HAMILTON-HF90

Operator's Manual

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HAMILTON MEDICAL

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Preface 11
Chapter 1 Safety information 15
1.1 Overview 16
1.2 Intended use, indications and contraindications for use 17
1.3 Electromagnetic susceptibility safety information 19
1.4 Electrical power and batteries safety information 20
1.5 Fire and other hazards safety information 21
1.6 Setup and operation safety information 21
1.6.1 Setup and operation safety information 22
1.6.2 Gas supply safety information 24
1.6.3 USB ports safety information 25
1.7 Setting up for therapy safety information 25
1.7.1 Breathing circuit set, humidification chamber, and patient interface safety information 25
1.7.2 Device/breathing circuit placement safety information 26
1.7.3 Nebulization safety information 27
1.8 Delivering therapy safety information 27
1.9 Monitoring and alarms safety information 28
1.10 Using the trolley safety information 28
1.10.1 Room-to-room transport safety information 29
1.10.2 Transporting the patient safety information 29
1.11 Maintenance safety information 30
1.12 Service and testing safety information 32
Chapter 2 System overview 33
2.1 Overview 34
2.1.1 Standard features and options 34
2.2 Physical descriptions 36
2.2.1 About the therapy device 36
2.2.2 About the patient breathing circuit sets 37

2.2.3 About the trolley 38
2.2.4 About the main display 39
2.3 Navigating the windows and controls 40
2.3.1 Navigating the windows and menus 40
2.3.2 Adjusting settings and controls 41
2.3.3 Selecting list items 41
2.3.4 Icons and shortcuts on the display 41
Chapter 3 Preparing the HAMILTON-HF90 for use 43
3.1 Overview 44
3.2 Connecting to a power source 44
3.2.1 Using battery power 45
3.3 Connecting the oxygen supply 47
3.3.1 Selecting the oxygen source type 47
3.4 About the patient groups 48
3.5 Setting up the patient breathing circuit set 48
3.5.1 Positioning of the breathing circuit set and device 51
3.6 Turning the device on and off 51
3.7 Working with the battery 52
3.7.1 Removing the battery bay cover 52
3.7.2 Connecting/removing the Li-ion rechargeable battery 53
3.8 Preparing for patient transport 55
3.8.1 Preparing the trolley for transport within the hospital 56
3.8.2 Attaching/removing the device from the trolley 57
3.9 Setting up nebulization 58
3.10 Connecting to external devices 59

Chapter 4 Working with the HAMILTON-HF90 61
4.1 Overview 62
4.2 Starting therapy and specifying settings 62
4.2.1 Adjusting settings 64
4.2.2 Setting alarm limits 64
4.2.3 Pausing the therapy 67
4.2.4 Unlocking the display 68
4.2.5 Operating the device on battery power 69
4.3 Monitoring therapy 69
4.3.1 Overview 70
4.3.2 Setting up SpO2 monitoring 70
4.3.3 Working with trend graphs 71
4.3.4 About the monitored parameters 73
4.4 Device settings and functions 74
4.4.1 Oxygen enrichment 74
4.4.2 Working with O2 assist 75
4.4.3 Working with a nebulizer 75
4.4.4 Calibrating the O2 sensor 77
4.4.5 Adjusting display options 77
4.4.6 About the Event log 78
4.4.7 Viewing device-specific information 79
4.5 Ending therapy 79
Chapter 5 Responding to alarms 81
5.1 Overview 82
5.2 Alarm limit indicators 84
5.3 Responding to an alarm 84
5.4 Temporarily silencing an alarm 85
5.5 Accessing on-screen troubleshooting help 85

5.6 Turning off (deactivating) an alarm 86
5.7 Adjusting alarm loudness 87
5.8 Troubleshooting alarms 88
5.9 Testing alarms 99
5.9.1 Testing the obstruction alarm 99
Chapter 6 Maintenance 101
6.1 Overview 102
6.2 About cleaning and disinfecting the device and components 102
6.2.1 Surface cleaning and disinfection (validated processing instructions) 103
6.3 Cleaning and replacement schedule 107
6.4 Replacing components 108
6.4.1 Placing the protective cap on the gas outlet adapter 108
6.4.2 Replacing the filters 108
6.5 Repacking and shipping 109
Chapter 7 Extended configuration 111
7.1 Overview 112
7.2 Accessing Extended configuration 112
7.3 Selecting the default language 112
7.4 Configuring the default therapy settings 113
7.5 Setting the maximum available Flow (neonatal/pediatric) 113
7.6 Configuring oxygen enrichment settings 113
7.7 Selecting an SpO2 sensor type 114
7.8 Configuring O2 assist default settings 114
7.9 Configuring device options 114
7.9.1 Adding software options 115
7.9.2 Removing software options 115

7.10 Copying configuration settings 116
7.11 Restoring the factory default settings 116
Chapter 8 Parts and accessories 117
8.1 Overview 118
Chapter 9 Specifications 121
9.1 Potential complications and residual risks 122
9.1.1 Risks associated with inadequate heating and humidification 122
9.1.2 Risks associated with the reliability and accuracy of pulse oximetry sensors 124
9.1.3 Risks associated with a too-low inspired oxygen fraction 124
9.1.4 Risks associated with an excessive (too high) inspired oxygen fraction 125
9.1.5 Conclusion 126
9.2 Physical characteristics 127
9.3 Environmental requirements 128
9.4 Pneumatic specifications 129
9.5 Electrical specifications 130
9.6 Control settings 132
9.7 Monitored parameters 133
9.8 Alarms 134
9.9 Configuration 135
9.10 Technical performance data 136
9.11 Essential performance 139
9.12 Applied parts 140
9.13 Functional description 140
9.13.1 Gas supply and delivery 141
9.13.2 Pneumatic diagram 142

9.14 Symbols used on device and trolley labels and packaging 143
9.15 Standards and approvals 145
9.16 Disposal and year of manufacture 146
9.17 Warranty 146
Index 149

HAMILTON-HF90 Documentation

Table 1. HAMILTON-HF90 documentation suite

Document title	Description
Operator's Manual (this guide)	Provides detailed information about the setup and use of the HAMILTON-HF90.
Pulse Oximetry Instructions for Use	Provides setup and use information for using SpO2 and related sensors with the therapy device.[1]
O2 assist Instructions for Use	Provides setup and use information for therapy using the O2 assist option.[1]
Communication Interface User Guide	Provides an overview of the communication interface, including how to connect the therapy device to external devices for data communication and support for nurse call remote alarms.[1]
Breathing circuit set Instructions for Use	Provides setup and use information for the HAMILTON-HF90 breathing circuit sets.
HAMILTON-HF90 Battery Quick Reference	Provides information about installing and removing the battery.
HAMILTON-HF90 Quick Guide	Provides quick reference information for delivering high flow oxygen therapy to adult, pediatric, and neonatal patients.
HAMILTON-HF90 Incubator extension Quick Reference	Provides quick reference information for the Incubator extension
Service Manual	Provides information about installing and setting up the medical equipment, as well as additional technical and servicing information for the device.
EMC Declarations	Provides emissions and EMC-related safety and use information.

[1] If the option is installed.

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.

Be sure to read all relevant documentation, including safety information, before using the device or accessories. For the list of related Hamilton Medical documentation, see the *Documentation suite* table in the device *Operator's Manual*.

Conventions used in this guide

In this manual:

- High flow oxygen therapy is referred to as HFOT.
- Button names are shown in a **bold** font.
- The notation **XX** > **XX** shows the sequence of buttons to touch to open the associated window.

  For example, the text "Touch  > **System configuration**" means touch the  (**Settings**) button, then touch **System configuration**.

- *Software version:* The software version for the device is displayed in the System information window and should match the version on the title page of this manual.
- *Units of measure:* Pressure is generally indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). 1 cmH2O equals 0.981 mbar, which equals 0.981 hPa.
- All patient-related pressure, volume, and flow measurements are expressed in BTPS (body temperature and pressure saturated).
- The graphics shown may not exactly match what you see in your environment.
- The term *USB drive* refers to a passive USB memory device, also known as a USB flash drive or USB memory stick.
- Not all features are available in all markets.
- Product description and order number may differ depending on region.

Safety messages are displayed as follows:

⚠ WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

⚠ CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

⚠ WARNING!

⚠ CAUTION!

NOTICE!

1 Safety information

1.1 Overview 16
1.2 Intended use, indications and contraindications for use 17
1.3 Electromagnetic susceptibility safety information 19
1.4 Electrical power and batteries safety information 20
1.5 Fire and other hazards safety information 21
1.6 Setup and operation safety information 21
1.7 Setting up for therapy safety information 25
1.8 Delivering therapy safety information 27
1.9 Monitoring and alarms safety information 28
1.10 Using the trolley safety information 28
1.11 Maintenance safety information 30
1.12 Service and testing safety information 32

1.1 Overview

This section provides safety information related to setting up, operating, and servicing the HAMILTON-HF90. It is designed for use in conjunction with the detailed use information provided later in the manual.

Carefully review all parts of this safety section before setting up and using the device.

Be sure to review the Instructions for Use before using the device.

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

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

⚠ CAUTION

(USA only): Federal law restricts this device to sale by or on the order of a physician.

1.2 Intended use, indications and contraindications for use

Table 1-1. Intended use information for the HAMILTON-HF90 high flow therapy device

Category	Description
Intended purpose/use	The HAMILTON-HF90 is intended to provide a continuous flow of heated and humidified respiratory gases to spontaneously breathing patients.
Intended patient/target group	The HAMILTON-HF90 is intended to be used for neonatal, pediatric, and adult patients.
Intended user/user group	The HAMILTON-HF90 is a medical device intended for use by qualified, trained healthcare professionals under the direction of a physician and within the limits of its stated technical specifications.
Intended use environment	• Healthcare facilities • During transfer and mobilization of patients within healthcare facilities
Indications	Support of respiratory insufficiency and need of oxygen.
Contraindications	High flow oxygen therapy (HFOT) should not delay advanced airway management in a patient deemed to require immediate endotracheal intubation. This may include patients with need for airway protection. HFOT should also be avoided in the following conditions: • Choanal atresia • Central apnea
Limitations	None

Table 1-2. Intended use information for the HAMILTON-HF90 trolley

Category	Description
Intended purpose/use	The HAMILTON-HF90 trolley is intended for ensuring mobility of the HAMILTON-HF90 within healthcare facilities.
Intended patient/target group	Same as HAMILTON-HF90.
Intended user/user group	Same as HAMILTON-HF90.
Intended use environment	Same as HAMILTON-HF90.
Indications	Not applicable.
Contraindications	Not applicable.
Limitations	Not applicable.

1.3 Electromagnetic susceptibility safety information

⚠ WARNING

- **DO NOT DEFIBRILLATE a patient when they are connected to the HAMILTON-HF90.** Always disconnect the patient from the device, remove the oxygen mask or nasal cannula, and place the device and all components at least one (1) meter away from the defibrillation pads. The use of self-adhesive defibrillation pads, rather than manual paddles, may minimize the risk of sparks occurring.
- **MR UNSAFE**. Keep away from magnetic resonance imaging (MRI) equipment. The HAMILTON-HF90 poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
- Functioning of the therapy device may be impaired by the operation of high-frequency surgical equipment, microwaves, shortwaves, or strong magnetic fields in close proximity.
- To prevent increased emissions, decreased immunity, or interrupted operation of the HAMILTON-HF90 or any accessories, use only accessories or cables that are expressly stated in this manual or in the Hamilton Medical e-catalog.
- 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 may result in improper operation.
- Follow precautions for electrostatic discharge (ESD) and electromagnetic interference (EMI) to and from the therapy device and any connected devices and accessories.
- 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 device, including any cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment can occur.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11, class A). If it is used in a residential environment (for which CISPR 11, class B is normally required) this equipment might *not* offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

NOTICE

- The HAMILTON-HF90 requires special precautions regarding EMC (Electromagnetic Compatibility), and must be installed and put into service according to the EMC information provided in the *HAMILTON-HF90 EMC Declarations*.
- Portable and mobile RF communications equipment can affect the HAMILTON-HF90 and all medical electrical equipment.

1.4 Electrical power and batteries safety information

For details about power and battery use, see Sections 3.2 and 3.7.

⚠ WARNING

- The therapy device is *not* protected against the effects of the discharge of a cardiac defibrillator.
- The HAMILTON-HF90 does *not* require protective earth grounding, because it is a class II device, as classified according to IEC 60601-1.
- 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.
- Do *not* use if the power cord is damaged.
- Only use the original power cord provided with the HAMILTON-HF90 to connect the device to the primary power supply.
- Ensure the power cord does *not* come in contact with the heater plate.
- In case of power failure or disconnection from the primary power supply when *no* battery is connected, therapy stops and the device emits an audible whistling sound. Turn the device off immediately and check for correct voltage.
- Therapy stops if the battery is discharged or removed, and no external power supply is connected.
- To avoid disconnection of the power cable, ensure the power cord retaining clip on the device is used.
- Periodically check or replace the battery.
- Check the battery charge level before providing therapy to the patient and before unplugging the device for transport.[1]
- The battery will *not* charge if the ambient temperature is above 40°C.
- Do *not* connect the equipment to the battery of a battery-powered wheelchair unless the connection is listed in the *Instructions for Use* of the equipment or wheelchair, as this can compromise the equipment performance, which consequently can result in degradation of the health of the patient.

NOTICE

- Set up the device in a location where the primary power supply is accessible.
- Only authorized service personnel may replace the power cable.
- Battery life indications are approximate. The actual battery life depends on therapy settings, battery age, and level of battery charge. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.

[1] As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed *only* within the hospital. Transporting patients between healthcare facilities is NOT supported.

- After power has been interrupted, the device stores the last settings, including any specified alarm limits. Upon reconnection with the power supply, the device resumes therapy with these stored settings.
- Do *not* subject batteries to mechanical shock.
- Do *not* expose batteries to heat or fire. Avoid storage in direct sunlight.
- If the device is operating without a battery, it *must* be connected to a primary (AC) power supply.

1.5 Fire and other hazards safety information

For device use instructions, see Chapter 3 and later in this manual.

⚠ WARNING

- It is *not* permitted to use any of the equipment with flammable gases or anesthetic agents, or in insufficiently ventilated areas. Danger of fire!
- Do *not* use near open flames. Danger of fire!
- Turn off the device when *not* in use. Failure to do so increases the risk of fire.
- There is a risk of fire associated with oxygen enrichment during oxygen therapy. Do *not* use the equipment or accessories near sparks or open flames.
- It is *not* permitted to smoke when the device is in use.

  If the patient intends to smoke, they must do so in a different room or turn off the device for at least 10 minutes before smoking.
- It is *not* permitted to use the device with helium or mixtures of helium.
- Do *not* use the device with any equipment or high-pressure gas hoses that are worn or contaminated with oil or grease.
- Do not lubricate any part of the equipment to avoid the risk of fire.
- Highly compressed oxygen together with flammable sources can lead to spontaneous explosions.
- In case of fire, immediately secure the patient's therapy needs, turn off the device, and disconnect it from its gas and electrical sources.
- Do *not* use if primary power source cables are damaged.

1.6 Setup and operation safety information

This section provides safety information for the following topics:

- Setup and operation
- Gas supply
- USB ports

For device setup information, see Chapter 3. For device operation details, see Chapters 4 and 5.

1.6.1 Setup and operation safety information

For details about device set up and operation, see Chapters 3 – 4.3.

⚠ WARNING

- **The HAMILTON-HF90 is NOT supported for home use.** It can only be used as specified in the *Intended use* (Section 1.2).
- 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.
- The use of this equipment is restricted to one patient at a time.
- The high flow mode of this equipment is only suitable for a spontaneously breathing patient.
- Modifications to the device and any accessories are *not* permitted.
- Ensure the device is placed on a flat and level surface to avoid tipping and possible damage to equipment.

  If using the trolley, ensure the device is securely mounted to the trolley using the mounting bracket.
- Before using the device on the patient, verify that the breathing circuit set is correctly connected.
- Do *not* use the device at an altitude above 4,000 meters or outside an environmental temperature range of 18°C to 30°C. Using the therapy device above this altitude or outside of this temperature range can affect the quality of the therapy and/or harm the patient.
- Incorrect settings can harm the patient.
- Take additional precautions in case of allergic reactions.
- Regularly check the breathing circuit for condensation and drain it, if required.
- Device humidification performance may be negatively affected by the simultaneous use of a nebulizer.
- Do *not* touch the hot plate or the bottom of the humidification chamber. The surfaces can reach temperatures up to 90°C. These hot surfaces radiate heat.
- Use only parts and accessories specified in Chapter 8 and in the product e-catalog, or that are specified as being compatible with this device. Doing so ensures proper therapy delivery, avoids degraded performance, and keeps your warranty in force.
- Adding attachments or other parts/assemblies to the device that are not listed in the *Instructions for Use* can adversely affect device performance and may lead to patient injury.

- Only use the device and its components and accessories according to the intended use and as described in the associated *Instructions for Use*.
- The device must *not* be used in a hyperbaric chamber.
- Do *not* simultaneously touch conductive components (for example, the USB port) or conductive parts of the device enclosure and the patient.
- Regularly inspect the device. If there is damage to any part of the device, do *not* use it. Technical service is required.

  Ensure connected components are also undamaged.
- Use of the device with a gas source that heats the provided gas above 30°C can result in impaired humidification output with the potential to cause severe deterioration of patient health.

⚠ CAUTION

- *When the device is turned on, it **immediately starts delivering high flow oxygen therapy** and is set to the patient group of the connected breathing circuit set.*

  – If the patient group is the same as the previous therapy session, the device uses the previous Flow and Temperature settings.

  – If the patient group has changed, the device uses the default settings.
- *Check the breathing circuit set for damage prior to use. Discard it if there is any sign of damage.*
- *The heating element and heater wires are automatically turned on when the humidification chamber and breathing circuit are correctly mounted, and the device is turned on.*
- *If the ambient or gas inlet temperature, and/or flow rate is outside the recommended range, physiological humidity levels may not be achieved.*

NOTICE

- Turn off the device before disconnecting from primary power.
- To prevent possible patient injury, **do NOT block the openings on the sides of the device**. These openings are vents for the fresh air intake and the cooling fan.
- The device may be connected to a power source even if the Power key is not lit.
- A fine, breath-dependent condensation (fogging) forming in the limb or flex tube indicates that humidity is being produced properly.
- Replace the product in accordance with hospital infection control procedures, or depending on the patient's secretions and nebulization of medication.
- The device provides automatic barometric pressure compensation.
- 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.

1.6.2 Gas supply safety information

Connection information is provided in Section 3.3. Specifications are in provided in Section 9.4.

⚠ WARNING

- Only connect the HAMILTON-HF90 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 these *Instructions for Use* (Section 9.4), as this can affect the performance of the equipment or pipeline system, which can consequently result in serious deterioration of health.
- The use of O2 concentrators is *not* permitted.
- Do *not* connect nitric oxide to the oxygen inlet; it is *not* permitted to use the device with nitric oxide or mixtures of nitric oxide.

⚠ CAUTION

Always check the status of the oxygen cylinders before using the device during transport.

NOTICE

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

1.6.2.1 Low-pressure oxygen supply safety information

For information about working with a low-pressure oxygen supply, see Section 3.3.1.

⚠ WARNING

- Ensure the device is turned on prior to connecting the oxygen supply.
- Do not leave the LPO connector connected to the device without a connected gas hose. This causes leakage inside the gas path.
- Disconnect the low-pressure oxygen supply when *not* in use.

  Be sure to disconnect both the connector and the oxygen supply hose from the oxygen supply to prevent ambient air from entering the device through the LPO gas inlet.
- As this medical device uses an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures must be taken by the user to mitigate these reasonable foreseeable risks.

NOTICE

- Do *not* connect a low-pressure oxygen supply that provides greater than 60 l/min oxygen.
- The delivered oxygen concentration can be affected by adjustments to the flow and oxygen control settings.
- To prevent oxygen buildup in the device, be sure to do the following:

  – When therapy is stopped or paused, or the device is turned off, turn off the oxygen source.

  – When therapy is completed, fully disconnect the LPO connector from the inlet port.

1.6.3 USB ports safety information

⚠ WARNING

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

NOTICE

- You can only connect one item to the USB port at a time.
- The USB drive must be FAT32 formatted and USB 1.1 compatible.
- Only the following components are allowed to be connected to the USB port:

  – USB drive

  – Hamilton Medical approved accessories, including Aerogen nebulizer with standalone controller. For other supported accessories, see your authorized representative.

1.7 Setting up for therapy safety information

This section provides the following safety information:

- Breathing circuit set, humidification chamber, and patient interface
- Device and breathing circuit set positioning
- SpO2 monitoring setup and operation (refer to the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* PN 10116548)

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

1.7.1 Breathing circuit set, humidification chamber, and patient interface safety information

Patient interfaces are components, such as cannulas and masks, that connect the breathing circuit to the patient.

For information about connecting the breathing circuit set, see Section 3.5.

⚠ WARNING

- Check the breathing circuit set for damage prior to use. Discard the breathing circuit set if there is any sign of damage.
- Only fill the humidification chamber with sterile, demineralized water that meets the hospital's hygiene requirements.
- Only connect patients to interfaces (for example, nonocclusive high flow nasal cannula) that are intended for high flow oxygen therapy; these types of interfaces allow the patient to exhale.

- Do *not* add any drugs or medication directly to the water in the humidification chamber. If the HAMILTON-HF90 is used in combination with any medical gases or nebulized medications, follow the *Instructions for Use* of the supplied application and make sure that it is suitable for use with active humidification.
- Ensure the water level in the humidification chamber does *not* exceed the maximum fill level.

  Do *not* operate the therapy device if the water level exceeds the marked maximum.
- Ensure that all of the components of the breathing circuit set and other accessories match the associated intended use for the target patient group.
- Failure to correctly connect the breathing circuit to the therapy device can injure the patient.
- Do *not* tilt the therapy device.
- Adding attachments or other components/assemblies to a breathing circuit can change the pressure gradient across the device, which can adversely affect device performance.
- Ensure both air intakes have their respective filters in place. For details, see Figures 6-2 and 6-3 in Section 6.4.2.
- For each new patient, always use a new breathing circuit set to avoid cross contamination.

NOTICE

- If the device does not detect the breathing circuit, replace the components.
- The refill water should *not* be warmer than 37°C.
- Ensure that the water supply to the chamber is functioning properly.
- Replace the product in accordance with hospital infection control procedures, or depending on the patient's secretions and nebulization of medication.

1.7.2 Device/breathing circuit placement safety information

For breathing circuit set connection information, see Section 3.5.

For placement/positioning information, see Section 3.5.1.

⚠ WARNING

- The therapy device must *always* be positioned below patient level.
- Do *not* operate the device at an angle in excess of 5° relative to the floor.
- Be sure to route the breathing circuit without tension and without any kinks from the device to the patient.
- The breathing circuit set must *not* be covered by any objects, such as sheets, towels, and so on.

  Covering the breathing circuit can affect therapy quality and may lead to patient injury.

- If the device is used adjacent to, or stacked on other medical electrical equipment, verify the device's normal operation in the configuration in which it will be used.
- Place the breathing circuit in such a way that liquid condensate runs back into the humidification chamber, *not* toward the patient.
- Attach breathing circuits or tubing clips appropriately to avoid mechanical forces on the high flow interface.

⚠ CAUTION

- ***To prevent possible patient injury, do NOT block the openings on the sides of the device. These openings are vents for the fresh air intake and the cooling fan.***
- *Heated breathing limbs must NOT be placed directly on the patient's skin.*

NOTICE

- Ensure all of the components are securely connected to each other and to the device.
- Prior to use, ensure the stability of all connections.
- The limb connector on the device combines electrical connections with the breathing circuit connector. Ensure proper orientation of electrical contacts to match the connecting element on the device.
- Place the water supply at least ≥ 0.5 m above the device.

1.7.3 Nebulization safety information

For nebulizer use information, see Sections 3.9 and 4.4.3.

⚠ WARNING

- Nebulization of drugs can cause an occlusion and increased resistance at the patient interface. Check the patient interface frequently for increased resistance or blockage.
- Ensure the nebulizer port on the humidification chamber is closed properly when a nebulizer is not connected. Failure to do so may result in leakage and possible patient injury.

1.8 Delivering therapy safety information

For device setup and operation information, see Chapters 3 – 5.

⚠ WARNING

- To avoid the risk of suffocation or barotrauma, use the correct cannula size for the patient and ensure the cannula does *not* block the nares.
- Use only water-based lotions or salves that are oxygen compatible before and during oxygen therapy. Never use petroleum-based or oil-based lotions or salves to avoid the risk of fire and burns.

- It is the clinician's responsibility to ensure that all therapy settings are appropriate, even when "automatic" features or options, such as O2 assist, or default settings are used.
- To prevent possible patient injury, make sure the device is set up for the appropriate patient group with the appropriate breathing circuit components.
- Prolonged exposure to high oxygen concentrations may cause irreversible blindness and pulmonary fibrosis in preterm neonates. Be especially careful when performing oxygen enrichment.
- Additional independent monitoring devices, including pulse oximeters measuring SpO2, **must be used** during therapy. The operator of the device must still maintain full responsibility for proper therapy and patient safety in all situations.

1.9 Monitoring and alarms safety information

For information about monitoring therapy, see Chapter 4.3.

For information about working with alarms, see Chapter 5.

⚠ CAUTION

- *To prevent possible patient injury make sure the alarm limits are appropriately set before delivering therapy to the patient.*
- *To ensure that oxygen monitoring is always fully functional, calibrate the O2 sensor when indicated by the O2 sensor calibration needed alarm.*

NOTICE

- When an alarm is active, it is shown in the alarm message bar on the device display. In the case of multiple alarms, the alarm messages alternate in the message bar.
- Upon turning off the device, the alarm loudness returns to the default value.
- The use of an alarm monitoring system does *not* give absolute assurance of warning for every type of issue that may arise with the device. Alarm messages may *not* pinpoint a problem exactly; the exercise of clinical judgment is necessary.
- Do *not* pause the audible alarm when leaving the patient unattended.
- All technical alarms, detailed technical information, and maintenance procedures are described in the *HAMILTON-HF90 Service Manual*.

1.10 Using the trolley safety information

For information about working with the trolley, see Section 3.8.

As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed only within the hospital.

Transporting patients between healthcare facilities is NOT supported.

For the *Intended use*, see Section 1.2.

⚠ WARNING

- To prevent possible personal injury and equipment damage, including tipping:

  – Lock the trolley's wheels when parking the device.

  – Take care when crossing thresholds.
- To prevent accidental disconnection of the patient interface, check the patient tubing support arm joints and secure as necessary.

NOTICE

Check the battery charge level before providing therapy to the patient and before unplugging the device for transport.

1.10.1 Room-to-room transport safety information

⚠ WARNING

During transport (with a patient or room-to-room), the trolley must always be equipped with at least one oxygen cylinder, and the tubing support arm positioned at 90° angles (as shown in Figure 3-18).

1.10.2 Transporting the patient safety information

As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed only within the hospital.

Transporting patients between healthcare facilities is NOT supported.

For the *Intended use*, see Section 1.2.

For details about working with the trolley and patient transport, see Section 3.8.

⚠ WARNING

- Before transporting the patient, ensure an adequate oxygen supply by checking the O2 consumption parameter and ensuring it is adequate for your estimated travel time and current oxygen capacity. O2 consumption is shown at the top of the device display when the device is running on battery power.
- During transport (with a patient or room-to-room), the trolley must always be equipped with at least one oxygen cylinder, and the tubing support arm positioned at 90° angles (as shown in Figure 3-18).
- Check the battery charge level before providing therapy to the patient and before unplugging the device for transport.
- The therapy device must *always* be positioned below patient level.
- Use of additional items, such as a tubing support arm, can result in the trolley tipping over.
- Ensure the device is securely attached to the trolley before use.

NOTICE

- Ensure that the accessories used during transport are adequately protected against water ingress.
- Ensure the device power cord is available during transport in case you must connect to a primary power source.

1.11 Maintenance safety information

For detailed maintenance and cleaning information, see Chapter 6.

⚠ WARNING

- Before cleaning the device, be sure to cover the gas outlet adapter with the protective cap to prevent any inadvertent intrusion of fluids.
- 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.
- To reduce the risk of cross-contamination, regularly clean and replace the fan and air intake filters. For details, see Table 6-3 and Section 6.4.2.
- Hamilton Medical does *not* assume any liability for the proper functioning of single-use items if they are reprocessed and reused by the user.
- Follow the cleaning and disinfection procedures for each component as described in this guide and in the cleaning agent manufacturer's *Instructions for Use*.
- Always disconnect the device and any accessories from electrical power before cleaning and disinfection to reduce the risk of electric shock.
- Modifications to the device are *not* permitted.

⚠ CAUTION

- *Handle used breathing circuit sets and humidification chambers as contaminated goods according to local laws and regulations or hospital internal procedures.*
- *Do NOT attempt to sterilize the interior components of the device.*
- *Do NOT attempt to sterilize the entire device with ETO or ozone gas.*
- *Do NOT pour fluids onto the device surfaces. Intrusion of fluids, or immersing the HAMILTON-HF90 in fluids, will damage the device.*

- *Use only approved cleaning agents for cleaning and disinfection.*
- *Thoroughly wipe all patient or airway contact components with sterile or distilled water to ensure removal of residual cleaning/disinfection agents.*
- *To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material. Use only registered/approved cleaning and disinfection solutions, as approved by your institution's protocol, after each patient use, according to the cleaning agent manufacturer's recommendations.*
- *(USA only) To prevent premature deterioration of parts, make sure the disinfecting chemical is compatible with the part material. Use only EPA-registered/approved cleaning and disinfection solutions, as approved by your institution's protocol, after each patient use, according to the cleaning agent manufacturer's recommendations.*
- *Spraying electrical interfaces with disinfectant reduces the service life.*
- *To ensure proper servicing and to prevent possible physical injury, only Hamilton Medical authorized service personnel may service the therapy device, using information provided in the HAMILTON-HF90 Service Manual.*
- *Use only replacement parts supplied by Hamilton Medical.*
- *Do NOT attempt service procedures other than those specified in the HAMILTON-HF90 Service Manual.*
- *Do NOT use abrasives materials (for example, steel wool or silver polish), hard brushes, pointed instruments, or rough materials on surfaces.*
- *Cleaning and disinfection agent residues can cause blemishes or fine cracks.*

NOTICE

- For specific information on cleaning and disinfecting accessories and components, refer to the appropriate *Instructions for Use* provided with each part.
- 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.
- We recommend that you document all maintenance procedures.
- You are *not* allowed to perform service or maintenance on the device while a patient is connected.
- If an air intake filter is *not* used, the device must be considered contaminated and must be serviced.

1.12 Service and testing safety information

- Gas outlet replacement is performed by a service technician. Related information is provided in the *HAMILTON-HF90 Service Manual*.
- To ensure proper servicing and to prevent possible physical injury, only Hamilton Medical authorized service personnel may service the device using information provided in the *Service Manual*.
  In addition, all accessories and devices must only be serviced by Hamilton Medical authorized service personnel.
- The manufacturer can only be responsible for the safety, reliability, and performance of the device if all of the following requirements are met:
  - Appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications, maintenance, or repairs.
  - The electrical installation of the relevant room complies with the appropriate requirements.
  - The therapy device is used in accordance with the device *Operator's Manual*.
  - Do *not* attempt service procedures other than those specified in the device *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.
  - Reprocessing is performed by reprocessing 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 agents, disinfectants, and reprocessing devices.
- Any attempt to modify the device hardware or software without the express written approval of Hamilton Medical automatically voids all warranties and liabilities.

2
System overview

2.1 Overview 34
2.2 Physical descriptions 36
2.3 Navigating the windows and controls 40

2.1 Overview

⚠ WARNING

- **The HAMILTON-HF90 is NOT supported for home use.** It can only be used as specified in the *Intended use* (Section 1.2).
- **As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed only within the hospital. Transporting patients between healthcare facilities is NOT supported.**

The HAMILTON-HF90 therapy device provides high flow oxygen therapy for adult, pediatric, and neonatal patients.

It comprises the device housing, touch screen display, integrated blower, humidification chamber, heater plate, and electrical connections for a heated breathing circuit set.

It offers the following main features:

- Connection to high- or low-pressure oxygen
- Adjustable flow, temperature, and oxygen controls
- Real-time trends and numerical monitoring
- Alarms and on-screen troubleshooting help
- Configurable startup settings for each patient group
- Optional connections to SpO2 sensors and external data interfaces
- O2 assist option, providing automated adjustment of oxygen to regulate the patient's SpO2[1]
- Optional trolley and battery for transport of patients within the hospital

The intended position of the operator is directly facing whichever part/side of the device with which they are interacting.

2.1.1 Standard features and options

The HAMILTON-HF90 therapy device offers a robust set of standard equipment and features, as well as optional therapy modes and features for the supported patient groups.

The following table lists the standard software and hardware device configuration and options.

[1] Not available in all markets.

Table 2-1. Standard configuration and options

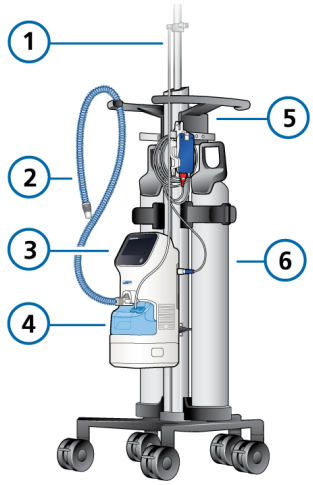
Function		HAMILTON-HF90
	Standard: X Option: O	
Standard software configuration and options		
Adult/Ped patient group		X
Neo/Ped patient group		X
On-screen help		X
O2 assist™ [1]		O
Standard hardware (equipment) configuration and options		
Trolley		O
Battery		O
Communication		
Communication boards	USB, Ethernet[2], Nurse call	O
	USB, Ethernet[2], SpO2, COM1 (RS-232)	O
	USB, Ethernet[2], SpO2, COM1 (RS-232), Nebulizer	O
Hamilton Block protocol		O

[1] Not available in all markets.
[2] The Ethernet port is for internal use only.

2.2 Physical descriptions

This section provides an overview of the therapy device, breathing circuit sets, and trolley.

Figure 2-1. HAMILTON-HF90 with accessories

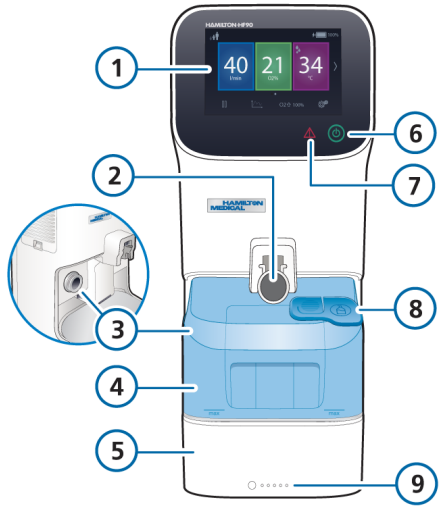


1	Water bag pole	4	Humidification chamber
2	Breathing circuit	5	Trolley
3	HAMILTON-HF90 therapy device	6	O2 cylinders

2.2.1 About the therapy device

Figures 2-2 and 2-3 provide an overview of the device.

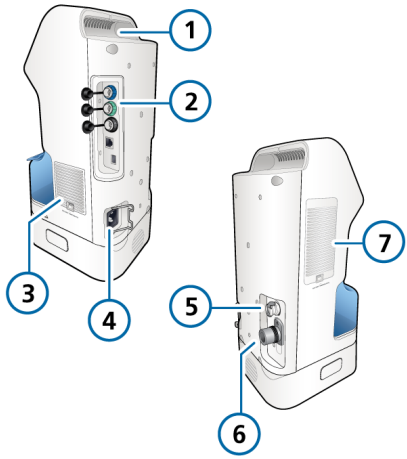
Figure 2-2. HAMILTON-HF90 front view



1	Touch screen display	6	Power button
2	Breathing circuit connection (inspiratory outlet to patient)	7	Caution indicator
3	Gas outlet adapter (behind humidification chamber)[1]	8	Nebulizer port
4	Humidification chamber[2]	9	Battery charge status indicator (see Section 3.2.1.1)
5	Battery		

[1] For maintenance details, see Section 6.3. Replacement is performed by trained hospital/service technicians.
[2] Only fill with sterile, demineralized water that meets your institution's hygiene requirements.

Figure 2-3. HAMILTON-HF90 rear and side view



1	Carrying handle	5	Low-pressure oxygen connector
2	Communication board	6	High-pressure oxygen DISS or NIST inlet fitting
3	Cooling air intake and dust filter	7	Breathing air intake and air intake filter[1]
4	Power socket		

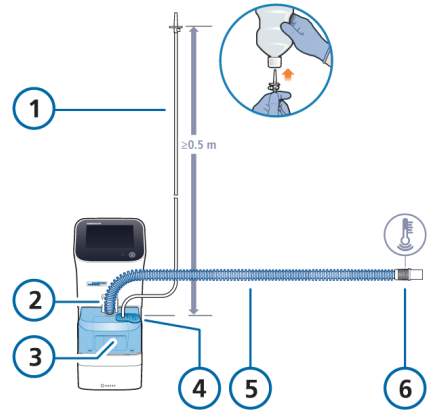
2.2.2 About the patient breathing circuit sets

The HAMILTON-HF90 high flow therapy device supports single limb breathing circuits for adult, pediatric, and neonatal patients.

For neonatal patients, an additional unheated inspiratory limb extension is available for use in an incubator (see Figure 2-5).

For details about connecting and setting up the breathing circuit, see Section 3.5.

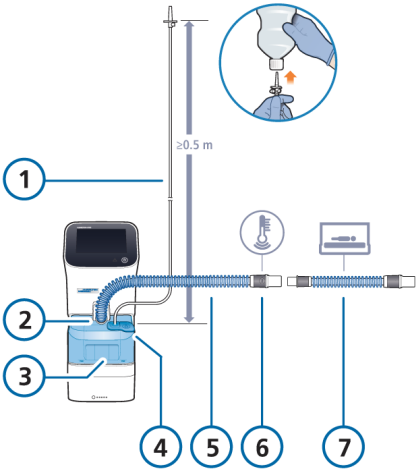
Figure 2-4. Breathing circuit set, single limb, adult/pediatric



1	Water feed line with spike	4	Nebulizer port
2	Connection to humidification chamber/device	5	Heated breathing circuit with temperature sensor
3	Humidification chamber	6	Connection to patient interface

[1] To prevent possible patient injury, do NOT block the openings on the sides of the device. These openings are vents for the fresh air intake and the cooling fan.

Figure 2-5. Breathing circuit set, single limb, neonatal/pediatric



1 Water feed line with spike

2 Connection to humidification chamber/device

3 Humidification chamber

4 Nebulizer port

5 Heated breathing circuit with temperature sensor

6 Connection to patient interface

7 (*Neonatal only*) Unheated inspiratory limb extension, for use in incubator

2.2.3 About the trolley

The HAMILTON-HF90 can optionally be ordered with a trolley solution. The trolley has space for up to three oxygen cylinders (see Figure 2-1).

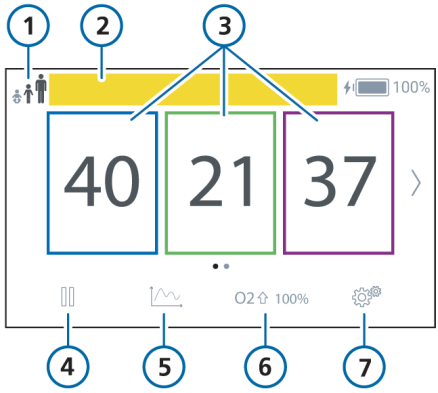
For details about using the trolley for transporting patients within the hospital, see Section 3.8.

2.2.4 About the main display

You can directly access settings, alarms, and controls on the main display while delivering therapy (Figures 2-6 and 2-7).

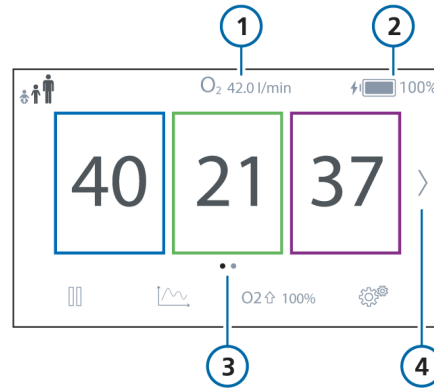
The main display shows the current control settings. The Extended view[1] (Figure 2-8) displays SpO2 monitoring data in addition to the current control settings.

Figure 2-6. Main display, part 1 (adult/pediatric patient group shown)



1 Patient group symbol
2 Alarm message bar (color coded)
3 Controls: Flow, Oxygen, and Temperature
4 Pause
5 Trends
6 Oxygen enrichment
7 Settings

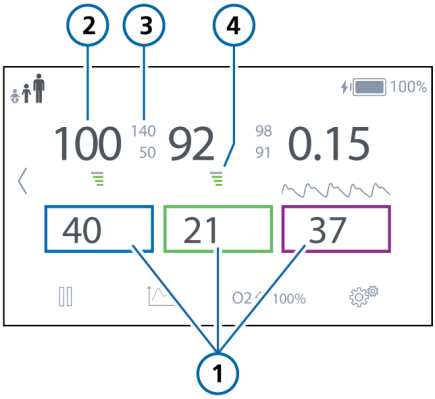
Figure 2-7. Main display, part 2 (adult/pediatric patient group shown)



1 Oxygen consumption[2]
2 Power source and battery status
3 Paging dots indicating number of pages (when available)
4 Navigation arrow, touch or swipe to access the Extended view (Figure 2-8)

[1] The Extended view is only available if the SpO2 option is installed.
[2] Only displayed when the device is running on battery power.

Figure 2-8. Extended view[1]



1	Controls	3	Upper/lower alarm limits
2	Monitored SpO2-related parameter (see Section 4.3)	4	Quality index

2.3 Navigating the windows and controls

Use the touch screen to access data and specify settings. You interact with the HAMILTON-HF90 user interface by touching elements on the display to open windows and make and confirm selections.

You can swipe left/right and up/down to access additional windows and menu items.

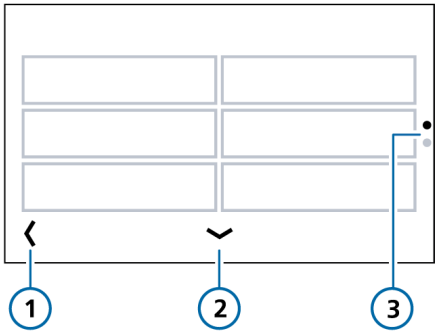
This section describes how to navigate the interface.

2.3.1 Navigating the windows and menus

Windows and settings can be found in the **Settings** menu ( ) and additional sub-menus.

Navigation arrows and dots on the display indicate when additional windows or menus are available (Figure 2-9). Swipe the screen or touch the arrow to access additional windows or menu items.

Figure 2-9. Navigating windows and menus on the display



1	Back arrow	3	Paging dots
2	Navigation arrow		

To open a window

1. Touch (**Settings**).
   The **Settings** menu is displayed.
2. Touch the button to open the desired window.

[1] The **Extended view** is only available if the SpO2 option is installed.

To close a window and return to the main display

1. If needed, touch 〈 at the bottom left-hand corner of the screen (Figure 2-9) to return to the **Settings** menu.
2. Touch ⌂ to return to the main display.

The main display is shown.

Note that after 2 minutes of inactivity, the device automatically returns to the main display and the screen is locked.

2.3.2 Adjusting settings and controls

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

To adjust a setting

1. Touch the control to select and activate it. For an example, see Figure 4-2
2. Adjust the value by doing any of the following:
   – To increase the setting, touch **+**.
   – To decrease the setting, touch **—**.
   – For some controls, you can hold the **+** or **—** button to adjust the setting by a larger increment.
   – If a slider is presented, you can touch and drag the slider to the desired value. For an example, see Figure 4-4.
3. Touch ✓ to confirm the setting.
   To cancel the setting change, touch **X**.

The new setting is immediately applied.

2.3.3 Selecting list items

Some selections are presented in a scrollable list. To scroll through the list, swipe up and down, or touch the up and down arrows.

To select a list item

1. In a list, touch the desired item to select and activate it.
2. Touch ✓ to confirm the selection.

2.3.4 Icons and shortcuts on the display

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

Table 2-2. Icons and shortcuts on the display

Touch icon/ shortcut on the display ...	To ...
	Unlock the display
	Access the **Settings** menu
	Show the main display
〈 XXX	Return to the previous menu where "XXX" is the name of the menu
〈 〉 ^ ⌄	Touch the arrow or swipe the display to access additional windows or menu items
	Pause therapy
	Access **Trends**

Touch icon/ shortcut on the display ...	To ...
O2⇧100%	Start O2 enrichment
STOP O2⇧	Stop O2 enrichment
	Open the **Nebulizer** window
	Silence the audible alarm (**Audio pause**)
+	Increase a setting
—	Decrease a setting
✓	Confirm the setting/ selection
×	Cancel the setting/ selection
Any monitored parameter in the **Extended** view	Open the **Alarm limits** window for that parameter

3 Preparing the HAMILTON-HF90 for use

3.1 Overview 44
3.2 Connecting to a power source 44
3.3 Connecting the oxygen supply 47
3.4 About the patient groups 48
3.5 Setting up the patient breathing circuit set 48
3.6 Turning the device on and off 51
3.7 Working with the battery 52
3.8 Preparing for patient transport 55
3.9 Setting up nebulization 58
3.10 Connecting to external devices 59

3.1 Overview

Preparing the high flow therapy device for use comprises the following steps:

To ...	See ...
Connect to a power source	Section 3.2
Connect the oxygen supply	Section 3.3
Set up the patient breathing circuit	Section 3.5
Turn on the device	Section 3.6
Prepare for transporting patients within the hospital	Section 3.8
Connect external devices	Section 3.10
Set up SpO2 monitoring	Section 4.3.2

3.2 Connecting to a power source

NOTICE

If the device is operating without a battery, it *must* be connected to a primary (AC) power supply.

Before proceeding, review the safety information in Chapter 1.

Always check the reliability of the primary power outlet before plugging in the device. The power icon (⚡) on the display indicates the device is plugged into primary power.

Furthermore, the battery status indicators on the battery itself provide information about the charge level of the battery, and indicate when the device is plugged in and the battery is charging. For details about the charge status indicators on the battery, see Section 3.2.1.1.

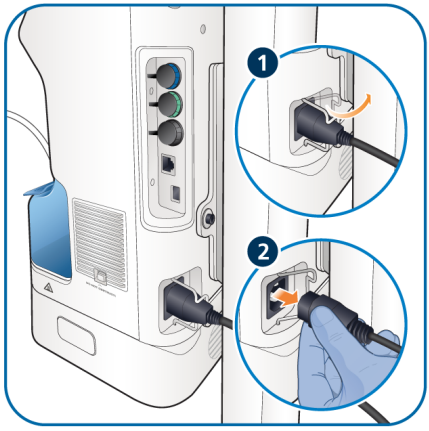
To connect the device to a primary power supply

- Connect the device to an outlet that supplies AC power.

  Make sure the power cord is well seated into the device socket and secured with the power cord retaining clip to prevent unintentional disconnection.

To disconnect the device from a primary power supply

Figure 3-1. Disconnect from primary power



3.2.1 Using battery power

An optional battery can be used when transporting patients within the hospital and to protect the device from low power or failure of the primary power source. For details about connecting or replacing the battery, see Section 3.7.2.

When the primary power source fails:

- If the optional battery is connected, the device automatically switches to operation on backup battery with no interruption in therapy. An alarm sounds to signal the switch-over. For details about operating the device on battery power, see Section 4.2.5.

  Silence the alarm to confirm notification of the power system change and reset the alarm.
- If no battery is connected or battery power is completely lost, the Total power loss technical fault is generated. A buzzer sounds continuously for at least two (2) minutes and the Caution indicator on the front of the device blinks (Figure 2-2 in Section 2.2.1). For details, see Table 5-2.

  Connect the device to primary power or install a charged battery.

The battery is charged whenever the device is connected to primary power, whether or not it is turned on. An optional battery charger is also available.

The battery indicator on the display (Figure 3-2) shows the charge status of the battery. See Table 3-1.

For details about the charge status indicators on the battery, see Section 3.2.1.1.

Figure 3-2. Power source indicators on the display

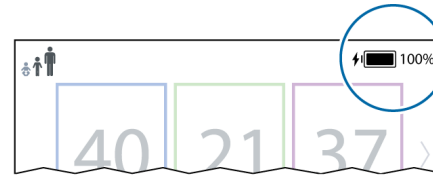


Table 3-1. Battery/power state shown on the HAMILTON-HF90 display

Power icon on display	Battery status
	When is displayed, the device is plugged into primary power and the battery is charging.
	Device is running on battery power and battery charge is greater than 50%.
	Device is running on battery power and battery charge is between 25% and 50%.
	Device is running on battery power and battery has less than 25% charge remaining.
	The device is plugged into primary power; no battery is connected.

If the battery is not fully charged, recharge it by connecting the device to primary power. For details about the electrical specifications, see Section 9.5.

3.2.1.1 About the charge status indicators on the battery

Lights on the front of the battery indicate the current battery charge level (Figure 3-3).

To check the battery charge status

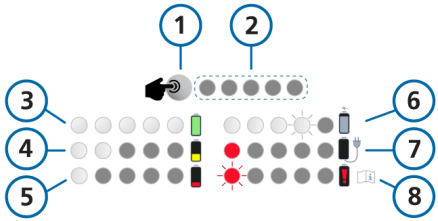
- Press the button on the battery (Figure 2-2 in Section 2.2.1).

  The indicators light and provide information about the charge status of the battery (Figure 3-3).

  Each indicator represents 20% of the charge level.

  The legend on the battery tells you what the current charge status is.

Figure 3-3. Charge status indicators on the battery



1	Indicator light button (press to check battery charge status)	5	Battery charge is below 20%
2	Indicator lights Each indicator represents 20% of the charge level.	6	Battery is charging
3	Five (5) lit indicators represent a charge level between 80% and 100%	7	Charge is critically low, connect to primary power
4	Battery charge is between 20% and 40%	8	Battery defective

3.3 Connecting the oxygen supply

Before proceeding, review the safety information in Chapter 1.

Oxygen for the HAMILTON-HF90 can be provided by a high- or low-pressure source.

High-pressure oxygen, provided by a central gas supply or a gas cylinder, is supplied through DISS or NIST male gas fittings. With the optional trolley, you can mount up to three oxygen cylinders. If you use gases from the cylinder, secure the cylinder to the trolley with the accompanying straps.

Low-pressure oxygen is provided by a liquid cylinder.

The selected setting is active until manually changed.

To connect the oxygen supply to the device

1. If applicable, remove the protective cap from the oxygen inlet.
2. Connect the oxygen hose to the HAMILTON-HF90's high-pressure or low-pressure oxygen inlet fitting (Figure 2-3 in Section 2.2.1).

See Section 3.3.1 for details on selecting the oxygen source on the device.

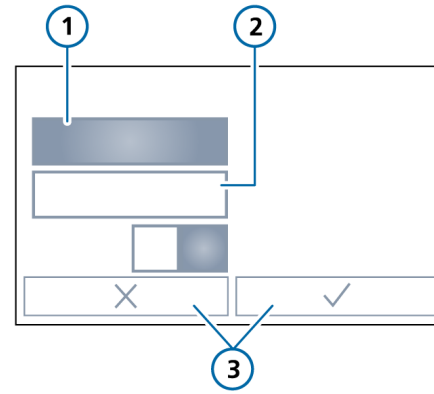
3.3.1 Selecting the oxygen source type

Before starting therapy, be sure to select the appropriate oxygen source. By default, the device is set to high-pressure oxygen (HPO).

To select the oxygen source

1. On the device display, touch > **System configuration**.
2. Touch **Gas source**.
3. Touch the appropriate button for the desired oxygen source.
   – Select **HPO mode** for high-pressure oxygen.
   – Select **LPO mode** for low-pressure oxygen.
4. Touch ✓ to confirm the selection.

Figure 3-4. Selecting the gas source



1 HPO mode
2 LPO mode
3 Cancel/Confirm

3.4 About the patient groups

The HAMILTON-HF90 supports the following patient groups: Adult/Ped and Neo/Ped.

You do *not* set the patient group on the device. The device detects the patient group of the connected breathing circuit and sets the patient group accordingly. The available range of the Flow setting varies by patient group (Table 3-2).

The current patient group is indicated in the top left corner of the display (Figure 3-5).

Figure 3-5. Patient group icon (1), adult/ped patient group selected

The following table describes the Flow range for each patient group, as well as the patient group icon shown on the device display.

Table 3-2. Flow range setting by patient group

Patient group	Icon	Flow range (l/min)
Adult/Ped		4 to 80[1]
Neo/Ped		2 to 30[2]

3.5 Setting up the patient breathing circuit set

⚠ WARNING

- Check the breathing circuit set for damage prior to use. Discard the breathing circuit set if there is any sign of damage.
- Only fill the humidification chamber with sterile, demineralized water that meets the hospital's hygiene requirements.
- Only connect patients to interfaces (for example, nonocclusive high flow nasal cannula) that are intended for high flow oxygen therapy; these types of interfaces allow the patient to exhale.
- Do *not* add any drugs or medication directly to the water in the humidification chamber. If the HAMILTON-HF90 is used in combination with any medical gases or nebulized medications, follow the *Instructions for Use* of the supplied application and make sure that it is suitable for use with active humidification.
- Ensure the water level in the humidification chamber does *not* exceed the maximum fill level.

  Do *not* operate the therapy device if the water level exceeds the marked maximum.
- Ensure that all of the components of the breathing circuit set and other accessories match the associated intended use for the target patient group.

[1] In some markets, the maximum possible **Flow** setting may be limited. In the USA, the **Adult/Ped** maximum can be set to 60.
[2] For neonatal/pediatric patients, you can specify the maximum **Flow** that can be set during therapy, in **Extended configuration**. See Section 7.5.

- Failure to correctly connect the breathing circuit to the therapy device can injure the patient.
- Do *not* tilt the therapy device.
- Adding attachments or other components/assemblies to a breathing circuit can change the pressure gradient across the device, which can adversely affect device performance.
- Ensure both air intakes have their respective filters in place. For details, see Figures 6-2 and 6-3 in Section 6.4.2.
- For each new patient, always use a new breathing circuit set to avoid cross contamination.

Before proceeding, review the safety information in Chapter 1.

Hamilton Medical provides breathing circuit sets for Neonatal/Pediatric and Adult/Pediatric patients, as well as a variety of interfaces (for example, the cannula or mask) that connect to the patient.

Have available all of the components you will use for the patient. Ensure the components you have selected match the patient group, and the patient interface (for example, the cannula or mask) is the right size for the patient and allows the patient to exhale.

When unpacking the breathing circuit set, inspect the set for damage and verify the expiration date.[1] If the set is damaged or falls on the ground, discard it and select a new one.

Each breathing circuit set is for single patient use, and can be used for a maximum of 14 days. The breathing circuit set *Instructions for Use* provides specifications and details.

To connect the breathing circuit set to the HAMILTON-HF90

For illustrations, see the figures at the end of the procedure.

1. If a protective cap is covering the gas outlet adapter, remove it (Figure 3-6).
2. Insert the humidification chamber completely into the device (Figure 3-7).

   To remove it, you *must* first disconnect the breathing circuit, and then pull the humidification chamber out of the device.
3. Connect the inspiratory limb to the humidification chamber/device (Figure 3-8).

   You must pinch the sides of the connector to disconnect the limb from the device.

   Ensure you do *not* place the limb directly on the patient's skin. See Section 3.5.1 for placement guidelines.
4. Insert the water feed spike into the water bag.

   Be sure to only use sterile, demineralized water to fill the humidification chamber.

   Place the water supply at least ≥ 0.5 m above the device.

   It may take a few minutes to fill the humidification chamber to a usable level.

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

5. Remove the safety cover and connect the patient end of the inspiratory limb to the interface (mask, cannula, or other component) that connects to the patient.

   The patient end includes a proprietary connection to Hamilton Medical In2Flow high flow interfaces and an ID15 connection.

Once connected, ensure that the device and tubing are properly connected and placed as described next in Section 3.5.1.

Figure 3-6. Removing/replace the gas outlet adapter cap

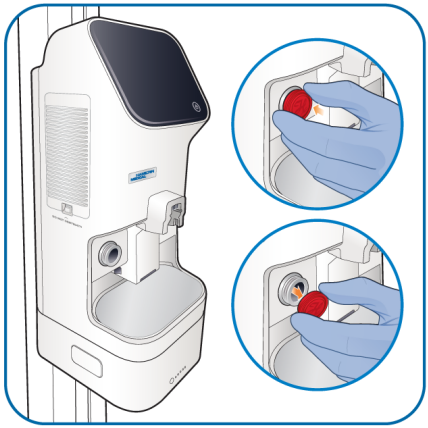


Figure 3-7. Inserting/removing the humidification chamber

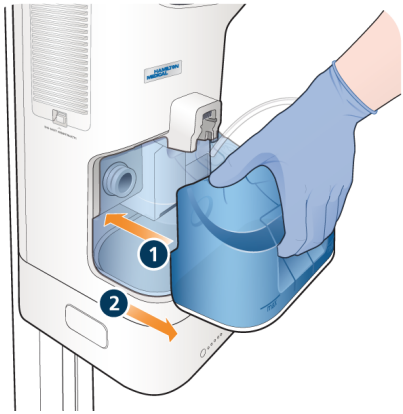
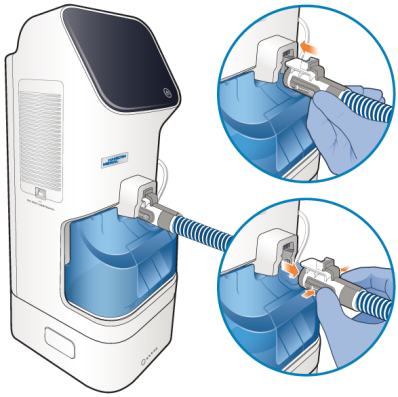


Figure 3-8. Connecting/disconnecting the breathing circuit



3.5.1 Positioning of the breathing circuit set and device

Review the safety information in Sections 1.7.1 and 1.7.2.

After assembly, place the breathing circuit and device so that:

- The device is placed lower than the patient level.
- The air intakes on the sides of the device are *not* blocked or covered in any way. These openings are for the breathing air intake and cooling fan.
- The heated circuit is *not* placed directly on the patient's skin.
- The circuit is without tension and will *not* be pushed, pulled, or kinked as a result of a patient's movement, transport, or other activities.
- Any condensation flows back into the humidification chamber, *not* toward the patient.
- The circuit and tubing are left uncovered and are on top of any sheets or bedclothes.

3.6 Turning the device on and off

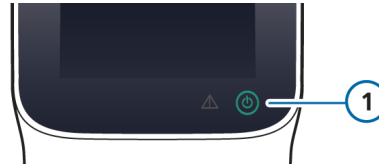
To turn on the device

- Press (Power) on the front of the device.

An acoustic signal sounds to inform you the device is starting and the device runs a self-test. The self-test includes testing the alarm system, including the speaker, buzzer, and Caution indicator.[1] A QR code is displayed during startup, which you can scan to access more product information. During startup, the Power key light blinks green.

Within 30 seconds, the device displays the Patient settings window (Figure 4-1). The Power key light is green.

Figure 3-9. Power key (1)



For details about beginning a therapy session or pausing ongoing therapy, see Sections 4.2 and 4.2.3.

[1] For more information about the alarm tests and manually testing the obstruction alarm, see Section 5.9.

To turn off the device

1. Press (Power) on the front of the device.

   A window opens prompting for confirmation to turn off the device.
2. Touch **Confirm shutdown**.

The device shows a shutdown screen when turning off, with a reminder to attach the red gas outlet protection cap after removing the breathing circuit.

The Power key light turns white, indicating the device is turned off and connected to primary power.

If the device is *not* connected to primary power, the Power key does not light.

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

- Press and hold for about 6 seconds to turn off the device.

Table 3-3. Power key light states

Key	State of the device
	Green. Device is on.
	White. Device is off and connected to primary power.
	Dark. Device is off and *not* connected to primary power.

3.7 Working with the battery

An optional battery is available for use with the HAMILTON-HF90.

3.7.1 Removing the battery bay cover

A plastic cover is provided for the battery bay on the bottom of the device when a battery is not connected.

To remove the battery bay cover

- Pull the cover down and out of the bay.

Figure 3-10. Remove battery bay cover (when battery not connected)

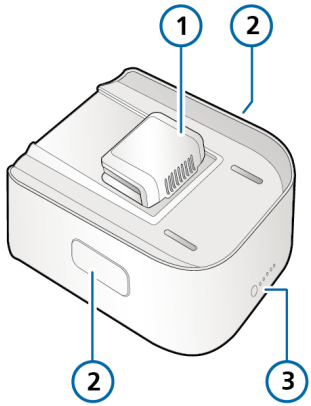
3.7.2 Connecting/removing the Li-ion rechargeable battery

NOTICE

To prevent the device from shutting off when removing the battery, ensure the device is connected to AC power before you start.

About the battery

Figure 3-11. Battery components



1	Electrical connector	3	Charge indicator
2	Release buttons		

To connect the battery

Figure 3-12. Insert the battery under the device, slightly to the front (A).
Fit the electrical connector of the battery into the well under the device (B).

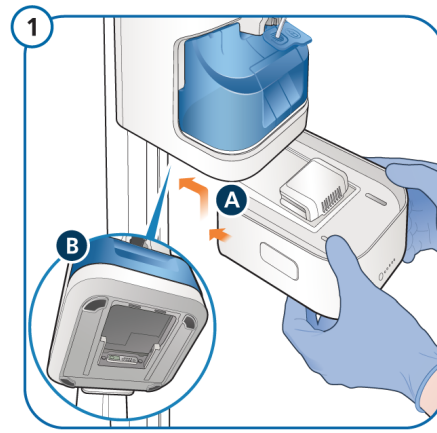


Figure 3-13. Slide the battery back until it clicks into place.

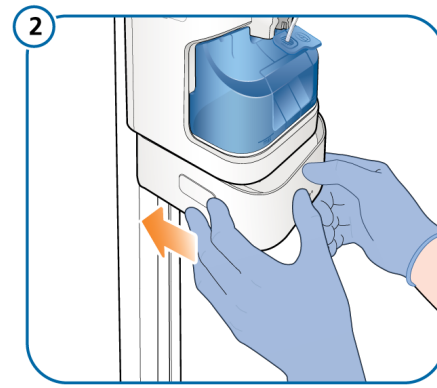
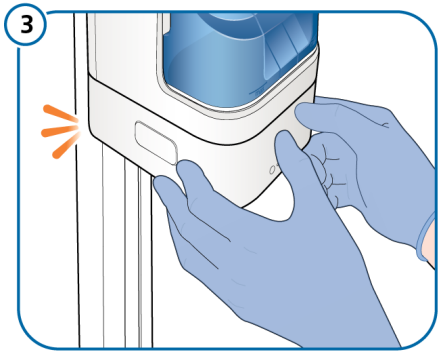


Figure 3-14. An audible click indicates the battery is locked in place.



To remove the battery

Figure 3-15. Press the buttons on the sides of the battery to unlock it, and start sliding it forward.

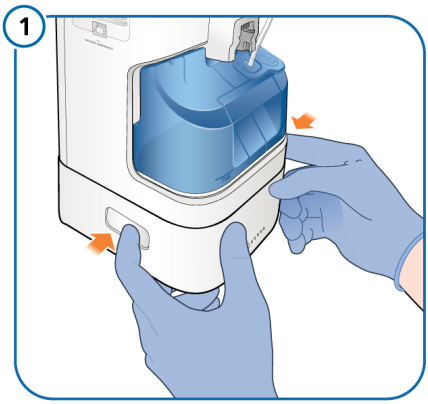


Figure 3-16. Carefully slide the battery forward. The electrical compartment on the battery will prevent it from sliding completely out of the device.

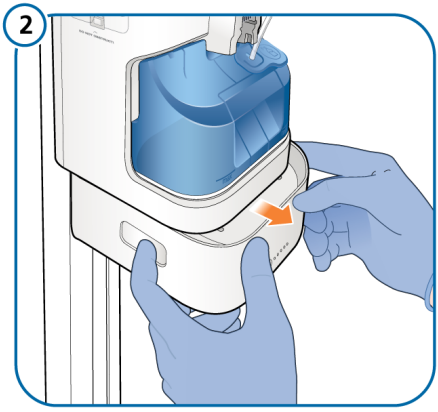
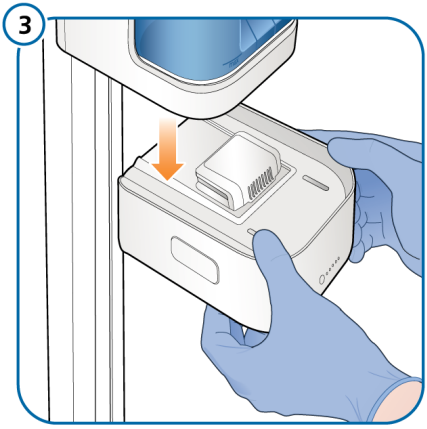


Figure 3-17. **CAUTION!** *The battery is heavy. Handle with care.*
When in position, bring the battery down and out from under the device.



3.8 Preparing for patient transport

As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed only within the hospital.

Transporting patients between health-care facilities is NOT supported.

For the *Intended use*, see Section 1.2.

⚠ WARNING

- Before transporting the patient, ensure an adequate oxygen supply by checking the O2 consumption parameter and ensuring it is adequate for your estimated travel time and current oxygen capacity. O2 consumption is shown at the top of the device display when the device is running on battery power.
- During transport (with a patient or room-to-room), the trolley must always be equipped with at least one oxygen cylinder, and the tubing support arm positioned at 90° angles (as shown in Figure 3-18).
- Check the battery charge level before providing therapy to the patient and before unplugging the device for transport.

NOTICE

- Ensure that the accessories used during transport are adequately protected against water ingress.
- Ensure the device power cord is available during transport in case you must connect to a primary power source.

When used with the optional trolley and battery, you can use the HAMILTON-HF90 to provide therapy during patient transport within the hospital. For details about how the device operates when running on battery power, see Section 4.2.5.

While transporting the patient, the current oxygen consumption is shown on the main display. For details, see Section 4.3.

For additional details about using the trolley when transporting patients within the hospital, see Section 3.8.1.

To prepare the device and trolley for transport within the hospital

1. Attach the device to the trolley (Section 3.8.2).
2. Ensure an oxygen cylinder is connected to the trolley.
3. Connect a charged battery.
4. Confirm the battery is fully charged using the charge status indicators on the battery or the device display (Section 3.2.1).
5. Disconnect the device from primary power.

   The Loss of external power alarm is generated.
6. Confirm the alarm in the Help window (Section 5.6).
7. If a patient is connected, observe the current O2 consumption on the device display and ensure the oxygen supply is adequate for your estimated travel time.

The device is now ready for transport with the patient.

3.8.1 Preparing the trolley for transport within the hospital

As stated in the Intended use, transport of a patient connected to the HAMILTON-HF90 is allowed only within the hospital.

Transporting patients between healthcare facilities is NOT supported.

For the *Intended use*, see Section 1.2.

Before proceeding, review the safety information in Chapter 1.

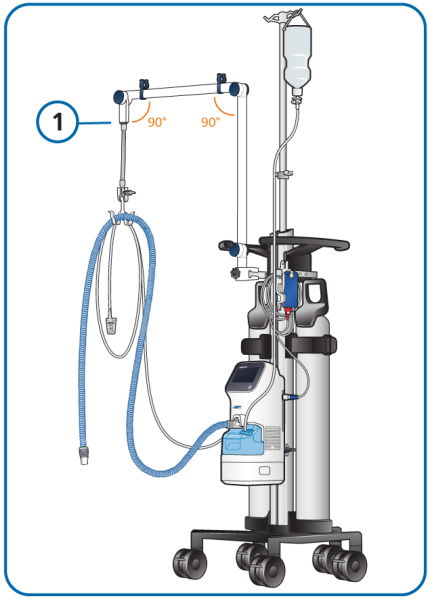
⚠ WARNING

- *Only* the components listed in this section are approved for intrahospital transport.
- During transport (with a patient or room-to-room), the trolley must always be equipped with at least one oxygen cylinder, and the tubing support arm positioned at 90° angles (as shown in Figure 3-18).
- The therapy device must *always* be positioned below patient level.
- Use of additional items can result in the trolley tipping over.
- Ensure the device is securely attached to the trolley before use.

If using a HAMILTON-HF90 trolley, the device and its components, as well as the trolley, **must be** configured and positioned as follows during patient transport within the hospital:

- The device and oxygen cylinders must be securely attached to the trolley.
- *Only* the following components are allowed to be connected when transporting a patient:
  - Breathing circuit
  - Tubing support arm (must be positioned with the arms at 90° angles, as shown in Figure 3-18)
  - Water bag/bottle
  - Water bag pole
  - O2 cylinder
  - SpO2 sensor, including Masimo adapter
  - Nebulizer

Figure 3-18. HAMILTON-HF90 trolley with tubing support arm in transport position (at 90° angles), as shown by **(1)**



3.8.2 Attaching/removing the device from the trolley

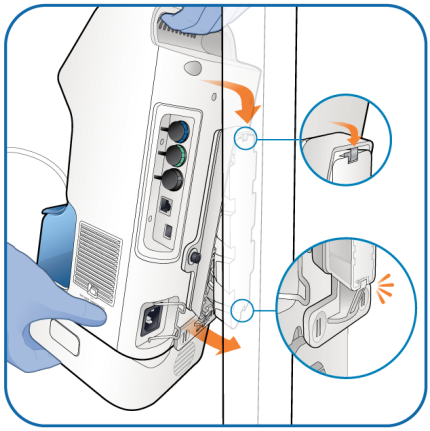
When preparing the device for patient transport within the hospital using the trolley (Section 3.8.1), attach the device to the trolley as follows.

To attach the HAMILTON-HF90 to the trolley

Refer to Figure 3-19.

1. Holding the device at a slight tilt, insert the clip on the back of the device into the slot on the trolley mount.
2. Push the bottom of the device toward the trolley until the clip on the bottom of the device clicks into place.

Figure 3-19. Attaching the HAMILTON-HF90 to the trolley

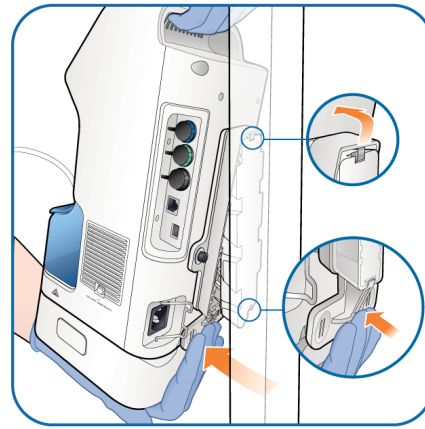


To remove the HAMILTON-HF90 from the trolley

Refer to Figure 3-20.

1. Pull the attachment clip on the bottom of device toward you to disengage the clip.
2. Pull the bottom of the device away from the trolley.
3. Lift the device up.

Figure 3-20. Removing the HAMILTON-HF90 from the trolley



3.9 Setting up nebulization

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-HF90 optionally supports the use of nebulizers for all patient groups. For details about which nebulizers are supported, contact your Hamilton Medical technical representative.

The use of pneumatic nebulizers is *not* supported.

The HAMILTON-HF90 comprises a communication board and connection port on the device humidification chamber (Figure 2-3), and the nebulizer.

Setting up and using a nebulizer comprises the following steps:

To ...	See ...
Insert the nebulizer into the device humidification chamber	This section
Connect the nebulizer to the device	This section
Configure duration and start nebulization	Section 4.4.3

To set up a nebulizer for use

1. Connect the nebulizer to the water chamber:

   a. Lift up the Nebulizer port flap (Figure 3-21).

   b. Insert the nebulizer into the port (Figure 3-22).

2. Connect the nebulizer cable to the connection port on the nebulizer and to the Nebulizer port on the HAMILTON-HF90 (Figures 3-22 and 3-23).

Figure 3-21. Nebulizer connection port (1) on humidification chamber

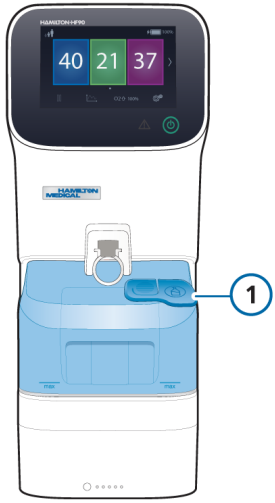


Figure 3-22. Connecting the nebulizer to the HAMILTON-HF90

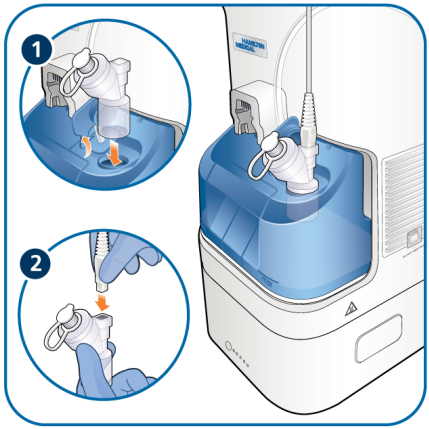


Figure 3-23. Connect cable to Nebulizer port (green)

3.10 Connecting to external devices

You can connect the HAMILTON-HF90 to a patient monitor, a patient data management system (PDMS), or computer using the communication port on the communication board, if installed. For details, see the *Communication Interface User Guide*, available in the Hamilton Medical Resource Center: https://www.hamilton-medical.com/Resource-center

4

Working with the HAMILTON-HF90

4.1 Overview 62
4.2 Starting therapy and specifying settings 62
4.3 Monitoring therapy 69
4.4 Device settings and functions 74
4.5 Ending therapy 79

4.1 Overview

For an overview of the HAMILTON-HF90 device and features, see Chapter 2.

Table 4-1. Operation overview

For details about ...	See ...
Turning the device on/off	Section 3.6
Intended use, indications, and contraindications	Section 1.2
Starting therapy and specifying therapy settings	Section 4.2
Monitoring therapy	Section 4.3
Device settings and functions	Section 4.4

4.2 Starting therapy and specifying settings

⚠ WARNING

DO NOT DEFIBRILLATE a patient when they are connected to the HAMILTON-HF90. Always disconnect the patient from the device, remove the oxygen mask or nasal cannula, and place the device and all components at least one (1) meter away from the defibrillation pads. The use of self-adhesive defibrillation pads, rather than manual paddles, may minimize the risk of sparks occurring.

⚠ CAUTION

Before use and during therapy, regularly inspect the device, all connections, and all connected components, including the patient interface, for wear or damage. If necessary, replace components as appropriate.

This section provides essential details for starting therapy and interacting with the device.

Table 4-2. Starting therapy overview

For details about ...	See ...
Starting therapy	This section
Adjusting therapy settings	Section 4.2.1
Setting alarm limits	Section 4.2.2
Pausing therapy	Section 4.2.3
Unlocking the display	Section 4.2.4
Operating the device on battery power	Section 4.2.5

When the device is turned on, it begins to deliver therapy as follows:

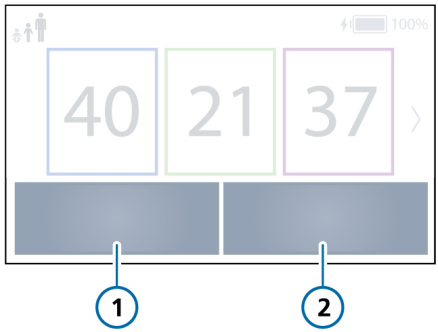
- The device is set to the patient group of the connected breathing circuit.
- If the patient group is the same as the previous therapy session, the device uses the previous settings, and the Patient settings window is shown (Figure 4-1).
- If the patient group has changed, the device uses the default settings defined in the Extended configuration, and the main display is shown (Figure 2-6 in Section 2.2.4).

To start therapy

1. Turn on the device (Section 3.6).
2. If the Patient settings window is displayed, do either of the following:
   – Touch **New patient** to begin a new therapy session using the default settings and alarm limits.
   – Touch **Resume therapy** to continue the previous therapy session using the previous settings and alarm limits.
3. Adjust the therapy settings, as desired.

You can temporarily pause ongoing therapy, as needed. See Section 4.2.3.

Figure 4-1. Patient settings window



1 Resume therapy 2 New patient

You can adjust the following controls on the device.

Table 4-3. Control parameters

Parameter	Description
Flow	The set flow of gas to the patient in liters per minute (l/min). The available range of the Flow setting varies by patient group. For details, see Section 3.4.
Oxygen	Oxygen concentration to be delivered in %.
Tempera-ture	Temperature of the delivered gas at the patient end of the breathing circuit in degrees celsius (°C). When the temperature is below 35°, droplets are displayed to indicate the potential for condensation. 

You can configure the default therapy settings for each patient group (Section 7.4). For the control parameter ranges and default settings, see Table 9-6 in Section 9.6.

4.2.1 Adjusting settings

To adjust a control setting

1. Touch the control to adjust.
2. Adjust the value by doing either of the following (see Figure 4-2):
   – To increase, touch **+**.
   – To decrease, touch **—**.
3. To confirm the new setting, touch ✓.
   To cancel the change, touch **X**.

The new setting is applied immediately.

While the device is adjusting the therapy to reach the new setting, the control displays a blinking white up arrow (to indicate increasing values) or down arrow (to indicate decreasing values) (Figure 4-2). Once the new setting is reached, the arrows are no longer displayed.

Figure 4-2. Adjusting a control setting

1 Control in adjustment mode, showing updated value

2 Updated display on device; white arrows show device is adjusting therapy to new setting

4.2.2 Setting alarm limits

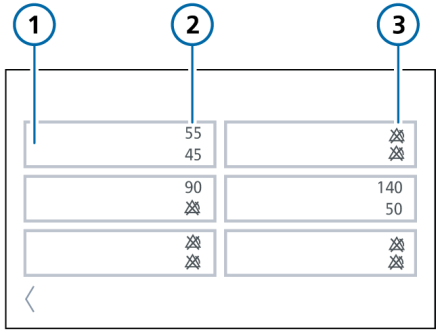
Before proceeding, review the safety information in Chapter 1.

You can access the **Alarm limits** window and change alarm settings at any time, without affecting therapy.

You can adjust the **Oxygen** alarm limits, as well as the alarm limits for SpO2-related alarms. The availability of SpO2-related alarm limits depends on whether the option is installed and an SpO2 sensor is connected. For details about SpO2-related adjustable alarms, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

For details about setting **Oxygen** alarm limits, see Table 4-4 and Section 4.2.2.1.

Figure 4-3. Alarm limits window



1 Buttons for available adjustable alarms

2 Currently set upper/lower alarm limits

3 **Alarm Off** symbol when an alarm limit is set to **Off**

To review and adjust alarms

1. Touch  > **Alarm limits**.

   The Alarm limits window is displayed (Figure 4-3).

2. Touch the button for the alarm to adjust.

   A window appears, showing a slider with the current set alarm limits and current monitored value for that parameter (Figure 4-4).

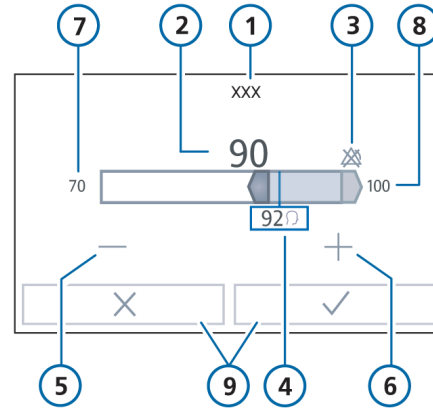
   You can also open the alarm limit control window for a specific parameter directly from the Extended view by touching the monitored parameter.

3. Touch an alarm limit to activate it and adjust the setting.

   You can adjust the setting either using the **+** and **-** buttons, or by dragging the alarm limit sliders left and right.

   The device displays  (Alarm Off) when an alarm limit is set to Off.

Figure 4-4. Adjusting alarm limits



1	Adjustable alarm name	6	Increase setting
2	Currently set lower alarm limit and slider (shown selected)	7	Lowest possible setting
3	Currently set upper alarm limit and slider  is shown when the limit is set to Off	8	Highest possible setting
4	Current monitored value	9	Cancel/Confirm
5	Decrease setting		

The following table describes the adjustable Oxygen alarms. Additional details are available in Table 9-8 (Section 9.8).

Table 4-4. Adjustable alarms

Alarm	Description
Oxygen (low and high)	Low and high monitored oxygen concentration (Oxygen). If either limit is reached, a high-priority alarm is generated. Applies only when low-pressure oxygen is used or the Set Oxygen alarm limits manually is ON with HPO.

4.2.2.1 About the Oxygen alarm limits

How the device sets the Oxygen alarm limits depends on the gas source used (LPO or HPO) and associated option settings.

Oxygen alarm limits are set as follows.

Table 4-5. Setting Oxygen alarm limits in LPO and HPO modes

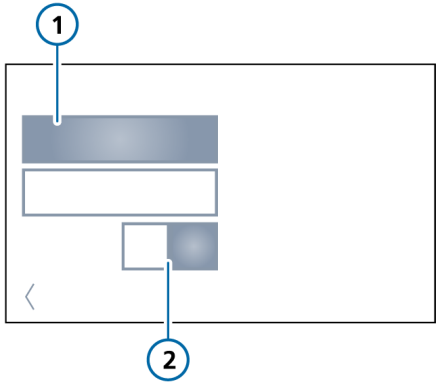
Gas source	Setting Oxygen alarm limits
LPO	Always manually. The Oxygen alarm limit controls are enabled in the Alarm limits window and are manually adjusted, as appropriate.
HPO	By default, automatically. The Oxygen high/low alarms are, by default, automatically set to the current Oxygen setting ± 5 (absolute value). The Oxygen alarm limit controls are disabled in the Alarm limits window. To set them manually, turn ON the Set Oxygen alarm limits manually option, as described next.
The minimum lower alarm limit is 18%.	

To enable the manual adjustment of Oxygen alarm limits in HPO mode

1. Touch ⚙ > **System configuration**.
2. Touch **Gas source**.
3. Touch **HPO** to select it as the gas source.
4. Touch ON to enable the Set Oxygen alarm limits manually option.

   When selected, the Oxygen alarm limit controls are enabled in the Alarm limits window. You can now set the limits as desired.
5. To have the limits set automatically, touch OFF.

Figure 4-5. Enabling manual setting of oxygen alarm limits with HPO



1	HPO	2	ON/OFF

4.2.3 Pausing the therapy

You can pause the therapy for a short period of time for care and treatment measures with the patient, so that, for example, the patient can use a restroom or the interface can be changed.

During a pause:

- The heater plate and breathing limb heating are turned off.
- The gas flow is stopped.
- Therapy-related alarms are suppressed.
- Trends and all Settings options remain available (except as noted next).
- O2 enrichment is unavailable.
- O2 assist, if running, is paused.[1]

To pause the therapy

1. Touch ⏸ (Pause).

   You are prompted to confirm this choice.
2. Touch ✓ to confirm.

   If the pause is *not* confirmed or you touch **X**, therapy continues uninterrupted.

Upon confirmation, the yellow Pause window is displayed (Figure 4-6), showing a timer that tracks the length of the pause.

[1] Not available in all markets.

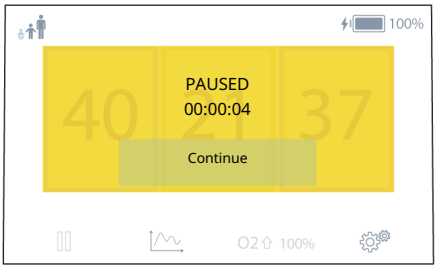
To restart therapy

- In the Pause window, touch **Continue**.

  Therapy resumes with the previous settings.

Note that, if during a pause, you change the breathing circuit to a different patient group, the Patient group changed alarm is generated, and therapy resumes using the default settings for the new patient group.

Figure 4-6. Pause window with active timer



4.2.4 Unlocking the display

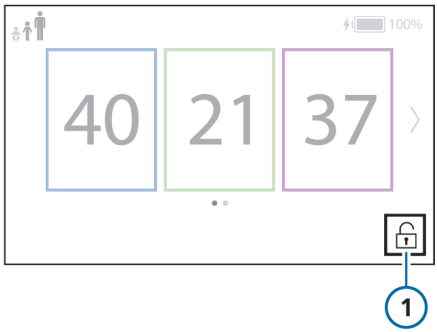
After 2 minutes of inactivity, the touch screen display automatically locks. To use the display, you must first unlock it by touching (Unlock) in the bottom right corner of the display (Figure 4-7).

Furthermore, if a menu or other window is open, the display returns to the last viewed main display window.

To unlock the touch screen display

- Touch (Unlock).

Figure 4-7. Unlocking the display (1)



4.2.5 Operating the device on battery power

When the device is running on battery power, the following occurs:

- The Oxygen consumption (O_2) in liters per minute is shown at the top of the display (Figure 4-8).
- The battery status icons on the display show the current charge status of the battery (Table 3-1 in Section 3.2.1).

Note that operating the device at high Flow settings and/or high temperature settings may lead to decreased operating times.

When the Battery low alarm is generated, the device may decrease performance and some features may be disabled to increase operating time. For details about the alarm, see Table 5-2 in Section 5.8.

4.3 Monitoring therapy

SpO2 monitoring data is displayed in the Extended view, together with a real-time plethysmogram (Figure 4-8). You can access the Extended view at any time during therapy.[1]

In the Extended view, the following monitored parameters are displayed:

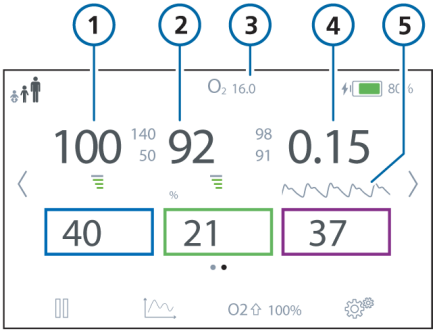
- SpO2
- Pulse
- PI (Masimo only)
- PVI (Masimo only)[2]
- RRp (Masimo only)[2,3]

Not all parameters monitored by the device are displayed. For a complete list and description of parameters monitored during therapy, see Section 4.3.4 and the *Pulse Oximetry Instructions for Use*.

The Trends window () displays additional monitored data. For details about trends, see Section 4.3.3.

[1] The Extended view is only available if the SpO2 option is installed.
[2] The parameter must be enabled on the adapter firmware and in the therapy device software. For details, contact your Hamilton Medical technical representative or Masimo area sales representative.
[3] Respiratory rate is measured from the plethysmogram.

Figure 4-8. Monitored parameters in the Extended view



1	Pulse/RRp[1]	4	PI/PVI[1]
2	SpO2	5	Plethysmogram
3	O2 consumption[2]		

4.3.1 Overview

Control settings and patient data are displayed on the main display and the Extended view[3]. You can also view parameters graphically as trends.

Table 4-6. Operation overview

For details about ...	See ...
Setting up SpO2 monitoring	Section 4.3.2
Working with trend graphs	Section 4.3.3
About the monitored parameters	Section 4.3.4

4.3.2 Setting up SpO2 monitoring

With the SpO2 option and a supported pulse oximeter connected to the device, the HAMILTON-HF90 provides integrated monitoring and data display of functional oxygen saturation of arterial hemoglobin (SpO2) and related pulse oximetry data.

To monitor SpO2, a sensor type must be configured for the device in Extended configuration (Section 7.7).

For details about the sensors and working with SpO2 data and related settings on the device, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

To start monitoring SpO2

- Connect an SpO2 sensor to the SpO2 port on the device and to the patient.

  The sensor automatically starts measuring data[4].

If SpO2 data is not displayed after connection, SpO2 monitoring may have been turned off.

[1] When a Masimo sensor is connected and supports this parameter, the monitored parameters alternate on the device display.
[2] Only displayed when the device is running on battery power.
[3] The Extended view is only available if the SpO2 option is installed.
[4] The SpO2 sensor type must already be selected in Extended configuration > SpO2 sensor type, and must match the connected sensor.

To enable or disable SpO2 monitoring

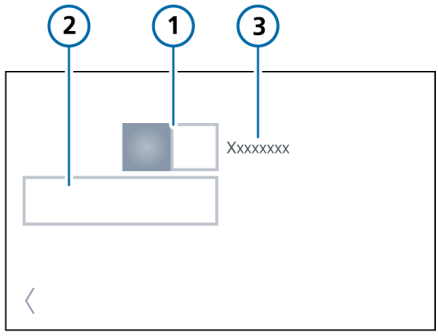
1. Touch  > **SpO2**.
2. Touch **ON** next to Monitoring to enable it.

   When enabled, a connected sensor starts automatically.
3. Touch **OFF** next to Monitoring to disable it.

   This can be useful when an SpO2 sensor is connected to the device, but you are not actively using it; disabling monitoring prevents generation of related alarms.

   Be sure to enable it again when ready to use the sensor.

Figure 4-9. SpO2 window



1	Monitoring ON/OFF	3	Sensor information
2	Settings (for details, see the *Pulse Oximetry Instructions for Use*)		

4.3.3 Working with trend graphs

You can display trend data of the following monitored parameters for 1, 6, 12, 24, or 72 hours:

- Flow, Oxygen
- SpO2, Oxygen[1]
- SpO2/FiO2 ratio[1]
- RRp (Masimo only)[1,2]
- ROX Index (Masimo only)[3]

In addition, the Therapy duration for the current patient is displayed above the trend.

You can temporarily freeze the display of a trend graph, allowing you to scroll through it for a detailed review. See Section 4.3.3.1.

When the device is turned on, it continuously stores up to 72 hours of monitored data in its memory. This data is deleted upon setting up a new patient.

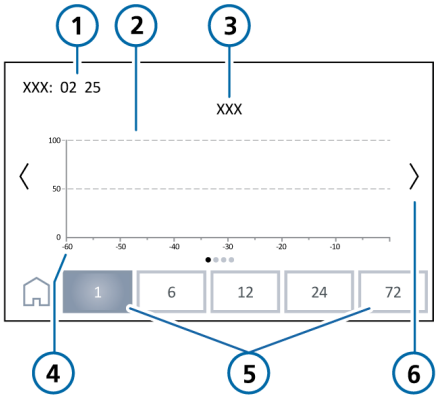
[1] If the option is installed.
[2] The parameter must be enabled on the adapter firmware and in the therapy device software. For details, contact your Hamilton Medical technical representative or Masimo area sales representative.
[3] The ROX Index is only available if the RRp parameter is installed.

To display a trend

1. Touch (Trends).
2. Touch the left and right navigation arrows to scroll through available trends, when displayed.

To review details, you can scroll through an individual trend graph by touching it, which displays the Freeze cursor and details. See Section 4.3.3.1.

Figure 4-10. Trends window



1	Therapy duration	4	Elapsed time relative to present
2	Trend graph	5	Time scale, in hours (1 hour selected)
3	Name of selected trend parameter(s)	6	Navigation arrow, touch to cycle through trends (when multiple available)

4.3.3.1 Freezing a trend graph

You can temporarily freeze the display of a trend graph, allowing you to scroll through it for a detailed review.

To freeze a trend graph

1. Touch anywhere on the graph.

   The Freeze cursor appears on the graph; the **Freeze** button and scroll arrows appear above the graph.

   All of the trends are frozen; the cursor is time-synced across all of the trends.
2. To scroll through a graph for analysis, do either of the following:

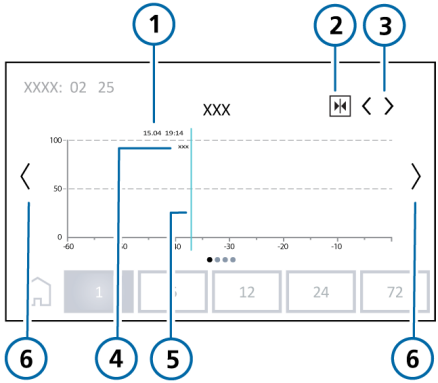
   – Place your finger at the desired location on the trend graph. The cursor moves to where your finger is.

   – Touch the left or right scroll arrows ❮ ❯ above the graph. The cursor moves in small increments in the same direction.
3. To cycle through available trends, touch the left or right navigation arrows at the sides of the window ❮ ❯.

   The cursor appears at the same point in each trend graph, together with the detailed information for that graph.
4. To unfreeze the trend graph, touch .

The display returns to displaying real-time data.

Figure 4-11. Trends window, Freeze enabled



1 Therapy date and duration length at cursor
2 Freeze button
3 Scroll arrows
4 Parameter value(s) at cursor
5 Freeze cursor
6 Navigation arrow, touch to cycle through trends (when available)

4.3.4 About the monitored parameters

The following table provides a list of the device's monitored parameters. See Section 9.7 for parameter specifications.

The display of monitored parameters is updated every 0.5 seconds.

For details about SpO2-related parameters, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

Table 4-7. Monitored parameters

Parameter (unit)	Definition
For details about SpO2-related monitored parameters, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).	
Flow (l/min)	The continuous and constant flow of medical gas to the patient.
Oxygen (%)	Oxygen concentration to be delivered.
Oxygen consumption (l/min)	The current oxygen consumption rate. Displayed when the device is running on battery power (Section 4.2.5).
Temperature (°C)	Temperature of the delivered gas at the patient end of the breathing circuit.
Therapy duration (hours, minutes)	The length of time the patient has received therapy. Displayed in the Trends window (Section 4.3.3).

4.4 Device settings and functions

This section describes special functions on the device.

Table 4-8. Device settings and functions

For details about ...	See ...
Oxygen enrichment	Section 4.4.1
Working with O2 assist	Section 4.4.2
Working with a nebulizer	Section 4.4.3
Calibrating the O2 sensor	Section 4.4.4
Adjusting display options	Section 4.4.5
Working with the Event log	Section 4.4.6
Viewing device-specific information	Section 4.4.7

4.4.1 Oxygen enrichment

NOTICE

- The Oxygen high/Oxygen low alarms are suppressed while O2 enrichment is active.
- O2 enrichment is not available when:
  - Using low-pressure oxygen.
  - When the high-priority Battery low alarm is active.
  - When therapy is paused.

When oxygen enrichment is active, the device delivers the configured oxygen concentration for 2 minutes. The total oxygen concentration to be delivered during enrichment is displayed on the O2⇧100% (O2 enrichment) button on the display.

You can configure the oxygen concentration to be delivered *in addition* to the current Oxygen setting for each patient group.

Note that the maximum delivered oxygen concentration will not exceed 100%. If the sum of the two settings is greater than 100%, the device delivers 100%.

For details about configuring the oxygen concentration during O2 enrichment, see Section 7.6.

To start oxygen enrichment

- Touch O2⇧100% (O2 enrichment) (Figure 2-6 in Section 2.2.4).

  The device starts delivering the configured oxygen concentration.

When active, the Oxygen control displays the currently applied concentration and a countdown timer.

When finished, the device resets the oxygen concentration to the previous setting.

To stop oxygen enrichment

- Touch **STOP** O2⇧.

  Therapy resumes at the previously set oxygen concentration.

4.4.2 Working with O2 assist

With the O2 assist option[1], the clinician sets the target for SpO2, as well as range limits for the patient. O2 assist then manages the Oxygen control based on the target, clinician-defined limits, and on the physiologic input from the patient (SpO2). O2 assist continuously monitors the patient condition, and automatically and safely adjusts the setting to keep the patient within the target range with minimal clinician interaction.

Use of the O2 assist option requires:

- SpO2 monitoring to be enabled[2]
- SpO2 sensor connected to the communication board on the device

You define the SpO2 target range, SpO2 emergency limits, and the SpO2 and O2 % Message alarm limits. The device adjusts the Oxygen setting to keep the patient's SpO2 within the target range.

For details on working with O2 assist, see the *O2 assist Instructions for Use* for the HAMILTON-HF90 (PN 10154637).

4.4.3 Working with a nebulizer

You can nebulize your patient using an Aerogen Solo nebulizer.[3]

For connection and setup details, see Section 3.9.

4.4.3.1 Specifying nebulizer settings

You can specify the following settings for nebulization: Timed and Continuous.

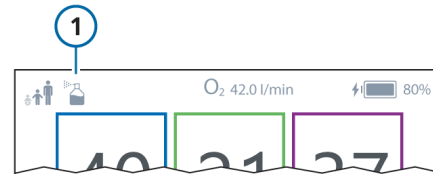
Table 4-9. Nebulizer setting options

Setting	Description
Timed	The length of time nebulization will be delivered. By default, 30 minutes.
Continuous	Nebulization is delivered for an unlimited length of time; you stop nebulization manually.

Nebulizer settings are specified in the > Nebulizer window.

During nebulization, the icon (Nebulizer) is shown on the main display to indicate that nebulization is active (Figure 4-12).

Figure 4-12. Nebulizer icon (1) displayed when nebulization is active



[1] Not available in all markets.
[2] For details, see the *Pulse oximetry Instructions for use*, HAMILTON-HF90.
[3] Nebulizer support is available with the communication board PN 10120404 (supports USB, Ethernet, SpO2, RS-232, and nebulizer connections).

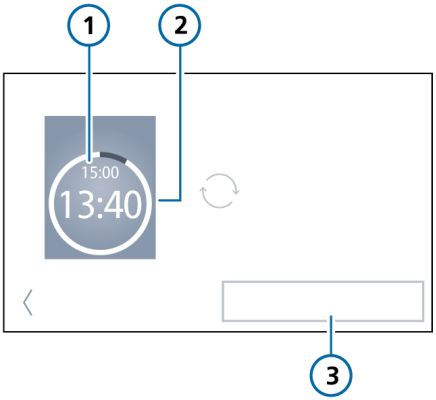
To deliver nebulization for a specified length of time

1. Ensure a nebulizer is connected (Section 3.9).
2. Touch  > **Nebulizer**.
3. Touch  (Timed).
4. Specify the desired time to deliver nebulization.

   The default duration is 30 minutes.
5. Touch **Start** to begin nebulization.
6. To stop nebulization before the time is up, touch **Stop**.

The Timed control displays a countdown timer showing the remaining nebulization time and the total length of nebulization time.

Figure 4-13. Nebulizer window during timed nebulization



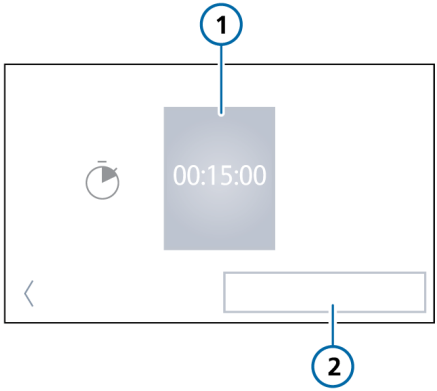
1 Set nebulization duration
2 Remaining nebulization time
3 STOP

To deliver nebulization for an unlimited length of time (continuous)

1. Ensure a nebulizer is connected (Section 3.9).
2. Touch  > **Nebulizer**.
3. Touch  (Continuous).
4. Touch **Start** to begin nebulization.
5. To stop nebulization, touch **Stop**.

The Continuous control displays the length of time that nebulization has been delivered.

Figure 4-14. Nebulizer window during continuous nebulization



1 Current length of nebulization time
2 STOP

4.4.4 Calibrating the O2 sensor

NOTICE

When using LPO, disconnect the oxygen supply during calibration.

If the therapy settings allow, the device will calibrate the O2 sensor automatically while delivering therapy. The time and date of the most recent calibration is shown in the > System configuration > O2 calibration window.

The O2 sensor calibration needed alarm is generated if the last calibration is older than 2 weeks. When this occurs, you *must* manually calibrate the O2 sensor as soon as possible.

You can confirm the alarm; however, it will sound every 24 hours until the calibration is performed.

Note that manual calibration of the O2 sensor requires you to stop therapy; you *cannot* calibrate the O2 sensor when delivering therapy to the patient. The breathing circuit set must be connected to the device during calibration.

To calibrate the O2 sensor

1. Provide alternative therapy and disconnect the patient.

   Keep the breathing circuit set connected to the device.

2. Touch > **System configuration**.
3. Touch **O2 calibration**.
4. Touch **Start** to begin calibrating the O2 sensor.

A countdown timer is displayed showing the remaining calibration time. The calibration takes about 90 seconds to complete.

When complete, the text Success is shown in the lower right hand corner of the display. You can continue using the device to deliver therapy.

4.4.5 Adjusting display options

You can set the day and night display brightness, as well as the device date and time.

4.4.5.1 Setting the date and time

When you turn on the device for the first time, you are prompted to set the date and time. You can later adjust these settings at any time.

You set the date and time in the > Date & Time window. Ensure the date and time are set correctly so that event log entries have accurate time and date stamps.

To set the date and time

1. Touch > **Date & Time**.
2. Adjust the date and time, as appropriate.

4.4.5.2 Setting the display brightness

Use these settings to set the brightness of the display for use during the day and night.

To set the display brightness

1. Touch > **Screen brightness**.
2. To select Day mode with a bright display, touch the **Day** button.

   To select Night mode with a dimmer display, touch the **Night** button.
3. Adjust the brightness of the display in each mode.

   The setting you choose becomes the new default for that mode.
4. To have the device switch between Day and Night mode automatically at 6 am and 6 pm, touch the **Automatic** button.

4.4.6 About the Event log

Once the device is turned on, event logs collect data about clinically relevant activities, including alarms, technical notes, setting changes, and special functions. The date, time, and a brief description of the event is included.

Alarms are indicated by a colored dot next to the event description, depending on priority level (yellow for low or medium, red for high).

A more extensive log including technical and configuration details is available to service engineers.

When turning on the device to begin therapy, data is appended to the existing event log.

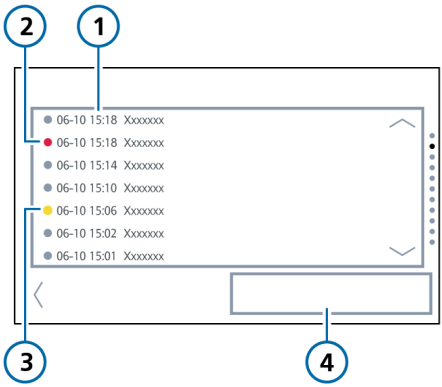
Event log data persists after shutting off the device or in the event of a power loss. A maximum of 1000 events is stored. When a log buffer is full, new events overwrite the oldest log entries.

You can export event log data. See Section 4.4.6.1.

To display the Event log

▸ Touch > **Events**.

Figure 4-15. Events window



1	Informational message	3	Low-/medium-priority alarm (yellow)
2	High-priority alarm (red)	4	Export logs

4.4.6.1 Exporting Event log data

Before using a USB drive with the device, review the safety information in Section 1.6.3.

You can export event and service logs to a USB drive.

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. Insert a USB drive into the USB port (Figure 2-3 in Section 2.2.1).
2. Touch  > **Events**.
3. Touch **Export logs** (Figure 4-15).
4. Remove the USB drive when the text Export successful is displayed.

   The log files are saved to a .zip folder on the USB drive named as follows.

HAMILTON-HF90-snxxxx_yyyy-mm-dd-hh-mm-ss

where:

xxxx 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

4.4.7 Viewing device-specific information

The System information window displays device-specific information including serial number, operating hours, software version, and installed options.

To view device-specific information

1. Touch  > **System configuration**.
2. Touch **System information**.

4.5 Ending therapy

⚠ WARNING

Ensure the power cord does *not* come in contact with the heater plate.

When therapy for a patient is ended, perform the following tasks:

1. Turn off the device (Section 3.6).
2. Remove the breathing circuit set and other components used.
3. Dispose of the used components appropriately (Section 9.16).
4. Attach the gas outlet adapter cap (Section 6.4.1).
5. Clean and disinfect the device per your institution's protocols (Sections 6.2 and 6.3).

5
Responding to alarms

5.1 Overview 82
5.2 Alarm limit indicators 84
5.3 Responding to an alarm 84
5.4 Temporarily silencing an alarm 85
5.5 Accessing on-screen troubleshooting help 85
5.6 Turning off (deactivating) an alarm 86
5.7 Adjusting alarm loudness 87
5.8 Troubleshooting alarms 88
5.9 Testing alarms 99

5.1 Overview

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

These alarms are categorized as high, medium, or low priority, as described in Table 5-1. The device's visual alarm indications are described in Figure 5-1.

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

Alarms are recorded in the device's event log. For details, see Section 4.4.6.

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

- The alarm message bar on the device display is shown in color and displays the alarm text.
- A monitoring parameter associated with an active alarm is shown in the same color.

When an alarm condition is serious enough to possibly compromise safe therapy, a Technical fault alarm is generated. The indicators on the device depend on the severity of the fault. Therapy continues, if possible. Table 5-1 provides details.

On-screen alarm troubleshooting help is available directly on the device display. See Section 5.5.

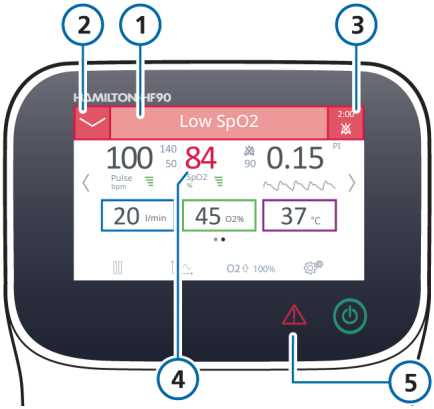
For details on setting alarm limits, see Section 4.2.2.

Table 5-1 describes the audio and visual characteristics of these types of alarms and provides guidance on how to respond.

Table 5-1. Alarm indicators

Alarm type	Alarm message bar	Audio/Indicators	Action required
High priority	Red, with alarm message	A sequence of 5 beeps, repeated until the alarm is reset.	The patient's safety is compromised. The problem needs immediate attention.
Medium priority	Yellow, with alarm message	A sequence of 3 beeps, repeated periodically.	The patient needs prompt attention.
Low priority	Yellow, with alarm message	Two sequences of beeps. This is not repeated.	Operator awareness is required.
Technical fault	The entire display is red and the alarm message is displayed	Depending on the severity of the fault; may be the same audio indicator as a high-, medium-, or low-priority alarm. Otherwise, a continuous buzzer tone; the buzzer cannot be silenced. In addition, the Caution indicator on the front of the device may blink red, depending on the severity of the fault. Therapy continues, if possible.	• Provide alternative therapy. • Turn off the device. • Have the device serviced.

Figure 5-1. Visual alarm indications



1 Alarm message bar

2 Access on-screen alarm troubleshooting

3 **Audio pause** button and countdown timer

4 Monitored parameter associated with alarm

5 Caution indicator

5.2 Alarm limit indicators

Alarm limits are shown:

- In the  > Alarm Limits window
- In the Extended view to the right of the monitored parameter

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

In the Extended view, touch any monitored parameter to open the alarm limits window for that parameter. For details about setting alarm limits, see Section 4.2.2.

5.3 Responding to an alarm

⚠ WARNING

When an Audio pause is active, the following critical alarms still generate an audible alarm:

- Battery totally discharged
- Blower fault
- Device tilted (*high priority*)
- Oxygen supply failed
- SpO2 low
- Cannot reach target flow
- Check for blockage
- Total power loss

⚠ 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.

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 therapy for the patient.

   You can pause the audible alarm, if appropriate and available. See Section 5.4.

   You can turn off (deactivate) some alarms. See Section 5.6.
3. Address the alarm conditions. See Section 5.8.

   For a technical fault, remove the device from use, note the fault code, and have the device serviced.
4. If appropriate, readjust the alarm limit.

5.4 Temporarily silencing an alarm

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

To temporarily silence an alarm

- Touch (Audio pause) in the top right corner of the display (Figure 5-1).

  The audible alarm is muted for two minutes.

  Pressing the button a second time cancels the Audio pause.

A countdown timer is displayed showing the remaining time for the Audio pause.

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

5.5 Accessing on-screen troubleshooting help

Troubleshooting help is available for alarms. The Help window is shown in the color associated with the alarm priority (Table 5-1).

For alarms that are associated with adjustable alarm limits (Section 4.2.2), a button is available in the Help window that opens the alarm limit window for that parameter.

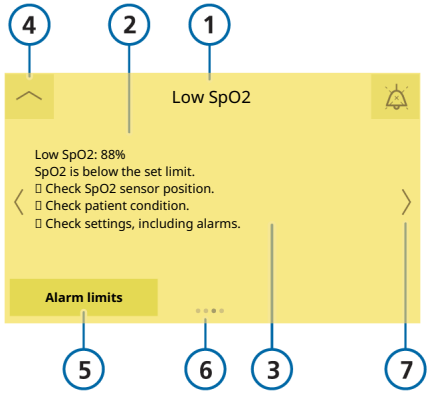
To view the help for an alarm

1. Touch ﹀ at the top left corner of the display.

   A Help window appears, providing troubleshooting information for the selected alarm.

   If multiple alarms are active, swipe left or right to scroll through the Help for all active alarms.
2. Touch ﹀ to close the Help window.

Figure 5-2. On-screen Help window (medium-priority alarm shown)



1	Alarm	5	Open alarm limits window for the associated parameter, if displayed
2	Monitored value related to alarm, if applicable	6	Paging dots, when multiple alarms are active
3	Troubleshooting information	7	Navigation arrows, when multiple alarms are active
4	Close on-screen help window		

5.6 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.

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:

Loss of power, Battery low (low priority), Consider battery replacement, Check ambient temperature, Check settings, Patient group changed, Could not resume therapy, Trial license expired, O2 sensor calibration needed, Blower service required, Gold cap service required, Maintain device

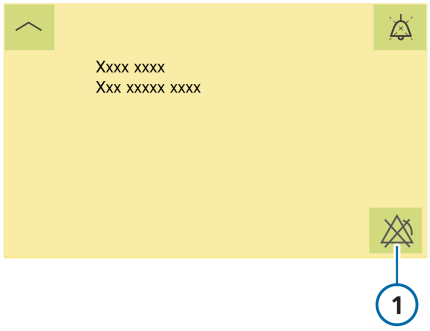
To turn off (deactivate) an alarm

1. Touch ⌄ to open the Help window (Section 5.5).
2. Read the on-screen help.
3. Touch  to turn off the alarm (Figure 5-3).

The alarm is no longer active.

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

Figure 5-3. Turning off (deactivating) an alarm in the Help window (1)



To review deactivated alarms

- Touch  > **Deactivated alarms**.

  The Deactivated alarms window opens (Figure 5-4), showing the list of currently inactive alarms.

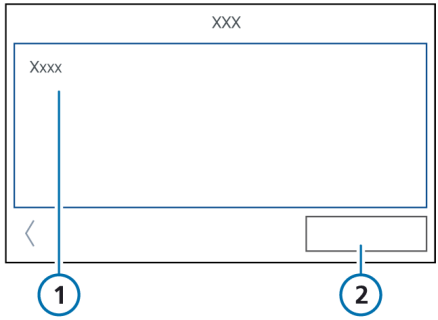
If desired, you can reactivate them.

To reactivate alarms

- In the Deactivated alarms window, touch **Reactivate**.

  All of the listed alarms become active again, both with alarm sounds and messages.

Figure 5-4. Deactivated alarms window



1	Turned off (deactivated) alarms	2	Reactivate

5.7 Adjusting alarm loudness

⚠ WARNING

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

You can set the loudness of the audible alarm.

By default, the loudness is set to 3 (Adult/Ped) or 2 (Neo/Ped).

If you set the loudness below the default value during a patient session, the value is reset to the default upon:

- Setting up a new patient
- Turning the device off and on again

To adjust the alarm loudness

1. Touch  > **Loudness**.
2. Adjust and confirm the setting, as desired.

5.8 Troubleshooting alarms

NOTICE

If no alarm delay is described in Table 5-2, the alarm is generated as soon as the condition is detected.

Table 5-2 is an alphabetical list of the alarm messages displayed by the HAMILTON-HF90, 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.

For SpO2-related alarms, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

For O2 assist-related alarms, see the *O2 assist Instructions for Use, HAMILTON-HF90* (PN 10154637).

Table 5-2. Alarms and other messages

Alarm	Definition	Action needed
Battery communication error	*High priority*. Battery data is not available. Therapy continues. Alarm delay: 5 seconds	• Check the battery connectors and that the battery is properly connected. • If the problem persists, replace the battery. • If the problem still persists, have the device serviced.
Battery defective	*High priority*. Battery is defective. Therapy continues as long as the device is connected to primary power. Alarm delay: 10 seconds	• Replace the battery. • Prepare alternative therapy. • If the problem still persists, have the device serviced.

Alarm	Definition	Action needed
Battery low	The Battery low alarm has different levels of priority (low, medium, and high) depending on the battery charge level. Alarm delay: 3 seconds The alarm priority levels are defined as follows: *Low priority*. The device is running on primary power and the battery charge is low (battery charge < 25%). You can turn off (deactivate) this alarm. For details, see Section 5.6. *Medium priority*. The device is running on battery power and the battery charge is low (battery charge < 25%). At least 10 minutes of use remain. To save energy and increase operating time, the heating plate is turned off and the humidity level is adjusted. *High priority*. The device is running on battery power, and the battery charge is critically low (battery charge < 20%). At least 5 minutes of use remain. To save energy and increase operating time, the heating plate and breathing circuit heating are turned off, O2 enrichment is unavailable, and O2 assist, if running, is paused.	• Connect the device to a primary power source. • Connect a charged battery. • If necessary, be prepared to provide alternative therapy.

Alarm	Definition	Action needed
Battery power line error	*High priority*. There is a problem with the battery power line, and power is not available. The issue may lie with the battery or the device. Alarm delay: 5 seconds	Have the device and battery serviced.
Battery replacement required	*Medium priority*. Battery capacity is insufficient for reliable operation and must be replaced immediately. Alarm delay: 4 seconds	Replace the battery.
Battery temperature high	*High priority*. The battery temperature is higher than expected. Alarm delay: 5 seconds	• Remove the device from the sun or other heat source. • Replace the battery. • Provide alternative therapy until the issue is resolved. • If the problem still persists, have the device serviced.
Battery totally discharged	*High priority*. The device is running on battery power, and the battery charge level is below 5%. Therapy continues for as long as possible. To save energy and increase operating time, the heating plate and breathing circuit heating are turned off, O2 enrichment is unavailable, and O2 assist is paused. Alarm delay: 3 seconds	• Connect the device to primary power; this also charges the battery. • Immediately provide alternative therapy until the issue is resolved. • Replace the battery.
Blower fault	*Technical fault*. A blower malfunction was detected. A technical alarm cannot typically be corrected by the operator. Therapy stops. Alarm delay: 20 milliseconds	• Immediately provide alternative therapy. • Have the device serviced.

Alarm	Definition	Action needed
Blower service required	*Low priority*. The blower has reached the end of it's lifespan. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	Have the device serviced.
Buzzer defective	*High priority*. A buzzer malfunction was detected. A technical alarm cannot typically be corrected by the operator. Alarm delay: 0 seconds	• Restart device. • Provide alternative therapy until the issue is resolved. • If the problem persists, have the device serviced.
Cannot reach target flow	*High priority*. The device has not been able to deliver the set flow to the patient for at least 60 seconds, due to any of the following: • Increased resistance on the blower intake side • Air intake filter is blocked • Performance is limited by high altitude Suppressed during a pause. Alarm delay: 5 seconds if the blower controller is at upper limit, 60 seconds if measured flow is out of the specified flow range	• Check patient condition. • Check patient interface for blockage. • Check breathing circuit limb and tubing for kinks. • Check breathing air intake and replace air intake filter, if required. • Consider reducing flow. • Ensure the device is operated below the maximum allowed altitude.
Chamber type mismatch	*Low priority*. The inserted humidification chamber is incompatible with the device. Alarm delay: 500 milliseconds	Insert a new humidification chamber and connect the breathing circuit.

Alarm	Definition	Action needed
Check ambient temperature	*Low priority*. The ambient air temperature is either below 18°C or above 30°C for at least 60 seconds. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 60 seconds	• If applicable, avoid direct air flow from air conditioning and the like to the device and breathing circuit. • If applicable, remove the device from the sun or other heat source. • Consider changing the environment of use such that the ambient temperature satisfies the operating requirements of the device.
Check chamber	*Medium priority*. The humidification chamber is missing or is not properly seated in the device. Suppressed during a pause. Alarm delay: 500 milliseconds	• Ensure the humidification chamber is properly inserted in the device. • Replace the humidification chamber. • If the problem persists, have the device serviced.
Check for blockage	*High priority*. Pressure limit reached due to increased resistance. There is an obstruction in the breathing circuit; possibly the circuit or interface is kinked. Alarm delay: 1 second	Ensure the breathing circuit and patient interface are properly positioned, and not kinked.
Check settings	*Low priority*. A change to a control or alarm setting was not saved. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	Check and confirm settings, including alarms.
Check tube	*Medium priority*. The breathing circuit is missing or is not properly connected to the device. Suppressed during a pause. Alarm delay: 500 milliseconds	• Ensure the breathing circuit is properly connected to the device. • Replace the breathing circuit. • If the problem persists, have the device serviced.

Alarm	Definition	Action needed
Confirm start-up message	*Medium priority*. The device was turned on more than 60 seconds ago and the startup message has not been confirmed. Alarm delay: 60 seconds	Confirm the startup message on the device display.
Consider battery replacement	*Low priority*. The battery can no longer hold a charge well. Therapy continues. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 4 seconds	• Ensure the device is connected to primary power. • Replace the battery as soon as possible.
Cooling fan failure	*Medium priority*. There is a problem with the cooling fan. Alarm delay: 5 seconds	• If possible, provide alternative therapy until the issue is resolved. • Have the device serviced.
Could not resume therapy	*Medium priority*. An error with the hard drive was detected. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	• Check settings, including alarms. • If the problem persists, have the device serviced.
Device temperature high	*High priority*. The internal temperature of the device is higher than expected. Alarm delay: 0 seconds	• Remove the device from the sun or other heat source. • Check the dust filter and cooling fan. • Prepare alternative therapy. • If the problem persists, have the device serviced.
Device tilted	*Medium priority*. The device is at a 10° or greater angle relative to the floor for at least 60 seconds. Alarm delay: 60 seconds *High priority*. The device is at a 45° or greater angle relative to the floor for at least 5 seconds. When this occurs, therapy stops. Alarm delay: 0 seconds	• Check the position of the device. • Operate the device at an angle less than 5° relative to the floor.

Alarm	Definition	Action needed
Exchange tube	*High priority*. A problem with the breathing circuit was detected. The breathing circuit may be damaged. Alarm delay: 0 seconds	• Check patient condition. • Replace the breathing circuit. • If the problem persists, have the device serviced.
High gas temperature	*High priority*. The gas temperature at the patient end of the breathing circuit has been more than 2 degrees (2°C) above the set value for at least 10 minutes. Alarm delay: 0 seconds if the temperature is over 43°C; otherwise, 10 minutes.	• Check whether the breathing circuit is covered by the patient's bed covers. • Check whether the breathing circuit or the humidification chamber is directly exposed to sunlight. • Replace the breathing circuit.
High oxygen	*High priority*. One of the following has occurred for at least 60 seconds: • If the Oxygen alarm limits are set automatically, the measured oxygen is more than 5% (absolute) above the current Oxygen control setting. • If Set Oxygen alarm limits manually is turned ON in the Gas source window, the measured oxygen is above the set upper limit. Suppressed during a pause. Alarm delay: 60 seconds. Note that the alarm is suppressed for 5 minutes when the Oxygen setting is changed, or when resuming therapy after a pause.	• Check alarm limits (if set manually). • Calibrate the O2 sensor. • If the problem persists, have the device serviced.
High water level	*High priority*. The water level in the humidification chamber is above the maximum level mark. Alarm delay: 10 seconds	• Empty humidification chamber to reduce the water level. • Replace the humidification chamber.

Alarm	Definition	Action needed
Humidity low	*Medium priority*. The humidity of the delivered gas is low. Alarm delay: 10 minutes	• Check patient condition. • Check ambient temperature • Check breathing circuit for condensation and drain, if required. • Check humidification chamber and fill, if required. • If the problem persists, have the device serviced.
Loss of external power	*Low priority*. The device is running on battery power due to loss of a primary power source. If a battery is not connected, the Total power loss alarm is generated. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 1 second	• Turn off the alarm. • Check the integrity of the connection to primary power. • Check the battery status. • Prepare for possible power loss.
Loudspeaker defective	*High priority*. A loudspeaker malfunction was detected. A technical alarm cannot typically be corrected by the operator. Therapy continues. Alarm delay: 0 seconds	• Check patient condition. • Provide alternative therapy until the issue is resolved. • If the problem persists, have the device serviced.
Low gas temperature	*Medium priority*. The gas temperature at the patient end of the breathing circuit is more than 2 degrees (2°C) below the set value for over 10 minutes. Suppressed during a pause. Alarm delay: 10 minutes	• Wait until the circuit heats up completely. For warm-up times, see Table 9-10 in Section 9.10. • Check ambient temperature. • Check whether all settings are correct. • Avoid direct air flow from air conditioning and the like to the device and breathing circuit.

Alarm	Definition	Action needed
Low oxygen	*High priority*. One of the following has occurred for at least 60 seconds: • If the oxygen alarm limits are set automatically, the measured oxygen is more than 5% (absolute) below the current Oxygen control setting. • If Set Oxygen alarm limits manually is turned ON in the Gas source window, the measured oxygen is below the set lower limit. Suppressed during a pause. Alarm delay: 60 seconds. Note that the alarm is suppressed for 5 minutes when the Oxygen setting is changed, or when resuming therapy after a pause.	• Check patient condition. • Check the oxygen supply. Provide an alternative source of oxygen, if necessary. • Calibrate the O2 sensor. • If the problem persists, have the device serviced.
Low water level	*Medium priority*. The water level in the chamber is below the low level mark. Alarm delay: 10 seconds	• Check water bottle and refill tubing. • If the water bottle is empty, connect a new water bottle. • Refill or exchange the empty humidification chamber.
Maintain device	*Medium priority*. Based on the device's operational hours, preventive maintenance of the filters and gas outlet adapter is required. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	Exchange all filters and the gas outlet adapter to ensure proper therapy. For details, see Section 6.4.

Alarm	Definition	Action needed
Nebulizer disconnected	*Medium priority.* Any of the following conditions apply during active therapy and nebulization: Aerogen is the selected nebulizer type and the countdown timer is running, but: • A nebulizer is *not* connected • The nebulizer is *not* properly connected and is *not* being powered Alarm delay: 1 second	• Verify that an Aerogen nebulizer is connected to the breathing circuit set. • Check cable connection to the nebulizer and to the Nebulizer port on the device. • If the problem still persists, have the device serviced. Check the cable connections to the nebulizer and to the Nebulizer port on the device. See Section 3.9.
O2 sensor calibration needed	*Low priority*. The O2 sensor needs to be calibrated. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	• If a patient is connected, confirm the alarm until you can interrupt therapy. • Disconnect the patient. • Calibrate the O2 sensor (Section 4.4.4).
Oxygen supply failed	*High priority*. Oxygen source flow is lower than expected for at least 5 seconds. Alarm delay: 5 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 therapy until the issue is resolved.

Alarm	Definition	Action needed
Patient group changed	*Medium priority*. A new breathing circuit set has been connected to the device and the patient group of the breathing circuit set differs from the previous. Therapy continues with the default settings for the patient group of the newly connected breathing circuit set. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	• Ensure the patient group of the new breathing circuit set is correct for the patient. • Check and confirm settings.
Service required (gold cap)	*Low priority.* The gold cap condenser has reached the end of its lifetime, and must be replaced. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	Have the device serviced.
Set date and time	*Low priority*. The date and time are not set. Alarm delay: 0 seconds	• Set the date and time ( > Date & Time). • If the problem persists, have the device serviced.
Total power loss	*Technical fault*. The device is not connected to primary power and either no battery is installed, or the battery has no charge. The device turns off, the Caution indicator blinks, and the backup alarm is generated. No message is shown. Upon device restart, the Event log shows the entry Therapy continued after power failure. Alarm delay: 0 seconds	Connect the device to primary power or install a charged battery. After the device is reconnected to power, therapy automatically starts using the previous settings, independent of the duration of the power outage.
Touch not functional	*Medium priority*. The touch screen is defective. Alarm delay: 10 seconds	• Turn the device off and on again. • If the problem persists, have the device serviced.

Alarm	Definition	Action needed
Trial license expired	*Low priority*. A trial license has expired and is no longer available for use. You can turn off (deactivate) this alarm. For details, see Section 5.6. Alarm delay: 0 seconds	Turn off the alarm.

5.9 Testing alarms

During startup, the HAMILTON-HF90 performs a self-check 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 device exceeds or fails to reach the set limit, thereby generating the associated alarm. For details on setting alarm limits, see Section 4.2.2.

5.9.1 Testing the obstruction alarm

Before starting therapy, you can confirm that the Check for blockage alarm is generated when the breathing circuit is obstructed, if desired.

To check the obstruction alarm

1. Turn on the device.
2. Ensure that Flow is set to at least 10 l/min.
3. Confirm that a flow of gas is exiting the breathing circuit.
4. Block the end of the breathing circuit (wearing a glove is recommended).
5. After a short time, the Check for blockage alarm is generated.

   To resolve the alarm, stop blocking the breathing circuit.

6
Maintenance

6.1 Overview 102
6.2 About cleaning and disinfecting the device and components 102
6.3 Cleaning and replacement schedule 107
6.4 Replacing components 108
6.5 Repacking and shipping 109

6.1 Overview

Before proceeding, review the safety information in Chapter 1.

The HAMILTON-HF90 is a low-maintenance device. It contains no serviceable parts.

The following information is available in this chapter.

For details about ...	See ...
Cleaning and disinfection instructions, as well as important safety information	Section 6.2.1
Device-related components that need regular cleaning, and the frequency thereof	Table 6-1
For breathing circuit sets and external devices and sensors	*Instructions for use* for the component
Approved cleaning and disinfection wipes for use with device components	Table 6-2
Preventive maintenance schedule	Section 6.3
Replacing the gas outlet adapter cap and filters	Section 6.4
Shipping the device	Section 6.5

For additional 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

6.2 About 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/disinfection agents are tested as a specific composition of different chemicals (see Table 6-2) by our certified laboratory, to validate their materials compatibility and cleaning/disinfection efficacy.

Other surface cleaning/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/disinfection wipes that are **not** listed in Table 6-2.

The 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 agents 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/disinfection agents, 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/disinfection wipes to use and the associated procedures, if you have specific questions about the use of a particular cleaning or disinfection agent, contact your Hamilton Medical technical representative or the manufacturer of the agent.

6.2.1 Surface cleaning and disinfection (validated processing instructions)

⚠ WARNING

- Do not clean the device interior to avoid damaging internal components.
- Before cleaning the device, be sure to cover the gas outlet adapter with the protective cap to prevent any inadvertent intrusion of fluids.
- Penetrating liquid may cause the following:
  - Damage to the device
  - Electric shock
  - Device malfunctions

  Use *only* the approved cleaning/disinfecting wipes listed in Table 6-2 and ensure that **no** liquid penetrates the device.
- When cleaning during therapy, do *not* clean the humidification chamber or the breathing circuit.
- When replacing a filter, be sure to clean the filter cover. Let the cover dry completely before reattaching it.
- Use nationally approved cleaning and disinfecting wipes, from the wipes listed in Table 6-2.
- Carefully follow the manufacturer's instructions of each validated wipe, for example, regarding shelf life or application conditions.

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.

Device components, such as the device surface, trolley, 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 and humidification chamber may become contaminated during use and in a single fault condition.

To surface clean a component

1. Unfold a clean disposable cleaning and disinfectant wipe (from Table 6-2), and wipe off visible soil from the component surface.
2. 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.
3. Dispose of the wipe.

To surface disinfect a component

After cleaning the surface as instructed previously, do the following.

1. Wipe cleaned surfaces again, until visibly wet, with a cleaning and disinfectant wipe selected Table 6-2.
2. Dispose of the wipe.
3. Wait for the contact time of your chosen wipe.
4. Wait until the surfaces are dry.
5. Check the surfaces for visible damage.

   If there is any damage, contact your Hamilton Medical technical representative.
6. After use of the wipes, ensure their packaging lid is firmly sealed.

Table 6-1. HAMILTON-HF90 component cleaning/disinfection frequency and methods

Component	Cleaning/disinfection frequency	Cleaning/disinfection method and wipes
Before proceeding, review the warnings and notices in Section 6.2.1.		
Touch screen display	After each patient use, and as needed during therapy	See instructions in Section 6.2.1, and use agents from Table 6-2. Avoid using a gritty cloth.
Device exterior, including: • Housing, including filter covers • Power cables • Mounting systems • Heater plate	After each patient use, and as needed during therapy	See instructions in Section 6.2.1, and use agents from Table 6-2.
Trolley-related accessories, including: • Trolley • O2 cylinder holding system	After each patient use, and as needed during therapy	See instructions in Section 6.2.1, and use agents from Table 6-2.

6.2.1.1 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.

Table 6-2. Approved cleaning/disinfection wipes for the HAMILTON-HF90

Cleaning/disinfection wipes	Active ingredients	Manufacturer	Regulatory approval
Before proceeding, review the warnings and notices in Section 6.2.1.			
EPA-registered cleaning/disinfection wipes			
Cavi Wipes 2.0	Propanol, isopropyl alcohol, isopropanol	Metrex	EPA[1]
Approved cleaning/disinfection wipes			
Cavi Wipes 2.0	Propanol, isopropyl alcohol, isopropanol	Metrex	CE[2]
universal wipes green line	Propanol, ethanol	Schülke & Mayr	CE
Environmental Cross V-Lock	Quaternary ammonium salts	Hazuko Medical	Registered in Japan
Incidin OxyWipes S	Hydrogen peroxide	ECOLAB	CE
Sani-Cloth active	Ammonium chloride	ECOLAB	CE

[1] United States Environmental Protection Agency (EPA)
[2] CE certification according to MDR 2017/745 and further amendments

6.3 Cleaning and replacement schedule

Perform preventive maintenance on your device according to the schedule in Table 6-3.

The > System configuration > System information window shows the number of hours the device has been in operation.

Table 6-3. Preventive maintenance schedule

Part/accessory	Frequency	Procedure
Breathing circuit (including humidification chamber)	Between patients and according to hospital policy (maximum 14 days)	Replace with new single-patient use parts.
SpO2 sensors	Between patients and according to hospital policy	Refer to the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548) and the sensor manufacturer's *Instructions for Use*.
Air intake and dust filters	Every 6 months, 1000 hours, or more often if required	Check for dust and lint. If needed, replace. See Section 6.4.2.
Battery		Recharge the battery by plugging the device into a primary power source for at least 8 hours.
Gas outlet adapter		Exchange the gas outlet adapter to maintain a proper seal. Performed by trained hospital/service technician.[1]
Battery	As necessary	Have the battery serviced.
Device		Have the device serviced as required.

[1] Instructions provided in the *HAMILTON-HF90 Service Manual*.

6.4 Replacing components

The following sections describe how to place the protective cap on the gas outlet adapter, and clean and replace filters.

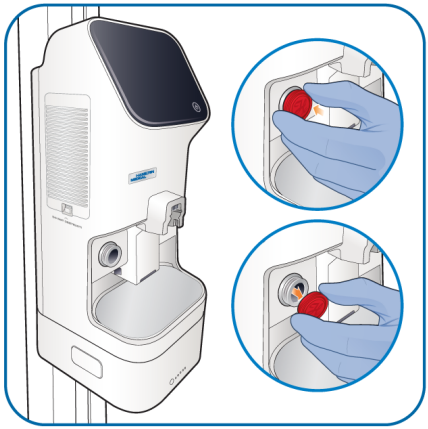
Gas outlet replacement is performed by a trained hospital/service technician. Related information is provided in the *HAMILTON-HF90 Service Manual*.

6.4.1 Placing the protective cap on the gas outlet adapter

Protective caps (PN 10159070) are provided with each breathing circuit set, and are used to cover the gas outlet to protect the gas path during device cleaning. The cap remains in place until the next breathing circuit set is attached.

Before cleaning the device, be sure to cover the gas outlet with a new protective cap to prevent any inadvertent intrusion of fluids.

Figure 6-1. Attaching/removing the gas outlet adapter protective cap



6.4.2 Replacing the filters

When replacing a filter, be sure to clean the filter cover. Let the cover dry completely before reattaching it.

The dust filter and air intake filter are provided in a dedicated maintenance set (PN 10160365).

Figure 6-2. Replacing the air intake filter. Ensure the checkmark faces up.

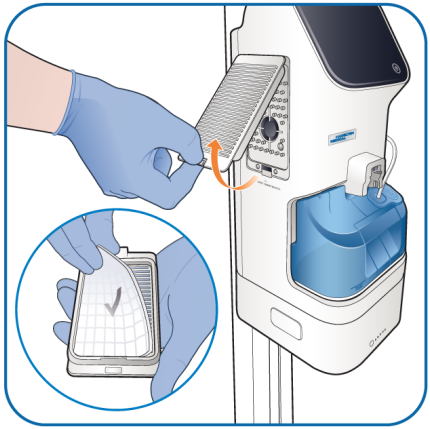
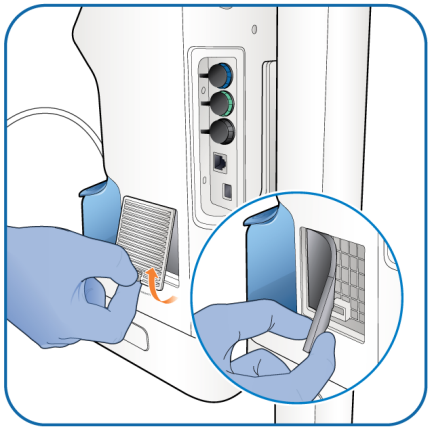


Figure 6-3. Replacing the dust filter



6.5 Repacking and shipping

⚠ CAUTION

- *Inform Hamilton Medical if you are shipping a contaminated (nondisinfected) device for service.*
- *If you must ship a battery, contact your Hamilton Medical technical representative for shipping materials and instructions.*

If you must ship the device, use the original packing materials. If these materials are not available, contact your Hamilton Medical representative for replacement materials.

7 Extended configuration

7.1 Overview 112
7.2 Accessing Extended configuration 112
7.3 Selecting the default language 112
7.4 Configuring the default therapy settings 113
7.5 Setting the maximum available Flow (neonatal/pediatric) 113
7.6 Configuring oxygen enrichment settings 113
7.7 Selecting an SpO2 sensor type 114
7.8 Configuring O2 assist default settings 114
7.9 Configuring device options 114
7.10 Copying configuration settings 116
7.11 Restoring the factory default settings 116

7.1 Overview

During configuration, you set up the device with a default language and startup settings for a new patient, among other settings.

Table 7-1. Extended configuration, overview

For details about ...	See ...
Accessing Extended configuration	Section 7.2
Selecting the default language	Section 7.3
Configuring default therapy settings	Section 7.4
Setting the maximum flow (Neo/Ped)	Section 7.5
Configuring O2 enrichment	Section 7.6
Selecting an SpO2 sensor	Section 7.7
Configuring O2 assist default settings	Section 7.8
Configuring device options	Section 7.9
Copying configuration settings	Section 7.10
Restoring the factory defaults	Section 7.11

7.2 Accessing Extended configuration

You can access Extended configuration at any time. Access requires a configuration code; contact your administrator.

To access Extended configuration

1. Touch  > **System configuration**.
2. Touch **Extended configuration**.
3. Provide the code to access Extended configuration.

You can now define settings and add or remove options.

7.3 Selecting the default language

To select the user interface language

1. In Extended configuration, touch **Language**.
2. Select the desired language from the list and confirm your selection.

7.4 Configuring the default therapy settings

You can set the default therapy settings for the device to use on startup for the Adult/Ped and Neo/Ped patient groups.

To set the default therapy settings

1. In Extended configuration, touch **Therapy defaults**.
2. Touch **Adult/Ped** or **Neo/Ped** to access the settings for each patient group.
3. Adjust the settings for Flow, O2, and Temperature, as desired.

The settings are applied when starting therapy with a new patient.

7.5 Setting the maximum available Flow (neonatal/pediatric)

You can specify the maximum Flow that can be set during therapy for neonatal/pediatric patients. Once set, the operator cannot set Flow above the value set here in Extended configuration.

To specify the Max. Flow setting for neonatal/pediatric patients

1. In Extended configuration, touch **Max. Flow (Neo/Ped)**.
2. Touch the control to activate it.
3. Adjust the control as desired and confirm the setting.

7.6 Configuring oxygen enrichment settings

The amount of Oxygen to be delivered during O2 enrichment can be set for each patient group in Extended configuration. For details about using O2 enrichment, see Section 4.4.1.

For the each patient group, you set the oxygen concentration to be delivered *in addition* to the current Oxygen setting.

Note that the maximum delivered oxygen concentration will not exceed 100%. If the sum of the two settings is greater than 100%, the device delivers 100%.

Example

Current Oxygen setting: 50%

Additional O2 for enrichment (+O2) setting: 40%

When you perform O2 enrichment by pressing O2⇧ 90%, the device increases the delivered oxygen to 90% for two minutes.

To specify the oxygen level to be delivered during O2 enrichment

1. In Extended configuration, touch **O2 enrichment**.
2. Touch **Adult/Ped** or **Neo/Ped** to access the settings for each patient group.
3. Adjust the +O2 setting, as desired.

The setting is applied when O2 enrichment is active. The **O2 enrichment** button on the device main display shows the *total* Oxygen level to be delivered during enrichment.

7.7 Selecting an SpO2 sensor type

With the SpO2 option, you can monitor SpO2 and related data. To activate the option, you select the sensor type to use with the device.

To select the SpO2 sensor type

1. In Extended configuration, touch **SpO2 sensor type**.
2. Touch **Sensor type**.
3. Touch the sensor type name to activate: **Masimo** or **Nihon Kohden**.

For additional information, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

7.8 Configuring O2 assist default settings

You can configure the default settings O2 assist[1] uses for the high- and low-SpO2 target range and Emergency limits.

You configure the defaults in the device's Extended configuration window.

You can access Extended configuration at any time. Access requires a configuration code; contact your administrator.

To access Extended configuration

1. Touch  > **System configuration**.
2. Touch **Extended configuration**.
3. Provide the code to access Extended configuration.

To configure the default O2 assist settings

1. In Extended Configuration, touch **O2 assist defaults**.
2. Touch **Adult/Ped** or **Neo/Ped** to configure the default settings for the desired patient group.
3. Define the high and low SpO2 target and Emergency limit settings in the respective windows.

When turned on, O2 assist begins with these settings. You can adjust the settings at any time in the  > O2 assist windows.

7.9 Configuring device options

Before use, you must add and enable any necessary software options on the device. You can review the currently installed options in the System configuration > System information (second page) window.

[1] Not available in all markets.

7.9.1 Adding software options

Software options are added using license keys that are provided on a USB drive. To obtain additional option license keys, contact your Hamilton Medical technical representative.

Trial versions of software options may be available. Trial options expire and are automatically deactivated after 30 days. Expired trial options are removed once the device is restarted.

To add a software option

1. Insert the provided USB drive into the device's USB port (Figure 2-3 in Section 2.2.1).
2. In Extended configuration, scroll down and touch **Add/Remove options**.
3. Touch **Add options**.

   The device begins installing all of the options that are on the USB drive.

   When complete, the device displays the message Import successful.

The added options are available for use.

7.9.2 Removing software options

Note that trial options expire at the end of the trial period. Expired trial options are removed once the device is restarted.

To remove a software option

1. In Extended configuration, scroll down and touch **Add/Remove options**.
2. Touch **Remove options**.
3. In the list of installed options, select the option or options to be removed.

   The **Remove options** button appears at the bottom right of the display.
4. Touch **Remove options**.

   You are prompted to confirm removal of the selected option or options.
5. Touch ✓ to confirm the removal of options and restart the device.

   To cancel, touch **X**.

The device restarts and the options are no longer installed.

7.10 Copying configuration settings

You can copy and transfer configuration settings to other HAMILTON-HF90 devices. For details about configuration settings, ranges, and defaults, see Table 9-9 in Section 9.9.

You can copy configuration settings to/ from the device using a USB drive.

To copy configuration settings using a USB drive

1. Insert a USB drive into the device USB port (Figure 2-3 in Section 2.2.1).
2. In Extended configuration, touch **Export/Import Settings**.
3. In the Export/Import Settings window, touch **Import** or **Export**.

   – The device begins transferring the files. A message is displayed after the files are successfully transferred.

   – Exported files are stored in the settings folder on the USB drive.

   – Imported configuration files are immediately applied to the device.

If you remove the USB drive before the files are successfully transferred, you must start over and repeat the process.

7.11 Restoring the factory default settings

You can restore the device's factory default settings. For details about the default settings, including configuration settings, and adjustable alarms, see Chapter 9.

For details about pulse-oximetry related default settings, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

To restore the factory default settings

1. In Extended configuration, touch **Factory reset**.

   You are prompted to confirm the reset.

2. Touch ✓ to confirm the reset.

   To cancel, touch **X**.

The device restarts and all settings are restored to the factory defaults.

8
Parts and accessories

8.1 Overview 118

8.1 Overview

This chapter lists the parts available for the HAMILTON-HF90 therapy device. Note that not all parts are available in all markets.

For additional parts and accessories and ordering information, refer to the e-catalog on the Hamilton Medical website or contact your Hamilton Medical representative.

Table 8-1. HAMILTON-HF90 parts and accessories

Description	PN
Breathing circuit sets	
Breathing Circuit Set, single limb, 1.88 m, pediatric/adults	10103207
Breathing Circuit Set, single limb, 1.80 m, neo/ped	10119946
Breathing Circuit Set, single limb, 1.60 m, neo/ped	10103261
Incubator Extension, 0.33 m, unheated, neonatal	10108298
Nasal cannulas	
In2Flow Nasal cannula with adapter, size S, adult/ped (orange), box of 20	10076606
In2Flow Nasal cannula with adapter, size M, adult/ped (blue), box of 20	10076605
In2Flow Nasal cannula with adapter, size L, adult/ped (green), box of 20	10076604
Nuflow Nasal cannula set, size S, neo/ped, single use, box of 10	10072354
Nuflow Nasal cannula set, size M, neo/ped, single use, box of 10	10072355
Nuflow Nasal cannula set, size L, neo/ped, single use, box of 10	10072356
Nuflow Nasal cannula set, size XL, neo/ped, single use, box of 10	10072357
Trolley	
Trolley, for HAMILTON-HF90	10098260
Blue-white support arm	282003
Basket, for trolley (maximum load 3 kg)	10098256

Description	PN
Oxygen Cylinder Holder Sets	
O2 Cylinder Holder Set, for 1 tank, with velcro strips	10142229
O2 Cylinder Holder Set, for 3 tanks, with velcro strips	10098257
Mounting solutions	
Trolley and Device Mounting Kit	10108285
Device Mounting Kit	10142950
Filters	
Filter Set, with 5 dust and air intake filters	10160365
Cleaning preparation	
Gas Outlet Adapter (GOA), set of 5 pieces	10150863
Power cord	
Power cord with US plug, 2-pin, 2.5 m	355353
Power cord with British angled plug, 2.5 m	355237
Power cord with continental European plug, 2-pin, 2.5 m (also for use in Korea)	355234
Power cord with Swiss plug, 2.5 m	355235
Power cord with Japanese plug, 2.5 m	355295
Power cord with Chinese plug, 2.5 m	355238
Communication	
Communication Board (USB, Ethernet[1], nurse call)	10098194
Communication Board (USB, Ethernet[1], SpO2, COM1)	10098195
Communication Board (USB, Ethernet[1], SpO2, COM1, nebulizer)	10120404
Battery	
Lithium-ion battery, with status indicator (when ordered together with the HAMILTON-HF90 device)	10164864
Lithium-ion battery, with status indicator (ordered on its own)	10155275
Battery Charger CH	10160359
Battery Charger EU/KR	10162515

[1] The Ethernet port is for internal use only.

Description	PN
Battery Charger US	10160360
Battery Charger UK	10160361
Battery Charger China	10160362
Battery Charger Japan	10160363
High pressure oxygen connector	
DISS O2 Connector — diameter index safety standard	10118409
NIST O2 Connector — no interchangeable screw thread	10118410
Low pressure oxygen (LPO) connector	
Low pressure oxygen adapter	279913
SpO2 sensors and accessories (Masimo and Nihon Kohden) *See the Hamilton Medical e-catalog.*	
Language kit	
English	10108590
German	10108592
Spanish	10108593
French	10108594
Portuguese	10108595
Italian	10108596
Chinese	10108597
Russian	10108598
Japanese	10142956
Korean	10159938
Extended warranty	
Extended warranty of 1 year (for a total of 3 years)	700911
Extended warranty of 2 years (for a total of 4 years)	700912
Extended warranty of 3 years (for a total of 5 years)	700913
Extended warranty of 6 years (for a total of 8 years)	700916

9 Specifications

9.1 Potential complications and residual risks 122
9.2 Physical characteristics 127
9.3 Environmental requirements 128
9.4 Pneumatic specifications 129
9.5 Electrical specifications 130
9.6 Control settings 132
9.7 Monitored parameters 133
9.8 Alarms 134
9.9 Configuration 135
9.10 Technical performance data 136
9.11 Essential performance 139
9.12 Applied parts 140
9.13 Functional description 140
9.14 Symbols used on device and trolley labels and packaging 143
9.15 Standards and approvals 145
9.16 Disposal and year of manufacture 146
9.17 Warranty 146

9.1 Potential complications and residual risks

The HAMILTON-HF90 is intended to provide high flow oxygen therapy (HFOT) with a continuous flow of heated and humidified respiratory gases to spontaneously breathing patients. It also includes the O2 assist software that is intended to automatically adjust the inspired oxygen fraction to achieve a previously defined oxygen saturation range.

For the intended use and contraindications, see Section 1.2.

Residual risks related to HFOT are analyzed and assessed in the following sections.

For details about ...	See ...
Risks associated with inadequate heating and humidification	Section 9.1.1
Risks associated with inadequate oxygen delivery	Section 9.1.3
Conclusion of risks and potential complications	Section 9.1.5

9.1.1 Risks associated with inadequate heating and humidification

This section assesses the risks related to inadequate heating and humidification of the inhaled gas, leading to excessive (too high) or inadequate (too low) gas temperature and humidification due to a defect in the active heating and humidification circuit integrated with the HAMILTON-HF90.

9.1.1.1 Too high gas temperature and humidity

A progression of events in the respiratory system takes place if there is a high temperature regardless of humidity at the airway opening during high flow oxygen therapy with active humidification:

1. Mucosal damage may occur due to direct epithelium burn or damage related to higher air temperature.
2. Mucociliary transport slows.
3. Accumulation occurs.
4. Desquamation of epithelial cells and ulceration occurs.

9.1.1.2 Too low gas temperature and humidity

Dry air ventilation can lead to several repercussions in the upper airways, ranging from discomfort and coughing to inflammatory changes and secretion retention with an increased risk of infections. In general, two variables seem to be important in this context: 1) the time of ventilation without adequate humidification and 2) the patient's level of consciousness.

A progression of events in the respiratory system takes place if there is a humidity deficit:[1,2]

- First, no damage occurs for a while.[3]
- Then, the mucus thickens.[1,4]
- Mucociliary transport slows (cilia bogged down in the thickening mucus).[1]
- Cilia stop beating.[1]
- Mucosal damage occurs due to moisture loss and mucosal dehydration.[1].
- Desquamation of epithelial cells and ulceration occurs.[1].
- Mucus secretion continues, and gobs of dried mucus begin to form, occasionally dropping into the deeper bronchi to occlude them, causing atelectasis.[5].

Theoretical considerations[6] led to the conclusion that, during ventilation with inadequate gas humidity, an increase in bronchial blood flow is necessary to keep the moisture and temperature of the airway wall within a physiological range.

Since the upper airway is bypassed during mechanical ventilation, the respiratory system is no longer able to warm and moisten inhaled gases.[7,8] The consequent delivery of cooler and dryer gases can cause a range of problems, including decreased body temperature, increased difficulty in breathing, and airway obstruction in people who already require assisted breathing.[8]

In the worst case, patients with tracheostomy are at risk of having the most physiological change when the upper airway is bypassed. Pre-clinical studies suggest that breathing dry air through a tracheostomy tube for 30 to 60 minutes caused immediate severe epithelial damage and inflammatory changes of the trachea in guinea pigs, but caused no change in total lung resistance,[9] despite an increase in airway responsivity to histamine that could be observed.[10]

[1] Sottiaux TM. Consequences of under- and over-humidification. *Respir Care Clin North Am* 2006; 12: 233–52.
[2] Chanques G, Constantin J-M, Sauter M, et al. Discomfort associated with underhumidified high-flow oxygen therapy in critically ill patients. *Intens Care Med* 2009; 35: 996–1003.
[3] Birk R, Händel A, Wenzel A, et al. Heated air humidification versus cold air nebulization in newly tracheostomized patients. *Head Neck* 2017; 39: 2481–7.
[4] Williams R, Rankin N, Smith T, Galler D, Seakins P. Relationship between the humidity and temperature of inspired gas and the function of the airway mucosa. *Crit Care Med* 1996; 24: 1920-1929.
[5] Solomita M, Palmer LB, Daroowalla F, et al. Humidification and secretion volume in mechanically ventilated patients. *Respir Care* 2009; 54: 1329–35.
[6] Hanna LM, Scherer PW. Regional control of local airway heat and water vapor losses. *J Appl Physiol* 1986; 61: 624–32.
[7] Ashry HSA, Modrykamien AM. Humidification during Mechanical Ventilation in the Adult Patient. *Biomed Res Int* 2014; 2014: 1–12.
[8] Restrepo RD, Walsh BK. Humidification During Invasive and Noninvasive Mechanical Ventilation: 2012. *Respir Care* 2012; 57: 782–8.
[9] Barbet JP, Chauveau M, Labbe S, Lockhart A. Breathing dry air causes acute epithelial damage and inflammation of the guinea pig trachea. *J Appl Physiol* 1988; 64: 1851–7.
[10] Oostdam JCV, Walker DC, Knudson K, Dirks P, Dahlby RW, Hogg JC. Effect of breathing dry air on structure and function of airways. *J Appl Physiol* 1986; 61: 312–7.

9.1.2 Risks associated with the reliability and accuracy of pulse oximetry sensors

Automated oxygen delivery systems are dependent on the reliability and accuracy of pulse oximetry. Although the algorithms can validate the reliability of the SpO2 measurement and enter into a fallback state, the clinician determining the use of oxygen in an individual patient should apply the same, or even stricter, criteria as that used routinely to monitor and assure the reliability of pulse oximetry for every patient.

9.1.3 Risks associated with a too-low inspired oxygen fraction

The lack of oxygen may be dangerous and life threatening. Acute hypoxemia leads to tachycardia (to increase cardiac output and oxygen transport to tissues)[1], increased minute ventilation (to increase oxygen intake)[2,3], systemic arterial vasodilatation[4,5], pulmonary vasoconstriction[6], increased tissue extraction of oxygen, and other mechanisms that increase oxygen delivery to tissues (such as a right-shift of the haemoglobin saturation curve).

When the protection mechanisms are overwhelmed, tissue hypoxia may occur, with risks of cardiac ischemia (especially due to associated tachycardia), cardiac arrhythmia[7,8], hepatic ischemia, cerebral ischemia, and cellular anaerobic respiration leading to increased lactate production[9].

To correct hypoxemia, oxygen must be administered urgently aiming to keep SpO2 above 88% in patients at risk of hypercapnia, and 90% in other patients.[10] Oxygen supplementation should be initiated only if SpO2 is below 93% in the general population.

[1] Slutsky AS, Rebuck AS. Heart rate response to isocapnic hypoxia in conscious man. *Am J Physiol-heart C* 1978; 234: H129–32.
[2] Easton PA, Slykerman LJ, Anthonisen NR. Ventilatory response to sustained hypoxia in normal adults. *J Appl Physiol* 1986; 61: 906–11.
[3] Bradley CA, Fleetham JA, Anthonisen NR. Ventilatory Control in Patients with Hypoxemia Due to Obstructive Lung Disease1–3. *Am Rev Respir Dis* 2015; 120: 21–30.
[4] Kogure K, Scheinberg P, Reinmuth OM, Fujishima M, Busto R. Mechanisms of cerebral vasodilatation in hypoxia. *J Appl Physiol* 1970; 29: 223–9.
[5] West JW, Guzman SV. Coronary Dilatation and Constriction Visualized by Selective Arteriography. *Circ Res* 1959; 7: 527–36.
[6] Weir EK, López-Barneo J, Buckler KJ, Archer SL. Acute Oxygen-Sensing Mechanisms. *New Engl J Medicine* 2005; 353: 2042–55.
[7] Galatius-Jensen S, Hansen J, Rasmussen V, Bildsøe J, Therboe M, Rosenberg J. Nocturnal hypoxaemia after myocardial infarction: association with nocturnal myocardial ischaemia and arrhythmias. *Brit Heart J* 1994; 72: 23.
[8] Gill NP, Wright B, Reilly CS. Relationship Between Hypoxaemic and Cardiac Ischaemic Events in the Perioperative Period. *Bja Br J Anaesth* 1992; 68: 471–3.
[9] Finfer SR, Vincent J-L, Backer DD. Circulatory Shock. *New Engl J Medicine* 2013; 369: 1726–34.
[10] Siemieniuk RAC, Chu DK, Kim LH-Y, et al. Oxygen therapy for acutely ill medical patients: a clinical practice guideline. *Bmj* 2018; 363: k4169.

9.1.3.1 Risk of hypoxemia during HFOT with HAMILTON-HF90

This harm might occur in the following situation: An inadequate (too low) desired SpO2 is pre-set and the Oxygen controller decreases the inspired oxygen fraction, but the patient's SpO2 doesn't decrease immediately and the Oxygen controller overshoots the desired SpO2, resulting in the patient being ventilated with a low oxygen fraction over a certain period (usually not higher than two (2) minutes). The risk of a transient desaturation can result in several critical consequences, and is highly dependent on both the severity of desaturation (SpO2 < 80%) and the time spent in such a condition. In unstable patients, the continuous monitoring of the SpO2 would alarm under these circumstances, and the clinician would be alerted to such a harm.

A severe desaturation might also be related to the necessity of restarting the HAMILTON-HF90 due to an internal error, leading to a short time interruption in ventilation/therapy during the restart time. This interruption might lead to patient desaturation (SpO2 between 80% and 87%), depending on the underlying patient condition.[1]

9.1.4 Risks associated with an excessive (too high) inspired oxygen fraction

Oxygen therapy may be toxic and increases mortality.[2,3,4,5] Oxygen toxicity is low-grade toxicity or hidden from view in most circumstances which may explain that it is neglected. However, the deleterious effects of oxygen have been described and compelling demonstrations are now available that hyperoxia may lead to increased mortality.[2,3,4,5,6]

In general, the liberal oxygen increased mortality in comparison with restrictive oxygen use in different populations of critically ill patients.[3]

[1] Neumann P, Berglund JE, Fernandez-Mondéjar E, Magnusson A, Hedenstierna G. Dynamics of lung collapse and recruitment during prolonged breathing in porcine lung injury. *Journal of Applied Physiology* 1998; 85: 1533–43.
[2] Austin MA, Wills KE, Blizzard L, Walters EH, Wood-Baker R. Effect of high flow oxygen on mortality in chronic obstructive pulmonary disease patients in prehospital setting: randomised controlled trial. *Bmj* 2010; 341: c5462.
[3] Chu DK, Kim LH-Y, Young PJ, et al. Mortality and morbidity in acutely ill adults treated with liberal versus conservative oxygen therapy (IOTA): a systematic review and meta-analysis. *Lancet* 2018; 391: 1693–705.
[4] Girardis M, Busani S, Damiani E, et al. Effect of Conservative vs Conventional Oxygen Therapy on Mortality Among Patients in an Intensive Care Unit: The Oxygen-ICU Randomized Clinical Trial. *Jama* 2016; 316: 1583.
[5] Helmerhorst HJF, Arts DL, Schultz MJ, et al. Metrics of Arterial Hyperoxia and Associated Outcomes in Critical Care. *Crit Care Med* 2017; 45: 187–95.
[6] Kilgannon JH, Jones AE, Shapiro NI, et al. Association Between Arterial Hyperoxia Following Resuscitation From Cardiac Arrest and In-Hospital Mortality. *Jama* 2010; 303: 2165–71.

9.1.4.1 Risk of hyperoxemia during HFOT with HAMILTON-HF90

This harm might occur in the following situation: An excessive (too high) desired SpO2 is pre-set and the Oxygen controller increases the inspired oxygen fraction, but the patient's SpO2 doesn't improve immediately, and the Oxygen controller overshoots the desired SpO2, resulting in the patient being ventilated with a high oxygen fraction over a certain period (usually not longer than two (2) minutes). However, and especially in critically ill patients, the PaO2 values might be routinely checked with arterial blood gas analysis.[1] The risk of a transient hyperoxia is still not well addressed in the literature[2,3,4,5], and the overshoot period is not expected to be as long as two (2) minutes.

9.1.5 Conclusion

All critically ill patients under invasive or noninvasive ventilatory support at hospitals and long-term acute care hospitals are continuously monitored with both noninvasive and invasive monitoring systems. The clinicians, nurses, and respiratory therapists are also closely and continuously assisting the patients, being always available to intervene at the bedside. They would be able to easily recognize the risks associated with inadequate ventilation and oxygenation, and to provide an alternative ventilatory strategy with conventional oxygen enrichment.

With the measures taken, the identified risks of this product have been reduced as far as possible without having a negative impact on the benefit-risk ratio. As a result, the residual risk associated with each hazard, as well as the overall residual risks, are judged to be acceptable for the HAMILTON-HF90.

[1] Fan E, Sorbo LD, Goligher EC, et al. An Official American Thoracic Society/European Society of Intensive Care Medicine/ Society of Critical Care Medicine Clinical Practice Guideline: Mechanical Ventilation in Adult Patients with Acute Respiratory Distress Syndrome. *Am J Resp Crit Care* 2017; 195: 1253–63.
[2] Kilgannon JH, Jones AE, Shapiro NI, et al. Association Between Arterial Hyperoxia Following Resuscitation From Cardiac Arrest and In-Hospital Mortality. *Jama* 2010; 303: 2165–71.
[3] Poder TG, Kouakou CRC, Bouchard P-A, et al. Cost-effectiveness of FreeO2 in patients with chronic obstructive pulmonary disease hospitalised for acute exacerbations: analysis of a pilot study in Quebec. *Bmj Open* 2018; 8: e018835.
[4] Barbateskovic M, Schjørring OL, Krauss SR, et al. Higher versus lower fraction of inspired oxygen or targets of arterial oxygenation for adults admitted to the intensive care unit. *Cochrane Db Syst Rev* 2019; 2019. DOI:10.1002/14651858.cd012631.pub2.
[5] Sjöberg F, Singer M. The medical use of oxygen: a time for critical reappraisal. *J Intern Med* 2013; 274: 505–28.

9.2 Physical characteristics

Table 9-1. Physical characteristics

Dimension	Specifications
Weight	Device (without options and trolley): ≤ 4.5 kg Device with battery (without options and trolley): ≤ 7 kg Maximum loading weight of water bag pole: 1 kg (a 1 liter water bag weighs approx. 1 kg)
Dimensions	See the following figures.

Figure 9-1. HAMILTON-HF90 device dimensions

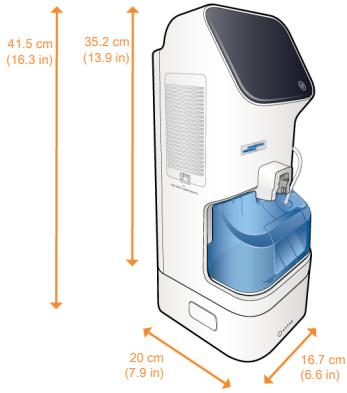


Figure 9-2. HAMILTON-HF90 with trolley dimensions

9.3 Environmental requirements

Table 9-2. Environmental requirements

Environment		Specifications
Temperature	Operation:	18°C to 30°C (64°F to 86°F)
	Storage:	15°C to 35°C (59°F to 95°F)
	Shipment/transit:	-20°C to 60°C (-4°F to 140°F), for a maximum period of 28 days
Altitude		-650 up to 4,000 m (13,123 ft) Note that at higher altitudes the device performance may be limited. The Cannot reach target flow alarm is generated and a message is shown on the display. See Table 5-2 in Section 5.8.
Atmospheric pressure	Operation and storage:	600 to 1100 hPa (60 to 110 kPa)
Relative humidity	Operation and storage:	10% to 95%, noncondensing
Water protection		IP22
For specifications related to any external devices and sensors, refer to the manufacturer's *Instructions for Use*.		

9.4 Pneumatic specifications

Table 9-3. Pneumatic specifications

Component	Specifications	
High-pressure oxygen inlet (HPO)	Pressure:	2.8 to 6 bar (41 to 87 psi)
	Flow:	≤ 100 l/min
	Connector:	DISS (CGA 1240) or NIST
Low-pressure oxygen inlet (LPO)	Pressure:	≤ 6 bar (87 psi)
	Flow:	≤ 60 l/min
	Connector:	Quick-coupling system, compatible with Colder Products Company (CPC) PMC series
Maximum working pressure		40 cmH2O
Gas mixing system	High pressure oxygen:	21% to 100% ± (volume fraction of 2.5% + 2.5% gas level)
	Peak flow:	80 l/min ± 10%
Inspiratory outlet (*To patient* port)	Connector:	Proprietary connection between the device and the breathing circuit

9.5 Electrical specifications

Table 9-4. Electrical specifications

Element	Specifications	
Input power	100 to 240 VAC, 50/60 Hz	
Power consumption	< 350 VA	
Battery	Supplier:	Hamilton Medical (offers optional battery)
	Electrical specifications:	10 Ah, 252 Wh
	Type:	Lithium-ion
	Recharge time:	≤ 8 hours
	Storage:	-20°C to 60°C (-4°F to 140°F)
	Lifetime (typical):	≥ 500 cycles
	Normal operating time:	Typically 2 hours Operating time is measured with a fully charged battery, with the following settings: Adult/Pediatric patient group, Flow = 40 l/min, Oxygen = 30%, Temperature = 37°C, SpO2 sensor connected. This operating time applies to a new, fully charged Li-ion battery not exposed to extreme temperatures. The actual operating time depends on battery age and on how the battery is used and recharged.

Table 9-5. Battery maximum operating time

Flowrate	Specification
This operating time applies to new, fully charged Li-ion batteries that have not been exposed to extreme temperatures. The actual operating time depends on battery age and on how the battery is used and recharged. To ensure maximum battery life, maintain a full charge and minimize the number of complete discharges.	
Flowrate = 80 l/min	40 minutes
Flowrate = 30 l/min	80 minutes
Flowrate = 15 l/min	130 minutes
Flowrate = 8 l/min	160 minutes

9.6 Control settings

Table 9-6. Control settings, ranges, and accuracy

Parameter or setting (unit)	Range	Default	Accuracy
Flow (l/min)	**Adult/Ped**: 4 to 80[1] **Neo/Ped**: 2 to 30	**Adult/Ped**: 40 **Neo/Ped**: 2	±10% or ±300 ml/min, whichever is greater
Oxygen (O2) (%)	21 to 100	21	± (volume fraction of 2.5% + 2.5% gas level)
Temperature (at tube exit) (°C)	31 to 39	37	±2

[1] In some markets, the maximum possible **Flow** setting may be limited. In the USA, the **Adult/Ped** maximum can be set to 60.

9.7 Monitored parameters

Pressure, flow, and volume measurements are based on readings from the flow sensor, and are expressed in BTPS (body temperature and pressure saturated).

For details about SpO2-related monitored parameters, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

Table 9-7. Monitored parameters, ranges, and accuracy

Parameter or setting (unit)	Range	Accuracy
Flow (l/min)	Adult/Ped: 0 to 80 Neo/Ped: 0 to 30	±10%
Oxygen (O2) (%)	18 to 105	± (volume fraction of 2.5% + 2.5% gas level)
O2 consumption[1] (l/min)	0 to 100	±10
Temperature (at tube exit) (°C)	25 to 45	±2

[1] Only displayed when the device is running on battery power.

9.8 Alarms

The alarm specifications listed here apply to all patient groups.

For details about SpO2-related adjustable alarms, see the *Pulse Oximetry Instructions for Use, HAMILTON-HF90* (PN 10116548).

Table 9-8. Adjustable alarm priority, ranges, defaults, and resolution

Alarm (units)	Priority	Range	Default	Resolution
Oxygen (high)[1] (%)	High	22 to 105	Set automatically: 5% above the current Oxygen setting Set manually: 55	1
Oxygen (low)[1] (%)	High	18 to 97	Set automatically: 5% below the current Oxygen setting Set manually: 45	1

[1] When set automatically, the high and low oxygen alarm limits are set in relation to the current **Oxygen** setting: **Oxygen setting** + 5 (high Oxygen alarm limit) and **Oxygen setting** - 5 (low Oxygen alarm limit). For example, if the **Oxygen** setting is 70%, the high **Oxygen** alarm limit is set to 75 and the low **Oxygen** alarm limit is set to 65. For details, see Section 4.2.2.1.

9.9 Configuration

Table 9-9. Extended configuration specifications

Parameter	Configuration range		Default setting
Therapy defaults	Flow (l/min)	Adult/Ped: 4 to 80	Adult/Ped: 40
		Neo/Ped: 2.0 to 30	Neo/Ped: 2.0
	Oxygen (%)	21 to 100	21
	Temperature (°C)	31 to 39	37
Maximum Flow (Neo/Ped) (l/min)	2.0 to 30		30
O2 enrichment (%)	Adult/Ped: 10 to 79		Adult/Ped: 79
	Neo/Ped: 10 to 79		Neo/Ped: 10
Language	Chinese, Croatian, Czech, Danish, Dutch, English, Finnish, French, German, Greek, Hungarian, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Turkish		English

9.10 Technical performance data

Table 9-10. Technical performance data

Description	Specification	
Stability of temperature (at tube exit)	Set temperature ± 2°C	
Maximum temperature (at tube exit)	43°C (109°F) (in accordance with ISO 80601-2-90)	
Flow range	Adult/Ped:	4.0 to 80 l/min[1]
	Neo/Ped:	2.0 to 30 l/min
Average input O2 flow rate	Maximum average input flow rate over 10 seconds at 2.8 bar (280 kPa):	80 l/min
	Maximum average input flow rate over 3 seconds at 2.8 bar (280 kPa):	80 l/min
Oxygen mixer accuracy	± (volume fraction of 2.5% + 2.5% of actual reading)	
Continuous oxygen measurement	The delivered oxygen concentration is continuously measured by the O2 sensor.	
	Sensing position:	Inspiratory pneumatics
	Measurement, delivered oxygen concentration, range:	18% to 105%
	Data sample rate:	220 milliseconds
	Initialization time (time from turning on device to operating performance):	No initialization time is required
Startup time	≤ 30 seconds	
Warm-up time (device startup to essential performance)	Less than 30 minutes with a Temperature setting of 38°C and Flow setting of 40 l/min (at an ambient temperature of 23°C and ambient relative humidity of 40%)	

[1] In some markets, the maximum possible Flow setting may be limited. In the USA, the Adult/Ped maximum can be set to 60.

Description	Specification	
Humidity	**Temperature** setting 38°C to 39°C and **Flow** 10 to 60 l/min	Minimum humidity: 33 mg H2O/l
	Temperature setting < 38°C and **Flow** < 60 l/min	Minimum humidity: 16 mg H2O/l
	Flow > 60 l/min	
	Flow < 10 l/min with temperature setting > 37°C	
Display on device	Display of settings, alarms, and monitored data	
	Type:	Color TFT
	Size:	800 x 480 pixels, 5 inches (127 mm) diagonal
Brightness setting for display	The range is 10% to 100% brightness. By default, **Day** is set to 80%; **Night** is set to 40%.	
	When set to **Automatic**, the brightness switches between the **Day** and **Night** setting at 6 am and 6 pm.	
Classification of applied parts (IEC 60601-1)	Type BF Heated breathing tubes, SpO2 sensor, Nebulizer (integrated or standalone (supply through USB))	
Audio pause	120 seconds	
Alarm volume (Loudness[1])	The range is 1 to 5. The default for the **Adult/Ped** patient group is 3; for **Neo/Ped**, 2.	
Sound power level[2]	54.5 dB(A)	

[1] The volume of the alarms at one (1) meter distance is between 50 dB(A) and 80 dB(A), depending on the (alarm) Loudness setting.
[2] Per ISO 80601-2-90.

Description	Specification
Sound pressure level[1]	46.5 dB(A)
Potential adverse effects on performance	Due to temperature, humidity, and pressure compensation on the device, there are no known adverse effects due to quantitative effects of gas sample humidity or condensate, leaks or internal venting of sampled gas, cyclical pressure of up to 10 kPa (100 cmH2O), or other sources of interference.
Potential gas pathway contamination	The gas pathways inside the device cannot be contaminated, neither in normal nor in single fault conditions. The patient interface can become contaminated during normal and single fault conditions.

[1] Per ISO 80601-2-90.

9.11 Essential performance

Table 9-11. Essential performance

Essential performance	Description
Humidification failure	If the humidity applied to the respiratory gas and breathing circuit falls outside of the range specified for the technical performance of the device, the device must detect this fact and inform the user through an alarm.
Temperature monitoring failure	The temperatures applied to the respiratory gas and breathing circuit must be maintained within the specified settings, and must be monitored. Should the temperature fall outside the specified limits, the device must detect this fact and inform the user through an alarm.
Gas supply failure	Gas supply failure must be detected by the device and the user informed through an alarm.
Obstruction detection failure	Any obstruction in the gas path must be detected by the device and the user informed through an alarm.
Oxygen level alarm condition	If delivered oxygen is higher or lower than the set alarm limits, this must be detected and the user informed through an alarm.
SpO2 level alarm condition	If SpO2 is higher or lower than the set alarm limits, this must be detected and the user informed through an alarm.
Power supply failure	An electrical supply failure must be detected by the device and the user informed through an alarm.
Internal electrical power source nears depletion	The remaining battery capacity must be monitored and qualitatively indicated. At least 5 minutes prior to depletion, an alarm must be generated.

9.12 Applied parts

Table 9-12. Applied parts

Applied part	Symbol	Description
SpO2 sensor		Type BF applied part
Nebulizer		Type BF applied part

9.13 Functional description

The HAMILTON-HF90 is designed to provide high flow oxygen therapy. The device is an electronically controlled pneumatic system with an integrated air compressing system. It runs on AC power, or optionally on battery power to facilitate patient transport within the hospital.

The user provides inputs to the HAMILTON-HF90 microprocessor through the touch screen. These inputs become instructions for the HAMILTON-HF90's pneumatics to deliver a precisely controlled flow of heated, humidified gas to the patient. Sensors within the device provide input to the microprocessor, and based on this monitored data, the device adjusts the temperature and humidity of the gas delivered to the patient. Monitored data is also displayed by the graphic user interface. Default settings for therapy and alarm limits are defined in Extended configuration, which is protected by an access code.

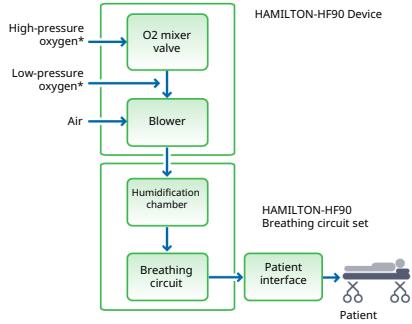
The device's microprocessor controls and monitors the gas being delivered to the patient. The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps minimize the possible hazards of software failure.

A comprehensive system of visual and audible alarms helps ensure the patient's safety. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the device's self-tests including ongoing background checks, can indicate a hardware or software failure. In the case of some technical alarms, therapy stops.

9.13.1 Gas supply and delivery

The HAMILTON-HF90 uses ambient air and high- or low-pressure oxygen (Figure 9-3). The use of medical oxygen is mandatory. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Oxygen enters through a high[1]- or low[2]-pressure inlet.

Figure 9-3. Gas delivery in the HAMILTON-HF90



** only one oxygen source required*

Within the device, the gas enters the device's pneumatic system. If high-pressure oxygen is supplied, a mixer valve provides for the operator-set concentration.

If low-pressure oxygen is supplied, the delivered oxygen concentration is determined by the flow of the oxygen source. The oxygen concentration is monitored by the device and oxygen-related alarms are active, however the device cannot adjust the delivered oxygen concentration.

Gas is supplied to the patient via the blower. The microprocessor controls the speed of the blower and the length of time it runs to meet the user settings.

The device delivers respiratory gas to the patient through the breathing circuit parts, which includes the humidification chamber and patient interface. The respiratory gas is heated and humidified as it passes through a chamber that is partially filled with heated water.

The humidifier has two sensor-controlled heating systems:

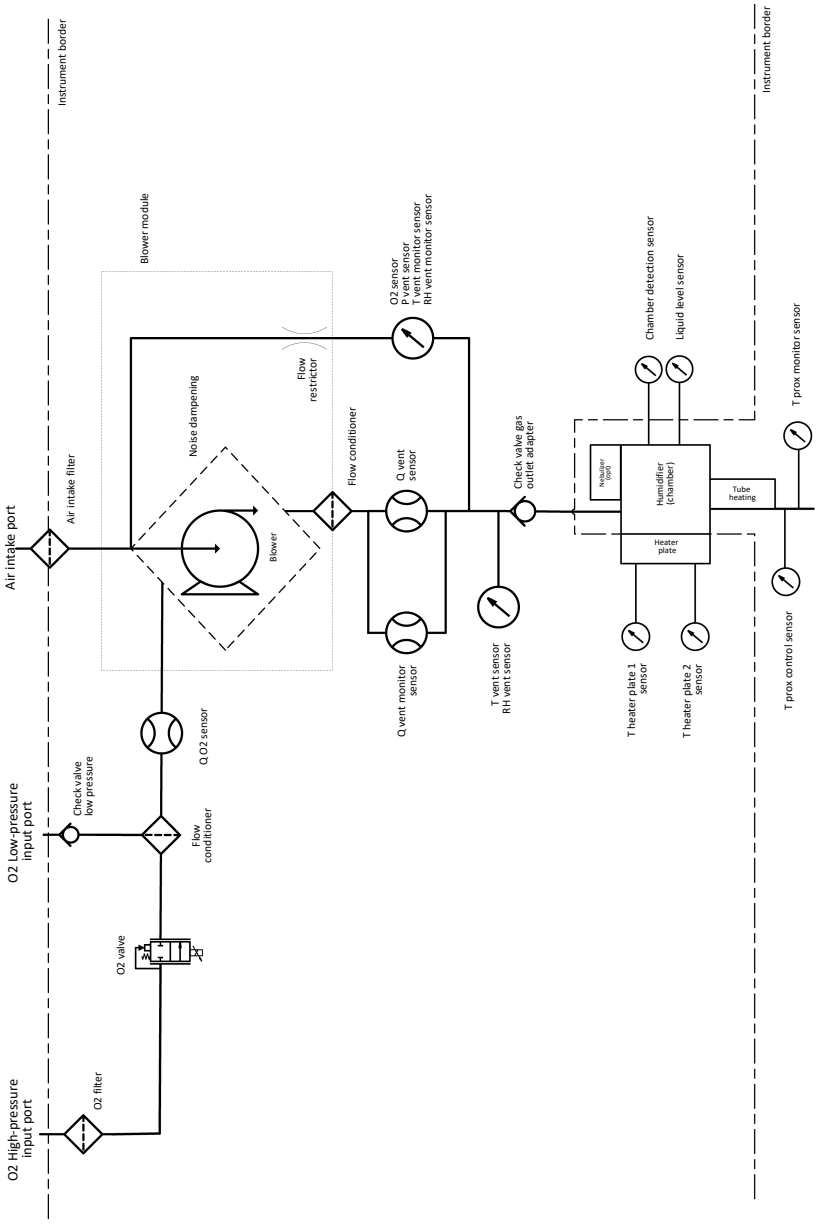
- *Heater plate*. Heats the water in the humidification chamber.
- *Integrated breathing circuit heating system*. Heats the breathing tube to prevent condensation.

The respiratory gas temperature is monitored in the breathing tube at the patient end.

The device monitors the oxygen concentration of the gas to be delivered to the patient using a thermal conduction O2 sensor.

[1] High-pressure oxygen: Maximum allowed pressure is 6 bar (600 kPa).
[2] Low-pressure oxygen: Maximum allowed flow 60 l/min.

9.13.2 Pneumatic diagram



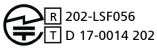
9.14 Symbols used on device and trolley labels and packaging

Table 9-13. Symbols used on the device and trolley, product labels, and packaging

Symbol	Definition
	Manufacturer
	Date of manufacture
	Part number
	Serial number
	Product version
	Quantity
	Do not use if packaging is damaged
	Medical Device
	*USA only*. Prescription device
	Do not use any blades, knives, or cutters to open; they can damage the product
	Refer to the operator's manual for complete information.
	

Symbol	Definition
	Symbol for "Caution". Applied parts not protected against defibrillation.
	Power on/off key
	USB port
	Ethernet port (internal use only)
	Nebulizer port
	Note: Hot surface The heater plate and the bottom of the chamber can reach a temperature of over 85°C.
	Alarm Off
	Unique device identification - device identifier
	Dispose according to Council Directive 2012/19/EC or WEEE (Waste Electrical and Electronic Equipment)
	This way up at transport and storage
	Fragile, handle with care at transport and storage
	Keep dry at transport and storage

Symbol	Definition
	Temperature limitations at transport and storage
	Humidity limitations at transport and storage
	Stacking limitations at transport and storage
	Mass
	Recyclable material
	Type BF applied part (classification of medical electrical equipment, type BF, as specified by IEC 60601-1)
	Applicable to Adult/Pediatric patient group
	Applicable to Neonatal/Pediatric patient groups
	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.
IP22	Protected against dripping water when the device is tilted to a maximum of 15 degrees, and from solid particles larger than 12.5 mm.

Symbol	Definition
	HAMILTON-HF90 poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
EC REP	Authorized representative in the European Community/European Union
FC	Federal Communications Commission (FCC) Licensing
CE 0197	CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Medical Device Regulation (EU) 2017/745 concerning medical devices (for device)
	The TÜV SÜD mark with the indicators “C“ and “US“ means that the product complies with Canadian requirements and the requirements of US authorities for safety.
	*Japan only*. Ministry of Internal Affairs and Communications Approval Label

Symbol	Definition
CE	CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Medical Device Regulation (EU) 2017/745 concerning medical devices (for trolley)
	Make sure the wheel brakes are unlocked when moving the trolley.
	Do not lean on the trolley.
	Do not park the trolley on an incline greater than 5 degrees.
	Weight The maximum safe working load applies to a stationary properly load-balanced trolley.

9.15 Standards and approvals

The HAMILTON-HF90 meets relevant parts of the following standards, listed in Table 9-14.

Table 9-14. Standards and approvals, valid versions

ANSI/AAMI ES60601-1:2005/AMD2:2021
ANSI/AAMI HE75:2009/(R)2018
CAN/CSA-C22.2 NO. 60601-1:2014/ AMD2:2022
IEC 60601-1:2005+A1:2012+A2:2020
IEC 60601-1-2:2014+AMD1:2020
IEC 60601-1-6:2010/AMD2:2020
IEC 60601-1-8:2006/AMD2:2020
IEC 60601-1-10:2007/AMD2:2020
IEC 62304:2006+AMD1:2015
IEC 62366-1:2015/AMD1:2020
IEC 80601-2-49:2018
ISO 80601-2-55:2018
ISO 80601-2-61:2017
ISO 80601-2-74:2021
ISO 80601-2-90:2021
EN ISO 13485:2016/A11:2021
EN ISO 14971:2019/A11:2021
ISO 5356-1:2015
ISO 5367:2023
ISO 10993-1:2018
ISO 18562-1:2020
ISO 18562-2:2020
ISO 18562-3:2020

9.16 Disposal and year of manufacture

Disposal

The device must be disposed of according to your institution's protocols and Directive 2012/19/EU of the European Parliament and of the council on waste electrical and electronic equipment (WEEE).

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-HF90 device.

9.17 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 yearly maintenance is not performed.
8. If the product is or has been used in any way that is not specified under "Intended Use" (see "General cautions and notes").
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.

A

- accessories and parts 118
- accessories, list of 118
- air filters, replacing 108
- air intake vents on side of device
  - do not block 27, 51
- alarm limits
  - adjusting 64
  - limit off symbol 65, 84
  - reviewing 64
  - setting for Oxygen with HPO source 66
  - setting for Oxygen with LPO source 66
  - setting to Manual for Oxygen with HPO 67
  - where displayed 84
  - window, illustrated 64, 65
- alarm limits, Oxygen 134
- alarms
  - about 82
  - adjustable 66
  - Audio pause 84
  - battery power lost 45
  - deactivated 86
  - indicators, about 82, 83, 84
  - limits, where displayed 84
  - list of 88
  - list of deactivated (turned off) 86
  - loudness, setting 87
  - on-screen help, accessing 85
  - reactivating inactive 86
  - responding to 85
  - silencing (Audio pause) 85
  - specifications 134
  - technical faults, about 82
  - testing 99
  - testing obstruction alarm 99
  - troubleshooting 88
- applied parts 140
- Audio pause (alarm silence)
  - about 85
  - alarms not affected 84

B

- batteries
  - about 45
  - alarm when power lost 45
  - charge status, checking 46
  - components of 53
  - connecting 53
  - removing 54
  - replacing 53
  - specifications 130
  - status indicators, about 45
- battery 36, 52
  - bay cover, removing 52
  - charge status indicator 36
  - connecting and removing 53
- Battery communication error alarm 88
- Battery defective alarm 88
- Battery low alarm 89
- Battery temperature high alarm 90
- Battery totally discharged alarm 90
- Blower fault alarm 90
- breathing circuits
  - 14 days max use 49
  - connecting 49
  - connecting and setting up 49
  - connecting to ventilator 49
  - connection diagrams 37
  - connection to device 36
  - ensuring proper fit/patient group of components 49

- expiration date, checking 49
- gas outlet adapter cap (red), removing/attaching 49
- heated limb not on patient's skin 51
- placement of, safety information 26
- placement with device and patient 51
- positioning once connected 51

BTPS, defined 12, 133

Buzzer defective alarm 91

C

Caution indicator 36

Check for blockage alarm 92

cleaning and maintenance, safety information 30

cleaning components
- cleaning/disinfection agents 105, 106
- guidelines 104
- methods 105

cleaning instructions 104

configuration
- accessing configuration settings 112, 114
- copying settings 116
- default therapy settings, specifying 113
- factory default settings 135
- factory default settings, restoring 116
- language, changing 112
- max. Flow for neo/ped patients, specifying 113
- O2 enrichment settings, specifying 113
- options, adding 115
- options, removing 115
- overview 112
- specifications 135

control parameters
- adjustable 63
- adjusting settings 64
- specifications 132

copying config settings to other devices 116

D

date/time, setting 77

defibrillation, not supported during use 19

device and breathing circuit, positioning of 51

Device temperature high alarm 93

Device tilted alarm 93

device-specific information, viewing 79

disinfecting components
- cleaning/disinfection agents 105, 106
- guidelines 104
- methods 105

disinfection instructions 104

display brightness
- Day mode 78
- Night mode 78
- setting 78

display, unlocking 68

documentation
- conventions used in this guide 12
- user guides for device, list of 11

E

ending therapy, tasks 79
event logs
about 78
copying 79
displaying 78
Exchange tube alarm 94
Extended view
monitoring therapy, using for 69
window, illustrated 70

F

factory default settings 135
restoring 116
filters, cleaning and replacing 108
filters, replacing 108
Flow 63, 73, 132, 133
max setting allowed for neo/ped patients, configuring 113
setting range per patient group 48

G

gas outlet adapter 36
placing the protective cap on the adapter before cleaning 108
replacement by trained hospital technician 107
replacing (performed by service technician) 108
gas outlet adapter cap
removing, replacing 49
gas supply or source. See oxygen (gas) supply 47

H

Hamilton Medical e-Academy 12
HAMILTON-HF90
not for home use 22, 34
placement of device, safety information 26
HAMILTON-HF90 intended use 17, 18
HAMILTON-HF90, overview of features
see also system overview 34
High gas temperature alarm 94
High oxygen alarm 94
High water level alarm 94
Home button, return to main display 41
home use, NOT supported 22, 34
humidification chamber 36
connecting 49
filling with sterile, demineralized water 49
humidification chamber, inserting/removing 49

I

intended position of operator 34
intended use, HAMILTON-HF90 17, 18

L

language, changing 112
list items, selecting 41
loudness, setting for alarms 87
Loudspeaker defective alarm 95
Low oxygen alarm 96
low-pressure oxygen (LPO) gas supply
connecting 47
safety information 24

M

main display, overview 39

maintenance 104, 108
- battery, replacing 53
- device operation hours 107
- filters, replacing 108
- packing/shipping device 109
- preventive maintenance schedule 107
- safety information 30

maintenance and service 107

monitored parameters
- list of 73
- specifications 133

monitoring therapy
- data display, overview 69

MRI environment, not for use in (MR Unsafe) 19

N

navigation
- list items, selecting 41
- menus and windows, using 40
- settings, adjusting 41
- user interface, getting around 40

nebulizer
- connecting 75
- continuous delivery 76
- setting up 58
- settings for 75
- starting or stopping 75
- timed delivery 76

Nebulizer port 36

New patient button, starting therapy 63

O

O2 assist
- about 75

O2 consumption 133

O2 enrichment
- delivery settings, configuring 113
- overview 74
- starting 74
- stopping 74

O2 sensor, calibrating 77

options
- adding 115
- installed, viewing 79, 114
- removing 115

Oxygen 63, 73, 132, 133
- alarm limits 66

oxygen (gas) supply
- connecting 47
- safety information 24
- selecting source 47

Oxygen consumption 73

Oxygen supply failed alarm 97

P

parameters
- control, adjustable 63
- monitored, list of 73

parts and accessories 118

parts, list of 118

patient groups, about 48

patient interface (mask/cannula/trach connector)
- ensuring it is appropriate for high flow O2 therapy 25, 48
- ensuring patient can exhale 25, 48

selecting proper component for patient 49

patient's skin, do not place heated breathing circuit on 51

placement of breathing circuit and device

safety information 26, 51

power button 36

Power button, turning on/off 52

power key, light states 52

power source

batteries, about 45

connecting to 44

where indicated on display 45

power supply, status indicators defined 45

preventive maintenance schedule 107

R

Resource Center website 12

Resume therapy button, continuing therapy 63

S

safety information 16

alarms 28

breathing circuits/accessories 26, 49

cleaning/disinfection 30

delivering therapy 27

device and breathing circuit positioning 26

electrical 20

fire/hazards 21

general operation/setup 22

low-pressure oxygen (LPO) gas supply 24

maintenance 30

monitoring 28

nebulization 27

oxygen (gas) supply 24

power and batteries 20

service/testing 32

transport 28, 29, 55, 56

trolley 29

USB port use 25

serial number, viewing 79

service and maintenance 107, 108

settings, adjusting 41

shortcuts

for alarm limits for a parameter 65

Home button, return to main display 41

list of 41

show Settings menu 41

to set alarm limits 42

silencing an alarm 85

software version, viewing 79

specifications

alarms 134

configuration 135

control settings 132

dimensions 127

disposal 146

electrical 130

environmental 128

essential performance 139

features and options 35

functional description of device operation 140

gas supply/delivery description 141

intended use, HAMILTON-HF90 17, 18

monitored parameters 133

pneumatic 129

pneumatic diagram 142

- standards/approvals 145
- technical performance data 136
- year of disposal 146

SpO2
- measuring 70
- monitoring, enabling/disabling 71

surface cleaning 104

surface disinfection 104

symbols
- on device, labels, packaging 145

system information, viewing 79

system overview 34
- attaching device to trolley 57
- breathing circuits 37
- date/time, setting 77
- device on trolley, illustrated 36
- device overview 36
- device-specific information, viewing 79
- extended display, overview 40
- features and options 35
- main display 39
- preparing for use, overview of steps 44
- starting therapy 62
- therapy delivery on startup 62
- turning device on/off 51

T

technical faults
- about 82
- turning device off during 52

Temperature 63, 73, 132, 133

Therapy duration 73
- display with trends 71

therapy settings, specifying defaults 113

therapy, ending, tasks for 79

therapy, starting 62
- New patient button 63
- Resume therapy button 63

Total power loss alarm 98

transporting the patient
- preparing the trolley/device for 28, 29, 55, 56
- preparing trolley/device for 56
- safety information 29, 56
- safety information for 28, 29, 55, 56
- within the hospital, preparing for 28, 29, 55, 56

trends
- displaying 72
- options 71
- window, illustrated 72
- working with 71

trolley
- attaching HAMILTON-HF90 to 57
- components allowed during transport 56
- detaching HAMILTON-HF90 from 57
- preparing for patient transport within the hospital 28, 29, 55, 56
- removing device from 57
- transport position of tubing support arm 56
- with device, illustrated 36

troubleshooting alarms 88

turning device on/off 51

U

unlocking display 68

W

warranty 146

water for humidification chamber, use sterile, demineralized only 25, 48

windows on display, opening/closing 40

Y

year of manufacture, where displayed 146

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