HAMILTON-EM7

Operator's Manual

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HAMILTON MEDICAL

Operator's Manual

HAMILTON-EM7

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HAMILTON-EM7 Documentation

Be sure to read the documentation *before* using the device or accessories.

This guide is part of a documentation suite[1] that includes, among others, the following documents.

Table 1. HAMILTON-EM7 documentation suite

Document title	Description
Operator's Manual (this guide)	Provides detailed information about the setup and use of the HAMILTON-EM7 ventilator.
Quick Start (PN 10175022)	Provides an overview of daily tasks related to the ventilator, connecting the breathing circuit set, and performing the preoperational checks.
Service Manual (PN 10148906)	Provides information about installing and setting up the medical equipment, as well as additional technical and servicing information for the ventilator.
EMC Declarations Guide (PN 10160380)	Provides emissions and EMC-related safety and use information for the ventilator.
Breathing circuit set *Instructions for use* (PN 10160379)	Provides specifications, and set-up and use information for the Hamilton Medical breathing circuit sets.

Documentation downloads and training

To download the latest version of this manual or other documents, visit the Hamilton Medical Resource Center: https://www.hamilton-medical.com/Resource-center

Hamilton Medical offers the Hamilton Medical e-Academy, which provides a variety of learning modules free of charge. To register, go to: https://e-academy.hamilton-medical.com

A QR code on the device display during startup provides a link to the Hamilton Medical Resource Center, where you can download this manual and related product documentation.

[1] The user documentation provided by Hamilton Medical is developed in English. The manuals are translated into all other languages by ISO 9001- and 17100-certified translators.

Conventions used in this guide

In this manual:

- Button and tab names are shown in a **bold** font.
- Window names are shown using the sequence of buttons/tabs used to open them.

  For example, "Alarms > Limits 2 window" means the window is accessed by touching the **Alarms** button, then the **Limits 2** tab.
- *Software version:* The software version for the ventilator is displayed in the  > Info / File export > System information window and should match the version on the title page of this manual.
- A green check mark  or button XXX indicates a selected item or feature.
- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.

  ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.

  Ⓐ These callouts show the sequence of steps. They are *not* directly related to the numbering in the text of any associated procedure.
- *Units of measure:* Pressure is indicated in mbar, length in cm, and temperature in degrees Celsius (°C). For values related to PetCO2, pressure is indicated in mmHg. The units of measure for pressure, length, and PetCO2 are configurable.
- All patient-related volume and flow measurements are expressed in BTPS (body temperature, ambient pressure, gas saturated with water vapor).
- Pneumatic-related volume and flow measurements are expressed in STPD (standard temperature, pressure, dry).
- The term *USB drive* refers to a passive USB memory device, also known as a USB flash drive or USB memory stick.
- The terms *user* and *operator* are used interchangeably and refer to the operator of the device.
- Unless otherwise indicated, the information in this manual applies to the HAMILTON-EM7 PN 10101723 (red, written as (r)) and 10163814 (gray, written as (g)).
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

Safety messages are displayed as follows:

⚠ WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or in damage to the medical device or other property.

NOTICE

A NOTICE provides additional information intended to avoid inconvenience during operation.

In tables, safety messages are indicated as follows:

⚠ WARNING!

⚠ CAUTION!

NOTICE!

1 Safety information

1.1 Overview

This chapter provides safety information related to setting up and operating the HAMILTON-EM7 ventilator, as well as providing service.

Be sure to review this Operator's Manual before using the ventilator and any accessories. Accessories include any and all consumables and other components used with the ventilator.

Be sure to read the Instructions for Use provided with any devices and accessories used with the ventilator before use.

Carefully review all sections of this safety chapter before setting up the ventilator and accessories, and ventilating the patient.

If you have questions about any of the information in this manual, contact your Hamilton Medical representative or technical service personnel.

1.2 Intended use, indications and contraindications for use

Table 1-1. Intended use information for HAMILTON-EM7 PN 10101723 (r), 10163814 (g)

Category	Text
Intended purpose / use	The HAMILTON-EM7 ventilator is designed to provide positive pressure ventilatory support.
Intended patient / target group	Adult and pediatric patients[1].
Intended user / user group	The HAMILTON-EM7 is intended to be used by health care professionals under the direct supervision of a licensed physician.
Intended use environment	Intended areas of use: • Health care facilities (emergency medical care only) • For emergency medical care • During transport within and outside the hospital • During transfer by rescue vehicles, fixed wing aircraft, helicopter, or ship
Indications	Respiratory insufficiency or failure.
Contraindications	Using noninvasive ventilation is contraindicated if any of the following conditions are met: • The patient does not have the drive to breathe • Partial or complete airway obstruction • Gastrointestinal bleeding • Anatomic or subjective intolerance of noninvasive interface • Patient is unable to cooperate or protect airway ASV is contraindicated with the following: • Infants and neonates • If there is a high leakage (noninvasive ventilation or bronchopleural fistula) • Irregular respiratory drive (Cheyne-Stokes respiration)
Intended part of the body or type of tissue applied to or interacted with	Indirect contact: airway mucosa and lung tissue

[1] *(USA only)* The pediatric patient group includes children and adolescent patients according to the FDA definition (Premarket Assessment of Pediatric Medical Devices Guidance for Industry and Food and Drug Administration Staff, 2014).

1.3 Electromagnetic susceptibility safety information

⚠ WARNING

- **MR UNSAFE.** Keep away from magnetic resonance imaging (MRI) equipment. The ventilator poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
- Correct function of the device may be impaired by the operation of high-frequency surgical equipment, microwaves, shortwaves, or strong magnetic fields in close proximity.
- Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from the ventilator and any connected devices and accessories. For details, see the *HAMILTON-EM7 EMC Declarations* (PN 10160380).
- Use of accessories, transducers, and cables other than those specified by Hamilton Medical can result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment, and can result in improper operation.
- Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should be placed no closer than 30 cm (12 in) to any part of the ventilator, including any specified cables. Otherwise, degradation of the performance of this equipment can occur.
- Certain RF transmitting devices (cellular phones, RFID equipment, walkie-talkies, cordless phones, paging transmitters, etc.) emit radio frequencies that could affect ventilator performance if operated too closely to the ventilator. Be aware of possible radio frequency interference if portable devices are operated in close proximity to the ventilator.

The ventilator requires special precautions regarding electromagnetic compatibility (EMC). It must be installed and put into service according to the EMC information provided in the ventilator *EMC Declarations* (PN 10160380).

Portable and mobile RF communications equipment can affect the ventilator and all medical electrical equipment.

1.4 Fire and other hazards safety information

For device use instructions, see Chapters 3 and later.

⚠ WARNING

- It is *not* permitted to use flammable gases or anesthetic agents that pass through the ventilator, or to run the ventilator in insufficiently ventilated areas.
  Danger of fire! Only air and oxygen are allowed for use in the ventilator. Other gases may be added at the breathing circuit set, external to the *To patient* port.
- To reduce risk of fire or explosion, do *not* place the ventilator in a combustible or explosive environment, or in insufficiently ventilated areas, where flammable liquids, gases, or vapors are likely to occur.
- To reduce the risk of fire, use only breathing circuit sets intended for use in oxygen-enriched environments. Do *not* use antistatic or electrically conductive tubing.
- Only use an approved Hamilton Medical battery in the ventilator (see Chapter 11 and/or the e-catalog on the Hamilton Medical website). **Danger of fire with use of third-party batteries.**
- It is *not* permitted to use the ventilator with helium or mixtures of helium. Such use might cause the ventilator to *not* function correctly, causing patient death or serious deterioration of health.
- During oxygen therapy or with noninvasive ventilation, do *not* use near open flames. Danger of fire, which can result in burns or death. Do *not* allow open flames within two (2) meters of the equipment or any oxygen-carrying accessories.
- Do *not* use the ventilator with any equipment or high-pressure gas hoses that are worn or contaminated with oil or grease.
- Highly compressed oxygen together with flammable sources can lead to spontaneous explosions.
- In case of fire, immediately secure the patient's ventilatory needs, turn off the ventilator, and disconnect it from its gas and electrical sources.
- Do *not* lubricate any part of the equipment, connections, tubing, or accessories to avoid the risk of fire and burns.
- Do *not* use if primary power cords are damaged.

⚠ CAUTION

If the carbon monoxide level is unsafe, use 100% O2 for the patient, and move the patient to an environment with breathable air.

1.5 General operation and setup safety information

This section provides the following safety information:

- General operation and setup
- Electrical: power and batteries
- Gas supply
- USB port
- Transport
- Nuclear, biologic, and chemical (NBC) environments

For device setup information, see Chapter 3. For device operation details, see Chapters 4 through 8.

1.5.1 General operation and setup

Additional operation and setup-related safety information is presented in Section 1.6.

⚠ WARNING

- This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury.
- Do *not* cover or enclose the ventilator or position it in such a way that the operation or performance of the ventilator is adversely affected. For example, do not place the ventilator in a bag.
- To prevent possible patient injury, do *not* block the air intake opening on the side of the ventilator (see Figure 2-3). This opening is for the fresh air intake.
- In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.
- An alternative means of ventilation *must* be available whenever the ventilator is in use. If a fault is detected in the ventilator or its life-support functions are in doubt, disconnect the ventilator from the patient and *immediately* start ventilation with an alternate device (for example, a resuscitation bag), using PEEP and/or increased oxygen concentration when appropriate.
  The ventilator *must* be removed from clinical use and serviced by Hamilton Medical authorized service personnel.
- Only use the ventilator, its components, accessories, and consumables according to the intended use and as described in the associated *Instructions for use*. Any other use might cause the ventilator to *not* function correctly, causing patient death or serious deterioration of health.
- Modifications to the device and any accessories are *not* permitted. Such use might cause the ventilator to *not* function correctly, causing patient death or serious deterioration of health.

- Use only Hamilton Medical-approved parts, spare parts, and accessories, including ventilator mounting solutions, that are specified in Chapter 11 and in the product e-catalog, that are specified as being compatible with this ventilator. Doing so safeguards the patient, ensures proper ventilation operation, avoids the risk of fire and burns, avoids degraded performance, and keeps your warranty in force.
- Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. All configurations must comply with the requirements for medical electrical systems, IEC 60601-1, clause 16.
- Anybody connecting additional equipment to medical electrical equipment configures a medical system and is responsible for ensuring that the system complies with the requirements for medical electrical systems. Local laws take priority over the above-specified requirements. When developing a medical system, to ensure patient safety, a double safeguard is required for overall isolation between mains-supplied IEC 62368-approved external devices up to the applied part in accordance with IEC 60601-1.
- Only use the ventilator within the temperature range specified in Table 12-2. Only use any components and accessories within the temperature range specified in their respective *Instructions for use*. Any use outside the stated temperature ranges might cause the ventilator to *not* function correctly and might impact the function of the components/accessories, causing patient death or serious deterioration of patient health.
- Ensure the oxygen source connected to the oxygen inlet is specified to operate within the limits of the ventilator specifications (see Section 12.3). Failure to do so may result in equipment damage, injury, or serious deterioration of health.
- The use of this equipment is restricted to one patient at a time.
- Do *not* let the ventilator touch the patient or place the ventilator in contact with the patient. The device may become hot and cause patient harm.
- The ventilator must *not* be used in a hyperbaric chamber. Such use might cause the ventilator to *not* function correctly, causing patient death or serious deterioration of health.
- If there is damage to any part of the ventilator, do *not* use the device. Technical service is required.
- If the ventilator is dropped or falls to the ground, proceed as described in Section 9.7, *Dropped device protocol*.
- If using night vision goggles (NVG), check to ensure compatibility of the equipment *before* initial use.

⚠ CAUTION

- *A HEPA inlet filter must be installed at the air intake. For details, see Chapter 9.*
- *Motion of the device and attached breathing system may increase the risk of auto-triggering. When used in rescue vehicles, fixed wing aircraft, helicopter, or ship, adjust the trigger sensitivity if needed (Section 4.6).*
- *Prior to use, check the stability of all connections.*
- *When in Standby, the ventilator does not automatically resume ventilation when the patient is reconnected. You must manually restart ventilation.*
- *When the ventilator is not in use, be sure to cover the To patient port and the flow sensor pressure plug connectors with the red protective caps to prevent contamination of the device or ingress of liquids.*
- *The IP protection of the device is not ensured if the device is opened.*

NOTICE

- Any incident with the device leading to serious patient injury, death, or a potential threat to public health must be reported to the manufacturer and the relevant authorities.
- The ventilator provides automatic barometric pressure compensation.
- Access to the device configuration settings requires a code; contact your administrator.

1.5.2 Electrical power and battery safety information

For details about power and battery use, see Sections 3.3 and 3.3.2.

⚠ WARNING

- Only use the original power cord provided with the HAMILTON-EM7 to connect the device to the primary power supply.
- Only connect the device power cord to a direct primary power supply. Do *not* connect the power cord to an extension cord or multiple outlet power strip.
- Check primary cord and power adapter before use for visible damage, for example, exposed electrical components. Do *not* use a damaged power cord or power adapter, as this can lead to electric shock.
- Only exchange the battery when an external power supply is connected; otherwise ventilation stops.
- Periodically check or replace the battery.
- Check the battery charge level before ventilating a patient and before unplugging the ventilator for transport or other purposes.
- The battery may *not* charge if the battery temperature is above 52°C.

NOTICE

- Battery life indications are approximate. The actual battery operating time depends on ventilator settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.
- The device stores the last settings, including any specified alarm limits, which will be available if the power is interrupted. If the device reconnects to the power supply within 120 seconds, ventilation resumes with these stored settings.
- To electrically isolate the ventilator electrical circuits from all poles of the primary power supply simultaneously, disconnect the power plug.

1.5.2.1 Connecting to DC power

For details about DC power use, see Section 3.3.1

NOTICE

- Only qualified technicians are allowed to configure the open end of the supplied DC cable with open contacts.
- The HAMILTON-EM7 DC cables may *only* be used with the HAMILTON-EM7 ventilator.
- The DC cables are for use only with a 12-28 V DC electrical power supply:

  – With the open-end cable (PN 10159938), an additional 15-amp fuse **must be** included (*not* provided with the cable).

  – The car cable (PN 10149117) is provided with an integrated 16-amp fuse.
- Always check the reliability of the DC power source. When DC power is connected, the charging icon (⚡) symbol is shown on the display. See Table 3-3.
- Set up the ventilator in a location where the DC power socket is easily accessible at all times.

1.5.3 Gas supply safety information

Connection and usage information is provided in Sections 3.4 and 4.5. Specifications are provided in Section 12.3.

⚠ WARNING

- Only connect the ventilator to an oxygen supply that complies with ISO 7396-1:2016+AMD1:2017.
- It is the responsibility of the operator to ensure that the oxygen source is compatible with the rated range of pressure, flow rate, and oxygen concentration as marked on the equipment and indicated in this *Operator's Manual* (Section 12.3), as this can affect the performance of the equipment or pipeline system, which can consequently result in serious deterioration of health.
- Before transporting the patient, ensure the oxygen supply is adequate by checking the O2 consumption parameter on the main display and ensuring it is adequate for your estimated travel time and current oxygen capacity. See Section 4.5.

⚠ CAUTION

- *Always check the status of the oxygen cylinders or other supply before using the ventilator during transport.*
- *When using a 93% oxygen gas supply, the delivered oxygen may be lower than the set value.*
- *When delivering therapy with the ventilator connected to an oxygen cylinder, pay particular attention to the oxygen consumption rate to ensure an adequate supply. Ensure the consumption rate remains below 40 l/min. Oxygen depletion can lead to desaturation and place the patient at risk.*

NOTICE

- To prevent damage to the ventilator, connect only clean, dry medical grade oxygen.
- When the ventilator is not in use, disconnect all oxygen supplies.

1.5.4 USB port safety information

⚠ WARNING

Do *not* use the USB port to make a wireless connection of any kind.

⚠ CAUTION

- *The USB port is not accessible during patient use of the ventilator.*
- *You may connect only a USB drive to the USB port.*

NOTICE

- Do *not* connect a USB hub to the USB port. Only one device may be connected at a time.
- The USB drive must be USB 2.0 compatible.
- During a file transfer, if you remove the USB drive before files are completely transferred, you *must* turn the ventilator off and on again to reset the USB port.

1.5.5 Transport safety information

For additional safety information related to the gas supply for transport, see also Section 1.5.3.

⚠ WARNING

- Do *not* place the ventilator in such a way that it touches the patient. During use the device may get hot.
- Device handle may be slippery. Hold the handle firmly while carrying the device.
- Only use components that are rated for the desired transport method.

  The rotation module (PN 10156529) is *not* certified for airborne equipment according to RTCA DO-160G.

⚠ CAUTION

Ensure that accessories used during transport are adequately protected against water ingress.

NOTICE

- The HAMILTON-EM7 must always be secured during transport.
- In rough environments (for example, aircraft or ambulance), use an oxygen hose with a slow release valve to safeguard against a rapid loss of pressurized O2.

1.5.6 Nuclear, biologic, and chemical (NBC) environments safety information

⚠ WARNING

- Always use an NBC filter when operating the device in an NBC environment.
- Always connect an oxygen supply when using the NBC filter.
- Do *not* block air intake.

⚠ CAUTION

The use of an NBC filter increases the flow resistance.

1.6 Setting up for ventilation safety information

This section provides safety information for the following:

- Patient breathing circuit sets, consumables, and accessories
- Performing preoperational check and testing
- CO2 monitoring setup and operation

For device and accessories preparation for use, see Chapter 3.

1.6.1 Patient breathing circuit sets, components, and accessories safety information

In addition to the information provided in this section, carefully review the information in Sections 1.4 and 1.5.

For breathing circuit set/component connection information, see Section 3.5. For placement/positioning information, see Section 3.5.4.

For details about the HAMILTON-EM7 breathing circuit set, see the *HAMILTON-EM7 Breathing circuit set Instructions for use* (PN 10160379).

⚠ WARNING

- **The use of a heat and moisture exchanging filter (HMEF) in the gas path is mandatory when ventilating a patient using the HAMILTON-EM7. Its use provides filtration and passive humidification, and reduces the risk of contamination of the patient, ventilator, and environment.** HMEFs must conform to the following standards:
  ISO 23328-1:2003 and
  ISO 23328-2:2002, as well as either
  ISO 9360-1:2000 or
  ISO 9360:2-2001
- Follow the manufacturer's *Instructions for use* for consumables and accessories, including masks.
- Discard the breathing circuit set if there is any sign of damage to any component or to the packaging, or it fails multiple preoperational checks.
- For each new patient, *always* use a new breathing circuit set to avoid cross contamination.

- During ventilation, regularly check any connected HMEF for increased resistance and blockage.
- Attaching components/assemblies to a ventilator breathing system can change the pressure gradient across the entire system, which can adversely affect ventilator performance.
- Placing the mandatory HMEF and any other additional components between the flow sensor and the breathing circuit set can increase dead space and lead to higher resistance.
- Ensure that all of the components of the breathing circuit set, including accessories, match the associated intended use for the target patient group.

⚠ CAUTION

- *When adding components to the Hamilton Medical breathing circuit set configurations, do not exceed the inspiratory and expiratory resistance values of the ventilator breathing system as required by ISO 80601-2-84.*
- *Pressure and volume measurement accuracy may be affected by using a breathing circuit set with high resistance. Accuracy was tested with the HAMILTON-EM7 using the breathing circuit set PN 10145821 and PN 10145823.*

NOTICE

- To prevent inaccurate flow sensor readings, make sure the flow sensor pressure plug tubes are *not* kinked.
- During ventilation, secretions, occlusions, and/or condensation can build up in the flow sensor and circuit components. Position the flow sensor upright, with the patient end facing downward. Ideally, the flow sensor should be at a 45° or greater angle relative to the floor.
- When connecting an HMEF to the breathing circuit set, pay special attention to the fit and seal of the filter to the breathing circuit set component.
- Ensure that the monitoring port on the HMEF housing is closed.
- The use of a mask or HMEF can increase dead space. Always comply with the mask or HMEF manufacturer's instructions.

1.6.2 Preoperational check and tests safety information

For details on performing the preoperational check and tests, see Section 3.6.

⚠ CAUTION

- *To prevent possible patient injury, disconnect the patient from the ventilator before running the preoperational tests, and use another source of ventilatory support.*
- *To ensure the ventilator's safe operation, always run the preoperational check before using the ventilator on a patient.*
- *Do NOT use the ventilator until necessary repairs are completed and all preoperational tests have passed.*

NOTICE

To ensure that all breathing circuit set connections are leak-tight, perform the preoperational check every time you connect a new breathing circuit set.

1.6.3 CO2 sensor setup and operation safety information

⚠ WARNING

- If the capnogram appears abnormal, inspect the adult/pediatric CO2 airway adapter and replace if needed.
- Elevated baseline can be caused by sensor problems or by the patient's condition.
- Do *not* use any CO2 sensor/adapter if it appears to be damaged or if it fails to operate properly. Refer servicing to Hamilton Medical authorized personnel.
- In noninvasive ventilation, leaks may influence the capnogram and the measured values.
- Always connect all components securely and check for leaks according to standard clinical procedures.
- Positioning of tubing and cables:
  – Do *not* position the cables in any manner that may cause patient entanglement or strangulation.
  – Support the tubing to avoid stress on any tubing or cables.
  – Do *not* apply excessive tension to any cable.
- During use, a system leak, such as that caused by an uncuffed ET tube or damaged airway adapter, may significantly affect sensor readings, including flow, volume, pressure, and other respiratory parameters.
- Leakages in the breathing system may cause the displayed CO2 values to be significantly underreported (too low).
- Periodically check the sensor and tubing for excessive moisture or secretion build-up, and replace if needed. Excessive moisture can affect measurements.
- Keep all cleaning agents away from the CO2 sensor electrical connections.
- For the CO2 sensor/adapter, use only cleaning and disinfection agents recommended in the manufacturer's *Instructions for use*.

⚠ CAUTION

- *Do NOT place the CO2 sensor directly on the patient's skin. It can burn the skin as the sensor may reach a temperature of 46°C (115°F).*
- *Do NOT use the CO2 components when they are wet or have exterior condensation. Condensation may harm the patient.*

NOTICE

- Position airway adapters with windows in a vertical, *not* a horizontal, position. This helps keep patient secretions from pooling on the windows. If pooling occurs, remove the adapter, rinse with sterile water, and reconnect.
- Do *not* place the CO2 sensor/adapter between the ET tube and any connected airway adapter, as this may allow patient secretions to enter the tubing and block the adapter windows.
- The CO2 sensors and accessories that have contact with the patient are not made with natural rubber latex.
- Nitrous oxide, elevated levels of oxygen, helium, and halogenated hydrocarbons can influence the CO2 measurement.

1.6.4 Nebulization safety information

For information on setting up and working with a nebulizer, see Sections 3.8 and 8.5.

⚠ WARNING

- Nebulization of drugs can cause an occlusion and increased resistance of a connected HMEF. Check the HMEF frequently for increased resistance or blockage, and replace as needed. Follow the manufacturer's *Instructions for use* of the HMEF.
- Nebulization can affect the accuracy of CO2 measurements.
- The use of a pneumatic nebulizer is not allowed as it adds gas to the ventilator breathing system, which can affect the accuracy of volume or flow measurements.

1.7 Ventilating the patient safety information

This section provides the following safety information:

- Specifying patient settings
- Noninvasive ventilation
- Using O2 therapy
- Volume-targeted modes

For information on ventilation settings, features, and procedures, see Chapters 4 through 8. Specifications are in Chapter 12.

1.7.1 Specifying patient settings safety information

Be sure to also review the safety messages related to alarms in Section 1.8.

For information on specifying patient settings, see Chapter 4.

⚠ CAUTION

- *It is the clinician's responsibility to ensure that all ventilator settings are appropriate, even when adaptive features, such as ASV or default settings, are used.*
- *To prevent possible patient injury:*

  – Make sure the ventilator is set up for the appropriate patient group with the appropriate breathing circuit set components.

  – Make sure you select the correct patient sex and height before starting ventilation. Correct entries help prevent hyper- or hypoventilation.

1.7.2 Noninvasive ventilation safety information

For information about working with noninvasive modes, see Chapter 5.

⚠ CAUTION

Hamilton Medical ventilators provide noninvasive ventilation through a helmet EXCEPT for CPAP therapy. The turbine-driven ventilators provide higher continuous flow levels, and the air supply is provided by filtered room air (with a HEPA inlet filter) with ambient humidity.

NOTICE

- As a precaution, while noninvasive ventilation is in use, you must be prepared to intubate the patient and start invasive ventilation at any time.
- The use of an NIV mask or HMEF can increase dead space. Always comply with the mask or HMEF manufacturer's instructions.
- The Vt high: breath terminated alarm is inactive in noninvasive modes.

1.7.3 Using O2 therapy safety information

For information on working with oxygen therapy, see Section 5.5.4.

⚠ WARNING

- Use only interfaces intended for O2 therapy that allow the patient to exhale. This is important because exhalation through the expiratory valve is not possible when using O2 therapy.
- Do not use O2 therapy with a nasal mask, facial mask, or any interface that increases patient dead space volume. Ensure the interface allows the patient to exhale.
- Ensure the ventilator's gas pipeline system does not exceed the pipeline design flow capacity. If the system exceeds the flow capacity, it can interfere with the operation of other equipment using the same gas source.

NOTICE

O2 therapy with high flows may cause airway dryness, leading to discomfort and potential mucosal irritation.

1.7.4 Volume targeted modes safety information

For information about modes, see Chapter 5.

⚠ CAUTION

Ensure Plimit is set appropriately in ASV mode. This setting provides a safety pressure limit for the device to appropriately adjust the inspiratory pressure necessary to achieve the target tidal volume. If Plimit is set too low, there may not be enough of a margin for the device to adjust its inspiratory pressure to deliver the target tidal volume.

1.8 Monitoring and alarms safety information

For information about monitoring ventilation/therapy, see Chapter 6.

For information about working with alarms, see Chapter 7.

⚠ WARNING

- The HAMILTON-EM7 is *not* intended to be a comprehensive vital sign monitor for patients on life-support equipment. Patients on life-support equipment should be appropriately monitored by qualified medical personnel and suitable monitoring devices.
- It is recommended that additional independent monitoring devices, including CO2 sensors, be used during mechanical ventilation. The operator of the ventilator must still maintain full responsibility for proper ventilation and patient safety in all situations.

⚠ CAUTION

- *The resistance values of the ventilator breathing system may exceed the limits specified in ISO 5367. When configuring ventilation, particularly for spontaneous breathing modes, ensure all ventilator alarms are active and carefully monitor ventilation parameters. Failure to do so may increase the patient's breathing effort / work.*
- *Always use an external oxygen monitor complying with ISO 80601-2-55 to verify that the set oxygen concentration is being delivered to the patient.*
- *Carefully set alarm limits according to the patient's condition. Setting limits too high or too low defeats the purpose of the alarm system.*
- *To prevent possible patient injury, be sure to use the same user-configured alarm settings on the ventilators in your area.*
- *To prevent possible patient injury, make sure the alarm limits are appropriately set before you place the patient on the ventilator.*
- *The factory default alarm limit settings are set in line with the selected patient group. These settings, however, can never replace individual review of the patient and adjustment of alarm limits based on their condition.*

NOTICE

- Do *not* pause the audible alarm when leaving the patient unattended.
- The use of an alarm monitoring system does *not* give absolute assurance of warning for every type of issue that may arise with the ventilator. Alarm messages may *not* pinpoint a problem exactly; the exercise of clinical judgment is necessary.

1.9 Maintenance safety information

For detailed cleaning/disinfection and maintenance procedures, including associated safety information, see Chapter 9.

1.10 Network safety information

For details about working with a network, see Section 8.10.

⚠ WARNING

- Connection to IT networks, including other equipment, can result in previously unidentified risks to patients, operators, or third parties.

  It is your organization's responsibility to identify, analyze, evaluate, and control these risks.

- Any changes to your organization's IT network can introduce new risks that require additional analysis.

  The following actions constitute a change in the IT network:

  – Changes to the network configuration

  – Connection or disconnection of additional devices

  – Update or upgrade of equipment

1.11 Service and testing safety information

- To ensure proper servicing and to prevent possible physical injury, *only* Hamilton Medical authorized service personnel may service the ventilator and related accessories/devices using information provided in the ventilator *Service Manual*.
- The manufacturer can *only* be responsible for the safety, reliability, and performance of the ventilator if *all* of the following requirements are met:
  - Appropriately qualified, trained health care professionals carry out assembly operations, extensions, readjustments, modifications, maintenance, or repairs.
  - The ventilator system is used in accordance with the ventilator *Operator's Manual*.
  - Do *not* attempt service procedures other than those specified in the ventilator *Service Manual*.
  - Follow the infection prevention policies and reprocessing regulations, including the reprocessing intervals, of the health-care facility.
  - Follow the national infection prevention policies and reprocessing regulations.
  - Use validated procedures for reprocessing the external surfaces of the device.
  - Reprocessing is performed by personnel who have specialist knowledge in the reprocessing of medical devices and who have read and understood this document.
  - Follow the manufacturer's instructions for cleaning and disinfection methodologies and reprocessing of the device.
- Any attempt to modify the ventilator hardware or software without the express written approval of Hamilton Medical automatically voids all warranties and liabilities.

1.12 Cybersecurity

Cybersecurity is the practice of protecting computer systems, networks, and data from digital attacks, damage, or unauthorized access.

This section provides cybersecurity-related information for trained personnel using the device. Note that it does not cover all possible device vulnerabilities or address all specific configurations and use cases.

By applying the secure configuration guidelines (Section 1.12.3), device security improves, and the possibility of cybersecurity-related disruptions to essential medical functions are reduced.

The organization using this device is responsible for ensuring its secure deployment, configuration, maintenance, and decommissioning.

Table 1-2. Cybersecurity overview

For details about ...	See ...
Roles and responsibilities	Section 1.12.1
Summary of risks	Section 1.12.2
Configuration guidelines	Section 1.12.3
Monitoring, logging, and detection	Section 1.12.4
Maintenance	Section 1.12.5
Safety ventilation	Section 1.12.6
Cybersecurity incident response	Section 1.12.7

1.12.1 Roles and responsibilities

Managing cybersecurity involves different tasks based on the different user groups working with the ventilator.

Clinical ventilator users are responsible for:

- Following the secure ventilator operation guidelines (Section 1.12.3)
- Contacting the Hamilton Medical authorized service representative for all maintenance requirements, including software

Hamilton Medical authorized service personnel are responsible for:

- Installing the latest software version available in your region, if requested
- Providing the ventilator network address and other software related information, if requested

The ventilator *Service Manual* provides this information for service personnel.

1.12.2 Security risk approach

A detailed threat model was developed for the ventilator to perform a thorough risk assessment. Where necessary, appropriate risk controls have been applied.

The HAMILTON-EM7 has been designed with multiple security controls to reduce cybersecurity risk. No device can be fully protected against all cybersecurity threats. By applying the guidelines in this section and keeping software current, cybersecurity risk can be significantly reduced.

All threats from third-party components are constantly monitored.

1.12.3 Secure configuration guidelines

Contact your Hamilton Medical authorized service representative to ensure secure device installation and configuration.

For details about connecting to external devices, see Section 8.10.

To securely operate the ventilator:

- Verify the ventilator device functionality before connecting the device to the patient.
- Only allow authorized personnel to access and operate the ventilator.
- Only connect compatible and Hamilton Medical-approved devices and components to the ventilator.[1]
- Do *not* access internal ventilator components. Only Hamilton Medical authorized service personnel may service the ventilator.

1.12.3.1 Physical security hardening guidelines

Only operate the ventilator in dedicated areas that meet the physical security requirements defined by your facility (for example, regarding access control and monitoring).

1.12.4 Monitoring, logging, and detection

Once the ventilator is turned on, the device starts collecting logging data about clinically relevant ventilator activities, including ventilator start and shutdown times, alarms, technical notes, setting changes, calibrations, maneuvers, and special functions. For details about the logging data, see Section 8.8.

This Operator's Manual provides detailed information about ventilator operation and capabilities.

When conditions generate an alarm, acoustic and visual notification is provided, as described in Chapter 7.

1.12.5 Maintenance

Maintenance tasks described in this manual clearly indicate whether they are performed by the ventilator user or by a Hamilton Medical approved service technician. For detailed maintenance information, see Chapter 9.

Hamilton Medical authorized service personnel perform security-related maintenance tasks. Preventive maintenance is performed as described in Section 9.4, Table 9-3.

[1] See the Technical Specifications for your device, as well as the Hamilton Medical e-catalog for compatible devices.

1.12.6 Safety ventilation

In the event of damage, error, or technical fault that affects ventilator function, the HAMILTON-EM7 automatically modifies operation to ensure essential function.

These special conditions are described in detail in Section 5.8. Note that some manual intervention is required from the user.

1.12.7 Cybersecurity incident response

This section describes what to do when a cybersecurity vulnerability occurs.

1.12.7.1 Monitoring and security scanning

Hamilton Medical constantly monitors evolving threats and employs various security scanning methods and technologies. In addition, Hamilton Medical has devices tested independently by third parties.

1.12.7.2 Security advisories

Hamilton Medical releases security advisories to the public in case of potential vulnerabilities. For details, go to: https://www.hamilton-medical.com/Services/Cybersecurity.html

To protect patients from harm, the following information is shared in case of a vulnerability occurrence:

- Information about products that are affected by a vulnerability and how they are affected
- Information about vulnerabilities of components that are used in other products
- Information about IT equipment that may impact the security of medical devices
- Information about attacks, potential attacks, and availability of exploit code
- Confirmation of incidents
- Availability of patches and other security mitigations
- If necessary, additional instructions on how to mitigate the issue as an interim measure

1.12.7.3 Incident reporting and emergency contact information

⚠ WARNING

Do *NOT* use the ventilator if any cybersecurity issue occurs and provide alternative respiratory support until the issue is resolved.

Hamilton Medical employs trained security personnel to react to product security incidents.

To report a security issue with Hamilton Medical, go to: https://www.hamilton-medical.com/Services/Cybersecurity.html

In case of a security-related emergency, contact your country's Hamilton Medical sales partner.

2
System overview

2.1 Overview

The HAMILTON-EM7 ventilator system comprises the following main components:

- Ergonomic design featuring integrated monitor with touch screen display and integrated alarm lamp
- Ventilation unit for gas mixing and control, and patient breathing circuit set for gas delivery and exchange
- High-pressure (HPO) oxygen supply connection
- Optional connection to a CO2 sensor
- A variety of wall, rail, ceiling, and shelf mounts/adapters

The ventilator system offers the following main features:

- *Monitoring:* Real-time waveforms and numerical monitoring showing the patient's real-time breathing status, targets, and CO2 measurements (when the CO2 option is activated)
- Rapid sequence induction (RSI) support
- Direct access to CPR ventilation from device keypad
- Alarms and on-screen troubleshooting help
- Configurable startup settings and ventilation modes for each patient group
- Opportunity for the use of mesh nebulizers
- Support for AC and DC primary power sources

The HAMILTON-EM7 does *not* support the use of a humidifier.

The intended position of the user is directly facing the relevant part or side of the device, at a distance close enough to allow full and effective operation.

2.1.1 Standard features and options

The ventilator offers a robust set of standard equipment and features, as well as optional modes and features for the supported patient groups.

Table 2-1 lists the standard software and hardware configuration and options.

Table 2-1. Software and hardware configuration and options

Function	HAMILTON-EM7
Standard: X Option: O Not applicable: --	
Patient groups	
Adult	X
Pediatric	X
Neonatal	--
Intelligent ventilation modes	
ASV®	X
Volume-controlled, flow-controlled modes	
(S)CMV	X
SIMV	O
Pressure-controlled modes	
DuoPAP	O
PCV+	X
SPONT	O
Noninvasive modes	
O2 therapy	O
NIV, NIV-ST	O
CPAP	X

Function	HAMILTON-EM7
Other functions	
Trigger sensitivity	X
On-screen help	X
CPR ventilation	X
Rapid sequence induction (RSI)	X
Hamilton Connect Module (HCM)	O
Hardware configuration and options	
A variety of wall, rail, ceiling, and shelf mounts/adapters	O
USB port[1]	X
Night vision compatibility (NVG)	O[2]
NBC filter compatibility	X
Software configuration and options	
CO2 monitoring	O

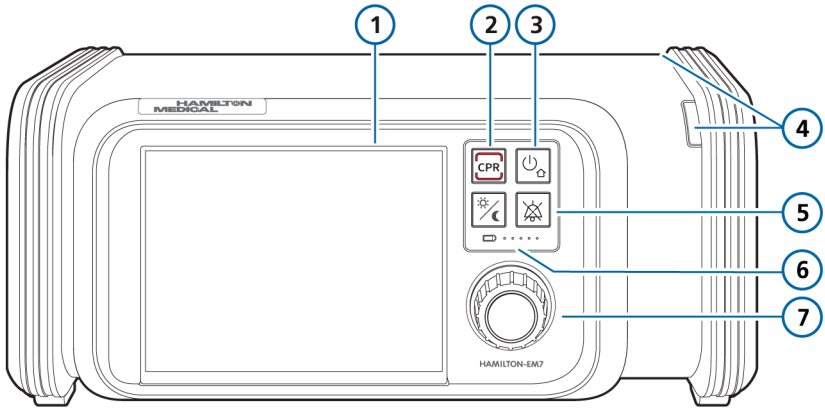
[1] To be used for software updates or log file export only.
[2] Standard feature on HAMILTON-EM7 ventilator PN 10163814 (g).

2.2 Physical descriptions

The following sections provide an overview of the ventilator, breathing circuit sets, and mount and carrying solutions.

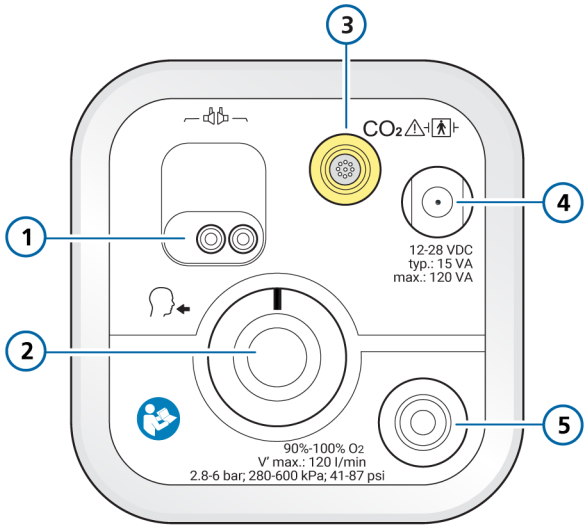
2.2.1 About the ventilator

Figure 2-1. Front view, HAMILTON-EM7



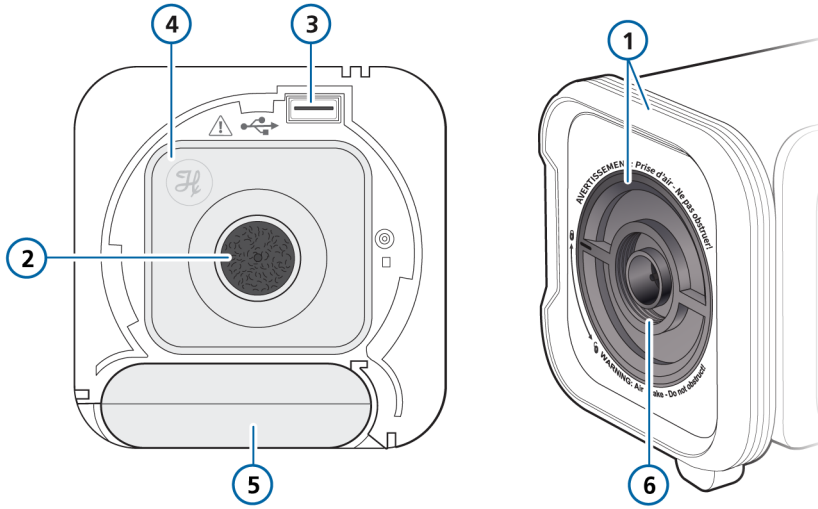
1	Touch screen display	5	Day/Night key (left) Audio pause key (right)
2	CPR key	6	Battery status indicator
3	Power/Standby key	7	Press-and-Turn (P&T) knob
4	Alarm lamps		

Figure 2-2. Side view, with breathing circuit set, gas, and power connections



1		Flow sensor pressure plug connection ports	4		DC power socket
2		*To patient* port (connection for the expiratory valve end of the breathing circuit set)	5		High-pressure oxygen connector
3		CO2 connection port *(CO2 option required)*			

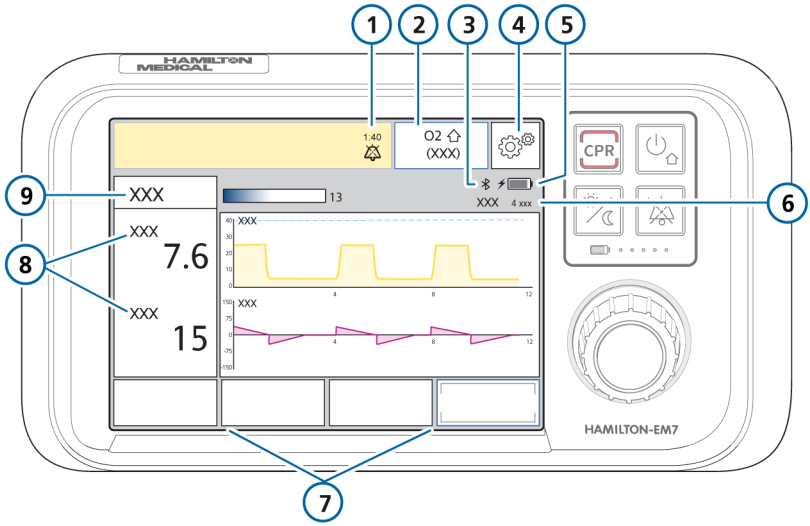
Figure 2-3. Side view, with filter and battery; image on left shows device with side cover off



1	Removable cover and locking ring (twist counter-clockwise to open)	4	HEPA inlet filter
2	Air intake with dust filter	5	Battery
3	USB port	6	NATO-compliant standard thread Rd 40 x 1/7 for NBC canister

2.2.2 About the main display

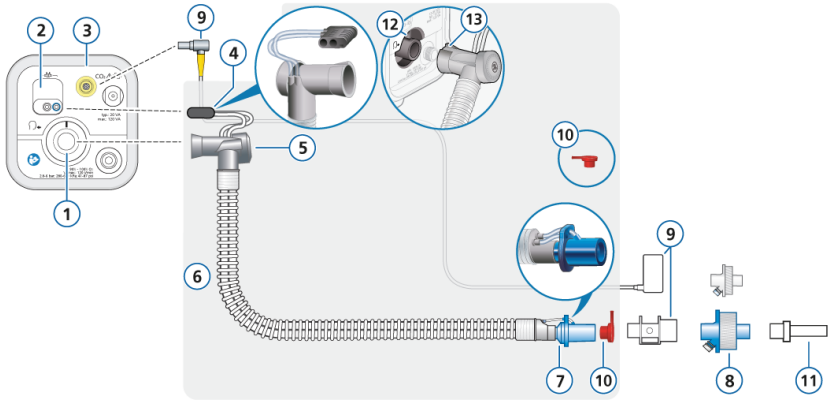
Figure 2-4. HAMILTON-EM7 main display, invasive mode shown



1	Message bar (color coded), Audio pause indicator	6	O2 consumption
2	O2 enrichment/RSI	7	Window buttons: Monitoring, Controls, Alarm limits, Pause / resume therapy
3	Bluetooth icon (displayed when device connected)	8	Main monitoring parameters (MMPs)
4	Settings	9	Active mode
5	Power source and battery status		

2.2.3 About the patient breathing circuit set

Figure 2-5. HAMILTON-EM7 breathing circuit set with integrated flow sensor and expiratory valve



1	*To patient* port (connection for the expiratory valve end of the breathing circuit set)	7	Flow sensor (FS), integrated
2	Flow sensor pressure plug connection port	8	Heat and moisture exchanging filter (HMEF), not included, adult and pediatric versions shown
3	CO2 connection port *(CO2 option required)*	9	CO2 sensor/airway adapter, connector *(not included)*
4	Flow sensor pressure plug, integrated	10	Flow sensor protective cap
5	Expiratory valve (EV), integrated	11	Interface connection (for example, ET tube, noninvasive mask)
6	Septum-walled single limb breathing circuit (inspiratory and expiratory gas flow)	12/13	Locking bar/Locking guides

2.3 Working with the mount and carrying options

The HAMILTON-EM7 offers a variety of mounting and carrying options.

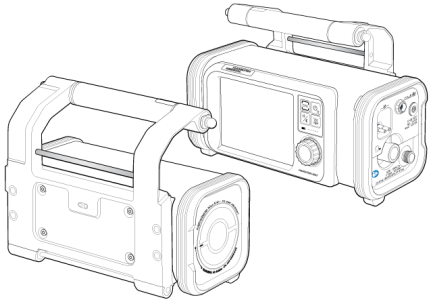
- Carry handle
- Multi-position hooks
- Wall mount, with or without optional integrated charging module
- Rotation module

Working with the handle

The handle attaches to the ventilator and can be used with the following additional accessories:

- Wall mount for attaching the ventilator to a fixed location
- Multi-position hooks, to allow hanging the ventilator, on a rail for example, and positioning it at different view angles
- Rotation module, for positioning the ventilator at multiple view angles

Figure 2-6. Carry handle attached to HAMILTON-EM7



2.3.1 Using the wall mount

The wall mount offers secure attachment of the ventilator to a fixed location. With the integrated charging module (optional), the ventilator battery charges while the ventilator is attached.

To attach the ventilator to the wall mount

1. Place the bottom of the handle securely into the well on the bottom of the wall mount (Figure 2-7).
2. Push the attachment bar in the handle into the wall mount locking port until the handle audibly clicks into place (Figure 2-8).

   Listen for the audible click upon attachment.
3. Gently pull on the handle to verify that the ventilator is securely attached to the wall mount before letting go of the handle.

Figure 2-7. Attaching the ventilator to the wall mount

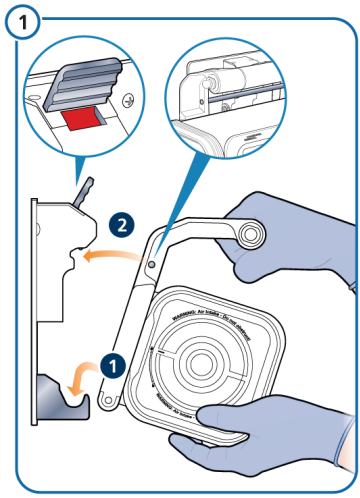
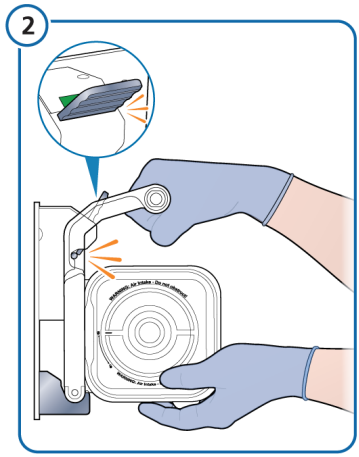


Figure 2-8. Verifying secure attachment



To detach the ventilator from the wall mount

1. While firmly holding on to the handle, push up the locking clip on the wall mount (Figure 2-9).
2. Lift the ventilator up and out of the wall mount (Figure 2-10).

Figure 2-9. Detaching the ventilator from the wall mount

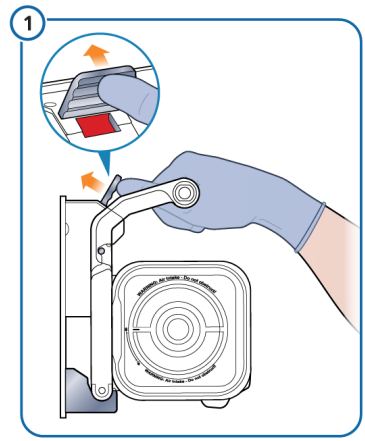
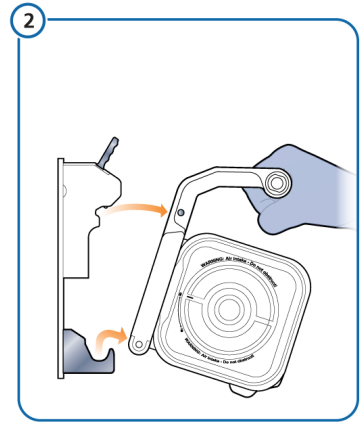


Figure 2-10. Removing the ventilator from the wall mount



2.3.2 Using the multi-position hooks

Using the optional multi-position hooks (PN 10172818) on the handle, you can hang the ventilator and position the display at different angles.

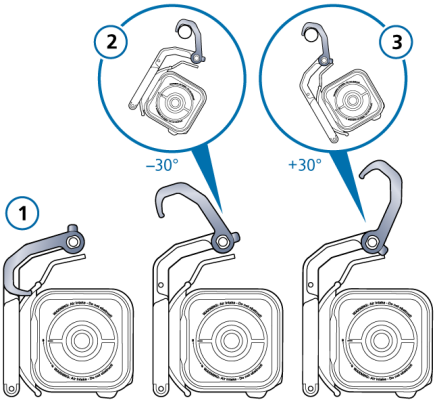
With the hooks, you can position the ventilator at either of the following display angles (relative to the floor):

- −30° (**2** in Figure 2-11)
- +30° (**3** in Figure 2-11)

When the hooks are not in use, you can keep them in the parked position (**1** in Figure 2-11), level with the handle.

The hooks are *not* supported for use during transport.

Figure 2-11. Hook positions, illustrated

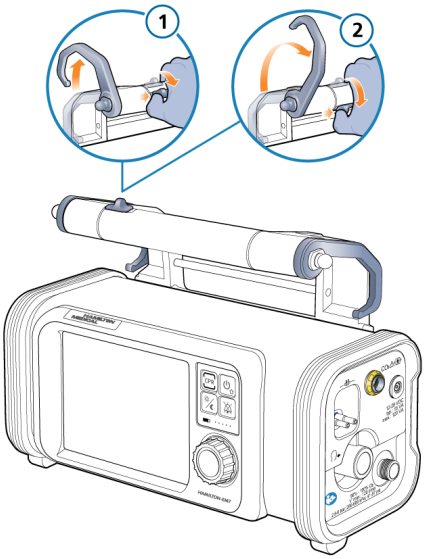


To change the hook position

1. On the handle, push and hold the locking switch to the right.
2. Rotate the handle to move the hooks to the desired position (see Figure 2-12), and release the switch.

The hooks lock into the selected position.

Figure 2-12. Changing hook position



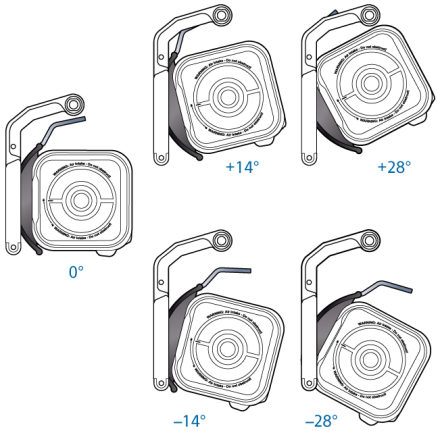
2.3.3 Working with the rotation module

⚠ WARNING

Only use components that are rated for the desired transport method. The rotation module (PN 10156529) is *not* certified for airborne equipment according to RTCA DO-160G.

Attachment of the optional rotation module (PN 10156529) allows you to position the ventilator at five (5) different display angles, relative to the floor (Figure 2-13): +28°, +14°, 0°, −14°, −28°

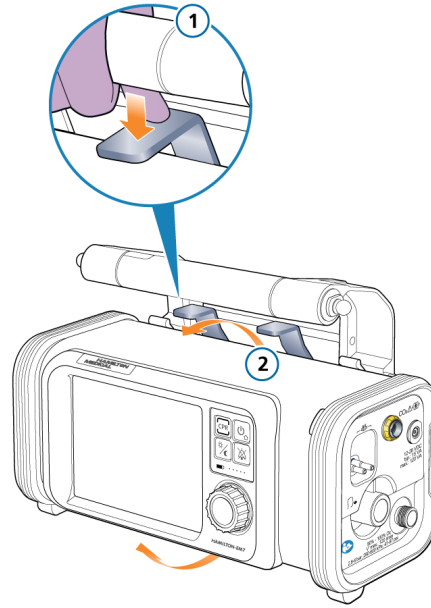
Figure 2-13. Ventilator display angles available when rotation module installed



To change the display angle of the ventilator (with rotation module)

1. With one hand, press down the locking lever (**1** in Figure 2-14); with the other hand, turn the ventilator (**2** in Figure 2-14) to the desired position.
2. Release the lever to lock the ventilator in place.

Figure 2-14. Changing the viewing angle of the ventilator (when rotation module installed)



2.4 Turning the ventilator on/off and entering Standby

This section describes how to turn the ventilator on and off, as well as how to directly start in CPR ventilation, and how to enter and exit Standby.

To turn ON the ventilator and enter Standby

1. To start the ventilator in Standby, press (Power/Standby) on the front of the ventilator.

   The ventilator runs a self-test. The self-test includes testing the alarm system, including the speaker, buzzer, and alarm lamp.

   After approximately 30 seconds, the Patient settings window is displayed.
2. Proceed with entering patient data and setting up the ventilator, as appropriate, and conducting the preoperational check before use.

When the ventilator is in Standby, the following message is displayed: Standby. No therapy running.

To turn ON the ventilator and directly start CPR ventilation

1. To start the ventilator directly in CPR ventilation, press CPR on the front of the ventilator.

   The ventilator runs a self-test. The self-test includes testing the alarm system, including the speaker, buzzer, and alarm lamp.

   After approximately 30 seconds, the Patient settings window is displayed, with the CPR mode already selected.

   The following message is also displayed: Standby. No therapy running.
2. Enter patient data.
3. Touch **Start CPR ventilation** ✓ to start ventilation.

For details about working with CPR ventilation, see Section 8.6.

To turn ON the ventilator directly in the Preoperational check

1. To start the ventilator directly in the Preop check window, long-press (Power/Standby) on the front of the ventilator for three (3) seconds.

   The ventilator beeps twice, and then runs a self-test. The self-test includes testing the alarm system, including the speaker, buzzer, and alarm lamp.

   Once complete, the Start Preop check window is displayed.
2. Touch ✓ to start the preop check. For details, see Section 3.6.

To turn ON the ventilator if startup is not successful

1. Turn off the ventilator by pressing and holding for about six (6) seconds.
2. Turn the ventilator on again by pressing either the or CPR key.

In the event of display problems

If there are display problems, such as a black screen, see Section 5.8.

To turn OFF the ventilator

1. Press ⏻ to open the Activate Standby window during active ventilation.
2. Touch ✓ to confirm.
   The ventilator enters Standby.
3. Press ⏻ for about two (2) seconds.
   The text Turn off device? is displayed, prompting you to confirm turning off the ventilator.
4. Touch ✓ to confirm.

The ventilator turns off.

In the event of a technical fault or the device will not turn off

- Press and hold ⏻ for about six (6) seconds to turn off the ventilator.

2.5 Unlocking the display (screen lock)

NOTICE

Screen lock is disabled when using RSI.

After a defined length of time of inactivity, the touch screen display automatically locks. The length of time is set in Configuration (Section 10.3.7); the screen lock function can also be turned off.

When locked, the 🔒 icon appears on the bottom right of the display

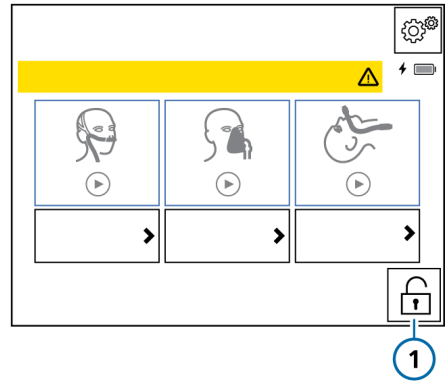
Table 2-2. Screen lock settings

Setting	Range	Factory default
Screen lock timeout (s)	Off/30 to 300	120

To unlock the touch screen display

- Do either of the following:
  - Touch 🔒 (Figure 2-15).
  - Press CPR.

Figure 2-15. Lock icon on display (1)



2.6 Navigating the display and controls

Use the touch screen and the Press-and-turn knob (referred to as the *P&T knob*) to access data and specify settings.

You interact with the HAMILTON-EM7 user interface as follows:

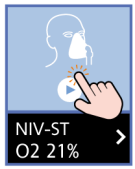
- Touch elements on the display to open windows and make and confirm selections.
- Use the P&T knob to select, specify, and confirm selections. A selected item is highlighted.

This section describes how to navigate the interface.

2.6.1 Accessing features and functions

The HAMILTON-EM7 uses color to differentiate *Action* buttons (blue) from *Settings* buttons (black), as described in the following table.

Table 2-3. HAMILTON-EM7 *Action* and *Settings* buttons, identifying

Color	Example	Description
Blue buttons		Blue buttons and controls denote *action*; touching a blue element immediately starts the related action. For example: • Touching the blue **Noninvasive therapy** Quick Start button (shown here) starts ventilation using the default noninvasive mode and settings. • Touching the blue **O2 enrichment** button starts O2 enrichment using the default settings.
Black buttons		Black buttons and controls denote *settings*; touching a black element displays the **Settings** window for the selected element, which you can update as needed. For example: • Touching the black **Settings** button under the therapy Quick Start button displays the mode and control **Settings** window, where you can review and update the therapy settings before starting. You start therapy directly from the **Settings** window. • Touching the black mode name displays the mode **Settings** window, where you can change modes or access therapy settings. • Touching the black **Alarm limits** button displays the **Alarms** window, where you can review and adjust limits for alarms.

To open a window

- Do either of the following to open a window:
  - Touch the button and any needed tabs.
  - Turn the P&T knob to move the cursor to the button or tab, then press the P&T knob.

To close a window

- Do any of the following to close a window:
  - Touch the window button again.
  - Touch the X button.
  - When in Standby, press ⏻ on the front of the ventilator.
  - Turn the P&T knob to move the cursor to the X button, then press the P&T knob.

2.6.2 Adjusting controls

Specifying settings involves *activating* a control, *adjusting* a value, and *confirming* the setting.

To adjust a control setting

1. **Activate** a control by doing either of the following:
   - Touch the control to select and activate it.
   - Turn the P&T knob to move the cursor to the control; the highlight indicates the element the P&T knob is on. Press the P&T knob to activate it.
2. **Adjust** the value using either the + and – buttons, or by turning the P&T knob to increase or decrease the value.
3. **Confirm** the setting by doing either of the following:
   - Touch ✓.
   - Press the P&T knob.

The new setting is immediately applied.

2.6.3 Selecting /deselecting items

Some selections are presented in a scrollable list.

To select an item

1. When presented with a list, do any of the following:
   - Turn the P&T knob to scroll through the list, and when the desired selection is highlighted, press the knob to select it.
   - Use your finger to swipe the list up or down, and touch the entry to select.
   - Touch the desired navigation arrow, 〈 〉 ∧ ∨, to move left, right, up, and down through the list or windows, then touch the desired entry to select it.
2. Touch ✓ to confirm the selection.

2.6.4 Using shortcuts

The ventilator provides shortcuts for some key functions.

The following table describes the icons and shortcuts found on the device display.

Table 2-4. Icons and shortcuts on the display

Touch icon/ shortcut on the display ...	To ...
Active mode (top left of display)	Access the **Modes** window for the current ventilation type
MMPs on the left of the main display during active ventilation	In an *invasive* mode: Toggle the displayed parameter between VTE and ExpMinVol In a *noninvasive* mode: Toggle the displayed parameter between VTE NIV and MinVol NIV
Any waveform	Open the **Waveforms** window and select a waveform
Active alarm message	Display active alarm(s) in the **Alarms** > **Buffer** window
	Display inactive alarms in the **Alarms** > **Buffer** window
Alarm message in the **Alarms** > **Buffer** window	Open on-screen alarm troubleshooting help
	Access the **Settings** menu
	Touch the left, right, up, or down arrow to access additional windows or menu items
O2 	Start O2 enrichment
Stop O2 	Stop O2 enrichment
	Deactivate alarm
	Delete element
	Increase a setting
	Decrease a setting
	Confirm the setting/ selection/dialog box
	Cancel the setting/ selection/dialog box

3
Preparing the ventilator

3.1 Overview

Preparing the ventilator for use comprises the following steps:

To ...	See ...
Turn on the ventilator	Section 2.4
Connect to a power source	Section 3.3
Connect the oxygen supply	Section 3.4
Set up the patient breathing circuit set	Section 3.5
Performing the preoperational check, tests, and calibrations	Section 3.6
Set up CO2 monitoring	Section 3.7
Select the patient group, mode, and alarm limits, and enter patient data	Chapter 4

3.2 Daily tasks

Before proceeding, review the safety information in Section 1.5*.*

The following sections provide a brief overview of the basic tasks to perform daily to ensure proper operation of the ventilator and availability of necessary supplies, as well as a quick overview of setting up the device for patient use. For a summary of tasks to end therapy, see Section 4.10.

The HAMILTON-EM7 Quick Start reference card (PN 10175022) provides this information in an individual card format.

Daily tasks

- Turn the ventilator on; the ventilator performs a variety of self-tests.
- Check the entire device, including power cord and power adapter for visible damage and dirt.
- Check the battery charge; charge the battery if it is not at full capacity.
- Ensure availability of a full complement of required consumables, accessories, and other required components.
- Ensure device/components are clean and ready for use.

  For cleaning/disinfection and maintenance details, see Chapter 9.
- Be sure to turn the device off when not in use.
- Verify the oxygen supply is securely connected to the ventilator.

3.3 Connecting to a power source

Before proceeding, review the safety information in Chapter 1.

⚠ WARNING

Only use the original power cord provided with the HAMILTON-EM7 to connect the device to the primary power supply.

Always check the reliability of the primary power outlet before plugging in the ventilator.

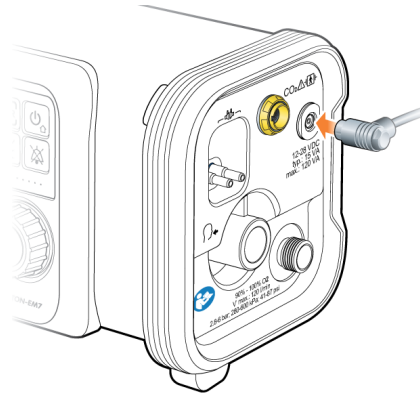
The HAMILTON-EM7 uses an external power supply comprising a power transformer and a country-specific AC cable.

The ventilator does *not* require protective earth grounding, because it is a class II device, as classified according to IEC 60601-1.

To connect the ventilator to a primary power supply

1. Connect the power cable from the transformer to the ventilator (Figure 3-1).
2. Connect the transformer to an outlet that supplies AC power between 100 and 240 V AC, 50/60 Hz. Always check the reliability of the AC outlet.

Figure 3-1. Primary power connector on ventilator



3.3.1 Connecting to DC power

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-EM7 can use DC power as a primary power supply, used during transport in ambulances, fixed-wing aircraft, helicopters, and ships that provide an appropriate electrical power supply.

The following DC cables are available for use with the ventilator.

Table 3-1. Supported DC power cables

Cable	Description
DC power cable, car PN 10149117	Intended for use during transport in ambulances and other rescue vehicles that are provided with appropriate plug connectors.
DC power cable, open end PN 10159938	Has a stripped end with two strands. This cable must be assembled only by authorized personnel using a UL-listed plug.

3.3.2 Using battery power

A battery must be installed at all times during operation of the HAMILTON-EM7. In addition to serving as a power source when not connected to primary power, it acts as a backup battery to protect the ventilator from low power or failure of the primary power source.

When the primary power source fails, the ventilator automatically switches to battery operation with no interruption in ventilation. An alarm sounds to signal the switch-over. You can deactivate this alarm; see Section 7.2.2.

If battery power is completely lost, a buzzer sounds continuously for at least two (2) minutes.

The battery is charged whenever the ventilator is connected to primary power, whether or not it is turned on.

The battery charge level/status is shown in two places on the ventilator:

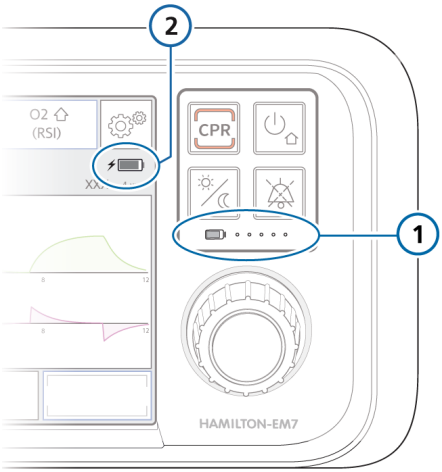
- On the right panel of the ventilator (item 1 in Figure 3-2)

  For details about the display, see Table 3-2.

- On the ventilator display when it is turned on (item 2 in Figure 3-2)

  For details about the icon states, see Table 3-3

Figure 3-2. Power source/status indicators on display and device



1	Battery status indicator on device	2	Battery/power state icon on display

To check the battery status when the ventilator is turned on

When the ventilator is turned on, the battery status indicator on the right panel of the ventilator shows the charge level/status of the battery, described in Table 3-2.

To check the battery status when the ventilator is turned off

- Long-press the battery status indicator ▪ • • • • • (item 1 in Figure 3-2) on the front of the device.

  For charge details, see Table 3-2.

If the battery is not fully charged, recharge it by connecting the ventilator to the primary power source.
For details, see Section 12.4.

Table 3-2. Battery status indicator on ventilator

Indicator on ventilator	Battery charge level/status
▪ ● ● ● ● ●	> 80% charge
▪ ● ● ● ● ○	Between 60% and 80% charge
▪ ● ● ● ○ ○	Between 40% and 60% charge
▪ ● ● ○ ○ ○	Between 20% and 40% charge
▪ ● ○ ○ ○ ○	Between 10% and 20% charge
▪ ● ○ ○ ○ ○	< 10% charge
▪ ● ○ ○ ○ ○ (Flashing)	There is a problem with the battery or the battery is not properly inserted.

Battery status icon on the ventilator display

When the ventilator is turned on, the battery icon on the display shows the status of the battery, described in Table 3-3.

When the device is connected to primary power, the charging icon (ϟ) is shown on the ventilator display.

Table 3-3. Battery/power state

Battery icon on display	Battery status
Note the following: • When the battery is charging, the battery icon is green. • When the battery is *not* charging, the battery icon is white. • The color inside the battery icon provides a visual indication of the remaining charge level.	
	When displayed next to the battery icon, the device is plugged into primary power, and the battery is charging.
	*Green.* The battery has a charge level above 10%, and the battery is charging.
	*White.* The battery has a charge level above 10%, and the battery is *not* charging.
	*Red*. The ventilator is *not* plugged into primary power, and the battery has less than 10% charge remaining.
	The battery is either defective or is *not* installed.

3.4 Connecting the oxygen supply

Before proceeding, review the safety information in Chapter 1.

Oxygen for the HAMILTON-EM7 ventilator can be provided by a high-pressure source.

High-pressure oxygen, provided by a central gas supply or a gas cylinder, is supplied through a DISS/NIST male gas fitting or O2-specific quick coupling. With the optional cylinder holder, you can mount an oxygen cylinder to a variety of the carrying and mounting solutions. When using the cylinder holder, secure the cylinder appropriately using the accompanying straps.

To connect the oxygen supply to the ventilator

- Connect the oxygen hose to the ventilator's high-pressure oxygen connection (Figure 2-2).

3.5 Setting up the patient breathing circuit set

Before proceeding, review the safety information in Chapter 1.

Connecting the breathing circuit set comprises the following steps.

To ...	See ...
Select the appropriate breathing circuit set and components.	Section 3.5.2
Connect the breathing circuit set.	Section 3.5.3
Adjust the position of the breathing circuit set.	Section 3.5.4
Connect a CO2 sensor, if desired.	Section 3.7
Perform any required tests, calibrations, and the preoperational check.	Chapter 4

3.5.1 Breathing circuit set connections on the ventilator

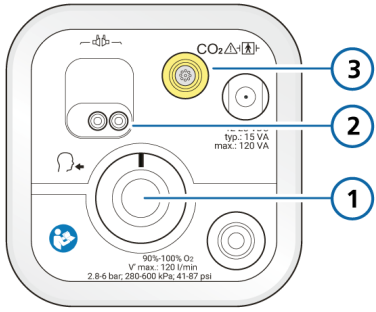
Figure 3-3 illustrates the key ports on the ventilator for connecting the breathing circuit set.

The flow sensor pressure plug can only be connected to the flow sensor ports in one orientation. This ensures the flow sensor tubes are connected to the correct ports.

For the breathing circuit set diagram, see Section 2.2.3.

For instructions for connecting the breathing circuit set, see Section 3.5.3

Figure 3-3. Breathing circuit set connections



1 *To patient* port

2 Flow sensor pressure plug connection port

3 CO2 connection port *(CO2 option required)*

3.5.2 Breathing circuit set components

The following table lists the breathing circuit set specifications.

Table 3-4. Breathing circuit set component specifications

Patient data/ Component	Adult	Pediatric
Patient height (cm)	> 130	58 to 150
PBW (kg)	> 30	5 to 48
Breathing circuit limb (mm)	ID15/OD22	
CO2 airway adapter	Adult/Ped	

3.5.2.1 Using heat and moisture exchanging filters (HMEF)

⚠ WARNING

The use of a heat and moisture exchanging filter (HMEF) in the gas path is mandatory when ventilating a patient using the HAMILTON-EM7. Its use provides filtration and passive humidification, and reduces the risk of contamination of the patient, ventilator, and environment.
HMEFs must conform to the following standards: ISO 23328-1:2003 and ISO 23328-2:2002, as well as either ISO 9360-1:2000 or ISO 9360:2-2001

NOTICE

- When connecting an HMEF to the breathing circuit set, pay special attention to the fit and seal of the filter to the breathing circuit set.
- Ensure that the monitoring port on the HMEF housing is closed.
- The use of an NIV mask or HMEF can increase dead space. Always comply with the NIV mask or HMEF manufacturer's instructions.

Before proceeding, review the safety information in Chapter 1.

The use of an HMEF provides passive humidification (moisture capture and return from the patient's exhaled gas), and also provides bi-directional gas filtration in the patient gas path to prevent potential contamination.

3.5.3 Connecting the breathing circuit set

⚠ WARNING

Discard the breathing circuit set if there is any sign of damage to any component or to the packaging, or it fails multiple preoperational checks.

Before proceeding, review the safety information in Section 1.6.1 *and the HMEF information in Section* 3.5.2.1.

Have available all of the components you will use for the patient. When unpacking the breathing circuit set, inspect the set for damage and verify the expiration date.[1] If the set is damaged, discard it and select a new one.

The flow sensor pressure plug connects in one orientation only to the connection port. We recommend positioning the breathing circuit in front of the ventilator to accommodate the proper direction of the flow sensor tubing when connecting the pressure plug to the connection port.

Be sure to retain the single use red protective cap to place onto the flow sensor anytime the breathing circuit set is *not* in use to protect the gas path.

[1] Expiration date is next to the icon on the product packaging label.

To connect the breathing circuit set to the ventilator

1. Connect the expiratory valve end of the breathing circuit set to the *To patient* port on the ventilator (Figure 3-4).

   Align the locking bar within the locking guides on the expiratory valve. Do *not* use excessive force!

2. Connect the flow sensor pressure plug to the flow sensor pressure plug connection port on the ventilator (Figure 3-5).

   The plug can only be connected in one orientation.

   Ensure that the tubing from the expiratory valve to the pressure plug is *not* kinked.

   Figure 3-6 shows the components properly connected.

3. Perform the preoperational check for the breathing circuit set as described in Section 3.6.

   Ensure the red protective cap is placed onto the flow sensor.

   Follow the instructions provided on the ventilator during the preoperational check.

4. After the preoperational check is successfully completed, connect an HMEF and any other required components to the breathing circuit set, as appropriate.

   Be sure to retain the red protective cap; ensure the cap is placed back onto the flow sensor anytime the breathing circuit set is *not* in use to protect the gas path.

5. Verify all components are connected securely.

6. Ensure the breathing circuit set is properly positioned, as described in Section 3.5.4.

The breathing circuit set is now ready for use.

Figure 3-4. Connect the expiratory valve end of the breathing circuit set to the *To patient* port. Align locking bar (1) within the locking guides (2) on the expiratory valve.

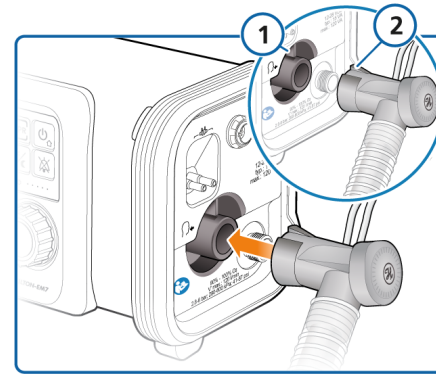


Figure 3-5. Connect the flow sensor pressure plug to the flow sensor pressure plug connection port

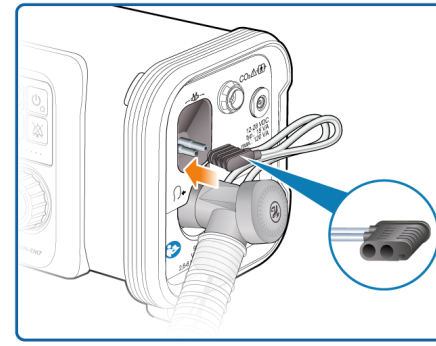
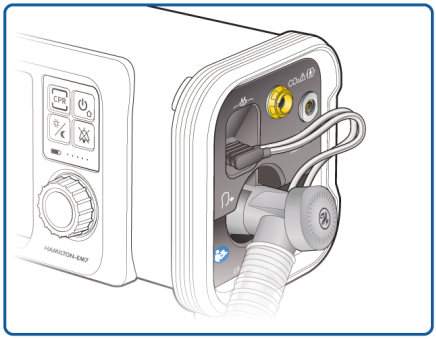


Figure 3-6. Breathing circuit set connected



3.5.4 Positioning the breathing circuit set and device

⚠ CAUTION

Ensure there is no undue stress placed on any tubing or cables.

After assembling the breathing system and connecting it to the ventilator, secure the breathing circuit set and all accompanying cables and tubing so that they are *not* pushed, pulled, or kinked as a result of a patient's movement, transport, or other activities, including scanner bed operation.

Position the flow sensor upright, with the patient end facing downward. Ideally, the flow sensor should be at a 45° or greater angle relative to the floor. This help minimize accumulation of secretions, occlusions, and/or condensation in the flow sensor.

The next step is to perform all required tests, calibrations, and the preoperational checks. See Section 3.6.

3.6 Performing the preoperational check, tests, and calibrations

The preoperational check calibrations and tests described in this section help verify the safety and reliability of the ventilator. They are performed in Standby, without any connected patient.

Table 3-5. Preoperational check, tests, and calibration overview

To ...	See ...
Perform the preoperational check	Section 3.6.1
Test alarms	Section 3.6.2
Perform a zero calibration of a CO2 sensor (if used)	Section 3.7.3

Make sure these tests and calibrations are successful before you return the ventilator to clinical use. If a test fails, troubleshoot the ventilator as indicated in this section or have the ventilator serviced.

The test results are stored in memory, including when the ventilator is turned off. This allows the ventilator to be checked and kept in storage, ready for use.

The time and date of the last test are displayed in the Start Preop check window (Figure 3-9). Ensure the last performed preoperational test is valid for your patient.

Table 3-6. When to perform tests and calibrations

Test or calibration	When to perform
Preoperational check	• Before connecting a new patient to the ventilator. • When connecting a new breathing circuit set or component. For details, see Section 3.6.1.
Alarm tests	As desired. For details, see Section 3.6.2.
CO2 sensor/ adapter zero calibration	Required after connecting a CO2 sensor or when a related alarm occurs. Recommended after switching between different airway adapter types. For calibration details, see Section 3.7.3.

3.6.1 Performing the preoperational check

Before proceeding, review the safety information in Chapter 1.

On the HAMILTON-EM7, the preoperational check performs the following tests and calibrations as a single integrated step:

- Leak test
- Verification of the proper functioning of the expiratory valve
- Calibration of the flow sensor and measuring of resistance and compliance of the breathing circuit

Perform the preoperational check before connecting a new patient to the ventilator.

To ensure that the ventilator functions according to specifications on your patient, perform the preoperational check using the breathing circuit set that will be used on the patient.

To access the Preop check window

Access the Preop check window from either of the following locations:

- Patient settings window (Figure 3-7)

  When turning on the ventilator, this window is displayed after the ventilator finishes the self-test process.

- Standby window (Figure 3-8)

  When the ventilator is in Standby, the following message is displayed: Standby. No therapy running.

Figure 3-7. Accessing the Preop check window from Patient settings (1)

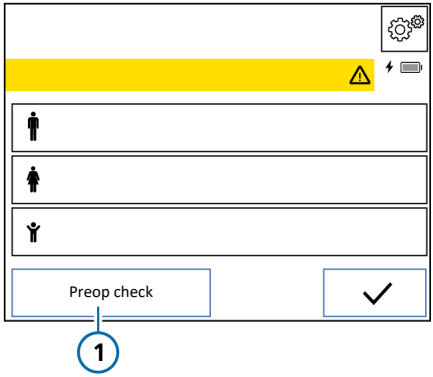
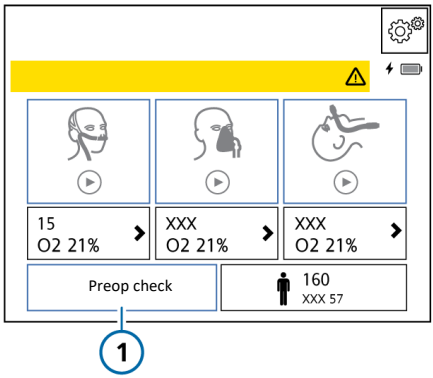


Figure 3-8. Accessing the Preop check window from the Quick start / Standby window (1)



To perform the system preoperational check

1. Connect the patient breathing circuit set to the ventilator (Section 3.5.3).
2. Do one of the following:

   – If the ventilator is turned off, turn it on. After the self-test is complete, the Patient settings window is displayed (Figure 3-7).

   – If the ventilator is already turned on, ensure you are in Standby (Figure 3-8).
3. Touch **Preop check**.

   The Preop check window opens (Figure 3-9), displaying the text Start Preop check?, together with the date/time of the last check.
4. Touch ✓ to begin.

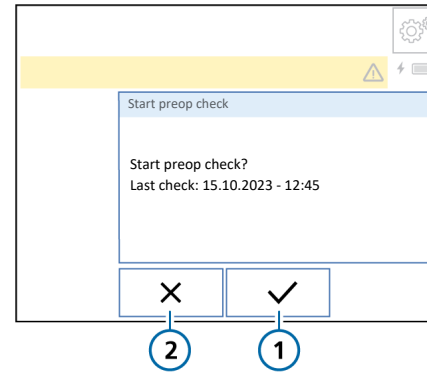
   To cancel and close the window, touch **X**.

   The window provides graphics and prompts to guide you through the process of performing a Leak test and calibrating the flow sensor and circuit.
5. Follow the onscreen instructions, touching ✓ when prompted.
6. At the end of the check, the ventilator displays the status of the tests: Preop check successful or Preop check failed.

   If the check failed, perform the steps described next, under *In case of calibration failure*.
7. Touch ✓ to confirm completion of the test and close the window.
8. If appropriate, perform a zero calibration of the CO2 sensor/ adapter (Section 3.7.3).
9. Generate test alarms (Section 3.6.2).

   The corresponding alarm message is displayed in the message bar. Note that patient alarms are suppressed in Standby.
10. When all checks are completed, place the red protective cap over the flow sensor to protect the gas path.

Figure 3-9. Start preop check window, Confirm (1) and Cancel (2) buttons



A ✓ indicates the component is calibrated and ready. **X** indicates the test/calibration was unsuccessful. A box with no marks indicates the test/ calibration has not been performed.

In case of calibration failure

Ensure that you have performed all steps of the test correctly. Perform the following checks, repeating the preop check after each one, until calibration is successful.

- Check the integrity of the breathing circuit set, and ensure it is not damaged.
- Check all of the breathing circuit set connections to the ventilator and ensure they are secure. Then repeat the preop check.
- If the preop check still fails, discard the breathing circuit set and connect a new one. Ensure the connections are secure and repeat the preop check.
- If the problem persists, have the ventilator serviced.

3.6.2 Testing the alarms

During ventilator startup, the HAMILTON-EM7 performs a self-test that also verifies proper alarm function, including generation of an audible alarm sound. You are *not* required to perform additional alarm tests.

If desired, you can test any adjustable alarm by manually changing the set limit such that the ventilator exceeds or fails to reach the set limit, thereby generating the associated alarm. For details on setting alarm limits, see Section 4.7.

When testing the alarms, use a demonstration lung.

3.6.2.1 Testing the Loss of external power alarm

You can optionally test the Loss of external power alarm as follows.

To test the alarm

1. Ensure a battery is installed in the ventilator.
2. Turn on the ventilator.
3. Unplug the ventilator from the primary power outlet.

   Verify that the low-priority Loss of external power alarm is generated, indicating that the device is running on battery power.
4. Reconnect the power cord to the primary power outlet.

The low-priority Loss of external power alarm disappears.

3.7 Setting up CO2 monitoring

⚠ WARNING

- Connect the CO2 airway adapter according to your institution's policy and procedures.
- Connecting the airway adapter adds 6 ml of dead space to the circuit.

⚠ CAUTION

Do NOT place the CO2 sensor directly on the patient's skin. It can burn the skin as the sensor may reach a temperature of 46°C (115°F).

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-EM7 supports mainstream CO2 measurement.[1] For calibration information, see Section 3.7.3.

CO2 monitoring data is helpful for the assessment of the patient's airway integrity or ensuring proper endotracheal tube placement, among other applications.

Table 3-7. CO2 measurement overview

For details about ...	See ...
CO2 measurement, connection, and use	Section 3.7.1
Enabling the CO2 sensor	Section 3.7.2
Performing a zero calibration prior to use	Section 3.7.3

3.7.1 CO2 measurement

The CO2 monitoring option comprises the airway adapter and CO2 sensor (shown in Figure 3-10).

For information about compatible, validated breathing circuit sets and accessories, see the ventilator *Technical Specifications*.

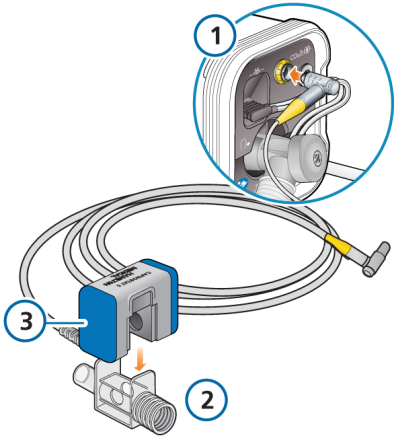
The sensor generates infrared light and beams it through the airway adapter to a detector on the opposite side. CO2 from the patient, flowing through the airway adapter, absorbs some of this infrared energy.

The system determines the CO2 concentration in the breathing gases by measuring the amount of light absorbed.

The ventilator displays the PetCO2 measurement as a numeric value and in the PCO2 waveform.

[1] Available with the CO2 option.

Figure 3-10. CO2 monitoring components and assembly



1	CO2 connection port	3	CO2 sensor
2	Airway adapter		

3.7.1.1 Connecting the CO2 sensor

Before proceeding, review the safety information in Chapter 1.

Ensure the CO2 sensor and airway adapter are clean and dry before connection.

To set up CO2 monitoring

Refer to Figure 3-10.

1. Connect the sensor cable to the CO2 connection port (**1**) on the ventilator.
2. Attach the CO2 sensor (**3**) to the airway adapter (**2**), aligning the arrows on both components.

   Press the components together until they click.

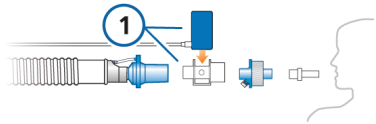
   Note that the adult/pediatric airway adapter adds 6 ml of dead space to the circuit.
3. When connecting a CO2 sensor for the first time, perform the zero calibration of the sensor/adapter, if needed, as described in Section 3.7.3.
4. Connect the sensor/adapter to the breathing circuit set proximal to the patient (Figure 3-11).

   Ensure that it is positioned at a ≥ 45° angle relative to the floor.

   Do *not* place the airway adapter between the ET tube and any connected adapter, as this may allow patient secretions to accumulate in the adapter.

   The cable side of the sensor should face away from the patient.
5. Secure the cable safely out of the way.

Figure 3-11. Connecting CO2 sensor/airway adapter (**1**) to breathing circuit set



To verify the quality of the connection

- Check the capnogram (PCO2 waveform) on the ventilator display.

If CO2 levels are higher than expected, check the patient condition. If you determine that the patient's condition is not contributing, calibrate the sensor (Section 3.7.3).

To disconnect the sensor cable from the ventilator

- Pull back on the connector and disengage from the connection port on the ventilator.

3.7.2 Enabling CO2 measurements

With the CO2 option and a supported CO2 monitoring device, the HAMILTON-EM7 provides integrated monitoring and data display of CO2 monitoring data.

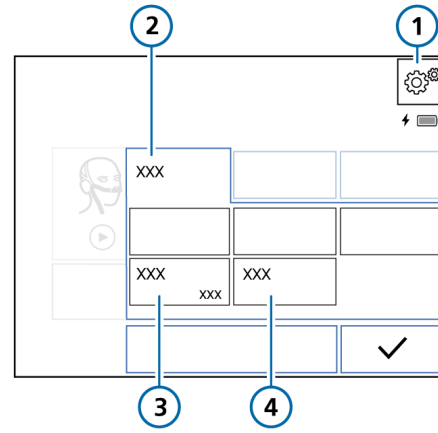
In addition to hardware activation for CO2 measurements, the sensor must be enabled for monitoring data to be available.

To enable CO2 sensor monitoring

If the CO2 sensor is connected to the device, it is automatically enabled.

1. Touch  > **General**.
2. Touch **CO2 sensor** to turn monitoring ON or OFF.

Figure 3-12. Enabling the CO2 sensor



1	Settings	3	CO2 sensor
2	General	4	CO2 sensor calibration

3.7.3 Performing a zero calibration of the CO2 sensor/adapter

⚠ CAUTION

- *Always perform zero calibration with the CO2 sensor connected to the airway adapter.*
- *Be sure to keep both ends of the airway adapter open.*

Before proceeding, review the safety information in Chapter 1.

The CO2 adapter zero calibration compensates for optical differences between airway adapters and for sensor drift.

Note that the CO2 sensors are calibrated at the factory; you only need to zero the adapters as described next.

Perform a zero calibration in the following cases:

- With the first use of the sensor
- When changing between airway adapter types (for example, from single use to reusable)
- When the CO2 calibration needed alarm is generated

To perform zero calibration of the CO2 sensor/airway adapter

Zero calibration is performed with the CO2 sensor and airway adapter connected to each other, *disconnected from the breathing circuit set*, with the ventilator in Standby.

1. Ensure the ventilator is in Standby.
2. Connect the CO2 sensor to the CO2 port on the ventilator (Figure 3-10), and ensure CO2 monitoring is enabled (Section 3.7.2).

   If this is the first time the CO2 sensor is connected, wait at least 2 minutes for the device to warm up.
3. Attach the CO2 sensor to the airway adapter, aligning the arrows on both components (Figure 3-13).

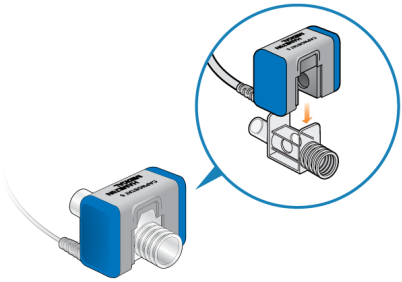
   Press the components together until they click.

   Calibration is performed with the sensor and airway adapter connected to each other, disconnected from the breathing circuit set.

   Keep the sensor and airway adapter away from all sources of CO2, including the patient's and your own exhaled breath, as well as the ventilator exhaust port.
4. Touch  > **General**.
5. Touch **CO2 calibration**.

   Do *not* move the components during calibration.
6. When the zero calibration is complete, verify that the window shows successful completion with a ✓.

Figure 3-13. Connect CO2 sensor to airway adapter



In case of zero calibration failure

If the zero calibration fails, **X** is displayed.

Perform the following checks, repeating the zero calibration after each one, until it is successful:

- Check the airway adapter and clean if necessary.
- If the zero calibration still fails, ensure there is no source of CO2 near the airway adapter.
- If the zero calibration still fails, connect a new adapter.
- If the zero calibration still fails, connect a new CO2 sensor.

If the problem persists, have the ventilator serviced.

3.8 Setting up nebulization

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-EM7 supports the use of mesh nebulizers. Compatible nebulizers are listed in the Hamilton Medical e-catalog.

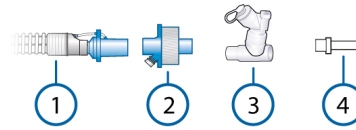
The use of a mesh nebulizer requires an external power source.

To connect a nebulizer to the breathing circuit set

- Connect the nebulizer to the breathing circuit as shown in Figure 3-14.

For additional setup, connection, and operation details, see Section 8.5 and the manufacturer's *Instructions for use*.

Figure 3-14. Connecting a nebulizer to the HAMILTON-EM7 breathing circuit set



1	Breathing circuit set	3	Mesh nebulizer
2	HMEF (compatible with drug nebulization)	4	Patient interface

3.9 Setting up for use with night vision goggles (NVG)

⚠ WARNING

If using night vision goggles (NVG), check to ensure compatibility of the equipment *before* initial use.

The HAMILTON-EM7 supports use with night vision goggles (NVG).

To this end, you can adjust the brightness of the display, and set the Day/Night key to toggle between Night and NVG settings.

For details, see Section 8.7.1

4 Delivering therapy

4.1 Process overview

This section explains how to set up the HAMILTON-EM7 for ventilation on an individual patient. Connecting power and oxygen supplies, and setting up the breathing circuit set are covered in Chapter 3.

Setting up ventilation parameters generally comprises the following steps.

Table 4-1. Setting up and delivering therapy, overview

To ...	See ...
Perform the preoperational check, tests, and calibrations	Chapter 3, Section 3.6
Select the patient group and enter patient data	Section 4.3
Start therapy	Section 4.4
Select the ventilation/ therapy mode and review/ adjust controls	Sections 4.4.3 and 4.6
Review and adjust alarm limits	Section 4.7
Pause therapy	Section 4.8
Stop therapy (enter Standby)	Section 4.9
End patient session	Section 4.10

4.2 Performing the preoperational check, tests, and calibration

Before starting therapy, be sure to perform the preoperational check and any calibration or alarm tests.

For details, see Section 3.6.

4.3 Entering patient data

⚠ CAUTION

Entering the correct patient data ensures safe therapy settings for start up and Apnea backup.

When the device is turned on, the device performs self-tests, and when finished, displays the Patient settings window (Figure 4-1) and the message: Standby. No therapy running. You can also access the Patient settings window from the Standby/Home window (Figure 4-3).

Specifying the correct patient data is particularly important, as the ventilator uses this data as a basis for some calculations and initial mode control settings.

- For Adult patients, you set the patient sex (Male, Female) and height to calculate the predicted body weight (PBW).
- For Pediatric patients, the ventilator uses the Patient height; patient sex is not used.

The following control settings are based on PBW: Vt, Rate, T high, TI, MinVol, and safety settings.

Table 4-2. Patient groups on the HAMILTON-EM7

Adult	Pediatric
Sex: Male, Female *Patient Height:* > 130 cm *PBW:* > 30 kg *Minimum delivered tidal volume:* 50 ml	*Patient Height:* 58 to 150 cm *PBW:* 5 to 48 kg *Minimum delivered tidal volume:* 50 ml

Before proceeding, review the safety information in Chapter 1.

To enter patient data

1. In the Patient settings window (Figure 4-1), touch **Male**, **Female**, or **Pediatric**, as appropriate for your patient.

   The Patient height window opens (Figure 4-2).

2. Set the height and confirm the setting.

   The device calculates the patient predicted body weight (PBW).

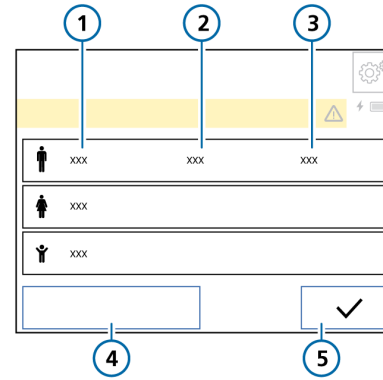
3. If you selected Pediatric as the patient group, you are prompted to confirm the group and patient height.

   Touch ✓ to confirm the settings.

The Standby/Home window is displayed. Parameter and alarm limit settings are set to their default values based on the specified patient data.

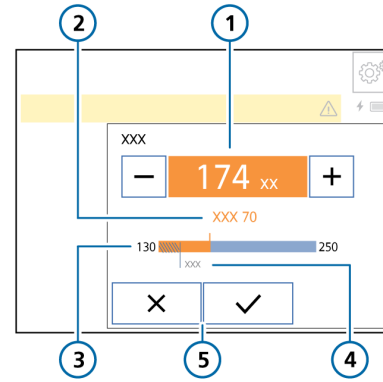
You can now proceed to setting up for the desired therapy.

Figure 4-1. Patient settings window



1 Patient group
2 Patient height
3 PBW (calculated)
4 Preop check
5 Confirm

Figure 4-2. Setting patient height



1 Patient height setting, adjustment +/− buttons
2 Calculated PBW for displayed height setting
3 Graphical view of patient height range, current setting
4 Indication of patient group boundary
5 Cancel/ Confirm buttons

4.4 Starting therapy

Before starting ventilation, review the patient information in the Standby/Home window and ensure it is correct. For details, see Section 4.3.

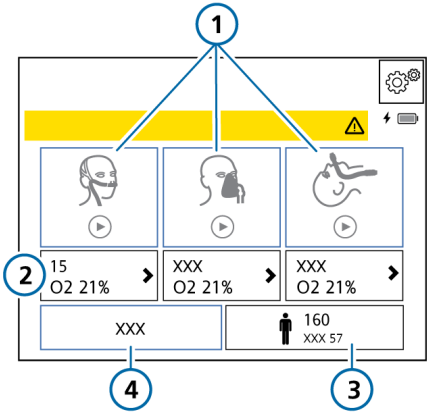
In the Standby/Home window, the therapy modes are arranged according to type as follows:

- O2 therapy[1]
- Noninvasive[1,2]
- Invasive

Each therapy type offers a blue Quick Start button and a black Controls button. The name of the default mode is displayed for each type.

The default mode for the noninvasive and invasive ventilation types can be set in Configuration (Section 10.4.2).

Figure 4-3. Standby/Home window: Starting therapy



1 *Blue Quick Start buttons:* Touch to directly start therapy: O2 therapy, Noninvasive, Invasive

2 *Black Controls buttons:* Touch to access settings for each therapy type

3 *Patient settings:* Touch to change patient type/height

4 *Preop check:* Touch to start the check

[1] If the option is installed and activated.
[2] Displayed only if one or more noninvasive modes have been configured (Section 10.4.2).

Table 4-3 provides an overview of the methods for starting therapy. Each option is described in detail after the table.

Table 4-3. Starting therapy, overview of methods

To ...	Do the following ...
Directly start therapy (Quick Start) using the configured mode and settings	Touch the blue **Quick Start** button. Therapy starts right away. See Section 4.4.1.
Directly start CPR ventilation	Touch the **CPR** key on the front of the ventilator. See Section 4.4.2.
Change the mode or adjust settings before starting therapy	Touch the black **Controls** button for the desired therapy type. After you make changes, you start therapy directly from the Controls window. See Section 4.4.3.

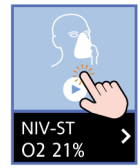
4.4.1 Starting therapy directly using default settings (Quick Start)

The blue Quick Start buttons directly start delivering the displayed therapy using the configured settings.

You can adjust the settings during therapy at any time (Section 4.6).

To directly start therapy using the configured settings

- In the Standby/Home window, touch the blue **Quick Start** button for the desired therapy.



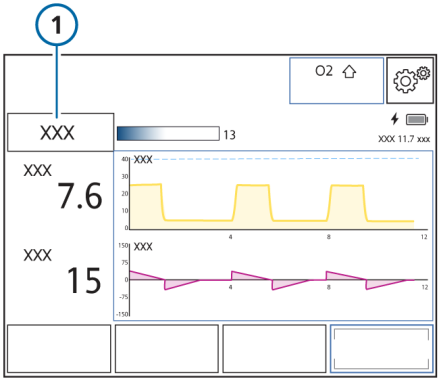
  Alternatively, using the P&T knob, move the cursor to the desired **Quick start** button, and press the P&T knob to select it.

The ventilator starts delivering therapy immediately using the default settings (Figure 4-4). The default settings can be changed in Configuration (Section 10.4.2).

During ventilation, the active mode is displayed on the left side of the display. You can change settings at any time (Section 4.6).

For monitoring details, see Chapter 6.

Figure 4-4. Therapy running, main display, active mode (1)



4.4.2 Starting CPR ventilation

You can start directly in CPR ventilation, either with the ventilator turned off or once it has been turned on.

For detailed information about CPR ventilation, including starting therapy, see Section 8.6.

4.4.3 Changing mode/settings before starting therapy

If needed, you can change the settings for O2 therapy, or the mode/settings for noninvasive or invasive therapy before starting.

To change the selected mode/settings before starting therapy

1. In the Standby/Home window, touch the black **Controls** button for the desired therapy (Figure 4-3).

   The Controls window opens (Figure 4-5).

2. To select a different mode, touch the **Modes** tab.

   The available modes for the selected therapy type are displayed.[1]

3. Touch the desired mode.

   The Basic controls window is displayed.

4. Review and, if needed, adjust the control settings in the Basic controls window and in the Extended controls window.

[1] The set of modes available for use on the ventilator is configurable. See Section 10.3.3.

5. Touch Alarm limits to review and adjust alarm limits, if necessary.

   When done, touch **X** to close the Alarm limits window.

6. When finished, touch **Start therapy**.

   Note that if you do *not* start therapy, the window stays open.

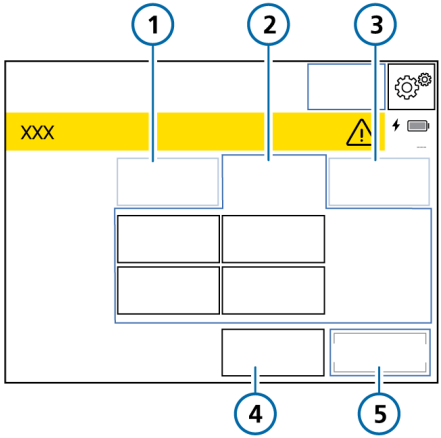
   To return to the Standby/Home window without starting therapy, touch the Power/Standby key.

Therapy starts in the selected mode using the selected settings.

For monitoring details, see Chapter 6.

For details on adjusting settings during therapy, see Section 4.6.

Figure 4-5. Controls window, adjusting settings before starting therapy



1 Modes
2 Basic controls
3 Extended controls
4 Alarm limits
5 Start therapy

4.5 Ensuring an adequate oxygen supply for patient transport

⚠ WARNING

Before transporting the patient, ensure the oxygen supply is adequate by checking the O2 consumption parameter on the main display (Figure 4-6) and ensuring it is adequate for your estimated travel time and current oxygen capacity.

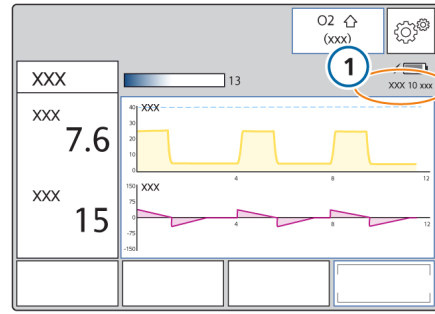
Before transporting the patient, review the current oxygen consumption.

4.5.1 Reviewing current oxygen consumption

The current oxygen consumption rate is always displayed at the top of the ventilator display (Figure 4-6).

The O2 consumption rate is updated every second and shows the average consumption rate over the last minute. The O2 consumption rate is available after 48 seconds of ventilation.

Figure 4-6. O2 consumption (1) on main display

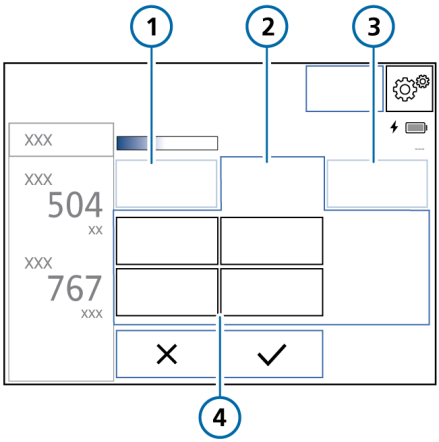


4.6 Reviewing and adjusting therapy settings

You specify therapy settings in the Controls window tabs:

- Modes
- Basic controls
- Extended controls

Figure 4-7. Controls window, settings



1	Modes tab	3	Extended controls tab
2	Basic controls tab	4	Adjustable controls

To change the mode or settings during therapy

1. During active therapy, touch **Controls**.

   You can change the ventilation mode in the Controls > Modes window.
2. Select and adjust settings as needed in the Basic controls and Extended controls windows. See Figure 4-7.
3. Touch ✓ to confirm any changes.

Any changes take effect as soon as they are confirmed.

Depending on the changes, the device might change the Pressure (high) alarm limit. For details, see Section 4.6.1.

4.6.1 About pressure-control settings

The total inspiratory pressure (Ptotal) to be applied during ventilation is determined by the setting of a combination of the following parameters, depending on the selected mode.

For details about these parameters, see Table 4-8.

Table 4-4. Pressure control settings in each mode

Pressure control settings	Mode
ΔPcontrol, PEEP	PCV+
ΔPsupport, PEEP	SIMV[1], SPONT[1], NIV[1]
ΔPinsp, PEEP	NIV-ST[1]
ΔPsupport, PEEP, or P high (whichever is greater)	DuoPAP[1]
ΔPinsp, PEEP	ASV
PEEP/CPAP	CPAP

In ASV mode, an additional parameter, Plimit, is available. Plimit defines the *maximum* allowed pressure to apply during ventilation. Plimit is available in the Basic controls window (Figure 4-7).

Note that Plimit and the Pressure (high) alarm limit are directly related: Plimit is always the Pressure (high) alarm limit minus 10 mbar, thus, changes to either value affect the other.

Adjustments to the total inspiratory pressure-related settings can change the Plimit control setting, as described in Section 4.6.1.1.

[1] If the option is installed and activated.

4.6.1.1 Adjusting pressure-related settings

Adjusting pressure-related settings can, in some cases, change the Pressure (high) alarm limit and/or the Plimit setting (ASV mode only), as described in the following table.

Table 4-5. Ventilator actions with changes to pressure-related control settings

When you ...	The ventilator makes the following changes ...
Change the Plimit setting. *(ASV mode only)*	The Pressure (high) alarm limit is set to Plimit + 10 mbar.
Set Ptotal < Plimit – 20 mbar, you are prompted to confirm the setting.	When confirmed, Plimit is set to Ptotal + 20 mbar. The Pressure (high) alarm limit is set to Plimit + 10 mbar.
Set Ptotal > Plimit, you are prompted to confirm the setting.	When confirmed, Plimit is set to the Ptotal value. The Pressure (high) alarm limit is set to Plimit + 10 mbar.
Set the Pressure (high) alarm limit > 60 mbar or > Ptotal + 30 mbar, you are prompted to confirm the setting.	When confirmed, the alarm limit is set to the defined value. Plimit is set to the new Pressure (high) alarm limit minus 10 mbar.

4.6.2 About Apnea backup ventilation

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-EM7 provides Apnea backup ventilation, a mechanism that minimizes possible patient injury due to apnea or cessation of respiration. Apnea backup is available in the following modes.

Table 4-6. Modes and their backup modes

Selected mode	Backup mode
SPONT	(S)CMV
NIV	NIV-ST

Apnea backup ventilation enabled

Apnea backup provides ventilation after the apnea time passes with no breath attempts detected. The apnea time is set in the Alarm limits > Limits 3 window using the Apnea time control.

When this occurs, the ventilator automatically and immediately switches into Apnea backup ventilation.

It generates a low-priority alarm, displays the alarm Apnea ventilation, and the ventilator switches to the backup mode. The mode name is displayed in yellow, indicating Apnea backup ventilation is active.

The control settings for the Apnea backup mode depend on the patient PBW and the previously applied therapy.

If the patient triggers two (2) consecutive breaths, the ventilator reverts to ventilation in the original support mode and at the original settings, and displays the message, Apnea ventilation ended.

Apnea backup ventilation requires no clinician intervention, although you can freely change the mode during Apnea backup ventilation, either switching to a new mode or accepting the backup mode as the new mode.

4.7 Setting alarm limits

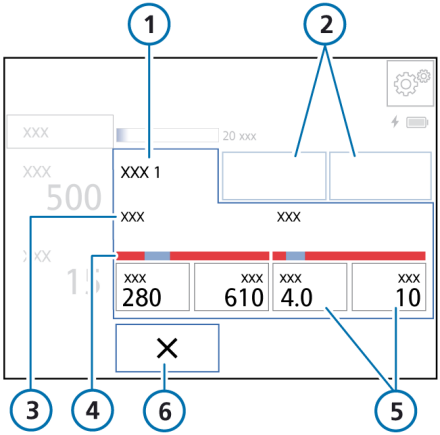
⚠ CAUTION

- *Carefully set alarm limits according to the patient's condition. Setting limits too high or too low defeats the purpose of the alarm system.*
- *To prevent possible patient injury, be sure to use the same user-configured alarm settings on the ventilators in your area.*
- *To prevent possible patient injury, make sure the alarm limits are appropriately set before you place the patient on the ventilator.*
- *The factory default alarm limit settings are set in line with the selected patient group, allowing for unattended monitoring. These settings, however, can never replace individual review of the patient and adjustment of alarm limits based on their condition.*

Before proceeding, review the safety information in Chapters 1 and 9.

You can access the Alarms window and change alarm settings at any time during noninvasive or invasive therapy.[1]

Figure 4-8. Alarm limits > Limits 1 window



1	Limits 1	4	Graphical representation of current settings
2	Limits 2 Limits 3	5	Current Low/ High alarm limit setting
3	Alarm parameter, unit of measure	6	Cancel

[1] Not available during O2 therapy.

To review and adjust the alarm limits

1. Touch **Alarm limits**.

   The button is available in the Settings window or during active ventilation.
2. To set an alarm limit individually, touch the desired low or high alarm limit setting button (**5** in Figure 4-8).
3. Adjust the setting as needed (Figure 4-9).

   – The currently selected limit is displayed in red (items **2** and **5**).

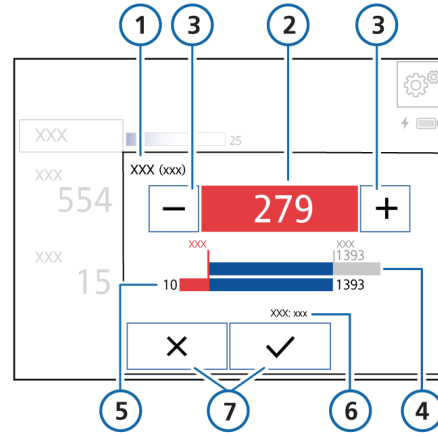
   – The available range of possible settings is displayed (in blue), with the minimum and maximum values.

   – The setting range is limited by the currently set opposite low/high alarm limit, displayed in gray.

   – While adjusting the alarm limit, the ventilator shows the associated monitoring parameter and its current value.
4. Touch ✓ to confirm the settings.
5. Access additional alarm settings in the Limits 2 and Limits 3 tabs.
6. Touch ✓ to confirm the settings and close the Alarm limits window.

Any changes take effect upon confirmation.

Figure 4-9. Adjusting alarm limits (this example shows setting the low limit for an alarm)



1	Alarm and limit (low/high) being set	5	*Bottom bar:* Low alarm bar (red indicates the current setting), showing the available range (in blue).
2	Currently set value	6	Related monitoring parameter and value
3	Decrease (–) / increase (+) setting	7	Cancel/Confirm
4	*Top bar:* High alarm bar (gray indicates the current setting)		

The following table briefly describes each of the adjustable ventilator alarms. Specifications are available in Table 12-13.

Table 4-7. Adjustable alarms

Alarm	Definition
Apnea time	The maximum time allowed from the beginning of one inspiration to the beginning of the next inspiration. If the apnea time passes with no breath attempts detected: • In NIV and SPONT modes, a low-priority alarm is generated. Apnea ventilation begins. • In all other modes, a high-priority alarm is generated. Not applicable when using O2 therapy.
ExpMinVol (low and high)	Low and high expiratory minute volume. If either limit is reached, a high-priority alarm is generated. During adjustment of the alarms, the ventilator displays the expiratory minute volume (ExpMinVol).
fTotal (low and high)	Low and high monitored total breath rate (fTotal), including both spontaneous and mandatory breaths. If either limit is reached, a medium-priority alarm is generated. During adjustment of the alarms, the ventilator displays the spontaneous breathing frequency (fTotal).
PetCO2 (low and high)	Low and high monitored PetCO2. If either limit is reached, a medium-priority alarm is generated. During adjustment of the alarms, the ventilator displays the end-tidal CO2 pressure (PetCO2).

Alarm	Definition
Pressure (low and high)	Low and high monitored pressure at the proximal flow sensor. If the Pressure (high) limit is reached or the pressure stays below the Pressure (low) limit, a high-priority alarm is generated. If the delivered pressure during inspiration is the same as the set Pressure (high) alarm limit, the device aborts the inspiration and reduces the pressure to PEEP level. During adjustment of the alarms, the ventilator displays the peak airway pressure (Ppeak).
Vt (low and high)	Low and high expiratory tidal volume, for two consecutive breaths. If either limit is reached, a medium-priority alarm is generated. During invasive ventilation, when the delivered Vt is more than 1.5 times the set upper Vt alarm limit, the Inspiratory volume limitation alarm is generated. In this case, the device stops inspiration and reduces the pressure to PEEP level. If the upper limit is reached, the ASV controls reduce the pressure for the next breath by 2 mbar. During adjustment of the alarms, the ventilator displays the expiratory tidal volume (VTE).

4.8 Pausing therapy

You can pause active therapy for up to one (1) minute, after which therapy automatically restarts.

During a pause, you can still adjust control settings and alarm limits, as needed.

To pause active therapy

1. Touch **Pause therapy** at the bottom right corner of the display (Figure 4-10).

   You are prompted to confirm this choice.

2. Touch ✓ to confirm.

The Pause window is displayed (Figure 4-11), counting down from 60 seconds.[1] When the timer reaches 0, therapy starts again automatically.

For details about pausing therapy during RSI, see Section 8.3.1.1.

Figure 4-10. Pause therapy button (1)

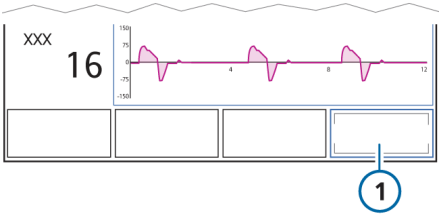
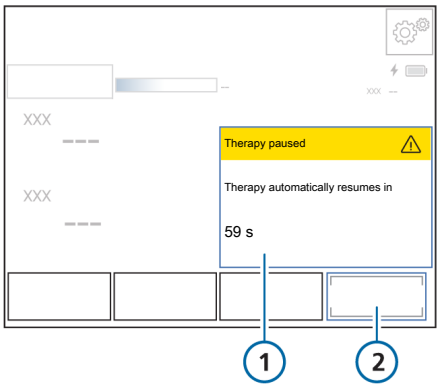


Figure 4-11. Pause window



1	Pause therapy countdown timer	2	Start therapy

To restart therapy manually

- To restart therapy manually while the countdown timer is running, touch **Start therapy** (item **2** in Figure 4-11).

Therapy resumes.

Note that, if during a pause, you change the breathing circuit set, you must enter Standby and perform the Preop check (Section 3.6) before resuming therapy.

[1] During RSI with O2 therapy, the countdown timer is *not* displayed; however, the countdown time is still running. Therapy restarts automatically after one (1) minute.

4.9 Stopping therapy (Standby)

⚠ CAUTION

When in Standby, the ventilator does not automatically resume ventilation when the patient is reconnected. You must manually restart ventilation.

NOTICE

- Patient alarms are suppressed in Standby.
- Acoustic patient alarms are suppressed for 30 seconds after starting ventilation from Standby.

Standby is a waiting mode that lets you maintain ventilator settings while the ventilator is not performing any ventilatory functions.

To stop ventilation and place the ventilator in Standby

1. Press ⏻ (Standby/Power).
   The Activate Standby window opens.
2. Touch ✓ to confirm.

The device enters Standby (Figure 4-3).

For details about pausing therapy, see Section 4.8.

To end Standby and start ventilation

▸ See Section 4.4.

4.10 Ending a patient session

When therapy is complete, perform the following tasks to dispose of used components and prepare the ventilator for the next patient:

- Dispose of single-use components appropriately.

  A used component must be handled as contaminated. Follow all local, state, and federal regulations with respect to waste management and environmental protection when disposing of used parts.
- Process reusable components in accordance with your institution's policies and protocols.

  Perform all cleaning and maintenance tasks to ensure the device is clean and ready for the next use. For details, see Chapter 9.
- Assemble/prepare available components for the next use.
- Ensure the protective cap is placed over the flow sensor to protect the gas path when the breathing circuit set is not in use.

4.11 About the control parameters

Table 4-8 provides a brief description of the ventilator's control parameters, also referred to as *control settings*. You can review and adjust these settings in various locations, depending on their function.

Table 12-10 in the *Specifications* chapter provides the control parameter ranges and default settings, including accuracy.

For a comparison of Hamilton Medical ventilation-related terminology with ISO 19223:2019, see Section 12.5.

Table 4-8. Control parameters, defined

Parameter	Definition
ETS	ETS (expiratory trigger sensitivity) is the percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation. Increasing the ETS setting results in a shorter inspiratory time. The ETS setting lets you match the inspiratory time of pressure-supported breaths to the patient's neural timing.
Flow	In O2 therapy, Flow is the continuous and constant flow of medical gas to the patient in liters per minute.
I:E	Ratio of inspiratory time to expiratory time. Applies to mandatory breaths. During adjustment of I:E, the ventilator displays the corresponding inspiratory time (TI) and expiratory time (TE), in seconds.
MinVol	The minute volume to be delivered in liters per minute. Only applies in ASV mode. During adjustment of MinVol, the ventilator displays the corresponding percentage of minute volume (%MinVol).
Oxygen	Oxygen concentration to be delivered.
P high	The high pressure setting in DuoPAP mode. Absolute pressure, independent of set PEEP.
Patient height	Patient height. Used to compute predicted body weight (PBW).
PBW	Predicted body weight. A calculated value using height and sex, used in calculations for ASV and startup ventilation settings.
PEEP/CPAP	Positive end expiratory pressure and continuous positive airway pressure, baseline pressures applied during the expiratory phase. Applies to all breaths, except during O2 therapy.

Parameter	Definition
Plimit	The maximum allowed pressure to apply during ventilation. Changes to the Pressure (high) alarm limit change Plimit; Plimit is always 10 mbar less than the Pressure (high) alarm limit. For details about Plimit, see Section 4.6.1.
P-ramp	Pressure ramp. The speed with which pressure rises to meet the set value. Options are Fast, Medium, and Slow. The P-ramp setting lets you fine-tune the initial flow output during a pressure-controlled or pressure-supported breath to match the ventilator flow to the patient's demand. Applies to pressure-controlled inflations. Notes: • Fast P-ramp settings provide higher initial flow rates and result in faster attainment of the target pressure. This may benefit patients with elevated respiratory drive. • Setting the P-ramp too fast, especially in combination with a small ET tube (high resistance), may result in a noticeable pressure overshoot during the early stage of inspiration and generation of a Pressure limitation alarm. • Setting the P-ramp too slow may prevent the ventilator from attaining the set inspiratory pressure. A square (rectangular) pressure profile is the goal. • If the set inspiratory time is shorter than P-ramp, the ventilator ignores P-ramp to attain the set inspiratory pressure.
Rate	Respiratory frequency or number of breaths per minute.
Sex	Sex of patient. Used to compute predicted body weight (PBW) for adult patients. The Pediatric patient group does not require patient sex to be defined.

Parameter	Definition
T high	Length of time at the higher pressure level, P high, in DuoPAP mode.
TI	Inspiratory time, the length of time to deliver gas for inspiration at the ΔPinsp or Vt setting. Used with Rate to set the breath cycle time. Applies in SIMV and NIV-ST modes.
TI max	Maximum inspiratory time for flow-cycled breaths. The switchover from inspiration to exhalation in spontaneous breaths is normally controlled by the ETS setting. If gas leakage is significant, however, the set cycle may never be reached. The TI max setting provides a backup so inspiration can be terminated. The ventilator switches over to exhalation when the set TI max is reached. TI max is adjustable in NIV and NIV-ST modes. For all other modes, TI max is set to 3 seconds.
Trigger	The patient's inspiratory effort triggers the ventilator to deliver a breath. Settings are 1 (low effort), 2, 3 (high effort). Set to OFF when CPR ventilation is on. See Section 8.6.
Vt	Tidal volume delivered during inspiration in (S)CMV, and SIMV modes.
ΔPcontrol	The pressure (additional to PEEP) to apply during the inspiratory phase in PCV+ mode.
ΔPinsp	Pressure (additional to PEEP) to apply during the inspiratory phase. Only applies in NIV-ST and ASV modes. It is adjustable only in NIV-ST mode.
ΔPsupport	Pressure support for spontaneous breaths in SIMV, SPONT, NIV, and DuoPAP modes. It is the pressure (additional to PEEP) to apply during the inspiratory phase. Pressure support helps the patient counteract the flow resistance of the breathing circuit and endotracheal tube. It compensates for the decreasing tidal volume and rising respiratory rate of a spontaneously breathing patient.

5 Ventilation modes

5.1 Overview

The HAMILTON-EM7 offers a full range of ventilation modes that provide full and partial ventilatory support.

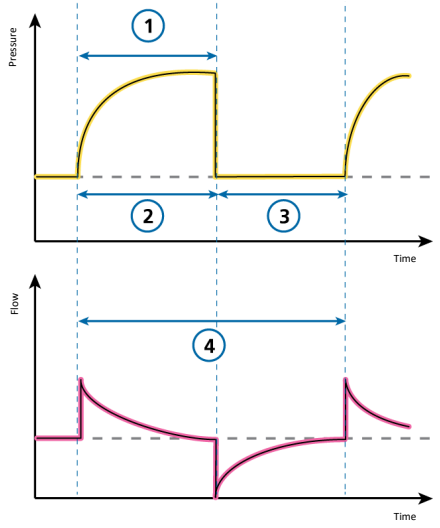
The primary aims of mechanical ventilation are:

- Elimination of CO2
- Oxygenation
- Decreased work of breathing
- Patient synchronization

The detailed mode descriptions provided in this chapter illustrate how the controls work to achieve these goals.

For a comparison of Hamilton Medical ventilation-related terminology with ISO 19223:2019, see Section 12.5.

Figure 5-1. Breath timing parameters



1	TI	4	Rate
2, 3	I:E ratio		

5.1.1 Breath types and timing options

Hamilton Medical ventilators support two main breathing methods: mandatory breaths and supported breaths.

Mandatory breaths. The start of inspiration (triggering) is determined by the patient (assisted breath) or by the ventilator (controlled breath). The end of inspiration (cycling) is determined by the ventilator. The ventilator controls mandatory breath timing using a combination of inspiratory time (I:E) and Rate.

Supported breaths. Pressure-support assistance for patient-initiated breaths; if ΔPsupport is set to 0, the breaths are unassisted. The start of inspiration (triggering) and end of inspiration (cycling) is determined by the patient.

5.1.2 Ventilation modes

The choice of mode is a medical decision that depends on the patient's CO2 elimination, oxygenation, activity, and breathing effort.

A ventilation mode combines breath type, breath sequence, and control variables.

The following two tables provide an overview of the available ventilation modes.

Table 5-1. HAMILTON-EM7 ventilation modes, terminology, and description (applicable to all patient groups)

Mode name	ISO 19223 mode name	Mode
Volume-controlled modes, flow controlled (invasive)		
(S)CMV	A/C-VC	Breaths are volume controlled and mandatory, including patient-triggered breaths.
SIMV	SIMV-VC\PS	Volume-controlled mandatory breaths can be alternated with pressure-supported breaths.
Pressure-controlled modes (invasive)		
PCV+	A/C-PC	All breaths, whether triggered by the patient or the ventilator, are pressure controlled and mandatory.
DuoPAP	SIMV-PC\PS	Mandatory breaths are pressure controlled. Supported breaths can be triggered at both pressure levels.
SPONT	CSV-PS	Every breath is supported with ΔPsupport.
Intelligent ventilation		
ASV	n/a[1]	Operator sets MinVol, PEEP, and oxygen. Rate, tidal volume, inspiratory pressure, and I:E ratio are based on physiological input from the patient.
Noninvasive modes		
NIV	CSV-PS	Every breath is supported with ΔPsupport.
NIV-ST	SIMV-PC\PS	Every breath is supported with ΔPinsp as long as the patient is breathing above the set rate. A backup rate can be set for mandatory breaths.
CPAP	CPAP	Every breath is unassisted.
O2 therapy	n/a[1]	Oxygen therapy. Oxygen concentration and constant flow are set. No supported breaths.

[1] EN ISO 19223 is not applicable as this therapy is *not* reflected in the standard.

Figure 5-2. Ventilation modes/settings overview

Mode type	Intelligent Ventilation	Volume controlled (invasive)		Pressure controlled (invasive)			Noninvasive (NIV)			
Mode	**ASV**	**(S)CMV**	**SIMV**	**PCV+**	**DuoPAP**	**SPONT**	**NIV**	**NIV-ST**	**CPAP**	**O2 therapy**
Timing	--	Rate	Rate	Rate	Rate	--	--	Rate	--	--
	--	I:E	TI	I:E	T high	--	--	TI	--	--
Mandatory breaths	--	Vt	Vt	ΔPcontrol	P high	--	--	ΔPinsp	--	--
Patient-initiated breaths	--	Vt	ΔPsupport	ΔPcontrol	ΔPsupport	ΔPsupport	ΔPsupport	ΔPinsp	--	--
	ETS	--	Exp. trigger	--	Exp. trigger	Exp. trigger	Exp. trigger	Exp. trigger	--	--
	--	--	--	--	--	--	TI max	TI max	--	--
Baseline pressure PEEP/CPAP	X	X	X	X	X	X	X	X	--	--
Insp. trigger	X	X	X	X	X	X	X	X	X	--
P-ramp	X	--	X	X	X	X	X	X	--	--
Oxygen	X	X	X	X	X	X	X	X	X	X
Male/Female/ Pediatric	X	X	X	X	X	X	X	X	X	X
Pat. height	X	X	X	X	X	X	X	X	X	X
Mode specific	MinVol	--	--	--	--	--	--	--	--	Flow
Apnea backup	--	--	--	--	--	(S)CMV	NIV-ST	--	--	--

-- N/A X applies to this mode

5.2 Volume-controlled modes, flow control

The following modes are volume controlled, with flow control:

- (S)CMV
- SIMV

5.2.1 (S)CMV mode

(S)CMV stands for *synchronized controlled mandatory ventilation*.

Breaths in (S)CMV mode are volume controlled and mandatory.

The breath can be triggered by the ventilator or by the patient. If the breath is triggered by the patient, the inspiratory rate may increase.

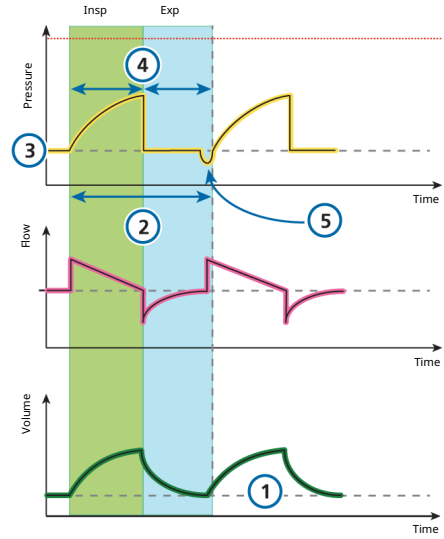
If a breath is not triggered by patient effort within a preset time, the ventilator delivers a set tidal volume with 100% decelerating flow for a set inspiratory time at a set respiratory rate.

The ventilator always delivers the set tidal volume; pressure in the airway can increase or decrease depending on the resistance and compliance of the patient's lungs.

To protect the patient's lungs it is important to carefully set an upper Pressure (high) alarm limit.

- The tidal volume (Vt) setting defines the delivered volume. Breath is terminated when the Pressure (high) alarm limit is reached; pressure reduced to PEEP.
- The Rate and I:E define the timing of the mandatory breath cycle.

Figure 5-3. (S)CMV mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1 Vt
2 Rate

Oxygenation

3 PEEP
4 I:E
Oxygen *(not shown)*

Patient synchronization

5 Trigger

5.2.2 SIMV mode

SIMV stands for *synchronized intermittent mandatory ventilation*.

The SIMV mode combines attributes of the (S)CMV and SPONT modes, delivering volume-controlled mandatory breaths or pressure-supported breaths.

SIMV mode ensures that the set volume is delivered during the mandatory breaths. After the mandatory breath is delivered, the patient is free to take additional pressure-supported breaths for the remainder of the SIMV breath interval. One mandatory breath is always delivered within this interval.

Each SIMV breath interval includes a synchronization window.

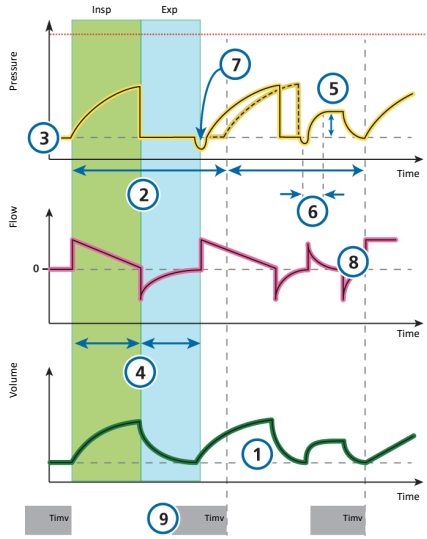
The first patient-triggered breath within the synchronization window is a synchronized mandatory (assisted) breath. If the patient does *not* trigger a breath within the synchronization window, the ventilator delivers a mandatory (controlled) breath at the end of the synchronization window.

In SIMV mode, parameters for both the mandatory and supported breath types are set.

- Synchronization window = 3*(TI), Synchronization window ≤ (60 seconds/Rate setting).[1]
- The tidal volume (Vt) setting defines the delivered volume of mandatory breaths.
- Rate and TI define the timing of the mandatory breath cycle.
- ΔPsupport defines the pressure support above PEEP. For supported breaths, the expiratory trigger sensitivity (ETS) setting affects the inspiratory timing of the breaths.

[1] The maximum synchronization window duration is 4 seconds.

Figure 5-4. SIMV mode:
Breathing pattern and controls



Ventilator controls

CO2 elimination

1	Vt	2	Rate
5	ΔPsupport		

Oxygenation

3	PEEP		Oxygen *(not shown)*
4	TI		

Patient synchronization

6	P-ramp	7	Trigger
8	ETS	9	Synchronization window[1]

[1] Not shown to scale. The Synchronization window is a calculated parameter based upon TI.

5.3 Pressure-controlled modes

The following modes are pressure-controlled:

- PCV+
- DuoPAP
- SPONT

5.3.1 PCV+ mode

PCV+ stands for *pressure-controlled ventilation*.

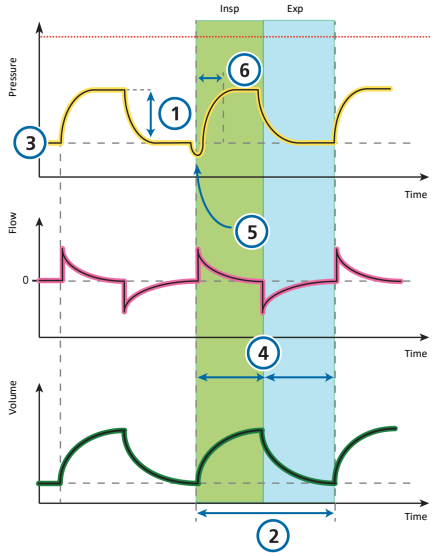
Breaths in PCV+ mode are pressure controlled and mandatory.

The ventilator delivers a constant level of pressure, so the volume depends on the pressure settings, the inspiration time, and the resistance and compliance of the patient's lungs.

In PCV+ mode, parameters are set only for mandatory breaths.

- The pressure control (ΔPcontrol) setting defines the applied pressure above PEEP.
- Rate and I:E define the timing of the breath cycle.
- The P-ramp setting controls the speed with which the ventilator arrives at the desired pressure.

Figure 5-5. PCV+ mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1	ΔPcontrol	2	Rate

Oxygenation

3	PEEP	4	I:E
	Oxygen *(not shown)*		

Patient synchronization

5	Trigger	6	P-ramp

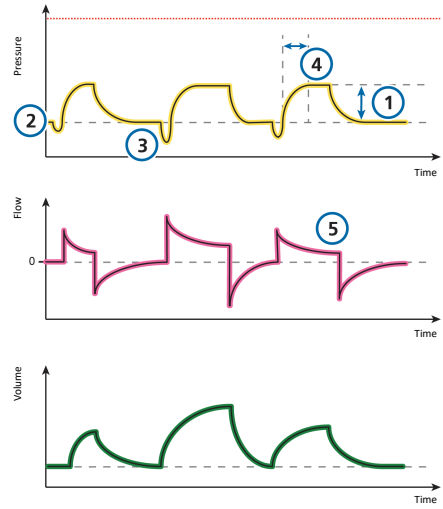
5.3.2 SPONT mode

SPONT stands for *spontaneous mode*; it delivers supported breaths.

When pressure support (ΔPsupport) is set to zero, the ventilator functions like a conventional CPAP system.

- The ΔPsupport setting defines the applied pressure during inspiration.
- The PEEP setting defines the PEEP applied during expiration.
- ETS affects the inspiratory timing of the breaths.
- The P-ramp setting controls the speed with which the ventilator arrives at the desired pressure.

Figure 5-6. SPONT mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1 ΔPsupport

Oxygenation

2 PEEP

Oxygen *(not shown)*

Patient synchronization

3 Trigger

4 P-ramp

5 ETS

5.3.3 DuoPAP mode

DuoPAP stands for *duo positive airway pressure*.

DuoPAP is a type of pressure ventilation designed to support spontaneous breathing on two alternating levels of CPAP.

In this mode, the ventilator switches automatically and regularly between two operator-selected levels of positive airway pressure or CPAP.

Cycling between the levels is triggered by DuoPAP timing settings or by patient effort.

In DuoPAP, the switch-over[1] between the two levels is defined by the pressure settings, P high and PEEP, and the time settings, T high and Rate.

Note the following:

- The maximum time between two breaths (mandatory or supported) is limited by the set respiratory cycle time (60/Rate)
- The P-ramp setting controls the speed with which the ventilator arrives at the desired pressure.

ΔPsupport can be set to assist spontaneous breathing in DuoPAP, whether it occurs at the PEEP or P high level.

ΔPsupport is set relative to PEEP, which means that spontaneous breathing at the P high level is supported only when this target pressure (PEEP + Psupport) is greater than P high.

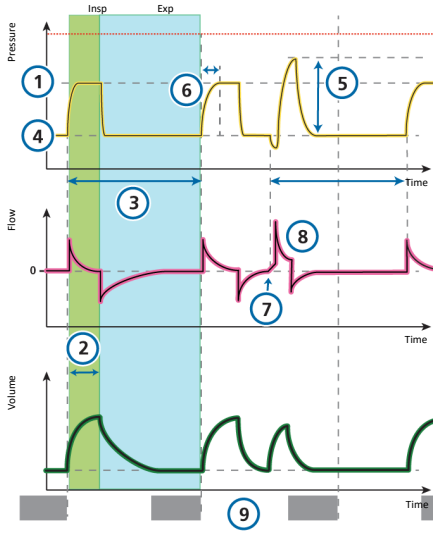
Each DuoPAP breath interval includes a synchronization window.

The first patient-triggered breath within the synchronization window results in a change to P high. If the patient does *not* trigger a breath within the synchronization window, the ventilator changes to P high at the end of the synchronization window.

- Synchronization window = 3*(T high), Synchronization window ≤ (60 seconds/Rate setting).[2]
- Rate and T high define the timing of the breath cycle.
- ΔPsupport defines the pressure support above PEEP. For supported breaths, the expiratory trigger sensitivity (ETS) setting affects the inspiratory timing of the breaths.

[1] The switch-over from PEEP to P high is synchronized to the patient's efforts in the Synchronization window.
[2] The maximum synchronization window duration is 4 seconds.

Figure 5-7. DuoPAP mode:
Breathing pattern and controls



Ventilator controls

CO2 elimination

1	P high	3	Rate
2	T high	5	ΔPsupport

Oxygenation

4	PEEP		Oxygen *(not shown)*

Patient synchronization

6	P-ramp[1]	8	ETS
7	Trigger	9	Synchronization window[2]

[1] Pressure rise time to **P high** and **ΔPsupport**.
[2] Not shown to scale. The **Synchronization window** is a calculated parameter based upon **TI**.

5.4 Intelligent Ventilation

ASV® is an adaptive pressure-controlled, volume-targeted Intelligent Ventilation mode.

5.4.1 ASV mode

ASV stands for *Adaptive Support Ventilation®*.

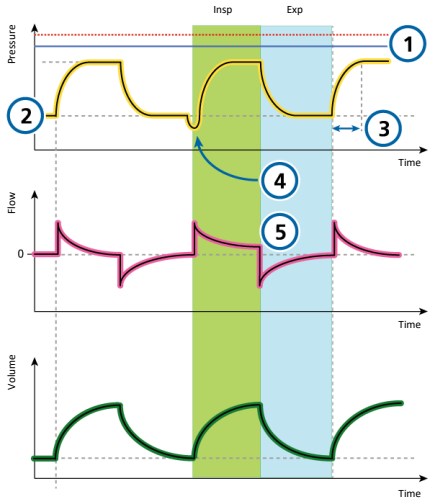
ASV maintains an operator-preset, minimum minute ventilation independent of the patient's breathing activity.

The target breathing pattern (tidal volume and respiratory rate) is calculated by the ventilator, based on the assumption that the optimal breathing pattern results in the least work of breathing, and the minimal force of breathing (driving pressure). For initial settings, see Table 5-2.

ASV adjusts inspiratory pressure, mandatory rate, and I:E ratio on a breath-by-breath basis taking into account the changing patient lung mechanics (resistance, compliance) and applying lung-protective strategies to meet the targets.

A decrease in pressure limitation (Plimit) will follow with a decrease in tidal volume (Vt) and an increase in Rate.

Figure 5-8. ASV mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1 Plimit

MinVol *(not shown)*

Oxygenation

2 PEEP

Oxygen *(not shown)*

Patient synchronization

3 P-ramp

4 Trigger

5 ETS

ASV maintains a **preset minimum minute ventilation**:

- Automatically adjusts for changing patient conditions between active and passive states
- Mandatory breaths are pressure controlled
- Spontaneous breaths are pressure supported
- Prevents tachypnea
- Prevents Auto-PEEP
- Prevents dead space ventilation
- The maximum inspiratory pressure is the set Plimit (equal to Pressure (high) alarm limit minus 10 mbar)

The operator sets the MinVol, PEEP, Plimit, and Oxygen.

For details about working with ASV, see Section 5.7.

Table 5-2. ASV mode initial breath pattern settings

PBW (kg)	ΔPinsp (mbar)	TI (s)	Initial rate (b/min)
< 6	15	0.4	30
6 to 11	15	0.6	25
12 to 14	15	0.7	20
15 to 20	15	0.8	20
21 to 23	15	0.9	20
24 to 29	15	1	20
30 to 39	15	1	18
40 to 89	15	1	15
90 to 99	18	1.5	15
≥ 100	20	1.5	15

5.5 Noninvasive modes

⚠ WARNING

- Use only interfaces intended for O2 therapy that allow the patient to exhale. This is important because exhalation through the expiratory valve is not possible when using O2 therapy.
- Do not use O2 therapy with a nasal mask, facial mask, or any interface that increases patient dead space volume. Ensure the interface allows the patient to exhale.
- Ensure the ventilator's gas pipeline system does not exceed the pipeline design flow capacity. If the system exceeds the flow capacity, it can interfere with the operation of other equipment using the same gas source.

⚠ CAUTION

Hamilton Medical ventilators provide noninvasive ventilation through a helmet EXCEPT for CPAP therapy. The turbine-driven ventilators provide higher continuous flow levels, and the air supply is provided by filtered room air (with a HEPA inlet filter) with ambient humidity.

The following modes are noninvasive:

- NIV
- NIV-ST
- CPAP
- O2 therapy

The NIV and NIV-ST modes are implementations of noninvasive positive pressure ventilation (NPPV).

CPAP is a mode that offers continuous positive airway pressure.

O2 therapy is a mode that delivers a continuous air/gas mixture to the patient. Note that on the HAMILTON-EM7, O2 therapy is available for use as its own therapy type, and has a dedicated Quick Start button in the Standby window. For details, see Section 4.4.1.

For details about working with noninvasive modes, see Section 5.6.

5.5.1 NIV mode

NIV stands for *noninvasive ventilation*; it supports spontaneous breaths.

NIV is designed for use with a mask or other noninvasive patient interface.

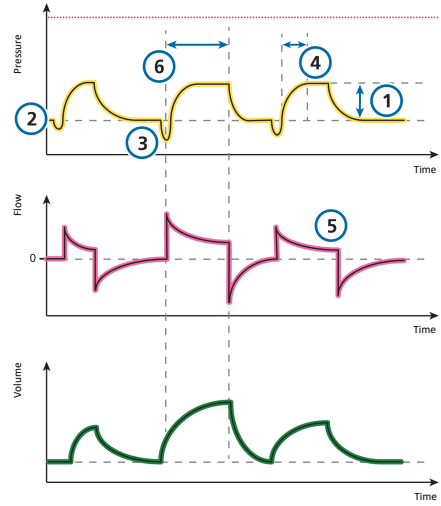
When pressure support is set to zero, the ventilator functions like a conventional CPAP system.

- The pressure support (ΔPsupport) setting defines the applied pressure during inspiration.
- The PEEP setting defines the PEEP applied during expiration.
- The P-ramp setting controls the speed with which the ventilator arrives at the desired pressure.
- The Trigger setting defines the level of patient inspiratory effort (low to high) for the ventilator to deliver a breath.
- ETS affects the inspiratory timing of the breaths.

  The inspiratory time can also be limited by TI max.

For additional details about working with noninvasive modes, see Section 5.6.

Figure 5-9. NIV mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1 ΔPsupport

Oxygenation

2 PEEP

Oxygen *(not shown)*

Patient synchronization

3 Trigger

4 P-ramp

5 ETS

6 TI max

5.5.2 NIV-ST mode

NIV-ST stands for *spontaneous/timed noninvasive ventilation*.

NIV-ST mode delivers time-cycled or flow-cycled breaths. Every patient trigger results in a flow-cycled, pressure-supported breath.

If the rate of patient-triggered breaths falls below the set mandatory Rate, time-cycled breaths are delivered at the set Rate and timing.

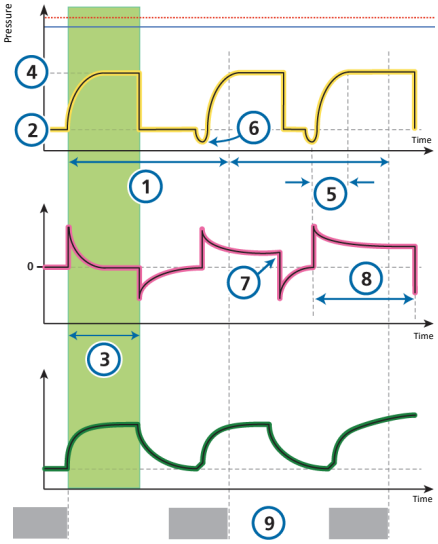
If the patient triggers a breath during the breath interval, the ventilator immediately delivers a spontaneous breath. If the patient does not trigger an inspiration during this time, the ventilator initiates a mandatory breath according to the set Rate.

This mode requires that you set the parameters needed for both mandatory and spontaneous breath types.

- The inspiratory pressure setting, ΔPinsp, defines the applied pressure for both mandatory and spontaneous breaths.
- The Rate and TI control settings define the breath timing.
- The Trigger setting defines the level of patient inspiratory effort (low to high) for the ventilator to deliver a breath.
- ETS affects the inspiratory timing of the breaths.

  The inspiratory time can also be limited by TI max.
- The P-ramp setting controls the speed with which the ventilator arrives at the desired pressure.

Figure 5-10. NIV-ST mode: Breathing pattern and controls



Ventilator controls

CO2 elimination

1 Rate

4 ΔPinsp

Oxygenation

2 PEEP

3 TI

Oxygen *(not shown)*

Patient synchronization

5 P-ramp

6 Trigger

7 ETS

8 TI max

9 Synchronization window[1]

[1] Not shown to scale. The Synchronization window is a calculated parameter based upon TI.

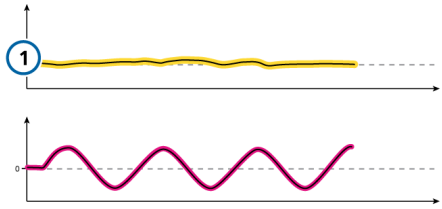
5.5.3 CPAP mode

CPAP stands for *continuous positive airway pressure*.

Breaths are unassisted at the set PEEP; the patient can breathe freely. The inspiratory flow follows the respiratory effort of the patient, and maintains the set PEEP airway pressure.

The following parameters are used in the CPAP mode: PEEP and Oxygen.

Figure 5-11. CPAP mode: Breathing pattern and controls



1 PEEP/CPAP 2 Oxygen (not shown)

5.5.4 O2 therapy

O2 therapy[1] is indicated for patients who are able to inhale and exhale spontaneously. It is *not* intended to be used with active humidification.

O2 therapy is an optional therapy in which a continuous flow of respiratory gases are delivered to the patient.

The set flow can vary from 2 to 15 l/min.[2] The operator sets the Oxygen and Flow. Therapy time is shown on the ventilator display.

Depending on the circuit and interface resistance, higher pressures may be required to deliver the set flow. Pressure is measured inside the ventilator.

Under certain conditions of excess pressure or limited flow being delivered, the Check for blockage alarm is generated. For details about the conditions that generate the alarm and alarm troubleshooting, see Table 7-2.

This respiratory support is usually delivered through a high flow nasal cannula or a mask.

The oxygen consumption during O2 therapy is displayed on the screen.

Oxygen Consumption = Set Flow * (Set Oxygen – 20.9%)/79.1%

During O2 therapy, disconnection and apnea alarms are inactive.

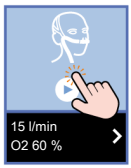
[1] If the option is installed and activated.
[2] In some markets, the maximum possible Flow setting may be higher.

5.5.4.1 Delivering O2 therapy

Note that you must be in Standby to change the mode.

To deliver O2 therapy

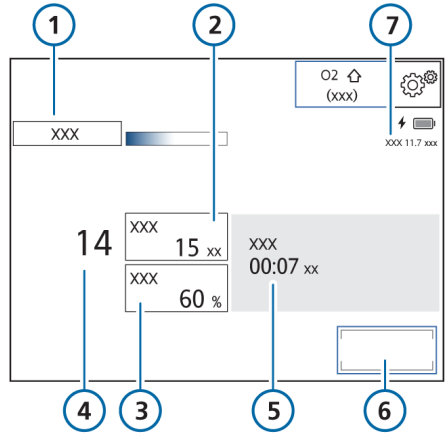
- In the Standby/Home window, touch the blue **Quick Start** button for O2 therapy.



The ventilator starts delivering therapy immediately using the default settings (Figure 5-12). The default settings can be changed in Configuration (Section 10.4.2).

You can change the Flow or Oxygen setting at any time by touching the black control button and adjusting the value.

Figure 5-12. O2 therapy, running



1 O2 therapy
2 Flow
3 Oxygen
4 Monitored Flow
5 Therapy time
6 Pause therapy
7 O2 consumption

5.6 Working with noninvasive modes

⚠ CAUTION

Placing the mandatory HMEF or any other additional component between the flow sensor and the patient adds resistance, limiting the ventilator's ability to identify disconnection at the patient. To correctly identify a patient disconnection, be sure to appropriately set the lower limit of the Pressure alarm, as well as the Volume alarm limits, and carefully monitor the patient's SpO2 and, if available, PetCO2 values.

This section provides an overview of noninvasive ventilation requirements, contraindications for use, and important information about settings and alarms.

When using noninvasive positive pressure ventilation (NPPV), use a noninvasive patient interface, for example a mask, rather than an invasive conduit.

5.6.1 Required conditions for use

Before proceeding, review the safety information in Chapter 1.

The following requirements **must be met** to use noninvasive ventilation:

- The patient must be able to trigger the ventilator and must have regular spontaneous breaths.

  Noninvasive ventilation is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.
- The patient must be conscious.
- The patient must be able to maintain an adequate airway.
- Intubation must be possible at any time.
- The mask or interface is a good fit.

5.6.2 Contraindications

⚠ CAUTION

- *To prevent possible patient injury, do NOT use noninvasive ventilation on patients with no or irregular spontaneous breaths. Noninvasive ventilation is intended to provide supplemental ventilatory support to patients with regular spontaneous breaths.*
- *To prevent possible patient injury, do NOT attempt to use noninvasive ventilation on intubated patients.*

Using noninvasive ventilation is contraindicated if **any** of the following conditions are met:

- The patient does not have the drive to breathe
- Partial or complete airway obstruction
- Gastrointestinal bleeding
- Anatomic or subjective intolerance of noninvasive interface
- Patient is unable to cooperate or protect airway

5.6.3 Potential adverse reactions

The following reactions to noninvasive ventilation are possible:

- Aspiration, gastric insufflation
- Increase of intracranial pressure (ICP)
- Decrease of arterial pressure
- CO2 rebreathing
- Claustrophobia
- Discomfort
- Dyssynchrony
- Skin or conjunctiva lesions

5.6.4 Control settings in noninvasive ventilation

⚠ WARNING

- The exhaled volume from the patient can differ from the measured exhaled volume due to leaks around the mask.
- Peak pressures exceeding 33 mbar may increase the risk of aspiration due to gastric insufflation. When ventilating with such pressures, consider using invasive ventilation.

When a significant leak occurs, the inspiratory flow can never fall below ETS, thereby preventing the ventilator from cycling into exhalation and resulting in endless inspiration. The TI max setting provides an alternate way to cycle into exhalation. When inspiration lasts longer than TI max, the ventilator cycles into exhalation.

Ensure the TI max setting is sufficiently long to give ETS the chance to cycle the ventilator.

- Adjusting the TI max setting increases or decreases the allowable inspiratory time.
- Increasing ETS above the default setting allows the ventilator to cycle to terminate inspiration at a higher flow, to accommodate larger leaks.

Other controls require special attention:

- Carefully observe the patient/ ventilator interaction.
- Carefully adjust the trigger to prevent auto-triggering (trigger threshold is set too low) or missed patient efforts (trigger threshold is set too high).
- Adjust ΔPsupport or ΔPinsp to obtain appropriate tidal volumes.
- The leakage in noninvasive modes can reduce the actual applied PEEP and give rise to auto-triggering.

5.6.5 Alarms in noninvasive ventilation

Due to the changing and unpredictable amount of leakage, volume alarms are less meaningful in noninvasive modes than in other modes. Alarms are based on the returned expiratory gas volume measured at the flow sensor; this value can be significantly lower than the delivered tidal volume, because the delivered tidal volume is the sum of the displayed VTE and the leakage volume.

To avoid nuisance volume alarms, set the low Vt and ExpMinVol alarms to a low level.

As the noninvasive modes are pressure-controlled modes, be sure to pay attention to the pressure-related alarms. If the defined PEEP and inspiratory pressure can be maintained, the ventilator is compensating the gas leak sufficiently.

5.6.6 Monitored parameters in noninvasive ventilation

NOTICE

- Continuous monitoring of clinical parameters and patient comfort is critically important.
- The parameters VTE NIV and MinVol NIV are leak compensated, and are used in noninvasive modes. These parameters are estimations and may not reflect exact values.

Due to the leakage at the patient interface, displayed exhaled volumes in the noninvasive modes can be substantially smaller than the delivered volumes.

The flow sensor measures the delivered volume and the exhaled tidal volume; the ventilator displays the difference as VLeak in percent (%). Use VLeak to assess the fit of the mask or other noninvasive patient interface.

While a leak at the patient interface influences the tidal volume measurement, leaks in the breathing circuit itself do not influence the tidal volume measurement.

In addition to other clinical parameters, Ppeak, PEEP/CPAP, I:E, fTotal, Pmean, and fSpont can be used to assess the patient's ventilatory status.

5.6.7 Additional notes about using noninvasive ventilation

Due to some unique characteristics, consider the following points when using noninvasive ventilation.

Maintaining PEEP and preventing autotriggering

Significant leakage can be present in noninvasive ventilation, which can serve to reduce the actual applied PEEP and give rise to autotriggering. If you cannot reach the set PEEP, check the mask fit.

The Loss of PEEP alarm alerts you to uncompensated leaks.

Inspect mask fit and position

Inspect the mask position regularly and adjust as necessary. React promptly and appropriately to any alarms.

The ventilator's VLeak parameter provides one indicator of mask fit.

To verify that the mask fits properly, ensure that the leakage value shown in the Monitoring window (VLeak) is acceptable.

To monitor leakage during ventilation, set the low limit of the Pressure alarm to a value near the set pressure for ventilation (PEEP + ΔPinsp/ΔPsupport). When excessive leaks are present, the ventilator may not be able to reach the set pressure, and generates an alarm.

5.7 Working with ASV

ASV is indicated for passive and spontaneously breathing adult and pediatric patients.

5.7.1 Contraindications

The use of ASV mode is contraindicated with the following:

- Infants and neonates
- If there is a high leakage (noninvasive ventilation or broncho-pleural fistula)
- Irregular respiratory drive (Cheyne-Stokes respiration)

5.7.2 Setting up ASV on the ventilator

Before proceeding, ensure that the ASV mode is configured for use. If it is not, enable it as described in Section 10.3.3.

To set up the ventilator using ASV

1. If ASV is configured as the default mode for invasive ventilation, touch the blue invasive **Quick Start** button to directly start ventilation.

   If ASV is *not* configured as the default mode, proceed as follows:
2. Touch the black **Controls** button.
3. Touch **Modes**.

   The displayed modes are available for selection.
4. Touch **ASV**.

   The Basic controls window opens.
5. Set the controls as appropriate:

   – MinVol: Set a value that results in the same minute volume as a previous mode, if applicable.

   – PEEP, Oxygen, Plimit: Set according to clinical requirements and the patient condition.

   The Plimit setting and the Pressure (high) alarm limit are connected: changing the Plimit value also changes the Pressure (high) alarm limit.
6. Touch the Extended controls tab to display additional controls to set: ETS, Trigger, and P-ramp. Set according to clinical requirements and the patient condition.
7. Touch **Alarm limits** to review and adjust alarm limits.

   Set the Pressure (high) alarm limit to an appropriate value.

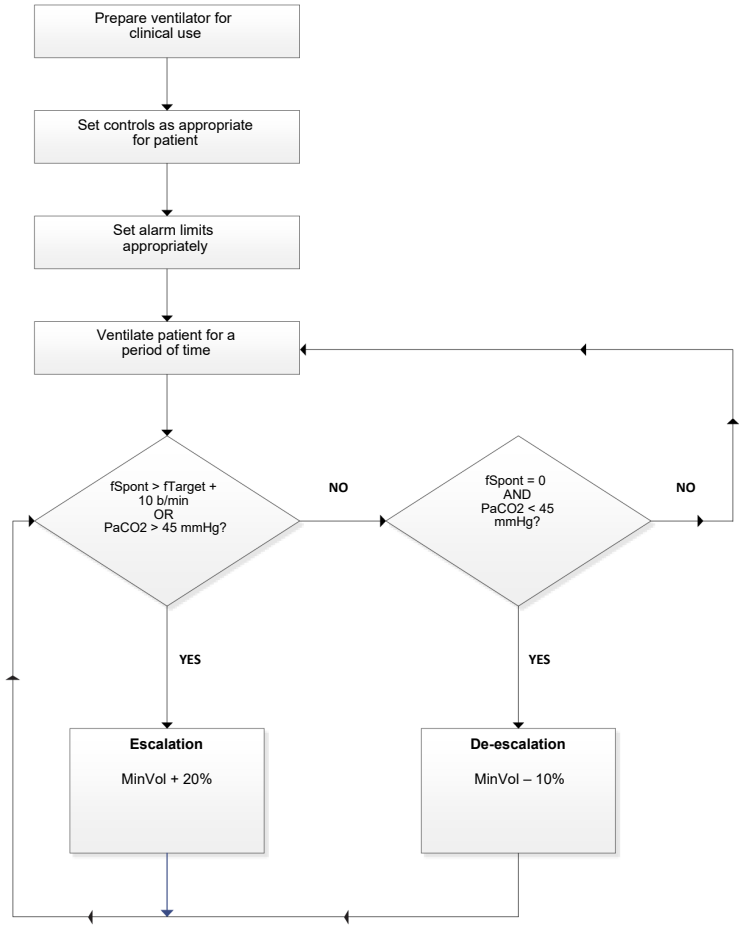
   The maximum peak pressure delivered in ASV (Plimit) is 10 mbar below the Pressure (high) alarm limit or equal to the Plimit setting. The maximum peak pressure for ASV can be also set using the Plimit control in the Controls window.
8. Connect the patient to the ventilator and start ventilation by touching **Start therapy**.

The ventilator initiates several test breaths.

The device automatically selects the values for respiratory rate (fTotal), inspiratory time (TI), and inspiratory pressure (ΔPinsp) based on the calculated PBW and as specified in Table 5-2.

5.7.3 Clinical workflow with ASV

Figure 5-13. Clinical use of ASV



5.7.4 Maintaining adequate ventilation

⚠ WARNING

To change the minute volume setting, always use the MinVol control. Do *not* manipulate the patient height setting to achieve the desired PBW to control minute volume.

Once ASV is started, the ventilator calculates an optimal breath pattern and associated target values for tidal volume and rate according to the rules in ASV and the set MinVol to achieve the targets. Depending on whether the patient is passive or actively breathing, the ventilator delivers pressure-controlled or pressure-supported breaths in compliance with a lung-protective strategy.

Once the calculated targets are reached, the result of the ventilation needs to be assessed. All monitored parameters can be used for this purpose.

However, to assess respiratory acid-base status, perform a blood gas analysis as soon as possible.

Table 5-3. Blood gas and patient conditions and possible adjustments for ASV

Condition	MinVol change
Normal arterial blood gases	None
High PetCO2 or PaCO2	Increase MinVol. Pay attention to inspiratory pressures.
Low PetCO2	Decrease MinVol. Pay attention to mean pressures and oxygenation status.
High respiratory drive	Consider increase in MinVol. Consider sedation, analgesia, or other treatments.
Low O2 saturation	None Consider increase in PEEP/CPAP and/or Oxygen.

5.7.5 Reviewing alarm settings

If ASV cannot achieve the set minute volume within the allowed pressure range, it may generate the Unable to meet target or the Pressure limitation alarm (see Section 7.4. Be sure to set the pressure alarm appropriately. For details, see Section 4.6.1.

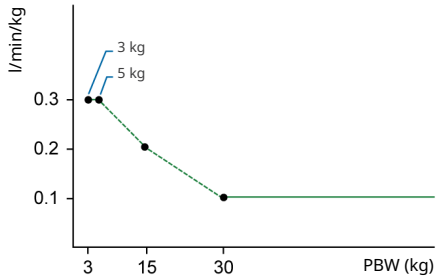
5.7.6 Functional overview

The following sections provide a brief overview of how ASV manages ventilation.

5.7.6.1 Normal minute ventilation

ASV defines normal minute ventilation according to the graph in Figure 5-14.

Figure 5-14. Normal minute ventilation as a function of predicted body weight (PBW)



For patients with a PBW of 30 kg or more, minute ventilation is calculated as 0.1 l/kg * PBW (solid line).

For example, for a PBW of 70 kg, normal minute ventilation corresponds to 7 l/min.

For patients with a PBW below 30 kg, the value is indicated by the dotted line in the previous figure.

Minute ventilation for a 15 kg patient is calculated as

0.2 l/kg * 15 kg = 3 l/min

5.7.6.2 Compensation for changes in apparatus dead space

Dead space is calculated as 2.2 ml per kilogram (kg) PBW. This dead space is a nominal value that is valid, on average, for intubated patients whose endotracheal tube is connected to the Y-piece of the ventilator by a standard catheter mount.

Changes in alveolar dead space due to ventilation/perfusion mismatch must be compensated using the MinVol control.

If this dead space is altered by an artificial airway configuration, such as the use of a heat and moisture exchanging filter (HMEF) or nonstandard tubing, modify the MinVol setting to take into account the added or removed dead space.

5.7.6.3 Targeted minute ventilation

When you choose ASV, you must select an appropriate minute ventilation for the patient. Minute ventilation is set with the MinVol control.

The default MinVol setting corresponds to normal minute ventilation (Section 5-14), equal to 100%.

For example, with a MinVol = 0.1 l/min/kg and a PBW = 70 kg (0.1 l/min/kg * 70 kg), a default target MinVol of 7 l/min is calculated. This target can be achieved with a number of combinations of tidal volume (Vt) and respiratory rate (f). This is shown in Figure 5-15, where all possible combinations of Vt and f lie on the bold line, the target minute volume curve.

Figure 5-15. MinVol = 7 l/min

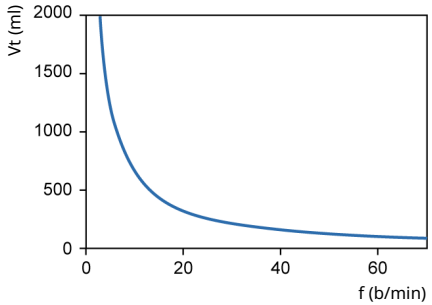
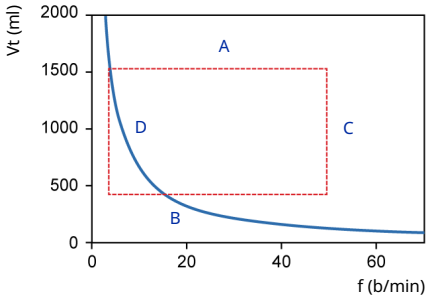


Figure 5-16. Lung-protective rules strategy



5.7.6.4 Lung-protective strategy

Not all combinations of Vt and f shown in Figure 5-15 are safe for the patient. The high tidal volumes will overdistend the lungs, and the small tidal volumes cannot produce alveolar ventilation at all.

Another risk lies in inadequate respiratory rates. High rates can lead to dynamic hyperinflation or breath stacking, resulting in AutoPEEP. Low rates can lead to hypoventilation and apnea. Therefore, it is necessary to limit the number of possible combinations of Vt and f.

When limits are imposed on the possible combinations of Vt and f, ASV uses a double strategy:

- The operator input for ASV determines the absolute boundaries.
- Internal calculations based on patient measurements further narrow the limits to counteract possible operator errors and to follow changes of respiratory system mechanics.

The effect of the strategy is shown in Figure 5-16 and explained in the subsequent sections.

A: High tidal volume limit

The tidal volume applied by ASV is limited (see A in Figure 5-16) by three operator settings: high Pressure alarm limit, high Vt alarm limit, and patient height.

Note the following:

- You must set the high Pressure limit before connecting a patient to the ventilator. The maximum pressure applied in the ASV mode is 10 mbar below the high Pressure alarm limit.
- Additionally, the target volume is limited by a factor of 1.5 of the high Vt alarm limit, and pressure support is limited such that the inspired volume does not exceed the high Vt alarm limit in mechanical breaths for more than a few breaths.
- If you set the Pressure alarm limit to a very high pressure, say 60 mbar, the target volume is limited by the second criterion: 15 ml/kg.
- Check the Vt high setting to make sure the target minute ventilation can be reached in passive patients.

B: Low tidal volume limit

You must use caution with low tidal volumes to avoid insufficient alveolar ventilation.

The determining parameter for alveolar ventilation is dead space. Tidal volume value must always be greater than the dead space value. It is widely accepted that a first approximation of dead space can be obtained by the following simple equation[1]:

Dead space = 2.2 * PBW

ASV calculates the lower limit for tidal volume based on the following equation: PBW * 4.4 ml/kg or 50 ml, whichever is greater. The multiplying factor is calculated to be at least twice the dead space.

C: High rate limit

The maximum rate (C in Figure 5-16) is derived from the operator-set MinVol and the calculated PBW, which is calculated from the operator-set patient height (Pat. height). The equation used to calculate the maximum rate is:

fmax = target MinVol / minimum Vt

However, if you choose an excessively high MinVol, increased by a factor of 3.5, the maximum rate becomes 77 b/min. To protect the patient against such high rates, ASV employs a further safety mechanism, which takes into account the patient's ability to exhale.

A measure of the ability to exhale is the expiratory time constant. To achieve a nearly complete exhalation to the equilibrium point of the respiratory system (90% of the maximum potential volume change), an expiratory time of at least 2 * RCexp is theoretically required.

For this reason, ASV calculates the maximum rate based on the principle of giving a minimum inspiratory time equal to 1 * Expiratory time constant and a minimum expiratory time equal to 2 * RCexp, which results in these equations:

fmax = 60 / (3 x RCexp) = 20 / Expiratory time constant fmax ≤ 60 b/min

This limit applies to the respiratory rate of the ventilator only, *not* to the respiratory rate of the patient.

D: Low rate limit

The lowest target rate (see D in Figure 5-16) is predefined according to the PBW (Table 5-2).

5.7.6.5 Optimal breath pattern

Although the lung-protective rules strategy limits possible combinations of Vt and f, ASV prescribes an explicit target combination. Using the example in Figure 5-16, this shows considerable room for selection within the dotted rectangle. The selection process is an exclusive feature of ASV.

The device works on the assumption that the optimal breath pattern is identical to the one a totally unsupported patient will choose naturally (assuming the patient is capable of maintaining the pattern).

[1] Radford 1954

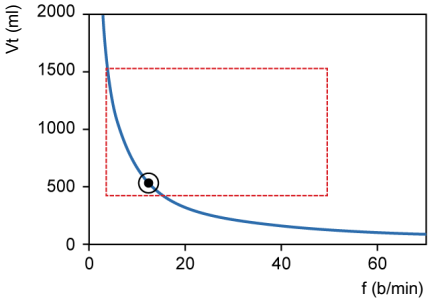
It is common knowledge that the choice of breathing pattern is governed by either work of breathing or the force needed to maintain a pattern. ASV calculates the optimal rate based on the operator-set MinVol and the calculated PBW, as well as on the measurement of RCexp (Section 5.4.1).

Once the optimal rate is determined, the target Vt is calculated as follows:

Vt = target MinVol / optimal rate

Figure 5-17 shows the position of the target breathing pattern as well as the safety limits imposed by the lung-protective rules strategy. The rectangle shows the safety limits; the circle shows the target breath pattern.

Figure 5-17. Target breath pattern and safety limits



5.7.6.6 Initial breaths: How ASV starts

How do you achieve the target values for a given patient if you do not know whether or not the patient can breathe spontaneously? For this purpose, ASV uses a predefined rate according to the calculated PBW (Table 5-2).

Patient-triggered breaths are pressure supported and flow-cycled.

If the patient does not trigger the breath, the delivery of the breath is time cycled, with a preset pressure.

The following controls are operator-set (manual):

- PEEP/CPAP
- Oxygen
- P-ramp
- ETS
- Trigger

The following controls are adjusted automatically by ASV, and cannot be adjusted by the operator:

- *Mandatory breath rate:* to change total respiratory rate
- *Inspiratory pressure level:* to change inspiratory volume
- *Inspiratory time:* to allow gas flow into the lungs
- Startup breath pattern

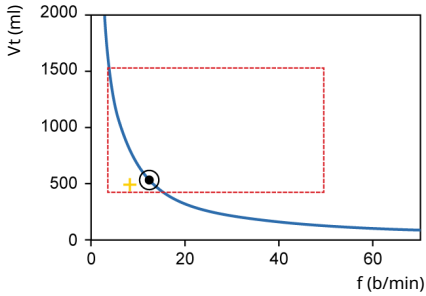
To safely start ASV, you set the patient height and sex, which are then used to calculate the PBW.

Upon starting ventilation, after some initial test breaths are delivered, the resulting rate and tidal volume are measured and compared with the target values. ASV then responds to the differences between the current and target tidal volumes, as well as the current and target rates.

5.7.6.7 Approaching the target

Figure 5-18 shows a possible scenario after the initial test breaths. The current breath pattern, which is plotted as the patient symbol, shows clear deviation from the target. ASV's task is to move the patient symbol as close to the circle as possible.

Figure 5-18. Example after three initial breaths



The patient symbol marks the actual measured value for Vt and Rate.

To achieve the target, ASV uses the following strategy:

- If actual Vt < target Vt, the inspiratory pressure is increased.
- If actual Vt > target Vt, the inspiratory pressure is decreased.
- If actual Vt = target Vt, the inspiratory pressure is left unchanged.
- If actual rate < target rate, the machine rate is increased.
- If actual rate > target rate, the machine rate is decreased.
- If actual rate = target rate, the machine rate is left unchanged.

As a result, the patient symbol in Figure 5-18 moves toward the circle. The current Vt is calculated as the average of inspiratory and expiratory volumes. This definition compensates in parts for leaks in the breathing circuit, including the endotracheal tube.

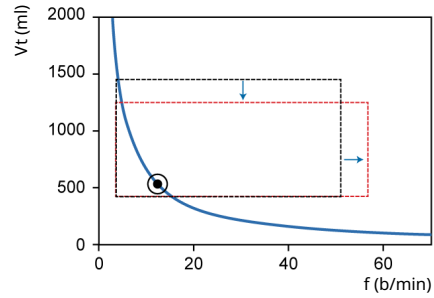
5.7.6.8 Dynamic adjustment of lung protection

The operator preset values are not changed by ASV, and the corresponding safety limits remain as defined in the previous sections. However, if the respiratory system mechanics change, the safety limits change accordingly, as defined in Section 5.7.6.4. The safety limits are updated on a breath-by-breath basis.

For example, if the lungs stiffen, the high Vt limit is lowered proportionally, and the high rate limit is increased.

This dynamic adjustment ensures that ASV applies a safe breathing pattern at all times. In graphical terms, the dotted rectangle changes as shown in Figure 5-19.

Figure 5-19. Lung-protective limits



Lung-protective limits are changed dynamically and according to the respiratory system mechanics.

However, the set Plimit is never violated.

5.7.6.9 Dynamic adjustment of optimal breath pattern

After the optimal breath pattern is calculated, it is revised with each breath according to the measurements. A new target breathing pattern is calculated using ASV algorithms. The targets do not change under steady-state conditions. However, if the patient's respiratory system mechanics change, the target values also change.

5.8 Special conditions

The following ventilator modes/states may be observed under certain error conditions.

Table 5-4. Special conditions overview

For details about ...	See ...
Ambient state	Section 5.8.1
Sensor failure mode	Section 5.8.2
Display errors	Section 5.8.3

5.8.1 Ambient state

If the issue/event alarm is serious enough to possibly compromise safe ventilation, the ventilator enters the Ambient state.

The following conditions apply to ventilation in the Ambient state:

- The expiratory valve is opened, letting the patient breathe room air unassisted.
- Provide alternative respiratory support immediately.
- You must turn off the ventilator to exit the Ambient state. Press ⏻ and hold for 3 seconds.

5.8.2 Sensor Failure mode

When there is a problem with an internal sensor, the Sensor failure alarm is generated (Section 7.4). Ventilation continues, but may not be delivered as set.

When there is a problem with the flow sensor:

- The Check breathing circuit set alarm is generated.
- Ventilation continues, but may not be delivered as set.
- Monitoring parameters related to the flow sensor measurement are shown in gray, indicating they are inaccurate.

If there is a problem with both internal and external sensors, the ventilator enters the Ambient state (Section 5.8.1).

5.8.3 Display errors

When a problem occurs with the display, a black screen may be shown for several seconds.

If this occurs during ventilation, ventilation continues while the device initiates a recovery process.

If the ventilator was in Standby, the device returns to Standby after the recovery process is complete.

If the problem is not resolved, arrange for alternate ventilation and have the ventilator serviced.

6
Monitoring ventilation

6.1 Overview

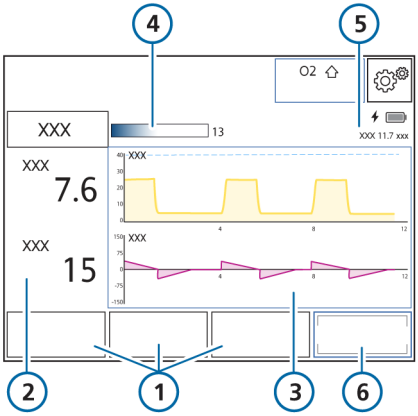
You can view patient data during ventilation, including viewing data numerically and graphically as waveforms and in the delivered pressure indicator (see Figures 6-1 and 6-2).

Numerical data is available in the Monitoring window, which you can access at any time without affecting breath delivery.

In addition, the estimated O2 consumption in liters per minute is shown at the top right of the display.

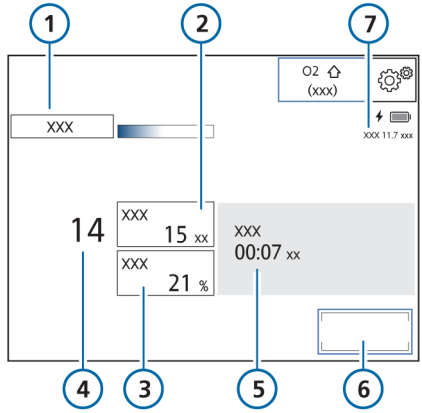
For the list of monitored parameters, see Section 6.4.

Figure 6-1. Main display, invasive and noninvasive modes



1	Monitoring, Controls, Alarm limits	4	Pressure indicator (Section 6.3.2)
2	Main monitoring parameters (MMPs)	5	O2 consumption
3	Waveforms (Section 6.3.1)	6	Pause therapy

Figure 6-2. Main display, O2 therapy



1	O2 therapy	5	Therapy time
2	Flow	6	Pause therapy
3	Oxygen	7	O2 consumption
4	Monitored Flow		

6.2 Viewing numerical patient data

Numerical patient data is readily available as follows:

- The main display prominently shows VTE and fTotal as main monitoring parameters (MMPs).
- The Monitoring window provides access to all of the parameter data. See Section 6.2.2.

6.2.1 About the main monitoring parameters (MMPs)

The MMPs are the numerical monitoring parameters shown on the left side of the display (**2** in Figure 6-1). Each of the displayed parameter shows the following elements: the current value, name, and unit of the monitoring parameter.

An MMP is normally displayed in white. When directly related to an active alarm, the MMP is shown in yellow or red, corresponding to the alarm priority. After the alarm resets, the affected MMP returns to white.

During active ventilation, you can toggle the display of MMPs.

To toggle the display of main monitoring parameters (MMPs) during ventilation

- In the main window, touch the MMP panel (**2** in Figure 6-1) to toggle the displayed parameters as follows:

  In an invasive mode:
  – Toggles the displayed parameter between VTE and ExpMinVol.

  In a noninvasive mode:
  – Toggles the displayed parameter between VTE NIV and MinVol NIV.

6.2.2 Viewing patient data in the Monitoring window

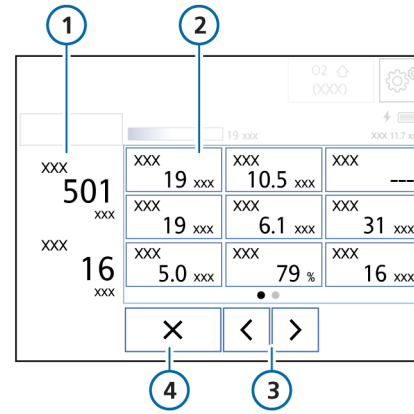
The Monitoring window (Figure 6-3) provides access to all of the monitored parameter data. You can cycle through the views using the left and right view navigation arrows at the bottom of the display.

To display the Monitoring window

1. Touch **Monitoring** (Figure 6-1).
2. Touch the left or right view navigation arrows to cycle between the views.

To close the Monitoring window, touch ✕.

Figure 6-3. Monitoring window



1	Main monitoring parameters (MMPs)	3	View navigation arrows
2	Parameter values	4	Close

6.3 Viewing graphical patient data

The HAMILTON-EM7 displays patient data graphically as follows:

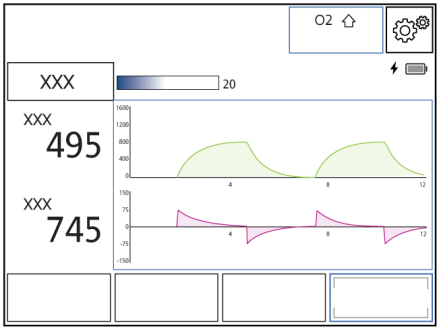
- As waveforms (Section 6.3.1)
- Pressure-related data with the indicator bar (Section 6.3.2)

6.3.1 Working with waveforms

The ventilator displays two waveforms during active ventilation (Figure 6-1). The following monitored parameters can be shown as waveforms:

- Paw (Pressure)
- Flow
- Volume
- PCO2[1]

Figure 6-4. Main display, active therapy, volume and flow waveforms shown



The waveforms provide an ongoing real-time graphical view of the selected parameters over the last 12 seconds. As a result, they also provide a way to assess the numerical monitored parameter values.

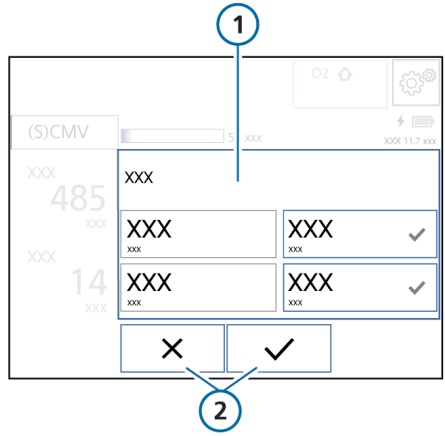
A yellow triangle is displayed on the pressure and flow waveforms to indicate when the patient initiates a spontaneous breath.

You can select the waveforms to display during ventilation.

To select the waveforms to display

1. During active ventilation, touch the currently displayed waveforms.
2. In the Waveforms window, touch the desired waveforms to be displayed.
3. Touch ✓ to confirm your selection and close the window.

Figure 6-5. Selecting waveform options



1 Waveform display options
2 Cancel/Confirm

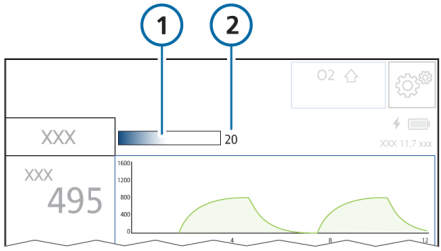
[1] CO2 option required.

6.3.2 About the pressure indication bar

The pressure indication bar at the top of the display provides a real-time view of the current delivered pressure, breath by breath.

As pressure increases, the bar fills from left to right. The monitored Ppeak value of the last delivered breath is shown to the right.

Figure 6-6. Pressure monitoring



1 Pressure indication bar

2 Ppeak (of the last delivered breath)

6.4 About the monitoring parameters

The following table provides a list of the ventilator's monitored parameters.

You can review all parameter values in the Monitoring window (Section 6.2.2). The display of monitored parameters is updated every breath or is time driven.

For parameter specifications, see Section 12.7.

For a comparison of Hamilton Medical ventilation-related terminology with ISO 19223:2019, see Section 12.5.

Table 6-1. Monitored parameters

Parameter (unit)	Definition
Pressure	
PEEP/CPAP (mbar)	Monitored PEEP/CPAP. The airway pressure at the end of exhalation. Measured PEEP/CPAP may differ slightly from the set PEEP/CPAP, especially in spontaneously breathing patients.
Pmean (mbar)	Mean airway pressure. The absolute pressure, averaged over the previous breath cycle.
Ppeak (mbar)	Peak airway pressure. The highest pressure during the previous breath cycle. It is influenced by airway resistance and compliance. Ppeak may differ noticeably from alveolar pressure if airway resistance is high.
Pplateau (mbar)	Plateau or end-inspiratory pressure. The pressure measured at the end of inspiration when flow is at or close to zero.
Flow	
Flow[1] (l/min)	The measured flow of gas to the patient when using O2 therapy.
Exp Flow (l/min)	Peak expiratory flow.
Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mandatory. Measured every breath.
Volume	
ExpMinVol MinVol NIV (l/min)	Expiratory minute volume. The moving average of the monitored expiratory volume per minute over the last 8 breaths. ExpMinVol changes to MinVol NIV in noninvasive modes. MinVol NIV is an adjusted parameter taking leakage into account.

[1] Only for O2 therapy.

Parameter (unit)	Definition
VLeak (%)	Due to the leakage at the patient interface, displayed exhaled volumes in the noninvasive modes can be substantially smaller than the delivered volumes. The flow sensor measures the delivered volume and the exhaled tidal volume; the ventilator displays the difference as VLeak in %, averaged over the past 8 breaths. VLeak can indicate leaks on the patient side of the flow sensor. It does not include leakage between the ventilator and the flow sensor. Use VLeak to assess the fit of the mask or other noninvasive patient interface.
VTE VTE NIV (ml)	Expiratory tidal volume, the volume exhaled by the patient. It is determined from the flow sensor measurement, so it does not show any volume added due to compression or lost due to leaks in the breathing circuit. If there is a gas leak on the patient side, the displayed VTE may be less than the tidal volume the patient actually receives. In noninvasive ventilation modes, VTE is replaced by VTE NIV. VTE NIV is an adjusted parameter taking leakage into account
VTI (ml)	Inspiratory tidal volume, the volume delivered to the patient, determined from the flow sensor measurement. If there is a gas leak on the patient side, the displayed VTI may be larger than the displayed VTE.
Vt/PBW	Tidal volume per predicted body weight (PBW).
Time	
fSpont (b/min)	Patient-initiated breaths frequency. The moving average of patient-initiated breaths per minute over the last 8 total breaths.
fTotal (b/min)	Total breathing frequency. The moving average of the patient's total breathing frequency over the last 8 breaths, including both mandatory and spontaneous breaths. When the patient triggers a breath, fTotal may be higher than the Rate setting.

Parameter (unit)	Definition
I:E	Inspiratory:expiratory ratio. Ratio of the patient's inspiratory time to expiratory time for the previous breath cycle. This includes both mandatory and spontaneous breaths. I:E may differ from the set I:E ratio if the patient breathes spontaneously.
Other calculated and displayed parameters	
CPR Timer	Displayed during CPR ventilation, shows how long CPR ventilation has been on. For details, see Section 8.6.
O2 consumption (l/min)	The oxygen consumption based on the current usage.
RSI preoxygenation timer (mm:ss)	The length of time preoxygenation has been in progress when using rapid sequence induction (RSI). The time is displayed in mm:ss. When running RSI, the preoxygenation timer starts as soon as you start the RSI workflow, and is shown on the main display. The timer stops when you proceed to the next step in the RSI workflow.
RSI apnea timer (mm:ss)	The length of time intubation has been active when using rapid sequence induction (RSI). When the timer reaches two (2) minutes, the medium priority RSI apnea timer alarm is generated. After three (3) minutes, the alarm changes to high priority.
CO2 related	
PetCO2 (mmHg)	End-tidal CO2 pressure. The maximum partial pressure of CO2 exhaled during a tidal breath (just before the start of inspiration). It represents the final portion of air that was involved in the exchange of gases in the alveolar area, thus providing a reliable index of CO2 partial pressure in the arterial blood under certain circumstances. PetCO2 does not reflect PaCO2 in the case of a pulmonary embolism. Available when a CO2 sensor is connected and enabled.

7
Responding to alarms

7.1 Overview

Operator-adjustable and nonadjustable alarms together with a visual alarm indicator notify you of conditions that require your attention.

For details on setting alarm limits, see Section 4.7.

Alarms are categorized as high, medium, or low priority, as described in Table 7-1. The ventilator's visual alarm indications are described in Figure 7-1.

Additional alarms conditions are associated with technical fault and technical note alarms, as well as informational messages.

Alarms are indicated in the color associated with the alarm priority as follows:

- The alarm lamp on top of the ventilator lights and flashes.
- The message bar on the ventilator display is shown in color and displays the alarm text.

  If multiple alarms are active, they alternate being displayed in the message bar.
- The alarm text is displayed in the alarm buffer.
- An MMP associated with an active alarm is shown in the associated color (red or yellow). The affected alarm limit is also shown in the associated color.
- If an Audio pause is active,  and elapsed time are displayed in the message bar.

When an alarm condition is serious enough to possibly compromise safe ventilation, the device defaults to the Ambient state (Section 5.8.1). The ventilator immediately stops gas flow to the patient. The expiratory valve is opened, letting the patient breathe ambient air unassisted.

You can view active alarms in the alarm buffer (Section 7.2). Information about the alarm is also stored in the Event log.

When reviewing alarms, you can access on-screen alarm troubleshooting help as described in Section 7.2.1.

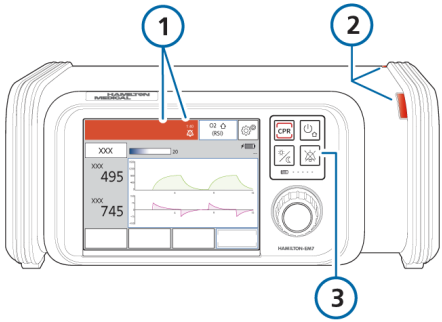
Table 7-1 describes the audio and visual characteristics of these types of alarms and provides guidance on how to respond.

Table 7-1. Alarm indicators

Alarm type	Indicator	Description
High priority	Message bar	Red, with alarm message
	Alarm lamp / Alarm status indicator	Red, flashing
	Audio	A sequence of five (5) beeps, repeated until the alarm is reset. After two (2) minutes of silence, the alarm sounds again if the condition has not been resolved.
	Action required	The patient's safety is compromised. The problem needs immediate attention.
Medium priority	Message bar	Yellow, with alarm message
	Alarm lamp / Alarm status indicator	Yellow, flashing
	Audio	A sequence of three (3) beeps, repeated periodically.
	Action required	The patient needs prompt attention.
Low priority	Message bar	Yellow, with alarm message
	Alarm lamp / Alarm status indicator	Yellow, solid
	Audio	Two sequences of beeps. This is not repeated.
	Action required	Operator awareness is required.
Technical fault	Message bar	Red, with the text *Technical fault: xxxxxx*
	Alarm lamp / Alarm status indicator	Red, flashing
	Audio	Same as for high-priority alarm, if technically possible. At a minimum, a continuous buzzer tone. The buzzer cannot be silenced.
	Action required	The ventilator enters the Ambient state. • Provide alternative respiratory support. • Turn off the ventilator. • Have the ventilator serviced.

Alarm type	Indicator	Description
Technical event	Message bar	Depends on severity of the event. Can be low, medium, or high.
	Alarm lamp / Alarm status indicator	Same as the associated alarm level
	Audio	Same as the associated alarm level.
	Action required	A technical alarm cannot typically be corrected by the operator. Ventilation continues. If needed, have the ventilator serviced.

Figure 7-1. Visual alarm indications



1 Message bar and Audio pause indicator and countdown

2 Alarm lamp

3 Audio pause key

7.1.1 Alarm limit indicators

Alarm limits are shown in the Alarm limits windows.

When an alarm limit is disabled, that is, no limit applies, the device shows the following Alarm Off icon.

For details about setting alarm limits, see Section 4.7.

7.1.2 Responding to an alarm

Before proceeding, review the safety information in Section 1.8.

Alarms may result from either a clinical condition or an equipment issue. In addition, a single alarm condition can generate multiple alarms.

Your search for the causes of the alarm condition should be assisted by, but not limited to, the alarm messages displayed.

To respond to an alarm

1. Approach the patient immediately.
2. Secure sufficient and effective ventilation for the patient.

   You can pause the audible alarm, if appropriate and available. See Section 7.1.3.

   Some alarms can be turned off (deactivated). For details, see Section 7.2.2.
3. Correct the alarm condition from the alarm messages. See Section 7.4.
4. For a technical fault, remove the ventilator from use, note the fault code, and have the ventilator serviced.
5. If appropriate, readjust the alarm limit.

7.1.3 Temporarily silencing an alarm

One component of an alarm is the audible alarm sound. With most alarms, you can pause (silence) the alarm sound for two (2) minutes at a time.

Some alarms can be turned off (deactivated). For details, see Section 7.2.2.

To temporarily silence an alarm

▸ Press (Audio pause) on the front of the ventilator (Figure 8-3).

The audible ventilator alarm is muted for two (2) minutes. Pressing the key a second time cancels the Audio pause. The Audio pause key is lit red while an Audio pause is active.

Note that the audio pause is canceled if a new alarm of the same or higher-priority is generated, or if a non-silence-able alarm is generated.

The display also indicates an Audio pause is active as follows (Figure 7-1):

- The Audio pause indicator is displayed.
- A countdown timer on the main display shows the remaining time for the Audio pause.

When the time expires and the issue has not yet been resolved, an audible alarm sounds again.

Alarms that cannot be silenced

When an Audio pause is active, the following critical alarms still generate an audible alarm; they cannot be silenced:

- Blower fault
- Blower temperature high
- High pressure: breath terminated
- Oxygen supply failed
- Pressure not released
- Ventilation canceled
- All technical faults

7.2 About the alarm buffer

The alarm buffer shows the list of the most recent alarms generated on the device. Alarm entries are shown in color (yellow, red) according to their priority.

- When an alarm is generated, it is displayed in the message bar and in the alarm buffer, where you can access on-screen troubleshooting help for each alarm.
- The alarm buffer shows the most recent inactive alarms, when accessed by the i-icon displayed next to the message bar.

To view the list of active alarms in the alarm buffer

- Touch an active alarm in the message bar at the top of the display.

The alarm buffer opens, showing the list of active alarms (Figure 7-2).

Alarms are sorted first by priority, then by recency. For example, an older high-priority alarm would appear above a more recent medium-priority alarm.

For details on accessing on-screen help, see Section 7.2.1.

To view the list of inactive alarms in the alarm buffer

- Touch the inactive alarm indicator, referred to as the i-icon (Figure 7-3).

The alarm buffer opens, showing the list of inactive alarms.

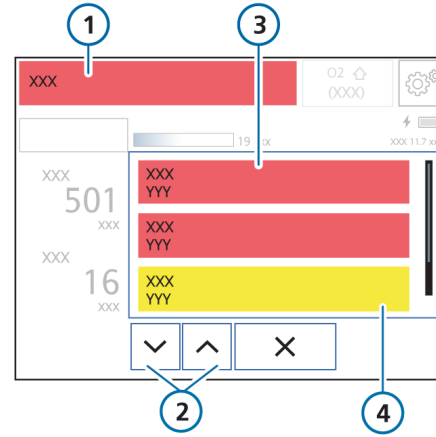
Alarms are sorted by recency.

To clear the list of inactive alarms

- In the alarm log, touch (Figure 7-3).

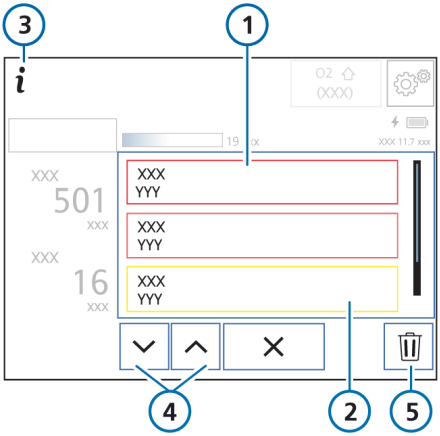
The inactive alarms are removed from the buffer, and the i-icon is no longer displayed.

Figure 7-2. Alarm buffer with active alarms



1	Alarm text in message bar	3	High-priority alarm (red)
2	Navigation arrows	4	Low- or medium-priority alarm (yellow)

Figure 7-3. Alarm buffer with inactive alarms



1	Inactive high-priority alarm (red)	4	Navigation arrows
2	Inactive low- or medium-priority alarm (yellow)	5	Delete
3	i-icon		

7.2.1 Accessing on-screen troubleshooting help

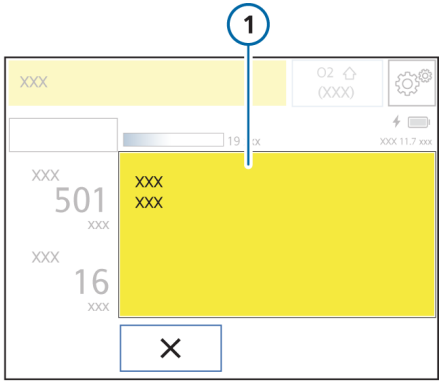
Troubleshooting help is available for active alarms.

To view the help for an alarm

1. Open the alarm buffer (Section 7.2).
2. Touch the desired alarm message in the buffer.

   A Help window opens, providing troubleshooting information for the selected alarm (Figure 7-4).
3. Touch X to close the Help window.

Figure 7-4. On-screen help window



1	Alarm description and troubleshooting information

7.2.2 Turning off (deactivating) an alarm

You can turn off some user messages and alarms. Turning an alarm off deactivates it.

You can view the currently deactivated alarms, and, if desired, reactivate them.

When an alarm is deactivated and its condition is resolved, the alarm is removed from the deactivated alarm list. The next time the conditions are met, the alarm will be generated again. Deactivation is *not* permanent.

Note that you *cannot* turn off all alarms. For alarms that cannot be turned off, you *must* resolve the conditions that generated the alarm.

You can turn off the following alarms:

- Alarm lamp defective
- Backup alarm lamp defective
- Battery calibration required
- Battery replacement recommended
- Battery replacement required
- Blower service required
- Buzzer defective
- Device temperature high
- External connections disabled
- HCM communication lost
- Inverse I:E ratio ventilation
- Loss of external power
- Loudspeaker defective
- Settings file error
- Touch not functional

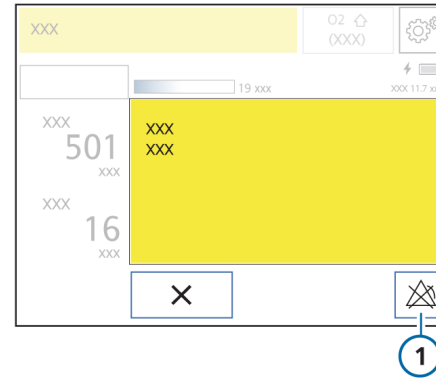
To turn off (deactivate) an alarm

1. Touch the alarm message bar to open the Help window (Section 7.2.1).
2. Read the on-screen help.
3. Touch  to turn off the alarm (Figure 7-5).

The alarm is no longer active.

You can review the list of deactivated alarms at any time, and reactivate them, if desired.

Figure 7-5. Turning off (deactivating) an alarm in the Help window (1)



To review deactivated alarms

- Touch  > **Info / File export** > **Events** > **Deactivated alarms**.

The Deactivated alarms window opens, showing the list of currently inactive alarms.

If desired, you can reactivate them.

To reactivate alarms

1. In the Deactivated alarms window, touch the alarm to reactivate.

   The on-screen troubleshooting help window for that alarm opens.

2. Touch  .

The alarm becomes active again, both with alarm sounds and messages.

7.3 Adjusting alarm loudness (volume)

⚠ WARNING

Be sure to set the auditory alarm loudness (volume) above the ambient sound level. Failure to do so can prevent you from hearing and recognizing alarm conditions.

You can set the loudness (volume) of the audible alarm. By default, it is set to 8.

If you set the loudness below the default value during a patient session, the value is reset to the default upon turning the ventilator off and on again.

A minimum loudness can be set for the device in Configuration.
See Section 10.3.8.

To adjust the alarm loudness

1. Touch  > **General**.
2. Touch **Loudness**.
3. Activate and adjust the **Loudness** control, as needed.
4. Touch ✓ to confirm the setting.

7.4 Troubleshooting alarms

Table 7-2 is an alphabetical list of the alarm messages displayed by the ventilator, along with their definitions and suggested corrective actions.

These corrective actions are sequenced to correct the most probable issue or to present the most efficient corrective action first. The proposed actions, however, may not always correct the particular problem.

If your issue is not resolved after performing the recommended tasks, contact your Hamilton Medical authorized service personnel.

Table 7-2. Alarms and other messages

Alarm	Definition	Action needed
Alarm lamp defective	*Low priority*. The alarm lamp is not functional. Ventilation continues. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Check patient condition. • Have the ventilator serviced.
Apnea ventilation ended	*Low priority*. Backup mode was reset, and the ventilator is again ventilating in its original support (pre-apnea) mode. Only active in NIV and SPONT modes.	No action required.
Apnea ventilation	*Low priority*. Apnea backup ventilation has started. No breath delivered for the operator-set apnea time or the ventilator does not detect any patient inspiratory effort. Apnea backup ventilation is on. Only active in NIV and SPONT modes.	• Check patient condition. • Consider changing the mode.
Apnea	*High priority*. No breath delivered within the operator-set apnea time in ASV, (S)CMV, SIMV, PCV+, DuoPAP, CPAP, or NIV-ST mode. Alarm delay: 60 seconds	• Check patient condition. • Check set Rate and apnea time. • Check trigger sensitivity. • Consider changing the mode.
Backup alarm lamp defective	*Low priority*. The backup alarm lamp is not functional. Ventilation continues. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Check patient condition. • Have the ventilator serviced.

Alarm	Definition	Action needed
Battery calibration required	*Low priority*. The battery requires calibration. You may continue to use the battery. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	Replace the battery with a properly calibrated battery to continue ventilation.
Battery communication error	*High priority*. The battery charge level is not available. Ventilation continues. Alarm delay: 17 seconds	• Check the battery connectors and that the battery is installed correctly. • Make sure the battery lock is properly closed. • If the problem persists, replace the battery. • If the problem still persists, have the ventilator serviced.
Battery defective	*High priority*. The battery is defective. Ventilation continues if an alternative power source is connected.	• Replace battery. • Prepare alternative respiratory support in case it is needed. • If the problem still persists, have the ventilator serviced.
Battery low	The alarm has different levels of priority depending on battery age and condition. The alarm priority levels are defined as follows: *Low priority*. The ventilator is running on battery power and the battery charge is low. *Medium priority*. The ventilator is running on battery power, and the battery charge is critically low.	• Connect the ventilator to a primary power source. • Install charged battery. • Be prepared to provide alternative respiratory support if necessary.

Alarm	Definition	Action needed
Battery not charging	*Low priority*. The battery cannot be charged for technical reasons.	• Connect the ventilator to primary power (AC or DC). • The battery temperature may be high. Remove the ventilator from the sun or other heat source. As the battery cools down, check whether it resumes charging. • Replace the battery. • Be prepared to provide alternative respiratory support if necessary. • If the problem still persists, have the ventilator serviced.
Battery power loss	*High priority*. No battery is installed.	Insert a battery.
Battery replacement recommended	*Low priority*. Battery capacity is reduced; battery should be replaced. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Connect the ventilator to primary power (AC or DC). • Replace the battery. • Be prepared to provide alternative respiratory support if necessary. • If the problem still persists, have the ventilator serviced.
Battery replacement required	*Low priority*. Battery capacity is insufficient for reliable operation and must be replaced immediately. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Connect the ventilator to primary power (AC or DC). • Replace the battery. • Be prepared to provide alternative respiratory support if necessary. • If the problem still persists, have the ventilator serviced.

Alarm	Definition	Action needed
Battery temperature high	The battery temperature is higher than expected. *Low priority*. The battery temperature has exceeded the first threshold. *High priority*. The battery temperature has exceeded the second threshold. If the temperature rises further, the battery will become inoperative.	• If the low-priority alarm is generated, be sure to remove the ventilator from the sun or other heat source. • Replace the battery. • If the high-priority alarm is generated, be prepared to provide alternative respiratory support if necessary. • If the problem still persists, have the ventilator serviced.
Battery totally discharged	*High priority.* The battery charge level is below the defined threshold. You have a minimum of five (5) minutes operating time left. If the high-priority Battery totally discharged alarm occurs when starting up the ventilator, you may have less than five (5) minutes of operating time remaining.	• Connect the device to primary power (AC or DC). Connecting to primary power also charges the battery. • Be prepared to provide alternative respiratory support if necessary. • If the problem still persists, have the ventilator serviced.
Blower fault	*Technical fault*. A blower malfunction was detected. The ventilator switches to the Ambient state (Section 5.8.1).	• Immediately provide alternative respiratory support. • Have the ventilator serviced.
Blower service required	*Low priority*. The blower has reached the end of its life span. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 62 seconds	Have the ventilator serviced.

Alarm	Definition	Action needed
Blower temperature high	*Low priority*. The blower temperature has exceeded the first threshold. *High priority*. The blower temperature has exceeded the second threshold. If the blower temperature exceeds the critical threshold, the ventilator switches to the Ambient state (Section 5.8.1). Alarm delay: 35 seconds	• If the low-priority alarm is generated, be sure to remove the ventilator from the sun or other heat source. • If the high-priority alarm is generated, be prepared to provide alternative respiratory support if necessary. • If the problem persists, have the ventilator serviced.
Buzzer defective	*Low priority*. A buzzer malfunction was detected. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: approximately 40 seconds after starting the ventilator, at the end of the startup sequence	• Restart device. • If the problem persists, have the ventilator serviced.
Check breathing circuit set	*Low priority*. The breathing circuit set is incompatible. *High priority*. There is a problem with the breathing circuit set. Alarm delay: Two (2) breaths	• Check flow sensor connection. • Replace with a new Hamilton Medical breathing circuit set. • Perform preoperational checks.
Check CO2 airway adapter	*Low priority*. Adapter disconnection, optical block, or adapter type changed.	• Check patient condition. • Check the airway adapter for excess moisture accumulation / contamination by secretions. • Replace / perform zero calibration on airway adapter.

Alarm	Definition	Action needed
Check for blockage	*Medium priority*. The difference between the set flow and delivered flow is greater than 10% or 1 l/min, whichever is greater, for two (2) seconds. *High priority*. Either of the following is the case: • The internal pressure in the device exceeds the defined threshold. • The delivered flow is significantly below the set value for three (3) seconds. When either condition applies, the flow stops and the pressure is released for eight (8) seconds. Only active during O2 therapy.	• Observe the patient • Check patient interface for blockage. If no blockage is observed, consider reducing the flow to decrease pressure. • Check breathing circuit limbs and tubing for kinks.
Check settings	*Low priority*. A mode change, control setting, or alarm limit setting is invalid and was not applied. Alarm delay: 67 seconds	Check and confirm settings, including alarms.

Alarm	Definition	Action needed
CO2 calibration needed	*Low priority*. A previous sensor zero calibration failed.	Perform the following checks, repeating the calibration after each one, until calibration is successful: • Clean or replace airway adapter. • Perform a zero calibration of the sensor, making sure there is no source of CO2 near the airway adapter. • Replace the airway adapter. • Replace the CO2 sensor. • If the problem persists, have the ventilator serviced.
CO2 sensor disconnected	*Low priority*. The CO2 module is installed, but there is no signal from the CO2 sensor. CO2 monitoring is enabled.	• Make sure a CO2 sensor is connected. • Check CO2 sensor connections (CO2 sensor cable to module, CO2 module to ventilator). • If the problem persists, have the ventilator serviced.
CO2 sensor faulty	*Low priority*. The CO2 sensor signal indicates a hardware error or a third-party sensor is installed.	• Verify the sensor is a genuine Hamilton Medical part. • Disconnect the sensor from the CO2 module. Wait a few seconds, and reconnect. • Perform a zero calibration of the sensor. Ensure the sensor is attached to the airway adapter during zero calibration. • Replace the CO2 sensor.

Alarm	Definition	Action needed
CO2 sensor over temperature	*Low priority*. The temperature at the CO2 sensor is too high. ⚠ **CAUTION!** *Do not place the CO2 sensor directly on the patient's skin. It can burn the skin as the sensor may reach a temperature of 46°C (115°F).*	• Check whether the sensor is affected by an external heating source. • Remove the sensor from the airway, and disconnect the sensor from the CO2 module. Reconnect. • Verify that system is running within the specified environmental conditions. Check for excessive airway temperature, which could be caused by defective humidifier, heater wire, or probe.
CO2 sensor warmup	*Low priority*. The CO2 operating temperature has not yet been reached or is unstable.	Wait for the sensor to warm up.
CO2: Poor signal	*Low priority*. The CO2 sensor signal quality is poor.	• Check patient condition. • Check CO2 sensor and adapter connections. • Ensure that airway adapters are not in a horizontal position relative to the floor to reduce accumulation of patient secretions. If accumulation occurs, remove the adapter, rinse with sterile water, and reconnect.
Device temperature critical	*High priority*. The internal temperature of the ventilator is higher than expected. Alarm delay: 35 seconds	⚠ **WARNING!** Hot surface. The device may be hot to the touch. • Remove the ventilator from the sun or other heat source. • Check the air intake filter. • Prepare alternative respiratory support. • If necessary, have the ventilator serviced.

Alarm	Definition	Action needed
Device temperature high	*Low priority*. The internal temperature of the ventilator is high. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 35 seconds	⚠ **WARNING!** Hot surface. The device may be hot to the touch. • Remove the ventilator from the sun or other heat source. • Check the air intake filter.
Disconnection on ventilator or patient side	*High priority*. The ventilator detects a disconnection between the device and the patient. Not active during O2 therapy.	• Check patient condition. • Verify that the breathing circuit set components are properly connected to the ventilator: – The expiratory valve is securely connected to the *To patient* port. – The flow sensor pressure plug is securely connected to both flow sensor connection ports. • Verify that all components of the breathing circuit set are securely connected to each other, including the connection to the patient.
Display problems	If there are problems with the device display, see Section 5.8.	
External connections disabled	*Low priority*. The Connectivity module is turned off. Repeated connection attempts have failed. Ventilation can continue but connection with other devices is not possible. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 60 seconds	• If no patient is connected, restart the ventilator. • If the problem persists, have the ventilator serviced.

Alarm	Definition	Action needed
Function key not operational	*Medium priority*. The function key is defective. Ventilation continues. Alarm delay: 60 seconds	• Turn off the ventilator using the Power/Standby key on the front of the ventilator. • If the Power/Standby key is defective, remove the battery to shut off the device. • Be prepared to provide alternative respiratory support if necessary. • Have the ventilator serviced.
HCM communication lost	*Low priority*. There is an error with the Hamilton Connect Module (HCM). Ventilation can continue but connection with other devices is not possible. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 12 seconds	• If no patient is connected, restart the ventilator. • If the problem persists, have the ventilator serviced.
High frequency	*Medium priority*. The measured fTotal exceeds the set alarm limit. Not active during O2 therapy. Alarm delay: Eight (8) breaths	• Check the patient for adequate ventilation (VTE). • Check alarm limits. • Check the trigger setting.
High minute volume	*High priority*. The measured ExpMinVol exceeds the set alarm limit. Not active during O2 therapy. Alarm delay: Eight (8) breaths	• Check patient condition. • Check and confirm settings, including alarms.

Alarm	Definition	Action needed
High PEEP	*Medium priority*. Monitored PEEP exceeds the set alarm limit for two (2) consecutive breaths. Not active during O2 therapy. Alarm delay: Two (2) breaths	• Check patient condition. • Check and confirm settings, including alarms. • Check the expiratory valve for possible obstructions. • Check for obstructions in the expiratory limb. • Check the flow sensor tubes for occlusion.
High pressure: breath terminated	*High priority*. The measured inspiratory pressure exceeds the set Pressure (high) alarm limit. The ventilator immediately switches to expiration. Not active during O2 therapy.	• Check patient condition. • Adjust the Pressure (high) alarm limit. • Check the artificial airway of the patient for kinks, occlusions, and leaks. • Check the breathing circuit limbs and flow sensor tubes for kinks, occlusions, and leaks.
Inverse I:E ratio ventilation (IRV)	*Low priority*. The set I:E ratio is above 1:1, leading to inverse ratio ventilation. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Not active in CPAP, SPONT, NIV, ASV, DuoPAP modes, or during O2 therapy. Alarm delay: One (1) breath	Check the timing control settings.
Loss of external power	*Low priority*. The ventilator is running on battery power due to loss of a primary power source. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Silence the alarm. • Check integrity of connection to primary power source. • Check battery status. • Prepare for possible power loss.

Alarm	Definition	Action needed
Loss of PEEP	*Medium priority*. One of the following conditions is in effect: • Pressure during exhalation is below the set alarm limit for more than 10 seconds • This alarm occurs only if you have set PEEP to 5 mbar or greater. The monitored PEEP is lower than one of the following for three (3) consecutive breaths: – *For patient-initiated breaths:* set PEEP − the maximum of either 5 mbar or 15% of set PEEP – *For ventilator-initiated breaths:* set PEEP − the maximum of either 3 mbar or 15% of set PEEP Not active in CPR or RSI ventilation, or during O2 therapy. Alarm delay: Three (3) breaths or 10 seconds	• Check patient condition. • Check the breathing circuit set for leaks. Replace the breathing circuit set, if necessary. • Check the condition of the expiratory valve. If anything is defective, replace the breathing circuit set.
Loudspeaker defective	*Low priority*. A loudspeaker malfunction was detected. Ventilation continues. You can turn off (deactivate) this alarm. For details, see Section 7.2.2.	• Check patient condition. • Provide alternative respiratory support until the issue is resolved. • Have the ventilator serviced.
Low frequency	*Medium priority*. Measured fTotal is below the set alarm limit. Not active during O2 therapy. Alarm delay: Eight (8) breaths	• Check patient condition. • Check and confirm settings, including alarms.

Alarm	Definition	Action needed
Low minute volume	*High priority*. Measured ExpMinVol is below the set alarm limit. Not active during O2 therapy. Alarm delay: Eight (8) breaths	• Check patient condition. • Check the breathing circuit set and artificial airway of the patient for leaks and/or disconnection. • Check and confirm settings, including alarms.
Low pressure	*High priority*. The set pressure during inspiration was not reached. Not active during O2 therapy. Alarm delay: Two (2) breaths	• Check patient condition. • Check the breathing circuit set for a disconnection between the patient and the flow sensor, or for other large leaks.
Oxygen mixer failure	*Medium priority.* Failure of the oxygen mixer. Oxygen mixing faulty due to defect of oxygen valve. Alarm delay: Four (4) breaths or 22 seconds	• Check patient condition. • Check oxygen supply, change supply if necessary. • Provide alternative respiratory support until the issue is resolved. • Have the ventilator serviced.
Oxygen supply failed	*High priority*. Oxygen source flow is lower than expected. Ventilation continues with 21% oxygen. Alarm delay: Four (4) breaths or 22 seconds	• Check patient condition. • Check the oxygen supply. Provide an alternative source of oxygen, if necessary. • Check the oxygen source/supply for potential leakage. • Provide alternative respiratory support until the issue is resolved.
Performance limited by high altitude	*Medium priority, low after Audio pause is activated*. The airway pressure cannot be reached at the current altitude. As long as the device remains above the altitude limit, the pressure cannot be reached, and the alarm is active. Alarm delay: 120 seconds	• Check patient condition. • If at all possible, consider lowering altitude to reach the target performance. • Provide alternative respiratory support until the issue is resolved.
PetCO2 high	*Medium priority*. PetCO2 exceeds the set alarm limit. Alarm delay: Five (5) breaths	• Check patient condition. • Check and confirm settings, including alarms.

Alarm	Definition	Action needed
PetCO2 low	*Medium priority*. PetCO2 is below the set alarm limit. Alarm delay: Five (5) breaths	• Check patient condition. • Check the breathing circuit set and flow sensor/artificial airway of the patient for leaks. • Check and confirm settings, including alarms.
Preop check needed	*High priority, low in Standby*. A valid preoperational check has not been run. One of the components failed the preoperational test.	Run the preoperational check. See Section 3.6.
Pressure limitation	*Low priority*. The ASV algorithm cannot deliver the set MinVol because it is limited by the set pressure limit. Only active in ASV mode. Alarm delay: Five (5) breaths	• Check the patient for adequate ventilation. • Check and confirm settings, including alarms.
Pressure not released	*High priority*. Airway pressure has exceeded the Pressure limit, and the pressure was not released via the expiratory valve after five (5) seconds. The ventilator enters the Ambient state (Section 5.8.1). Not active during O2 therapy.	• Check expiratory valve and breathing circuit set for kinks and occlusions. • Provide alternative respiratory support until the issue is resolved. • Restart the device. • Have the ventilator serviced.
Real-time clock failure	*Medium priority*. The date and time are not set. Alarm delay: 62 seconds	Set the date and time in the system configuration. See Section 10.3.4.
RSI apnea timer	*Medium priority.* Intubation during RSI has been active for two (2) minutes. *High priority.* After three (3) minutes, the alarm is raised to high priority.	• Check patient condition. • Touch **Start therapy** to begin invasive ventilation. • Touch **Cancel RSI** to return to noninvasive ventilation.

Alarm	Definition	Action needed
Self-test failed	*High priority*. The self-test failed during startup. Note that if this error occurs when the device is restarting from a complete power loss, the device enters the Ambient state (Section 5.8.1). Alarm delay: approximately 40 seconds after starting the ventilator, at the end of the startup sequence.	• Restart device. • If the problem persists, have the ventilator serviced. • If the device enters the Ambient state, provide alternative respiratory support and have the ventilator serviced.
Sensor failure	*High priority*. A hardware or software issue was detected. Ventilation continues but may not be delivered as set.	• Check patient condition. • Provide alternative respiratory support until the issue is resolved. • If the problem persists, have the ventilator serviced.
Settings file error	*Low priority*. The ventilator settings information cannot be loaded. All settings are replaced with factory default settings. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 40 seconds at the conclusion of the ventilator startup sequence	• Check ventilation settings and dismiss the alarm. Ventilation continues normally. • Restart device if possible. • If the problem persists, have the ventilator serviced.
Technical event: xxxxxx	*Low, medium, or high priority*. A hardware or software issue was detected. Ventilation continues. Alarm delay: Up to 40 minutes	• Restart device if possible. • If the problem persists, have the ventilator serviced.
Technical fault: xxxxxx	*Technical fault*. A hardware or software issue was detected. The ventilator switches to the Ambient state (Section 5.8.1).	• Provide alternative respiratory support until the issue is resolved. • Have the ventilator serviced.

Alarm	Definition	Action needed
Technical state failed	*High priority*. There is a problem with the hardware configuration. Ventilation is not possible. Alarm delay: 40 seconds at the conclusion of the ventilator startup sequence	Have the ventilator serviced.
Touch not functional	*Low priority*. The touch screen is defective. You can turn off (deactivate) this alarm. For details, see Section 7.2.2. Alarm delay: 122 seconds	• Turn the ventilator off and on again. • If the problem persists, have the ventilator serviced.
Unable to meet target	*Low priority*. The target MinVol cannot be delivered, possibly due to setting conflicts or lung-protective rules. Active only in ASV mode. Alarm delay: Five (5) breaths	• Check patient condition. • Check the Plimit setting and adjust, if appropriate.
Unknown part number	*High priority*. A hardware or software issue was detected. The ventilator switches to the Ambient state (Section 5.8.1). Alarm delay: 40 seconds at the conclusion of the ventilator startup sequence	• Provide alternative respiratory support until the issue is resolved. • Have the ventilator serviced.
Vent outlet temperature high	*Low or high priority*. Inspiratory temperature is too high. Alarm delay: 35 seconds	• Check whether the room temperature exceeds the ventilator's operating temperature limit. • Check that the air intake on the device is not obstructed. • Provide alternative respiratory support until the issue is resolved. • Have the ventilator serviced if temperature cannot be reduced.

Alarm	Definition	Action needed
Ventilation canceled	*High priority*. During therapy, the ventilator switches to the Ambient state (Section 5.8.1).	• Provide alternative respiratory support until the issue is resolved. • Restart the ventilator. • Contact your Hamilton Medical representative. • Have the ventilator serviced.
Vt high	*Medium priority*. Measured VTE exceeds the set limit for two (2) consecutive breaths. Not active during O2 therapy. Alarm delay: Two (2) breaths	• Reduce the pressure and volume settings. • Check and confirm settings, including alarms.
Vt high: breath terminated	*Medium priority*. The delivered Vt is more than 1.5 times the set high Vt alarm limit. Pressure is reduced to PEEP level. Not active in noninvasive modes and during O2 therapy.	• Reduce pressure and volume settings. • Adjust the high Vt alarm limit.
Vt low	*Medium priority*. Measured VTE is below the set limit for two (2) consecutive breaths. Not active during O2 therapy. Alarm delay: Two (2) breaths	• Check patient condition. • Check and confirm settings, including alarms. • Check the breathing circuit set and artificial airway of the patient for leaks, kinked limbs or tubing, or disconnection.
Wrong battery	*High priority*. The battery in use is not the correct battery for this ventilator.	• Replace the battery. • Connect the ventilator to primary power (AC or DC). • Provide alternative respiratory support until the issue is resolved.

8

Ventilator settings and functions

8.1 Overview

Before proceeding, review the safety information in Chapter 1.

This chapter describes changing ventilation settings during active ventilation, as well as how to perform special functions on the ventilator.

8.2 Accessing settings during ventilation

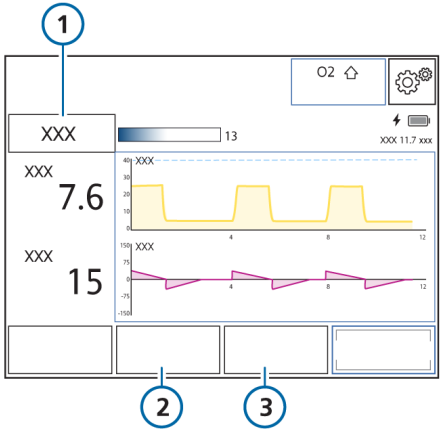
At any time during ventilation, you can adjust settings, as needed. Changes to controls and modes are applied, at the latest, at the end of the current breath cycle.

To adjust settings during ventilation

See Figure 8-1 for reference.

- Touch the mode name at the top left of the display (**1** in Figure 8-1) to change the selected ventilation mode.
- Touch **Controls** (**2**) to access the mode controls.
- Touch **Alarm limits** (**3**) to access the alarm limit controls.

Figure 8-1. Accessing settings during ventilation



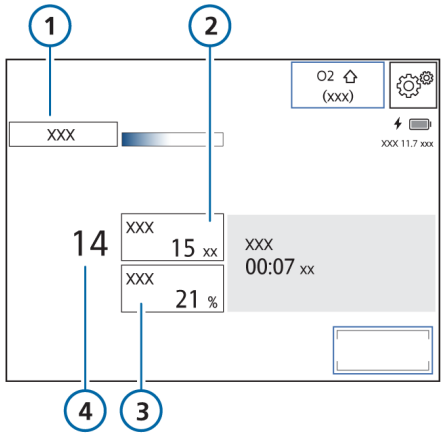
1 Mode
2 Controls
3 Alarm limits

To adjust settings during O2 therapy

See Figure 8-2 for reference. Additional details are available in Section 5.5.4.

- Touch **Flow** (**2**) to change the Flow setting.
- Touch **Oxygen** (**3**) to change the Oxygen setting.

Figure 8-2. Accessing settings during O2 therapy

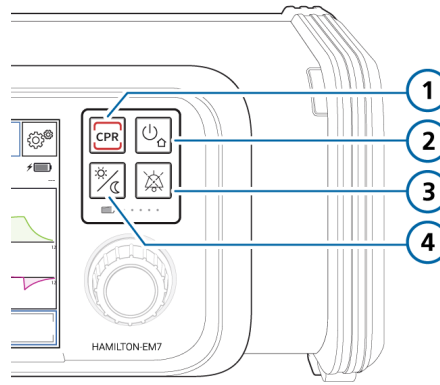


1	Mode	3	Oxygen
2	Flow	4	Monitored Flow

Function keys on the ventilator

Keys on the front of the ventilator (Figure 8-3) provide fast access to important functions, including entering Standby, CPR mode, and pausing the audible alarm.

Figure 8-3. Function keys



1	CPR	3	Audio pause
2	Standby/Power	4	Day/Night

8.3 Rapid Sequence Induction (RSI) workflow

The HAMILTON-EM7 offers support for the rapid sequence induction (RSI) intubation method.

The RSI workflow supports you during each step of the intubation process, from preoxygenation to medication and intubation, to starting invasive mechanical ventilation, offering:

- Preoxygenation, with display of a preoxygenation timer, showing time elapsed
- Apnea timer, showing the time elapsed during the medication/ intubation process
- Delivery of manual breaths, if needed[1]
- Display of key parameters and waveforms
- Distinctive display with yellow bars making it clear RSI is activated
- One-touch start of ventilation therapy; the mode and settings are preconfigured, and can be adjusted at any time
- The ability to temporarily pause the RSI workflow at any time[2], as well as cancel the process and return to the previous therapy

The sequence of steps and the display on the ventilator vary slightly, depending on which therapy type you are accessing the RSI workflow from:

- Noninvasive therapy (O2 therapy)
- Noninvasive ventilation

For an overview of the workflows, see Figures 8-4 and 8-5.

Current therapy	For RSI workflow details, see ...
O2 therapy using a high flow nasal cannula	Section 8.3.1
Noninvasive mask ventilation mode	Section 8.3.2

[1] Only when accessing the RSI workflow from noninvasive modes (NIV, NIV-ST, and CPAP).
[2] Only when accessing the RSI workflow from O2 therapy.

Figure 8-4. RSI workflow overview, starting from O2 therapy

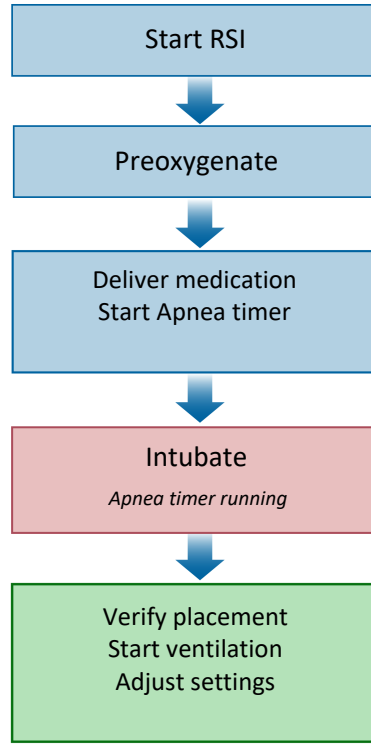
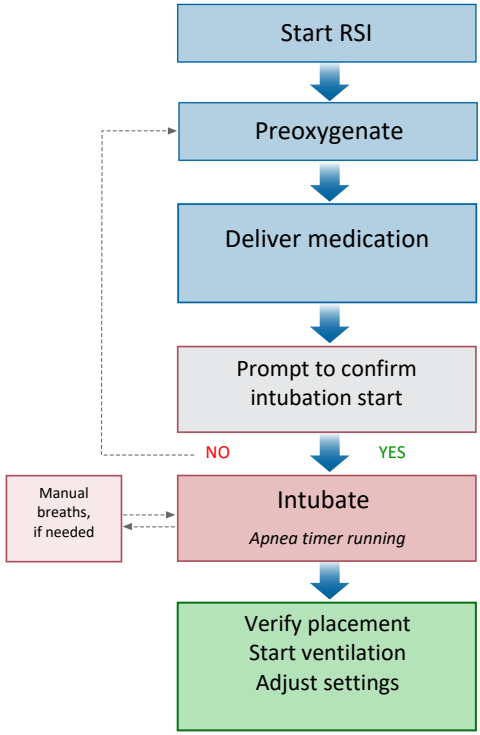


Figure 8-5. RSI workflow, starting from noninvasive ventilation



8.3.1 RSI workflow starting from O2 therapy

When transitioning from O2 therapy to intubation and invasive ventilation, the RSI workflow is flexible. The workflow is illustrated in Figure 8-5.

At any time, you can change the Oxygen and/or Flow settings, as well as the post-intubation ventilation mode and control settings. The default Oxygen value is set in Configuration (Section 10.4.6).

To work with RSI starting from O2 therapy

You can touch **Cancel RSI** at the top of the window at any time to return to delivering O2 therapy using the previous settings.

1. In the O2 therapy main window (Figure 8-6), touch O2 ⇧ (O2 enrichment) at the top right.

   The device starts delivering increased oxygen, and the **Start RSI** button is available.

2. Touch **Start RSI** (Figure 8-7).

   The O2 therapy RSI window is displayed, showing the elapsed preoxygenation time, and current Oxygen and Flow settings (Figure 8-8).

   Oxygen is set to the configured RSI Oxygen value (Section 10.4.6).

   The window shows yellow bars on the sides and the text RSI in yellow to clearly indicate RSI support is active.

3. If you need to change preoxygenation settings, touch the black button for the control to change, and update as needed.

4. When you are ready to start intubation, touch **Start apnea timer**.

   The oxygen flow continues, and a timer shows the elapsed apnea time (Figure 8-6).

   A medium-priority Apnea alarm is generated after two (2) minutes; the alarm changes to high priority after three (3) minutes.

5. When intubation is complete and verified, and you are ready to ventilate the patient, touch **Start therapy**.

   The mode and Oxygen (O2) setting are displayed under the **Start therapy** button (Figure 8-8).

   To change the mode or settings, touch the black Mode button to display the Settings window. Update as appropriate, then touch **Start therapy**.

Ventilation starts with the configured mode and settings.

Figure 8-6. O2 therapy running, O2 (RSI) button (1)

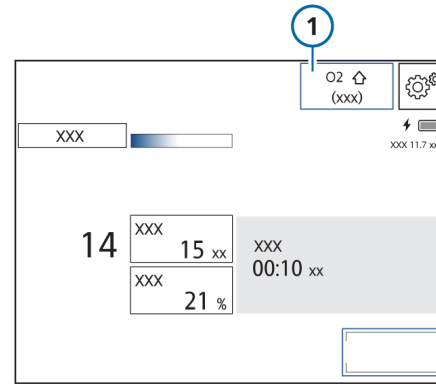


Figure 8-7. Start RSI button (1)

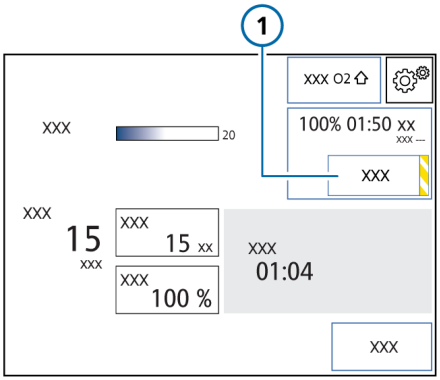
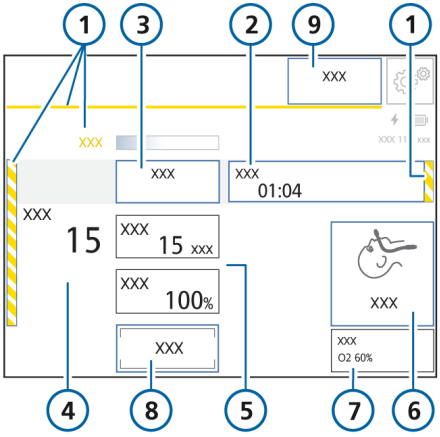
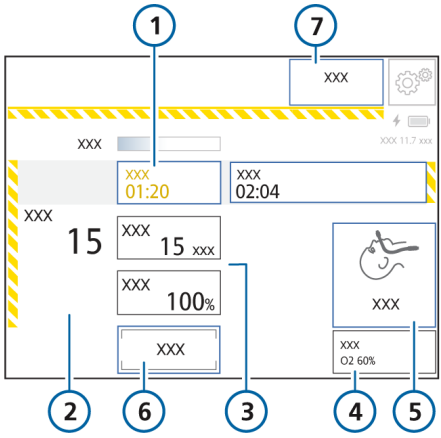


Figure 8-8. Preoxygenation in progress (from O2 therapy)



1 RSI workflow active indicators
2 Elapsed preoxygenation time
3 Start apnea timer
4 Current Flow
5 Current settings, adjustable
6 Quick start therapy
7 Adjust mode/ settings, start therapy
8 Pause therapy
9 Cancel RSI

Figure 8-9. Apnea timer active (from O2 therapy)



1 Elapsed apnea time
2 Current Flow
3 Current settings, adjustable
4 Adjust mode/ settings, start therapy
5 Quick start therapy
6 Pause therapy
7 Cancel RSI

8.3.1.1 Pausing therapy during RSI (from O2 therapy)

If you are in RSI from O2 therapy, you can pause active therapy during RSI preoxygenation or during the apnea time for up to one (1) minute, if needed, after which therapy automatically restarts.

During a pause, you can still adjust settings, as needed.

To pause active therapy during RSI (from O2 therapy)

1. Touch **Pause therapy** at the bottom right corner of the display (Figures 8-8 and 8-9).

   You are prompted to confirm this choice.

2. Touch ✓ to confirm.

The therapy is paused for one (1) minute. When the time is up, therapy starts again automatically.

8.3.2 RSI workflow starting from a noninvasive mode

When transitioning from mask ventilation to intubation and invasive ventilation, the RSI workflow follows a defined sequence. The workflow is illustrated in Figure 8-5.

By default, the ventilator's preconfigured settings for preoxygenation (using the settings defined for the NIV-ST mode) and invasive ventilation are used. The default Oxygen value is set in Configuration (Section 10.4.6).

You can change the ventilation settings during preoxygenation.

To work with RSI starting from noninvasive ventilation

You can touch **Cancel RSI** at the top of the window at any time to return to delivering noninvasive ventilation using the previous settings.

1. In the noninvasive therapy main window (Figure 8-10), touch O2 ⇧ (O2 enrichment) at the top right.

   The device starts delivering increased oxygen, and the **Start RSI** button is available.

2. Touch **Start RSI** (Figure 8-11).

   The ventilator switches to NIV-ST mode, and Oxygen is set to the configured RSI Oxygen value (Section 10.4.6).

   The NIV-ST RSI window is displayed, showing the elapsed preoxygenation time and current Oxygen setting.

   It also shows the VTE NIV[1] and Rate parameters, and the Paw waveform (Figure 8-12).

   The window shows yellow bars on the sides and the text RSI in yellow to clearly indicate the RSI workflow is active.

3. When ready to start intubation, touch **Start intubation**.

   You are prompted to confirm the selection.

   To return to preoxygenation, touch **X**.

[1] Touch the parameter to toggle between VTE NIV and MinVol NIV. For details, see Section 2.6.4.

4. To proceed with intubation, touch ✓.

   Ventilation is stopped, and the apnea timer starts, showing the elapsed apnea time (Figure 8-13).

   A medium-priority Apnea alarm is generated after two (2) minutes; the alarm changes to high priority after three (3) minutes.

5. You can deliver one or more manual breaths during this period, by touching **Manual breath**, if required (Figure 8-13).

   A manual breath is delivered for each touch of the button, using NIV-ST mode settings.

6. When intubation is complete and you are ready to ventilate the patient, touch **Start therapy**.

   The mode and Oxygen (O2) setting are displayed under the **Start therapy** button (Figure 8-8).

   To change the mode or settings, touch the black mode button to display the Settings window. Update as appropriate, then touch **Start therapy**.

Ventilation starts with the configured mode and settings.

Figure 8-10. Noninvasive therapy running, O2 (RSI) button (1)

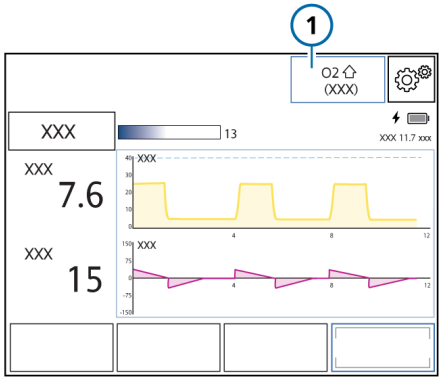


Figure 8-11. Start RSI button (1)

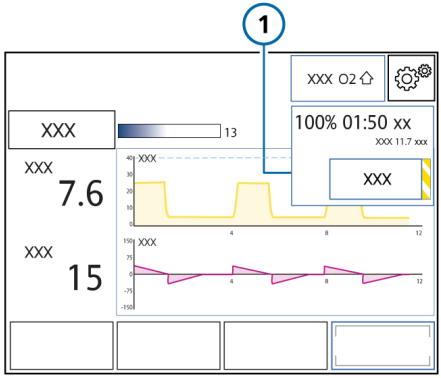
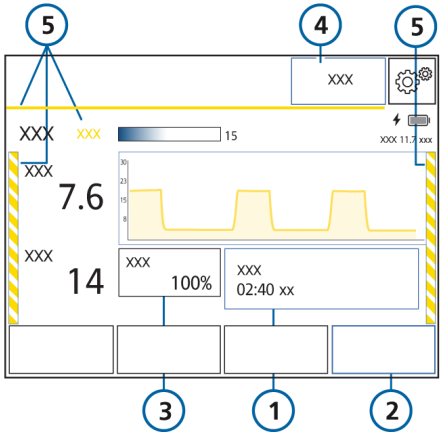
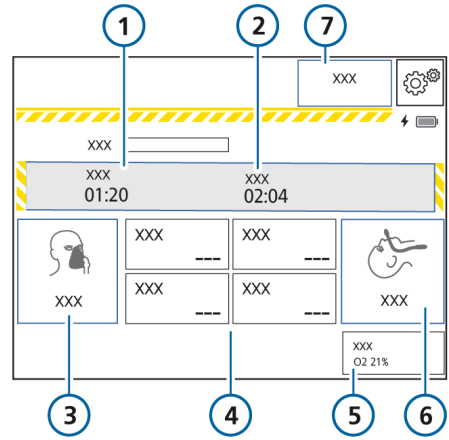


Figure 8-12. Preoxygenation in progress (from a noninvasive mode)



1 Elapsed preoxygenation time
2 Start intubation (and apnea timer)
3 Current Oxygen setting, adjustable
4 Cancel RSI
5 RSI support active indicators

Figure 8-13. Intubation started, Apnea timer started (from a noninvasive mode)



1 Apnea timer
2 Total preoxygenation time
3 Manual breath
4 Monitoring parameters
5 Adjust mode/ settings, start therapy
6 Quick start therapy
7 Cancel RSI

8.4 Oxygen (O2) enrichment

NOTICE

The HAMILTON-EM7 is *not* intended for use with closed suctioning.

Oxygen enrichment is useful before or after tracheal/endotracheal suctioning or for other clinical applications.

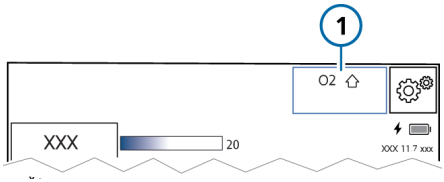
The device delivers increased oxygen (default 100%) for two (2) minutes. You can set the oxygen level and duration in Configuration (Section 10.3.2).

To start O2 enrichment

- Touch O2 ⇧ (O2 enrichment) at the top right of the display (Figure 8-14).

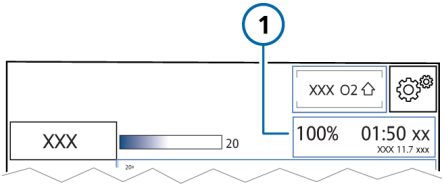
After a short time, the ventilator starts delivering the configured oxygen level or the currently set oxygen level, whichever is greater.

Figure 8-14. O2 enrichment button (1) in main window



When active, the display shows the currently applied concentration, with a countdown timer (Figure 8-15).

Figure 8-15. O2 enrichment active with countdown timer (1)



To stop O2 enrichment manually

- Do either of the following:
  - Touch **Stop** O2 ⇧.
  - Touch the Oxygen control and change the setting.

Ventilation resumes at the set oxygen concentration.

8.5 Working with a nebulizer

Before proceeding, review the safety information in Chapter 1.

You can use a standard inline nebulizer for delivery of prescribed medications in the ventilator circuit. Compatible nebulizers, as well as nebulizer-compatible HMEFs, are listed in the Hamilton Medical e-catalog.

The ventilator allows the use of mesh nebulizers in the following ventilation modes: PCV+, DuoPAP, NIV, NIV-ST, and CPAP

For proper connection of the nebulizer to the HAMILTON-EM7 breathing circuit set, see Section 3.8.

For further setup and use information, see the manufacturer's *Instructions for use*.

8.6 Cardiopulmonary resuscitation (CPR) ventilation

The HAMILTON-EM7 uses CPR ventilation to continue respiration during the administration of cardiopulmonary resuscitation.

When activated, CPR ventilation adjusts the ventilator to:

- Use either (S)CMV or PCV+ ventilation mode (set in Configuration)
- Display relevant MMPs, waveforms, and a CPR duration timer
- Modify the alarm limits while CPR ventilation is in use (see Table 8-3)
- Activate and display a CPR timer
- Display red bars making it clear CPR is activated

CPR ventilation is available for adult and pediatric patients, and can be accessed from all ventilation modes.

Table 8-1 provides an overview of working with CPR ventilation.

Table 8-1. CPR ventilation overview

For details about ...	See ...
Configuring a default mode	Section 10.4.2
CPR-related control settings	Section 8.6.1
Starting CPR ventilation	Section 8.6.2
Monitoring and display when CPR ventilation is on	Section 8.6.3
CPR-related alarms	Section 8.6.4
Return of spontaneous circulation (ROSC)	Section 8.6.5

8.6.1 About the CPR modes and settings

The ventilator uses one of two modes during CPR ventilation:

- (S)CMV
- PCV+

You can change the default ventilation mode and specify settings in Configuration. For details, see Section 10.4.4.

The mode control settings are described in Table 8-2.

The modes, settings, and factory default settings apply to both the Adult and Pediatric patient groups. You can adjust the parameter values for each patient group.

The following table is organized by mode, adjustable controls, and other settings:

- *Mode*. The mode to use during CPR ventilation can only be adjusted in Configuration. It cannot be changed when the CPR ventilation is active.
- *Adjustable controls, during CPR ventilation*. You can change the settings for the parameters listed in this section when CPR ventilation is active.
- *Adjustable controls, in Standby*. You can only change the settings for the parameters listed in this section when in Standby.
- *Other settings.* The values for the parameters in this section can only be adjusted in Configuration. They are used as settings during CPR ventilation, and cannot be changed when it is active.

Table 8-2. CPR ventilation modes and settings

Mode or parameter (unit)	Default setting, Adult	Default setting, Pediatric
Mode		
(S)CMV / PCV+	(S)CMV[1]	(S)CMV[1]
Adjustable controls, during CPR ventilation		
These controls are set in Configuration and can be adjusted during CPR ventilation.		
Oxygen (%)	100	100
Vt (ml) *(S)CMV only*	Based on the Vt/PBW set in Configuration and the patient's PBW	
ΔPcontrol (mbar) *PCV+ only*	25	25
Adjustable controls, in Standby		
These controls are set in Configuration and can be adjusted in Standby.		
Vt/PBW (ml/kg) *(S)CMV only*	6	6
Rate (b/min)	10	20
PEEP (mbar)	5	5
I:E	1:5	1:3
Other settings		
These controls are set in Configuration; they cannot be adjusted during CPR ventilation		
P-ramp[2]	Fast	Fast
Trigger[2]	Off	Off

8.6.2 Starting CPR ventilation

You can start CPR ventilation *at any time*, including turning on the ventilator directly into CPR ventilation, as described in this section.

When you start CPR ventilation, the ventilator switches to the configured mode and settings.

Note the following when CPR ventilation is active:

- Trigger is set to OFF.
- P-ramp is set to Fast.
- In (S)CMV mode, the Vt/PBW setting is defined in Configuration; together with the set patient data, this defines the initial startup setting for tidal volume (Vt). For details, see Section 10.4.4.
- Upper and lower alarm limits (that are not turned off) are set to the maximum and minimum values for each of the following alarms: ExpMinVol, fTotal, Vt, and PetCO2.

  You can turn off alarm limits, as appropriate.

[1] Unless a different default mode is set in Configuration.
[2] Setting is *not* adjustable.

To start CPR ventilation from Standby

1. Touch CPR on the front of the ventilator.

   The Patient settings (CPR) window is displayed.
2. Specify the patient data (Section 4.3).
3. Touch **Start CPR ventilation**.

The ventilator starts CPR ventilation, showing the CPR main display. For details, see Section 8.6.

To start CPR ventilation when already delivering therapy

1. Touch CPR on the front of the ventilator.

   You are prompted to change to CPR ventilation.
2. Touch ✓ to confirm.

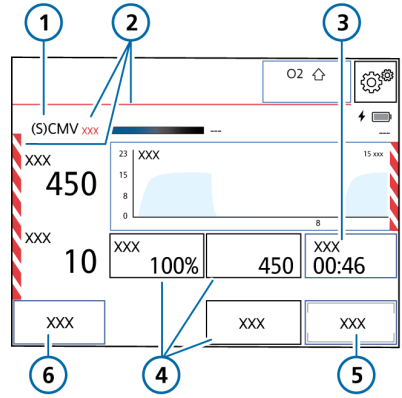
   Touch **X** to cancel the change and continue with the previous therapy.

The ventilator starts CPR ventilation, showing the CPR main display. For details, see Section 8.6.

To start directly with CPR ventilation, when the ventilator is turned off

See Section 2.4.

Figure 8-16. CPR ventilation on



1	*Active CPR ventilation mode:* (S)CMV or PCV+	4	Settings for active ventilation mode, adjustable
2	CPR active indicators	5	Pause therapy
3	CPR timer	6	*ROSC:* Stop CPR and return to default invasive ventilation mode

8.6.3 Monitoring and display during CPR

When CPR ventilation is on, the following MMPs are displayed: VTE[1], fTotal, O2 consumption, and the CPR Timer.

In addition to the MMPs, the pressure indication bar provides a real-time view of the current delivered pressure, breath by breath.

The PCO2 waveform is shown when CO2 monitoring is available, otherwise the Pressure waveform is displayed.
See Figure 8-16.

8.6.4 CPR-related alarms

Table 8-3. CPR ventilation-related alarm conditions

Alarm	Status
Pressure high	**CPR mode is PCV+.** The alarm limit is set using the following calculation: Pressure high limit = (PEEP + ΔPcontrol) + 30 mbar **CPR mode is (S)CMV.** The alarm limit is set to 60 mbar.
Low/high alarms for the following: ExpMinVol fTotal Vt PetCO2[2]	The low alarm limits are automatically set to the minimum value, and the high alarm limits are automatically set to the maximum value. If any alarm limit was previously set to OFF, it remains OFF during CPR ventilation.

8.6.5 Return of spontaneous circulation (ROSC)

ROSC is the resumption of cardiac activity after an arrest. At this point, CPR ventilation is no longer needed.

To end CPR ventilation and start invasive ventilation

▸ Touch the **ROSC** button.

The ventilator does the following:

- CPR ventilation ends.
- The ventilator switches to the default invasive mode (set in Configuration).
- The adjustable alarm limits return to the default settings.
  If the limits are set to OFF during CPR ventilation, they remain OFF.
- The Oxygen control setting does not change; ventilation continues with the value set during CPR ventilation.

[1] Touch the parameter to toggle between VTE and ExpMinVol. For details, see Section 2.6.4.
[2] If the option is installed and activated.

8.7 Setting display options

You can set the day and night display brightness, as well as the device date and time. The date and time are set in Configuration (Chapter 10).

8.7.1 Setting the display brightness

You can set the brightness of the display for use during the day, night, and with night vision goggles (NVG)[1]. See Table 8-4 for details of each mode.

Once set, you can switch between two settings using the key on the front of the ventilator.

You can also manually adjust the brightness settings, as needed.

Table 8-4. Brightness settings (Day, Night, NVG)

Setting	Brightness range	Factory default
Day	10% to 100%	80%
Night	10% to 100%	40%
NVG[1]	1 to 10	5

To set the display brightness for Day, Night, and NVG[1]

1. Touch > **General** (Figure 8-17).
2. Touch **Modes**.
3. In the Modes window (Figure 8-18), touch the mode to adjust: **Day**, **Night**, or **NVG**[1], then touch ✓ to close the window.
4. Touch **Brightness**.
5. Adjust the Brightness setting as desired for the selected mode.
6. Touch ✓ to confirm the setting(s).

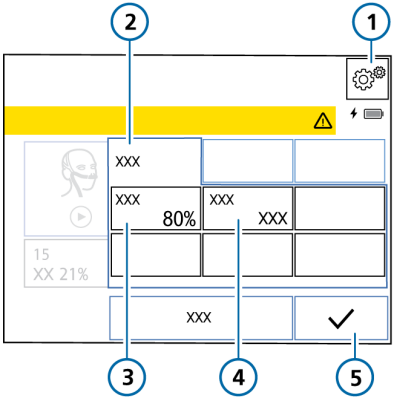
The brightness of the display is updated. The setting is applied as the default brightness for the currently selected Day, Night, or NVG display mode.

For details on switching between the modes, see Section 8.7.2.

For details on switching between the modes with NVG, see Section 8.7.3.

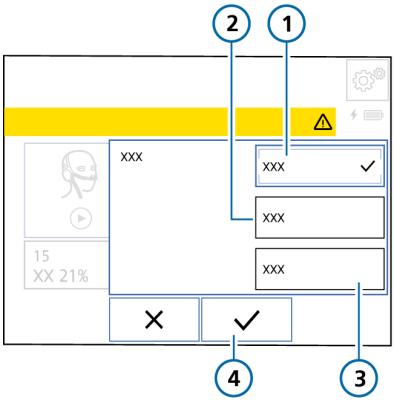
[1] If the NVG option is installed.

Figure 8-17. Brightness and Modes (Day/Night) window



1	Settings	4	Modes (Day/Night)
2	General	5	Confirm
3	Brightness		

Figure 8-18. General > Modes window, Day/Night/NVG display mode



1	Day (shown selected)	3	NVG[1]
2	Night	4	Confirm

[1] If the NVG option is installed.

8.7.2 Selecting Day or Night display settings

Changing the display brightness using the Day/Night key

The (Day/Night) key allows you to quickly switch the display between defined Day and Night settings.

You can also manually adjust the setting (Section 8.7.1).

To change the display brightness to the defined Day or Night setting

- Do either of the following:

  – Press (Figure 8-3).

  – Adjust the setting in the > General > Modes window (Figure 8-18). Touch ✓ to accept the setting and close the window.

The display brightness is adjusted to the selected setting.

8.7.3 Selecting NVG or Night display settings

If the NVG option is installed, the ventilator provides a way to expand the use of the key to allow for toggling between Day/Night brightness settings, as well as between NVG/Night settings for use with night vision goggles.

You can still manually change the brightness settings of the display, and reset the default values for any of the three brightness modes, as described in Section 8.7.1.

To change the mode set between Day/Night and NVG/Night

- *Long-press*  on the front of the ventilator for about five (5) seconds, until the display brightness changes.

The mode set changes as follows:

- If it was Day/Night before, it is now NVG/Night.

  Short-pressing the  key now toggles between the NVG brightness setting and the Night setting.

- If it was NVG/Night before, it is now Day/Night.

  Short-pressing the  key now toggles between the Day brightness setting and the Night setting.

8.8 About the Event log

Once the ventilator is turned on, event logs collect data about clinically relevant ventilator activities, including when the ventilator was powered on/powered off (the time for each is provided), alarms, technical notes, setting changes, calibrations, and the like.

Each entry in the log starts with a colored dot and includes a unique identification reference (ID) for event classification, and the date, time of occurrence, and the event description.

The color of the dot indicates the event type.

- For alarm events, the color reflects the priority level (yellow for low or medium, red for high).
- For non-alarm events, the dot is colored white.

In the Events window you can access the following information.

Table 8-5. Events window

Tab / Description	Where located
All Lists all events that have occurred on the ventilator.	 > Info / File export > Events > All
Alarm log Provides alarm-related events that have occurred on the ventilator.	 > Info / File export > Events > Alarm log
Deactivated alarms Displays any alarms that are currently deactivated. For details, see Section 7.2.2.	 > Info / File export > Events > Deactivated alarms

A more extensive log including technical and configuration details is available to service engineers.

Event log data persists after shutting off the ventilator or in the event of a power loss. A maximum of 10,000 events is stored. When a log buffer is full, new events overwrite the oldest log entries.

You can export event log data.
See Section 8.8.1.

To display the Event log

1. Touch  > **Info / File export**.
2. Touch **Events**.

8.8.1 Exporting event log data

Before using a USB drive with the ventilator, review the safety information in Section 1.5.4.

You can export event and service logs to a USB drive. Log files are saved in text (.txt) format, and can be read by any application that supports .txt files.

The USB drive must have a FAT or FAT32 format and it must *not* have an operating system or a security system installed.

To export the log files

1. Place the ventilator into Standby.
2. Insert a USB drive into the USB port, located under the removable side cover.

   For details on removing the side cover to access the USB port, see Section 9.5.1.
3. Touch > **Info / File export** (Figure 8-19).
4. Touch **Export logs**.

   The log files are exported to the USB drive.
5. Remove the USB drive when the text Export successful is displayed.

Log files are saved to the USB drive. The event log file name is: EM7_snXXX_yyyy-mm-dd_hh_ss on the USB drive, where:

snXXX is the device serial number

yyyy is the year

mm is the month

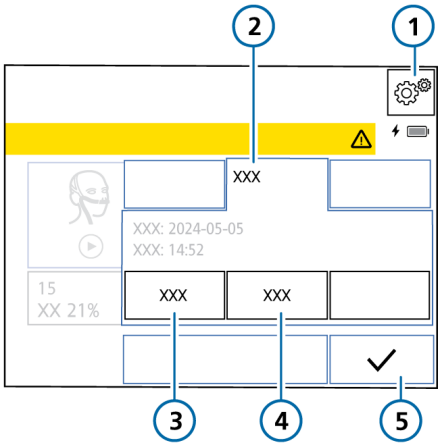
dd is the date

hh is the hour (in 24-hour format)

mm is the minute

ss is the second

Figure 8-19. Exporting the event log



1 Settings
2 Info / File export
3 Events
4 Export Logs
5 Confirm

8.9 Viewing device-specific information

The  > Info / File export > System information window displays device-specific information including serial number, model, software version, installed options, CE label, and information about third-party open source libraries that were used to develop the ventilator software.

To view device-specific information

- Touch  > **Info / File export** > **System information**.

Use the navigation arrows to page through the windows.

8.10 Working with external devices

Before proceeding, review the safety information in Section 1.10.

The Hamilton Connect Module (HCM) is available on the HAMILTON-EM7 ventilator, providing support for Bluetooth connections.

You can connect the ventilator to third-party applications.

Preparing the ventilator for connectivity comprises the following steps:

- Configuring ventilator connectivity for use in your institution, performed by technical personnel (see Table 8-7)
- For medical caregivers, enabling Bluetooth and connecting to the desired device.

Table 8-6. Connectivity tasks for medical caregivers

To ...	See ...
The following tasks are performed by medical personnel caring for patients.	
Connect to/ disconnect from a device using Bluetooth	Section 8.10.1

Table 8-7. Connectivity tasks for technical personnel

To ...	See ...
These configuration tasks are performed by technical personnel.	
Configure network and connectivity	See the *Hamilton Connect Configuration Tool User Guide* (PN 10110032), *Hamilton Connect Communication Guide* (PN 10102528).
Copy Connectivity configuration settings to the ventilator	Section 10.3.6

8.10.1 Working with a Bluetooth connection

⚠ WARNING

Do *NOT* use the ventilator if any cybersecurity issue occurs and provide alternative respiratory support until the issue is resolved.

Depending on your institution's network policy, you can connect the ventilator to supported devices/systems using Bluetooth.

Bluetooth connectivity is disabled by default. Enabling Bluetooth increases the risk of unauthorized attackers gaining remote access to the device. For details about cybersecurity incident reporting and emergency contact information, see Section 1.12.7.3.

To enable Bluetooth on the ventilator

1. Touch > **Connectivity** (Figure 8-20).
2. Touch **Bluetooth**.

   The ventilator starts pairing mode, and the Bluetooth window opens (Figure 8-21), displaying the following information:

   Ventilator name (MAC address), name of any connected device.
3. On the device to connect to the ventilator, select the ventilator name and connect.

   If successfully paired, the connected device name is displayed in the Bluetooth window, and a **Disconnect** button is displayed.

The ventilator is now connected to the listed device.

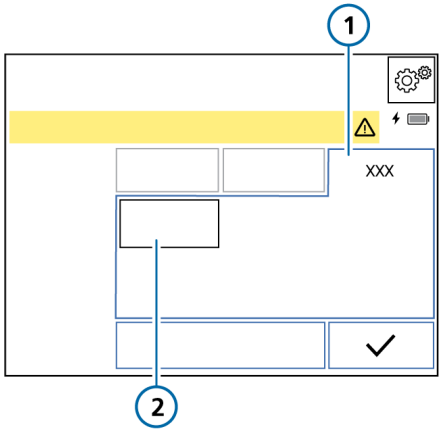
To disconnect from a device

1. Touch > **Connectivity** (Figure 8-20).
2. Touch **Bluetooth**.

   The Bluetooth window opens (Figure 8-21).
3. Touch **Disconnect**.

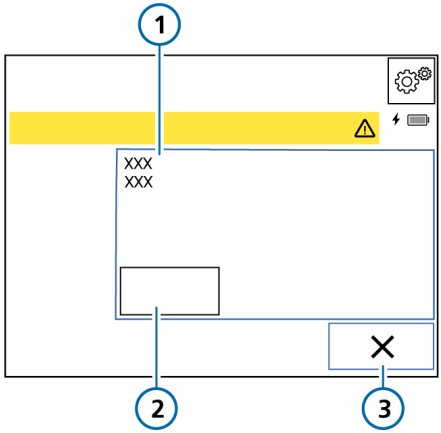
The ventilator is disconnected.

Figure 8-20. Settings > Connectivity window



1	Connectivity	2	Bluetooth

Figure 8-21. Bluetooth window



1	Ventilator name (MAC address), connected device name	3	Cancel
2	Disconnect		

9 Maintenance

9.1 Overview

Before proceeding, review the safety information in Chapter 1.

This chapter provides information about ventilator maintenance procedures and schedule, as well as cleaning and disinfection instructions.

All of the procedures in this chapter are to be performed by the operator.

For additional maintenance requirements, contact your Hamilton Medical service representative. Any documents referenced in this chapter are available in the Hamilton Medical Resource Center (https://www.hamilton-medical.com/Resource-center).

For details about...	See ...
Safety information	Section 9.2
Cleaning and disinfecting the device and components (including wipes to use)	Section 9.3
Preventive maintenance schedule	Section 9.4
Performing maintenance tasks	Section 9.5
Charging and storing batteries	Section 9.6
Dropped device protocol: what to do if the device falls on the ground	Section 9.7
Repacking and shipping the device	Section 9.8

9.2 Safety information

The following sections provide safety information related to cleaning/ disinfection of the device and components, as well as related to maintenance requirements and procedures.

9.2.1 General maintenance, surface cleaning, and disinfection safety information

⚠ WARNING

- Reprocessing of Hamilton Medical single-use products can affect the product properties and may cause injury to the patient. For example, a change to the surface structure during reprocessing may lead to a change in the tear strength or cause actual cracking. Furthermore, an altered surface structure may result in a microbial aggregation of spores, allergens, and pyrogens, for example, or cause an increase in the number of particles released as a result of chemical changes in the material properties.
- Hamilton Medical does *not* assume any liability for the proper functioning of single-use items if they are reprocessed and reused by the user.
- To prevent patient exposure to sterilizing agents and to prevent premature deterioration of parts, sterilize parts using only the techniques recommended in this chapter and in any associated *Reprocessing guide* or *Instructions for use* provided with each part.

- Always use caution when handling HMEFs to minimize the risk of viral or bacterial contamination, or physical damage. Follow the manufacturer's *Instructions for use* of the HMEF. Dispose of a used HMEF immediately after use. Follow your organization's procedures for disposal.
- Follow the cleaning, disinfection, and sterilization procedures for each component as described in this manual and in the cleaning agent manufacturer's *Instructions for use*.
- Use only registered/approved cleaning and disinfection solutions, as approved by your institution's protocol, according to the cleaning agent manufacturer's recommendations.
  See Section 9.3.1.2.
- Always disconnect the device and any accessories from electrical power before cleaning and disinfection to reduce the risk of electric shock.

⚠ CAUTION

- *Be sure to cover the To patient port and the flow sensor pressure plug connection port with the red protective caps to prevent contamination of the device and liquid ingress.*
- *Do NOT attempt to sterilize the interior components of the ventilator.*
- *Do NOT attempt to sterilize the entire device with ETO gas.*
- *Incorrect concentrations or residence times of sterilization agents may lead to bacterial resistance.*
- *To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material. See Section 9.3.1.2.*
- *Clean parts (Table 9-1) after each patient use. See Section 9.3.1.2.*
- *Intrusion of fluids, or immersing parts in fluids, will damage the device.*
- *Do NOT pour fluids onto the device surfaces.*
- *Do NOT sterilize or immerse the CO2 sensor in liquids.*
- *Do NOT use abrasive materials (for example, steel wool or silver polish), hard brushes, pointed instruments, or rough materials on any component or surface.*
- *Thoroughly rinse all patient- or airway-contact components to ensure removal of residual cleaning/disinfection agents.*
- *Using cleaning and disinfection methods that are not validated can cause blemishes.*
- *(USA only) Only use EPA-registered/approved cleaning and disinfection wipes, as approved by your institution's protocol, according to the cleaning wipe manufacturer's recommendations. See Section 9.3.1.2.*

9.2.2 Surface cleaning and disinfection safety information

⚠ WARNING

- Do *not* clean the device interior to avoid damaging internal components.
- Penetrating liquid may cause the following:
  - Damage to the device
  - Electric shock
  - Device malfunction

  Use *only* the approved cleaning/disinfecting wipes listed in Section 9.3.1.2, and ensure that *no* liquid penetrates the device.
- When cleaning during therapy, do *not* clean the breathing circuit.
- Use nationally approved cleaning and disinfecting wipes, from the wipes listed in Section 9.3.1.2.
- Carefully follow the manufacturer's instructions of each validated wipe, for example, regarding shelf life or application conditions.

⚠ CAUTION

Be sure to cover the To patient port and the flow sensor pressure plug connection port with the red protective caps to prevent contamination of the device and liquid ingress.

NOTICE

- *(EU only)* Only use surface cleaning/disinfecting wipes that are certified as *medical device*.
- (*USA only*) Only use EPA-registered and approved surface cleaning/disinfection agents.
- Perform the manual cleaning/disinfection according to the respective *Instructions of use* of the individual cleaning/disinfection product.
- Use of cleaning and disinfectant wipes based on propanol, isopropyl alcohol, and/or isopropanol may cause marginal color change in some materials. Marginal color change on its own is *not* an indicator of product malfunction.

9.2.3 Preventive maintenance safety information

⚠ WARNING

If the mandatory HMEF is *not* connected to the breathing circuit set proximal to the patient, the device *must* be considered contaminated and *must* be serviced.

Dispose of all parts removed from the device according to your institution's protocols. Comply with all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it.

⚠ CAUTION

Failure to perform preventive maintenance tasks as documented in this chapter may lead to unacceptable risk to the patient.

NOTICE

- We recommend that you document all maintenance procedures.
- It is *not* allowed to perform service or maintenance on the device while a patient is connected.

9.3 Cleaning and disinfecting the device and components

The compatibility and efficacy of disinfectants on surfaces depends on their composition, active substances, and excipients. All of the ingredients, even substitutes, such as stabilizers or tensides, can have an influence on the material compatibility and cleaning/disinfection efficacy.

Therefore, material compatibility of disinfectants cannot be classified by the active substance groups, such as peroxides, chlorides, quarternary ammonium compounds, alcohols, or aldehydes, only. As a result, cleaning and disinfection agents are tested as a specific composition of different chemicals (see Section 9.3.1.2) by our certified laboratory, to validate their materials compatibility and cleaning/disinfection efficacy.

Other surface cleaning and disinfection agents are used at your own risk. Hamilton Medical is **not** responsible for damages, incidents, or adverse events due to the use of any cleaning and disinfection wipes that are **not** listed in Section 9.3.1.2.

An independent and ISO 17025 accredited laboratory has performed many tests on the compatibility and efficacy of the main and common disinfectant groups with regard to material groups of medical technology used worldwide. For further information on Hamilton Medical-tested disinfectants, contact your Hamilton Medical representative.

Using tested wipes that are suitable for Hamilton Medical devices and accessories improves the safety of your patient and workstations, and also protects your investment in the medical devices.

When working with the device components, cleaning/disinfection methods, and cleaning and disinfection wipes, keep the following in mind:

- Do *not* attempt decontamination procedures unless specified by Hamilton Medical or the original manufacturer.
- While we provide instructions for cleaning and disinfection wipes to use and the associated procedures, if you have specific questions about the use of a particular cleaning and disinfection wipe, contact your Hamilton Medical technical representative.
- After cleaning and decontaminating parts, be sure to perform any tests and calibrations, as described in Section 3.6.

9.3.1 Surface cleaning and disinfection (validated processing instructions)

Device components, such as the device surface and additional noncritical components, must be regularly cleaned and disinfected, using the validated cleaning methods and wipes specific to the individual components.

It is important that you use the appropriate method and materials when cleaning and disinfecting the device and its components, not only to avoid damaging the equipment, but also to avoid cross-contamination.

Note that the breathing circuit set may become contaminated during use and in a single fault condition.

For details about device component cleaning/disinfection frequency and methods, see Section 9.3.1.1.

Before proceeding, review the safety information in Sections 9.2.1 and 9.2.2.

To surface clean a component

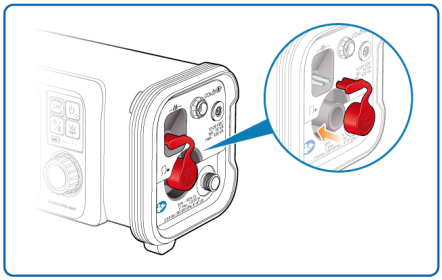
1. Cover the *To patient* port and flow sensor pressure plug connection port with a new single-use red protective cap (PN 10188157) to prevent any inadvertent intrusion of substances. See Figure 9-1.
2. Unfold a clean disposable cleaning and disinfectant wipe (from Section 9.3.1.2), and wipe off visible soil from the component surface.
3. Wet all surfaces, working from top to bottom, from clean to dirtier areas, in an S-shaped fashion.

   Should your wipe dry out or become soiled, replace it with a new wipe to complete the area.

   Ensure that the surface is visually free of soil.

   Do *not* overuse the wipe.
4. Dispose of the wipe.
5. Keep the red protective cap in place until the next breathing circuit set is connected to the device.

Figure 9-1. Covering the *To patient* port and flow sensor pressure plug connection port with red protective cap



To surface disinfect a component

After cleaning the surface as instructed previously, do the following.

1. Ensure the *To patient* port and flow sensor pressure plug connection port are covered by the single-use red protective cap (PN 10188157). See Figure 9-1.
2. Wipe cleaned surfaces again, until visibly wet, with a cleaning and disinfectant wipe (from Section 9.3.1.2).
3. Dispose of the wipe.
4. Wait for the contact time of your chosen wipe.
5. Wait until the surfaces are dry.
6. Check the surfaces for visible damage.

   If there is any damage, contact your Hamilton Medical technical representative.
7. After use of the wipes, ensure their packaging lid is firmly sealed.
8. Keep the red protective cap in place until the next breathing circuit set is connected to the device.

9.3.1.1 Component cleaning/ disinfection frequency and methods

Table 9-1. HAMILTON-EM7 component cleaning/disinfection frequency and methods

Component	Cleaning/disinfection frequency	Cleaning/disinfection method and wipes
For supported cleaning and disinfection wipes, see Section 9.3.1.2.		
Ventilator exterior including: • Housing • Power cables • Gas supply hoses • Mounting systems	After each patient use, and as needed during therapy.	See instructions in Section 9.3, and use wipes from Table 9-2.
Touch screen	After each patient use, and as needed during therapy.	See instructions in Section 9.3, and use wipes from Table 9-2. Avoid using a gritty cloth.
CO2 sensors	After each patient use, and as needed during therapy.	See the *CO2 monitoring Instructions for use* for cleaning and disinfection instructions. • Ensure that the sensor/ module is disconnected and cooled to room temperature before cleaning. • Do *not* immerse the sensor/ module in liquid. • Dry before use.

9.3.1.2 Approved cleaning/disinfection wipes

Follow the manufacturer's instructions for surface cleaning and disinfecting wipes. All of the listed wipes are ready for use.

The listed surface cleaning and disinfecting wipes were compatible with the materials and effective at the time of testing.

Note that one wipe can be used for both cleaning and disinfection.

Table 9-2. Approved cleaning/disinfection wipes for the HAMILTON-EM7

Cleaning/ disinfection wipes	Active ingredients	Contact time for cleaning/ disinfection	Manufac-turer	Regulatory approval
Before proceeding, review the warnings, cautions, and notices in Section 9.2.				
Approved cleaning/disinfection wipes				
CaviWipes 2.0	Quaternary ammonium compounds, Isopropyl alcohol	3 min	METREX® RESEARCH	EPA
Environ-mental Cross V-Lock	Quaternary ammonium salt, Alkaline agent	3 min	Hakzo Medical Co.	Registered in Japan
Incidin OxyWipe S	Hydrogen peroxide	3 min	Ecolab Deutschland GmbH	CE
mikrozid® universal wipes green line	Propan-2-ol, Ethanol	2 min, 30 sec	Schülke & Mayr GmbH	CE
Sani-cloth active AF3	Ammonium chloride	3 min	ECOLAB	CE

9.4 Preventive maintenance

⚠ WARNING

Use only Hamilton Medical-approved parts, spare parts, and accessories, including ventilator mounting solutions, that are specified in this guide and in the product e-catalog, or that are specified as being compatible with this ventilator. Doing so safeguards the patient, ensures proper ventilation operation, avoids degraded performance, and keeps your warranty in force.

Perform preventive maintenance on your ventilator according to the schedule shown in Table 9-3.

The System > Info window shows the number of hours the ventilator has been in operation.

Table 9-3. Preventive maintenance schedule

Interval	Part/accessory	Procedure
Between patients, within seven (7) days of unpacking the set, or according to your organization's policy.	Breathing circuit set	Replace with a new Hamilton Medical Breathing circuit set for HAMILTON-EM7 and run the preoperational checks (Section 3.6).
	Entire ventilator	Run the preoperational checks (Section 3.6).
Every month (or more often if required)	Dust filter	Check for dust and lint. If needed, replace. See Section 9.5.2.1.
Every 6 months	Battery	Recharge the battery by plugging the ventilator into a primary power source for at least 4 hours.
As necessary	Battery[1]	Have the battery serviced.[2]
Every year	HEPA inlet filter[3]	Replace. See Section 9.5.2.2. **Note:** Maximum operating lifetime: 24 months.

[1] The expected service life of the battery is 3 years. To ensure proper battery function, follow the recommended preventive maintenance schedule.
[2] Must be performed by Hamilton Medical authorized service personnel according to instructions in the *Service Manual*.
[3] HMEFs must conform to the following standards: ISO 23328-1:2003 and ISO 23328-2:2002, as well as either ISO 9360-1:2000 or ISO 9360:2-2001

9.5 Performing maintenance tasks on the HAMILTON-EM7

Maintenance tasks must only be performed when a patient is NOT connected to the ventilator.

This section provides instructions for the following tasks:

To ...	See ...
Remove the side cover	Section 9.5.1
Replace filters	Section 9.5.2
Replace the battery	Section 9.5.3

9.5.1 Removing the side cover

You must remove the side cover (Figure 9-2) to access:

- USB port
- HEPA inlet filter assembly (Section 9.5.2.2)
- Battery (Section 9.5.3)

To remove the side cover

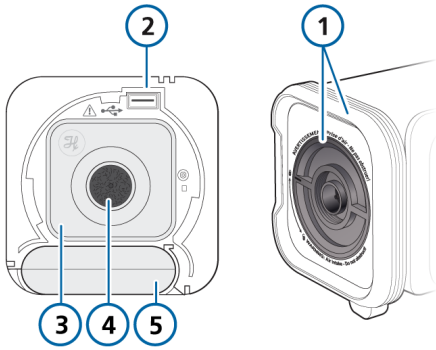
1. Turn off the ventilator.
2. Turn the locking ring counter-clockwise to unlock it (Figure 9-3).
3. With one hand holding the ventilator, loosen the covers edges with the other hand, and pull the cover off the side of the ventilator (Figures 9-4 and 9-5).

To replace the side cover

1. Align the elements of the cover and push it on to the side of the ventilator.

   Ensure the fit is snug and secure.
2. Turn the locking ring clockwise to lock it (Figure 9-6).

Figure 9-2. Side view, without cover (left), with cover (right)



1 Removable cover and locking ring
2 USB port
3 HEPA inlet filter
4 Air intake with dust filter
5 Battery

Figure 9-3. Turn locking ring counter-clockwise to unlock cover

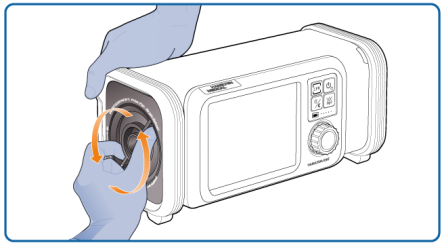


Figure 9-4. Loosen side cover along the top and bottom of the ventilator

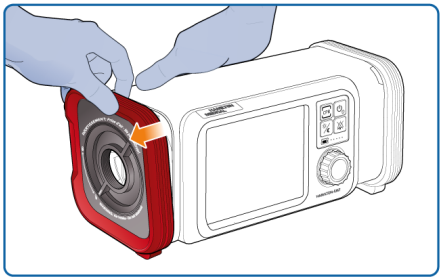


Figure 9-5. Remove side cover

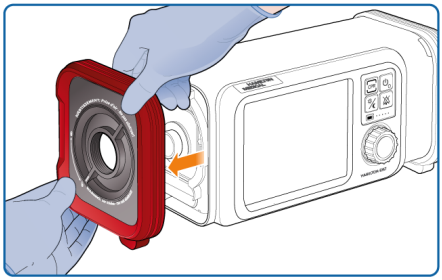
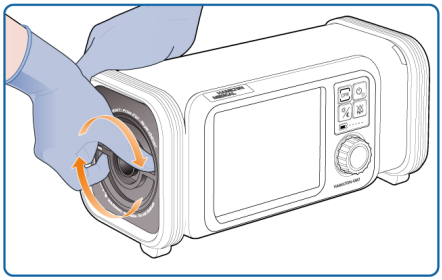


Figure 9-6. Turn locking ring clockwise to secure cover in place



9.5.2 Maintaining device filters

This section describes how to replace the dust filter and HEPA inlet filter.

9.5.2.1 Replacing the dust filter

1. Pull out the dust filter from the air intake (center of locking ring) (Figure 9-7).
2. Insert a new filter into the air intake (Figure 9-8).

Figure 9-7. Remove dust filter

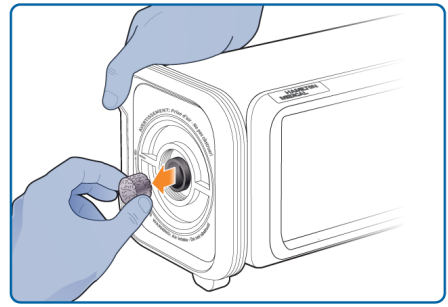
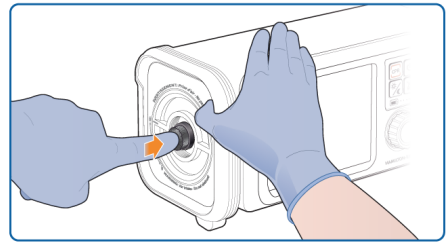


Figure 9-8. Replace dust filter



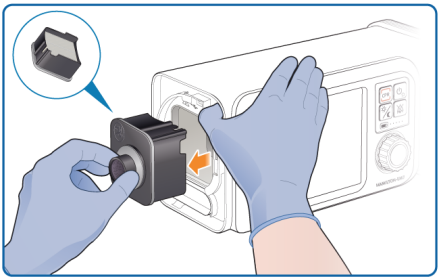
9.5.2.2 Replacing the HEPA inlet filter

NOTICE

Carefully check the HEPA inlet filter and its packaging. Pay particular attention to the integrity and placement of the filter's two sealings. Discard the filter if the packaging is damaged or there is any sign of damage to the filter.

1. Remove the side cover (Section 9.5.1).
2. Using the sides of the air intake, pull out the HEPA inlet filter assembly (Figure 9-9).
3. Insert a new HEPA inlet filter assembly.
4. When finished, attach the side cover.

Figure 9-9. Remove HEPA inlet filter



9.5.3 Replacing the battery

1. Remove the side cover (Section 9.5.1).
2. Holding the tab on the bottom of the battery, pull the battery straight out of the ventilator (Figure 9-10).
3. Insert a replacement battery straight into the ventilator, all the way in (Figure 9-11).

   Ensure that the tab is facing you and is visible under the battery.
4. When finished, attach the side cover.

Figure 9-10. Remove battery

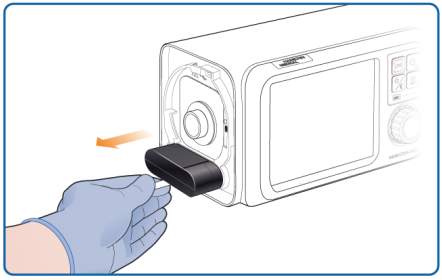
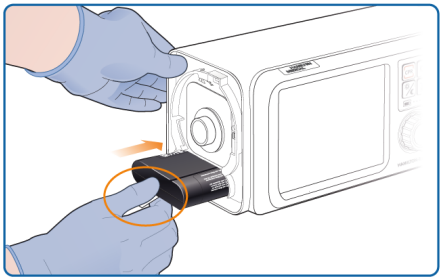


Figure 9-11. Insert battery



9.6 Charging and storing batteries

To maintain the battery charge and to prolong the life of the battery, keep the ventilator connected to its primary power source.

Have the battery recharged every six (6) months, depending on storage conditions. For details, see Section 12.4.

9.7 Dropped device protocol

Should the ventilator be dropped, follow these steps, in order:

1. Check for visible damage.

   If no apparent damage is visible, proceed to the next step.

2. Turn the device on; the ventilator performs a variety of self-tests.

   – If the device starts up successfully, you may use the device. No further action is necessary.

   – If startup is unsuccessful or there is visible damage, have the device serviced.

9.8 Repacking and shipping

⚠ CAUTION

Inform Hamilton Medical if you are shipping a contaminated (nonsterilized and nondisinfected) device for service.

If you must ship the ventilator, use the original packing materials. If these materials are not available, contact your Hamilton Medical representative for replacement materials.

10
System configuration

10.1 Overview

NOTICE

Access to the device configuration settings requires a code; contact your administrator.

During system configuration, you set up the ventilator with a default language, available ventilation modes, startup settings for a new patient, and units of measure, among other settings.

In System configuration, you can access settings in the General, Adult, and Pediatric windows.

- General settings apply to all patient groups.
- Adult settings apply to both male and female adult patients.
- Pediatric settings apply to pediatric patients.

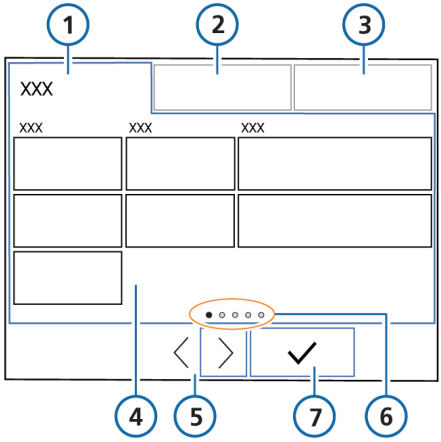
Use the navigation arrows to access the available settings in each window (Figure 10-1).

Configuration settings are available in each window as follows:

Table 10-1. Configuration windows, overview

Window and settings	
General	
Units	Service options
O2 ⇧ (O2 enrichment)	Screen lock
Available modes	Alarm
Date & Time	Configuration
Language	SW options
Connectivity	
Adult, Pediatric	
These settings are available separately for each of the Adult and Pediatric patient groups.	
General settings	O2 therapy
Default mode	RSI settings
Alarms	ASV
CPR	

Figure 10-1. Configuration windows, navigating settings (General shown)



1 General
2 Adult
3 Pediatric
4 Settings
5 Navigation arrows
6 Paging dots
7 Confirm and exit Configuration

10.2 Accessing Configuration mode

You can only access Configuration mode settings when the ventilator is in Standby. Access requires a configuration code; contact your administrator.

If desired, you can change the configuration code. For details, see Section 10.2.1.

To access Configuration mode

1. Ensure the ventilator is in Standby.
2. Touch > **System configuration**.
   The onscreen keypad is displayed.
3. Using the keys on the onscreen keypad, type the configuration code; then touch ✓ to confirm.

The Configuration window is displayed, showing the General window.

You can now define settings and add options.

10.2.1 Setting a new configuration code (PIN)

You can change the configuration code (PIN) for your device, if desired.

To change the configuration code

1. Touch > **System configuration**.
2. Touch **Change PIN**.
3. Using the onscreen keypad, enter the old PIN; then touch ✓.
4. Enter the new PIN; then touch ✓.
5. Enter the new PIN again to confirm the setting; then touch ✓.

The new PIN you have defined is now used to access Configuration.

10.3 Configuring general settings

You can configure some general default settings for the ventilator, including language, units of measure, O2 enrichment default settings, and the ventilation modes available for use on the device.

This section describes the settings available in the Configuration > General window.

For details about configuring ventilation-related settings for Adult and Pediatric patients, see Section 10.4.

Table 10-2. Configuration settings in the General window

To ...	See ...
Select the units of measure	Section 10.3.1
Set O2 enrichment defaults	Section 10.3.2
Configure available ventilation modes	Section 10.3.3
Set the date and time	Section 10.3.4
Select the default language	Section 10.3.5
Configure connectivity settings	Section 10.3.6
Configure the screen lock time interval	Section 10.3.7
Configure the minimum alarm volume	Section 10.3.8
Copy/reset configuration settings	Section 10.3.9
Configure device options	Section 10.3.10

10.3.1 Selecting the units of measure

You can set the unit of measure for Pressure, Length, and CO2 measurements.

To select the units of measure

1. In the General window under Units, touch the unit of measure to change.

   Options are:

   – Pressure

   – Length

   – CO2[1]
2. In the popup window, touch the desired setting to select it as the unit of measure.
3. Touch ✓ to confirm the setting.

[1] CO2 option required.

10.3.2 Setting the O2 enrichment defaults

You can set the Oxygen level and duration for which O2 ⇧ (O2 enrichment) will be delivered. The setting applies to both the Adult and Pediatric patient groups.

To set the default Oxygen enrichment settings

1. In the General window under O2 ⇧, touch the setting to change.
   Options are:
   – Oxygen
   – Duration
2. In the popup window, adjust the setting.
3. Touch ✓ to confirm the setting.

10.3.3 Configuring the available ventilation modes

You can define the ventilation modes that are available for use with both the invasive and noninvasive therapy types. You can select up to a maximum of four (4) modes for each type.

The following rules apply:

- SPONT requires (S)CMV (must be available for use as apnea backup mode).
- NIV requires NIV-ST (must be available for use as apnea backup mode)

To define the available ventilation modes

1. In the General window under Available modes, touch either Invasive or Noninvasive to define the modes.
2. In the popup window, touch the mode or modes as desired.
3. Touch ✓ to confirm the setting.

10.3.4 Setting the date and time

To set the date and time

1. In the General window, use the navigation arrows (Figure 10-1) to page to the Date & Time section.
2. Touch the Date or Time button and adjust the setting, as desired.
3. Touch ✓ to confirm the setting.

10.3.5 Selecting the default language

To select the user interface language

1. In the General window, use the navigation arrows (Figure 10-1) to page to Language.
2. Touch the **Language** button.
3. Scroll the list using the navigation arrows or the P&T knob and select the desired language.
4. Touch ✓ to confirm the setting.

10.3.6 Configuring connectivity settings

⚠ WARNING

Do *NOT* use the ventilator if any cybersecurity issue occurs and provide alternative respiratory support until the issue is resolved.

With the Hamilton Connect Module (HCM), your ventilator supports wireless communication using Bluetooth, allowing the ventilator to connect to a third-party application.

On the ventilator, you can update the HCM firmware, import configuration settings, export HCM log files, and delete data and settings that are saved to the module.

The Hamilton Connect Configuration Tool is a separate application that allows IT personnel to define the Connectivity configuration settings for the ventilator. For details, see the *Hamilton Connect Configuration Tool User Guide* (PN 10110032).

Any changes to your organization's IT network can introduce new risks that require additional analysis. For details about cybersecurity incident reporting and emergency contact information, see Section 1.12.7.3.

10.3.6.1 Updating Hamilton Connect Module firmware

NOTICE

Turning off the device while the firmware is being installed may corrupt the Hamilton Connect Module.

Module firmware updates are provided to you by your Hamilton Medical technical representative.

An update can take up to 10 minutes to complete. Note that you cannot install a firmware version that is older than the version currently installed on the Hamilton Connect Module.

To update the Hamilton Connect Module firmware

1. Insert the provided USB drive containing the update into the USB port on the ventilator (Figure 2-3).
2. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
3. Touch **Com module update**, then select the desired version from the popup window.
4. Touch ✓ to confirm the update.

   Do not turn off the device during the update.

When the new firmware is installed, the text, Update successfully completed is displayed. Ensure that the new firmware version is displayed.

The ventilator is ready to use. You do *not* need to restart the ventilator.

10.3.6.2 Creating Connectivity configuration settings

To enable communication using the Hamilton Connect Module, you must first import the connectivity configuration file created for your ventilator.

This file defines the connection types to enable on your ventilator, as well as the ventilator name and various settings associated with your institution's network.

Connectivity configuration settings are created using the Hamilton Connect Configuration Tool. For details, see the *Hamilton Connect Configuration Tool User Guide* (PN 10110032).

10.3.6.3 Importing Connectivity configuration settings

Once the Connectivity configuration file has been created or updated, you can import the file to the ventilator using a USB drive.

To import the Connectivity configuration file

1. Insert the provided USB drive containing the update into the USB port on the ventilator (Figure 2-3).
2. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
3. Touch **Import configuration**, then select the desired file from the popup window.
4. Touch ✓ to begin the import.

The features defined in the file are now enabled in the > Connectivity window.

10.3.6.4 Exporting Hamilton Connect Module log files

You can export Hamilton Connect Module (HCM) log files from the ventilator to a USB drive.

To export HCM log files from the ventilator

1. Insert a USB drive into the USB port on the ventilator (Figure 2-3).
2. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
3. Touch **Export log**.

The export begins, saving the HCM log files to the USB drive. When complete, Export successful is displayed.

10.3.6.5 Deleting data from the Hamilton Connect Module

You can delete data (such as ventilation-related data) that has been saved to the Hamilton Connect Module.

To remove saved data

1. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
2. Touch **Delete recorded data**.

All recorded data is deleted from the Hamilton Connect Module. When complete, Recorded data deleted successfully is displayed.

10.3.6.6 Resetting Bluetooth pairings

You can remove (reset) paired device entries from the ventilator.

To remove (reset) paired devices

1. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
2. Touch **Reset Bluetooth pairing**.

The device removes any device-pairing data. When complete, Reset pairings successful is displayed.

10.3.6.7 Setting the Hamilton Connect Module to the factory default settings

NOTICE

When ventilator connectivity is reset to the factory defaults, all connection types are disabled.

You can reset the Hamilton Connect Module to the factory default settings, which removes the Connectivity configuration file and deletes all saved data.

To delete only the saved data while retaining the Connectivity configuration, see Section 10.3.6.5.

Note that the currently installed Hamilton Connect Module firmware version remains unchanged.

To reset the Hamilton Connect Module to the factory default settings

1. In the General window, use the navigation arrows (Figure 10-1) to page to Connectivity.
2. Touch **Factory reset**.

The Hamilton Connect Module factory defaults are restored. When complete, Reset successful is displayed.

10.3.7 Configuring screen lock time interval

You can configure the time interval after which the ventilator display locks using the Screen lock timeout setting.

For details on unlocking the display, see Section 2.5

To set the screen lock time interval

1. In the General window, use the navigation arrows (Figure 10-1) to page to the Screen lock section.
2. Touch the **Timeout** button.
3. Set the time to the desired interval, in seconds.

   Options are: OFF, 30 to 300 seconds
4. Touch ✓ to confirm the setting.

10.3.8 Configuring the minimum alarm loudness (volume)

You can configure the minimum alarm loudness (volume) for the device.

For details on adjusting the volume during use, see Section 7.3.

To set the minimum alarm volume for the device

1. In the General window, use the navigation arrows (Figure 10-1) to page to the Alarm section.
2. Touch the **Min. loudness** button.
3. Set the volume to the desired level.
4. Touch ✓ to confirm the setting.

10.3.9 Copying and resetting configuration settings

Before proceeding, review the safety information in Chapter 1.

You can copy the configuration settings to a USB drive and quickly transfer the settings to other HAMILTON-EM7 devices. You can also restore all configuration settings to the factory defaults.

For details about configuration settings, ranges, and defaults, see Table 12.9.

If you remove the USB drive before the files are successfully transferred, you must start over and repeat the export.

To copy configuration settings using a USB drive

1. Insert a USB drive into the ventilator USB port. See Figure 2-3.
2. In the General window, use the navigation arrows (Figure 10-1) to page to Configuration.
3. Touch **Import** or **Export**.

The device begins transferring the files. Note that no personally identifiable information is exported. A message is displayed after the files are successfully transferred.

Exported files are stored in the EM7_yyyy_mm_dd_hh_mm.conf file on the USB drive.

Imported configuration settings are immediately applied to the ventilator.

If you remove the USB drive before the files are successfully transferred, you must start over and repeat the process.

To restore configuration settings to the factory defaults

1. In the General window, use the navigation arrows (Figure 10-1) to page to the Configuration section.
2. Touch **Factory reset**.

Factory default settings are restored. When complete, Factory reset successful is displayed.

10.3.10 Configuring device options

You can add and enable or remove software options in Configuration.

10.3.10.1 Adding software options

Software options are added using a USB drive.

Trial versions of software options may be available. Trial options expire and are automatically deactivated after 30 days.

To add a software option

1. Insert the provided USB drive into the ventilator USB port (Figure 2-3).
2. In the General window, use the navigation arrows (Figure 10-1) to page to SW options.
3. Touch **Add options**.

   The software options available on the USB drive are displayed.

4. Touch the option(s) to add.

   To scroll the list, swipe up or down, or use the navigation arrows under the list.

   As an alternative, use the P&T knob to scroll the list; push the knob to select an entry.

5. Touch ✓ to add the selected option(s).

   To cancel and close the window, touch X.

When complete, the options are available for use.

10.3.10.2 Removing options

You can remove one or more options from the ventilator.

Note the following:

- Trial options are automatically removed at the end of the trial period.
- You cannot re-add trial options that you have removed or that have expired.

To remove software options

1. In the General window, use the navigation arrows (Figure 10-1) to page to SW options.
2. Touch **Clear options**.

   The software options available on the device are displayed.
3. Touch the option(s) to remove.

   To scroll the list, swipe up or down, or use the navigation arrows under the list.

   As an alternative, use the P&T knob to scroll the list; push the knob to select an entry.
4. Touch ✓ to remove the selected option(s).

   To cancel and close the window, touch X.

When complete, the options are removed from the ventilator.

10.4 Configuring ventilation-related settings

For the Adult and Pediatric patient groups you can configure some ventilation-related default settings. The Adult patient group configuration settings apply to both the Male and Female patient groups.

This section describes the available settings in the Adult and Pediatric configuration windows. The available configuration settings are the same in both windows.

For details about configuring general settings, see Section 10.3.

Table 10-3. Configuration settings in the Adult and Pediatric configuration windows

To configure ...	See ...
General settings	Section 10.4.1
The default mode	Section 10.4.2
Adjustable alarms	Section 10.4.3
CPR settings	Section 10.4.4
O2 therapy settings[1]	Section 10.4.5
RSI settings	Section 10.4.6
ASV settings	Section 10.4.7

10.4.1 Configuring general default settings

You can configure the following default settings for each patient group:

- Patient height
- Vt/PBW
- PEEP
- Oxygen
- Invasive and noninvasive default modes (Section 10.4.2)

General settings do not apply to O2 therapy, RSI, or CPR.

To configure the general default settings

1. In the Adult > General window, touch the setting to change, and adjust the value.
2. Repeat for each setting that needs adjustment.
3. In the Pediatric > General window, touch the setting to change, and adjust the value.
4. Repeat for each setting that needs adjustment.
5. Touch ✓ to confirm.

The setting defined is used as the default setting when ventilating a new patient. The default Vt setting is calculated using the predicted body weight (PBW).

[1] Available with the O2 Therapy option.

10.4.2 Configuring the default ventilation mode

From the available modes configured for the device (Section 10.3.3), you can configure the default modes to use for each patient group for each of the therapy types: Noninvasive and Invasive

To configure the default noninvasive and invasive modes

1. In the Adult > General window, under Default mode, touch the **Noninvasive** button.
2. Touch the mode to set as the default for noninvasive ventilation for adult patients.
3. Under Default mode, touch the **Invasive** button.
4. Touch the mode to set as the default for invasive ventilation for adult patients.
5. In the Pediatric > General window, under Default mode, touch the **Noninvasive** button.
6. Touch the mode to set as the default for noninvasive ventilation for pediatric patients.
7. Under Default mode, touch the **Invasive** button.
8. Touch the mode to set as the default for invasive ventilation for pediatric patients.
9. Touch ✓ to confirm.

The mode defined is used as the default for the Quick Start button for the associated therapy type in the Standby/ Home window (Figure 4-3).

The selected *invasive* mode is also used as:

- The Quick Start therapy during rapid sequence induction (RSI) (Section 8.3)
- The Quick Start therapy used when touching **ROSC** (return of spontaneous circulation) to end CPR ventilation (Section 8.6.5)

10.4.3 Configuring adjustable alarm settings

For the Adult and Pediatric patient groups, you can configure the default settings for some adjustable alarms.

To configure the default adjustable alarm limits

1. In the Adult or Pediatric window, use the navigation arrows (Figure 10-1) to page to Alarms.
2. Touch the setting to change:

   Options are:

   – Apnea

   – Pressure (high)

   – fTotal (high)/(low)

   – PetCO2[1] (high)/(low)
3. In the popup window, adjust the setting.
4. Touch ✓ to confirm.

[1] Available with the CO2 option.

10.4.4 Configuring CPR settings

For the Adult and Pediatric patient groups, you can configure the following default settings for use with CPR ventilation:

- CPR ventilation mode
- Vt/PBW when using (S)CMV mode
- ΔPcontrol when using PCV+ mode
- PEEP
- Rate
- Oxygen
- I:E

For details about working with CPR ventilation, see Section 8.6.

To configure default CPR ventilation settings

1. In the Adult or Pediatric window, use the navigation arrows (Figure 10-1) to page to CPR.
2. Touch the setting to change.
3. In the popup window, adjust the setting.
4. Touch ✓ to confirm.

The settings are used as the defaults in each patient group when starting CPR ventilation.

10.4.5 Configuring settings for O2 therapy

You can configure the following O2 therapy default settings for each patient group: Flow, Oxygen.

To configure the general default settings

1. In the Adult or Pediatric window, use the navigation arrows (Figure 10-1) to page to O2 therapy.
2. Touch the setting to change.

   Options are:

   – Flow

   – Oxygen
3. In the popup window, adjust the setting.
4. Touch ✓ to confirm.

The setting defined is used as the default startup setting when starting O2 therapy.

10.4.6 Configuring RSI settings

For the Adult and Pediatric patient groups, you can configure the default Oxygen setting for RSI. For details about RSI, see Section 8.3.

To configure the default RSI Oxygen setting

1. In the Adult or Pediatric window, use the navigation arrows (Figure 10-1) to page to RSI settings.
2. Touch the **Oxygen** button.
3. In the popup window, select the desired Oxygen value.
4. Touch ✓ to confirm.

10.4.7 Configuring ASV settings

For the Adult and Pediatric patient groups, you can configure the default Min. ΔPinsp setting for ASV mode.

For details about ASV, see Sections 5.4 and 5.7. For information about Min. ΔPinsp range settings, see Table 12.6.

To configure the default Min. ΔPinsp setting for ASV

1. In the Adult or Pediatric window, use the navigation arrows (Figure 10-1) to page to the ASV section.
2. Touch the **Min. ΔPinsp** button.
3. In the popup window, select the desired value.
4. Touch ✓ to confirm.

11
Parts and accessories

11.1 Overview

This chapter lists parts available for the HAMILTON-EM7 ventilator. Note that not all parts are available in all markets.

For information about compatible, validated breathing circuit sets and accessories, see the ventilator *Technical Specifications*.

For ordering information, refer to the e-catalog on the Hamilton Medical website or contact your Hamilton Medical representative.

Figure 11-1. Ventilator parts and accessories

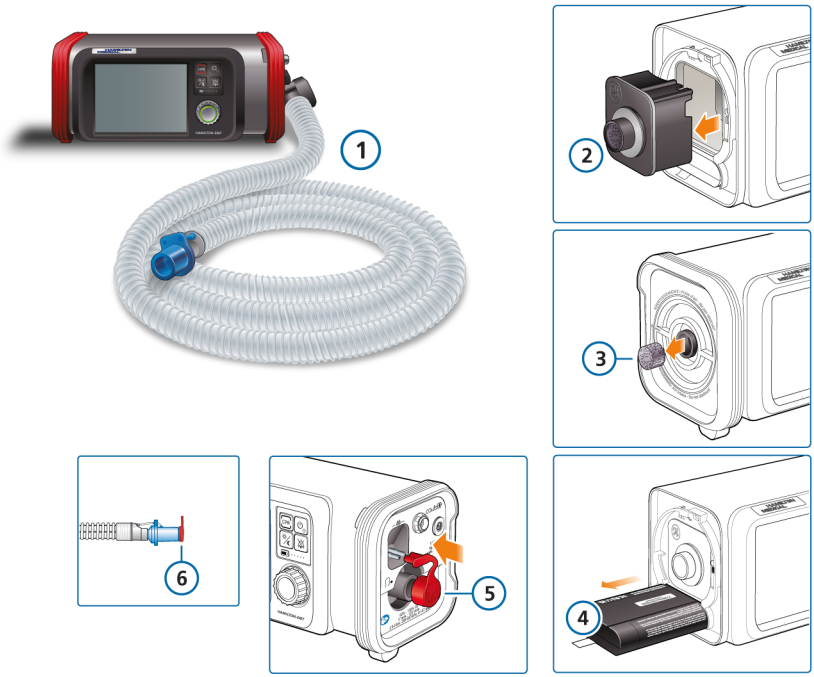


Table 11-1. Ventilator parts and accessories

Item no. (see Figure 11-1)	Description	Part number (PN)
1, 6	**Breathing circuit sets**	
	HAMILTON-EM7 Breathing circuit set, 180 cm	10145821
	HAMILTON-EM7 Breathing circuit set, 240 cm	10145823
not shown	**High flow nasal cannulas, adult/pediatric** *See the Hamilton Medical e-catalog.*	
not shown	**NIV masks and accessories, adult/pediatric** *See the Hamilton Medical e-catalog.*	
not shown	**Breathing circuit set filters** Heat and moisture exchanging filter (HMEF) *See the Hamilton Medical e-catalog.*	
not shown	**Catheter mounts** *See the Hamilton Medical e-catalog.*	
not shown	**Adapters/connectors** *See the Hamilton Medical e-catalog.*	
not shown	**Demonstration lung** *See the Hamilton Medical e-catalog.*	
	Protective covers	
5	HAMILTON-EM7 red cover cap, covers the *To patient* port and the flow sensor pressure plug connection ports, box of 10	10188157
5	HAMILTON-EM7 red cover cap, covers the *To patient* port and the flow sensor pressure plug connection ports, box of 30	10082911
not shown	**Nebulizer and accessories** *See the Hamilton Medical e-catalog.*	

Item no. (see Figure 11-1)	Description	Part number (PN)
not shown	**CO2 sensors and accessories** *See the Hamilton Medical e-catalog.*	
	Device filters	
2	HEPA inlet filter	10156644
3	Dust filter, set of 5	10180358
not shown	**Power cord** ⚠ **WARNING!** Only use the original power cord provided with the HAMILTON-EM7 to connect the device to the primary power supply.	
	Power cord with US plug, 2-pin, 3.0 m	355198
	Power cord with British angled plug, 2-pin, 3.0 m	355199
	Power cord with continental European plug, 2-pin, 3.0 m (also for use in Switzerland and Korea)	355200
	Power cord with Australian plug, 2-pin, 3.0 m (also for use in New Zealand)	10195270
	Power cord with Chinese plug, 2-pin, 3.0 m	355308
	Power cord with Japanese plug, 2-pin, 3.0 m	355198
not shown	**DC input cables**	
	DC power cable, open end (for individual assembly)	10159938
	DC power car cable (for cigarette lighter and DIN4165 standard socket ⦰ 12 mm)	10149117
4	**Battery/Power supply**	
	Li-Ion battery 14.40 V	10150774
	AC power supply 100-240 VAC / 24 VDC 110 W	10159989
	Battery charger	369104

Item no. (see Figure 11-1)	Description	Part number (PN)
not shown	**Oxygen connectors**	
	O2 DISS connector	10187224
	O2 quick coupling	10187225
	O2 DISS connector + quick coupling adapter	10191251
	O2 NIST connector	10204564
not shown	**Tools and test equipment** *See the Hamilton Medical e-catalog.*	
not shown	**Ventilator hardware and mounting options** *See the Hamilton Medical e-catalog.*	
	Shoulder strap (r)	10188176
	Shoulder strap (g)	10192199
	Language kit	
	English	10168542
	English-US	10178777
	German	10168543
	French	10168545
	Spanish	10168544
	Portuguese	10168547
	Italian	10168546
	Russian	10168550
	Chinese	10168548
	Japanese	10168551
	Extended warranty	
	Extended warranty of 1 year	700001
	Extended warranty of 2 years	700002
	Extended warranty of 3 years	700003
	Extended warranty of 6 years	700006
	Extended warranty of 8 years	700008

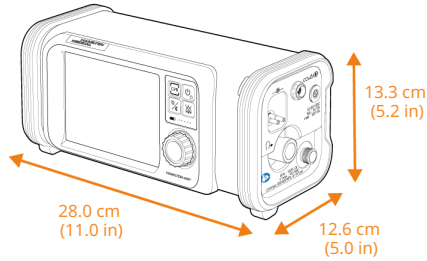
12 Specifications

12.1 Physical characteristics

Table 12-1. Physical characteristics[1]

Dimension	Specifications
Weight (kg)	
Device only	3.5
Device with handle	4.4
Device, handle, hooks, rotation module, and charging module	4.95
Breathing circuit (1.80 m)	0.25
Breathing circuit (2.40 m)	0.3
Oxygen supply hose (depending on length)	0.5 minimum
Wall mount plate	1.0
Single rail adapter	0.33
Dimensions (cm)	
Device	See Figure 12-1.
Device, handle, hooks, breathing circuit, and O2 supply hose (90°)	34.6 (W) x 21.6 (H) x 14.2 (D)
Device, handle, hooks, breathing circuit, and O2 supply hose, mounted in wall mount	34.6 (W) x 21.6 (H) x 16.9 (D)
Depth added when using the rotation module[2]	1.7

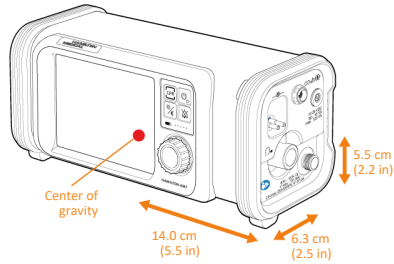
Figure 12-1. HAMILTON-EM7 dimensions



Center of gravity of the ventilator

The center of gravity of the HAMILTON-EM7 is shown in Figure 12-2.

Figure 12-2. HAMILTON-EM7 center of gravity



[1] For accessories, see Chapter 11.
[2] See Section 2.3.3.

12.2 Environmental requirements

Table 12-2. Environmental requirements

Environment		Specifications
Temperature	Operation[1,2]:	−10°C to 40°C (14°F to 104°F) continuous operation −20°C to 50°C (−4°F to 122°F) transient operation, for a maximum of 20 minutes
	Shipment/storage:	−20°C to 60°C (−4°F to 140°F)
Altitude		−650 to 4,000 m (−2,132 to 13,123 ft) 4,000 to 8,000 m (13,123 to 26,247 ft) Note that at higher altitudes the ventilator performance may be limited (Figure 12-3 and Table 12-3). The Performance limited by high altitude alarm (Table 7-2) is generated and a message is shown on the display.
Atmospheric pressure	Operation,[3] shipment, and storage:	376 to 1,100 hPa
Relative humidity	Operation,[3] shipment, and storage:	5% to 95%, noncondensing
Ingress protection		IP54
For specifications related to any external devices and sensors, refer to the manufacturer's *Instructions for use*.		

[1] If the device is stored below -10°C, it must warm up for 30 minutes at a temperature of 20°C.
[2] If therapy is performed at a temperature below -10°C, the device must warm up for 45 minutes at a temperature of 20°C.
[3] The stated operating conditions apply to both continuous and transient operation of the ventilator within the limitations specified in the Intended use.

12.2.1 Variations in maximum delivered pressure by altitude

Figure 12-3. Variations in maximum delivered pressure by altitude

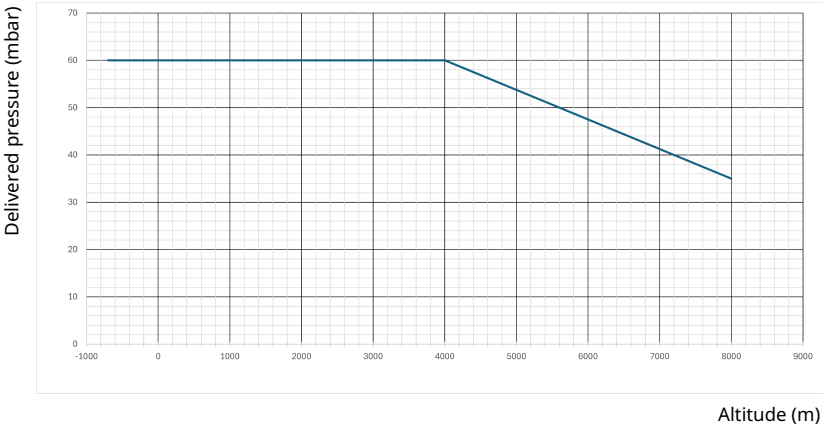


Table 12-3. Variations in maximum delivered pressure by altitude

Altitude (m)	Maximum delivered pressure (mbar)
0	60
4000	60
5000	54
6000	47
7000	41
8000	35

12.3 Pneumatic specifications

Table 12-4. Pneumatic specifications

Component	Specifications	
High-pressure oxygen inlet[1]	Pressure:	2.8 to 6 bar / 41 to 87 psi
	Flow:	≤ 40 l/min (10 seconds average, according to ISO 80601-2-84)
	Peak flow at device input:	At least 120 l/min at 2.8 bar / 41 psi
	Connectors:	DISS (CGA 1240) or NIST O2-specific quick coupling
Air supply	Integrated blower	
Gas mixing system	Peak flow:	At least 215 l/min against ambient pressure (at sea level)
	Delivered pressure:	0 to 60 mbar (altitude < 4000 m) ≥ 30 mbar (altitude 4,000 m to < 8,000 m)
	Flow accuracy:	±20% or ±1 l/min (whichever is greater)
Inspiratory outlet (*To patient*)	Connector:	ISO 5356-1 (ID15/OD22 conical)
Air intake port	NATO-compliant standard thread, RD 40 x 1/7, EN 148-1	

[1] Measurement expressed in STPD (standard temperature and pressure, dry).

12.4 Electrical specifications

⚠ WARNING

Only use the original power cord provided with the HAMILTON-EM7 to connect the device to the primary power supply.

This section provides specifications for the HAMILTON-EM7 ventilator and power supply.

Table 12-5. Ventilator electrical specifications

Element	Specifications	
Input power	12 V DC to 28 V DC (total range: 10 V DC to 36 V DC)	
Max inlet power	10 A	
Power consumption	15 VA typical, 120 VA maximum	
Battery	Hamilton Medical provides a high-capacity battery.	
	Electrical specifications:	14.4 V DC, 6.8 Ah, 97.9 Wh
	Type:	Lithium-ion, supplied by Hamilton Medical only
	Recharge time:	While ventilator is connected to primary power, approximately 3 hours to recharge the battery at a temperature of 25°C.
	Storage:	−20°C to 50°C, ≤ 85% relative humidity. The storage location should be free from vibration, dust, direct sunlight, moisture, and corrosive gases, and with a recommended temperature range of −20°C to 25°C. Extended storage at temperatures above 40°C can degrade battery performance and life.

Element	Specifications	
Battery	Normal operating time:	Typically ≥ 6 hours. Operating times are measured with a fully charged battery, the blower in use, without CO2 monitoring or Bluetooth, and with the following settings[1]: Mode = PCV+, Rate = 20 b/min, ΔPcontrol = 10 mbar, I:E = 1:2, PEEP = 5 mbar, Trigger = 2, Oxygen = 30%, Vt = 500 ml, Temperature = 25°C (±3°C), Altitude = 940 mbar (±30 mbar) Approximate operating times under these conditions are as follows: • Display brightness = 80%: 7.5 hours • Display brightness = 20%: 9.0 hours This operating time applies to new, fully charged Li-ion batteries not exposed to extreme temperatures. The actual operating time depends on battery age and on how the battery is used and recharged.

[1] Laboratory Bonaduz

Table 12-6. HAMILTON-EM7 AC/DC external power adapter specifications

Element	Specifications	
Physical characteristics		
Weight		780 g (1.7 lb)
Dimensions	L x W x H	140 mm x 63 mm x 33 mm (5.50 in x 2.48 in x 1.29 in)
Type		DTM110PW240C8
Environmental requirements		
Temperature	Operation:	-20°C to 60°C (-4°F to 140°F) Derate linearly to 50% load from 40°C to 60°C Derate linearly to 80% load from 0°C to -20°C
	Shipment/storage:	-20°C to 85°C (-4°F to 185°F)
Altitude	Operation/shipment/ storage:	up to 5,000 m (16,400 ft)
Relative humidity		0% to 95% noncondensing
Ingress protection		IP41 (indoor use only)
Electrical specifications		
Input power		100 V AC to 240 V AC (total range: 90 V AC to 264 V AC)
Input frequency		50 Hz to 60 Hz (total range: 47 Hz to 63 Hz)
Output voltage		24 V DC
Power consumption (no load)		< 150 mW
Insulation class		Class II

12.5 Ventilation-related terminology

Table 12-7. Ventilation mode terminology comparison, Hamilton Medical ventilators and EN ISO 19223:2019

Hamilton Medical mode name	EN ISO 19223 mode terminology	Description
(S)CMV	A/C-VC	Synchronized controlled mandatory ventilation with volume control
SIMV	SIMV-VC\PS	Synchronized intermittent mandatory ventilation with volume control and pressure support
PCV+	A/C-PC	Synchronized pressure-controlled ventilation
DuoPAP	SIMV-PC\PS	Synchronized intermittent mandatory ventilation with synchronized termination pressure control, pressure support and ACAP[1]
SPONT	CSV-PS	Continuous spontaneous ventilation with pressure support
ASV	n/a	Synchronized intermittent mandatory ventilation with volume-targeted pressure control and pressure support
NIV	CSV-PS	Continuous spontaneous ventilation with pressure support
NIV-ST	SIMV-PC\PS	Synchronized intermittent mandatory ventilation with pressure control
CPAP	CPAP	Continuous positive airway pressure with ACAP[1]

[1] ACAP is defined as *assured constant airway pressure.*

Table 12-8. Control-related terminology comparison, Hamilton Medical ventilators and EN ISO 19223:2019

Hamilton Medical terminology	EN ISO 19223 terminology
ΔPsupport	Δp (support pressure)
ΔPcontrol	Δp (delta inspiratory pressure)
ΔPinsp	Δp
P high	BAP_H (baseline pressure high)
PEEP/CPAP	BAP (baseline pressure)
P-ramp	Rise time
Plimit	APL (adjustable pressure limit)
Vt	V_T (tidal volume)
MinVol	$\%V_M$ (minute volume in relation to ideal body weight)
Flow (in O2 therapy)	Continuous flow
Rate	Rate
TI	ti (inspiratory time)
I:E	I:E ratio
T high	t_H
Trigger	Trigger
ETS	Term'n Flow % (inspiratory termination flow or termination flow)

Table 12-9. Monitoring-related terminology comparison, Hamilton Medical ventilators and EN ISO 19223:2019

Hamilton Medical terminology	EN ISO 19223 terminology
PEEP/CPAP	PEEP
Paw	paw
Ppeak	Peak inspiratory pressure or peak pressure
Pplateau	Plateau inspiratory pressure or plateau pressure
Insp Flow	Peak inspiratory flow
Exp Flow	expiratory flow
ExpMinVol MinVol NIV	V_M (minute volume)
VTI	V_I
VTE	V_{TE}
VLeak	V_{TLeak} (airway leak)
fTotal	RRtot (total rate)
fSpont	RRspont (spontaneous rate)
I:E	I:E

12.6 Control settings

The following table provides control setting specifications. For details about the control settings, see Section 4.11. For details about CPR-related parameters, see Section 12.9.

Table 12-10. Control settings, ranges, and accuracy

Parameter or setting (unit)	Range	Factory default setting	Accuracy[1]
ETS[2,3] (%)	5–80	25 NIV, NIV-ST: 35	--
Flow[4] (l/min)	2–15[5]	15	±20% or ±1 l/min, whichever is greater
I:E	1:9–4:1	1:2	--
Min. ΔPinsp[6] (mbar)	5-15	5	±15% or ±3 mbar, whichever is greater
MinVol[6] (l/min)	0.2–41.7	Based on PBW	--
Oxygen (%)	21–100	60 O2 therapy: 60 CPR, RSI: 100	±5% ±10% if Oxygen 93 is used
P high (in DuoPAP) (mbar)	4–60	PEEP + 15	±15% or ±3 mbar, whichever is greater
Pat. height (cm)	*Adult:* 130–250 *Pediatric:* 58-150[7]	*Adult:* 174 *Pediatric:* 100	--
PBW[8] (kg)	5–139	--	--

[1] The stated accuracy includes the tolerance interval for each measurement.
[2] Expiratory trigger sensitivity, in % of inspiratory peak flow.
[3] When changing ventilation modes, the device uses the ETS value set in the previous mode, if available. If the previous mode did not use ETS, the device sets ETS to default values.
[4] Only for O2 therapy.
[5] In some markets, the maximum possible Flow setting may be different.
[6] Only in ASV mode.
[7] Limit may be different depending on configured Vt/PBW. See Table 12-14.
[8] PBW is calculated using height and sex for adult patients, and using height for pediatric patients.

Parameter or setting (unit)	Range	Factory default setting	Accuracy[1]
PEEP/CPAP (mbar)	0–30[2,3] CPAP: 4–30	5	±15% or ±3 mbar, whichever is greater
Plimit[4] (mbar)	20–60[5]	30	--
P-ramp	Slow Medium Fast	Fast	--
Rate[6] (b/min)	5–60[7] DuoPAP: 1–60[7]	35 (≤ 5.9 PBW) 30 (6.0–8.9 PBW) 25 (9.0–19.9 PBW) 20 (20–30 PBW) 17 (31–39 PBW) 15 (40–59 PBW) 12 (≥ 60 PBW)	±1
Sex (Adult only)	Male, Female	Male	--
T high (in DuoPAP)[8] (s)	0.1–40[9]	--	±0.01
TI max[10] (s)	0.5–3.0	1.5	±0.1
TI[8,11] (s)	0.1–11.8[9]	--	±0.1
Trigger[12]	1 (low effort), 2, 3 (high effort) (S)CMV, PCV+: 1, 2, 3, OFF	2	--
Vt/PBW (ml/kg)	5–12[13]	8	--

[1] The stated accuracy includes the tolerance interval for each measurement.
[2] Depending on the set ΔPsupport, the range may be different.
[3] In DuoPAP, depending on the set P high, the range may be different.
[4] Only in ASV mode.
[5] Depending on the set PEEP, the range may be different.
[6] Default setting derived from PBW.
[7] Depending on the set TI or T high, the range may be different.
[8] Default setting derived from PBW and I:E.
[9] Depending on the set Rate, the range may be different.
[10] Maximum inspiratory time for spontaneous breaths in NIV and NIV-ST modes.
[11] Only in NIV-ST, SIMV modes.
[12] Trigger is leak compensated.
[13] Limit may be different depending on configured patient height.

Parameter or setting (unit)	Range	Factory default setting	Accuracy[1]
Vt[2] (ml)	50–2000	Based on PBW and Vt/PBW	±20% or ±20 ml, whichever is greater
ΔPcontrol[3] (mbar)	5–60[4]	15	±15% or ±3 mbar, whichever is greater
ΔPinsp[5] (mbar)	5–60[4]	15 NIV-ST: 6	±15% or ±3 mbar, whichever is greater
ΔPsupport[6] (mbar)	0–60[4]	15 NIV: 6	±15% or ±3 mbar, whichever is greater

[1] The stated accuracy includes the tolerance interval for each measurement.
[2] Default setting derived from PBW.
[3] Control pressure, added to PEEP/CPAP.
[4] Depending on the set PEEP, the range may be different.
[5] Inspiratory pressure, added to PEEP/CPAP Only in ASV and NIV-ST modes.
[6] Pressure support, added to PEEP/CPAP.

12.7 Monitored parameters

Table 12-11 provides monitored parameter details. Table 12-12 lists the ranges of the real-time waveforms.

All patient-related volume and flow measurements are expressed in BTPS (body temperature and pressure saturated).

Pneumatic-related volume and flow measurements are expressed in STPD (standard temperature and pressure dry).

The monitored parameters displayed on the ventilator are rounded to the nearest whole number, when required.

Waveforms displayed on the ventilator are not filtered and represent the actual monitored values.

Table 12-11. Monitored parameters, ranges, and accuracy

Parameter (units)	Range	Accuracy[1]
Pressure		
PEEP/CPAP (mbar)	0–99	±2 mbar + 8% of the actual reading
Pmean (mbar)	0–99	±2 mbar + 8% of the actual reading
Ppeak (mbar)	0–99	±2 mbar + 8% of the actual reading
Pplateau (mbar)	0–99	±2 mbar + 8% of the actual reading
Flow		
Insp Flow (l/min)	0–260	±20% or ±1 l/min, whichever is greater
Exp Flow (l/min)	0–120	±20% or ±1 l/min, whichever is greater
Flow[2] (l/min)	0–100	--

[1] The stated accuracy includes the tolerance interval for each measurement, except for measurements displayed from external sensors (CO2). See Section 12.12.1 for details.
[2] Only for O2 therapy.

Parameter (units)	Range	Accuracy[1]
Volume		
ExpMinVol[2] MinVol NIV[3] (l/min)	0–99.9	±20% or ±1 l/min, whichever is greater
VTE[2] VTE NIV[3] (ml)	0–9000	±20% or ±20 ml, whichever is greater
VTI (ml)	0–9000	±20% or ±20 ml, whichever is greater
VLeak (%)	0–100	±20%
Vt/PBW (ml/kg)	2-20	--
Time		
I:E	9.9:1–1:99	--
fSpont (b/min)	0–999	±1 b/min
fTotal (b/min)	0–999	±1 b/min
Other calculated and displayed parameters		
O2 consumption (in STPD) (l/min)	0–300	±20% or ±1 l/min, whichever is greater
CPR timer (minutes:seconds)	0–999:59	--
RSI apnea timer (minutes:seconds)	0–99:59	--
RSI preoxygenation timer (minutes:seconds)	0–99:99	--

[1] The stated accuracy includes the tolerance interval for each measurement, except for measurements displayed from external sensors (CO2). See Section 12.12.1 for details.
[2] Only for invasive modes.
[3] Only for use with noninvasive modes.
[4] CO2 option required.

Parameter (units)	Range	Accuracy[1]
CO2 related[2]		
PetCO2 (mmHg)	0–150	CO2 (BTPS): 0–40 mmHg: ±2 mmHg 41–70 mmHg: ±5% of reading 71–100 mmHg: ±8% of reading 101–150 mmHg: ±10% of reading

Table 12-12. Real-time waveforms

Parameter	Range	Y-axis scale
All waveforms show time, in seconds, on the x-axis. The x-axis scale is 0 to 12 seconds.		
Volume[3] / time (ml/s)	0 to 3200	0–100, 0–200, 0–400, 0–800 (*default*), 0–1600, 0–3200
Flow[3] / time (l/min/s)	-400 to 400	±15, ±25, ±45, ±75 (*default*), ±150, ±300
Airway pressure (Paw) / time (mbar/s)	-10 to 120	0–10 to 0–120 in steps of 10, -10–40 (*default*)
PCO2[4] / time (mmHg/s)	0 to 150	0–60 (*default*), 0–100

[1] The stated accuracy includes the tolerance interval for each measurement, except for measurements displayed from external sensors (CO2). See Section 12.12.1 for details.
[2] CO2 option required.
[3] Scaled automatically. Not leak compensated.
[4] Available with the CO2 option.

12.8 Alarms

The following table provides alarm specifications. For details about the alarms, see Section 7.4.

Table 12-13. Adjustable alarm priority, range, defaults, and resolution

Alarm (units)	Priority	Range	Factory default setting	Resolution
Apnea time (s)	High	5–60	20	5
ExpMinVol (high)[1] (l/min)	High	0.1–50 / OFF	Based on Rate and Vt 1.5 * Rate * Vt ASV: 1.5 * MinVol	0.1 (< 1) 0.5 (≥ 1) 1 (≥ 10)
ExpMinVol (low)[1] (l/min)	High	OFF / 0.1–50	Based on Rate and Vt 0.6 * Rate * Vt ASV: 0.6 * MinVol	0.1 (< 1) 0.5 (≥ 1) 1 (≥ 10)
fTotal (high) (b/min)	Medium	1–99	40	1
fTotal (low) (b/min)	Medium	OFF / 1–98	OFF	1
PetCO2 (high)[2] (mmHg)	Medium	11–100 / OFF	60	1
PetCO2 (low)[2] (mmHg)	Medium	OFF / 10–99	30	1
Pressure (high) (mbar)	High	30–70[3]	40 CPAP: PEEP + 30	1
Pressure (low) (mbar)	High	4–35	PEEP − 1	1

[1] Default setting derived from PBW.
[2] CO2 option required.
[3] Depending on the pressure control settings, the range may be different.

Alarm (units)	Priority	Range	Factory default setting	Resolution
Vt (high) (ml)	Medium	50–2000 / OFF	Vt is based on PBW 20 ml per kg PBW	5 (< 100) 10 (< 500) 50 (≥ 500)
Vt (low) (ml)	Medium	OFF / 10–2000	Vt is based on PBW 0.5 * Vt	5 (< 100) 10 (< 500) 50 (≥ 500)

12.9 Configuration

Table 12-14. Configuration specifications

Parameter	Configuration options/units	Factory default setting
General		
Units	Pressure: mbar, cmH2O, hPa	mbar
	Length: cm, inch	cm
	CO2: mmHg, Torr, kPa	mmHg
O2 enrichment	Oxygen (%)	100
	Duration (seconds)	120
Available modes	Invasive: (S)CMV, SIMV, ASV, PCV+, DuoPAP, SPONT	(S)CMV, PCV+, ASV
	Noninvasive: CPAP, NIV, NIV-ST	CPAP
Date & Time	YYYY-MM-DD	--
	HH:MM	--
Language	Chinese, Croatian, Czech, Danish, Dutch, English, US English, Finnish, French, German, Greek, Hungarian, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Turkish, Ukrainian	English
Connectivity	Com module update, Import configuration, Export configuration, Reset pairings, Delete recorded data, Factory reset	--
Service options	Software update	--
Screen lock	Timeout (seconds)	120
Alarms	Min. loudness	1
Configuration	Export, Import, Factory reset	--
SW options	Add options, Clear options	--

Parameter	Configuration options/units	Factory default setting
Adult/Pediatric		
General	Patient height, Adult (cm) Patient height, Pediatric (cm)	Adult: 174 Pediatric: 100
	Vt/PBW (ml/kg)	8
	PEEP (mbar)	5
	Oxygen (%)	60
Default mode[1]	Noninvasive: NIV, NIV-ST, CPAP	CPAP
	Invasive: (S)CMV, SIMV, ASV, PCV+, DuoPAP, SPONT	(S)CMV
Alarms	Apnea time (s)	20
	Pressure, high (mbar)	40
	fTotal, high (b/min)	40
	fTotal, low (b/min)	OFF
	PetCO2, high (mmHg)	60
	PetCO2, low (mmHg)	30
CPR	See the CPR tables in this section.	
O2 therapy[2]	Flow (l/min)	15
	Oxygen (%)	60
RSI settings	Oxygen (%)	100
ASV	Min. ΔPinsp (mbar)	5

[1] Only modes that have been selected in General > Available modes are available for selection.
[2] If option is installed.

Table 12-15. CPR factory default settings, adult/pediatric patients

Parameter	(S)CMV	PCV+
Mode	X[1]	--
Oxygen (%)	100	100
Vt/PBW[2] (ml/kg)	Based on the Vt/PBW set in Configuration	
ΔPcontrol (mbar)	--	*Adult:* 15 *Pediatric:* 25
Rate (b/min)	*Adult:* 10 *Pediatric:* 20	*Adult:* 10 *Pediatric:* 20
PEEP (mbar)	5	5
I:E	*Adult:* 1:5 *Pediatric:* 1:3	*Adult:* 1:5 *Pediatric:* 1:3
P-ramp[3]	Fast	Fast
Trigger[3]	Off	Off

[1] Unless a different default mode is set in Configuration.
[2] Vt is calculated based on the Vt/kg setting and the patient's PBW.
[3] Setting is *not* adjustable.

Table 12-16. CPR ventilation modes and settings, adult/pediatric patients

Mode or parameter (Unit of measure)	Factory default setting for adult patients	Factory default setting for pediatric patients
Mode		
(S)CMV / PCV+	(S)CMV	(S)CMV
Adjustable controls *Values are set in Configuration and can be adjusted during CPR ventilation*		
Oxygen (%)	100	100
Vt/PBW (ml) *(S)CMV only*	6[1]	6[1]
ΔPcontrol (mbar) *PCV+ only*	25	25
Other settings *Values are set in Configuration; they cannot be adjusted during CPR ventilation*		
Rate (b/min)	10	20
PEEP (mbar)	5	5
I:E	1:5	1:3
Vt/PBW (ml/kg) *(S)CMV only*	6	6
P-ramp[2]	Fast	Fast
Trigger[2]	Off	Off

[1] Vt is calculated based on the Vt/kg setting and the patient's PBW.
[2] Setting is *not* adjustable.

12.10 ASV technical data

Table 12-17. ASV technical data

ASV-related data	Specifications
ASV-related operator settings	
MinVol	0.2 l/min to 41.7 l/min
Patient height	*Adults:* 130 to 250 cm / 50 to 100 in *Pediatric:* 58 to 150 cm / 23 to 60 in
Internal calculations	
PBW	In kg, calculated based on patient height and sex (see Section 4.3)
MinVol (target)	In l/min, target minute volume is calculated as: PBW (in kg) x NormMinVent (in l/kg/min) = MinVol where NormMinVent is the normal minute ventilation. See Figure 5-14 in Section 5.7.6.1.
ΔPinsp	In mbar
Alarms	
All alarms are functional	See Chapter 7
Special	ASV: Cannot meet target and Pressure limitation alarms
Performance specifications	
Response time (90% of steady state)	< 1 min (typical)
Overshoot/undershoot	< 25%
Maximum pressure change	During initialization: 8 mbar
	Per breath: 3 mbar
Settling time	< 120 seconds
Steady state deviation	< 10%

ASV-related data	Specifications
Lung-protective rules	
Minimum Vt	Whichever is greater: (4.4 ml/kg x PBW) or 50 ml
Maximum Vt	The maximum tidal volume in ASV is the smallest value of the following conditions: • Median compliance of the last 6 breaths x (Plimit – PEEP) • 15 ml/kg x PBW • 1.5 x Vt (high) alarm limit
Maximum machine rate	The maximum rate in ASV is the smallest value of the following conditions: • 1 / (minimum inspiratory time + minimum expiratory time) • MinVol / Minimum Vt
Minimum target rate	8 to 15 b/min (depending on PBW)
Minimum ΔPinsp	Configurable setting. See Table 12-14.
Maximum ΔPinsp	Plimit – PEEP
Minimum inspiratory time (TI)	0.5 seconds or RCexp, whichever is longer
Maximum inspiratory time (TI)	PBW ≥ 30 kg: 2 seconds PBW < 30 kg: 1.5 seconds
Minimum expiratory time (Te)	0.5 seconds or 2 x RCexp, whichever is longer
Maximum expiratory time (Te)	12 seconds
I:E range	1:4 to 1:1

12.11 Ventilator breathing system specifications

For information about breathing circuit set specifications, see the *Instructions for use* for the breathing circuit set.

12.12 Technical performance data

The following table specifies the range of conditions used to verify device performance.

Table 12-18. HAMILTON-EM7 device performance

Setting	Specification
Minimum pressure setting conditions	
Compliance	3 ml/mbar
Resistance	50 mbar x $(l/s)^{-1}$
Inspiratory pressure (ΔP)	25 mbar
Intended tidal volume	50 ml
Respiratory rate	20 b/min
I:E ratio	1:4
FiO2	60%
BAP	5 mbar
Maximum pressure setting conditions	
Compliance	30 ml/mbar
Resistance	5 mbar x $(l/s)^{-1}$
Inspiratory pressure (ΔP)	60 mbar
Respiratory rate	10 b/min
I:E ratio	1:2
FiO2	90%
BAP	0 mbar
Minimum volume setting conditions	
Compliance	3 ml/mbar
Resistance	50 mbar x $(l/s)^{-1}$
Tidal volume	50 ml
Respiratory rate	20 b/min
I:E ratio	1:4
FiO2	60%
BAP	5 mbar
Maximum volume setting conditions	
Compliance	50 ml/mbar
Resistance	5 mbar x $(l/s)^{-1}$
Tidal volume	2000 ml
Respiratory rate	10 b/min
I:E ratio	1:2
FiO2	90%
BAP	10 mbar

Table 12-19. Technical performance data

Description	Specification
Patient predicted body weight (PBW, determined from Patient height setting)	5 to 139 kg (11 to 306 lb)[1]
Inspiratory pressure	4 to 60 mbar
Maximum inspiratory peak flow	> 215 l/min
Tidal volume/target tidal volume	50 to 2000 ml
Maximum inspiratory time (spontaneous breaths)	0.5 to 3 seconds
Means of inspiratory triggering	Combined flow and pressure trigger
Oxygen mixer accuracy	±5% ±10% if Oxygen 93 is used

[1] Actual patient weight can be much greater (e.g., 300 kg or 661 lb).

Description	Specification	
Measuring devices		
Pressure and volume measurements	Type:	Differential pressure transducer, variable orifice
	Sensing position:	Patient Y-piece
	Measurements:	See Table 12-11
CO2 measurement	CO2 sensor	
	Type: CAPNOSTAT 5	
	Sensing position:	Mainstream
	Principle of operation:	Nondispersive infrared (NDIR) technology
	Measurements:	See Table 12-11
	Rise time:	< 60 ms
	Initialization time:	Capnogram displayed in < 15 seconds at an ambient temperature of 25°C, full specifications within 2 minutes
	Sampling frequency:	100 Hz
	CO2 calculation method:	BTPS
	CO2 stability[1]:	Short-term drift: ≤ 0.8 mmHg over 4 hours Long-term drift: Accuracy specification maintained over 120 hours
	CO2 accuracy:	0–40 mmHg ± 2 mmHg 41–70 mmHg ± 5% of reading 71–100 mmHg ± 8% of reading 101–150 mmHg ± 10% of reading Temperature at 35°C. No degradation due to respiration rate or I:E ratio.
	CO2 noise (rms):	≤ 0.25 mmHg at 7.5% CO2

[1] Neither humidity (noncondensing) nor cyclical pressures have any effect on the stated accuracy of the device.

Description	Specification	
CO2 measurement	Operating conditions[1]:	Temperature: 0°C to 45°C (32°F to 113°F) Humidity: 10% to 90% relative humidity, noncondensing Pressure (barometric + airway pressure): 400 mmHg to 850 mmHg
	Shipment/storage conditions:	Temperature: -40°C to 70°C (-40°F to 158°F) Humidity: < 90% relative humidity, noncondensing Pressure (atmospheric): 375 mmHg to 795 mmHg
Tests and special functions	Preoperational check/CO2 sensor zero calibration[2], O2 enrichment, leak compensation, CO2 sensor port, compensation of breathing circuit resistance and compliance	
Display device	Display of settings, alarms, and monitored data *Type:* Color TFT *Size:* 640 x 480 pixels, 5.7 in (144.8 mm) diagonal	
Brightness setting for display	The range is 10% to 100% brightness. By default, Day = 80%; Night = 40%.	
Brightness with NVG option	The range is 1 to 10. The default is 5.	

[1] The stated operating conditions apply to both continuous and transient operation of the sensor within the limitations specified in the Intended use.
[2] Zero calibration may not be successful at 0°C or if the temperature is not stable. If the zero calibration fails, try again in a warmer environment with stable temperatures.

Description	Specification
Other	
Alarm loudness (volume)	The range is 1 to 10. The default is 8.
Alarm sound pressure level[1]	Minimum alarm volume (set to 1): (48 ±2) dB(A) Maximum alarm volume (set to 10): (63 ±2) dB(A)
Sound power level[1]	≤ 60 dB(A)
Sound pressure level[1]	≤ 50 dB(A)
Lifetime	10 years lifetime of the device with approximately 11,500 hours use time. Measured with fully charged battery with the following settings: Mode = PCV+, Rate = 20 b/min, ΔPcontrol = 15 mbar, I:E = 1:2, PEEP = 10 mbar, Trigger sensitivity = OFF, Oxygen = 60%, P-ramp = Medium, Brightness = 80%, Compliance = 50 ml/hPa (±10%), Resistance = 5 hPa/l/s (±10%)

[1] Measured according to ISO 3744:2010, positions as in Table B.2 of the standard.

12.12.1 Accuracy testing

The ventilator's parameter and measurement accuracy is tested using a Fluke VT900A Gas Flow Analyzer. The tolerance intervals for the data generated by the Gas Flow Analyzer are as specified below.

A k-factor of 2 as measurement uncertainty applies to all tolerances.

Table 12-20. Tolerance intervals for accuracy testing

Parameter type	Tolerance interval of measurement
Volume	> 50 ml: ±1.75%
Pressure	±0.75% or ±0.1 mbar, whichever is greater
Flow	±1.75% or ±0.5 l/min, whichever is greater
O2	±1%

12.12.2 Essential performance

Table 12-21. Essential performance requirements fulfilled by the HAMILTON-EM7 ventilator

Component	Requirement
System recovery	Following a malfunction, the EMS ventilator shall attempt to perform a system recovery to restore essential performance of the EMS ventilator. The system recovery time is 10 seconds.
Oxygen supply failure	O2 supply failure must be detected and the operator informed.
CO2 level alarm condition[1]	If CO2 is higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.
Pressure	The airway pressure must be monitored within disclosed tolerances. If it is higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.
Volume	The expired volumes must be monitored within disclosed tolerances. If they are higher or lower than the set alarm limits, this must be detected and the operator informed through an alarm.

[1] If the CO2 option is installed.

Component	Requirement
Electrical power supply failure	An electrical supply failure must be detected and the operator informed.
Internal electrical power source nears depletion	The remaining battery capacity must be monitored and qualitatively indicated. An escalating technical alarm condition shall indicate when the internal electrical power source nears depletion, prior to the loss of all power at least five (5) minutes prior to depletion.

12.12.3 Applied parts

Table 12-22. Applied parts according to IEC 60601-1

Part	Description
Applied parts	
Type BF	CO2 sensor and airway adapter
Type BF	HAMILTON-EM7 mesh nebulizer
Treated as applied parts	
Type BF	The proximal 30 cm of the HAMILTON-EM7 breathing circuit sets

12.12.4 Detachable parts

The HAMILTON-EM7 uses the following detachable parts:

- External power adapter
- CO2 sensor
- Breathing circuit set
- Battery
- Dust filter
- HEPA inlet filter

12.13 Biocompatibility information

The materials used in this product, including all known components, have no known toxicological effects or other adverse effects on the patient according to the current state of science and technology. This assessment is based on available data on biocompatibility in accordance with ISO 18562-2 and ISO 18562-3.

12.14 Residual risks

Residual risks related to the use of the HAMILTON-EM7 ventilator and its dedicated HAMILTON-EM7 breathing circuit set are analyzed and assessed in the following sections.

For details about ...	See ...
Risks related to gas delivery and circuit integrity	Section 12.14.1
Risks related to thermal and environmental stress	Section 12.14.2
Risks related to patient monitoring and alarms	Section 12.14.3
Risks related to biocompatibility and alarms	Section 12.14.4

Conclusions are presented in Section 12.14.5.

12.14.1 Risks related to gas delivery and circuit integrity

Disconnection or leakage of circuit components

Even with secure latching and bonded components, inadvertent disconnection or micro-leakage at connection points remains a low-probability risk.

In transport settings, patient movement or mechanical stress during transfer may exacerbate this possibility.

Potential consequences: Hypoventilation, loss of PEEP, alarms, desaturation

Mitigation: Redundant visual and auditory alarms, rigorous validation of circuit durability, operator training, and single-use design to ensure mechanical integrity

Condensate accumulation and incorrect humidification

Breathing circuit sets may accumulate condensate, particularly in variable ambient temperatures or suboptimal handling. Incorrect use of passive humidifiers or improper routing of circuits may impair humidification.

Potential consequences: Airway occlusion, thermal injury, increased infection risk

Mitigation: Clear instructions for use (provided in this *Operator's Manual*), optimized design to reduce condensate pooling, and compatibility with humidification accessories

12.14.2 Risks related to thermal and environmental stress

High gas temperature due to environmental exposure

Although the ventilator is designed to operate in extreme environments, residual risk remains if the device or breathing circuit tubing is exposed to excessive heat (for example, prolonged sunlight in enclosed transport).

Potential consequences: Thermal airway injury, mucosal damage, reduced mucociliary clearance

Mitigation: Thermally resistant circuit materials, device temperature monitoring, guidance in the *HAMILTON-EM7 Operator's Manual* (this guide) and the *HAMILTON-EM7 Breathing circuit set Instructions for use* regarding transport and storage conditions

12.14.3 Risks associated with patient monitoring and alarms

Alarm oversight or suppression in high-noise environments

During helicopter or field transport, ambient noise may mask audio alarms or distract from visual alerts. This is especially critical during apnea, circuit disconnection, or power failure scenarios.

Potential consequences: Delay in intervention, hypoxemia, ventilator-associated complications

Mitigation: Prioritization of high-severity alarms, persistent visual indicators, redundancy in alarm logic with acoustic and visual alarms as required

Non-recognition of breathing irregularities in pediatric patients (ASV mode)

Due to irregular respiratory drive (for example, Cheyne-Stokes) or high leak conditions (for example, broncho-pleural fistula), the ASV mode may not perform optimally in certain pediatric patients.

Potential consequences: Inadequate ventilation, missed detection of deterioration

Mitigation: Device default to manual modes, contraindication presented in the *HAMILTON-EM7 Operator's manual* (this guide), explicit safety messages in the *HAMILTON-EM7 Operator's manual* (this guide)

12.14.4 Risks related to biocompatibility and contamination

Hypersensitivity to biocompatible materials

Despite compliance with ISO 10993-1:2018 and ISO 18562 standards, there remains a rare possibility of patient sensitivity or allergic reaction to materials within the breathing gas pathway.

Potential consequences: Local airway irritation, bronchospasm, systemic allergic reaction.

Mitigation: Certified biocompatibility testing, post-market surveillance, labeling

Single-use deviation: Reprocessing of breathing circuit sets

Improper reuse or sterilization of breathing circuit sets could result in degradation, contamination, or loss of mechanical integrity.

Potential consequences: Cross-infection, increased resistance, component failure

Mitigation: Clear single-use labeling, *Instructions for use* safety messages, staff training protocols

12.14.5 Conclusion

The HAMILTON-EM7 ventilator and HAMILTON-EM7 breathing circuit sets provide substantial clinical benefits in their intended role as emergency and transport ventilatory support systems. Regardless of location, this system enables the delivery of advanced respiratory care in environments where standard ICU ventilators may be unavailable or impractical.

The HAMILTON-EM7 breathing circuit sets are specifically intended to provide positive pressure ventilatory support in conjunction with the HAMILTON-EM7 ventilator. Their design integrates several key safety and usability features that mitigate common operational risks: the circuits are preassembled, require no manual assembly, and are easy to use, reducing the likelihood of setup errors under stress. Furthermore, the mandatory use of heat and moisture exchange filters enhances infection control and maintains adequate humidification, which is especially critical during extended transports and in vulnerable patient populations.

The combined system's strengths, including versatile ventilation modes, portability, and specialized emergency features, empower clinicians to initiate or maintain life-saving ventilation in difficult conditions.

The ventilator's robust construction, battery-powered operation, integrated air supply, and intuitive interface further support dependable performance when every second counts. While some risks are inherent to emergency and transport ventilation, these are addressed through device design, visual and acoustic alarms, and comprehensive user documentation. Built-in safeguards include automatic adaptation to ambient conditions, alerts for system faults, and fallback to ambient air ventilation if oxygen supply is lost. Use is also limited to trained healthcare professionals under the direct supervision of a licensed physician, further reducing the likelihood of operator-related errors.

By adhering to recommended operational protocols, the residual risks are manageable and outweighed by the significant clinical benefits.

In conclusion, when used as intended, within specified environmental limits, and with careful attention to alarms and device indicators, the HAMILTON-EM7 ventilator and HAMILTON-EM7 breathing circuit sets demonstrate a favorable benefit-risk profile. Their ability to extend critical respiratory support across pre-hospital, intrahospital, and transport scenarios represents a vital contribution to the continuum of emergency and intensive care.

12.15 Functional description of ventilator system

The HAMILTON-EM7 is an electronically controlled pneumatic ventilation system with an integrated air compressing system. It runs on battery power and can be charged by AC (via power supply), or DC power. The ventilator's pneumatics deliver a respiratory gas mixture, and its electrical system controls the pneumatics, monitors alarms, and distributes power.

The user provides inputs to the HAMILTON-EM7 microprocessor system through a touch screen, keys, and a press-and-turn knob. Through the microprocessor system, these inputs become instructions for the HAMILTON-EM7's pneumatics to deliver a precisely controlled gas mixture to the patient. The ventilator receives inputs from the proximal flow sensor and other sensors within the ventilator. Based on this sensor data, the ventilator monitors and adjusts gas delivery to the patient. Monitored data is also displayed by the graphical user interface.

A comprehensive system of visual and audible alarms helps ensure the patient's safety. Clinical alarms indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests including ongoing background checks, indicate a hardware or software failure.

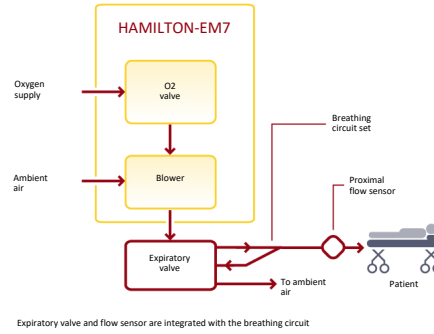
When a condition is critical enough to possibly compromise safe ventilation, the HAMILTON-EM7 is placed into the Ambient state. The inspiratory channel and expiration valve are opened, letting the patient inhale ambient air through both the inspiratory gas path and the expiration valve. Expiration is permitted through the expiration valve.

The HAMILTON-EM7 has several means to ensure that safe respiratory pressures are maintained. The maximum working pressure is ensured by the Pressure (high) alarm limit.
If the set high pressure limit is reached, the ventilator cycles into exhalation.
The maximum operator-set pressure is 60 mbar.

12.15.1 Gas supply and delivery

The HAMILTON-EM7 uses ambient air and high-pressure oxygen (Figure 12-4). Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Oxygen enters through a high-pressure inlet[1].

Figure 12-4. Gas delivery in the HAMILTON-EM7



[1] High-pressure oxygen: Maximum allowed pressure is 6 bar (600 kPa).

Within the ventilator, oxygen enters the pneumatic system through the O2 high pressure inlet. The valve in the high-pressure gas path (O2 valve) provides the correct oxygen flow to achieve the operator-set oxygen concentration. Oxygen consumption is monitored by the Q O2 flow sensor. The correct oxygen concentration is achieved by combining the flow data coming from the Q O2 and Q vent flow sensors. For the pneumatic diagram, see Section 12.15.3.

During ventilation, the blower creates the breathing pattern according to the user settings. It uses the measured data from the internal flow sensor (Q vent) and from the pressure sensors (P vent control and P aw), which respectively measure the pressure in the gas path and at the patient connection port. The pressure monitoring sensor (P vent monitor) also measures the pressure in the gas path; its data is used for protective purposes.

The proximal flow sensor, an accessory which is connected to the proximal end of the breathing circuit set, is used for proximal (near patient) flow (Q aw) and pressure (P aw) measurements, which are needed for monitoring purposes.

The two pressure lines (tubes) of the proximal flow sensor are connected to the ventilator through the flow sensor pressure plug at the flow sensor connection ports. The pressure sensor (P flow sensor) measures the differential pressure in the proximal flow sensor, which is used to calculate the proximal flow (Q aw).

One of the two pressure lines also provides a proximal pressure measurement (P aw), through the dedicated pressure sensor. Overall, measurements taken at the proximal flow sensor are used as pressure, flow, and volume data for patient monitoring purposes.

A continuous flow rate (rinse flow) in the flow sensor pressure lines is provided by the rinse flow tank to avoid back-contamination of the ventilator.

The inspiratory and expiratory gas path through the single limb breathing circuit is separated by a septum / wall. In the expiratory valve, the inspiratory and expiratory gas flow is also separated by construction.

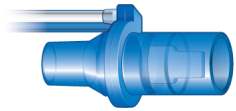
During inspiration, the inspiratory gas passes an open non-return check valve and flows through inspiratory half of the breathing circuit and flow sensor to the patient.

During expiration, the exhaled gas passes through the expiratory half of the breathing circuit to the expiratory valve. The expiratory membrane is opened, allowing venting into the environment.

The positive end-expiratory pressure PEEP is measured and controlled by the pressure sensor (P aw). The non-return check valve is closed during expiration to ensure the exhaled gas is vented without coming into contact with any internal components of the HAMILTON-EM7 ventilator.

12.15.2 Gas monitoring with the flow sensor

Figure 12-5. Flow sensor, illustrated

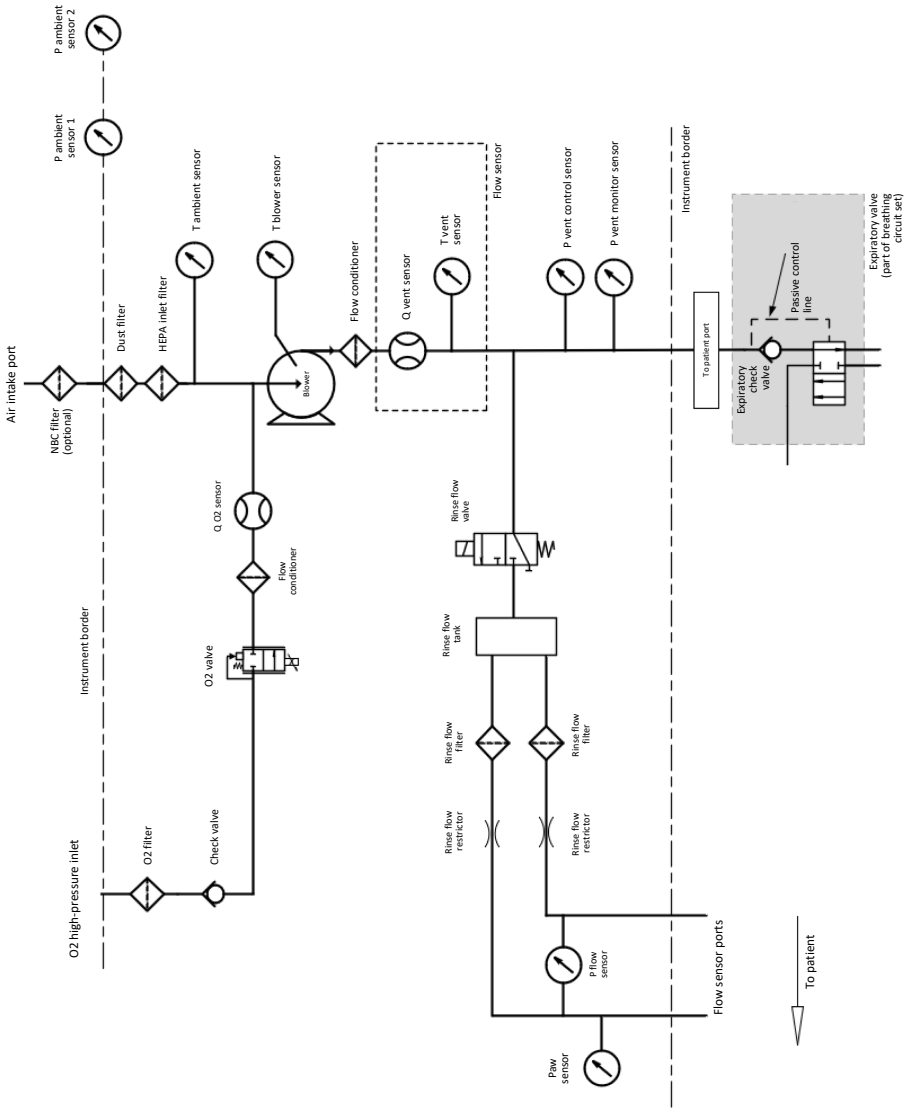


The HAMILTON-EM7 accurately measures flow, volume, and pressure in the patient's airway with the Hamilton Medical flow sensor. This proximal flow sensor lets the ventilator sense even weak patient breathing efforts.

The flow sensor contains a thin membrane affixed to the outer housing and has a pressure port on either side of this membrane. The membrane allows bidirectional flow through its variable orifice.

The area of the orifice changes depending on the flow rate. It opens progressively as the flow increases, creating a pressure drop across the orifice. The pressure difference is measured by a high-precision differential pressure sensor inside the ventilator. The pressure difference varies with flow (relationship determined during flow sensor calibration), so the patient's flow is determined from the pressure drop. The ventilator calculates volume from the flow measurements.

12.15.3 Pneumatic diagram



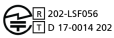
12.16 Symbols used on device labels and packaging

Table 12-23. Symbols used on device, device labels, and packaging

Symbol	Definition
	CPR key
	Power/Standby key
	Brightness (Day/Night) key
	Audio pause key
	Battery status indicator
	Flow sensor connection ports
CO_2	CO2 connection port
	Caution
	Type BF applied part with defibrillation protection
12 – 28 V DC	DC power connection
90% – 100% O2	External gas source port
	Refer to the operator's manual for complete information.

Symbol	Definition
	Gas output port (*To patient* port)
	Bayonet lock (on side cover); twist locking ring counter-clockwise to unlock, clock-wise to lock
	USB port and warning for electrical connection
WARNING: Air intake – Do not obstruct!	Removable cover and locking ring / Air intake filter cover
	Alarm Off
	Manufacturer
EU REP	Authorized representative in the European Community/ European Union
MD	Medical device
REF	Part number
SN	Serial number
	Date of manufacture
UDI	Unique device identifier
	GS1/UDI code

Symbol	Definition
CE 0197	Conformity with Medical Device Regulation (EU) 2017/745
IP54	Protected from water spray from any direction, and from limited dust ingress
	Temperature limitations at transport and storage
	Humidity limitations at transport and storage
	Atmospheric pressure limitations at transport and storage
	Indicates the degree of protection against electric shock according to IEC 60601-1. Class II devices have double or reinforced insulation, as they have no provision for protective grounding.
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment)
	The TÜV NRTL mark with the indicators “C“ and “US“ means that the product complies with Canadian requirements and the requirements of US authorities for safety.
	The HAMILTON-EM7 poses unacceptable risks to the patient, medical staff, or other persons within the MRI environment.

Symbol	Definition
	Hot surface
	The RCM (Regulatory Compliance Mark) indicates a device’s compliance with applicable ACMA (Australian Communications and Media Authority) technical standards for telecommunications, radio communications, or broadcasting equipment.
	Federal Communications Commission (FCC) Licensing
	UK importer
	*Japan only*. Ministry of Internal Affairs and Communications Approval Label
	Chinese RoHS
	Certification and Accreditation Administration of the People’s Republic of China (CNCA) Applicable for Wireless LAN products.

12.17 Disposal and year of manufacture

Disposal

The device must be disposed of according to your institution's protocols and Directive 2012/19/EU.

All parts removed from the device must be considered contaminated, and pose infection risk.

Dispose of all parts removed from the device according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection, especially when disposing of the electronic device or parts of it (for example, batteries).

Year of manufacture

The year of manufacture is shown on the serial number label on the HAMILTON-EM7 ventilation unit.

12.18 Warranty

LIMITED WARRANTY

THE WARRANTY DESCRIBED IN THIS AGREEMENT IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. HOWEVER, IMPLIED WARRANTIES ARE NOT DISCLAIMED DURING THE PERIOD OF THIS LIMITED WARRANTY.

Hamilton Medical guarantees its products to be shipped free from defects in material and workmanship.

The warranty does not include disposable items. Disposable items and consumable products are considered to be of single use or of limited use only and must be replaced regularly as required for proper operation of the product following the operator's manual.

Hamilton Medical shall have no obligations nor liabilities in connection with the product other than what is specified herein, including without limitation, obligations and/ or liabilities for alleged negligence, or for strict liability.

In no event shall the company be liable for incidental or consequential damages, either direct or contingent.

This Limited Warranty shall be void and not apply:

1. If the product has not been installed and connected by an authorized local representative of Hamilton Medical in accordance with the instructions furnished by Hamilton Medical and by a Hamilton Medical representative.
2. If replacements and/or repairs have not been performed by authorized or properly trained personnel.
3. If no evidence is present that the occurrence of damage/ repair happened within the certified warranty period.
4. If the serial number has been altered, effaced or removed and there is no bill of sale or evidence to verify the product's purchase date.
5. If the defects arise from misuse, negligence, or accidents or from repair, adjustment, modification or replacement made outside Hamilton Medical's factories or other than an authorized service center or authorized service representative.
6. If the product has been modified, or in any nature altered without prior written authorization from Hamilton Medical.
7. If the preventative maintenance schedule according to Table 9-3 in the *Operator's Manual* is not performed.
8. If the product is or has been used in any way that is not specified under "Intended Use" (see Section 1.2).
9. If the product has been used by anyone but properly trained personnel under the supervision of a physician. Replacements and/or repairs furnished under this Limited Warranty do not carry a new warranty, but carry only the unexpired portion of the original Limited Warranty. The warranty of repaired and/or replaced components does not exceed the Limited Warranty of the device.

To obtain service under this Limited Warranty, claimant must promptly notify the country's sales partner of Hamilton Medical regarding the nature of the problem, serial number and the date of purchase of the Product.

Except as stated above, Hamilton Medical shall not be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages. Nor will Hamilton Medical be liable for any damages, claims or liabilities including, but not limited to, personal bodily injury, or incidental, consequential, or special damages resulting from misuse of the device or failure to comply with any of the provisions made in this manual.

The general terms and conditions of Hamilton Medical shall be applicable. This agreement shall be governed by and construed in accordance with the laws of Switzerland and may be enforced by either party under the jurisdiction of the court of Chur, Switzerland.

(S)CMV
Synchronized controlled mandatory ventilation, a ventilation mode

alarm lamp
Lamp on top of the ventilator that lights in the color corresponding to the active alarm

ASV
Adaptive support ventilation mode. ASV adjusts pressure and rate on a breath-by-breath basis, taking into account changing patient conditions and applying lung-protective strategies to meet the targets

b/min
Breaths per minute

backup
Apnea backup ventilation

backup buzzer
A buzzer that sounds for at least 2 minutes in certain conditions; also functions as a backup for the ventilator loudspeaker

breathing circuit set
Breathing limbs and components used to deliver respiratory gases to the patient

CPAP mode
Continuous positive airway pressure, a noninvasive mode.

CPR ventilation
CPR ventilation allows you to continue respiration during the administration of cardiopulmonary resuscitation.

DuoPAP
Duo positive airway pressure, a ventilation mode

EMC
Electromagnetic compatibility

EMI
Electromagnetic interference

ET tube
Endotracheal tube. Tube inserted into the patient airway, used in invasive ventilation, to deliver breathing gas from the ventilator.

ETS
Expiratory trigger sensitivity is the percent of peak inspiratory flow at which the ventilator cycles from inspiration to exhalation. Increasing the ETS setting results in a shorter inspiratory time. The ETS setting lets you match the inspiratory time of pressure-supported breaths to the patient´s neural timing.

event log
A record of clinically relevant ventilator occurrences, including alarms, settings changes, calibrations, maneuvers, and special function uses that have occurred since the ventilator was turned on

Exp Flow
Peak expiratory flow, a monitored parameter

ExpMinVol
Expiratory minute volume, a monitored parameter and alarm setting.

f
Respiratory rate

fSpont
Patient-initiated breath frequency, a monitored parameter

fTotal
Total breathing frequency, a monitored parameter and alarm setting

Hamilton Connect Module (HCM)
A communication processor that is integrated with the therapy device and related software. It permits communication with other devices using supported wireless connection types.

HPO
High-pressure oxygen

I:E
Ratio of inspiratory time to expiratory time, a setting, timing parameter, and monitored parameter

ID
Inner diameter

Insp Flow
Peak inspiratory flow, a monitored parameter

inspiratory pressure
The total inspiratory pressure to be applied during ventilation. In some modes, this is the sum of the pressure control + PEEP/CPAP

IRV
Inverse ratio ventilation: the set expiratory time is less than the inspiratory time

MinVol (l/min)
Minute volume in liters per minute. A control parameter used in ASV mode.

NIV
Noninvasive ventilation, a ventilation mode

NIV-ST
Spontaneous/timed noninvasive ventilation, a ventilation mode

NPPV
Noninvasive positive pressure ventilation

OD
Outer diameter

P high
High pressure in DuoPAP mode

PaCO2
Partial pressure of carbon dioxide in arterial blood

Pat. height
Patient height; a control setting used to compute the patient's predicted body weight (PBW) in calculations for ASV and startup settings

PCV+
Pressure controlled ventilation, a ventilation mode

PEEP/CPAP
PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure), a control setting and monitored parameter; PEEP and CPAP are constant pressures applied during both the inspiratory and expiratory phases

PetCO2
Partial pressure of end-tidal CO2, the measure of CO2 present in the exhaled air

Plimit
Maximum pressure to apply during ventilation with ASV; a control setting

Pmean
Mean airway pressure, a monitored parameter

Ppeak
Peak airway pressure, a monitored parameter

Pplateau
Plateau or end-inspiratory pressure, a monitored parameter

P-ramp
Pressure ramp, a control setting

pressure control
Maintenance of a consistent transrespiratory pressure waveform despite changing respiratory system mechanics

Rate
Breath frequency or number of breaths per minute, a control setting

RCexp
Expiratory time constant, a monitored parameter

ROSC
Return of spontaneous circulation, the resumption of cardiac activity after cardiac arrest. During CPR ventilation, touching this button stops CPR ventilation and starts ventilation using the default invasive mode.

Sex
Sex of patient, a control setting

SIMV
Synchronized intermittent mandatory ventilation, a ventilation mode

SPONT
Spontaneous (pressure support) mode of ventilation, a ventilation mode

Standby
The ventilator is in a waiting state; there is no breath delivery

STPD
Standard temperature and pressure, dry; pressure of 101,325 kPa at a temperature of 20°C (68°F), dry

T high
Set time interval for the high pressure level in DuoPAP mode

technical fault
A type of alarm generated when the ventilator's ability to safely ventilate the patient may be at risk

TI
Inspiratory time, a control setting and monitored parameter

TI max
Maximum inspiratory time, a control setting

touch screen
The glass portion of the monitor that you touch to interact with the display elements

VLeak
Leakage percent, a monitored parameter

Vt
Tidal volume; a control setting and alarm setting

Vt/PBW
Tidal volume calculated according to predicted body weight, used for adult/pediatric patients; a monitored parameter and a configuration parameter

VTE
Expiratory tidal volume, a monitored parameter; it is the integral of all negative flow measurements during exhalation

VTI
Inspiratory tidal volume, a monitored parameter

ΔPcontrol
Pressure control, a control setting valid during mandatory breaths; pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase

ΔPinsp
Inspiratory pressure, the target pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase. Set by the operator in the NIV-ST mode, set by the ventilator in ASV.

ΔPsupport
Pressure support, a control setting valid during spontaneous breaths. ΔPsupport is pressure (additional to PEEP/CPAP) to be applied during the inspiratory phase.

Icons

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More information and free software simulation:
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