. The final VHT-200 System set-up will look similar to the image below.



List of Boxed System Components.

- Equipment
- Basin
- Pole
- Vaporizer
- Treatment Kit

System Unboxing

Unbox Equipment

- Open the Equipment Box top which is identified by the “This Side UP” label.

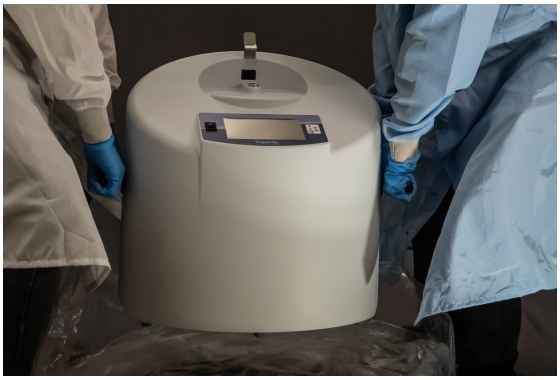


- With two people reach into the box, grab the handles, lift and set onto floor.



- Remove the Bag from the Equipment by unwrapping and lifting the equipment up and away.







- Remove the Power Cord and Product Insert from the Equipment box.

Unbox Basin

- Open the Basin Box top which is identified by the “This Side UP” label.





With two people reach into the box, grab the inside edge of the enclosure, lift and set onto floor.





- Remove the Basin Product Insert from the Basin box.

Unbox Vaporizer

- Open the Vaporizer Box top which is identified by the “This Side UP” label and remove wrapped Vaporizer.



- Remove the Vaporizer from the bubble wrap.





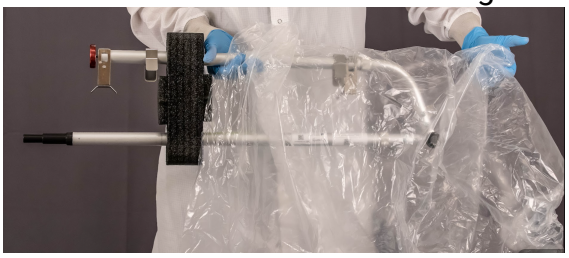
- Remove the Vaporizer Product Insert from the Vaporizer box.

Unbox Pole

- Open the Pole Box and remove bagged pole from Box.



- Remove the Pole from the Bag.





- Remove the Pole Product Insert from the Equipment box.

Unbox Treatment Kit

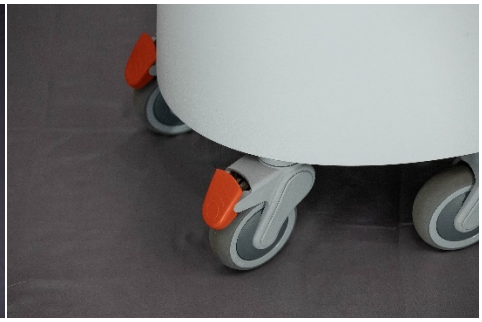
- Open the Treatment Kit Box Top






Equipment to Basin Installation

- Lock the outer wheels on the Basin prior to assembly by pressing the red levers downward.

- Assemble the VHT-200 by lifting the Equipment with two people, one person lifting the handles on each side of the Equipment and then aligning the Equipment to the top of the Basin.





- Lock the two latches on each side to secure the Equipment to the Basin by lifting and engaging the latch to the hook and pressing the two pieces together.



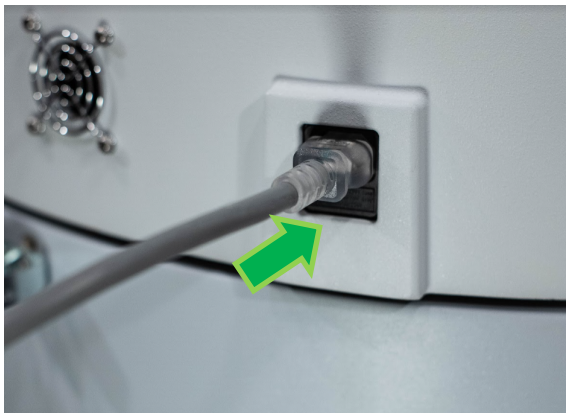


*NOTE: Per provider's recommendation, the Basin may be lined with the treatment chamber bag and used for treatment if the wound cannot be elevated comfortably to the desired height as intended with the full VHT 200 System setup (refer to **Limited Patient Mobility Setup** below).*

	WARNING! Two person lift required for Equipment.
	WARNING! Do not lift the Equipment and Basin together using the handles. Detach latches before lifting
	WARNING! The Equipment must be latched to the Basin during use and before moving.

Power Cord Installation

- Plug the power cord into the Equipment and into the wall outlet.





- Place the VHT-200 System in the desired position and re-lock the wheels of the VHT-200 System.

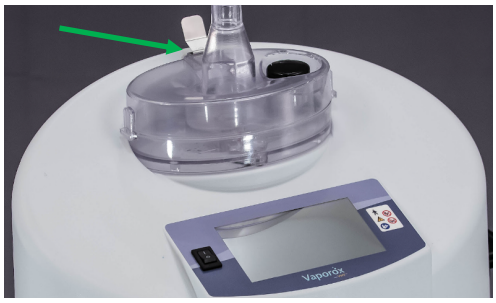
  NOTE: *When setting up the VHT-200 System, ensure the power cord is out of the way and not under foot. Do not tangle cords. Ensure that the unit is not placed in a position that will prevent safe disconnection of the power cord.*

Vaporizer Installation

- Install the Vaporizer by pulling the retaining clip back and placing the Vaporizer onto the top of the Equipment enclosure and then releasing the retaining clip.



- After installation ensure that the retaining clip rests inside the Vaporizer retaining pocket.




Pole Installation

- Install Pole vertically through the hole of the Basin ring and Basin Pole retention feature. Gently press down and Pole will seat into Basin.




Pole Vertical Adjustment

- Turn twist lock feature by hand counter clock wise until loose.





- Move the Pole Vertically to the desired height.



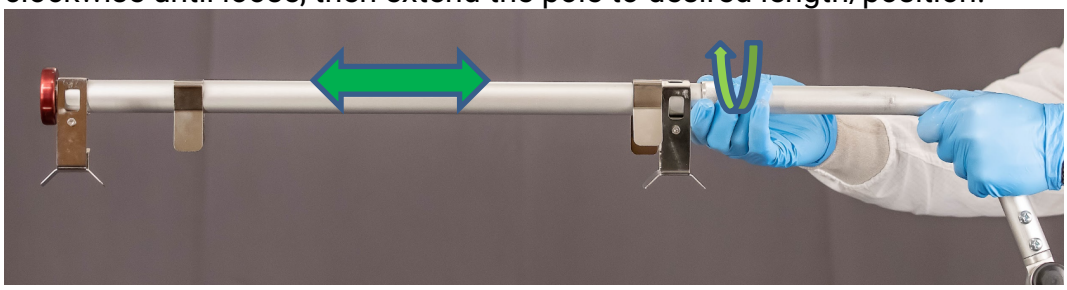
- Turn the twist lock feature by hand clock wise until snug. Do not over tighten.



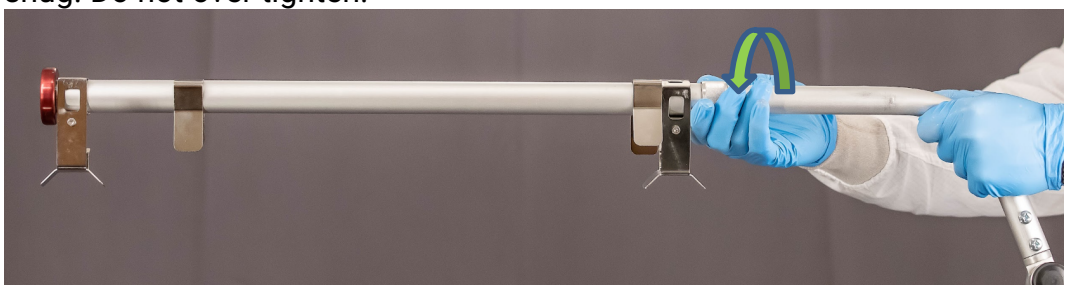


Pole Horizontal Adjustment

- Adjust the pole horizontally by turning twist lock feature by hand counter clockwise until loose, then extend the pole to desired length/position.



- After adjustment is made, turn the twist lock feature by hand clockwise until snug. Do not over tighten.



Pole Angle Adjustment

- Adjust the angle of the pole by pushing the button at the hinge point.



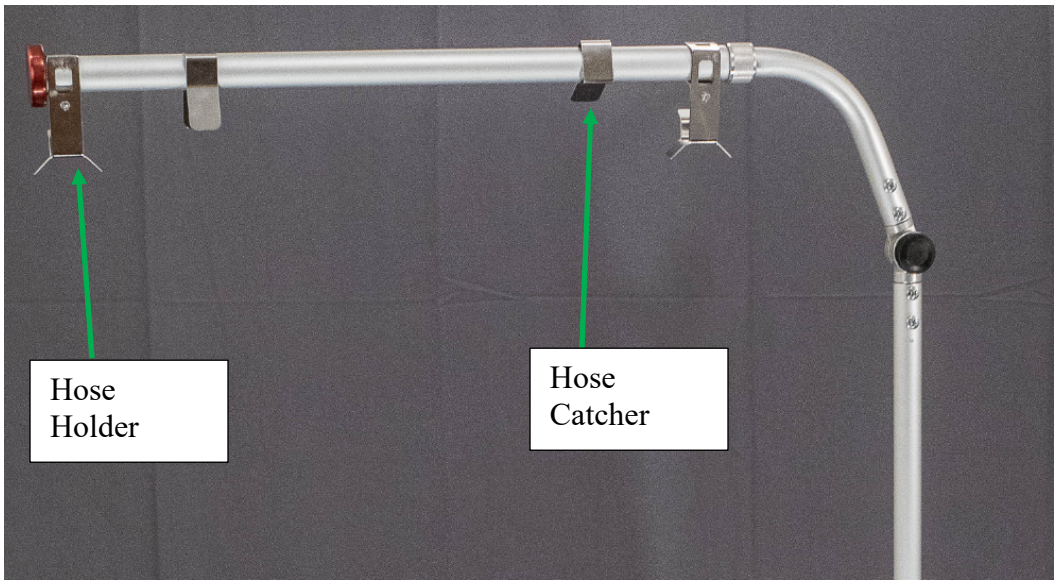
- Rotate the pole to the horizontal position.



⚠	**WARNING!** The pole is intended to support only the treatment chamber and it is not intended to support or stabilize persons.

Hose Holder and Catcher Position and Adjustment

- The hose holders contain a thumb screw and if needed can be loosened to adjust the position. If adjustments are made afterwards ensure that the thumb screw is tight.
- The hose catchers can be slid and rotated to a desired location.



Treatment Preparation

Treatment Set-up

- The final VHT-200 System configuration with a patient receiving treatment will look similar to the images below.



Foot placement



Hip/Sacral placement



Residual limb placement



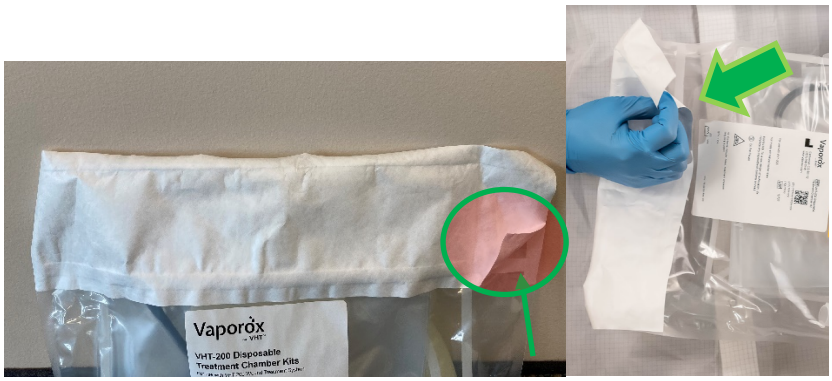
Armpit placement

Treatment Preparation

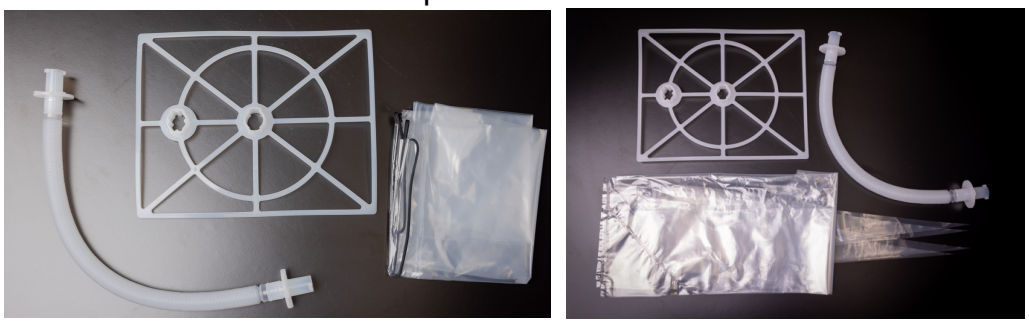
- Place the VHT-200 System in the treatment room near the patient.
- Retrieve one unopened Treatment Kit.

Treatment Chamber Bag

- Open the Tyvek side of the bagged Treatment Kit by peeling the Tyvek seal away from the bag.



- Remove all contents from the pouch.

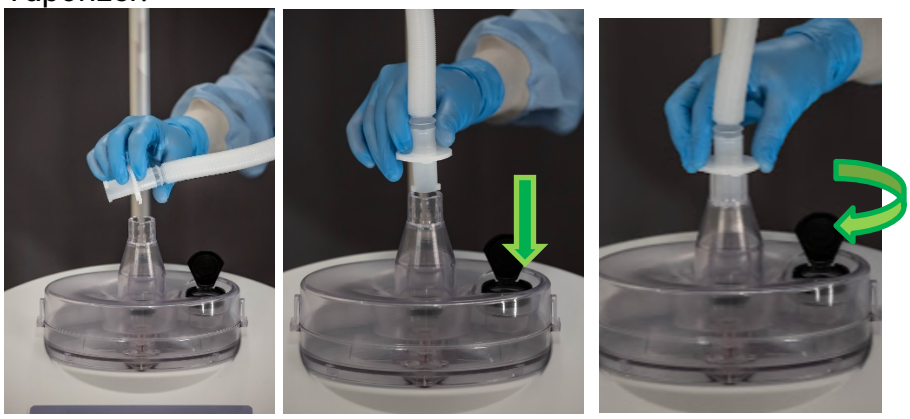


NOTE: TheTtreatment Kits must be disposed of in a sanitary manner. All components in the Treatment Kit are Single Use Only and should be disposed of properly after one use. Improper disposal may lead to cross contamination

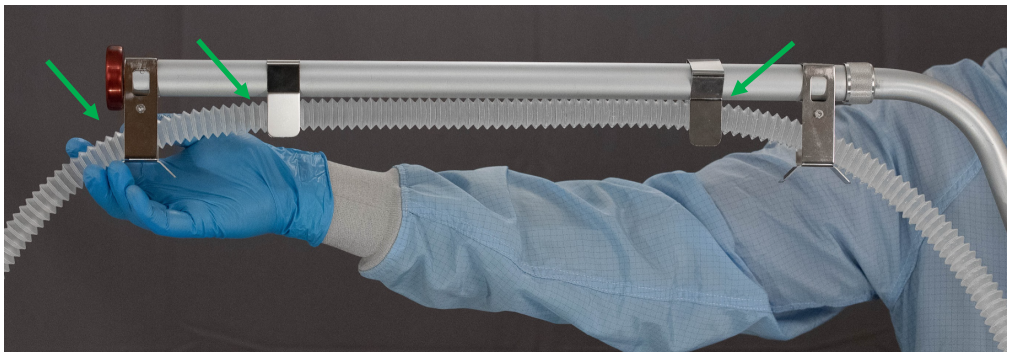
NOTE: All treatment kit components are not made with natural rubber latex.

Hose Attachment

- Take one end of the hose, align the ears of the hose connector to the Vaporizer, insert fully and twist ~90 degrees until connector locks into the Vaporizer.



- Extend the hose and route the other end into the hose holders and under the hose catchers.

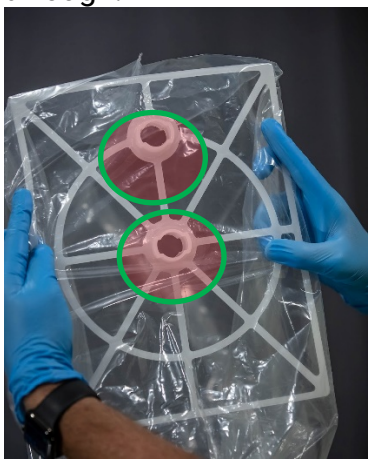


Extremity Treatment Kit Set-up

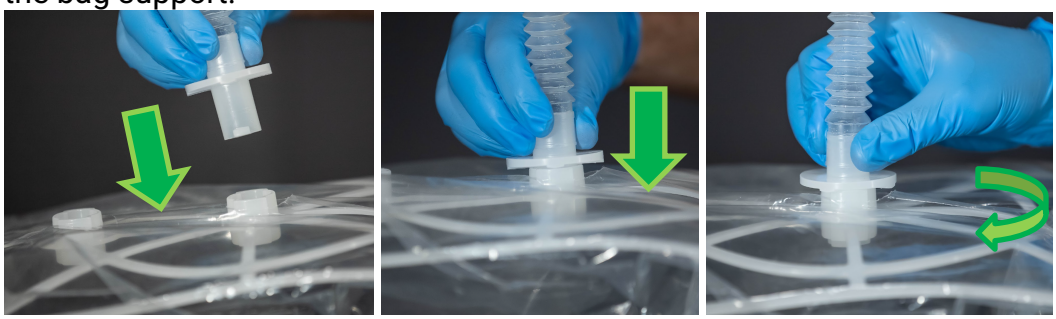
- Place one hand into the bag to open it and find the two punched holes.



- Place the bag support inside the treatment chamber bag, align the bag support bosses with the holes, insert the bosses into the bag and push through.



- Take the hose end, align the ears of the hose connector to the bag support connection point, insert fully and twist ~90 degrees until connector locks into the bag support.



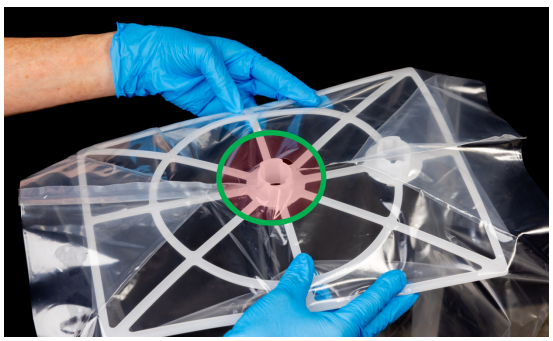
Universal Treatment Kit Set-up

- In the Universal Treatment Kit there are two options for the Bag Support Placement.



- After determining which hole to insert the bag support into place the bag support inside the universal bag, align the bag support hose boss with that hole and push through.





- Take the hose end, align the ears of the hose connector to the bag support connection point, insert fully and twist ~90 degrees until connector locks into the bag support.

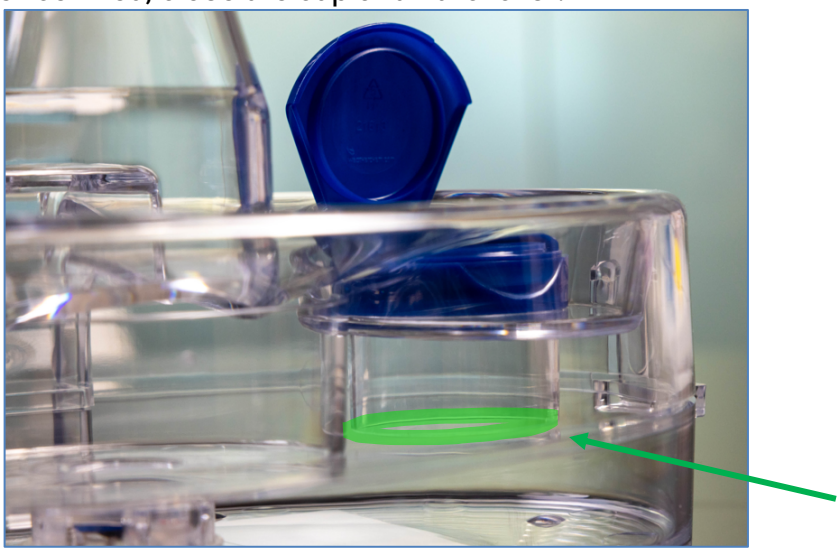




	WARNING! For treatment of wounds, this device should be used under close supervision and direction of a medical provider or professional therapist
	WARNING! The device is not intended for any use other than indicated
	WARNING! The treatment chamber kits must be disposed of in a sanitary manner. The treatment kit (hose, connectors, treatment bag and bag support) is single-use only and must be disposed of after treatment is completed.
	WARNING! Unattended use of the VHT-200 by children or incapacitated persons may be dangerous

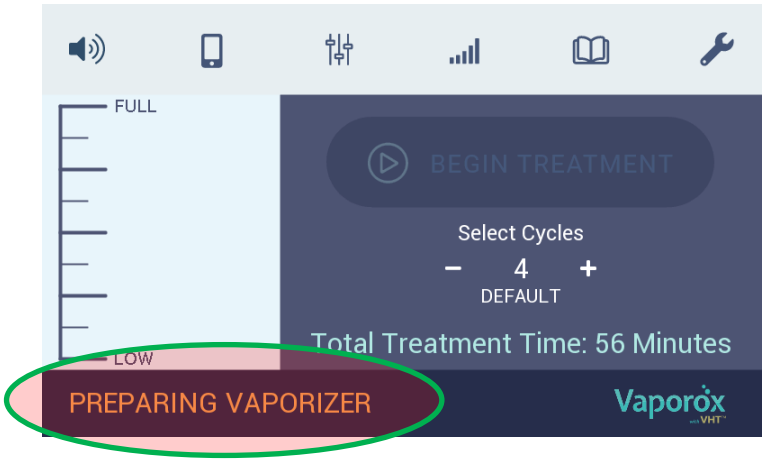
Vaporizer Fill

- Open the Vaporizer cap and fill the Vaporizer with sterile water for water for irrigation to the indicated maximum fill line, making sure to observe fluid level while filling.
- Once filled, close the cap until it “clicks”.



*NOTE: If the Vaporizer is overfilled, carefully remove the Vaporizer from the system, being careful not to spill any water, empty in a sink, place the Vaporizer back on the system (refer to **Vaporizer Installation** section above), and refill to the indicator line. If water is spilled on Equipment, soak up excess water immediately with a cloth or paper towel and clean Equipment (refer to **Cleaning** section below) before proceeding with treatment.*

Note: If the Equipment is powered on, it will begin to create mist as soon as water is added to Vaporizer and the user interface will indicate “preparing vaporizer”. This is the Vaporizer preparing for treatment and is a normal function.



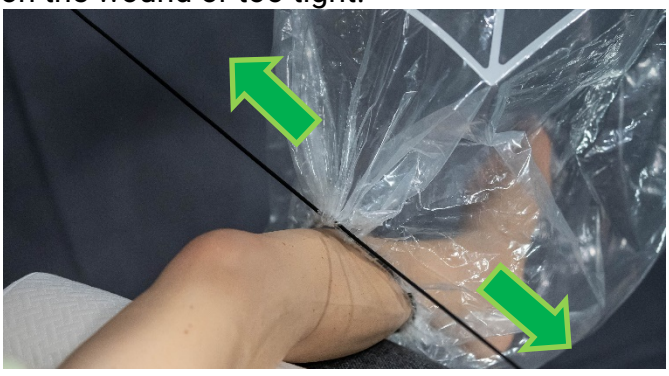
	WARNING! Avoid overfilling the solution in the Vaporizer.

Extremity Patient Setup

- Position the patient in a comfortable position on a chair or exam table.
- Adjust the VHT-200 system as needed by aligning the bag opening to the patient's foot.
- Guide the patient's foot into the Treatment Chamber, being careful not to touch the wound. Ensure that the wound is completely inside the treatment chamber.



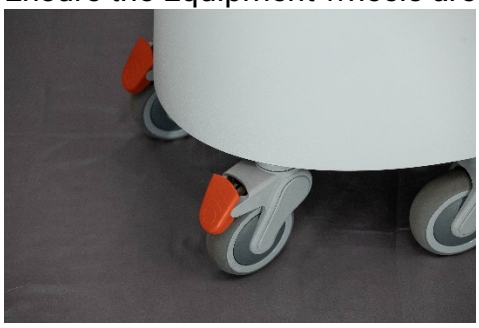
- Pull the cord ends away from the patient's leg to close the bag opening and create a snug fit around the patient's leg, making sure the cord is not cinched on the wound or too tight.



	WARNING! Spills and leaks may pose a slip-and-fall hazard. Be cautious about patient slip hazards during patient set up.
	WARNING! Do not tie or knot the draw string on treatment bag.

Limited Patient Mobility Setup

- An alternative set-up available for patients with limited mobility (per the provider's recommendations), is to place the disposable Treatment Chamber and wound area in the Basin of the System rather than in the Treatment Chamber suspended from the Pole. The alternate set-up does not use the Pole. Prepare the patient for alternate set-up treatment as follows:
- Ensure the Equipment wheels are locked.



- Unlock the Equipment unit from the Basin on both sides by lifting the latches from the hooks and releasing them down.



  - With two-people, one person lifting the handles on each side of the Equipment, lift the Equipment from the Basin and set onto the floor.





- With the Extremity Treatment Kit parts all disconnected, place the bag into the Basin with the holes in the bag located towards the back of the Basin.



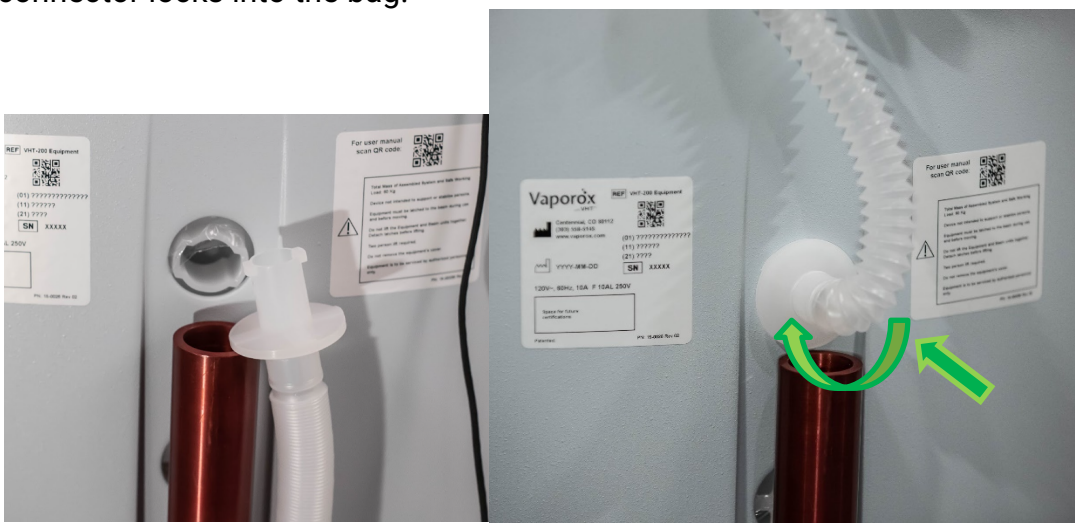




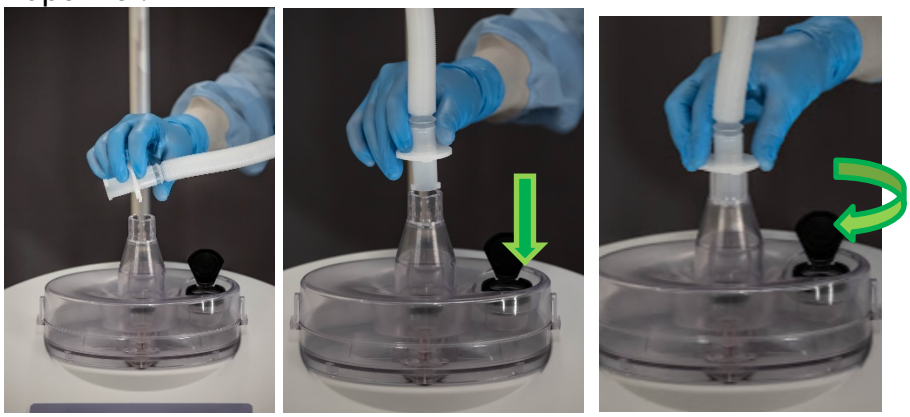
- Insert the bag support into the Basin, aligning the bag support boss to holes in bag and Basin.



- Connect the hose to the bag connector on the outside of the Basin by inserting the connector into the bag fully and twisting ~90 degrees until connector locks into the bag.



- Take one end of the hose, align the ears of the hose connector to the Vaporizer, insert fully and twist ~90 degrees until connector locks into the Vaporizer.



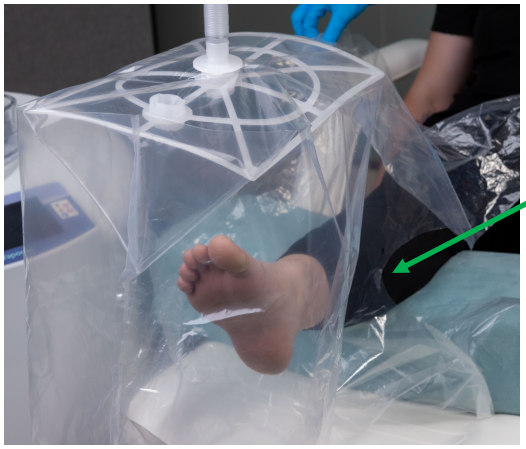
- Guide the patient's foot into the Treatment Chamber, being careful not to touch the wound. Ensure that the wound is completely inside the treatment chamber.
- Pull the cord ends away from the patient's leg to create snug fit around the patient's leg, making sure the cord is not cinched on the wound or too tight.



	**WARNING!** Spills and leaks may pose a slip-and-fall hazard. Be cautious about patient slip hazards during patient set up.
	**WARNING!** Do not tie or knot the draw string on treatment bag.

Universal Treatment Setup

- Position the patient in a comfortable position.
- Adjust the VHT-200 system as needed by aligning the bag opening to the patient's wound.
- Guide the bag opening to the patient's wound, being careful not to touch the wound. Ensure that the wound is completely covered by the bag opening.
- Below are examples of wound locations.



Universal bag use on foot wound



Universal bag use on hip/sacral wound



Universal bag use on armpit wound



Universal bag use on residual limb wound

- Wrap the universal bag flaps round the patient to close the bag opening and create a snug fit around the patient making sure the flaps are not cinched on the wound.

- Below is an example of installing the universal bag.







Treatment

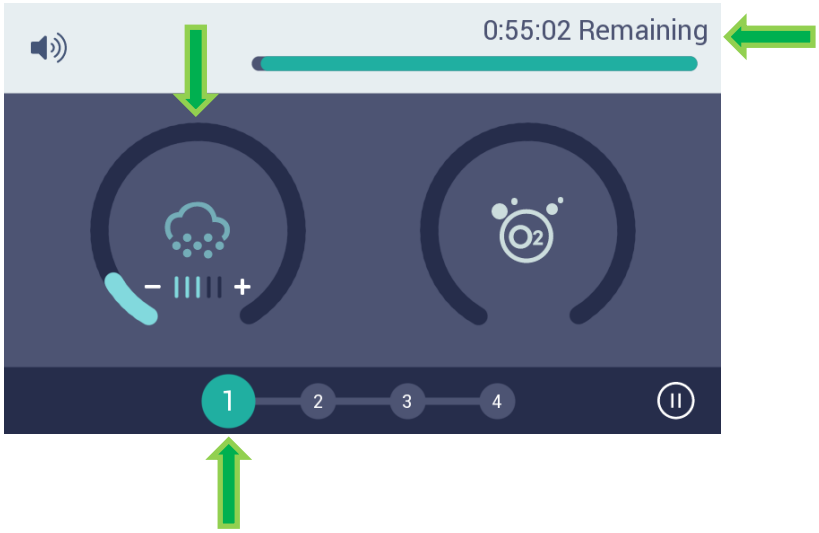
Prior to running a treatment ensure that the system has been setup properly as described in the Treatment Preparation section and that power is on. Note: the ideal treatment will leave the treated limb hydrated but not overly wet. If excess water or condensation is visible on the treated area, contact Vaporox customer support to determine whether treatment parameter refinements are recommended to optimize results.

Treatment Options

- The VHT-200 has a default treatment setting. The default setting consists of 4 cycles, 9 minutes of vapor per cycle and 5 minutes of oxygen per cycle.

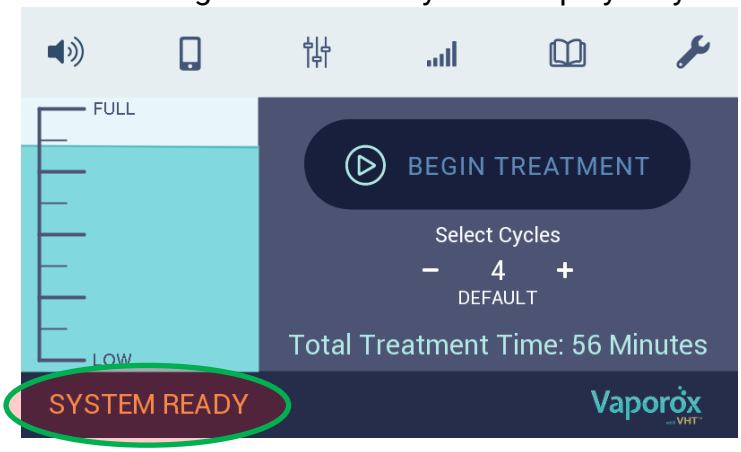


- During the treatment, the touchscreen continually displays the current treatment cycle, if vapor or oxygen is running in the cycle, and treatment time remaining.

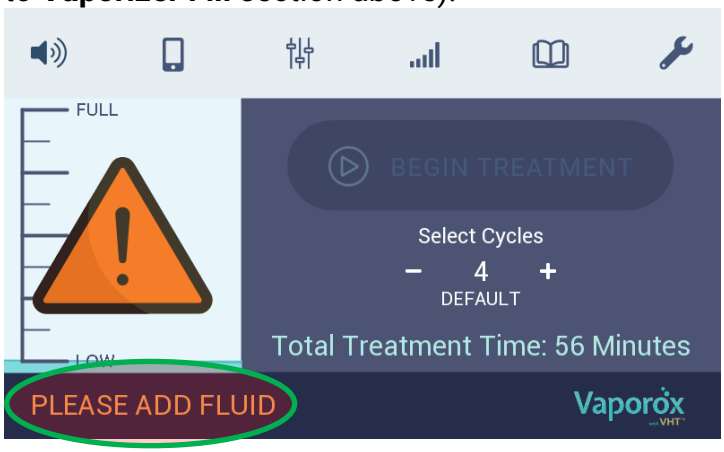


Running Default Treatment

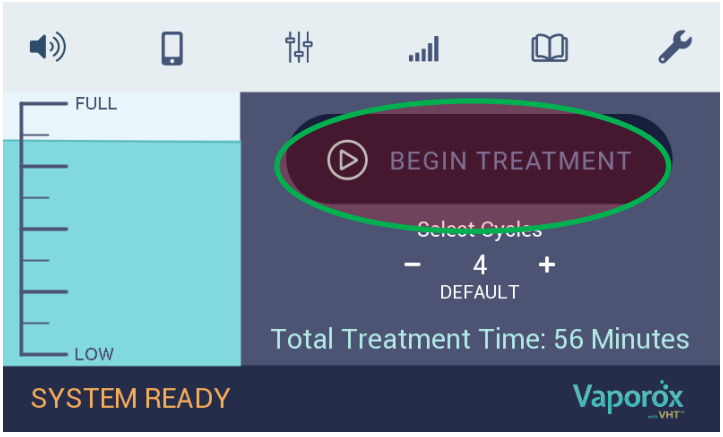
- The system is ready to run once the Vaporizer is filled with enough sterile water for irrigation and the system displays “System Ready”.



- If the Vaporizer does not have enough fluid to run the treatment, the system displays “Please Add Fluid”. Add sterile water for irrigation if necessary (refer to **Vaporizer Fill** section above).

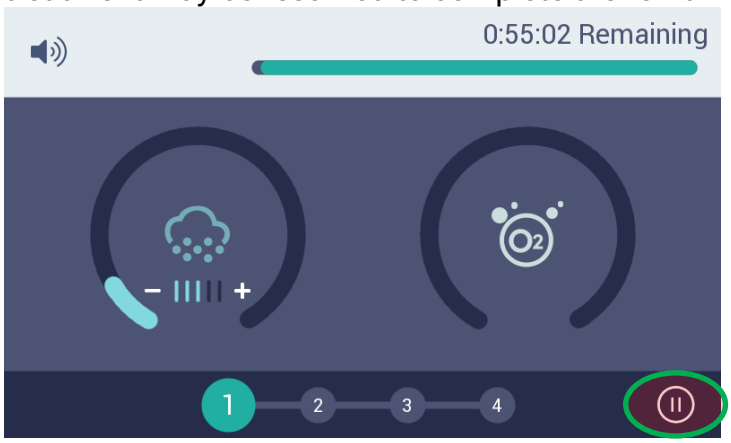


  - Touch “Begin Treatment”.



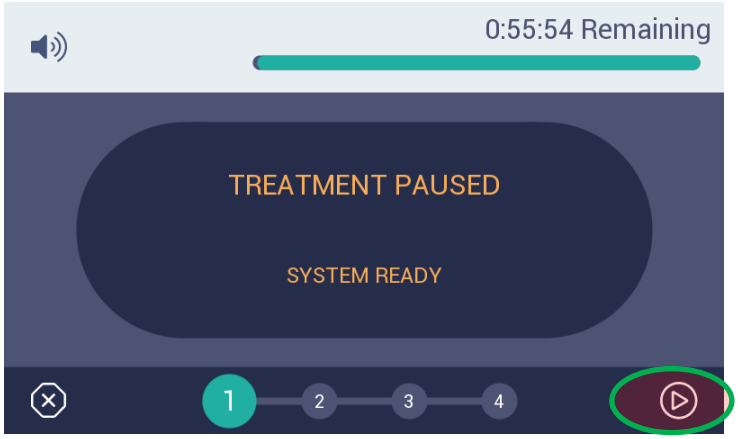
Pausing Treatment

- The treatment may be temporarily paused for any reason by touching the Pause button (⏸) on the touchscreen. During a pause in treatment, the touchscreen displays a “Treatment Paused” message. If the treatment is paused, the System maintains the status of the current treatment and the treatment may be resumed to complete the remainder of the full treatment.

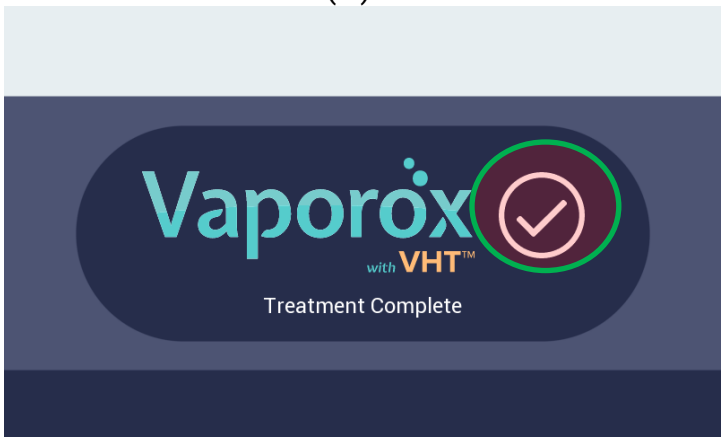


Resuming Treatment

- Before resuming treatment after pausing, ensure the patient limb and the Treatment Chamber are properly positioned. Press the Resume button.

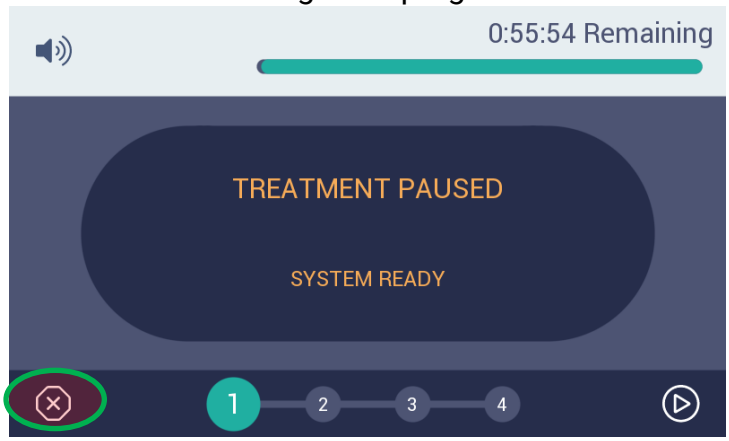

0:55:54 Remaining
TREATMENT PAUSED
SYSTEM READY
1
2
3
4

- Once the treatment is complete a “Treatment Complete” screen will appear. Select the check mark (✓) in the box to return to the home screen.



Ending Treatment

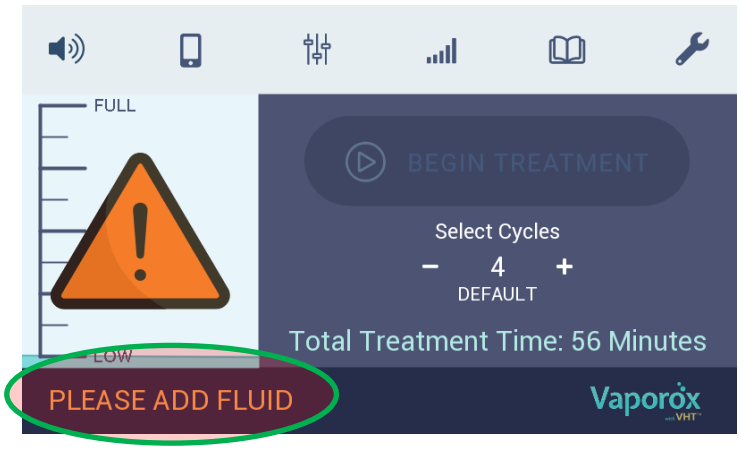
- The treatment may be ended for any reason by touching the end treatment button on the touchscreen after pausing. If the treatment is ended, the current treatment and settings and progress are cancelled and cannot be resumed.



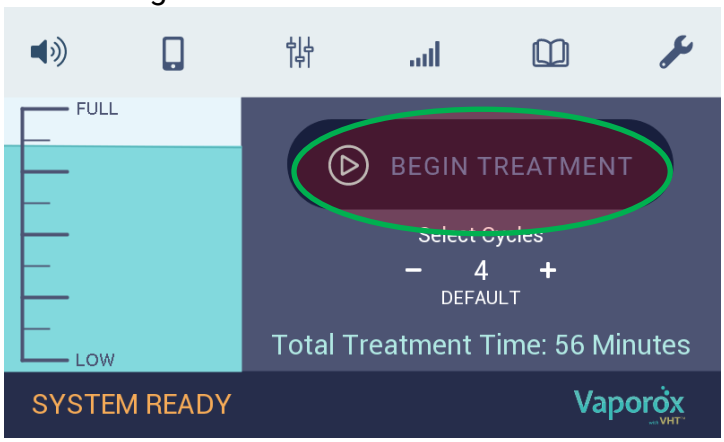
NOTE: The System can be safely powered OFF at any time by using the ON/OFF switch to the left of the touchscreen.

Running Modified Default Treatment

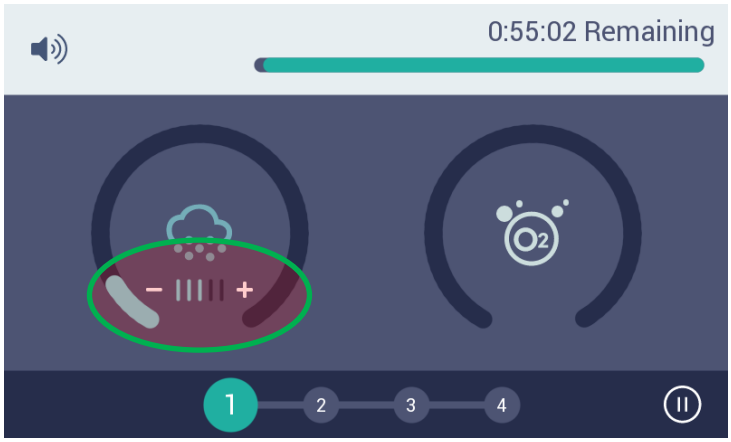
- Confirm the Vaporizer is filled with enough water by checking the fluid fill level on the left side of the touchscreen.
- If the Vaporizer does not have enough fluid to run the treatment, a warning of “Pease Add Fluid” appears. Add more sterile water for irrigation if necessary (refer to **Vaporizer Fill** section above).



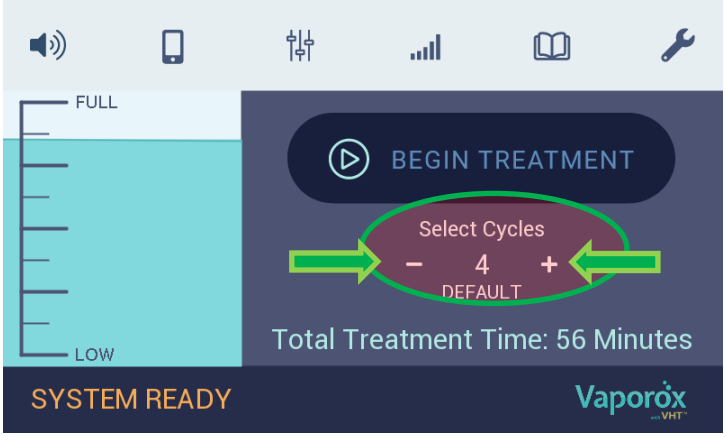
- Touch “Begin Treatment”.



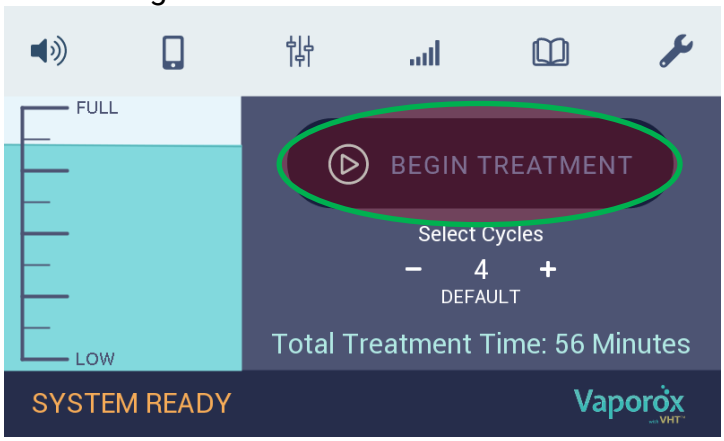
- To change the Vaporizer flow control level, touch the indicator bars under the Vapor status. Press the (+) to increase the Vapor amount or (-) to decrease the Vapor amount.



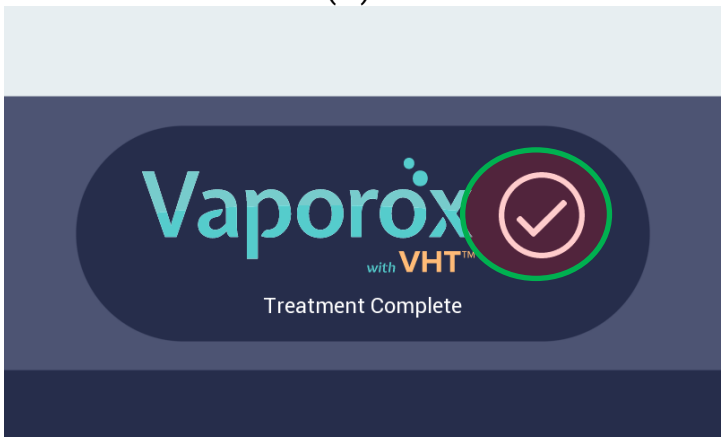
- The default treatment setting will automatically be set to four treatment cycles. If a different number of treatment cycles is desired, select the - or + to either increase or decrease the number of treatment cycles on the touchscreen.



- Touch “Begin Treatment” button.



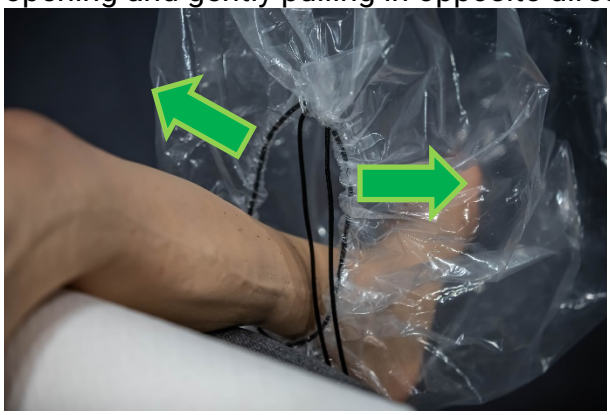
- Once the treatment is complete a “Treatment Complete” screen will appear. Select the check mark (✓) in the box.



Post Treatment Activity

Extremity Treatment Kit Patient Removal

- Loosen the bag cord around patient's leg by placing fingers inside the opening and gently pulling in opposite directions.



- Remove the Treatment Chamber from the patient's foot and leg being careful not to touch the wound and being careful to contain any moisture inside the treatment bag. Once removed, cinch the cord to close the empty bag.
- Post treatment care should follow providers discretion.

Universal Treatment Kit Patient Removal

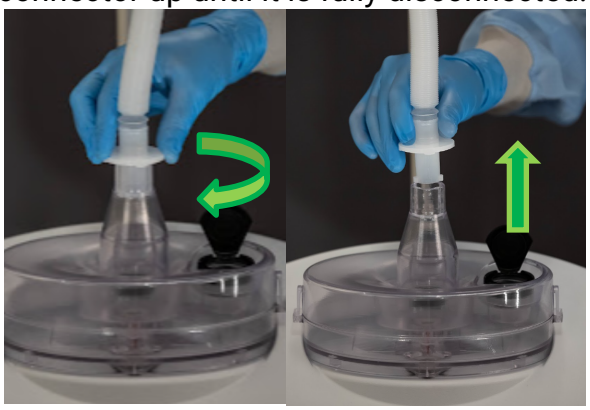
- Loosen the bag flaps around patient by gently pulling on the flaps



- Remove the bag from the patient being careful not to touch the wound and being careful to contain any moisture inside the bag. Once removed, cinch the flaps to close the empty bag.
- Post treatment care should follow providers discretion.

Treatment Kit Removal and Disposal

- Disconnect the hose from the Vaporizer by twisting the hose connector ~90 degrees until connector unlocks from the Vaporizer. The pull the hose connector up until it is fully disconnected.



- Properly dispose of the Treatment Chamber bag and hose, being careful to contain any moisture inside the bag.

	**WARNING:** The treatment chamber kits must be disposed of in a sanitary manner. Always dispose of the Disposable Treatment Chamber accessories immediately as a single use and do not reuse disposables. Improper disposal may lead to cross contamination.

Shutting Down System

- Power OFF the Equipment by selecting the “O” on the ON/OFF switch next to the touchscreen.



- Disconnect the power cord from the power outlet.

- Fold the Pole down by pushing the button at the hinge point Pole hinge and folding the arm down until the two Pole segments are parallel to each other.





	**WARNING:** Retract the pole when not in use.

Cleaning

The VHT-200 should receive regular cleaning to prevent bacterial growth.

Equipment, Basin, Pole Cleaning Solutions

- Clorox® Disinfecting wipes
- Sani-Cloth Plus Germicidal Disposable Cloth
- Mild Soap and water.

Equipment, Basin, Pole Cleaning Process

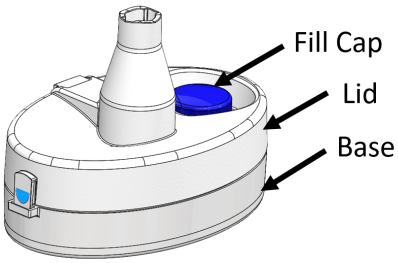
1. Thoroughly wipe all outer surfaces of the system with one recommended cleaning solution as listed above and allow to dry between treatments.
2. If the Basin was used for the Limited Patient Mobility setup, thoroughly wipe all inside surface of the basin with one recommended cleaning solution as listed above and allow to dry between treatments.

Vaporizer Cleaning Solutions

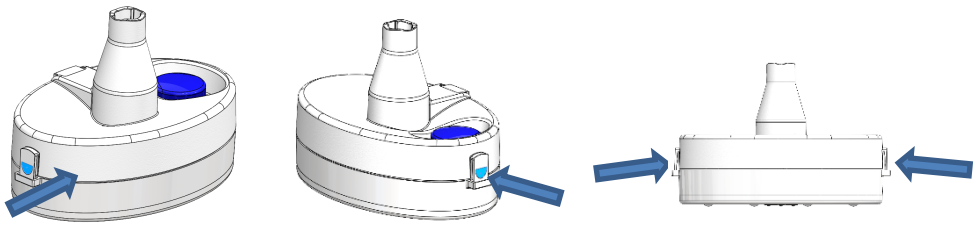
- Mild dishwashing detergent
  Note: Dawn® Ultra Dishwashing Liquid was used in the cleaning validation.

Vaporizer Cleaning Process

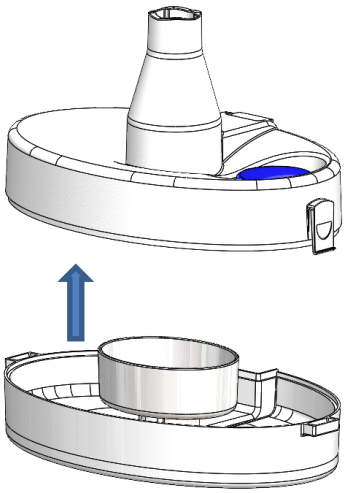
1. Wear medical grade gloves while handling and cleaning the Vaporizer and Vaporizer components.
2. At the end of every day of use, remove the Vaporizer and empty any remaining water into a sink.
3. The Vaporizer is composed of three components as shown below.



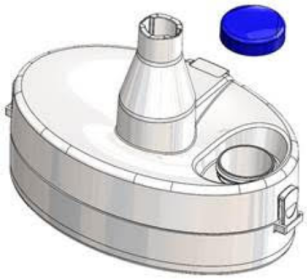
4. Disassemble the two Vaporizer components as follows:
   a. Push in on both tabs of the Vaporizer lid.



b. With both tabs pushed in, pull and detach the lid of the Vaporizer from the base.



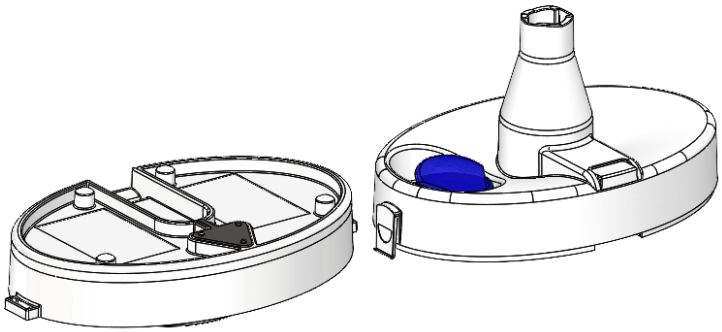
c. Unthread and remove fill cap from vaporizer lid, and drain remaining liquid into a sink.



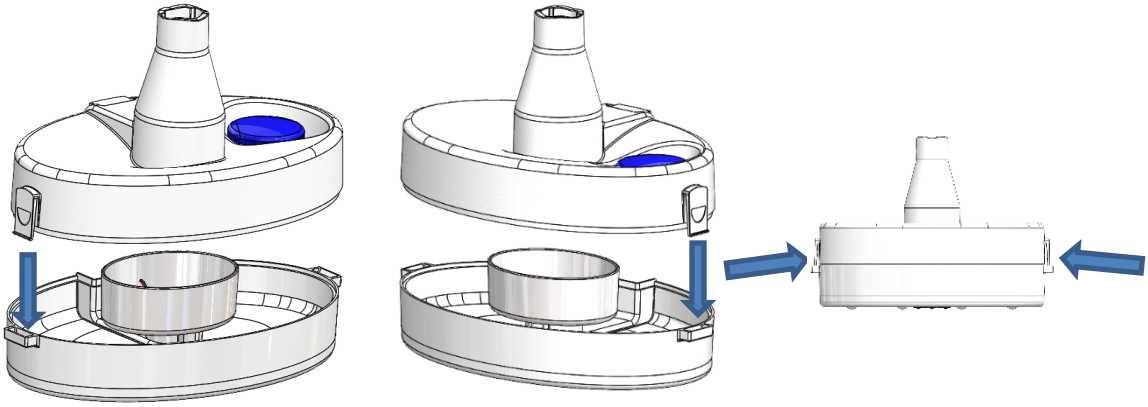
5. Clean each Vaporizer component separately as described below.
   6. Mix 1 teaspoon (5 milliliters) mild dishwashing detergent in 1 gallon (3.8 liters) of room-temperature (20-25ºC) utility (tap) water.
   7. Submerge vaporizer lid and fill cap in mild dishwashing detergent solution in a basin. Open fill cap hinge and brush all water-contacting surfaces of the vaporizer with a soft, nylon brush, paying special attention to the hinge and threading of the fill cap as well as any crevices, recesses, lumens, openings, or gaskets in the vaporizer lid. Brush for a minimum of 1 minute.
   8. Dampen a lint-free cloth (not dripping) with the mild dishwashing detergent solution and wipe the interior water-contacting surfaces and exterior of the vaporizer base, paying special attention to any crevices, recesses, lumens, openings or gaskets. Wipe, for a minimum of 1

minute. Note: Do not submerge vaporizer base containing electronics in liquid.

9. Brush all interior water-contacting surfaces of the vaporizer base with a soft, nylon brush, paying special attention to any crevices, recesses, lumens, openings, or gaskets. Brush for a minimum of 1 minute. Note: Do not submerge vaporizer base containing electronics in liquid.
10. Rinse all components of vaporizer lid and base, including separate fill cap, under running, room-temperature (20-25ºC) utility (tap) water while rotating and turning the components for 1 minute each to remove detergent residue. Note: Do not submerge vaporizer base containing electronics in liquid.
11. Rinse all components of vaporizer lid and base, including separate fill cap, with room-temperature (20-25ºC) sterile water for irrigation (i.e., treatment water) in a sink while rotating and turning the components for 15 seconds each. Note: Do not submerge vaporizer base containing electronics in liquid.
12. Apply 70% v/v Isopropyl Alcohol (IPA) by spray to saturate the interior water-contacting surfaces and exterior of the vaporizer lid and base, including separate fill cap, paying special attention to the hinge and threading of the fill cap as well as any crevices, recesses, lumens, openings, or gaskets in the vaporizer lid and base.
13. Allow surfaces to remain wet with IPA for a minimum of ten (10) minutes. Re-apply 70% IPA if surfaces become dry, paying special attention to the hinge and threading of the fill cap as well as any crevices, recesses, lumens, openings, or gaskets in the vaporizer lid and base.
14. Rinse all components of vaporizer lid and base, including separate fill cap, with room-temperature (20-25ºC) sterile water for irrigation (i.e., treatment water) in a sink while rotating and turning the components for 15 seconds each.
15. Shake vaporizer lid and base, including separate fill cap, to remove excess liquid, dry with lint-free cloth, and spray apply 70% IPA to, paying special attention to the hinge and threading of the fill cap as well as any crevices, recesses, lumens, openings, or gaskets in the vaporizer lid and base the challenge areas. Set the components on a flat surface covered with clean and dry lint-free cloths in the orientation with inner water-contacting surfaces facing downwards towards the cloths. Let the components air-dry for a minimum of 2 hours.
16. Perform a visual inspection, paying special attention to the hinge and threading of the fill cap as well as any crevices, recesses, lumens, openings, or gaskets in the vaporizer lid and base. Inspect the device for any signs of soil and confirm device has dried before reassembly of vaporizer lid and fill cap with base. If soil is observed, repeat steps 6 –



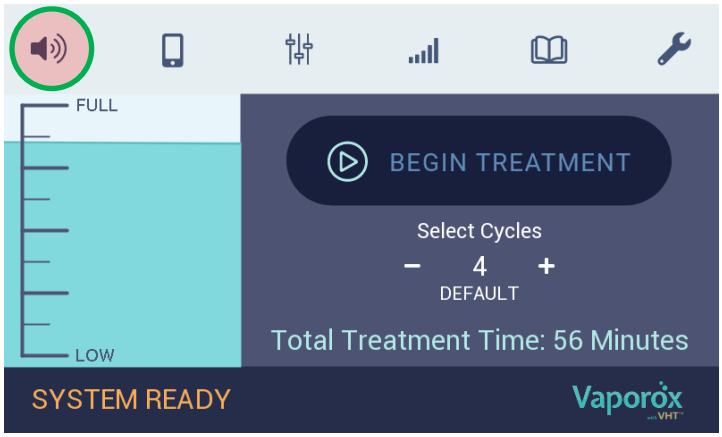
17. Once dry, visually inspect the Vaporizer components for damage or degradation. If any area appears to be damaged or degraded, do not use components and contact Vaporox customer support for a replacement.
18. Reassemble the Vaporizer components by align the end snap features and gently pressing the components together until an audible snap is either heard or felt.



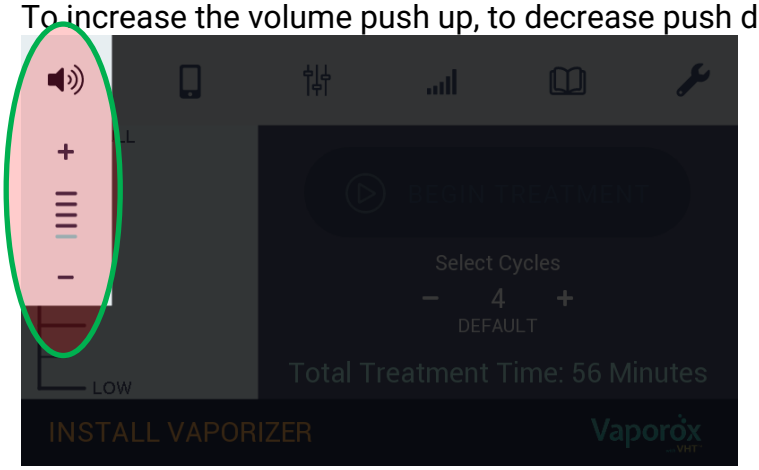
User Interface Menus

Volume/ Sound

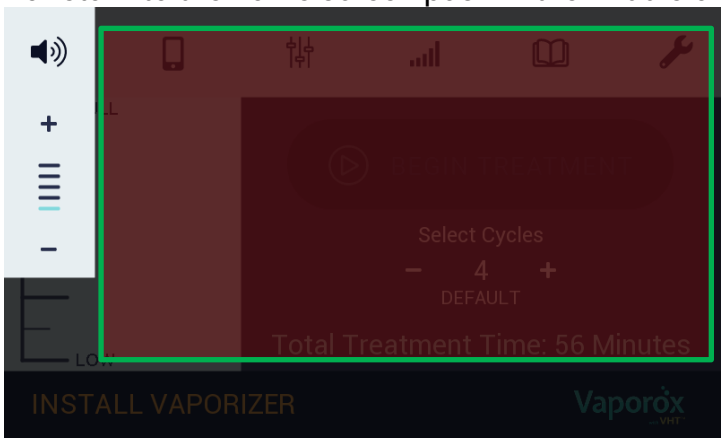
- To adjust the Volume of the Equipment, push the Volume icon at the top of the home screen



- To increase the volume push up, to decrease push down.

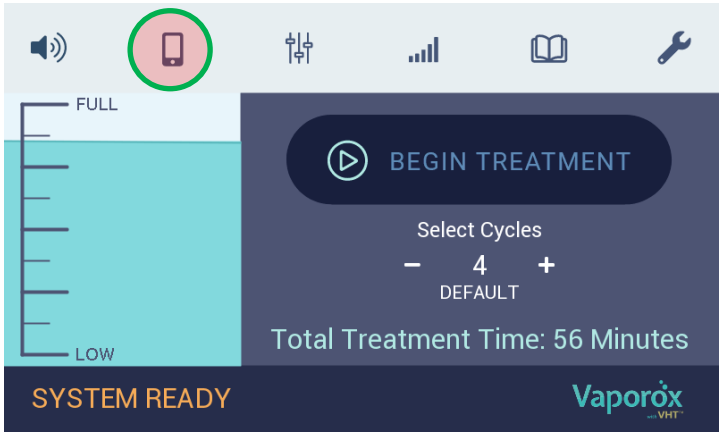


- To return to the home screen push in the middle of the screen.



Mobile App

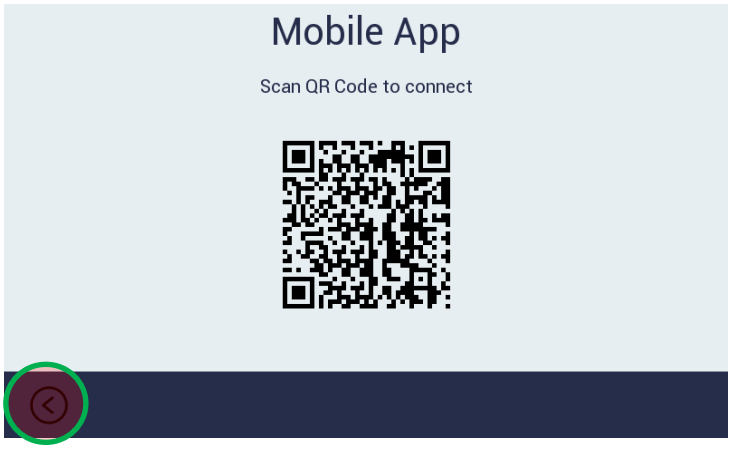
- To connect to the Mobile App push the Mobil App icon at the top of the home screen.



- Scan the QR connect to connect to the Mobile App.

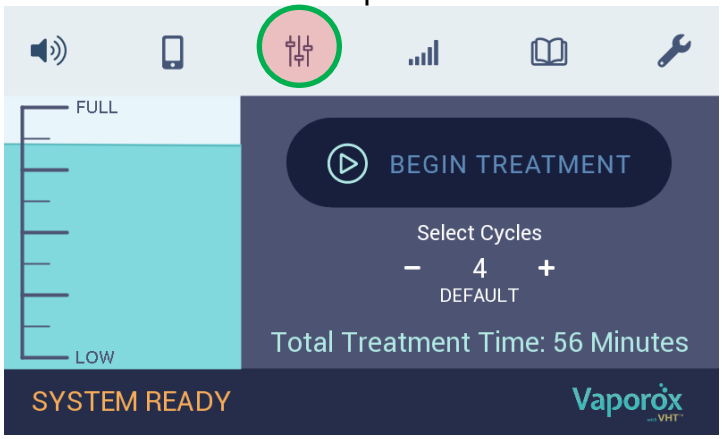


- To return to the home screen select the back button



Treatment Parameters

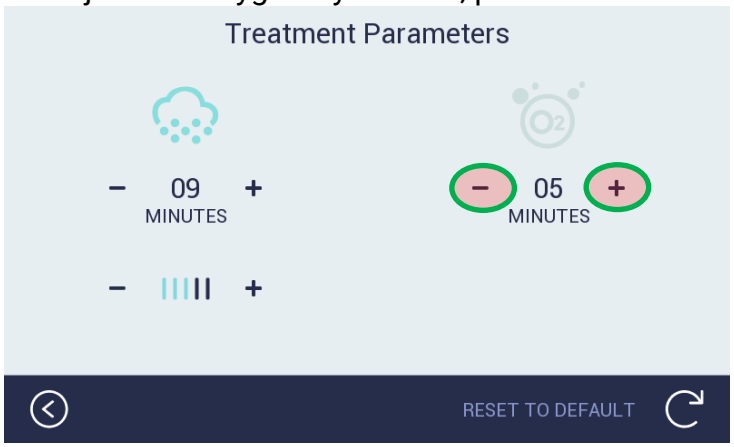
- To display and change the Treatment Parameters push the Treatment Parameters icon at the top of the home screen.



- To adjust the Vapor Cycle time, push the – or + below the Vapor graphic



- To adjust the Oxygen Cycle time, push the – or + below the Oxygen graphic



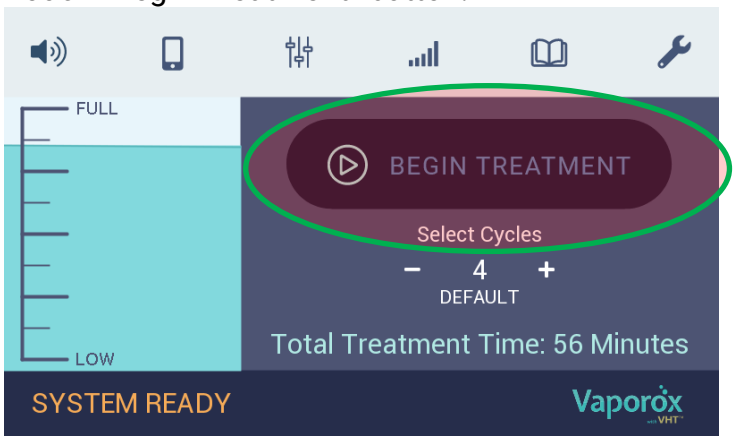
- To reset the treatment parameters back to default, select the RESET TO DEFAULT arrow.



- To return to the home screen select the back button.



- Touch “Begin Treatment” button.



- Once the treatment is complete a “Treatment Complete” screen will appear. Select the check mark in the box.

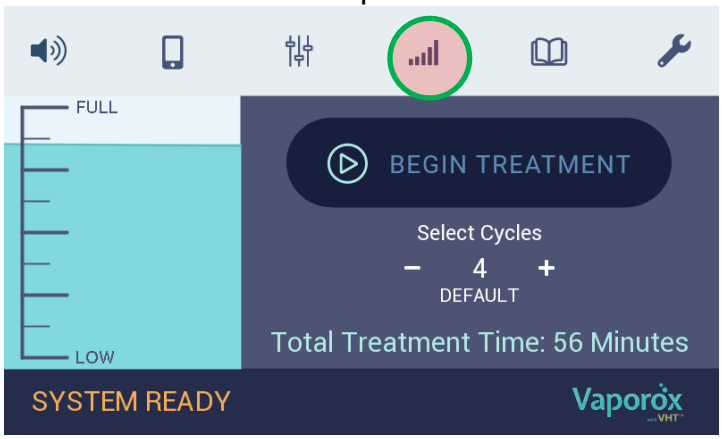


Note: The system calculates the total treatment time needed to complete all cycles, and this time varies depending on the custom treatment parameters selected. During the treatment, the touchscreen continually displays the current

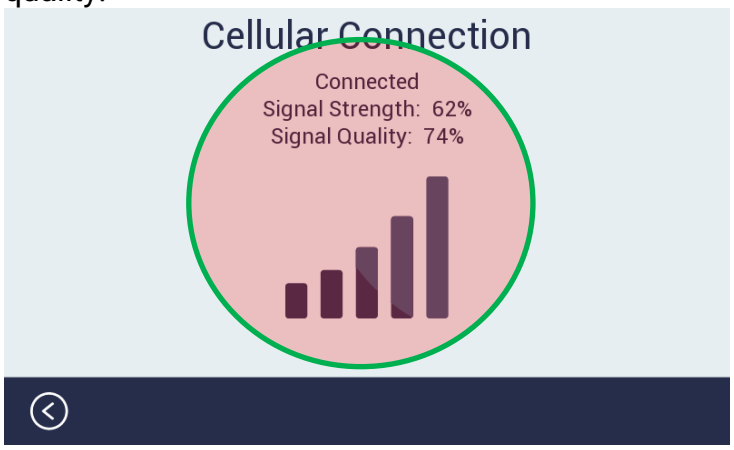
treatment cycle, the current treatment cycle type (vapor or oxygen) and treatment time remaining.

Cellular Connection

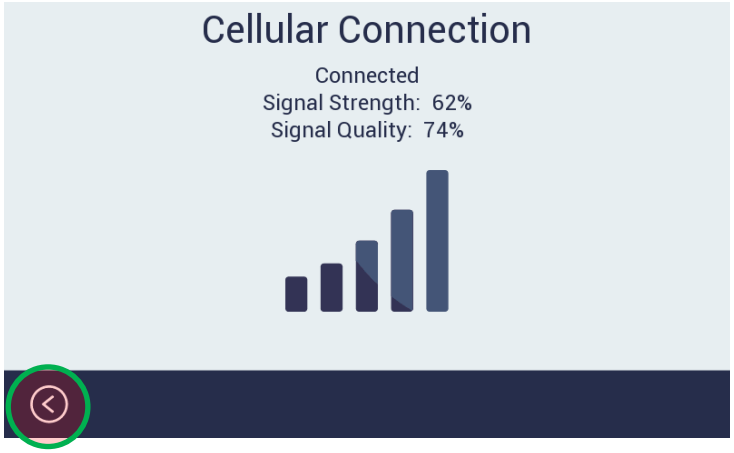
- To display Cellular Connection status, strength and quality push the Cellular Connection icon at the top of the home screen.



- The cellular connection screen displays connection status, strength and quality.

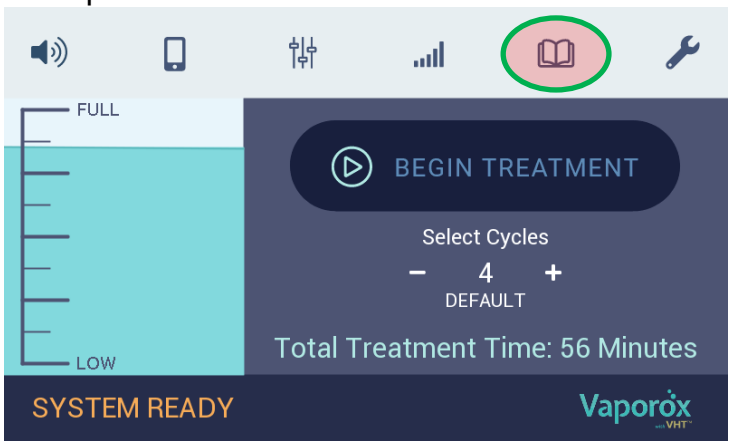


- To return to the home screen select the back button

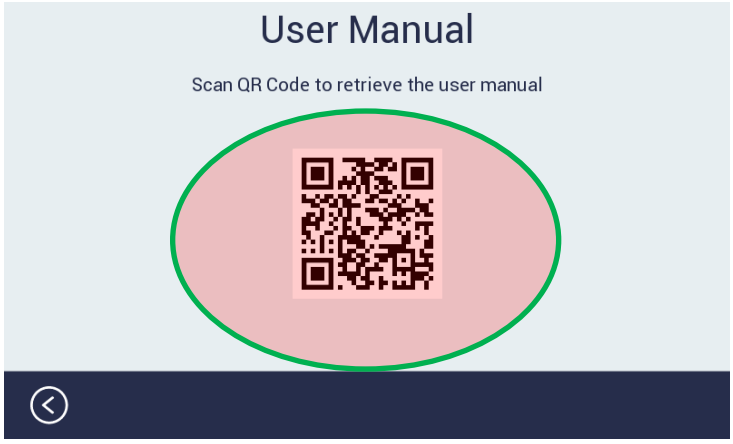


User Manual

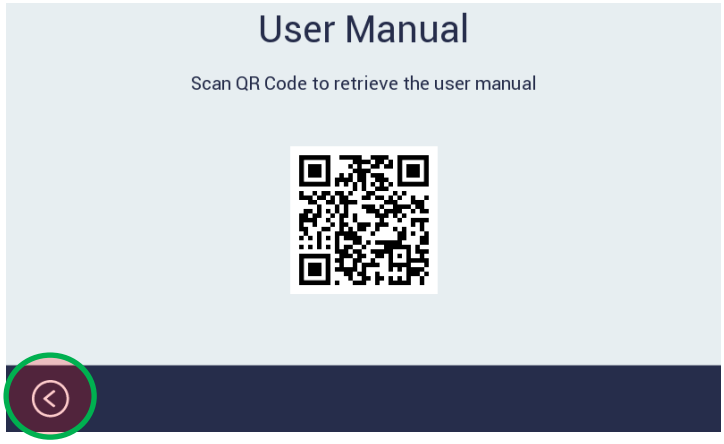
- To access the latest version of the user manual, push the User Manual icon at the top of the home screen



- Scan the QR code for access to the latest user manual

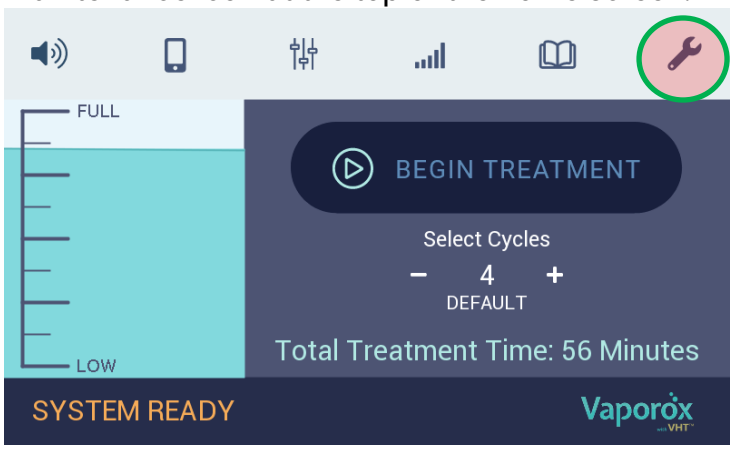


- To return to the home screen select the back button

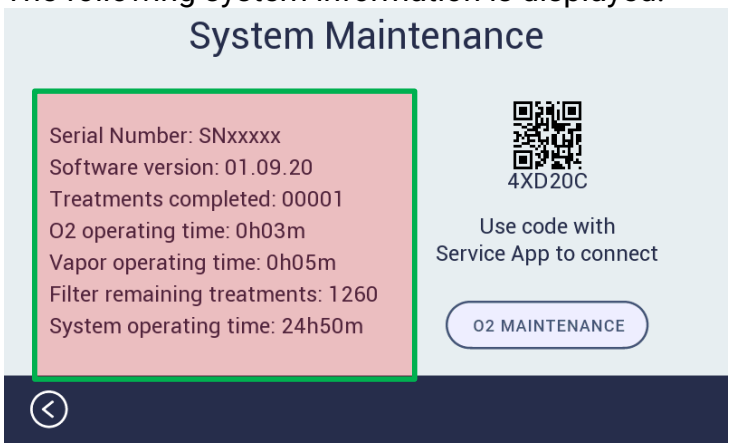


System Maintenance

- To access the System Information and O2 Maintenance function, push the Maintenance icon at the top of the home screen.



- The following system information is displayed.

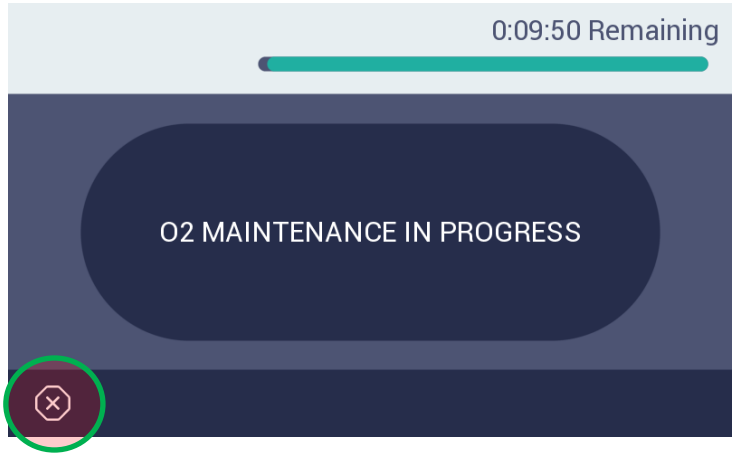


Note: The 2D barcode is only to be used during service and is not required for normal operation.

- To run the O2 maintenance cycle push the O2 MAINTENANCE button.



- The O2 maintenance will run for 10 minutes. To cancel at any time press x.



- To return to the home screen select the back button.



	**WARNING:** If patient shows any discomfort or pain during the treatment, stop the treatment immediately.
	**WARNING:** Greater than 22mm Hg of mercury oxygen pressure in chamber may occlude arterial circulation, which may lead to a decrease in local tissue circulation.
	**DANGER:** Equipment may cause or intensify fire. An oxidizing material may or may not burn itself, but will release oxygen or another oxidizing substance, thereby causing or contributing to the combustion of another material. If a fire or spark is detected, immediately turn the on/off switch to the off position, if possible, unplug the equipment from the outlet and evacuate the area.
	**Do not smoke near the system.**

Maintenance

Software updates shall be performed over the air by Vaporox, Inc. as required. Software release notes and new version being updated to will be communicated by Vaporox, Inc. prior to the upgrade.

Once an over the air software update occurs the following screen will appear after a power cycle of the device notifying the user when to finalize the software upgrade. To finalize the software update, select "Update", to finalize the software update later select “Later”. The user will be prompted to update the software after each power cycle until the “Update” is selected.



Other than periodical software updates and cleaning no other regular maintenance of the VHT-200 System is necessary by the user. Vaporox, Inc. or an authorized service provider will perform all other maintenance and service duties not referenced in this manual, if necessary.

The expected service life of the VHT-200 System including the Equipment, Basin and Pole is one year. The expected service life of the VHT-200 Vaporizer is three months. The expected service life of the VHT-200 Treatment Chamber is a single treatment. The Equipment and accessories must be properly disposed of in accordance with local and federal laws.

⚠	**WARNING:** No user serviceable parts are inside the VHT 200. Equipment enclosure should only be opened by an authorized service provider.
ⓘ	NOTE: Periodically running the VHT-200 System is required to preserve the life of the oxygen concentrator. Run the O2 Maintenance function once per week (if the system has not been used) to preserve the life of the oxygen concentrator
ⓘ	NOTE: Periodically check the power cord for damage (fraying, cuts, scrapes etc.).
ⓘ	NOTE: No lubricants other than those recommended by the manufacturer are to be used

Transport Configuration

The VHT-200 is designed to be stored in a clinical setting or treatment room. When moving the VHT-200 System between rooms or within the office environment:

- Power OFF the Equipment by using the ON/OFF switch to the left of the touchscreen.
- Disconnect the power cord from the power outlet.
- Ensure the Vaporizer has been emptied of any water.
- Ensure the Equipment is latched to the Basin via the two latches located on the sides of the Basin (refer to **Equipment to Basin Installation** section above).
- Fold the Pole down by pressing on the incremental Pole hinge and folding the arm down until the two Pole segments are parallel to each other.
- Unlock all wheels before moving.
- Move the device by pushing from either side of the System using the handles.
- When the machine is at its final location, lock at least two wheels when the device is in use to prevent movement when placing the patient's limb in the device and reposition the Pole as desired.

NOTE: Do not push the device from the front or back direction, only push from the left or right side using the handles.

NOTE: Ensure wheel locks are set when in storage.

Troubleshooting

- Prior to contacting Vaporox Technical Support, please read the troubleshooting table below.
- Replacement of any failed module of the VHT-200 system starts by contacting Vaporox, Inc. and requesting for a replacement item and having it shipped to the user. This applies to the replacement of: Vaporizer, Pole, Basin, or Power Cord.
- When physically replacing the component, the removal of the item is performed in the reverse manner as the instructions listed in the **Treatment Preparation** section. Then, when the replacement item is received, the system shall be set back up in the exact same manner following the instructions in the **Treatment Preparation** section.

Troubleshooting Table

Symptom	Possible Cause	Corrective Action
No Power VHT-200 does not turn on	VHT-200 not connected to power source	Ensure the power cord is properly connected to power

		source and the VHT-200.
	No power at outlet	Check the outlet by connecting to another electrical unit known to be working. If unit does not work, relocate VHT-200 to a functioning electrical outlet.
	Power switch turned OFF	Ensure the power switch is in the “on” position.
	Blown fuse	Replace fuses (see section for Fuse Replacement).
No flow during oxygen cycle	Compressor malfunction	Contact Vaporox Technical Serives.
No vapor during vapor cycle	Loose hose connection	Ensure hose is inserted snugly into the Vaporizer.
	Vaporizer not properly installed	Confirm the Vaporizer is connected to the Top Equipment Unit with a snug fit.
	Vaporizer empty	Confirm the Vaporizer still has sterile water for irrigation in it. Remove the cap to observe level if needed.
	Vaporizer malfunction	Contact Vaporox Technical Services.
VHT-200 is not responding	Touchscreen malfunction	Turn power OFF and turn power back ON to reset the system.

User Interface Messages and Resolutions:

Symptom Displayed	Possible Cause	Corrective Action
Please Add Fluid	Vaporizer empty or does not have enough sterile water for irrigation to perform a treatment.	Add fluid to the Vaporizer according to instructions in Preparing for Treatment.
Install Vaporizer	No Vaporizer located on the machine or Vaporizer connection to the Equipment was interrupted or jostled.	Remove and replace the Vaporizer ensuring it is seated fully on top of the Equipment Module.
Vaporizer Overfilled	Vaporizer has been overfilled with sterile water for irrigation.	Empty and refill the Vaporizer according to instructions in Preparing for Treatment.
System Fault State -Flow sensor test (zero flow) : 0x00000040, "Flow sensor test failure." -Flow sensor test (maximum flow) : 0x00000080, "Flow sensor test failure." -Low oxygen flow detected : 0x00000100, "Oxygen flow malfunction detected." -High oxygen flow detected : 0x00000200, "Oxygen flow malfunction detected." -Low oxygen concentration fault : 0x00000400, "During the last treatment oxygen level dropped below acceptable performance." -Vapor crystal low current: 0x00000004, "Vaporizer malfunction detected. Please check the vaporizer's connection and cycle power." -Vapor crystal high current: 0x00000002, "Vaporizer malfunction detected. Please check the vaporizer's connection and cycle power." -Vapor crystal high current when idle: 0x00000001, "Vaporizer malfunction detected. Please check the	Unexpected operation or software condition has occured internally to the VHT-200 System.	Power cycle the device and see if the fault clears, if it does not, call Vaporox, Inc Tech support for help trouble shooting.

Symptom Displayed	Possible Cause	Corrective Action
vaporizer's connection and cycle power." -Pump crystal low current: 0x00000020, "Vaporizer malfunction detected. Please check the vaporizer's connection and cycle power." -Pump crystal high current: 0x00000010, "Vaporizer malfunction detected. Please check the vaporizer's connection and cycle power." -Pump crystal high current when idle: 0x00000008, "Vaporizer malfunction detected. Please check the vaporizer's connection and cycle power." -Intake fan stalled: 0x00000800, "Internal fan stall detected." -Exhaust fan stalled: 0x00001000, "Internal fan stall detected." -Compressor fan stalled: 0x00004000, "Internal fan stall detected." -Heat exchanger fan stalled: 0x00002000, "Internal fan stall detected." -Blower stalled: 0x00008000, "Internal fan stall detected."		
Low oxygen was detected during this treatment	Oxygen Concentrator is failing, compressor is failing, O2 Sensor is bad.	Contact technical support. NOTE: Device is ok to continue to use on patients.
VHT-200 filter needs to be changed soon. “XXX” treatments of use remain. Please contact Vaporox service."	Device filter will need service soon.	Contact technical support. NOTE: Device is ok to continue to use on patients.
Filter expired – machine disabled	Device filter needs service.	Contact technical support. Device will not operate.

Part Replacement

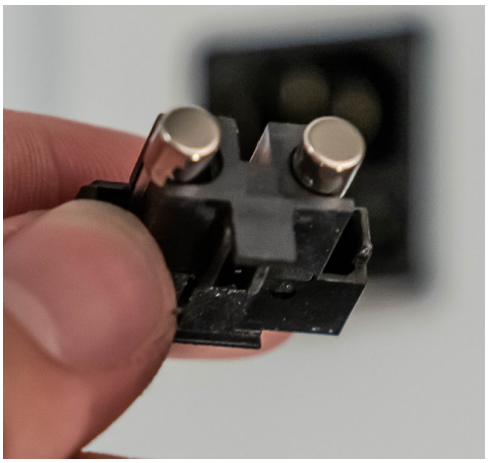
Fuse Replacement

The power outlet on the side of the VHT-200 Equipment houses a fuse compartment, which contains two active 250V / 10A fuses that may need to be replaced periodically. Replace fuses as follows:

- Power OFF the Equipment and disconnect the AC power cord from the wall (refer to **System Power Connection** section above).
- With a small screwdriver, gently remove the fuse compartment on the power module and replace the bad fuse.

NOTE: A new fuse may be stored in the small sliding compartment of the fuse holder. Always keep a spare fuse in the compartment to ensure a replacement is readily available.





- Insert the fuse holder into the power module at the back of the VHT-200 Equipment.

SHOCK HAZARD! To avoid risk of electric shock, replace fuses only with the same type and rating.

Vaporizer Replacement

The Vaporizer may need to be replaced periodically and can only be replaced with Vaporox approved components. To replace the Vaporizer, contact Vaporox Technical Services.

Pole Replacement

The Pole is not anticipated to need replacement; however, if a problem occurs or the Pole is lost and the Pole requires replacement, it can only be replaced with Vaporox approved components. To replace Pole, contact Vaporox Technical Services.

Filter Replacement

The HEPA filter within the VHT-200 Equipment will be replaced intermittently by Vaporox, Inc. or an authorized service provider.

Power Cord Replacement

The power cord is not anticipated to need replacement; however, if a problem occurs or the power cord is lost and the power cord requires replacement, it can only be replaced with Vaporox approved components. To replace power cord, contact Vaporox Technical Services.



WARNING! Do not use an alternate power cord with system as it could affect device safety, specifically electric shock being introduced, or affect compliance with electromagnetic emissions and immunity. A risk of increased emissions or decreased immunity may result if any additional cables are attached.

Warranty

Vaporox Limited Warranty (U.S. Customers Only)

A. This Limited Warranty provides the following assurance to the purchaser of Vaporox Products, hereafter referred to as “Equipment”:
(1) Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, Vaporox will at its option: (a) repair or replace any part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A (2), against the purchase of the replacement Equipment or (c) provide a functionally comparable replacement Equipment at no charge.
(2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Equipment.
B. To qualify for Limited Warranty set forth in Section A (1), the following conditions must be met:
(1) The Equipment must be returned to Vaporox within thirty (30) days after discovery of the defect, (Vaporox may, at its option, repair the Equipment on site).
(2) The Equipment must not have been repaired or altered outside of Vaporox factory in any way which, in the judgment of Vaporox affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse or accident.
C. This Limited Warranty is limited to its express terms. In particular:
(1) Except as expressly provided by this Limited Warranty, VAPOROX IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.
(2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, VAPOROX MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A (1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.
(3) The exclusions and limitations set out above are not intended to and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

(4) No person has any authority to bind Vaporox to any representation, condition or warranty except this Limited Warranty.

*This Limited Warranty is provided by Vaporox, Inc. 8375 S. Willow Street, Lone Tree, CO 80124, USA. It applies only in the United States. Areas outside the United States should contact their local Vaporox representative for exact terms of the Limited Warranty.