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1610010, 1610060, 1610090,
1610100

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English | 10147776/00
Software version 3.0.x

Store this Addendum together with your ventilator Operator's Manual.

This Addendum summarizes changes and corrections to the *HAMILTON-C1/T1/MR1 Operator's Manuals*.

1 Corrections to the HAMILTON-C1/T1/MR1 Operator's Manuals

1.1 Using a low-pressure and high-pressure oxygen supply

A new warning has been added when using both low-pressure and high-pressure oxygen.

WARNING

You must remove the low-pressure oxygen adapter before using high-pressure oxygen.

1.2 Turning on the ventilator

If the startup process does not complete successfully when turning on the ventilator, proceed as follows.

To turn on the ventilator if startup is not successful

1. Turn off the ventilator by pressing and holding  for about 10 seconds.
2. Turn the ventilator on again by pressing .

1.3 NIV-ST mode

The description for the NIV-ST mode has been updated as follows:

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

1.4 About closed-suctioning maneuvers

When performing a closed-suctioning maneuver, ventilation continues and the current settings do *not* need to be adjusted.

1.5 Vt/Weight in Controls window

Due to space constraints in some languages, the Vt/Weight parameter is shown as Vt/kg in the lower left corner of the Controls window. This occurs when either the (S)CMV+ /APVcmv or SIMV+/APVsimv mode is selected (Neonatal patient group only).

1.6 Control parameters

In the control settings specifications table, the default **Oxygen** setting for the Neonatal patient group is incorrect. It has been corrected in the table below.

Parameter or setting (unit)	Default: Neonatal
Oxygen (%)	50

1.7 Monitored parameters

The monitored parameters displayed on the ventilator are rounded to the nearest whole number, when required.

Waveforms displayed on the ventilator are not filtered and represent the actual monitored values.

1.8 Alarm related updates

This section lists changes to alarm descriptions.

1.8.1 CO2 Poor signal alarm

HAMILTON-C1/T1 only. The following alarm is *not* described in the ventilator *Operator's Manual*.

Alarm	Definition
CO2: Poor signal	<i>Low priority.</i> The CO2 sensor signal quality is poor.

Alarm	Definition
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Action needed

- Check patient condition.
- Check CO2 sensor and adapter connections.
- Ensure that airway adapters are not in a horizontal position relative to the floor to reduce accumulation of patient secretions. If accumulation occurs, remove the adapter, rinse with water, and reconnect.

1.8.2 TeslaSpy integrated alarm

HAMILTON-MR1 only. The TeslaSpy navigator onscreen alarms are available on devices with the TeslaSpy board PN 161942/01 and higher.

This board was introduced for ventilator serial number (SN) 3067 and higher.

1.8.3 External connections disabled alarm

HAMILTON-C1/T1 only. The description of the **External connections disconnected** alarm in the ventilator *Operator's Manual* is incorrect. It has been updated in the table below.

Alarm	Definition
External connections disabled	<i>Medium priority. Low after silence.</i> The Connectivity Module is turned off. Repeated connection attempts have failed. Ventilation can continue, but connection with other devices is not possible.

1.9 Using the COM1 RS-232 port

HAMILTON-C1/T1 only. RS-232 connection over the COM1 port is only available when using the communication Y-cable (PN 10077038).

1.10 Setting up a bluetooth connection

HAMILTON-C1/T1 only. When setting up the connection of a mobile device using the bluetooth connection type, the text "Pairing available" is *not* displayed in the **System > Settings > Connectivity > Bluetooth** window.

1.11 Galvanic lead-free O2 sensor

A galvanic lead-free O2 sensor (PN 10110473) is now available.

The new sensor is for use with HAMILTON-C1/T1/MR1 ventilators running software version 3.0.2 and higher. The specification for the sensor is as follows:

Description	Specification
The delivered oxygen concentration is continuously measured when an O2 sensor is enabled.	
Sensing position	Inspiratory pneumatics
Measurement, delivered oxygen concentration, range	18% to 105%
Response time	< 45 seconds to reach 90% final oxygen concentration
Initialization time (time from turning on device to operating performance)	< 40 seconds

Description	Specification
Drift	< 1.5% at 60% Oxygen over 6 hours
Shipment/storage temperature	To maximize the shelf life of unused galvanic O2 sensors, store them between -20°C and 50°C (-4°F and 122°F). Storage at higher temperatures will shorten the life of the lead-free O2 sensor.
Replacement	Every 2 years or when depleted, whichever comes first

1.12 HAMILTON-C1/T1 About humidifier-related alarms

Alarms on the HAMILTON-H900 are displayed on the HAMILTON-C1/T1 ventilators immediately.

For more information about humidifier-related alarms, see the *HAMILTON-H900 Instructions for use*.

1.13 HAMILTON-C1/T1 water protection

HAMILTON-C1/T1 only. The water protection rating of the HAMILTON-C1 and HAMILTON-T1 ventilators has changed, and the device labels have been updated accordingly.

Part number	Water protection
HAMILTON-C1	
161001	IP21
1610010	IP22
HAMILTON-T1	
161006, 161009	IP24
1610060, 1610090	IP54

Note that the software 3.0.x can be installed on the ventilator regardless of the IP rating indicated on the device.

See Section 1.18 for more information about the updated HAMILTON-C1 and HAMILTON-T1 ingress protection ratings.

1.14 HAMILTON-C1/T1 potential equalization

HAMILTON-C1/T1 only: a potential equalization conductor is now available on the HAMILTON-C1 and HAMILTON-T1 ventilators.

1.14.1 Working with the potential equalization conductor

The potential equalization conductor is located on the back of the HAMILTON-C1 and HAMILTON-T1 ventilators. See Figure 1.

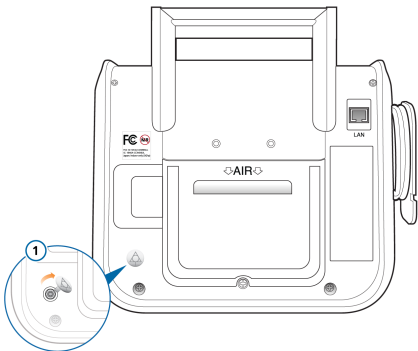
Consider using the potential equalization conductor when working with a CO2 sensor, SpO2 sensor, or similar medical devices.

To connect the potential equalization conductor

- 1. Connect one end of a grounding cable to the potential equalization conductor.
- 2. Connect the other end to a properly grounded outlet.

When not in use, a cover can be placed over the conductor.

Figure 1. Potential equalization conductor with cover (1)



1.14.2 Parts and accessories

The table below lists the parts available for the potential equalization conductor.

Description	PN
Cover for HAMILTON-C1, white	10112719
Cover for HAMILTON-T1, gray	10112494

1.14.3 Standards and approvals

The potential equalization conductor is designed for the connection of a potential equalization conductor according to DIN 42 801 and IEC 60601-1. The function of the potential equalization conductor is to equalize potentials between the ventilator system and other medical devices that can be touched simultaneously. The potential equalization conductor must *not* be used as a protective earth connection.

1.15 HAMILTON-T1 environmental requirements

HAMILTON-T1 only. When the device is *not* stored in its original packaging, the permitted storage temperature range is -15°C to 60°C.

1.16 Battery electrical specifications

The battery electrical specifications are as follows:

Element	Specifications
Battery	10.8 V DC, 6.7 Ah, 72 Wh

1.17 HAMILTON-MR1 electrical specifications

The electrical specifications for the HAMILTON-MR1 are as follows:

Element	Specifications
Input power	100 to 240 VAC, 50/60 Hz
Power consumption	90 VA typical, 180 VA maximum

1.18 Symbols used on device labels and packaging

The following table provides new symbol details.

Symbol	Definition
IP22	<i>HAMILTON-C1 only:</i> Protected against dripping water when the device is tilted to a maximum of 15 degrees, and from solid particles larger than 12.5 mm.
IP54	<i>HAMILTON-T1 only:</i> Protected from water spray from any direction, and from limited dust ingress.
	Terminal for the connection of a potential equalization conductor.

1.19 Standards and approvals

The ventilators meet relevant parts of the following standards and approvals, with the versions shown, in addition to those listed in the *Operator's Manuals*:

- ISO 80601-2-55:2018
- EN ISO 13485:2016

2 Corrections to the Pulse Oximetry Instructions for Use for HAMILTON-C1/T1

2.1 Operating conditions

The stated operating conditions of the SpO2 sensor apply to both continuous and transient operation of the sensors.

2.2 Nihon Kohden Technical specifications

Ingress protection

For Nihon Kohden pulse oximeters, the degree of protection (solid particle and liquid ingress) has been updated to a rating of IPX2.

Wavelength and maximum light intensity specifications

Nihon Koden pulse oximeters have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is less than 5.5 mW/sr. The wavelength range can provide especially useful information to clinicians.

2.3 Masimo Technical specifications

Ingress protection

For Masimo pulse oximeters, the degree of protection (solid particle and liquid ingress) has been updated to a rating of IP22.

3 Corrections to the INTELLi-VENT-ASV Operator's Manual for HAMILTON-C1/T1

3.1 Vent Status and Quick Wean panels

In the Vent Status and Quick Wean panels, green bars are shown above and below the target zone when *all* the parameters are within the weaning zone.

When individual parameters are within their weaning zone, an individual timer is shown indicating the amount of time the parameter has been in the weaning zone.

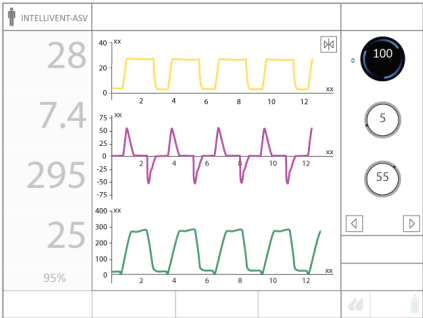
3.2 Waveforms, view 7

When a CO2 sensor is connected, the following waveforms are shown in view 7: Paw, Flow, PCO2

When no CO2 sensor is connected the Volume waveform is shown in place of PCO2.

Note that the order of the waveforms on the display has changed (Figure 2).

Figure 2. Waveforms, view 7 in INTELLiVENT-ASV



3.3 Quality index and ventilation management

If the signal quality is unreliable, the PetCO₂ quality index can show gray, red, or orange bars. The table below shows the correct quality indicators.

Table 1. PetCO₂ quality index and automated ventilation management

Quality indicator	These conditions apply ...
The data from the sensor is unavailable or not reliable for more than 30 seconds Gray, red, or orange bars 	• The %MinVol control is a solid red circle; it is frozen. • The Ventilation adjustment OFF alarm is generated. • The minute volume adjustment works as it does in ASV, with a constant minute ventilation equal to the last valid automatic %MinVol setting. For details, see your ventilator <i>Operator's Manual</i>.
The data from the sensor is reliable Green bars 	• The %MinVol control is a blue rotating circle. • The Ventilation adjustment OFF alarm is reset. • Automated ventilation management resumes.

3.4 Quick Wean parameters

In Section 2.2.2 About the Quick Wean Parameters, $\Delta P_{\text{support max}}$ is listed as a parameter. This is incorrect. It should be ΔP_{insp} .

