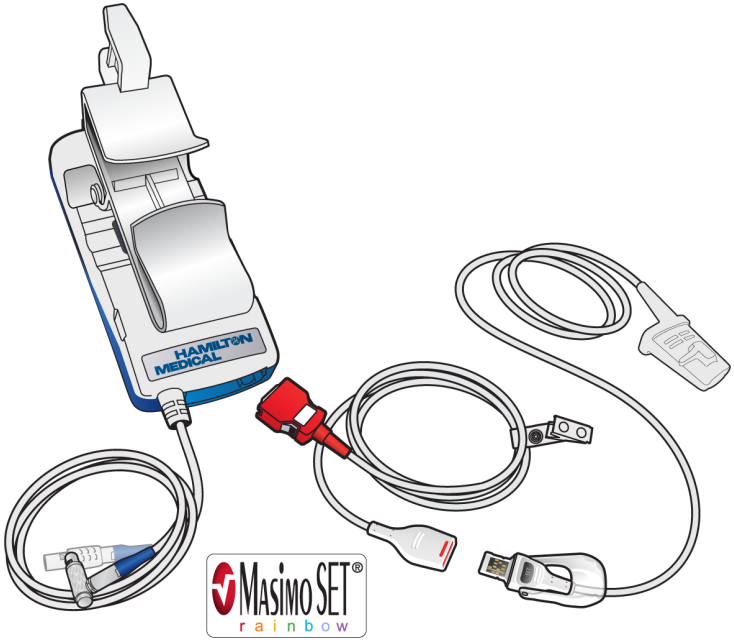

Masimo Rainbow SET

Instructions for use

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1 Preface

About this guide

When a supported pulse oximeter is connected, selected Hamilton Medical ventilators provide integrated monitoring and data display of functional oxygen saturation of arterial hemoglobin (SpO2) and related pulse oximetry data.

This guide provides information about the use and configuration of the Masimo rainbow SET option, used together with Masimo SET pulse oximetry. It is designed for use together with your ventilator *Operator's Manual* and the *Pulse Oximetry Instructions for use*.

Conventions used in this guide

In this manual:

- The SpO2 sensors and cables shown in this manual may not exactly match what you see in your environment.
- The screen diagrams may not exactly match what you see on your display, depending on the options you have installed and your exact ventilator model. However, the window and tab names, as well as their general location are the same.
- Button and tab names are shown in a **bold** font.
- The notation **XX** > **XX** shows the sequence of buttons/tabs to touch to open the associated window.

  For example, the text "Touch **System** > **Settings**" means touch the **System** button, then touch the **Settings** tab.
- Window names are shown using the sequence of buttons/tabs used to open them.

  For example, "**Alarms** > **Limits 2** window" means the window is accessed by touching the **Alarms** button, then the **Limits 2** tab.
- Pressure is indicated in cmH2O, length in cm, and temperature in degrees Celsius (°C). 1 cmH2O equals 0.981 mbar, which equals 0.981 hPa.
- A green check mark ✓ or button XXX indicates a selected item or feature.
- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
  ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.
  ❶ These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.
- The pulse oximeter is also referred to as a pulse *CO-oximeter/SpO2 adapter*, and the sensor is also referred to as a *probe*. The terms as used in this manual are synonymous.

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.

2 Safety

Masimo rainbow SET is an option to the Masimo SET pulse oximetry system to provide additional monitoring.

The safety information provided here is for the rainbow SET option. Be sure to also read the Masimo SET safety information in your ventilator's *Pulse Oximetry Instructions for Use* .

⚠ WARNING

- Verify the compatibility of the adapter, sensor, and cables before use. Use of incompatible components can result in patient injury.
- SpO2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO2 measurement.

  – For increased COHb: COHb levels above normal tend to increase the level of SpO2. The level of increase is approximately equal to the amount of COHb that is present.

  – Note that high levels of COHb may occur with a seemingly normal SpO2. When elevated levels of COHb are suspected, laboratory analysis (CO-oximetry) of a blood sample should be performed.

  – For increased MetHb: The SpO2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-oximetry) of a blood sample should be performed.
- Hemoglobin synthesis disorders may cause erroneous SpHb readings.
- Very low arterial oxygen saturation (SpO2) levels may cause inaccurate SpCO and SpMet measurements.
- Elevated levels of total bilirubin may lead to inaccurate SpO2, SpMet, SpCO, SpHb, and SpOC measurements.
- Motion artifact may lead to inaccurate SpMet, SpCO, SpHb, and SpOC measurements.
- For measurements of high or low SpHb readings, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.

NOTICE

- *(USA only)* Federal law restricts this device to sale by or on the order of a physician.
- Only use components specified by Hamilton Medical.
- Use only Masimo sensors for SpO2 and related measurements.
- DO *not* use or store outside of specified environmental conditions.
- *HAMILTON-T1 only*. The environmental limitations for the SpO2 sensors are different from those for the ventilator. The ventilator can operate in conditions up to 50°C (122°F). The supported SpO2 sensors are rated to 40°C (104°F).
- Read all of the safety information before using the sensor. Before use, carefully read the sensor's *Directions for use*.

- Equipment used to test pulse oximeter components (probe, adapter) cannot be used to assess their measurement accuracy.
- Only qualified personnel may operate the pulse oximeter. Read this manual, safety information, accessory directions for use, and specifications before use.
- When a parameter shows dashes or no value, it is *not* used in any calculations.
- The specific values displayed depend on which options are enabled.
- Time is only counted when the sensor is connected. To extend the lifespan of the sensor, disconnect it from the patient cable when it is *not* in active use.
- If you are running the SpHb sensor in **Spot Check** mode, the **SpHb** high and low alarms are only active for 1 minute. The alarm is also listed in the Event log.
- The Masimo rainbow SET option is enabled on the ventilator with a license key, which is assigned to a specific ventilator serial number. Ensure you have the correct license key for the ventilator you are configuring.
- Note that individual data options (**SpHb/SpOC**, **SpMet**, **SpCO**) are sold separately and are then enabled on the adapter. Adding a data option is performed using the **Upgrade** tool.
- Enable and configure the **SpO2** option board/module first.

  See your ventilator *Operator's Manual* and documentation provided with the option board/module.
- For upgrade information, contact your Hamilton Medical technical representative.

This guide includes several descriptions, warnings and specifications for the Masimo adapter and sensors.

Related documentation

Not all of the information is included here. See also:

- *Masimo Adapter Kit User Guide*
- Your ventilator's *Pulse Oximetry Instructions for Use*
- The manufacturer's *Directions for use*
- The safety information for your ventilator, provided in your ventilator's *Operator's Manual*

Additional information may also be available at the manufacturers' website: **http://www.masimo.com**. For information on Masimo patents, see **www.masimo.com/patents.htm**.

Note that possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.

3 Monitoring with Masimo rainbow SET option

3.1 Overview

With the Masimo rainbow SET option, in addition to the Masimo SET parameters **SpO2**, **pulse rate**, **perfusion index (PI)**, and **pleth variability index (PVI)**, you can also monitor additional parameters (see Table 1), depending on what is purchased and configured on the adapter.

Table 1. Masimo pulse oximeter measurement options

Options, measurements	Masimo SET§	Masimo rainbow SET§
SpO2	X	X
Pulse rate	X	X
Perfusion Index (PI)	X	X
Pleth variability index (PVI)	X	X
SpCO (carboxy-hemoglobin)[1]		X
SpMet (methemo-globin)[1]		X
SpHb (total hemo-globin)[1]		X
SpOC (oxygen content)[2]		X

The Masimo rainbow SET option is enabled on the ventilator with a license key.

The adapter is the hub of the pulse oximetry system. Individual measurements are enabled on the adapter. Table 1 lists the available data options. The data for these parameters is displayed together with the other Masimo SET SpO2-related information.

You must use rainbow SET-compatible cables and sensors that support the purchased parameters.

3.2 Viewing rainbow SET pulse oximetry data

The rainbow SET parameters (Table 2) are displayed together with Masimo SET SpO2 parameters. Sensor data is updated every second.

The data is readily available as follows:

- In your ventilator's **Monitoring** window (Section 3.2.1).
- On the main display (Section 3.2.2).
- As a trend graph (Section 3.2.3).
- SpHb data is a special case. For details on measuring and viewing this data, see Section 3.2.4.

[1] Each of these measurements is offered as a separate option, and must be used with compatible sensors.
[2] SpOC is a calculated value using SpHb data as an input; it is provided together with SpHb.

Table 2. Rainbow SET parameters and settings[3]

Setting	Description
See your ventilator's Pulse Oximetry Instructions for Use for details on other pulse oximetry parameters.	
SpCO (%)	Carbon monoxide concentration in arterial blood. **Display range**: 0 to 100
SpHb[4] (g/dl) (mmol/l)	Total hemoglobin in arterial blood. Available in **Continuous** or **Spot check** mode (Section 3.3). **Display range**: 0 to 25 g/dl (0 to 16 mmol/l)
SpOC (md/dl)	Calculated measurement of amount of oxygen in arterial blood. Provided together with **SpHb**. **Display range**: 0 to 40
SpMet (%)	Methemoglobin concentration in arterial blood. **Display range**: 0 to 100

3.2.1 Viewing rainbow SET data in the Monitoring window

Data is available in your ventilator's **Monitoring** window, which you can access anytime without affecting breath delivery.

Table 3 shows the location of rainbow SET data on your ventilator.

Table 3. Rainbow SET Monitoring parameters window

Ventilator	Window
HAMILTON-C1/C3/C6/T1	**Monitoring** > **SpO2** > **1** **Monitoring** > **SpO2** > **SpHb**[5]
HAMILTON-G5/S1	**Monitoring** > **2**[6]

The quality index shows the sensor's evaluation of the signal quality. A low quality index indicates a poor signal due to interference from excessive motion or other causes.

[3] Each of these measurements is offered as a separate option with Masimo rainbow SET.
[4] Note that when the **rainbow SET** option is enabled and an SpHb-enabled sensor is connected, the remaining time or spot checks available on the sensor are shown. See Section 3.2.8.
[5] Only available if **Spot Check** is enabled for **SpHb measurement** in **Configuration**.
[6] If two sensors are in use, additional data is available in the **SpO2raw** window.

Table 4. Quality index display

Quality indicator	Confidence value
4 gray (or blue) bars, no data 	OFF (no information).
1 red bar, poor quality 	The data from the sensor is not usable or the parameter measurement is still initializing.
2 orange bars, medium quality 	The data from the sensor is acceptable for most uses. An alarm may be active that could affect how accurately this parameter is currently measured.
3 green bars, good quality 	The data from the sensor is reliable.
4 green bars, best quality 	The data from the sensor is highly stable and reliable.

3.2.2 Viewing rainbow SET data on the main display

As with other parameters, any of the monitored pulse oximetry parameters can be configured to be displayed as a main monitoring parameter (MMP). For configuration details, see your ventilator *Operator's Manual*.

On the HAMILTON-C6/G5/S1 ventilators, the monitored pulse oximetry parameters can also be displayed as secondary monitoring parameters (SMPs).

3.2.3 Viewing trends

You can view trend data for enabled rainbow SET-related parameters.

For details on generating trend graphs, see your ventilator *Operator's Manual*.

You can view trend data for the following Masimo rainbow SET-related parameters:

- SpHb
- SpOC
- SpCO
- SpMet

Note that when using **Spot Check** mode (Section 3.2.6) for **SpHb** measurement, the trend graph for **SpHb** or **SpOC** shows a single point, as only the last measured value is stored in the system.

3.2.4 Viewing SpHb data

Unlike the other pulse oximetry-related parameters, **SpHb** can be measured using either of two modes:

- **Continuous**. **SpHb** and **SpOC** are updated every second. See Section 3.2.5.
- **Spot Check**. You manually request an **SpHb** measurement when needed. See Section 3.2.6.

For details on configuring the measurement mode for **SpHb**, see Section 4.3. Also, SpHb sensors have a finite lifespan, and must be replaced when they expire. To see the time remaining on the sensor, see Section 3.2.8.

3.2.5 About Continuous mode for SpHb monitoring

In **Continuous** mode, **SpHb** is measured every second for the total number of hours allotted to the sensor (for example, 61 hours). This is the same mode used for the other parameters.

Table 5 shows the location of **SpHb** and **SpOC** data on your ventilator.

Table 5. SpHb and SpOC parameter display window

Ventilator	Window
HAMILTON-C1/C3/C6/T1	Monitoring > SpO2 > 1
HAMILTON-G5/S1	Monitoring > 2[7]
All ventilators	On the main display as an MMP, if configured.

Note that in **Continuous** mode, the following windows are unavailable:

- HAMILTON-C1/C3/C6/T1: Monitoring > SpO2 > SpHb
- HAMILTON-G5/S1: Tools > Spot Check

3.2.6 About Spot Check model for SpHb monitoring

In **Spot Check** mode, you manually request an **SpHb** measurement, up to the total number of spot checks allotted to the sensor (for example, 360 spot checks).

Each measurement takes a short while to read.

Table 6 shows the location of **SpHb** and **SpOC** data in **Spot Check** mode on your ventilator.

Table 6. Spot Check parameter display window

Device	Path
Parameters are displayed for one minute	
HAMILTON-C1/C3/C6/T1	Monitoring > SpO2 > 1
HAMILTON-G5/S1	Monitoring > 2[7]
All ventilators	On the main display as an MMP, if configured.
Parameters are displayed with a date and time stamp[8]	
HAMILTON-C1/C3/C6/T1	Monitoring > SpO2 > SpHb
HAMILTON-G5/S1	Tools > Spot Check

[7] If two sensors are active, parameters are displayed in **Monitoring** > **SpO2raw**.

[8] **Spot Check** date and time are displayed until the next spot check, the device is restarted, or a new patient is configured.

For each spot check requested, you have an additional five-minute Free Retry period during which you can request repeat measurements without affecting the remaining available spot checks.

If the sensor cannot get a reading, it continues to try to measure **SpHb** until the Free Retry period is over. If unsuccessful, the spot check attempt is not deducted from the sensor lifespan.

When a measurement is out of range, an alarm is activated for one minute. Alarm history is available in the **alarm buffer** and **Event log**.

3.2.7 Requesting an SpHb measurement (Spot Check)

To view **SpHb** data, see Table 3.

To request an SpHb measurement

1. Access the **Spot Check** window.

   HAMILTON-C1/C3/C6/T1: Touch **Monitoring** > **SpO2** > **SpHb**.

   HAMILTON-G5/S1: Touch **Tools** > **Spot check**.

   Note the following:

   – If the button is not visible, the **rainbow SET** option is not enabled.

   – If the button is disabled, the measuring mode is set to **Continuous**.

2. Touch **Spot Check**.

   The sensor measures **SpHb** and the system calculates **SpOC**.

   A progress bar indicates a measurement is in progress. You cannot cancel an ongoing measurement.

   When the values are updated, the **SpHb** window indicates your remaining **Free Retry** time available. The system also updates the **Remaining Checks** total.

   You can select **Spot Check** again one or more times during the **Free Retry** period and not have it count against the remaining available spot checks.

   Note that if the button is disabled, an incompatible sensor is attached to the system. Attach a Masimo rainbow sensor and repeat the spot check request.

3. Close the window when done.

3.2.8 Viewing remaining SpHb sensor lifetime

The SpHb sensor life span information is displayed as follows:

- HAMILTON-C1/C3/C6/T1: **System** > **Sensors** > **On/Off**.
- HAMILTON-G5/S1: **System** > **Info**.

38h/61h 228/361	Time remaining on sensor (in hours)
38h/**61h** 228/361	Total lifespan of sensor (in hours)
38h/61h **228**/361	Spot checks remaining on sensor
38h/61h 228/**361**	Total spot checks allotted to sensor

3.3 Working with rainbow SET alarms

You can specify alarm limits for the **SpMet**, **SpHb**, and **SpCO** parameters.

On the **HAMILTON-C1/C3/C6/T1** the default alarm ranges can be set in **Configuration**.

On the **HAMILTON-G5/S1** you can activate/deactivate the alarms in **Configuration**.

For the list of rainbow SET alarms, see Section 6.1.

For details on SpO2 alarms, see your ventilator's *Pulse Oximetry Instructions for Use*.

3.3.1 Setting rainbow SET alarm limits

Use the **Alarms Limits 2** or **3** window (depending on your ventilator model) to set the acceptable value ranges for each of the enabled rainbow SET parameters. Parameters that are not purchased and enabled are not available.

For details on how to set alarm limits and work with alarms, see your ventilator *Operator's Manual*.

Table 7 lists the rainbow SET-related alarms and messages displayed by the ventilator, along with their definitions and suggested corrective actions.

Note that the proposed actions may not always correct the particular problem.

Table 7. Alarm descriptions and priority

Alarm	Priority and definition
In all cases, the low alarm limit must be set lower than the high alarm limit.	
SpCO high/ SpCO low	*Medium priority.* Measured **SpCO** value exceeds or is below the set limit.
SpHb high/ SpHb low	*Medium priority.* Measured **SpHb** value exceeds or is below the set limit.
SpMet high/ SpMet low	*Medium priority.* Measured **SpMet** value exceeds or is below the set limit.
Corrective actions	
For all of these alarms, the recommended corrective action is to observe the patient and verify ventilator settings, including alarm settings.	

Section 6.1 provides the rainbow SET-related adjustable alarm ranges, default settings and resolution, and measurement accuracy details.

3.3.2 Troubleshooting issues

Alarm messages appear in the message bar, the same as other ventilator alarms.

Table 8 describes how to address some potential rainbow SET-specific issues.

For details on the Masimo-generated sensor codes, refer to the individual Masimo component *Directions for use*.

Table 8. Troubleshooting rainbow SET-related issues

Message or issue	Details	Action
No rainbow SET parameters are displayed	The rainbow SET option is not enabled. When the rainbow SET option is enabled, the **Configuration** > **Options** > **SW options** window shows the text, **Masimo Rainbow**.	Enable the option.
	The adapter that is connected is not configured with any rainbow SET measurements.	• Attach an adapter that has the desired measurements enabled. • Update the adapter with the desired measurements, using the Upgrade tool. For upgrade information, contact your Hamilton Medical technical representative.
	A non-rainbow SET sensor is in use.	Connect the appropriate rainbow SET-enabled sensor.
HAMILTON-C1/C3/C6/T1: SpHb window not active in **Monitoring** > **SpO2** HAMILTON-G5/S1: Spot Check window not active in **Tools**	In **Configuration**, **SpHb measurement** must be set to **Spot Check**.	Enable **Spot Check**.

Message or issue	Details	Action
Spot Check button not active	An incompatible sensor is connected to the system.	Replace the sensor with a Masimo rainbow SET sensor that supports SpHb measurements.
	The following conditions must be met: • **SpHb** is enabled on the adapter • A supported SpHb sensor is connected	• Attach an adapter that has the desired measurements enabled. • Connect the appropriate rainbow SET-enabled sensor.
No pulse oximetry data in the **Upgrade** window in **Configuration**	No adapter is connected	Connect an adapter.
Parameter is marked as **OFF** in the **Upgrade** window in **Configuration**	Parameter is not enabled on the adapter.	Update the adapter with the desired measurements, using the Upgrade tool. For upgrade information, contact your Hamilton Medical technical representative.

4 Configuration

4.1 Overview

Masimo rainbow SET is an option available for Masimo SET pulse oximetry. Configuration requires access to the ventilator **Configuration**, and comprises the following steps:

To ...	See ...
Configure Masimo SET, including sensor settings	Your ventilator's *Pulse Oximetry Instructions for Use*
Enable the Masimo rainbow SET option	Section 4.2
Configure SpHb sensor options	Section 4.3

You can see which options are configured in the **Upgrade** window (Section 4.4).

4.2 Enabling the Masimo rainbow SET software option

To enable the rainbow SET software option

1. Access **Configuration**.
2. Touch **Options**.
3. Follow the instructions for adding a software option in the Configuration chapter of your ventilator *Operator's Manual*.
4. Type the Masimo rainbow SET license key when appropriate.

Once enabled, the system can work with any of the rainbow SET measurements that are enabled on the connected adapter.

In addition, you can perform spot checks, if configured (Section 3.2.6):

- HAMILTON-C1/C3/C6/T1: **Monitoring** > **SpO2** > **SpHb**
- HAMILTON-G5/S1: **Tools** > **Spot check**

4.3 Selecting sensor data options for SpHb

When first setting up **SpHb** measurement on the ventilator, you select the desired sensor data settings in **Configuration**.

Typically, these settings are configured once and do not need to be regularly updated. They can only be changed when the ventilator is in **Standby**.

These settings are persistent. Once you change a setting, the new selection is in force until manually changed.

To configure SpHb sensor data acquisition options

1. Access **Configuration**.
2. Access sensor settings.

   HAMILTON-C1/C3/C6/T1: Touch **Sensors** > **SpO2**.

   HAMILTON-G5/S1: Touch **SpO2** > **Masimo**.
3. Specify the desired **SpHb** settings (Table 9), as appropriate.
4. When done, return to the main **Configuration** window.

   HAMILTON-C1/C3/C6/T1: Touch **Back**.

   HAMILTON-G5/S1: Touch **Close**.

Table 9. SpHb sensor data acquistion settings

Paramter	Description and settings
SpHb averaging	The length of time over which to collect data to include in the calculation of the average. Options are: • **Long** (default) • **Medium** • **Short**
SpHb mode	Hemoglobin measurement. Options are: • **Arterial** (default) • **Venous**
SbHb precision	Precision level of the displayed data. Options are: • **0.1** (default) • **0.5** • **1.0**
SpHb unit	Unit of measurement for the **SpHb** parameter. Options are: • **g/dl** (default) • **mmol/l**
SpHb measure-ment	Measurement mode. For details on each mode, see Section 3.2. Options are: • **Continuous** • **Spot Check** (default)

4.4 Reviewing the configured options

Once enabled, sensor configuration data is displayed in the following locations:

- HAMILTON-C1/C3/C6/T1: **Configuration** > **Sensors** > **Upgrade** window.
- HAMILTON-G5/S1: **Configuration** > **SpO2** > **Masimo** > **Upgrade** window.

The window shows the firmware version number, Masimo sensor codes, and which rainbow SET parameters (if any) are enabled on the connected adapter.

Note the following:

- An adapter is not connected if:

  HAMILTON-C1/C3/C6/T1: The window displays dashes (---) for the data.

  HAMILTON-G5/S1: The window displays the text **Connect Masimo SpO2 sensor on LEFT sensor slot and use the Masimo upgrade tool to add parameters**.
- If a parameter is set to **Off**, it is not enabled on the adapter.

For details on the Masimo-generated sensor codes, refer to the individual Masimo component *Directions for use*.

To view Masimo sensor configuration data

1. Access **Configuration**.
2. Access sensor settings.

   HAMILTON-C1/C3/C6/T1: Touch **Sensors** > **SpO2**.

   HAMILTON-G5/S1: Touch **SpO2** > **Masimo**.

   Sensor data is displayed in the **Upgrade** window.
3. When done, return to the main **Configuration** window.

   HAMILTON-C1/C3/C6/T1: Touch **Back**.

   HAMILTON-G5/S1: Touch **Close**.

5 Maintenance

⚠ WARNING

- If a sensor or cable is damaged in any way, discontinue use immediately. Do *not* use a sensor or patient cable with exposed optical or electrical components.
- Do *not* soak or immerse the sensor or cables in any liquid solution. The sensor and connectors are *not* waterproof.
- Unless otherwise specified, do *not* sterilize sensors or patient cables by irradiation, steam, autoclave, or ethylene oxide. See the cleaning instructions in the *Directions for use* for the Masimo reusable sensors.
- Do *not* attempt to reprocess, recondition, or recycle any Masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to harm.
- Before maintenance or cleaning, disconnect the SpO2 adapter from the device. Failure to comply with this instruction can result in electrical shock and SpO2 problems or both.

⚠ CAUTION

- *Do NOT modify or alter the adapter or sensor in any way. Alterations or modification may affect performance and/or accuracy.*
- *Do NOT disinfect and sterilize the SpO2 adapter. Doing so will damage the adapter.*
- *Do NOT immerse the SpO2 adapter in any chemical solution or water. If the adapter is immersed, wipe off liquid with a dry cloth and thoroughly dry the adapter.*
- *After cleaning and before use, wipe liquid off with a dry cloth and thoroughly dry the adapter.*

This section provides cleaning, replacement, and disposal recommendations.

5.1 Cleaning the adapter and sensor

To clean the adapter

▸ Periodically clean the SpO2 adapter by wiping it with a soft cloth moistened with ethanol (15°C (59°F), 76.9% to 81.4% by volume).

To clean a reusable sensor

1. Remove the sensor from the patient.
2. Disconnect the sensor and the patient cable from the adapter.
3. Wipe the components with a soft cloth moistened with a 70% isopropyl solution.
4. Allow to dry before reuse.

5.2 Replacing the adpater, cables, or sensor

When an SpO2 adapter, cable, or sensor is broken, cracked, or visibly damaged, immediately stop using it and replace it with a new one.

5.3 Disposing of the adapter, cables, or sensor

Follow your local laws for environmental protection when disposing of the SpO2 adapter, cables, and sensor. For detailed information, contact your Hamilton Medical technical representative.

6 Specifications

6.1 Alarm specifications

Table 10 lists the Masimo rainbow SET-related adjustable alarms, ranges, default settings, and resolution.

Table 10. Adjustable rainbow SET alarm ranges and defaults for HAMILTON-C1/C3/C6/T1

Alarm (units)	Range	Default setting	Resolution
The ranges and the default settings are the same for adult, pediatric, and neonatal patients.			
SpMet low (%)	OFF / 0.1 to 99	OFF	0.1 < 2 0.5 ≥ 2
SpMet high (%)	1.0 to 99.5 / OFF	OFF	0.1 < 2 0.5 ≥ 2
SpCO low (%)	OFF / 1 to 97	OFF	1
SpCO high (%)	2 to 98 / OFF	OFF	1
SpHb low (g/dl)	OFF / 1 to 23	OFF	0.1, 0.5, 1[9]
SpHb high (g/dl)	2 to 24 / OFF	OFF	0.1, 0.5, 1[9]
SpHb low (mmol/l)	OFF / 1 to 14	OFF	0.1, 0.5, 1[9]
SpHb high (mmol/l)	2 to 15 / OFF	OFF	0.1, 0.5, 1[9]

[9] This setting is configurable. See Section 4.3.

Table 11. Adjustable rainbow SET alarm ranges and defaults for HAMILTON-G5/S1

Alarm (units)	Range	Default setting	Resolution
The ranges and the default settings are the same for adult, pediatric, and neonatal patients.			
SpMet low (%)	OFF / 0.1 to 99	OFF	0.1 < 2 0.5 ≥ 2
SpMet high (%)	1.0 to 99.5 / OFF	3	0.1 < 2 0.5 ≥ 2
SpCO low (%)	OFF / 1 to 97	OFF	1
SpCO high (%)	2 to 98 / OFF	10	1
SpHb low (g/dl)	OFF / 1 to 23.5[10]	7	0.1, 0.5, 1[11]
SpHb high (g/dl)	2 to 24.5[10]/ OFF	17	0.1, 0.5, 1[11]
SpHb low (mmol/l)	OFF / 1 to 14.5[10]	4	0.1, 0.5, 1[11]
SpHb high (mmol/l)	2 to 15 / OFF	11	0.1, 0.5, 1[11]

[10] Alarm limit depends on **Resolution** setting in **Configuration**.
[11] This setting is configurable. See Section 4.3.

6.2 Safety/compliance specifications

For additional specifications, refer to the corresponding ventilator *Operator's Manual* and the Masimo product documentation.

Table 12. Masimo pulse oximeter specifications

Feature	Specification
EMC compliance	EN 60601-1-2
Electrical safety	IEC 60601-1, 3rd edition; UL 60601-1
Degree of protection (patient cable)	Type BF - applied part
Degree of protection (liquid ingress)	IP22
Mode of operation	Continuous

Table 13. Nominal wavelength specifications for SpO2 sensors

Sensors	LED/Wavelenth
RD SET sensors	Red / 660 nm
	Infrared / 905 nm

Table 14. Radient power specifications for Masimo Rainbow SpO2 sensors

Radiant power of light and RD SET sensors, at 50 mA, pulsed
≤ 15 mW

6.3 Accuracy

The following tables and data provide accuracy information for the Masimo pulse oximetry measurements.

Table 15. Masimo rainbow SET parameters, accuracy

Parameter	Accuracy
Refer also to the Masimo sensor documentation for information about sensor accuracy.	
SpCO (%)	1% to 40%: ±3% adult/ pediatric/infant
SpMet (%)	1% to 15%: ±1%, adult/ pediatric/infant/neonatal
SpHb (g/dl)	8 to 17 g/dl: ±1 g/dl (arterial or venous), adult/pediatric

The following information relates to accuracy of sensor measurements.

- SpO2, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range of 60% to 100% SpO2, 0 to 40% SpCO, and 0 to 15% SpMet against a laboratory pulse oximeter. SpO2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 to 135 days old and weighing between 0.5 and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70% to 100% SaO2 and 0.5% to 2.5% MetHb with a resultant accuracy of 2.9% SpO2 and 0.9% SpMet.
- The Masimo sensors have been validated for no-motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory pulse oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory pulse oximeter and ECG monitor. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo SET technology has been validated for low-perfusion accuracy in bench-top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70% to 100%. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- The Masimo sensors have been validated for pulse-rate accuracy for the range of 25 to 240 bpm in bench-top testing against a Biotek Index 2 simulator. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.
- SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 to 17 g/dl SpHb against a laboratory pulse oximeter. This variation equals plus or minus one standard deviation, which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.
- The following substances may interfere with pulse oximetry measurements:

  – Elevated levels of methemoglobin (MetHb) may lead to inaccurate SpO2 and SpCO measurements.

  – Elevated levels of carboxyhemoglobin (COHb) may lead to inaccurate SpO2 and SpCO measurements.

  – Very low arterial oxygen saturation (SpO2) levels may lead to inaccurate SpCO and SpMet measurements.

  – Severe anemia may cause erroneous SpO2 measurements.

  – Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

  – Elevated levels of total bilirubin may lead to inaccurate SpO2, SpMet, SpCO, and SpHb measurements.

For more information:
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