Anexa 5

Specificație tehnică completată

Ventilator pulmonar Adult, pediatric (caracteristici de baza)

Model: Hamilton C1 Producător: Hamilton Medical Țara: Elveția

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Ventilator pulmonar Adult, pediatric (caracteristici de bază) Descriere Ventilatoare mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menţinînd o ventilare adecvată. Parametrul Specificația Tip Mobil, pe suport cu rotile da Tip pacient Adult, pediatric da Gama de control/setări Volum total 20-2,000 mL Flux inspir maxim ≥180 L/min Presiune inspir 0-80 cm H2O Rata respiratorie 0-80 rpm Timp inspir 0-10 s Rata I:E 1:9 la 4:1 FiO2, % 21-100 Buton pentru respirație manuală da PEEP/CPAP 0-35 cm H2O Suport presiune 0-60 cm H2O Mecanism triger Presiune, flux Flow triger 1 to 20 l/min Ajustarea presiunii pantă/rampă da Funcția suspin da Buton 100 % O2 da Timpul maxim activ al butonului 100 % O2 2 min Blocarea panoului de control da Moduri de ventilare APVcm/(S)CMV se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da APVsimv/SIMV- se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da PCV - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da PSIMV - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da SPONT -se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da ASV sau alte moduri de control inteligent al respirației	Ventilator pulmonar Adult, pediatric (caracteristici de bază) **DA** Descriere Ventilatoare mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menținând o ventilare adecvată.**DA** Parametrul Specificația Tip Mobil, pe suport cu rotile **DA** Tip pacient Adult, pediatric **DA** Gama de control/setări Volum total 20-2,000 mL **DA** Flux inspir maxim - 260 L/min **DA** Presiune inspir 0-60 cm H2O **DA** Rata respiratorie **0-80 rpm DA** Timp inspir 0-12 s **DA** Rata I:E 1:9 la 4:1 **DA** FiO2, % 21-100 **DA** Buton pentru respirație manuală **DA** PEEP/CPAP 0-35 cm H2O **DA** Suport presiune 0-60 cm H2O **DA** Mecanism triger Presiune, flux **DA** Flow triger **0.5** to 20 l/min **DA** Ajustarea presiunii pantă/rampă **DA** Funcția suspin **DA** Buton 100 % O2 **DA** Timpul maxim activ al butonului 100 % O2 2 min **DA** Blocarea panoului de control **DA** Moduri de ventilare APVcm/(S)CMV se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA** APVsimv/SIMV- se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA** PCV - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA** PSIMV - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA** SPONT -se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA** ASV - **DA**

NIV si NIV-ST - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. da	NIV si NIV-ST - se permite si alte abrivatori doar ca eficacitate sa coespunda cu modul sus mentionat. **DA**
Parametri monitorizați/afișați Presiunea inspiratorie maximă da	Parametri monitorizați/afișați Presiunea inspiratorie maximă **DA**
Presiunea medie în căile respiratorii da	Presiunea medie în căile respiratorii **DA**
Presiunea PEEP da	Presiunea PEEP **DA**
Volumul total da	Volumul total **DA**
Monitorizarea FiO2 da	Monitorizarea FiO2 **DA**
Rata respiratorie da	Rata respiratorie **DA**
Timp inspir da	Timp inspir **DA**
Timp expir da	Timp expir **DA**
Rata I:E da	Rata I:E **DA**
Volumul minutar spontan da	Volumul minutar spontan **DA**
Alarme pacient FiO2 mare/mic da	Alarme pacient FiO2 mare/mic **DA**
Volum minutar mare/mic da	Volum minutar mare/mic **DA**
Presiune inspir mare/mică da	Presiune inspir mare/mică **DA**
PIP mare da	PIP mare **DA**
PEEP mare da	PEEP mare **DA**
Lipsă PEEP da	Lipsă PEEP **DA**
Apnea da	Apnea **DA**
Presiune/ocluzie continuă ridicată da	Presiune/ocluzie continuă ridicată **DA**
Inversare IE da	Inversare IE **DA**
Circuit respirator deconectat da	Circuit respirator deconectat **DA**
Alarme echipament Lipsă alimentare gaz da	Alarme echipament Lipsă alimentare gaz **DA**
Lipsă alimentare electrică da	Lipsă alimentare electrică **DA**
Baterie descărcată da	Baterie descărcată **DA**
Eroare de sistem	Eroare de sistem
Sensor decalibrat, scurgere prin valve	Sensor decalibrat, scurgere prin valve **DA**
Autodiagnostic da	Autodiagnostic **DA**
Interfața Raportarea alarmelor și starea pacientului Afișare pe display da	Interfața Raportarea alarmelor și starea pacientului Afișare pe display **DA**
Posibilitatea conectării în rețea centralizată da	Posibilitatea conectării în rețea centralizată **DA**
Display LCD /TFT colot tip touch screen ≥ 8 inch	Display TFT colot tip touch screen – 8,4 inch **DA**
Alimentare Gaze medicale	Alimentare Gaze medicale
Turbina integrata Aer	Turbina integrata Aer **DA**
Gazele comprimate O2	Gazele comprimate O2 **DA**
Presiunea în rețea 3-6 atm	Presiunea în rețea 3-6 atm **DA**
Electrică Rețea electrică 220 V, 50 Hz da	Electrică Rețea electrică 220 V, 50 Hz **DA**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
Timp operare baterie ≥ 3 h	Timp operare baterie - **4 h** DA
Accesorii Valva de expir Obligatoriu sa fie ca componeta separta nu integrata in dispozitiv. 1 buc	Accesorii Valva de expir Obligatoriu sa fie ca componeta separta nu integrata in dispozitiv. 1 buc **DA**
Sensor de oxigen Obligatoriu sa fie ca componeta separta nu integrata in dispozitiv. 1 buc	Sensor de oxigen Obligatoriu sa fie ca componeta separta nu integrata in dispozitiv. 1 buc **DA**
Flow sensor De tip detașabil, să nu fie integrat în interiorul dispozitivului. Cu posibilitatea de prelucrare, dezinfectare și sterilizare. 1 buc	Flow sensor De tip detașabil, să nu fie integrat în interiorul dispozitivului. Cu posibilitatea de prelucrare, dezinfectare și sterilizare. 1 buc **DA**
Circuite respiratorii cu camera de umidificare Adult 1 set.	Circuite respiratorii cu camera de umidificare Adult 1 set. **DA**
Umidificator Compatibil cu ventilatorul indicati modelul da	Umidificator Compatibil cu ventilatorul indicati modelul **DA**
Suport pe rotile Min. 4 rotile da	Suport pe rotile Min. 4 rotile **DA**

Min. 2 roți cu frînă da Braț articulat pentru fixarea furtunelor respiratorii da Mîner pentru transportare da	Min. 2 roți cu frînă **DA** Braț articulat pentru fixarea furtunelor respiratorii **DA** Mîner pentru transportare **DA**

Declaration of Conformity

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, confirm that the following products	Wir, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, bestätigen, dass die folgenden Produkte	La société Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, confirme que les produits ci-dessous

CEDCL-HAM-C1, Attachment on page 2

meet the following EC directive (including all applicable amendments):	mit der folgenden EG-Richtlinie (einschliesslich aller zutreffenden Änderungen) übereinstimmt: EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3 All listed products are classified as class IIb.	sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant):
Please note, this EU Declaration of Conformity is issued under the sole responsibility of Hamilton Medical AG.	Bitte beachten Sie, dass diese EU Konformitätserklärung unter der alleinigen Verantwortung der Hamilton Medical AG ausgestellt wird.	Veuillez noter que cette déclaration de conformité UE est émise sous la seule responsabilité de Hamilton Medical AG.

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany

Registration No: HD 60137935 0001

EC REP

medin Medical Innovations GmbH
Adam-Geisler-Strasse 1
82140 Olching
Germany

Validity:	**Gültigkeit:**	**Validité:**
This declaration is valid for products manufactured in 2021. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report.	Diese Konformitätserklärung gilt für Produkte, welche 2021. produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll.	Cette déclaration est valable pour les produits fabriqués en 2021. Les numéros de lot peuvent être retracés par les preuves de production. Cette déclaration est valable associée au rapport d'inspection final.

Hamilton Medical AG

Jens Hallek
CEO

Bonaduz, 2021 -05- 25

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following manufacturing sites:

No.	Location
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland
/03	Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierstelle

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification also covers the following locations:

No.	Facility	Scope
/01	c/o Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems
/02	c/o Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing
/03	c/o Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing
/04	c/o Hamilton Medical AG Parc Industrial Vial 4 7013 Domat/Ems Switzerland	Manufacturing of ventilator sensors and tubing systems

Report No.: 3348226-90
Effective date: 2021-05-19
Expiry date: 2023-07-08
Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

HAMILTON-C1

Minimum size for maximum performance

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983

We live for ventilation technology

We live for ventilation technology. Technology that helps caregivers improve the lives of their critically ill patients. We believe that innovation is essential to meet the demands of critical care. To us, innovation is about realizing visionary new ideas and continuously improving existing products, always maintaining the focus on safe, individualized ventilation, as well as ease of use.

We learn from our customers and from multi-disciplinary experts. And we invest in long-term research and development. We develop Intelligent Ventilation solutions: devices and consumables for the ventilation of all critically ill patients – from neonates to adults.

Jens Hallek
CEO
Hamilton Medical AG

Bob Hamilton
CEO
Hamilton Medical, Inc.

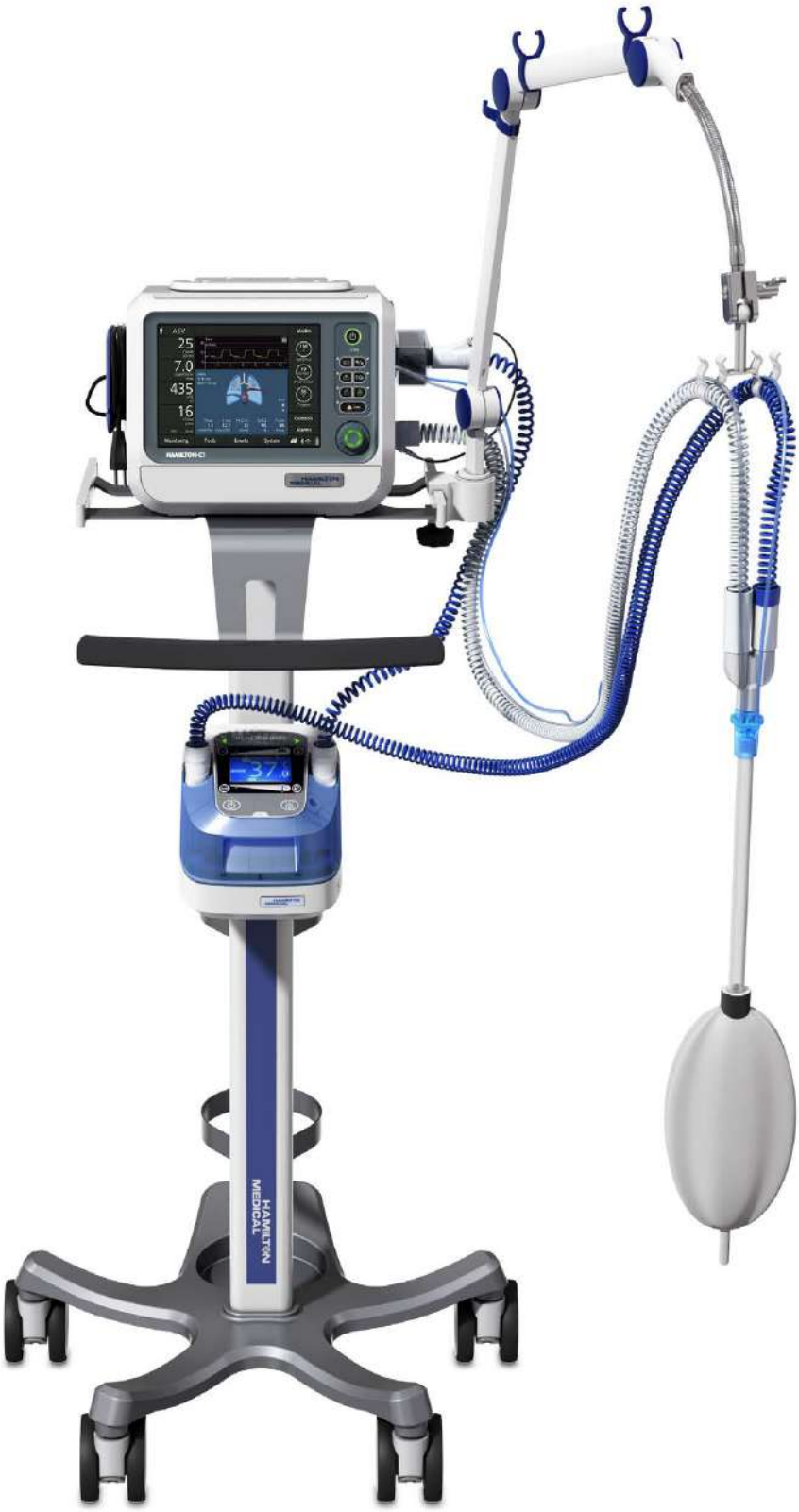
Meet the HAMILTON-C1

The HAMILTON-C1 is a versatile and feature-rich ventilator packaged in a compact size. It is the ideal companion for all patient groups, including neonates. The HAMILTON-C1 adapts effortlessly to a variety of different settings, such as the intensive care unit, emergency ward, recovery room or intermediate care, as well as long-term acute care facilities and during intrahospital transport.

- ✓ Adult, pediatric, and neonatal ventilation
- ✓ Noninvasive ventilation and integrated high flow oxygen therapy
- ✓ High-performance turbine and battery
- ✓ Individualized, lung-protective ventilation modes ASV® and INTELLiVENT®-ASV
- ✓ CPR ventilation
- ✓ Digital solutions for respiratory care: Hamilton Connect Module and App

Compact and convenient for transport

The high-performance turbine enables the HAMILTON-C1 mechanical ventilator to be completely independent from compressed air. Its integrated high-capacity battery allows you to ventilate your patients during intrahospital transport and mobilization, without needing an external power source. The compact and lightweight design makes handling easier.


HAMILTON
MEDICAL

Ease of use

In close cooperation with users and ventilation experts, our engineers have designed the user interface to be particularly intuitive. Switching between the HAMILTON-C1 and all other Hamilton Medical ventilators is easy, because they are all operated according to the same principles.

The Ventilation Cockpit on the HAMILTON-C1 consolidates the monitoring data and displays it as advanced graphics. These provide a quick overview of the patient's current ventilation status and provide a reliable basis for therapy decisions.

With the Hamilton Connect App on your smartphone, you can take advantage of the Live View to keep an eye on all essential parameters and ventilation data, and review them even when you are not in front of the ventilator screen.

"

Small but mighty! Despite its compact size, the HAMILTON-C1 is a fully featured ventilator for use in almost any environment.

Jesko Mertha, Group Leader,
Clinic for Intensive Care Medicine
Cantonal Hospital St. Gallen, St. Gallen,
Switzerland

The Ventilation Cockpit

1 Main monitoring parameters

All of the main monitoring parameters at a glance. The large characters allow you to see them even from a distance.

2 Dynamic Lung

One quick look shows you tidal volume, lung compliance, patient triggering, and resistance in real-time. The lungs expand and contract in synchrony with the actual breaths.

3 Vent Status

The Vent Status panel displays six parameters related to the patient's dependence on the ventilator. When all values are in the weaning zone, the panel is framed in green, indicating that spontaneous breathing trials or extubation can be considered.

4 Direct access to main controls

Access and adjust the most important controls for the current mode directly on the main display.

For use in any hospital situation, from neonates to adults

In the intensive care unit

The HAMILTON-C1 offers the performance of a high-end ICU ventilator in a compact size:

- ✓ State-of-the-art and advanced ventilation modes, including ASV and INTELLiVENT-ASV
- ✓ Noninvasive ventilation and integrated high flow oxygen therapy
- ✓ Advanced lung-protective features and options

During intrahospital transport and for mobilization

The HAMILTON-C1 is a reliable companion for intrahospital transport and mobilization:

- ✓ High-performance turbine, battery operation, and compact size
- ✓ State-of-the-art ventilation modes appropriate for early mobilization of all patient populations
- ✓ Wireless connectivity with the Hamilton Connect Module

In the neonatal intensive care unit

The HAMILTON-C1 can provide continuity of care for neonatal patients by means of dedicated modes and features:

- ✓ Noninvasive ventilation modes and therapies developed especially for neonatal patients (synchronized noninvasive ventilation, demand-flow nCPAP modes, Volume Support mode, and high flow oxygen therapy)
- ✓ Invasive ventilation modes developed for neonatal patients
- ✓ Robust proximal sensor to provide accurate flow measurement
- ✓ Single-use consumables that may help in controlling infections

For long-term acute care

The HAMILTON-C1 can eliminate the need to use multiple ventilators for patients requiring long-term respiratory support:

- ✓ Portability, making it suitable for mobilization
- ✓ Different modes and therapies in one device (invasive ventilation modes including ASV and INTELLiVENT-ASV, NIV, and high flow oxygen therapy)
- ✓ The Speak Valve option gives tracheostomized patients a voice, and allows them to swallow even while receiving respiratory support from the ventilator

Adult, pediatric, and neonatal ventilation

is provided. For neonatal patients, a specially designed neonatal proximal flow sensor is used. The tidal volume range goes down to as low as 2 ml.

High-performance turbine

enables the HAMILTON-C1 to be completely independent from compressed air. This reduces weight and saves space.

INTELLiVENT-ASV, your bedside assistant

is an advanced ventilation mode based on ASV. The clinician defines the clinical goal for PetCO2 and SpO2. INTELLiVENT-ASV then adjusts CO2 elimination and oxygenation, and keeps the patient within the predefined ranges. Quick Wean supports the clinician in weaning patients from mechanical ventilation.

High-performance noninvasive ventilation (NIV)

is enabled by the ventilator's integrated high-performance turbine and peak flow rate of up to 260 l/min. Optimal flow delivery is ensured even in the event of large leaks.

Integrated high flow oxygen therapy

can be applied using the same device and breathing circuit, simply by changing the patient interface. With the optional integrated high flow oxygen therapy, the ventilator offers you a range of ventilation and therapy options in one device.

Hamilton Connect Module

provides wireless and wired connectivity protected by state-of-the-art security. It also enables connection with the Hamilton Connect App.

Features and options

Integrated pneumatic and optional Aerogen[§] nebulizer

Pulse oximetry
(SpO2 and pulse measurement)

Leak compensation for NIV and invasive ventilation

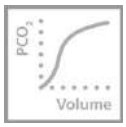
Compatible with conventional speaking valves

CPR ventilation

nCPAP modes

Serial interface for connection to PDMS or patient monitors

Hamilton Connect App



Mainstream (volumetric) and sidestream capnography

Remote access to HAMILTON-H900 controls and status

From the ventilation specialist

E-learning

Hamilton Medical College provides free and open e-learning on mechanical ventilation and ventilators.
Join at: www.hamilton-medical.com/elearning.

Universal ventilator consumables

Our accessories and consumables are specially developed for the highest possible patient safety and ease of use. Choose between reusable and disposable parts according to your institutional policies.

Peripheral devices

Our ventilation portfolio includes an active humidifier, the HAMILTON-H900, as well as the automatic cuff pressure controller, IntelliCuff. Both devices may be used with all kinds of mechanical ventilators.

More information:
www.hamilton-c1.com

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

689330.07

HAMILTON-C1

HAMILTON-C1

Technical specification for SW version 3.0.x

Ventilation modes

Standard: ✓ Option: O Not applicable: --

Mode form	Mode name	Mode	Adult/Ped	Neonatal
Volume-targeted modes, adaptive pressure controlled	APVcmv / (S)CMV+	Breaths are volume targeted and mandatory.	✓	✓
	APVsimv / SIMV+	Volume-targeted mandatory breaths can be alternated with pressure-supported spontaneous breaths.	✓	✓
	VS	Breaths are flow cycled and deliver a set tidal volume to support patient-initiated breaths.	✓	✓
Pressure-controlled modes	PCV+	All breaths, whether triggered by the patient or the ventilator, are pressure-controlled and mandatory.	✓	✓
	PSIMV+	Mandatory breaths are pressure controlled. Mandatory breaths can be alternated with pressure-supported spontaneous breaths.	✓	✓
	DuoPAP	Mandatory breaths are pressure controlled. Spontaneous breaths can be triggered at both pressure levels.	O	O
	APRV	Spontaneous breaths can be continuously triggered. The pressure release between the levels contributes to ventilation.	O	O
	SPONT	Every breath is spontaneous, with or without pressure-supported spontaneous breaths.	✓	✓
Intelligent ventilation	ASV	Operator sets %MinVol, PEEP, and Oxygen. Frequency, tidal volume, pressure, and I:E ratio are based on physiological input from the patient.	✓	--
	INTELLiVENT-ASV	Ventilator management of CO2 elimination and oxygenation is based on clinician-defined target ranges and parameter limits, and physiological input from the patient. The underlying mode is ASV.	O	--
Noninvasive modes	NIV	Every breath is spontaneous.	O	O
	NIV-ST	Every breath is spontaneous as long as the patient is breathing above the set Rate. A backup Rate can be set for mandatory breaths.	O	O
	nCPAP	Demand flow nasal continuous positive airway pressure.	--	O
	nCPAP-PC	Breaths are pressure controlled and mandatory.	--	O
	HiFlowO2	High flow oxygen therapy. No supported breaths.	O	O

Swiss Quality

HAMILTON MEDICAL
Intelligent Ventilation since 1983

Standard configuration and options (in alphabetical order)

Standard: ✓ Option: O Not applicable: --

Functions	Adult/Ped	Neonatal
Capnography, mainstream (volumetric) and sidestream	O	O
Communication board: CO2/Nurse Call/COM1, CO2/SpO2/COM1[1], CO2/SpO2/Humidifier & COM1[1, 2]	O	O
Communication protocols. For details, see the *Connectivity* brochure	O	O
CPR ventilation	✓	✓
Dynamic Lung	✓	--
Event log (up to 10,000 events with data and time stamp)	✓	✓
Flow trigger	✓	✓
Hamilton Connect Module (connectivity)	O	O
HAMILTON-H900 humidifier integration	O	O
IntelliTrig (leak compensation)	✓	✓
Languages (English, US English, Chinese, Croatian, Czech, Danish, Dutch, Finnish, French, German, Greek, Hungarian, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Spanish, Swedish, Turkish, Ukrainian)	✓	✓
Manual breath/prolonged inspiration	✓	✓
Nebulization, pneumatic	✓	--
O2 enrichment	✓	✓
On-screen help	✓	✓
Patient group HAMILTON-C1 neo	--	✓
Patient group HAMILTON-C1	✓	O
Print screen	✓	✓
RJ-45 Ethernet port[3]	✓	✓
Screen lock	✓	✓
Speak valve compatibility	O	--
SpO2 monitoring	O	O
Standby with timer	✓	✓
Suctioning tool	✓	--
Trends/Loops	O	O
USB port	✓	✓
Vent Status (visual representation of ventilator dependence)	✓	✓

[1] Applies only to devices with serial number > 6000
[2] Only available with the HAMILTON-H900 Y-cable
[3] Only available for use if the Hamilton Connect module is activated.

Technical performance

Description	Specification
Automatic expiratory base flow	*Adult/Ped:* Fixed at 3 l/min *Neonatal:* Fixed at 4 l/min
Inspiratory pressure	0 to 60 cmH2O
Maximum limited pressure	60 cmH2O
Maximum working pressure	*Adult/Ped:* 60 cmH2O (total inspiratory pressure); ensured through pressure limiting *Neonatal:* 45 cmH2O (limitation depending on frequency)
Maximum inspiratory flow	260 l/min (120 l/min with 100% O2)
Means of inspiratory triggering	Flow trigger control
Minimum expiratory time	20% of cycle time; 0.2 to 0.8 seconds
Minute volume capability	Up to 60 l/min
Oxygen mixer accuracy	± (volume fraction of 2.5% + 2.5% of actual reading)
Tidal volume	*Adult/Ped:* 20 to 2000 ml *Neonatal:* 2 to 300 ml
Preoperational checks	Leak test, flow sensor/circuit/O2 sensor calibration, CO2 sensor zero calibration[4]
Display device	Display of settings, alarms, and monitored data *Type:* Color TFT *Size:* 640 x 480 pixels, 8.4 in (214 mm) diagonal
Brightness setting for display	The range is 10% to 100% brightness. By default, Day = 80%; Night = 40%.
Alarm volume (loudness)[5]	The range is 1 to 10. The default setting is 5.
Sound power level[6]	51 dB(A) ± 3dB(A)
Sound pressure level[6]	43 dB(A) ± 3dB(A)

[4] CO2 option required
[5] Volume at 1 meter distance from ventilator. A setting of 1 = 62 dB(A), 5 = 76 dB(A), and 10 = 85 dB(A), with accuracy of ±3 dB(A).
[6] Per ISO 80601-2-12.

Standards and approvals

Classification	Class IIb, continuously operating according to EC directive 93/42/EEC
Valid versions	IEC 60601-1:2005/A1:2012, ANSI/AAMI ES60601-1:2005/(R)2012, CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1-2:2014, ISO 80601-2-12:2011 + Cor.:2011, ISO 80601-2-55:2018, EN ISO 5356-1:2015, ISO 80601-2-61:2017, ISO 80601-2-49:2018
Declaration	The HAMILTON-C1 was developed in accordance with pertinent international standards and FDA guidelines. The ventilator is manufactured within an EN ISO 13485 and EN ISO 9001, Council Directive 93/42/EEC, Annex II, Article 3 certified quality management system. The ventilator meets the Essential Requirements of Council Directive 93/42/EEC, Annex I.
Electromagnetic compatibility	According to IEC 60601-1-2:2014
Safety class	Class II, Type B applied part (ventilator breathing system, VBS), type BF applied part CO2 sensor including CO2 module connector; SpO2 sensor including adapter, continuous operation according to IEC 60601-1

Pneumatic performance

High-pressure oxygen inlet	Pressure:	2.8 to 6 bar / 41 to 87 psi
	Flow:	Maximum of 200 l/min
	Connector:	DISS (CGA 1240) or NIST
Low-pressure oxygen inlet	Pressure:	Maximum 6 bar / 87 psi
	Flow:	≤ 15 l/min
	Connector:	Quick-coupling system, compatible with Colder Products Company (CPC) PMC series
Air supply	Integrated blower	
Gas mixing system	Delivered flow:	• > 260 l/min ±10% against ambient pressure (at sea level) • > 200 l/min with 100% oxygen
	Delivered pressure:	*Adult/Ped*: 0 to 60 cmH2O
		Neonatal: 0 to 45 cmH2O
	Flow accuracy:	±10% or ±300 ml/min (whichever is greater)
Inspiratory outlet (*To patient* port)	Connector:	ISO ID15/OD22 conical
Expiratory outlet (*From patient* port)	Connector (on expiratory valve):	ISO ID15/OD22 conical

Electrical specifications

Input power	100 to 240 VAC ±10%, 50/60 Hz	
Power consumption	50 VA typical, 150 VA maximum	
Battery	Hamilton Medical provides a high-capacity battery[7].	
	Electrical specifications:	6.7 Ah, 72 Wh, 50 W typical, 150 W maximum
	Type:	Lithium-ion, supplied by Hamilton Medical only
	Recharge time:	While the ventilator is connected to primary power, approximately 3.25 h to fully recharge one battery.
	Storage:	-20°C to 60°C, ≤ 85% relative humidity. The storage location should be free from vibration, dust, direct sunlight, moisture, and corrosive gases, and with a recommended temperature range < 21°C. Extended exposure to temperatures above 45°C can degrade battery performance and life.
	Normal operating time:	Operating times are measured with one fully charged battery, the blower in use, without communication board, and with the following settings: Mode = PCV+, Rate = 10 b/min, ΔPcontrol = 10 cmH2O, I:E = 1:4, PEEP = 5 cmH2O, Flow trigger = 5 l/min, FiO2 = 40%. Approximate operating times under these conditions are as follows: • One battery, display brightness = 80%: 4 h • One battery, display brightness = 20%: 4.5 h 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.

Graphical patient data

Graphic type/tab name	**Options**
Waveforms	Pressure, Volume, Flow, PCO2[8], FCO2[8], Plethysmogram[9], Capnogram[10]
Intelligent panels	Dynamic Lung[11], Vent Status, ASV Graph[12], INTELLiVENT-ASV Oxygenation and CO2 elimination maps and horizons[10]
Trends	1-, 6-, 12-, 24-, or 72-h trend data for a selected parameter or combination of parameters
Loops	Pressure/Volume, Pressure/Flow, Volume/Flow, Volume/PCO2[8], Volume/FCO2[8]

[7] PN 369108, revision 4 and later.
[8] CO2 option required
[9] SpO2 option required
[10] INTELLiVENT-ASV required
[11] Only for adult/pediatric patients
[12] Only in ASV mode

Alarms

Priority	Alarm
High priority	Apnea, Apnea time, ExpMinVol high/low, Oxygen high/low, Minute volume high/low, Pressure high/low, High Pressure during Sigh, Pressure not released Flow sensor calibration needed (during ventilation), Check flow sensor tubing, Check flow sensor, Check patient interface, External flow sensor failed, Replace O2 sensor, Oxygen supply failed, Buzzer defective, Loudspeaker defective Disconnection on patient/ventilator side, Exhalation obstructed, Obstruction Options not found, Self test failed, Blower fault, Device temperature high, Vent outlet temperature high Battery low, Battery power loss, Battery totally discharged, Battery temperature high, Battery communication error, Battery defective *SpO2:*[13] SpO2 low
Medium priority	High Flow, fTotal high/low, Frequency high/low, Vt high/low, Inspiratory volume limitation, High PEEP, Loss of PEEP, Pulse high/low, Pressure limitation Wrong expiratory valve, Circuit calibration needed, Flow sensor calibration needed, Flip the flow sensor, Check flow sensor for water (Neonatal) Check for blockage, Fan failure, Function key not operational, Performance limited by high altitude, Real-time clock failure, Battery low *CO2:*[14] PetCO2 high/low *INTELLiVENT-ASV:* FiO2 set to 100% due to low SpO2, Oscillation %MinVol, Oscillation PEEP/CPAP, Oxygenation adjustment off, Oxygen control limit exceeded, Ventilation adjustment off *SpO2:*[13] SpO2: Adapter missing, SpO2: Light interference, SpO2: Low perfusion mode, SpO2: Poor signal, SpO2: Probe missing, SpO2: Patient disconnected, SpO2: Sensor error, PI low/high, PVI low/high, Pulse low/high, SpO2 low
Low priority	Check Plimit, ASV: Cannot meet the target, Maximum leak compensation, Pressure limit has changed, CPR ON, SpeakValve ON/OFF, Suctioning maneuver, Apnea ventilation/Apnea ventilation ended Flow sensor calibration needed, Preventive maintenance required, Replace HEPA filter, Blower service required, Loss of external power, IRV (inverse ratio ventilation), Release valve defective, Touch not functional, Check settings Battery calibration required, Battery replacement required, Wrong battery, Battery low O2 sensor calibration needed, O2 sensor defective, O2 sensor missing, O2 sensor not system compatible External connections disabled[15], JTAG not working, Invalid communication board *CO2:*[14] CO2 calibration needed, CO2 sensor defect, CO2 sensor disconnected, CO2 sensor over temperature, CO2 sensor warmup, Check CO2 sampling line, Check CO2 airway adapter, CO2: Poor signal *INTELLiVENT-ASV:*[16] Oxygen controller at limit, PetCO2 target range changed, Ventilation controller at limit *SpO2:*[13] SpO2 high

[13] If the SpO2 option is installed and enabled.
[14] If the CO2 option is installed and enabled.
[15] If the Hamilton Connect module is installed and enabled.
[16] If INTELLiVENT-ASV is installed.

Control settings and ranges

Parameter (units)	Range Adult/Ped[17]	Range Neonatal[17]
%MinVol (%)[18]	25 to 350	--
Apnea backup	On, Off	On, Off
ETS (%)	5 to 80	5 to 80
Flow (l/min)[19]	2 to 100[20]	2 to 30
I:E[21]	1:9 to 4:1	1:9 to 4:1
IBW (kg) *(calculated)*	3 to 139	--
Oxygen (%)	21 to 100	21 to 100
P high (in APRV) (cmH20)	0 to 60	0 to 45
P high (in DuoPAP) (cmH20)	0 to 60	3 to 45
P low (in APRV) (cmH2O)	0 to 35	0 to 25
Pat. height (cm) (in)	 30 to 250 12 to 98	 --
PEEP/CPAP (cmH2O)	0 to 35	3 to 25
Plimit (cmH2O)	5 to 60	5 to 60
P-ramp (ms)[22]	0 to 2000 *ASV, NIV, NIV-ST, SPONT, VS:* max = 200	0 to 600 *NIV, NIV-ST, SPONT, nCPAP-PC, VS:* max = 200
Rate (b/min)[23]	1 to 80 *APVcmv, PCV+:* 4 to 80 *PSIMV+, NIV-ST:* 5 to 80	1 to 80 *PSIMV+:* 5 to 80 *APVcmv, PCV+, PSIMV+PSync, nCPAP-PC, NIV-ST, APVsimv + Apnea backup:* 10 to 80
Set temp (°C)	INV: 35 to 41 NIV: 30 to 35 HiFlowO2: 33 to 37	INV: 35 to 41 NIV: 30 to 35 HiFlowO2: 33 to 37
Sex	Male, Female	--
Sigh	On, Off	--
SpeakValve	On, Off	--
T gradient (°C)	-2 to 3	-2 to 3
T high[23] (in APRV and DuoPAP) (s)	0.1 to 40.0	0.1 to 40.0
T low (in APRV) (s)	0.2 to 40.0	0.2 to 40.0
TI (s)[21,23]	0.1 to 12.0	0.1 to 12.0
TI max (s)	0.5 to 3.0	0.25 to 3.0

[17] Parameter settings and ranges can vary depending on the selected mode.
[18] Only in ASV mode.
[19] Only for high flow oxygen therapy.
[20] In some markets, the maximum possible Flow setting may be limited.
[21] In PCV+, (S)CMV, and APVcmv modes, mandatory breath timing can be controlled by using a combination of inspiratory time (TI) and Rate, or by the I:E ratio; set the method in Configuration. All other modes are controlled by using a combination of inspiratory time (TI) and Rate.
[22] P-ramp is limited to one-third (1/3) of TI time. Adjustment of TI time can override the P-ramp setting.
[23] Startup setting derived from IBW (adult/pediatric), body weight setting (neonatal). Does not apply in ASV mode.

Parameter (units)	Range Adult/Ped[17]	Range Neonatal[17]
Trigger, flow (l/min)[24]	0.5 to 20.0 *APVcmv, PCV+:* 0.5 to 20.0 / Off	0.1 to 5.0 *APVcmv, PCV+:* 0.1 to 5.0 / Off
Vt (ml)	20 to 2000	2 to 300
Vt/IBW Vt/Weight (ml/kg)[25]	5 to 12	5 to 12
Weight (kg)	--	0.2 to 30.0
ΔPcontrol (cmH2O)[26]	5 to 60	3 to 45 *nCPAP-PC:* 0 to 45
ΔPinsp (cmH2O)[26]	3 to 60	3 to 45
ΔPsupport (cmH2O)[26]	0 to 60	0 to 45

[24] Flow trigger is leak compensated.
[25] IBW is calculated using height and sex, for adult and pediatric patients. Actual body weight is used for neonates.
[26] *ΔPcontrol:* Control pressure, added to PEEP/CPAP. *ΔPinsp:* Inspiratory pressure, added to PEEP/CPAP. *ΔPsupport:* Pressure support, added to PEEP/CPAP.

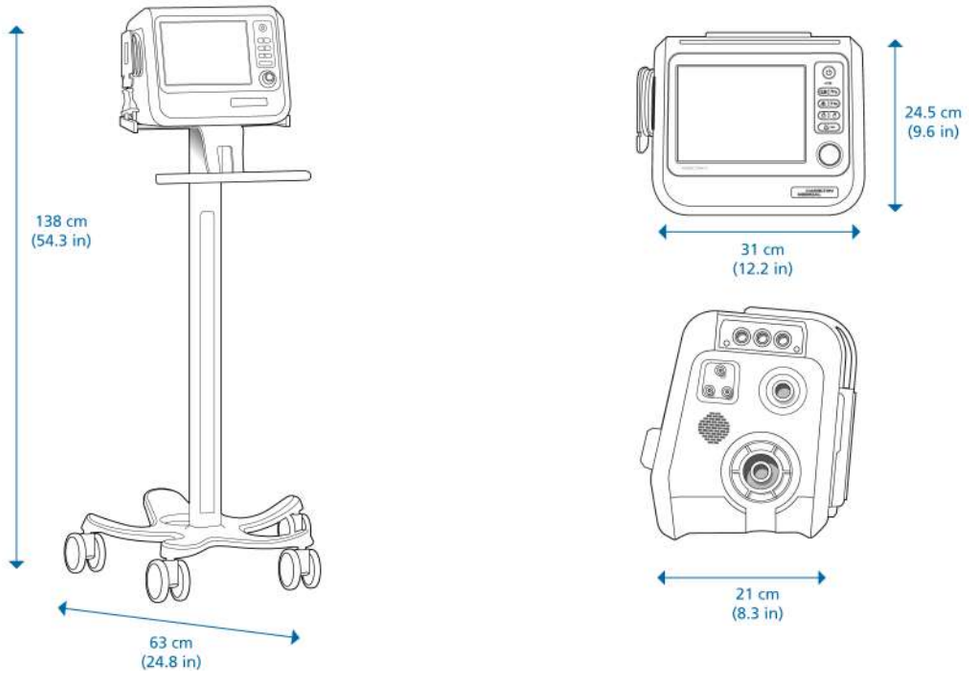
Monitoring parameters

Parameter (units)		Description
Pressure	AutoPEEP (cmH2O)	Unintended positive end-expiratory pressure
	PEEP/CPAP (cmH2O)	PEEP (positive end-expiratory pressure) and CPAP (continuous positive airway pressure)
	Driving pressure, ΔP (cmH2O)	Driving pressure, calculated value reflecting the difference between Pplateau and PEEP
	ΔPinsp (cmH2O)	Inspiratory pressure
	Pmean (cmH2O)	Mean airway pressure
	Ppeak (cmH2O)	Peak airway pressure
	Pplateau (cmH2O)	Plateau or end-inspiratory pressure
	Pprox (cmH2O)	Airway pressure at proximal patient interface
Flow	Flow (l/min)	HiFlowO2: The set flow of gas to the patient
		nCPAP: The average flow updated every second
		nCPAP-PC: The average flow during expiration, updated every breath
	Insp Flow (peak) (l/min)	Peak inspiratory flow, spontaneous or mandatory
	Exp Flow (peak) (l/min)	Peak expiratory flow
Volume	ExpMinVol or MinVol NIV (l/min)	Expiratory minute volume
	MVSpont or MVSpont NIV (l/min)	Spontaneous expiratory minute volume
	VTE or VTE NIV (ml)	Expiratory tidal volume
	VTESpont (ml)	Spontaneous expiratory tidal volume
	VTI (ml)	Inspiratory tidal volume
	VLeak (%)	Leakage percent or total minute volume leakage
	MVLeak (l/min)	Leakage percent or total minute volume leakage
	Vt/IBW or Vt/Weight (ml/kg)	Tidal volume is calculated by ideal body weight (adult/pediatric patients) or actual body weight (neonatal patients)
Oxygen	Oxygen (%)	Oxygen concentration of the delivered gas
	O2 consumption (l/min)	The current oxygen consumption rate
Time	CPR timer	MMP during CPR ventilation showing duration of CPR ventilation
	I:E	Ratio of the patient's inspiratory time to expiratory time for every breath cycle
	fControl (b/min)	Mandatory breath frequency
	fSpont (b/min)	Spontaneous breathing frequency
	fTotal (b/min)	Total breathing frequency
	TI (s)	Inspiratory time
	TE (s)	Expiratory time
Lung mechanics	Cstat (ml/cmH2O)	Static compliance
	P0.1 (cmH2O)	Airway occlusion pressure
	PTP (cmH2O*s)	Pressure time product
	RCexp (s)	Expiratory time constant
	Rinsp (cmH2O / (l/s))	Inspiratory flow resistance
	RSB (1 / (l*min))	Rapid shallow breathing index

Parameter (units)		Description
CO2	FetCO2 (%)	Fractional end-tidal CO2 concentration
	PetCO2 (mmHg)	End-tidal CO2 pressure
	slopeCO2 (%CO2/l)	Slope of the alveolar plateau in the PetCO2 curve, indicating the volume/flow status of the lungs
	V'alv (l/min)	Alveolar minute ventilation
	Vtalv (ml)	Alveolar tidal ventilation
	V'CO2 (ml/min)	CO2 elimination
	VDaw (ml)	Airway dead space
	VDaw/VTE (%)	Airway dead space fraction at the airway opening
	VeCO2 (ml)	Exhaled CO2 volume
	ViCO2 (ml)	Inspired CO2 volume
SpO2	SpO2 (%)	Oxygen saturation
	Pulse (1/min)	Pulse
	SpO2/FiO2 (%)	The SpO2/FiO2 ratio (%) is an approximation of the PaO2/FiO2 ratio, which, in contrast to PaO2/FiO2, can be calculated noninvasively and continuously
	OSI	Oxygen saturation index
	PI (%)	Perfusion index
	PVI (%)	Pleth variability index
Humidifier[27]	T Y-piece (°C)	Measured temperature at the Y-piece
	T humidifier (°C)	Measured temperature at water chamber exit

[27] If HAMILTON-H900 humidifier integration is enabled, and a humidifier is connected and turned on.

Physical characteristics



Weight	4.9 kg (10.8 lb) 16.9 kg (37.3 lb) with trolley The trolley can accommodate a maximum safe working load[28] of 44 kg (97 lb).
Dimensions	See graphic above
Trolley accessories	HAMILTON-H900 mounting kit, optional O2 bottle holding system, optional tubing support arm, water bottle holder, basket

[28] The maximum safe working load applies to a stationary, properly load-balanced trolley.

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

10101895/01

HAMILTON-C1

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

Certificate Holder: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
Switzerland

including the locations according to annex

Scope: Design and development, manufacturing, distribution and servicing of ventilators and ventilator systems

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-09 until 2023-07-08.
First certification 2017

2021-01-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1710001**

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland	Design and development and distribution of ventilators and ventilator systems
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland	Manufacturing and servicing of ventilators and ventilator systems
/03	Hamilton Medical UK Ltd. Unit 1 Forge Mills Park Station Road Coleshill Birmingham B46 1JH United Kingdom	Distribution and servicing of ventilators and ventilator systems

2021-01-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.