Specificație Completată
Ventilator transport Adult (caracteristici de bază)
Model: Hamilton-C1 Producător: HAMILTON Medical AG; Tara: ELVEȚIA.

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către autoritatea ofertantă
Ventilator transport Adult (caracteristici de bază)	Ventilator transport Adult (caracteristici de bază)
Cod 110340	Cod 110340
Descriere Ventilatorul de transport este destinat pentru a lua locul ventilaţiei manuale sau "ambalare" în situaţii de urgenţă sau de transport.	Descriere Ventilatorul de transport este destinat pentru a lua locul ventilaţiei manuale sau "ambalare" în situaţii de urgenţă sau de transport. **DA**
Parametrul Specificația	Parametrul Specificația
Tip pacient Adult	Tip pacient Adult
Game control/setări Volum total 100-1,000	Game control/setări Volum total 20-2,000 **DA**
Flux inspir > 60 L/min	Flux inspir > 120 L/min maxim este de 260 l/min **DA**
Nivelul de presiune da	Nivelul de presiune **DA**
Presiune în rampe da	Presiune în rampe **DA**
Rata respiratorie 0-60 rpm	Rata respiratorie 0-80 rpm **DA**
Timp inspir 0-2 s	Timp inspir 0-12 s **DA**
Rata I:E 1:1 to 1:3	Rata I:E 1:9 to 4:1 **DA**
FiO2, % 40-100	FiO2, % 20-100 **DA**
PEEP, cm H2O 0-20	PEEP, cm H2O 0-35 **DA**
Suport presiune da	Suport presiune **DA**
Mecanism trigger Flux sau presiune	Mecanism trigger Flux sau presiune **DA**
Moduri de operare	Moduri de operare
Modul A/C A/C după volum respirator da	Modul A/C A/C după volum respirator **DA**
A/C după după presiune respiratorie da	A/C după după presiune respiratorie **DA**
Modul SIMV SIMV volum respirator da	Modul SIMV SIMV volum respirator **DA**
SIMV presiune respiratorie da	SIMV presiune respiratorie **DA**
SIMV suport presiune da	SIMV suport presiune **DA**
Modul SIPAP/spontan CPAP suport presiune da	Modul SIPAP/spontan CPAP suport presiune **DA**
Ventilație neinvazivă da	Ventilație neinvazivă **DA**
Modul Apnea-backup da	Modul Apnea-backup **DA**
Monitorizări/afișări Presiune inspiratorie de maximă da	Monitorizări/afișări Presiune inspiratorie de maximă **DA**
Presiunea PEEP da	Presiunea PEEP **DA**
Volum total da	Volum total **DA**
Rata respiratorie da	Rata respiratorie **DA**
Timp inspir da	Timp inspir **DA**
Alarme pacient Presiune inspiratorie joasă da	Alarme pacient Presiune inspiratorie joasă **DA**
Presiune mare da	Presiune mare **DA**
Presiune/ocluzie continuă mare da	Presiune/ocluzie continuă mare **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**
Eroare sistem da	Eroare sistem **DA**
Baterie descărcată da	Baterie descărcată **DA**
Autodiagnostic eșuat da	Autodiagnostic eșuat **DA**
Display LCD TFT sau LED da	Display LCD TFT **DA**
	Dimesiunea 8.4 inch
	Tip touchscreen
Alimentare electrică Rețeaua electrică 220 V, 50 Hz da	Alimentare electrică Rețeaua electrică 220 V, 50 Hz **DA**
Baterie internă da	Baterie internă **DA**
Timp de operare 2 h	Timp de operare 4 h **DA**
Greutatea totală a ventilatorului cu accesorii ≤ 8 kg	Greutatea totală a ventilatorului cu accesorii - 4.9 kg **DA**
Accesorii	Accesorii
Circuite respiratorii adult tip reutilizabil 2 set.	Circuite respiratorii adult tip reutilizabil 2 set. **DA**
Mască respiratorie adult tip reutilizabil 2 set.	Mască respiratorie adult tip reutilizabil 2 set. **DA**

Filtre antibacteriale adult unică utilizare 100 buc. Senzor de debit adult tip reutilizabil 2 buc. Plamăn de test adult tip reutilizabil 1 buc. Suport suport pentru fixarea ventilatorului de brancadă da Butelie de oxigen cu reductor și manometru, volumul min. 2 litri 2 buc.	Filtre antibacteriale adult unică utilizare 100 buc. **DA** Senzor de debit adult tip reutilizabil 2 buc. **DA** Plamăn de test adult tip reutilizabil 1 buc. **DA** Suport suport pentru fixarea ventilatorului de brancadă **NU se pune la piceoarele pacientului.** Butelie de oxigen cu reductor și manometru, volumul min. 2 litri 2 buc. **DA**

Freigabedeckblatt zur handschriftlichen Freigabe von Hamilton Dokumenten

Gültig für Dokument:	Declaration of Conformity
Nummer	DoC-CEDCL-H900Acc_17
Revision	17
oder	
Version	--

Dieses Freigabedokument ist zwingend dem Master-Exemplar beizulegen

Erstellt	Geprüft		Freigegeben
Datum / Visum / Pers. Nr. 2020-12-14 22098	Geprüfter Aspekt Inhalt	Datum / Visum / Pers. Nr. 2020-12-14 12378	Datum / Visum / Pers. Nr. 2020-12-14
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	

* Wird zur Prüfung eine unbeteiligte Person (ohne direkte Projekt Beteiligung) hinzugezogen, ist diese mit „U“ zu kennzeichnen.

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Declaration of Conformity

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products

CEDCL-H900Acc, Attachment on page 2

meet the following EC directive (including all applicable amendments):

mit der folgenden EG-Richtlinie (einschliesslich aller zutreffenden Änderungen) übereinstimmt:

sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant):

EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3

All listed products are classified as class IIb.

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

Validity:

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.

Gültigkeit:

Diese Konformitätserklärung gilt für Produkte, welche 2021. produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll.

Validité:

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, 04. JAN. 2021

DoC-CEDCL-H900Acc_17

HAMILTON MEDICAL

Intelligent Ventilation since 1983

CEDCL-H900Acc Attachment

Product name	P/N	Basis UDI-DI / GTIN
HAMILTON-BC8022	260161	07630002801560
HAMILTON-BC4022	260186	07630002804189
HAMILTON-BC8010	260185	07630002800846
HAMILTON-BC4010	260187	07630002801416
HAMILTON-BC8022-A	260188	07630002805568
HAMILTON-BC8010-A	260189	07630002807197

Freigabedeckblatt zur handschriftlichen Freigabe von Hamilton Dokumenten

Gültig für Dokument:	Declaration of Conformity
Nummer	DoC-CEDCL-HAM-C1_14
Revision oder Version	14 / --

Dieses Freigabedokument ist zwingend dem Master-Exemplar beizulegen

Erstellt	Geprüft		Freigegeben
Datum / Visum / Pers. Nr.	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	Datum / Visum / Pers. Nr.
2020-12-14 22098	Inhalt	2020-12-14 12378	2020-12-14
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	
	Geprüfter Aspekt	Datum / Visum / Pers. Nr.	

* Wird zur Prüfung eine unbeteiligte Person (ohne direkte Projekt Beteiligung) hinzugezogen, ist diese mit „U“ zu kennzeichnen.

HAMILTON MEDICAL
Intelligent Ventilation since 1983

Declaration of Conformity

We, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland, confirm that the following products	Wir, Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Schweiz, bestätigen, dass die folgenden Produkte	La société Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Suisse, 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:	sont en conformité avec le directive CE suivant (y compris leurs amendements, le cas échéant):
	EC Medical Device Directive: 93/42/EEC, Annex II, Art. 3 All listed products are classified as class IIb.	
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

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, 04. JAN. 2021

DoC-CEDCL-HAM-C1_14

HAMILTON MEDICAL

Intelligent Ventilation since 1983

CEDCL-HAM-C1 Attachment

Product name	P/N	Basis UDI-DI / GTIN
HAMILTON-C1	161001	07630002800747
	1610010	07630002813426

EC Certificate

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

Registration No.: HD 60137935 0001

Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products:
Ventilators and ventilator systems

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60136804 0001

Expiry Date: 2024-05-26

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.

Effective Date: 2019-07-09

Date: 2019-04-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60137935 0001
Report No.: 21213508 015

Manufacturer:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Additional site:

Hamilton Medical AG
Parc Industrial Vial 10
7013 Domat/Ems
Switzerland

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date: 2019-07-09

HAMILTON-C1

Technical specification for SW 2.2.x

Ventilation modes

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.	✓	✓
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.	✓	--
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
High flow oxygen therapy	HiFlowO2	High flow oxygen therapy.	O	O

Standard: ✓ Option: O Not applicable: - -

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Standard configuration and options (in alphabetical order)

Functions	Adult/Ped	Neonatal
Capnography, mainstream (volumetric) and sidestream	o	o
Communication ports: COM1 port, USB port, Nurse call	o	o
Communication protocols: for details see Connectivity brochure	o	o
Dynamic Lung	✓	--
Event log (up to 1000 events with data and time stamp)	✓	✓
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)	✓	✓
Manual breath/prolonged inspiration	✓	✓
Nebulization, pneumatic	✓	--
O2 enrichment	✓	✓
Patient group	✓	o
Print screen	✓	✓
Screen lock	✓	✓
Speak valve compatibility	o	--
SpO2 monitoring	o	o
Standby with timer	✓	✓
Suctioning tool	✓	--
Trends/Loops	o	o
Flow trigger	✓	✓
Vent Status (Visual representation of ventilator dependence)	✓	✓

Standard: ✓ Option: o Not available: --

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 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
Oxygen mixer accuracy	± (volume fraction of 2.5% + 2.5% of actual reading)
Preoperational checks	Tightness test, Flow Sensor/O2 sensor/CO2 sensor calibration
Tidal volume	Adult/Ped: 20 to 2000 ml Neonatal: 2 to 300
Brightness setting for display	The range is 10% to 100% brightness. By default, Day is set to 80%; Night is set to 40%.

Standards and approvals

Classification	Class IIb, continuously operating according to EC directive 93/42/EEC
Certification	IEC 60601-1:2005/A1:2012, IEC 60601-1-2:2014, ANSI/AAMI ES60601-1:2005/(R)2012, ISO 80601-2-12:2011, CAN/CSA-C22.2 NO. 60601-1:14, EN ISO 5356-1:2015, ISO 80601-2-55:2011
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 O2	Pressure:	2.8 to 6 bar / 41 to 87 psi
	Connector:	DISS (CGA 1240) or NIST
Low-pressure O2	Pressure:	Maximum 6 bar / 87 psi
	Connector:	Quick-coupling system, compatible with Colder Products Company (CPC) PMC series
Air supply	Integrated turbine	
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	Electrical specifications:	6.7 Ah, 72 Wh, 50 W typical, 150 W maximum
	Type:	Lithium-ion, supplied by Hamilton Medical only
	Normal operating time:	One battery, display brightness = 80%: 4 h One battery, display brightness = 20%: 4.5 h

Graphical patient data

Graphic type/tab name	**Options**
Waveforms	Pressure, Volume, Flow, PCO2 [1], FCO2 [1], Plethysmogram[2]
Intelligent panels	Dynamic Lung [3], Vent Status, ASV Graph [4]
Trends	1-, 6-, 12-, 24-, or 72-h[5] trend data for a selected parameter or combination of parameters
Loops	Pressure/Volume, Pressure/Flow, Volume/Flow, Volume/PCO2[1], Volume/FCO2[1]

Alarms[6]

Priority	**Alarm**
High priority	Apnea time (s), ExpMinVol high/low (l/min), Oxygen high/low (%), Pressure high/low (cmH2O), Flow sensor calibration needed, Exhalation obstructed, Disconnection, Oxygen supply failed
Medium priority	fTotal high/low (b/min), PetCO2 high/low (mmHg), Pressure limitation (cmH2O), Vt high/low (ml), SpO2 high/low, High PEEP, Loss of PEEP, Pulse high/low
Low priority	High SpO2, Loss of external power

[1] CO2 option required.
[2] SpO2 option required.
[3] Only for adult/pediatric patients.
[4] Only in ASV mode.
[5] 72-hour trend not available in all markets.
[6] For a complete list of alarms, see your ventilator *Operator's Manual*.

Control settings and ranges[7]

Parameter (units)	Range Adult/Ped	Range Neonatal
Apnea backup	On, Off	On, Off
ETS (%)	5 to 80	5 to 80
Flow (l/min)	2 to 80[8]	2 to 12
Flow trigger (l/min)	1 to 20	0.1 to 5
Height (cm)	30 to 250	--
Height (in)	12 to 98	--
I:E	1:9 to 4:1	1:9 to 4:1
%MinVol (%)	25 to 350	--
Oxygen (%)	21 to 100	21 to 100
PEEP (cmH2O)	0 to 35	3 to 25
Pasvlimit (cmH2O)	5 to 60	--
Pcontrol (cmH2O)	5 to 60	3 to 45
Phigh APRV (cmH2O)	0 to 60	0 to 45
Phigh DuoPAP (cmH2O)	0 to 60	3 to 45
Pinsp (cmH2O)	3 to 60	3 to 45
Plow APRV (cmH2O)	0 to 35	0 to 25
Pramp (ms)	0 to 2000	0 to 600
Psupport (cmH2O)	0 to 60	0 to 45
Rate (b/min)	1 to 80	1 to 80
Sex	Male, Female	--
Sigh	On, Off	--
SpO2 monitoring	On, Off	On, Off
SpeakValve	On, Off	--
TI (s)	0.1 to 12	0.1 to 12
TI max (s)	1 to 3	0.25 to 3
Thigh APRV (s)	0.1 to 40	0.1 to 40
Thigh DuoPAP (s)	0.1 to 40	0.1 to 40
Tlow APRV (s)	0.2 to 40	0.2 to 40
Vt (ml)	20 to 2000	2 to 300
Vt/Weight (ml/kg)	--	5 to 12
Weight (kg)	--	0.2 to 30

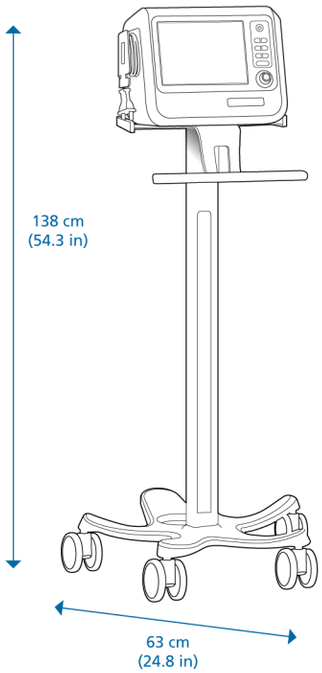
[7] Parameter settings and ranges can vary depending on the selected mode.
[8] Flow limited to 60 l/min in some markets.

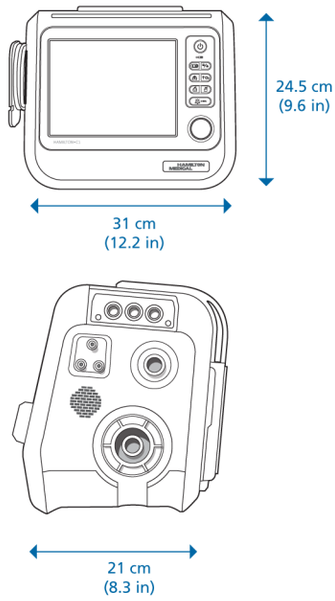
Monitoring parameters

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)
	Pinsp (cmH2O)	Inspiratory pressure
	Pmean (cmH2O)	Mean airway pressure
	Ppeak (cmH2O)	Peak airway pressure
	Pplateau (cmH2O)	Plateau or end-inspiratory pressure
Flow	Control Flow (l/min)	The set flow of gas to the patient when using HiFlowO2.
	Flow (l/min)	In nCPAP mode, the average flow, updated every second. In nCPAP-PC mode, 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
	VTI (ml)	Inpiratory tidal volume
	VLeak (%)	Leakage percent or total minute volume leakage
	MVLeak (l/min)	Leakage percent or total minute volume leakage
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.
	PI (%)	Perfusion index
	PVI (%)	Pleth variability index
	SpCO (%)	Carboxyhaemoglobin saturation

Parameter (units)		Description
SpO2	SpMet (%)	Methaemoglobin saturation
	SpHb (g/dl or mmol/l)	Total haemoglobin
	SpOC (ml/dl)	Oxygen content
Oxygen	Oxygen (%)	Oxygen concentration of the delivered gas
	Oxygen consumption (l/min)	The current oxygen consumption rate
Time	I:E	Inspiratory:expiratory ratio
	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

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 of 44 kg (97 lb).
Dimensions	See graphic above
Monitor	Type: TFT color Size: 640 x 480 pixels, 8.4 in (214 mm) diagonal
Trolley accessories	HAMILTON-H900 mounting system, optional O2 bottle holding system, optional tubing support arm

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

689333/08

HAMILTON-H900

Technical specifications for software v1.10x

Operating modes

Manual and auto mode	For invasive and noninvasive ventilation, and high flow oxygen therapy (HiFlow).

Control settings

Parameter	Mode	Range	Default	Resolution
Chamber exit temperature	Invasive	35°C to 41°C	37°C	0.5°C
	Noninvasive	30°C to 35°C	31°C	0.5°C
	HiFlow	33°C to 37°C	35°C	1°C
Temperature gradient	Invasive	-2°C to 3°C	Adult/Ped: 2°C Neo: 3°C	0.5°C
	Noninvasive	-2°C to 3°C	Adult/Ped: 2°C Neo: 3°C	0.5°C
	HiFlow	--	2°C	--
Resulting airway temperature (Y-piece)[1]	Invasive	33°C to 42°C	--	--
	Noninvasive	28°C to 38°C	--	--
	HiFlow	35°C to 39°C	--	--

Monitoring

Parameter	Temperature	Accuracy
Chamber exit temperature	10°C to 60°C / 30°C to 41°C	±1°C / ±0.5°C
Y-piece temperature	28°C to 43°C	±0.5°C

1 Airway temperature is limited by the humidifier software to 42°C

Swiss Quality

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Alarms

High priority	Temperature too high, water level too high, humidifier dangerously inclined
Medium priority	No humidifier chamber inserted or defective chamber, no limb or defective limb connected, a limb is not properly connected, low temperature, low water level
Additional	Visual alarm light, on-screen alarms
Audio pause	120 s
Alarm loudness	For medium- and high-priority alarms at 1 m distance from humidifier: A setting of 1 = 50 db(A), 5 = 60 db(A), and 8 = 65 db(A), with an accuracy of ±6 db(A).

Performance

Description	Specifications		
Flow rates	Invasive	Up to 60 l/min	
	Noninvasive	Up to 120 l/min	
	HiFlow	Up to 100 l/min	
Warm-up time	Less than 30 minutes		
Humidity	At an ambient temperature of 18°C to 26°C:		
	Invasive	Temperature setting of 37°C to 41°C	Minimum humidity 33 mg H2O/l
	Noninvasive	Temperature setting of 31°C to 35°C	Minimum humidity 12 mg H2O/l
	HiFlow	Flow rate ≤ 60 l/min	Minimum humidity 33 mg H2O/l
		Flow rate > 60 l/min	Minimum humidity 12 mg H2O/l
Standby	Limited to 30°C on Y-piece		

Electrical characteristics

Input voltage	220 – 240 V / 110 – 127 V / 100 V
Frequency	50 / 60 Hz
Maximum power	283 VA (230 V version) / 293 VA (115 V version) / 260 VA (100 V version)
Potential equalization	Terminal for the connection of a potential equalization conductor according to DIN 42801
Connectors[2]	Interface RS-232 connection only with a Hamilton Medical ventilator

2 Not available in all markets

Standards and approvals

Classification	Class I (in accordance to IEC 60601-1), Class IIb (in accordance with MDD/MDR)
Certification	IEC 60601-1:2012, IEC 60601:2007, ISO 8185:2007, ISO 5356-1:2015, ISO 80601-2-74:2017
Applied parts	Heated breathing circuit tubes (Type BF)

Environments

Temperature	10°C to 40°C (operation), -20°C to 60°C (storage) Recommended ambient temperature: 18°C to 26°C
Relative humidity	30 to 95% noncondensing (operating) / 10 to 95% noncondensing (storage)
Altitude	Up to 4,000 m (13,123 ft) / 61 kPa to 106 kPa atmospheric pressure
Gas input temperature	18°C to 31°C (recommended)
Ingress Protection (IP)	IP 21

Physical dimensions

Dimensions (W×D×H)	18 cm (7.1 in) × 16 cm (6.3 in) × 19 cm (7.5 in)
Weight	2.5 kg (5.5 lb)
Display	3 in / 64 × 128 pixels, inverted dot matrix display (backlit)

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 (0)58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

689509/04

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 2017-07-09 until 2020-07-08.

2020-02-06 (Change)

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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

2020-02-06 (Change)

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