VAPOTHERM®

HVT 2.0

High Velocity Therapy System

Instructions for Use

The screen images shown in this IFU may not match the layout of the screen on your device due to configurable parameters the user may have selected during set-up of the device.

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Appendices

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HVT 2.0

Section 1: Indications, Warnings & Precautions

The HVT 2.0 high-velocity therapy system consists of the HVT 2.0 device and a Disposable Patient Circuit (DPC).

The HVT 2.0 system is equipped with an internal air blower. The addition of an external oxygen source (wall, tank or oxygen concentrator) enables FiO_2 delivery from 21% to 100%, dependent on the oxygen source.

The HVT 2.0 system is intended to be used by qualified medical professionals, such as physicians, nurses and respiratory therapists.

Accessories may not be available in all countries. Contact the local Vapotherm representative for more information.

If there is a serious incident with the device, it should be reported to Vapotherm Technical Support at the number specified on the final page of the IFU or to your Authorised Vapotherm Representative. Follow local regulations and report the incident to the competent authority or regulating agency.

Indications/Intended use

The HVT 2.0 system is intended to deliver warmed and humidified high-flow respiratory gases to spontaneously breathing adult, paediatric and infant patients (5 kg and up). The device is intended to be used in hospital, skilled nursing facilities and sub-acute facilities. It adds heat and moisture to a blended medical air/oxygen mixture and assures the integrity of the precise air/oxygen mixture via an integral oxygen analyser. The flow rates may be from 5 to 45 l/min (BTPS) via a nasal cannula.

The HVT 2.0 system provides high-flow, high-velocity nasal insufflation (HVNI) with simultaneous warmed and humidified oxygen delivery to provide ventilatory support to spontaneously breathing adult and paediatric patients (5 kg and up) suffering from respiratory distress with or without hypoxaemia in the hospital setting. The HVT 2.0 is not intended to provide total ventilatory requirements for the patient and is not for use during field transport.

Contraindications

- Not appropriate for patients who are not spontaneously breathing, are unable to protect their airway, or have anatomic or injury-induced blockage of the nasal pathway to the nasopharyngeal space.
- Not for treating OSA and snoring.
- The HVT 2.0 is not for field transport.
- HVT 2.0 is MRI unsafe. Do not use it in an MR environment.

Warnings & Precautions

Please take the time to review and become familiar with the warnings, precautions and notes listed in this Instructions for Use document. They cover safety considerations, special requirements and regulations. Warnings and precautions must be understood by the user to prevent adverse events to the patient or to the operator due to electromagnetic disturbances.

The user of this product shall have sole responsibility for any malfunction due to operation or maintenance errors by unauthorised/untrained personnel. Federal Law (US) restricts the sale of this device to or by order of a physician. This device should be used only by a trained operator.

WARNING	PRECAUTION	NOTE
A **Warning** indicates that a situation may occur which is potentially harmful to the patient or user.	A **Precaution** indicates a condition that may lead to equipment damage, malfunction or inaccurate operation.	A **Note** indicates a point of emphasis to make operation more efficient or convenient.

General Warnings

- HVT 2.0 is not a Continuous Positive Airway Pressure (CPAP) device. There are no controls to deliver or monitor airway pressure. HVT 2.0 should not be used to deliver pressure in a closed system.
- Patients receiving supplemental oxygen are often acutely ill and appropriate clinical vigilance should be observed by the care team. Additional patient monitoring, including pulse oximetry, is necessary if the HVT 2.0 is used to give supplementary oxygen.
- Use only the accessories, transducers and cables specified or provided by the manufacturer of this equipment. Use of other 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.
- Do not add any attachments or accessories to the HVT 2.0 system that are not listed in the Instructions for Use. The HVT 2.0 device might not function correctly, which could affect the quality of the therapy or could cause harm to the patient.
- **Oxygen supports combustion. This device should not be used near open flames, flammables, oil or grease. The device is not intended for use in oxygen-rich environments.**
- **Do not use the device in or around water (with the exception of the water bag that feeds the system).**
- The oxygen must be clean, dry, medical-grade gas to prevent harm to the patient and to prevent damage to the device.
- Improperly sizing the cannula, specifically complete occlusion of the nares by the nasal prongs, may lead to a risk of pneumothorax.
- Cannula prongs should not obstruct more than 50% of the patient's nares.
- Change nasal cannulas when soiled. Replace cannulas according to clinical judgement and hospital policy but do not exceed 30 days of continuous use.
- If used with an oxygen concentrator, the maximum oxygen percentage will be limited depending on the type of concentrator used and total set flow.

General Warnings (continued)

- Only use sterile or distilled water. Failure to utilise a sterile or distilled water supply or clean oxygen source may increase the risk of bacterial contamination.
- In specific countries, this device can be used to deliver nebulised medications inhaled through the nasal cannula and patient circuit.
- Always follow the aseptic technique (including proper hand washing and avoiding direct hand contact with connection points) when setting up the HVT 2.0 device and use Standard Precautions when placing on a patient.
- Use with magnetic resonance imaging (MRI) and radio frequency (RF) equipment may cause patient injury.
- Medical electrical equipment needs special precautions regarding radio frequency (RF) electromagnetic radiation. Portable and mobile RF communications equipment, such as base stations for cordless telephones and land mobile radios, amateur radio and AM and FM radios, can affect medical equipment and should not be used near the device.
- If the HVT 2.0 system is placed in close proximity to RF emitters, indications that HVT 2.0 performance is being affected by the emitters are false alarms and the front panel display showing values that are out of specification. In certain circumstances, the HVT 2.0 may affect or be affected by nearby equipment due to electromagnetic interference. If this should happen, try moving the HVT 2.0 device or moving the device causing interference or consult with the manufacturer.
- 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 HVT 2.0 system, including specified cables. Otherwise, degradation of the performance of this equipment may occur.
- 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 correctly.
- Use only the power supply cable that was provided with the device. Do not use any other cable. Do not use extension leads.
- **Do not operate the device if the power supply cable is damaged.**
- The power supply cable can be disconnected to isolate the product from the mains. It is recommended that the device be unplugged when not in use to prevent hazards occurring when unattended.
- Do not modify this equipment without authorisation from the manufacturer.
- The HVT 2.0 is MR-unsafe and is not intended for use in MRI environments. Keep away from magnetic resonance imaging (MRI) equipment.
- Do not connect any device, system or accessory that has not been approved by Vapotherm.
- **Do not use the HVT 2.0 device at an altitude above 3,000 m or outside a temperature of 18 to 30 °C. Using the device outside of this temperature range or above this altitude can affect the quality of the therapy or harm the patient.**
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only use tubes in compliance with ISO 5367 or ISO 80601-2-74.
- The device should not be turned on and left unattended when not connected to a patient.
- Before cleaning and disinfecting, unplug the device from a direct power source.
- General Fault alarms are failures in the control or measurement systems. Depending on the cause of the failure, gas delivery may or may not be interrupted. If a General Fault alarm occurs, disconnect the patient and shut off the device. The device must be repaired by trained service personnel.
- To reduce the risk of strangulation from patient tubing, use the provided tubing clip to secure the patient tubing.

General Warnings (continued)

- The internal safety battery is designed for temporary use only when AC or external DC power to the unit has been interrupted, and no transfer battery is present. When the HVT 2.0 device is running on the internal safety battery, there is no heat or humidity provided with the set flow and FiO_2 and the humidity level may drop below safe limits. After the internal safety battery is fully discharged, the device will not operate and patient gas flow will cease. When fully charged, the internal safety battery provides at least 15 minutes of power. The internal safety battery is not intended for patient transport.
- All disposable components are labelled as 'single patient use only' and must be replaced after 30 days of use on a single patient. Cannulas should be replaced according to clinical use, but must not exceed 30 days. Do not attempt to sterilise or reuse any of these components, and follow all local and US federal regulations for disposal. Outside the US, follow national or international regulations.
- Do not use disposables on more than one patient. Multi-patient use may lead to patient injury from infection and/or delivery of therapy outside of published specifications.
- To reduce the risk that the patient may aspirate condensed water from the breathing circuit, regularly observe the patient and output of the patient interface for excess water, and if detected, remove the patient interface from the patient. Water in the centre lumen can result from condensation or due to a leak from the outer lumens that surround the breathing circuit. Condensation in the cannula may also occur in certain ambient conditions and at low flow rates. If minimal condensation occurs after confirming there are no leaks, it is recommended to select a lower temperature set point.

General Precautions

- The HVT 2.0 will not operate without the internal safety battery in place. Have an internal safety battery on hand to ensure the continued availability of the use of the device. To ensure safe and reliable operation, use only the Vapotherm-specified replacement battery.
- **Do not**
  - **cover the device (blocking the vent may damage the device)**
  - **immerse the device in water**
  - **steam or gas sterilise the device.**
- Even a fully charged battery will lose its charge over a period of weeks when the device is not connected to a direct source of power. It is recommended that the device be connected to a direct source of power for at least 2 hours a month to maintain the battery charge. The internal safety battery should only be accessed or replaced by trained service personnel.
- Do not use bleach, organic solvents or abrasive cleaners. Hypochlorite solutions liberate toxic gases such as chlorine when acidified or heated. The reaction with ammonia or with substances that can generate ammonia can produce chloramines which are also toxic and have explosive potential.

NOTE: A flexible sterile or distilled water supply is recommended. If rigid or semi-rigid bottles are used, a Vapotherm-approved venting bottle cap spike must be used.

NOTE: The HVT 2.0 may be operated with limited performance at oxygen inlet pressures as low as 4 psi (28 kPa). However, for the full specified range of gas flows and oxygen percentages, oxygen inlet pressures must be 40 psi (276 kPa) or above. (Caution: Do not exceed 65 psi.)

HVT 2.0

Section 2: Overview of the HVT 2.0 System

The HVT 2.0 high-velocity therapy system consists of the HVT 2.0 device and a Disposable Patient Circuit (DPC).

While the HVT 2.0 device can be used again on another patient, each patient will require a Disposable Patient Circuit (DPC) and nasal cannula, which are attached to the HVT 2.0 device and enable the delivery of high-velocity therapy to the patient. The ProSoft nasal cannula is proprietary to Vapotherm and the HVT 2.0. device will not work correctly unless using ProSoft cannulas.

Other accessories validated for use with the device are the roll stand, the Transfer Upgrade Kit and the HVT 2.0 Nurse Call Interface Cable and the HVT 2.0 EMR Link Cable.

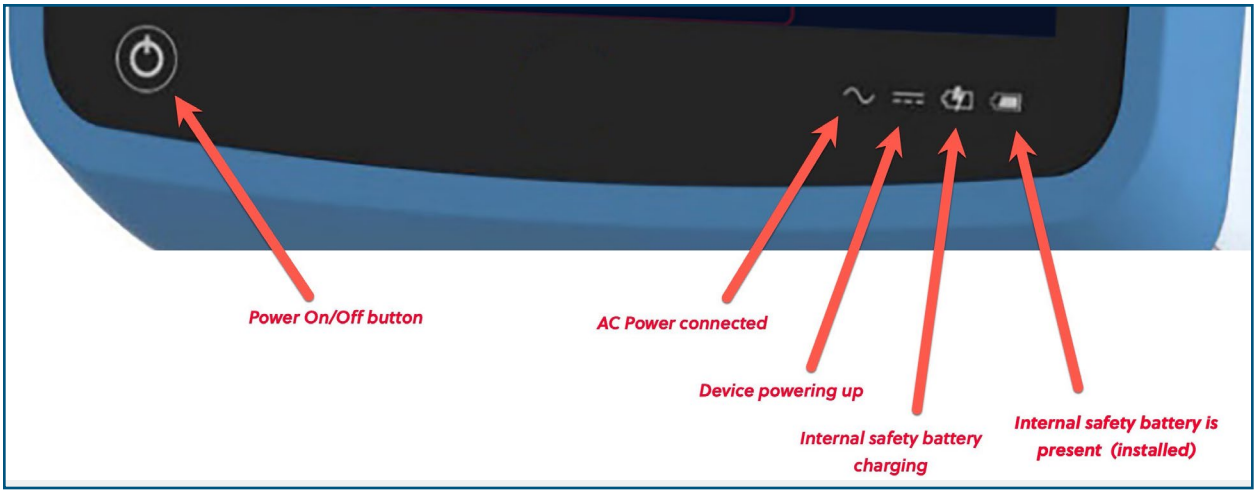

Figure 1: HVT 2.0 Device (above) and LED indicators on the front of the device

Features of the HVT 2.0 System

- Flow range from 5 to 45 l/min BTPS.
- The oxygen percentage is fully adjustable when connected to a 40 psi (276 kPa) oxygen gas source (non-oxygen concentrator).
- Temperature can be adjusted from 33 to 39 °C.
- Built-in oxygen/air blender.
- All internal sensors are self-calibrating and self-monitoring.
- Flow, oxygen and temperature settings are adjusted via touchscreen scroll bars.
- Built-in electronic flow meters and controllers.
- Minimal downtime between patients: less than ten minutes to change disposables and disinfect.
- Warm-up time is less than five minutes.
- The preheat feature circulates water and warms the circuit water to 33 °C.
- EMR and Nurse Call connectivity capable of indicating an alarm condition on a hospital Nurse Call system and interfacing with Electronic Medical Record technologies.
- The Disposable Patient Circuit (DPC) is detachable and disposable: no disinfection necessary.
- A single DPC enables the full system flow range (5 to 45 l/min). The DPC is fully assembled and ready to use straight out of the packaging.
- Universal power requirements allow use anywhere with only a change of power cable.
- An internal safety battery maintains flow and oxygen percentage for at least 15 minutes if AC or external DC power is cut off. Safety battery recharges in two hours.

Operation Principles

The HVT 2.0 system utilises an integrated internal blower to deliver warmed and humidified breathing gas at flows up to 45 l/min to spontaneously breathing patients, without the need for wall air or any pressured air source. The device incorporates a proportional valve and flow sensors that allow the oxygen percentage and total gas flow to be set independently.

The HVT 2.0 system consists of two parts: the HVT 2.0 device and the Disposable Patient Circuit (DPC). A validated patient interface (e.g. Vapotherm ProSoft nasal cannula) is required to deliver therapy to the patient. In addition, there are optional accessories that can be added to the therapy based on a patient's needs.

HVT 2.0 Device

The HVT 2.0 device contains all the electrical and electronic components, including the proportional valve and flow controllers and remote sensors to monitor the disposable water path. The device has no water pathways, and the gas pathway contains only dry gas at room temperature, and consequently does not need internal cleaning or disinfection.

The flow of oxygen and air is measured by mass flow sensors. The operating software calculates the required flow of each needed to reach the target flow and oxygen percentage set by the operator. The system controls gas flow accordingly by adjusting the proportional solenoid valves on the gas line.

Firmware running in the device uses sensors to monitor gas pressure and water temperature. Alarms are activated if any parameters are outside the normal range. Troubleshooting instructions for the alarms can be immediately displayed on the screen. Other indicators show a low charge in the internal safety battery.

After a two-hour charging period, the internal safety battery will maintain the set flow and oxygen blend for at least 15 minutes should AC, or external DC power be interrupted.

⚠	**WARNING:** The internal safety battery is designed for temporary use only when AC or external DC power to the unit has been interrupted, and no transfer battery is present. When the HVT 2.0 device is running on the internal safety battery, there is no heat or humidity provided with the set flow and FiO_2 and the humidity level may drop below safe limits. After the internal safety battery is fully discharged, the device will not operate and patient gas flow will cease. When fully charged, the internal safety battery provides at least 15 minutes of power. The internal safety battery is not intended for patient transport.

Disposable Components

The following disposable components are compatible with the HVT 2.0:

- **Disposable Patient Circuit** (DPC) [**REQUIRED**] – A single disposable patient circuit that enables delivery of high-velocity therapy for adult, paediatric and infant patients, for flows between 5 and 45 l/min. The DPC is provided fully assembled and ready to use.
- **ProSoft® Nasal Cannula** [**REQUIRED**] – Various sizes are available so that a cannula can be selected to fit the patient comfortably. The cannula is connected to the DPC.
- **Tubing Adapter** – (optional). Available should the therapy need to be delivered through a trach mask or t-piece instead of the nasal cannula.

All disposable components are labelled as 'single patient use only' and must be replaced after 30 days of use on a single patient. Cannulas should be replaced according to clinical use, but must not exceed 30 days. Do not attempt to sterilise or reuse any of these components, and follow all local and US federal regulations for disposal. Outside the US, follow national or international regulations.

	**WARNING**: All disposable components are labelled as 'single patient use only' and must be replaced after 30 days of use on a single patient. Cannulas should be replaced according to clinical use, but must not exceed 30 days. Do not attempt to sterilise or reuse any of these components, and follow all local and US federal regulations for disposal. Outside the US, follow national or international regulations.

	**WARNING**: Do not use disposables on more than one patient. Multi-patient use may lead to patient injury from infection and/or delivery of therapy outside of published specifications.

HVT 2.0 Disposable Components

Disposables	Patient Weight (kg) / Age					Flow Range (l/min)
	5 - 10 kg ≥ 1 mo	10 - 20 kg ≥ 1 mo - 6 yrs	20 - 40 kg ≥ 6 - 18 yrs	> 40 kg > 12 yrs	>100 kg > 12 yrs	
Disposable Patient Circuit (DPC)						
Air/O_2 (Standard)	X	X	X	X	X	5-45
Cannulas						
ProSoft Adult Long					X	5-45
ProSoft Adult				X		5-45
ProSoft Adult Small/Paediatric			X			5-45
ProSoft Paediatric Small		X				5-20
ProSoft Intermediate Infant	X					5-8
ProSoft Infant	X					5-8
Optional add-on						
Tubing Adapter	X	X	X	X	X	8-45

WARNING: Cannula prongs should not obstruct more than 50% of the patient's nares.

NOTE: When delivering therapy to paediatric patients (via a nasal cannula or the tubing adapter), the recommended guidance for setting starting flow rate is 2 l/min/kg. See "Performance" on see page C-2 for humidification output at specific flow rates.

NOTE: The Tubing Adapter is not intended to be connected directly to a trach collar. An open system must be maintained to ensure gas egress. To facilitate humidification via a bypassed upper airway, connect to a tracheostomy mask or T-piece.

Accessories

- **Roll Stand** – rolling stand to hold the HVT 2.0 device.
- **Transfer Upgrade Kit** – to allow for moving the patient from one location to another within the hospital, includes:
  - Transfer Battery – 1-hour Lithium-ion battery (VTBP-2.0, 14.4Vdc; 2 x6,900 mAh; 2 x99.4 Wh)
  - Oxygen manifold
  - Oxygen hoses (US only)
  - Adjustable oxygen tank holder (fits tank up to E-cylinder size)
- **HVT 2.0 Nurse Call Interface Cable** (2.9 m) – to allow connectivity to the hospital's Nurse Call System.
- **HVT 2.0 EMR Link Cable** (2.9 m) – to allow interface with the hospital's Electronic Medical Record System.

	**WARNING:** Use only the accessories, transducers and cables specified or provided by the manufacturer of this equipment. Use of other 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:** Do not add any attachments or accessories to the HVT 2.0 system that are not listed in the Instructions for Use. The HVT 2.0 device might not function correctly, which could affect the quality of the therapy or could cause harm to the patient.

HVT 2.0

Section 3: Setting Up the HVT 2.0 System

The following steps must be taken in preparation for using the HVT 2.0 System:

1. Assemble the HVT 2.0 device for use (including the Transfer Upgrade Kit, if applicable). (See details below).
2. Complete the Initial Set-up of device settings. (See "HVT 2.0 Initial Device Set-up Process" details below).
3. Insert the Disposable Patient Circuit (DPC) unit. **Note**: The DPC is provided fully assembled and ready to use.
4. Select the patient and interface type.
5. Connect the HVT 2.0 device to the patient.

Assembling the HVT 2.0 Device for Use

1. Attach the HVT 2.0 device securely to the sturdy roll stand or place it on a tabletop. See "Appendix C – Technical Specifications" for the roll stand dimensions.
2. Visually check that the patient air filter has been installed. (The HVT 2.0 device comes with one pre-installed, and there is a replacement in the user kit).
3. [**Optional**] Install the Transfer Upgrade Kit. For step-by-step instructions, see the "Set up the Transfer Upgrade Kit" section below.
4. Insert power supply cable into a facility-approved wall socket.

	**WARNING:** Do not operate the device if the power supply cable is damaged.
	**WARNING:** The power supply cable can be disconnected to isolate the product from mains supply. It is recommended that the device be unplugged when not in use to prevent hazards occurring when unattended.
	**WARNING:** Use only the power supply cable that was provided with the device. Do not use any other cable. Do not use extension leads.

5. Connect the oxygen hose to the oxygen inlet at the back of the device or tubing if using an oxygen concentrator.

6. If applicable, connect the Nurse Call cables to the appropriate port on the back of the HVT 2.0 device.

   Once connected, the Nurse Call System will be enabled.

   See "Appendix A – Nurse Call System Installations" for complete instructions for use on connection and use of Nurse Call.

   If available, connect the EMR system. See "Appendix B – Electronic Medical Records (EMR) Integration" for more information.

Set up the Transfer Upgrade Kit

Setting up the Transfer Upgrade Kit involves four (4) steps:

1. Insert the Transfer Battery into the HVT 2.0 device.
2. Attach the oxygen manifold to the Roll Stand.
3. Connect the oxygen hoses to their appropriate locations according to the labels on each hose.
4. Attach the tank holder to the Roll Stand.

For more information on transferring patients, see "Intra-hospital patient transfer" on page 43.

NOTE: The maximum weight capacity of the roll stand when equipped with the transfer kit is 40 kg. The basket has a maximum weight capacity of 5 kg.

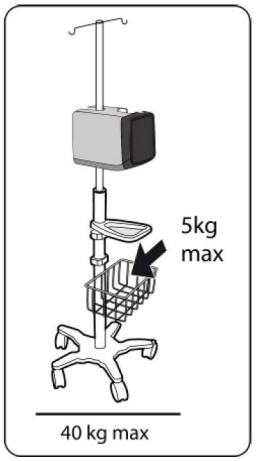

Figure 2: Roll Stand

HVT 2.0 Initial Device Set-up Process

There is a five-step process for initial set-up of the HVT 2.0 device. **Note**: Initial set-up screens will only appear when powering on the dervice for the first time or after Factory Reset is selected (from the Admin Settings menu).

"Step 1: Set up language"

"Step 2: Set up date and time"

"Step 3: Set up the Admin passcode"

"Step 4: Set up therapy presets"

"Step 5: Set up device preferences"

Step 1: Set up language

On the Set device language screen, tap the language button from the language optionsdisplayed.

NOTE: Changing the language will restart (reboot) the system afteryou confirm the change in language.

Figure 3: Language setting

Step 2: Set up date and time

Set the device date/time.

Note: The time is in the 24-hour format (e.g. no AM or PM).

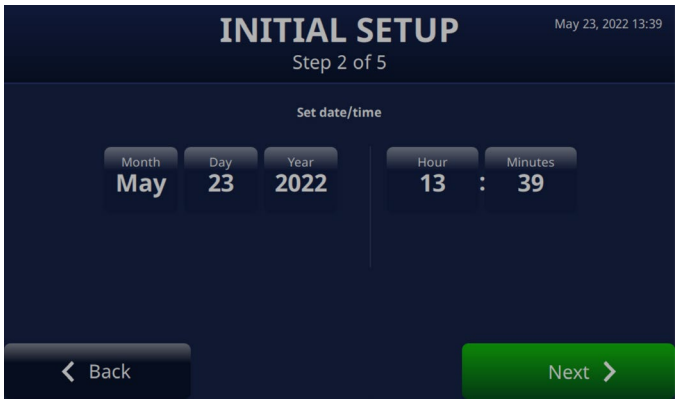

Figure 4: Date and time setting

Step 3: Set up the Admin passcode

Create a 4-digit Admin passcode.

The passcode must be confirmed by inputing it twice in order to continue the set-up process. If the passcodes do not match, a message will display and the passcode must be re-entered.

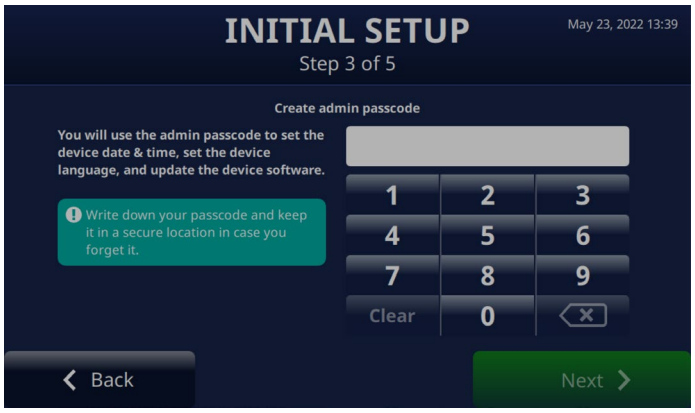

Figure 5: Admin passcode setting

Step 4: Set up therapy presets

Set up therapy presets.

Figure 6: Therapy presets setting

Step 5: Set up device preferences

Set up the device preferences.

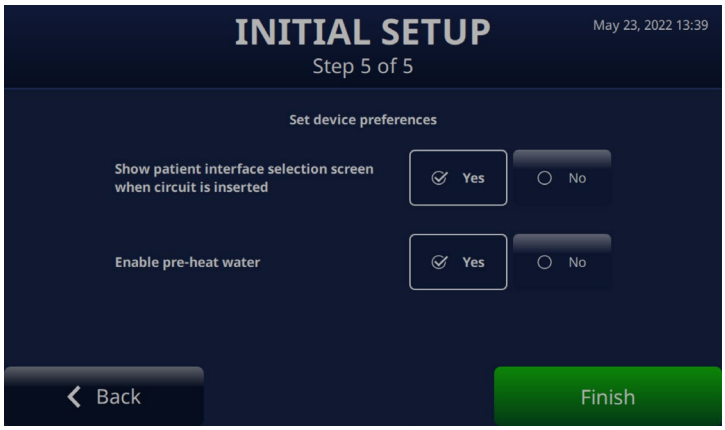

Figure 7: Device preferences settings

HVT 2.0 Device Settings

The HVT 2.0 device has a number of settings that can be accessed and adjusted, if necessary. These settings can be adjusted from the Settings menu.

To access the Settings menu:

1. Tap the [**Unlock**] button at the top-left corner of the main screen.

   The [**Unlock**] button will be replaced by a [**Lock**] button and a [**Menu**] button will be displayed next to it.

2. Next, tap the [**Menu**] button to display the Settings menu.

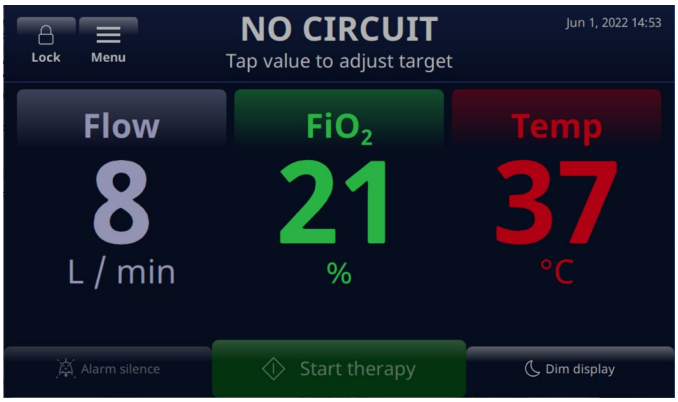

*Figure 8: Tap the [**Unlock**] button to access Settings [**Menu**] button*

The [**Menu**] button enables users to access the General Settings and Admin Settings in order to establish settings for the device in both Standby and Run modes.

The following settings can be defined from the General Settings menu:

- **Circuit details** – Select the patient interface (trach adapter or cannula size). See "Circuit Details" on page 23 for more details on this feature.
- **Screen brightness** – Set the desired screen brightness level.
- **Audio volume** – Set the volume level of the alarms.
- **Event log** – Displays all events captured on the device, including event details, date and time. See "Event Log" on page 23 for more details on this feature.
- **Oxygen Source** – Select the source of the oxygen that will be connected to the device (e.g. Wall/tank or Concentrator). See "Oxygen source" on page 24 for more details on this feature.
- **Software details** – Displays the Controller board and GUI application software versions.
- **Admin settings access** – Enables the user to open the Admin Settings menu.

The following settings can be defined from the Admin Settings menu:

- **Preferences** (includes Patient Type selection and Preheat)
- **Preheat water** – Enable the Preheat water mode, which circulates water and warms the circuit water to 33 °C. See "Preheat water" on page 25 for more details on this feature.

- **Therapy presets** – Add or edit therapy preset configurations for Flow, Oxygen and Temperature. See "Therapy presets" on page 26 for more details on this feature.
- **Date & time** – Set the format for the device date and time.
- **Language** – Select the screen language.
- **Calibrate water level** – Activate water-level calibration, only if advised by Vapotherm to do so.
- **Admin Passcode** – The user is able to change the admin passcode.
- **Software update** – Update Controller board and GUI application software, when directed by Vapotherm personnel. See "Appendix D: Software update process" for more instructions on how to update the device software
- **Factory reset** – The user is able to restore the device to factory settings from the Admin menu. Settings menu when not in therapy. Stop therapy when resetting the device. Select '**Factory Reset**' from the Admin Settings Menu. The Factory reset will reboot the device and display the "HVT 2.0 Initial Device Set-up Process".

NOTE on Screen Lock functionality: the screen will lock automatically after three minutes of non-activity. To unlock the screen, tap the [**Unlock**] button in the top left of the screen.

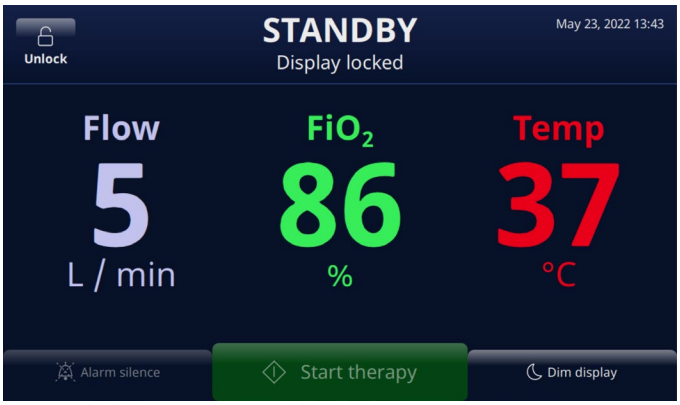

Figure 9: Screen Lock/Unlock

Circuit Details

Select patient interface

When you select **Circuit Details** from the General settings menu, the Select patient interface screen is displayed.

From the screen, select the correct cannula size or select Trach adapter for the patient.

Figure 10: Patient interface setting

Event Log

1. To access the **Event Log**, select [**Event log**] from the General settings menu.

The Event Log can hold up to 2,000 events.

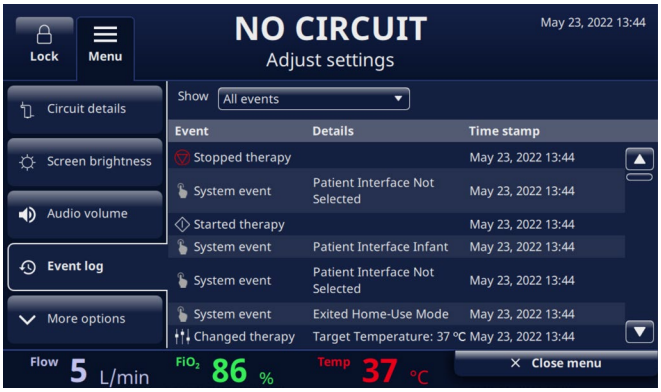

Figure 11: **Event log** *– all events*

2. To filter the list, tap the [**Show button**] above the Event listing table.

Events can be limited to a particular category, including:

- All events
- All alarms
- Therapy changes
- System changes

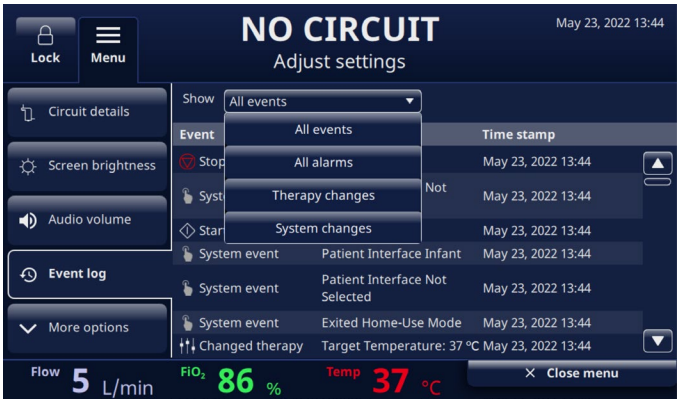

Figure 12: Event Log filter selection

Oxygen source

Oxygen source can be selected from the General settings menu.

1. Select the source of oxygen for the patient by tapping either the **Wall/tank** option or the **Concentrator** option.

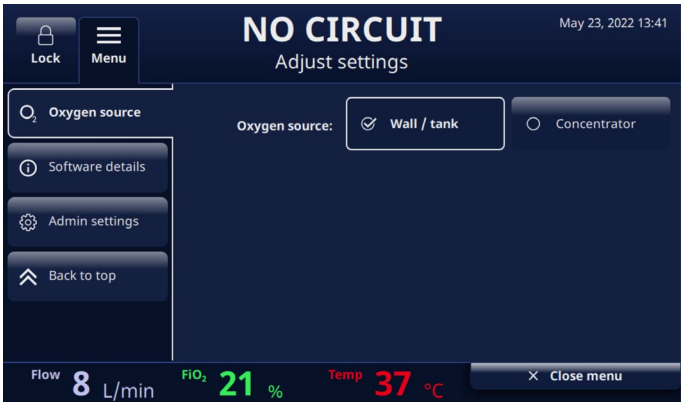

Figure 13: Therapy presets setting

NOTE: When using an oxygen concentrator, refer to the Concentrator Flow Rate table in Appendix C "Use with oxygen concentrators" for the estimated oxygen concentration.

2. If **Concentrator** is selected, the current O_2 percentage and maximum flow rate will be displayed. To make a change, tap on **O_2 concentration** to select a new oxygen concentration percentage. To set the maximum flow rate, tap either **5 l/Min** or **10 l/Min**. A tick will appear next to the selected flow rate.

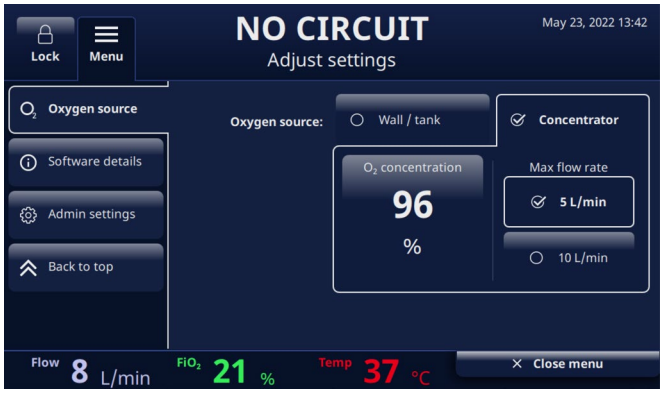

*Figure 14: Oxygen source: **Concentrator** selected*

3. The system will default to 92% oxygen concentration. If you need to change the oxygen concentration, tap the **92** and select the new percentage from the scroll bar.
4. Tap the [**Confirm**] button below the scroll bar to save the changes.

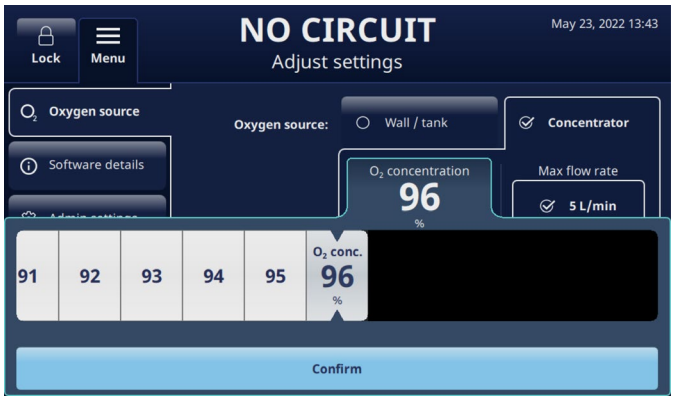

*Figure 15: **Concentrator** - Scroll bar to change O_2 changes*

Preheat water

Enabling the Preheat water mode circulates water and warms the circuit water to 33 °C. When the system is operating from AC power, preheating automatically starts once circuit priming is complete or when therapy is stopped.

Preheat water is part of the **Preferences** option from the Admin settings menu.

The Preheat water mode is enabled during Initial Set-up or can be enabled by selecting it from the Admin settings menu.

Once enabled, while the system is operating on AC power, the preheat water feature will automatically start. A Preheat status bar will appear on the screen.

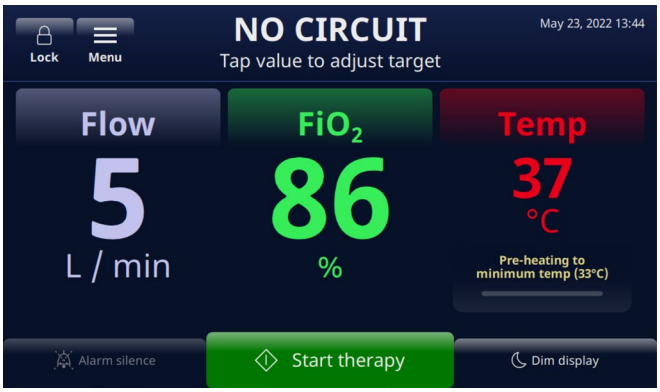

Figure 16: Preheat status bar displays

Note that when the system operating power transitions from AC power to Transfer battery power, preheating the water can be activated via the [**Warm-up**] button that will appear on the screen. Press the button to begin the pre-heating process.

Figure 17: Preheat warm-up button

Therapy presets

1. From the Admin settings menu, tap the [**Therapy presets**] button to view the screen.

2. The Therapy presets settings allow you to set up two different therapy settings that are ready for quick therapy initiation. To create a preset, tap the [**Edit**] button to the right of the preset.

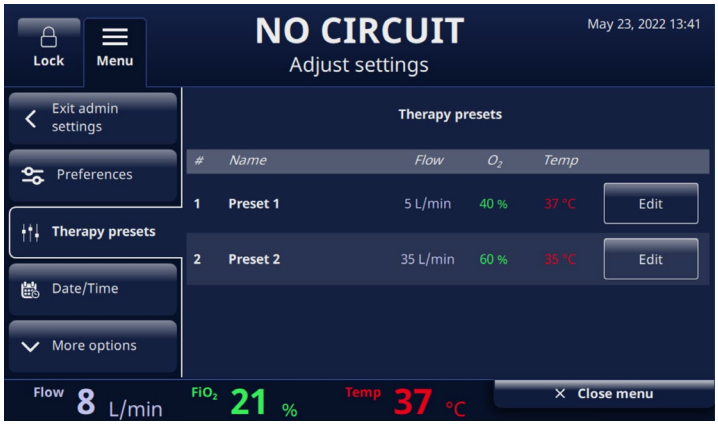

Figure 18: **Therapy presets**

3. To select your preset values, select the **Flow**, **FiO_2** or **Temp** by tapping them.

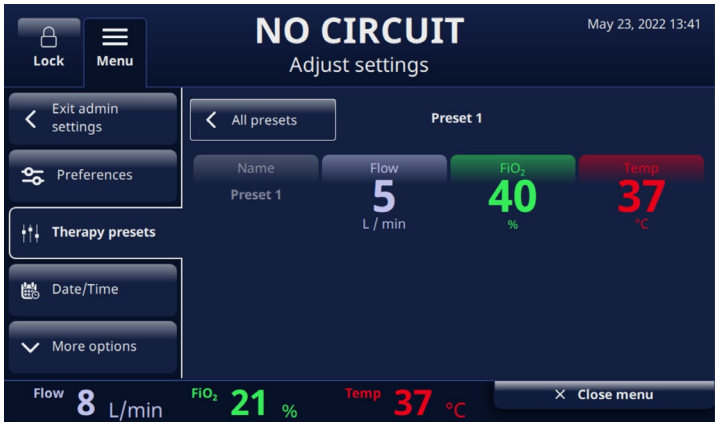

Figure 19: Edit **Therapy preset**

4. When the parameter is tapped, a scroll bar will appear below it. Use the scroll bar to select your target value(s) for each parameter: **Flow**, **FiO_2** or **Temp**.

   Tap [**Confirm**] to save the value as a part of the preset.

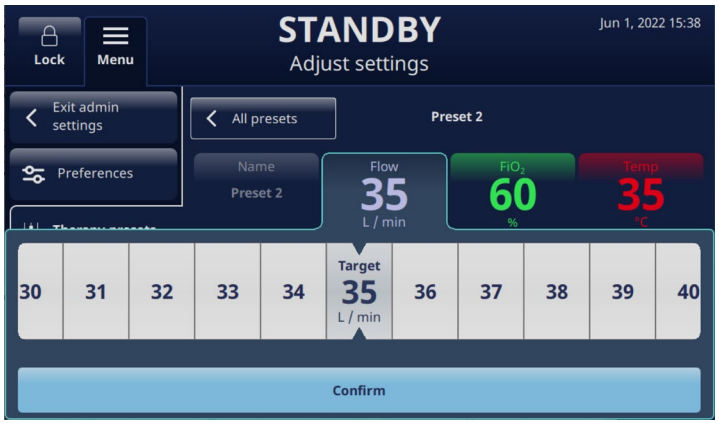

Figure 20: **Adjust settings – Therapy preset flow target**

Software update

From the Admin Settings menu, tap the **[Software update]** button to view the screen.

The screen will display the latest software versions and dates for the Controller board and Graphic User Interface (GUI) application.

NOTE: The button will only be enabled when a USB is placed in the back of the device. See "Appendix D: Software update process" for software update instructions.

Figure 21: **Software update** *selections*

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HVT 2.0

Section 4: Using the HVT 2.0 system

Modes of operation overview

The HVT 2.0 has three modes of operation: sleep, standby and run. The mode is displayed at the top of the screen.

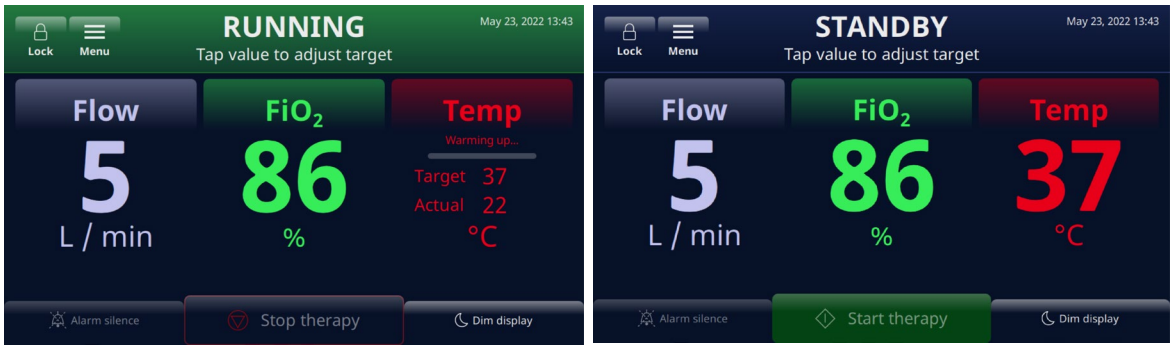

Figure 22: Modes of operation

Sleep: the device is plugged in but is not turned on. No therapy is being delivered.

Standby: the device is on, and the screen is illuminated. No therapy is being delivered. This mode is indicated by either '**NO CIRCUIT**' (DPC is not installed) or '**STANDBY**' (DPC installed but therapy not started). To start therapy, tap the [**Start therapy**] button at the bottom of the screen.

Run: the device is on and delivering therapy according to the parameters set. This mode is indicated by '**RUNNING**' being displayed at the top of the screen and the [**Stop therapy**] button at the bottom of the screen.

Start-up preparation

Before assembling the device for use, make sure that the following items are available:

- Disposable Patient Circuit (DPC)
- Sterile or distilled water supply
- Validated patient interface (ProSoft nasal cannula or trach adapter)
- Adequate oxygen source and connectors

1.	Visually inspect the power supply cable to verify that it is not damaged or kinked. Then, plug the power supply cable into a facility-approved wall socket.
2.	Connect the oxygen hose to the facility-approved oxygen wall socket, oxygen tank or an oxygen concentrator. **NOTE:** When using an oxygen concentrator, a 6.35 mm barb nipple is required.
3.	Press the ⏻ [**Power**] button on the device. The screen will illuminate and display the software revision number and will automatically conduct the alarm sound test.

Starting therapy

⚠	**WARNING:** The device should not be turned on and left unattended when not connected to a patient.

If the device has been exposed to very hot or very cold temperatures, allow it to reach operating temperature before use. After being exposed to extreme temperatures, the device can take up to 12 hours to reach room temperature.

The Start Therapy procedures have been divided into the following sections:

1. "Insert the Disposable Patient Circuit (DPC)"
2. "Select a patient interface type"
3. "Select therapy parameters"
4. "Start therapy"

NOTE: Optional Therapy Presets or the "Paediatric flow calculator" are available to select your therapy parameters.

Initiate and start therapy

Insert the Disposable Patient Circuit (DPC)

1. Insert the Disposable Patient Circuit (DPC) according to the illustrations below.

   NOTE: The DPC is provided fully assembled and ready to use.

   NOTE: If the device is not powered on, inserting the DPC will automatically power on the unit (if it is connected to a wall socket or transfer battery).

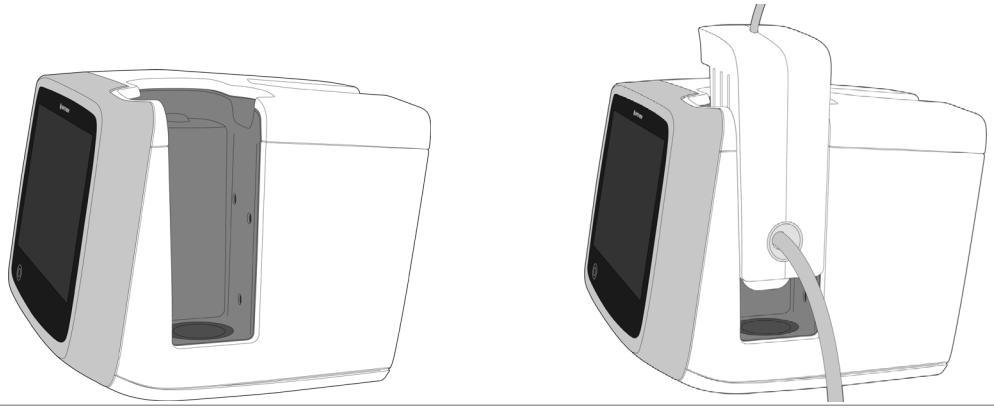

Figure 23: Insert the Disposable Patient Circuit (DPC) into the device.

2. Hang the sterile or distilled water supply from the Roll Stand and connect it to the DPC via the water inlet tube. Spike the water supply and unclip the tubing, if necessary, to begin the flow of water to the device.

   NOTE: When using some water bottles, it may be necessary to use a hook to lower and hang the water bottle (included in the user kit) to facilitate connection with the spike tube.

   A flexible sterile or distilled water supply is recommended. If rigid or semi-rigid bottles are used, a Vapotherm-approved venting bottle cap must be used.

WARNING: Only use sterile or distilled water. Failure to utilise a sterile or distilled water supply or clean oxygen source may increase the risk of bacterial contamination.

3. Next, select the patient interface type on the screen.

   Selecting a cannula will lock in the flow range that the cannula is labelled for.

Figure 24: New circuit detected

Select a patient interface type

1. Select the desired patient interface type on the screen. If selecting a cannula, place the cannula on the patient to allow the cannula to warm to the patient's skin temperature. This helps minimise condensation during therapy delivery.

   NOTE: The Infant cannula selection includes both the infant and intermediate-sized cannulas. The Paediatric Small is limited to the paediatric small-sized cannula. And, the Paediatric/Adult cannula selection includes the Paediatric/Adult small, Adult and Adult long cannulas. [For more information on cannula sizes, see "HVT 2.0 Disposable Components" on page 15.].

⚠	**WARNING:** Cannula prongs should not obstruct more than 50% of the patient's nares.

NOTE: If the flow rate was set prior to selecting the cannula, the device will verify that the flow rate is within the range permitted for the selected cannula. If it is not within the appropriate range, a message will be displayed indicating that either the flow rate needs to be lowered or a different patient interface type should be selected.

Sample screen message: *Current flow (35 l/min) higher than the selected cannula limit (20 l/ min). Selecting this cannula will decrease flow to 20 l/min.*

2. Select an optional therapy preset or use the starting paediatric flow calculator by tapping [**Paediatric flow calc**]. For detailed instructions on using the Paediatric Flow Calculator, see "Paediatric flow calculator" on page 38.

   NOTE: The paediatric flow calculator is intended to provide suggested starting flow rates for paediatric patients up to 13 years of age, and flow can be subsequently titrated to clinical effect.

   NOTE: Select 'none' to manually-adjust therapy parameters.

3. Tap to confirm the cannula or trach adapter and preset settings.

Figure 25: Select and confirm the patient and patient interface type

4. The home screen will display the three therapy parameters and the message bar will display ***'PRIMING***'.

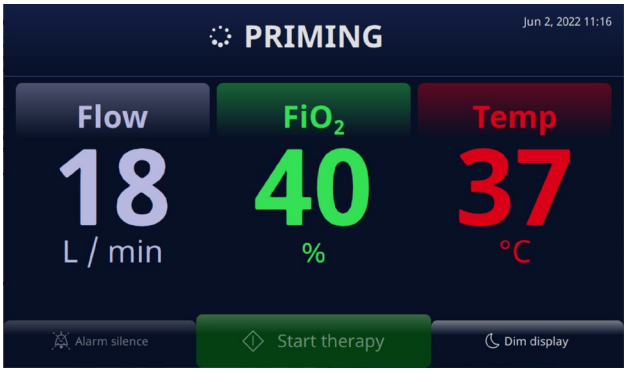

Figure 26: Priming in progress message

5. If the water is not circulating through the DPC when priming, the screen top banner will show an advisory to unclamp the water line. Unclamp the water line to proceed.

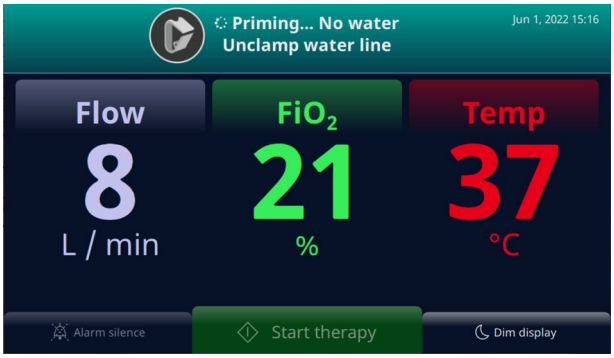

Figure 27: Priming in progress message

6. Allow the DPC to prime with water before starting therapy. The device will indicate when priming is complete. It takes 60 seconds for a flexible sterile or distilled water supply to prime the DPC; it takes 180 seconds for rigid or semi-rigid water bottles to do so.

7. If you selected a Therapy Preset, your therapy settings will be automatically loaded and you can proceed to "Start therapy" on page 37.

Select therapy parameters

If you have not selected a therapy preset or used the paediatric flow calculator, follow the steps below to manually adjust the therapy settings.

1. To change the therapy parameters, first tap the [**Unlock**] button at the top left of the screen.

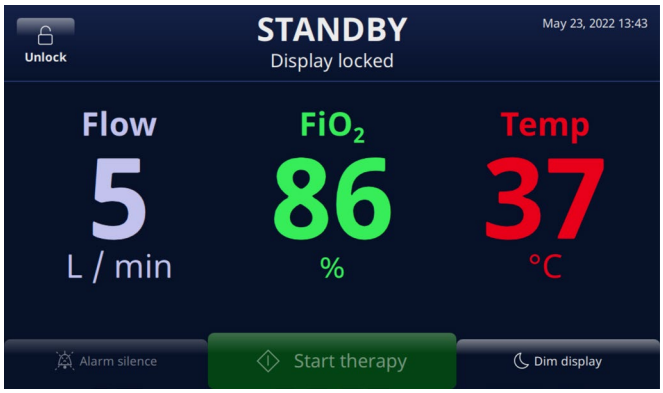

Figure 28: Unlock the screen to change the settings

2. To set a therapy parameter, tap the parameter on the screen (**Flow**, **FiO_2** or **Temp**). A scroll bar appears allowing a new parameter target to be set.

3. For each parameter, select a setting from the onscreen horizontal scroll bar. The scroll bar allows you to slide to the left or right in order to find the right setting. Adjustments can be made to one or more of the parameters before saving the changes.

4. Tap the [**Close**] button to save the new therapy parameters.

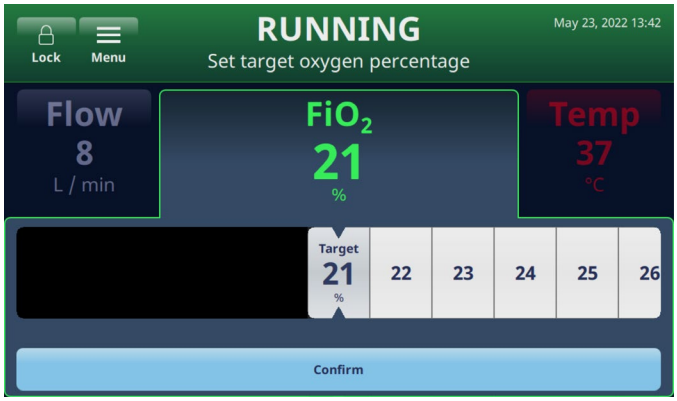

Figure 29: Setting the FiO_2 parameter using the scroll bar

NOTE on the 100% FiO_2 button: while in therapy, a **[100% FiO_2]** button is available. If pressed and confirmed, FiO_2 is administered at 100% for 2 minutes.

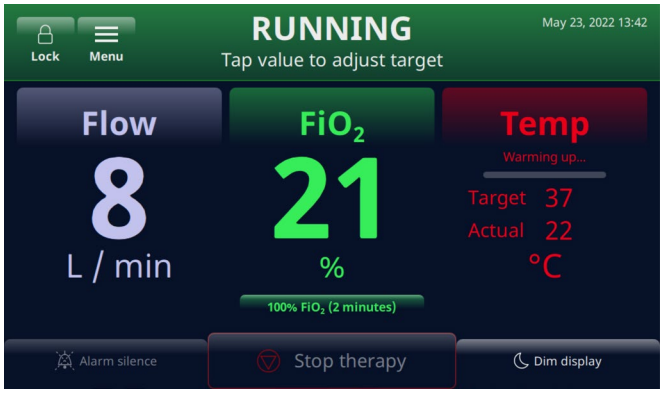

Figure 30: 100% FiO_2 button

When the **[100% FiO_2]** button is pressed and confirmed, FiO_2 is administered at 100% for 2 minutes and a timer displays on the screen.

When the 2 minutes expire, the FiO_2 setting returns to the initial setting.

NOTE: To stop administering 100% FiO_2 before the 2 minutes expire, press and hold the "**X**" on the status bar for 2 seconds.

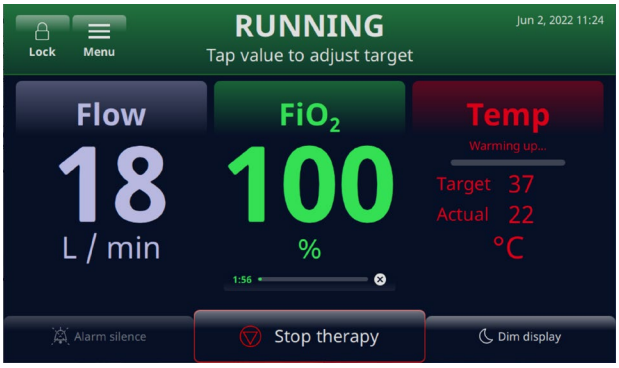

Figure 31: 100% FiO_2 timer displays

NOTE: When using an oxygen concentrator, the system will notify you of changes in delivered FiO_2 as the flow rate is titrated up. [See "Adjust therapy parameters with an oxygen concentrator" for more details.]

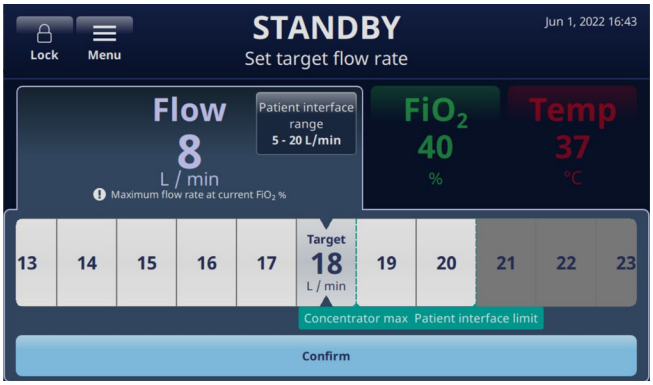

Figure 32: Notification of changes in FiO_2 as flow rate changes

5. After setting the therapy parameters and when the temperature on the screen has reached at least 33 °C, connect the patient's cannula interface to the delivery tube.

   NOTE: Check water level, temperature display, gas flow rate and oxygen percentage.

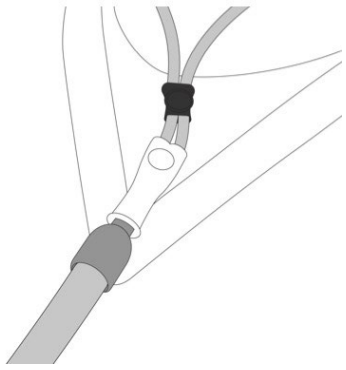

Figure 33: Connect the cannula to the delivery tube

WARNING: always follow the aseptic technique (including proper hand-washing and avoiding direct hand contact with connection points) when setting up the HVT 2.0 device, and use standard precautions when placing on a patient.

⚠	**WARNING:** Cannula prongs should not obstruct more than 50% of the patient's nares.
⚠	**WARNING:** Change nasal cannulas when soiled. Replace cannulas according to clinical judgement and hospital policy but do not exceed 30 days of continuous use.
⚠	**WARNING:** Improperly sizing the cannula, specifically complete occlusion of the nares by the nasal prongs, may lead to a risk of pneumothorax.
⚠	**WARNING:** to reduce the risk that the patient may aspirate condensed water from the breathing circuit, regularly observe the patient and output of the patient interface for excess water, and if detected, remove the patient interface from the patient. Water in the centre lumen can result from condensation or due to a leak from the outer lumens that surround the breathing circuit. Condensation in the cannula may also occur in certain ambient conditions and at low flow rates. If minimal condensation occurs after confirming there are no leaks, it is recommended to select a lower temperature set point.

NOTE: Droplets of condensation may appear at the end of the patient delivery tube while the unit is warming up. This is normal and will stop within a few minutes when the set temperature is reached and the cannula is fitted to the patient.

NOTE: Some condensation around the nose is possible. In addition, a high moisture level may mobilise mucus from the nose and sinuses. Make sure that the patient has a supply of facial tissues.

NOTE: Take precautions to minimise cooling of the unheated cannula by trying to maintain contact with the patient's skin and insulating the exposed portion of the cannula with bedding.

Start therapy

1. Start therapy by tapping the [**Start therapy**] button at the bottom of the screen to begin delivering flow.

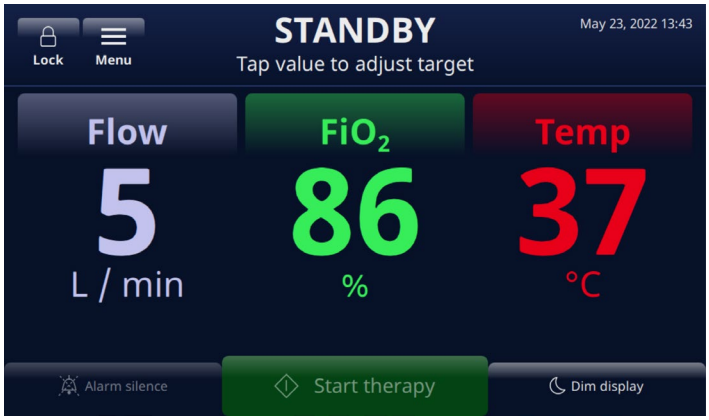

*Figure 34: [**Start therapy**] button*

2. After tapping the [**Start therapy**] button, the device is in Run mode. This is indicated by the word '**RUNNING**' displayed at the top of the screen.

NOTE: If the target temperature has not been reached, the screen will also indicate the Actual versus Target temperatures as it monitors the status of the temperature.

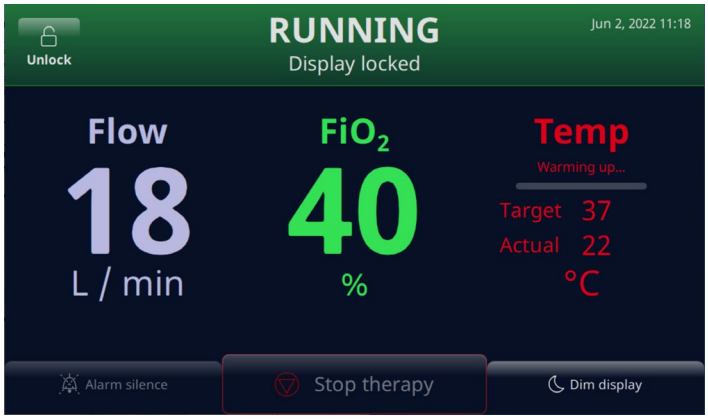

Figure 35: Device in Run mode

Paediatric flow calculator

The Paediatric Flow Calculator provides suggested starting flow rates for paediatric patients up to 13 years of age. It uses a patient's weight and respiratory rate to calculate a suggested starting flow rate. This feature is accessible in Start Therapy when a DPC is inserted into the device.

1. If you tapped [**Paediatric flow calc**], the Paediatric Flow Calculator screen is displayed.

NOTE: The default measurement is kilograms (kg). You can switch to pounds (lb), if preferred, by tapping the [**Switch to lb**] button.

2. To enter the patient's weight, tap the **Patient weight** tab on the screen.

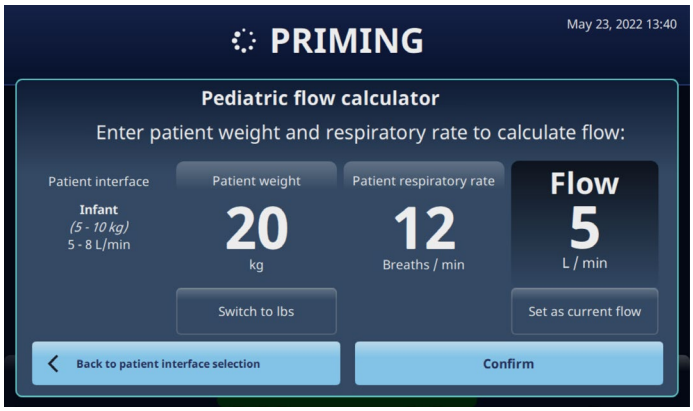

Figure 36: Paediatric flow calculator

3. A scroll bar will be displayed. Use the scroll bar to select the patient's weight.

4. Tap [**Confirm**] to save your patient weight selection.

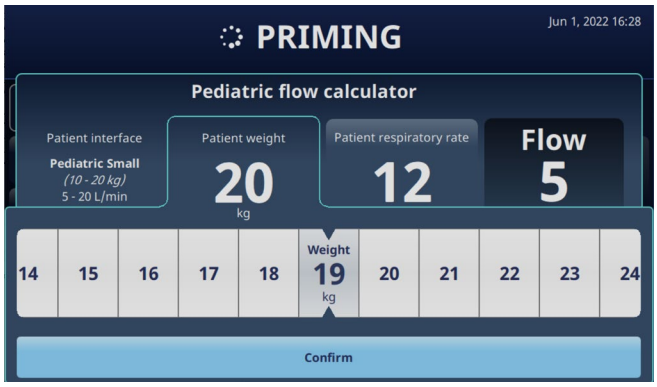

Figure 37: Select and then confirm patient's weight

5. To enter the patient's current respiratory rate, tap the **Patient respiratory rate** tab.

6. A scroll bar will be displayed. Select the respiratory rate (breaths/ minute) from the scroll bar.

7. Tap [**Confirm**] to save the respiratory rate selected.

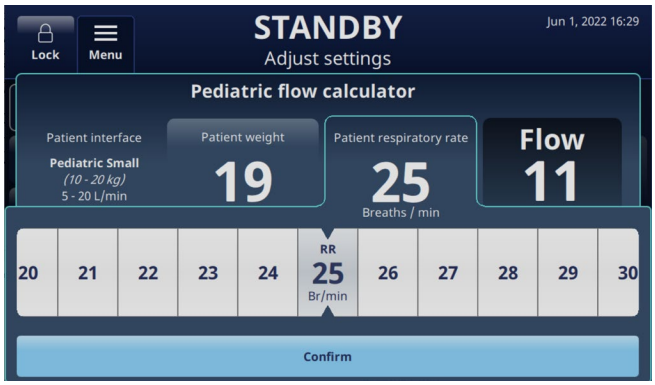

Figure 38: Select and confirm the patient's respiratory rate

8. Tap [**Set as current flow**] if you want to use the provided value as the starting flow rate. Then tap [**Confirm**] to exit the screen and view the home screen.

   If you do not want to use the suggested flow rate, tap the [**<Back to patient interface selection**] button to exit the paediatric flow calculator.

The suggested starting flow rate will be displayed.

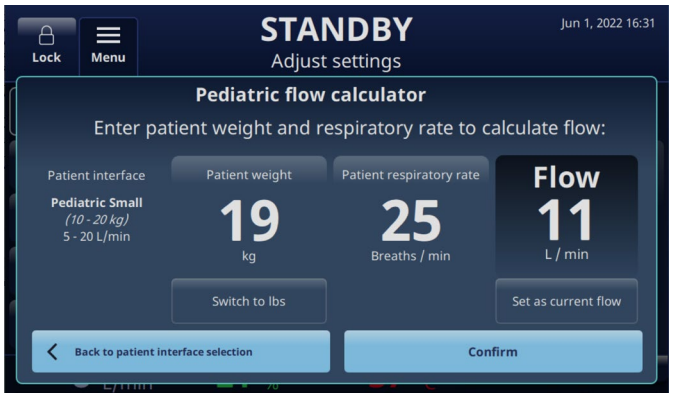

Figure 39: Confirm the patient and patient interface type

9. If the suggested starting flow is higher than the currently selected cannula range, a notification will appear.

10. To change the patient interface selection, tap the [**<Back to patient interface selection**] button. Make the change, then re-select the paediatric flow calculator by tapping [**Paediatric flow calc**] and follow the steps above.

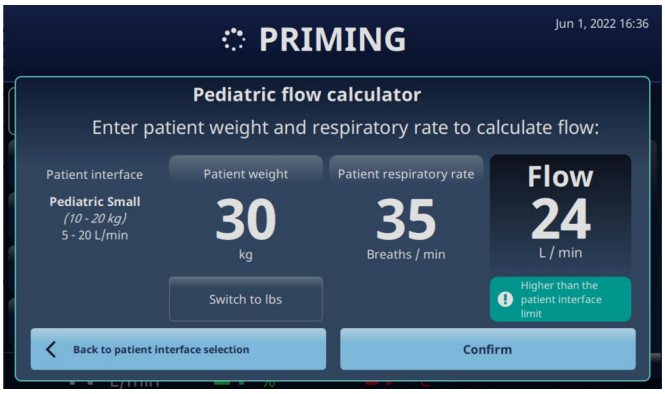

*Figure 40: Notification displays: **Higher than cannula rate***

NOTE on therapy adjustments: you can adjust any of the parameters (Flow, FiO_2 and Temp) while the device is in Run mode. Simply tap the desired parameter on the screen and select the desired setting from the scroll bar that appears.

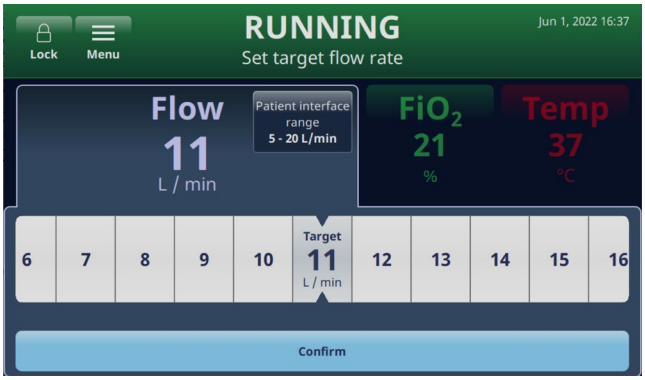

Figure 41: Adjusting flow using the scroll bar

Adjustments can be made between any or all of the three parameters (Flow, FiO_2 and Temp) before saving the changes. When adjustments are made, tap the [**Close**] button at the bottom of the screen to save the setting(s). The system automatically adjusts to the new setting with no interruption to the therapy delivery.

Adjust therapy parameters with an oxygen concentrator

To adjust therapy parameters for a system that is set up to work with an oxygen concentrator, do the following:

1. Tap the [**Unlock**] button at the top left of the screen. The [**Lock**] and [**Menu**] buttons will be displayed, and the instruction '***Tap value to adjust target***' appears under the '**READY**' label at the top of the screen.
2. To set a therapy parameter, tap the parameter on the screen (**Flow**, **FiO$_2$** and **Temp**). A scroll bar will appear, allowing a new parameter target to be selected.

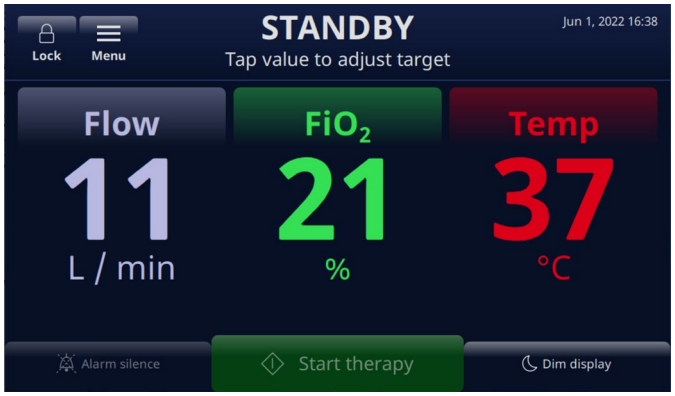

Figure 42: Unlock screen to change the Flow, FiO$_2$ or Temp settings

3. Tap the **Flow** parameter on the screen to set a target flow rate. The target rate will be highlighted on the scroll bar. If this is a maximum rate for the concentrator, a message will appear under the scroll bar stating '**Concentrator max.**' Initially, the slider will not go past the maximum limit, and the system will beep.

   To select a higher flow rate (above the maximum), slide the scroll bar a second time or directly select a value above the limit. The system will update the target to the selected value.

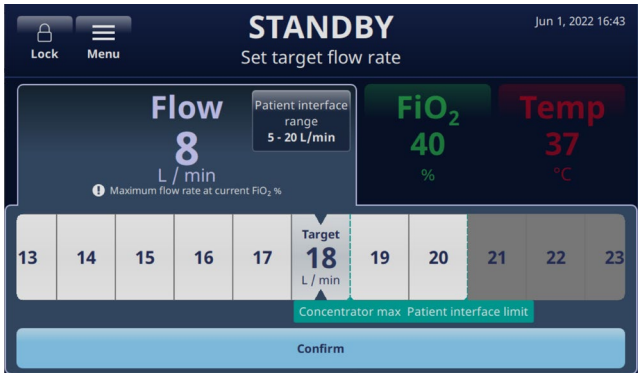

Figure 43: Setting target flow rate parameter

4. Once a higher-than-the-maximum target has been selected, the system automatically adjusts the oxygen percentage, and a message to that effect appears on the screen (see the message '**FiO_2 lowered to 56% due to high flow rate**' on the screen below).

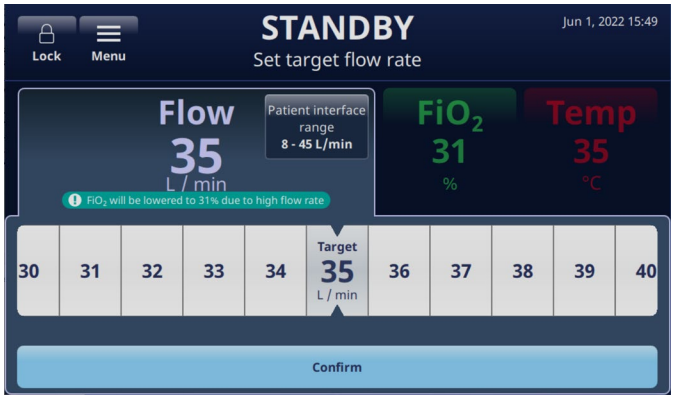

Figure 44: System resets the oxygen percentage based on high flow rate

5. In order to provide therapy adjustment guidelines, the system displays the following messages above and below the scroll bar (see the screen below):

   - **FiO_2 lowered to XX% due to high flow rate** (displays to indicate the system-adjusted oxygen percentage based on the high flow rate selected)
   - **Concentrator Max** (displays to indicate the maximum flow rate for the oxygen concentrator).
   - **Cannula limit** (displays to indicate the upper flow rate limit for the cannula selected)

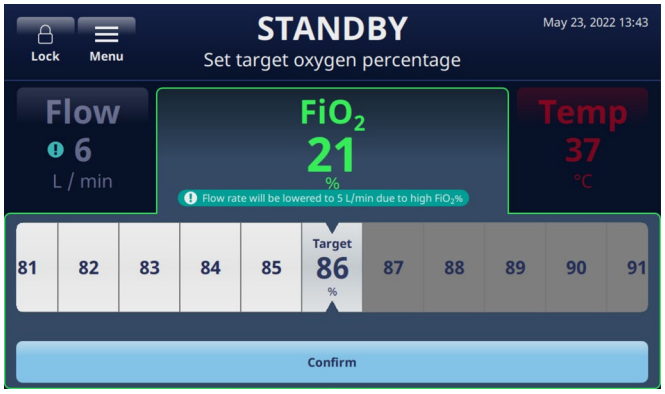

Figure 45: Screen messages providing high flow rate guidelines

6. When adjustments are complete, tap the [**Confirm**] button at the bottom of the screen.

Stop therapy

When the device is in Run mode, tap the [**Stop therapy**] button to do any of the following:

1. Remove the cannula from the patient.
2. Discontinue therapy.
3. Shut down the device.

When you tap the [**Stop therapy**] button, a Confirmation pop-up screen appears:

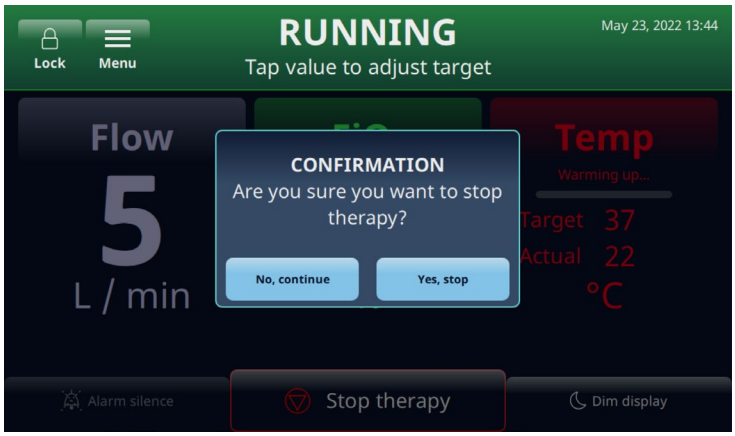

*Figure 46: [**Stop therapy**] Confirmation pop-up screen*

Discontinue therapy

When a patient is ready to discontinue use of the HVT 2.0 device, follow the instructions below to stop therapy:

1. Remove the cannula from the patient.
2. Remove the DPC unit from the HVT 2.0 device.
3. Dispose of the cannula, the DPC and the water supply according to hospital waste-management policies.
4. Press the ⏻ [**Power**] button to place the device in Sleep mode.
5. Clean and disinfect the device according to the instructions in "Cleaning and disinfection" in "Section 7: Maintenance and disinfection".

Shut down

To fully power down the device, proceed as follows:

1. First, ensure that no therapy is being delivered to the patient.
2. Disconnect the power supply cable from the wall socket.
3. Press the ⏻ [**Power**] button on the device to power down. The [**Power**] button must be pressed, otherwise the internal safety battery will become active.

⚠	**Caution:** even a fully charged battery will lose its charge over a period of weeks if the device is not connected to mains power. It is recommended that the device be connected to a direct source of power for at least 2 hours a month to maintain the battery charge. The internal safety battery should only be accessed or replaced by trained service personnel.

Intra-hospital patient transfer

NOTE: This section is only applicable if the HVT 2.0 device is equipped with the HVT 2.0 Transfer Upgrade Kit.

The HVT 2.0 system with the transfer upgrade supports the transfer of patients and patient ambulation within the hospital environment, including from Accident & Emergency to inpatient care areas, to and from tests and procedures (non-MRI), and to rehabilitation activities. In mobile use, the HVT 2.0 device is powered by an optional transfer battery pack.

Before using the device to transfer patients, confirm that:

1. The tanks contain adequate oxygen supplies.
2. The transfer battery is fully charged and installed into the HVT 2.0.
3. There is no leaking from the manifold.

The chart below provides estimates of the transfer battery runtime based on flow rates at 21 °C ambient temperature and at 37 °C temperature set point.

Flow rate (l/min)	Run time
25	75 minutes
45	35 minutes

How to transfer a patient

1. Insert up to two oxygen tanks into the tank holder.
2. If tanks do not have a built-in regulator, attach the gas regulator. Connect the tanks to the gas manifold using the hoses.
3. Disconnect the wall oxygen hose.
4. Unplug the HVT 2.0 device from the wall socket. (**Note**: keep the power cable with the device.) The device will now run on the transfer battery without interruption to deliver therapy. The transfer battery indicator at the top of the screen will indicate how much transfer battery life is left.
5. Continuously monitor the oxygen tank and transfer battery life throughout the transfer process to ensure that there is no interruption in therapy delivery.

   NOTE: The status of the transfer battery charge is displayed on the upper right of the device screen, as follows:

    4 green bars plus border (full)

    4 green bars (almost full)

    3 green bars (~ 75% charge)

    2 yellow bars (~ 50% charge)

    1 red bar (~ 25% charge)

    Empty battery icon (empty)
6. Once the destination is reached, plug the device's power supply cable into a facility-approved wall socket.
7. Connect the wall oxygen hose to the wall oxygen source. Close the oxygen cylinders. The manifold will automatically switch to the wall socket.

HVT 2.0

Section 5: Alarms & Advisories, Hospital/ Clinician Use

Alarms & Advisories Overview

The essential performance of the device consists of proper humidification at high flow rates, heating of water to physiologic levels and delivery of appropriate FiO_2. The user needs to appropriately respond to alarms and perform the required maintenance to ensure that the essential performance of the device is maintained. All alarms and advisories within the system are visible on the display as they occur. The steps to address the alarm or advisory will also be visible on the display via the [**More information**] button. Refer to the section "How to get information about an alarm" on page 47 for more details.

The HVT 2.0 employs two levels of alarms, depending on the urgency of the alarm.

Medium priority alarms: the alarm tone is a series of three beeps, repeated every 5 seconds. Medium-priority alarms take priority over and are sounded at a higher volume than all low-priority alarms. The alarm banner flashes yellow. In this state, the system is not delivering the prescribed therapy to the patient.

Low-priority alarms: the alarm tone is a series of two beeps, repeated every 20 seconds. The alarm banner is displayed in blue and does not flash. In this state, the system may be delivering the prescribed therapy to the patient.

Advisory: advisory messages are only visible when no alarms are present. Only one advisory is visible at a time. The advisory tone is one beep.

Keep in mind that:

- All alarms interface with the Nurse Call system, if it is enabled.
- Multiple simultaneous alarms will be displayed on the alarm list on the screen.

NOTE: **During start-up, the device will automatically perform a self-test to ensure proper operation. If any issues are detected, the system will give an alarm and prevent the starting of therapy.**

What to do if an alarm or alert occurs

Alarms will be audible and visual. A tone will sound, indicating the level of priority (low or medium), and the warning message will appear on the screen. Tap the [**Alarm silence**] button to silence the alarm for 2 minutes. [**Note**: to cancel the alarm silencing, tap the [**Alarm silence**] button again]. For more information about the specific alarm and what action to take, refer to the lists of alarms: Table: Medium-priority alarms and Table: Low-priority alarms.

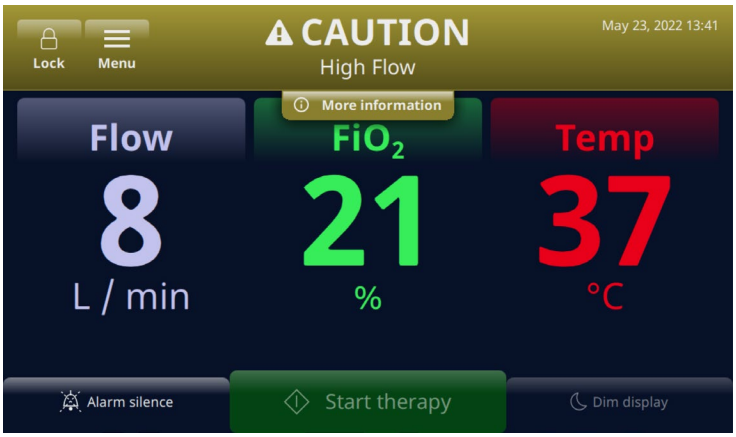

Figure 47: Sample of a caution being displayed on the screen

⚠	**WARNING:** General Fault alarms are failures in the control or measurement systems. Depending on the cause of the failure, gas delivery may or may not be interrupted. If a General Fault alarm occurs, disconnect the patient and shut off the device. The device must be repaired by trained service personnel.

NOTE on the operator's position: the alarm priorities have been designed for an operator positioned within 3 metres of the device.

Alarm system functionality verification

To test Alarm system functionality, insert a DPC into the unit and enter Run mode (parameter settings can be variable). Do not connect a cannula to the end of the delivery tube. While the unit is in Run mode, place your gloved thumb over the end of the delivery tube (see illustrations below). Verify that the Occluded/Blocked Tube alarm message displays on the screen and an audible alarm occurs. After verifying alarm functionality, wipe down the delivery tube outlet connector using the aseptic technique.

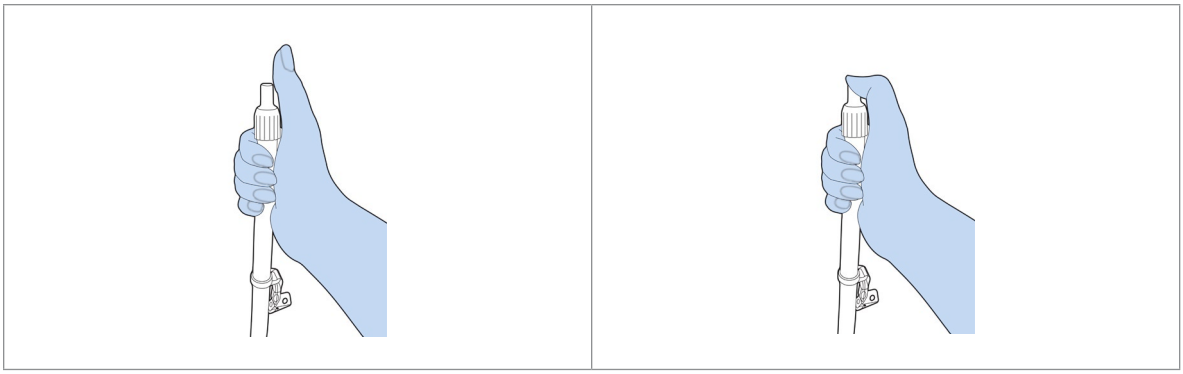

Figure 48: Verifying alarm system functionality

How to get information about an alarm

When an alarm sounds and flashes a banner on the screen, the device will display the name of the alarm. A [**More information**] button is available just below the banner to provide more details about the alarm.

NOTE: All alarms can be found on the "Event Log".

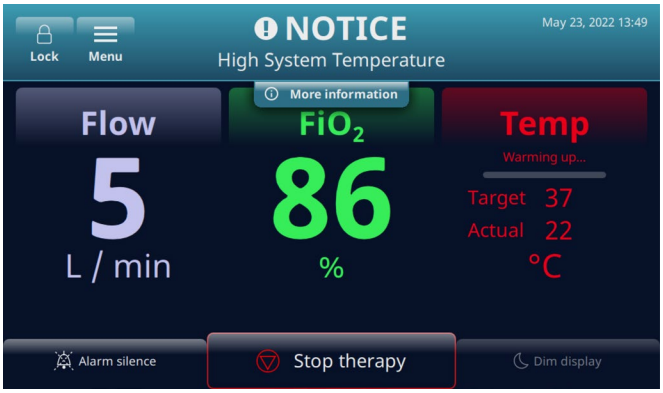

Figure 49: Sample of alarm displaying on the screen

After tapping the [**More information**] button, details about the alarm and what action to take will appear. Tap the [**Hide info**] button when you are finished in order to return to the previous screen.

Figure 50: Sample of **[More information]** *displaying on the screen*

Multiple alarms – Medium priority and low priority

When an alarm sounds and flashes a banner on the screen, the device will display the name of the alarm. A [**More information**] button is available just below the banner to provide more details about the alarm.

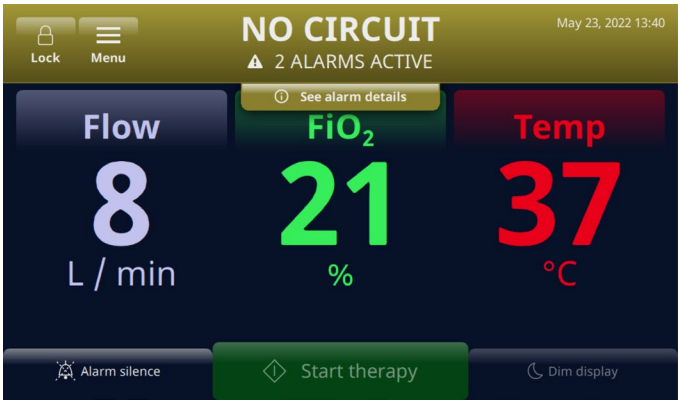

Figure 51: Sample of two active alarms displaying on screen

If there is more than one alarm at the same time, the alarms will be displayed on the screen and allow the user to scroll through the alarm list to address the alarms.

Select an alarm to get more information on the alarm and how to correct the problem.

For serious situations, such as ***Water out,*** tap the [**More information**] button for actions to take to rectify the problem.

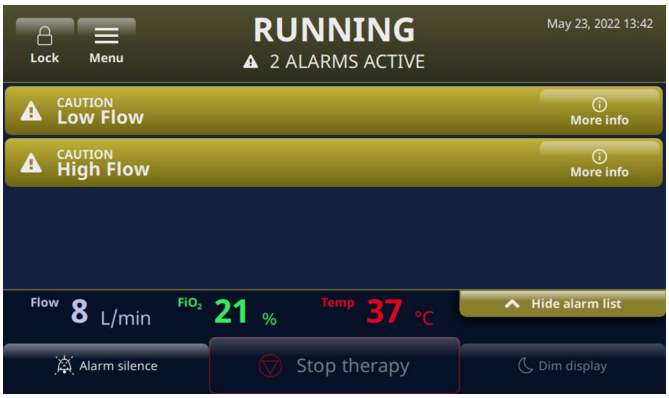

*Figure 52: Sample of caution with **[More information]** button*

Table: Medium-priority alarms

Message	Description and actions required
Low flow	Detected flow does not match user setting. Check cannula selection. If the alarm re-occurs, call your Vapotherm service provider for help.
High flow	Detected flow does not match user setting. If the alarm re-occurs, call your Vapotherm service provider for help.
Low gas temperature	Delivered gas temperature low. If the alarm re-occurs, call your Vapotherm service provider for help.
Low gas temperature [Transfer Battery]	Delivered gas temperature is low while operating the Transfer battery. The maximum temeperature when using the Transfer battery is 37 °C. To clear the fault condition, reduce the temperature set point. If the alarm re-occurs, call your Vapotherm service provider for help.
High gas temperature	Delivered gas temperature high. If the alarm re-occurs, call your Vapotherm service provider for help.
High gas temperature – Therapy stopped	Gas temperature exceeded limit. If the alarm re-occurs, call your Vapotherm service provider for help.
FiO_2 low	Detected FiO_2 does not match user setting. Check oxygen source. If the alarm re-occurs, call your Vapotherm service provider for help.
FiO_2 high	Detected FiO_2 does not match user setting. If the alarm re-occurs, call your Vapotherm service provider for help.
Water out	Water empty. Replace supply.
Occluded/ Blocked tube	Occluded delivery tube/cannula. Remove any kinks, clamps or obstructions in the delivery tube and cannula.
No power connected	Device running on safety battery. Therapy is being provided with unheated gas. Connect the device to power.
Oxygen input overpressure	Oxygen source input pressure too high.

Table: Medium-priority alarms (Continued)

Message	Description and actions required
Circuit removed during therapy	Circuit removed while therapy running. Therapy stopped. To continue therapy, re-insert the circuit.
FiO_2 Error – Therapy stopped	Detected FiO_2 does not match user setting. If the alarm re-occurs, call your Vapotherm service provider for help.
Safety battery failure	Safety battery failed or not installed. Call your Vapotherm service provider for help.
System error	If the error persists, remove the oxygen source from the device. Call your Vapotherm service provider for help.
Oxygen concentrator error	Low oxygen concentration from concentrator detected. Check that the selected value in the **Oxygen source** menu matches the connected oxygen concentrator.
Overheat warning – High system temperature	Check that the vents at the back and the bottom of the device are not obstructed. If the error persists, call your Vapotherm service provider for help.
System error – Therapy stopped	A device fault has occurred. Therapy stopped and cannot restart. To clear the fault condition: **power off the device, then power it on again**. If the alarm re-occurs, call your Vapotherm service provider for help.
Circuit error – Therapy stopped	Circuit error. Therapy stopped. If the alarm re-occurs, call your Vapotherm service provider for help.
Overheat system error – Therapy stopped	Device overheated. Therapy stopped and cannot restart. To clear the fault condition: **power off the device, then power it on again.** Call your Vapotherm service provider for help.

Table: Low-priority alarms

Message	Description and actions required
Water low	Water running low. Replace supply.
No power connected	Device running on safety battery. Connect the device to power.

Table: Information advisories

Message	Description and actions required
Water low	Water running low. Replace supply.
Water out	Water empty. Replace supply.
Safety battery low	Safety battery charge is low.
O_2 configuration mismatch	Detected O_2 input pressure (wall/tank) does not match selected O_2 source (concentrator). Confirm oxygen source selection in the settings menu.
O_2 configuration mismatch	Detected O_2 input pressure (concentrator) does not match selected O_2 source (wall/tank). Confirm oxygen source selection in the settings menu.

Water-level sensing

The HVT 2.0 device is equipped with water-level sensing to notify clinicians of the water level and indicate when water must be added. It provides notifications in the following intervals:

Alarm notification	Water-level
Low-priority alarm – Message: **Water supply low. Replace water supply.**	**First alarm:** Water supply running low.
Medium priority alarm – Message: **Water supply empty. Replace water supply.**	**Second alarm**: out of water.

Table: Recommended water-change interval based on flow rate and operation at 37 °C.

Flow rate	Average water usage per day	Recommended change interval
5-10 l/min	650 ml	500 ml/12 h
10-20 l/min	1,300 ml	500 ml/8 h
20-30 l/min	2,000 ml	1,000 ml/12 h
30-45 l/min	2,600 ml	1,000 ml/8 h

HVT 2.0

Section 6: Training

See your Vapotherm Service Provider or contact Vapotherm for detailed product training.

Additional training can be found at the Vapotherm Academy website accessible from the Vapotherm website and at the following:

- **US**: academy.vapotherm.com
- **UK**: uk.Academy.Vapotherm.com
- **Brazil**: https://academia-vapotherm.teachable.com/
- **Mexico**: https://academia-vapotherm-espanol.teachable.com/
- **All others**: global.academy.vapotherm.com

Section 7: Maintenance and disinfection

All HVT 2.0 disposables (patient circuits, cannulas and accessories) are validated for single patient use for up to 30 days.

Preventative maintenance

The table below outlines the anticipated schedule of routine maintenance.

Part number/Item description	Maintenance required (replace)	Requires return to a Vapotherm Service Centre
Patient air intake filter	• Replace the filter as recommended according to your institution's policy. (See instructions below, "Replace the patient air intake filter")	No
Internal safety battery	• Replace every 5 years (See instructions below, "Replace the internal safety battery")	No
Internal blower	• Replace every 5 years	Yes

Inspect the power supply cable

Visually inspect the power supply cable whenever you connect the device to mains power to verify that the power supply cable is not damaged or kinked.

Inspect the chassis vent and cooling fan

Visually inspect the chassis vent (below the device) and cooling fan (on the device's back panel) to verify that they are not obstructed and are allowing the free flow of air.

Replace the patient air intake filter

The patient air intake filter should be inspected frequently for particulate contamination and replaced every 6 months or as recommended according to your institution's policy.

To replace, insert the patient air intake filter into the back of the HVT 2.0 device.

Figure 53: Insert the patient air intake filter into the back of the device

Replace the internal safety battery

⚠	**Caution**: the HVT 2.0 will not operate without the internal safety battery in place. Have an internal safety battery on hand to ensure the continued availability of the use of the device. To ensure safe and reliable operation, use only the Vapotherm-specified replacement battery.

After five years of use, the internal safety battery must be replaced. The internal safety battery is located in the same compartment as the Transfer Battery. Remove the Transfer Battery access door, then remove the four screws holding the internal safety battery cover. Use the pull tab to slide out the internal safety battery. Slide in the new internal safety battery until it rests on the bottom of the compartment. Replace the cover and screws to assure that the internal safety battery is secured in position.

Cleaning and disinfection

⚠	**WARNING**: before cleaning and disinfecting, **unplug the device from mains power.**

⚠	**Caution**: do not use bleach, organic solvents or abrasive cleaners. Hypochlorite solutions liberate toxic gases such as chlorine when acidified or heated. The reaction with ammonia or with substances that can generate ammonia can produce chloramines which are also toxic and have explosive potential.

The entire disposable patient circuit (DPC) is disposable, and no disinfection is required. The main unit, including the docking station for the disposable water path, should be wiped down with a Super Sani-Cloth® or another approved cleaner (see list below). **Unplug the HVT 2.0 while cleaning and disinfecting.** The HVT 2.0 device must always be cleaned and disinfected between patients. Follow the steps below to ensure a clean and disinfected device.

1. Wipe down the main unit with a Super Sani-Cloth® or another approved cleaner.
2. Visually inspect for visible dirt. If visible dirt is present, repeat step 1. A brush (e.g. Spectrum M16 brush) may be used in addition to wiping down the unit.
3. Wet the main unit with another Super Sani-Cloth®. Keep the surface wet for at least six minutes. Use an additional Super Sani-Cloth®, if needed.

The following detergent wipes can be used to remove any dirt from the device:

- 70 to 90% isopropyl alcohol wipe
- 2% (maximum) chlorine cleaning solution
- 6% (maximum) hydrogen peroxide
- Metrex CaviWipes®
- PDI Healthcare Sani-Cloth® AF3 Germicidal
- EcoLab Incidin® OxyWipe
- BODE Chemie GmbH Bacillol® 30 Tissues
- GAMA Healthcare LTD. Clinell® Alcohol Wipes
- Vernacare Tuffie Disinfectant Wipes

⚠	**WARNING:** all disposable components are labelled as 'single patient use only' and must be replaced after 30 days of use on a single patient. Cannulas should be replaced according to clinical use, but must not exceed 30 days. Do not attempt to sterilise or reuse any of these components, and follow all local and US federal regulations for disposal. Outside the US, follow national or international regulations.

NOTE: The HVT 2.0 device should be cleaned according to the above instruction after each patient.

Disposal instructions

HVT 2.0 device disposal

The HVT 2.0 device contains electronics. Do not discard with regular waste. Instead, return the device to Vapotherm or dispose of it according to local guidelines on disposing of electronics.

For the European Union, dispose of the device according to the Waste Electrical and Electronic Equipment (WEEE) directive. 

Patient circuit and accessories disposal

At the end of use, place the cannula, the Disposable Patient Circuit (DPC) and any other Vapotherm consumable accessories that have been used into a waste supply. No disassembly of the disposable is needed prior to disposal. Discard all disposables according to hospital guidelines and local regulations for the safe disposal of medical single-use items.

Service

Service on the device should only be performed by qualified, certified service technicians. To prevent injury, do not attempt to do any service to the device while the device is connected to a patient.

Do not use the device if it is damaged or not working properly. If it is damaged or not working properly, contact Vapotherm or your authorised Vapotherm representative.

Vapotherm provides 24/7* Technical Support: +1 (888) 320–4506.

* Only available in the US. Customers outside the US should contact their distributor or local authorised Vapotherm Service Centre. If you do not know who your service centre or distributor is, contact Vapotherm.

Software updates

Software updates can be made locally via the USB port. Software updates will be made available to customers upon release.

HVT 2.0

Appendix A – Nurse Call System Installations

Nurse Call Installation Instructions

Introduction

The information below describes the Nurse Call communication interface of the HVT 2.0 device. This information is intended for use by hospital IT, biomedical engineering or other experts who wish to connect the HVT 2.0 into a Nurse Call System.

Scope

This information applies to the current design and embedded firmware version of the HVT 2.0 device.

Nurse Call Hardware Interface Description

The Nurse Call Communication Cable is available in four variants:

Part number	Cable type
RN	NO contact
RN-10	NO + 10k contact
RN-RC	NC contact
RN-RC10	NC + 10k contact

Please order the cable type compatible with your Nurse Call system.

Installation verification procedure

Verify that the complete system is functioning by creating a Test Alarm and checking that the correct result has been received.

1. Connect and turn on the HVT 2.0 device. (Refer to the "Starting therapy" section of the HVT 2.0 Instruction for Use (Part No. "43000656-EN-GB Rev A").
2. Force an alarm occurrence by placing your thumb over the distal end of the delivery tube to simulate a blocked tube condition.
3. Confirm that you've received the result you expect in the system according to the hospital standard for that alarm, such as a warning light is turned on or an audio signal is received.
4. Release your thumb from over the distal end of the delivery tube to clear the blocked tube condition and confirm that the nurse call alarm condition clears.

After the test has been successfully concluded, the Nurse Call is ready for use.

HVT 2.0

Appendix B – Electronic Medical Records (EMR) Integration

The HVT 2.0 provides an isolated RS-232 serial interface to support hospital integration of HVT 2.0 operational data with an electronic medical record. Information for the hardware interface and data format are available from Vapotherm upon request.

The HVT 2.0 data stream is a transmit-only communication protocol. When enabled, the data stream is transmitted when therapy is on. Transmitted data includes:

- Therapy parameters (flow rate, temperature, FiO_2, etc.)
- Pulse oximetry data (if unit is OAM capable)
- System state information

No patient-identifiable information is included in the data stream.

NOTE: To maintain electrical safety, use only Vapotherm-provided interface cables.

Integration with an EMR system is the responsibility of the customer and is often done by third-party integrators. While operation of HVT 2.0 is not affected by the configuration of devices connected to this port, safe and effective use of transmitted data is the responsibility of the integrator and responsible organisation. Bernoulli Systems (formally Nuvon) and Capsule are the Vapotherm-supported third-party integrators.

Figure B1: HVT 2.0 EMR Link cable placed in the EMR data port

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HVT 2.0

Appendix C – Technical Specifications

Physical characteristics

Dimensions:	Height 9.1" (23.114 cm), width 11.1" (28.194 cm), depth 12.1" (30.734 cm)
Weight:	7.26 kg.
Mounting:	Tabletop or roll stand; fits IV poles up to 38 mm (1.5") in diameter
Gas connections:	Standard NIST non-interchangeable fittings for oxygen
Fuses:	Type T4AH250V
Contact with patient:	Indirectly via the delivery tube and cannula
Context of use:	General care floors, accident and emergency departments, intensive-care units, long-term acute care facilities, skilled nursing facilities.

System requirements

AC power:	110 to 240 VAC, 50 to 60 Hz
Back-up power/Safety battery:	The reserve power will last for a minimum of 15 minutes at 45 l/min flow rate
Oxygen supply:	Oxygen or oxygen concentration at inlet pressures between 4 and 65 psi (450 kPa)
Water supply:	Sterile or distilled water in pre-filled sealed bags or bottles.

Environment

Operation:	Ambient temperature: 18 to 30 °C
	Ambient relative humidity: 15 to 90% non-condensing
	Ambient pressure: standard atmospheric (not to be used in hyperbaric cond.)
Storage and delivery:	Ambient temperature: -10 to +50 °C
	Ambient relative humidity: 10 to 90% RH non-condensing
Altitude:	0 to 3,000m (0 to 9,843 ft): full flow range available.

Performance

Temperature:	Range: 33 °C to 39 °C at exit from the delivery tube; adjustable
	Resolution: 1 °C
	Accuracy: ± 2 °C
Warm-up time:	± 2 °C of 33 °C set point < 5 minutes (at ambient 23 °C)
Oxygen percentage:	Range: 21% to 100% O_2
	Accuracy: ± 3% wall or tank source ± 4% oxygen concentrator
	Resolution: 1%
Flow rate:	5 to 45 l/min BTPS
Flow rate accuracy	Greater than 0.5 l/min or 10% of setting
Expected service life of device:	5 years

NOTE: Temperature, O_2%, and flow rate accuracies have been established inclusive of all test equipment measurement uncertainties.

NOTE: Absolute Humidity > 16 mg/L at all combinations of flow rates, temperatures and oxygen concentrations.

NOTE: Absolute Humidity ≥ 33 mg/l is maintained at flow rates of ≥ 8 l/min, temperatures ≥ 37 °C, and at all available FiO_2 settings.

NOTE: When using an oxygen concentrator, 45 l/min flow often has a maximum FiO_2 range of 36%.

Useful life

Part	Useful life
HVT 2.0 device	5 years
Disposable Patient Circuit (DPC)	30 days
ProSoft Nasal Cannulas	30 days
Tubing Adapter	30 days
Power supply cable	5 years
Patient air intake filter	6 months, or as recommended according to institution policy
Internal safety battery	5 years
Internal blower	5 years
Roll Stand	5 years
Transfer upgrade kit	5 years

Use with oxygen concentrators

⚠	**WARNING**: If used with an oxygen concentrator, the maximum oxygen percentage will be limited depending on the type of concentrator used and total set flow.

The table below shows the maximum % O_2 delivered for the set HVT 2.0 flow rate and concentrator flow limit of 5 l/min and 10 l/min. The HVT 2.0 is compatible with the Philips EverFlo Concentrator, Inogen Home Concentrator and Respironics Millennium M10 Concentrator.

HVT 2.0 flow rate	HVT 2.0 FiO_2 output		
		OC output of 5 l/min	**OC output of 10 l/min**
	5	90%	90%
	10	56%	90%
	15	44%	67%
	20	38%	56%
	25	35%	49%
	30	33%	44%
	35	31%	41%
	40	30%	38%
	45	*29%*	*36%*

Inputs

Airway gas:	Oxygen NIST connector or oxygen 6.35 mm barb nipple
External device comm.:	USB and Ethernet

Outputs

(Only compatible with other IEC60601-1-approved devices)

Nurse Call:	6.35 mm modular jack

Bidirectional connectivity

USB:	USB 2.0, Type A Connector. Up to 64 MB capability. ⚠ **WARNING**: Do not connect any device, system or accessory that has not been approved by Vapotherm.
Ethernet:	RJ45 modular jack
EMR connectivity:	RS-232 serial connection via an interface cable
Wi-Fi:	2.4 GHz, 802.11 b/g/n

Minimum alarm sound pressure ranges

High-priority alarm	> 80 dBA
Medium-priority alarm:	> 50 dBA
Low-priority alarm:	> 45 dBA

Alarm type and test conditions	Calculated average A-weighted sound pressure level (dBA)	
	Max	Min
Medium-priority alarm	75.65	51.46
Low-priority alarmS	72.27	45.00

Available parameter settings and factory defaults

Parameter	Available settings	Factory defaults
TEMP set point	33 °C to 39 °C	37 °C
Gas flow	5 to 45 l/min	n/a
Percentage oxygen	21% to 100%	n/a
Care area (service setting)	Acute Care (hospital or sub-acute)	Acute Care (hospital or sub-acute)

NOTE: When using an oxygen concentrator, 45 l/min flow often has a maximum FiO_2 range of 36%.

Cybersecurity

Vapotherm has designed the HVT 2.0 system to be resistant to cyberattacks in order to maintain the integrity and availability of the device. These features do not require any user configuration or action.

- The device does not collect or maintain any protected health information (PHI).
- Real-time therapy control is isolated through a secure proprietary link to hardware with no available network ports.
- The device is configured securely to prevent unauthorised access either wirelessly or through the communication ports intended for future use.
- Software updates are performed via USB drive, rather than over the Internet.
- Software updates are verified by digital signature.

Standards/References

Reference	Description
ANSI/AAMI ES60601-1: 2005 / I2012 CAN/CSA-C22.2 No. 60601-1:14 IEC 60601-1: 2005 + A1: 2012, Third Edition –	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2 ed 4.0 (2014-02)	Medical Electrical Equipment – General Requirements for Safety – Collateral Standard Electromagnetic disturbances
IEC 60601-1-6:2010, AMD1:2013	Medical Electrical Equipment Part 1 – 6 General Requirements for Safety – Collateral Standard: Usability
IEC 60601-1- 8: 2006 (Second Edition) + Am.1: 2012	General requirements for basic safety and essential performance – Collateral Standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-1-9:2007, AMD1:2013	General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design
IEC 62366-1: 2015	Medical Devices – Application of Usability Engineering to Medical Devices
ISO 80601-2-74:2017	Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems
IEC 60601-1-10:2007, AMD1:2013	General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers

Guidance and Manufacturer's Declaration

Electromagnetic emissions

The HVT 2.0 is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Manufacturer's Declaration – Electromagnetic Immunity

IEC 60601-1-2:2014	
Sub test	**Passed parameters**
Electro-static discharge* IEC 61000-4-2 ed2.0 (2008-12)	±8 kV Contact discharge ±15 kV Air discharge
Radiated RF susceptibility IEC 61000-4-3:2006, +A1:2007, +A2:2010	80- 2700MHz @ 20 V/m, 80% AM @2Hz
Electrical fast transients IEC 61000-4-4 ed3.0 (2012-04)	±2 kV AC mains
Surges IEC 61000-4-5 ed2.0 (2005)	±0.5, 1 kV line to line
Line-conducted RF susceptibility IEC 61000-4-6 ed4.0 (2013)	0.15-80MHz @ 3Vrms (6Vrms in ISM and Amateur Radio Bands) 1 kHz AM 80% modulation
Power frequency magnetics IEC 61000-4-8 ed2.0 (2009-09)	30 A/m @ 50/60Hz
Voltage dips and dropouts IEC 61000-4-11 ed2.0 (2004-03)	Per standard

***ESD mitigation measures include maintaining adequate relative humidity and touching a large metal object that is away from the HVT 2.0 and the patient before touching the device. Note that a '**Water out**' message could be displayed in response to electrostatic discharge to the device.

Test specifications for enclosure port immunity to RF wireless communications equipment

Test Frequency (MHz)	Immunity Test level (V/m)
385	27
450	28
710	9
745	
780	
810	28
870	
930	
1720	
1845	
1970	
2450	
5240	9
5500	
5785	

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Appendix D: Software update process

The software update process allows the user to press one button on the Software Update screen to update both the Controller software and GUI application.

! IMPORTANT NOTES on the Software Update Process:

- Therapy must be stopped before a software update can be started.
- The device will update the Controller software first and then the GUI.
- The device will reboot after each software application update.
- Dialogue boxes will be displayed throughout the update process to keep the user informed on the progress of the update.
- A software update will not be allowed while in therapy. A dialogue box will be displayed telling the user they must stop therapy to perform a software update.
- The [**Update software**] button will only be enabled when a USB (which contains the complete update package) is plugged in to the back of the device.
- A dialogue box will display if a failure occurs. However, the device will be in a recoverable state, i.e., it will automatically revert to the previous state before the failed software update attempt.
- A final dialogue box will be displayed when the software update is successful.

Steps to update Controller and GUI software:

1. Place the USB stick containing the update into the back of the device.

   When the USB is in place, the [**Update software**] button will be enabled on the device screen.

2. Press the [**Update software**] button to begin.

*Figure D1: [**Update software**] button enabled when the USB is plugged in to the back of the device*

3. A confirmation pop-up will display.

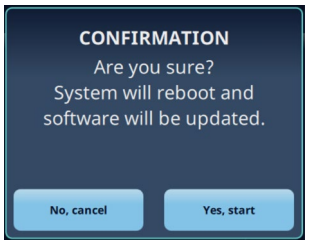

Figure D2: Confirmation pop-up screen

4. Press the [**Yes, start**] button to begin the process.

   The Software Update process will begin with the Controller software update and then will reboot the system.

5. After the Controller software update and reboot, the GUI update occurs.

   The device reboots after updating the GUI software.

6. When the process is complete, a success dialogue box will appear on the screen.

   Software update succeeded.

7. Press the [**OK**] button to acknowledge that the software update succeeded.

   NOTE: If the update failed, a dialogue box will appear informing the user to contact customer service.

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Appendix E: Symbol & Icon Key

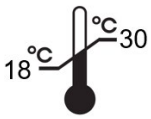
Device Screen Icons

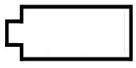
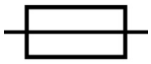
	Silence alarm button
	Internal safety battery charge status
	Dim display
	Settings menu
	Touchscreen Lock/Unlock selector (System Settings Menu)
	Start therapy/Stop therapy buttons
	Power button
	AC power connected
	Device powering up
	Internal safety battery charging (when AC power is connected)
	Internal safety battery is active
	Transfer battery – 4 green bars plus border (full)
	Transfer battery – 4 green bars (almost full)
	Transfer battery – 3 green bars (~ 75% charge)

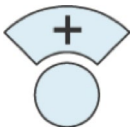
	Transfer battery – 2 yellow bars (~ 50% charge)
	Transfer battery – 1 red bar (~ 25% charge)
	Transfer battery – empty battery (empty)
Temp	Temperature
Flow	Flow rate
FiO_2	FiO_2 percentage

Labelling symbols

	Caution: US Federal Law restricts this device to sale by or on the order of a physician.
	Medical Device Symbol. (Note: This is not an internationally recognised symbol.)
	Product complies with requirements of the RoHS Directive 2011/65/EU and must bear the CE marking.
	For indoor use only.
IP22	IP22 drip-proof and prevents adult finger ingress
	Alternating current
	Single patient use; Do not re-use
	Do not cover

	CLASS II equipment
	Shock protection: Type BF
	This symbol indicates that electrical and electronic equipment waste must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorised representative of the manufacturer for information concerning the decommissioning of your equipment.
	Ambient temperature operating range
	Consult instructions for use
	e-IFU: Consult Instructions for Use, indicates the web address where the e-IFU is located, e.g. https://vapotherm.com/international-documents/
	MR-unsafe – keep away from magnetic resonance imaging (MRI) equipment
CE 0297	Mandatory marking for devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Directives. Accompanied by the 4-digit ID number of the notified body.
	Manufacturer, adjacent to name and address of the manufacturer
	Date of manufacture, YYYY-MM-DD
	Lot number, accompanied by the manufacturer's batch code.

	Reference number
	Manufacturer's serial number
	Use by expiry date, YYYY-MM-DD
	Non-sterile – Device has not been sterilised
	Caution, consult accompanying documents, or Attention, see Instructions for Use
	Authorised Representative in the European Community, accompanied by the name and address of the authorised representative in the European Union.
	Authorised Representative in Switzerland, accompanied by the name and address of the authorised representative in Switzerland.
	External DC power input
	Internal battery: Lithium-ion 14.4V, 6,900 mA hour. Replaceable by service technician only. See the "Service" section in "Maintenance and disinfection".
	Fuse: replace with an indicated fuse only
	Oxygen connection port. See oxygen supply specifications in "System requirements" of "Appendix C – Technical Specifications".

	Nurse Call connection. See "Appendix A – Nurse Call System Installations".
	Electronic medical record connection.
aux	Auxiliary connection. For factory use only.

Vapotherm Inc. has declared that this product conforms with the European Council Directive 93/42/EEC Medical Device Directive when it is used in accordance with the instructions provided in the Instructions for Use.

Trademark citations:

Masimo SET™, X-Cal™, LNCS® and RD SET™ are registered trademarks of Masimo Corporation

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Appendix F: Glossary

Terms

- **Disposable Patient Circuit (DPC)** – The DPC (or 'Circuit') enables delivery of high-velocity therapy for paediatric and adult patients for the full flow range from 5 to 45 L/ min. The DPC is a component of the HVT 2.0 system and is detachable and disposable. **Note**: The DPC is provided fully assembled and ready to use.
- **Electronic Medical Records (EMR) System** – Electronic Medical Records system. The HVT 2.0 system can be interfaced with the hospital's Electronic Medical Records (EMR) system.
- **FiO_2** – Fraction of inspired oxygen. It is the concentration or percentage of oxygen that a person inhales.
- **HVT 2.0 device** – The HVT 2.0 system is made up of the controller device and the disposable patient circuit (DPC), which together enable the delivery of high-velocity therapy to the patient.
- **Nasal Cannula** – Device used to deliver supplemental oxygen or increased airflow to a patient in need of respiratory help. It consists of a lightweight tube that, at one end, splits into two prongs that are placed in the nostrils and from which a mixture of air and oxygen flows.
- **Nurse Call System** – A system in the health care facility that allows patients to call or contact their nurse or nurse's station. The HVT 2.0 allows connectivity between the device and the hospital's Nurse Call system.
- **Transfer Upgrade Kit** – This kit is used with the roll stand and allows moving the patient from one location to another within the hospital while the patient continues to be connected and receiving therapy. The kit includes a battery, oxygen manifold, oxygen hoses and adjustable oxygen tank holder.
- **Tubing Adapter** – This adapter allows the DPC to be connected to a trach collar or t-piece in place of a nasal cannula.

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Warranty

Vapotherm expressly warrants, for a period of one (1) year from the date of shipment by Vapotherm to the initial purchaser of the HVT 2.0 device ('Customer'), that the HVT 2.0 device shall meet the specifications set forth in the applicable official operating Instructions for Use provided with each HVT 2.0 device (the 'Instructions'). The sole remedy for this warranty is that Vapotherm shall, at its sole discretion, either refund, repair or replace any or all of any HVT 2.0 device that is defective at no cost to the Customer. Vapotherm shall pay any delivery charges required in repairing or replacing any part, or all of an HVT 2.0 device during the warranty period. Thereafter, delivery charges shall be paid by the Customer. The Customer shall also be responsible for the cost of labour for repairs. This warranty does not apply to any disposable component to the HVT 2.0 device, including without limitation the disposable patient circuits and hoses supplied with the HVT 2.0 device.

The warranty set forth herein shall become null and void if: (1) the HVT 2.0 device is not used or serviced in accordance with the applicable instructions or any related preventative maintenance instructions provided with the HVT 2.0 device; or (2) the HVT 2.0 device is opened or tampered with, or if repairs or service are performed or attempted on the HVT 2.0 device by anyone other than Vapotherm or a Vapotherm-certified service centre.

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