Specificație tehnică completată

Model: Hamilton T1, Producător: Hamilton Medical AG, Tara: Elvetia

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Ventilator Portabil pentru ambulanta	Ventilator Portabil pentru ambulanta **DA**
Cod 110360	Cod 110360
Descriere Ventilator Portabil - potrivit pentru urgente,tratament pe durata transportarii pacientului.	Descriere Ventilator Portabil - potrivit pentru urgente,tratament pe durata transportarii pacientului. **da**
Parametru Specificație	Parametru Specificație
Gama de control/setări Volum total 20-2,000 ml	Gama de control/setări Volum total 20-2,000 mL **DA**
Flux inspir 0-170 L/min	Flux inspir maxim **260 L/min DA**
Presiune inspir 0-80 cm H2O	Presiune inspir 0-60 cm H2O **DA**
Rata respiratorie 0-120 rpm	Rata respiratorie 0-80 rpm **DA**
Timp inspir 0-3 s	Timp inspir 0-12 s **DA**
Timp expir 1 la 8 s	Timp expir 1 la 8 s **DA**
Rata I:E 1:1 to 1:4	Rata I:E 4:1 to 1:9
Pauză la inspir 0-3 sec	Pauză la inspir 0-3 sec **DA**
FiO2, % 21-100	FiO2, % 21-100 **DA**
PEEP/CPAP 0-45 cm H2O	PEEP/CPAP 0-35 cm H2O **DA**
Mecanism triger Presiune, flux	Mecanism triger Presiune, flux
Moduri de operare Modul A/C A/C după volum respirator da	Moduri de operare 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**
Alimentare gaz O2 medical da	Alimentare gaz O2 medical **DA**
Sistem conducte/Rezervor da	Sistem conducte/Rezervor **DA**
Rezervor Volum ≥ 2l	Rezervor Volum – 2 l **DA**
Reductor da	Reductor **da**
Volumul de respirație Reglabil, continuu 0-20 l/min	Volumul de respirație Reglabil, continuu 0-20 l/min **DA**
Greutatea ventilatorului ≤ 7 kg	Greutatea ventilatorului 6.5 kg **DA**
Alarme pacient Presiune inspiratorie joasă da	Alarme pacient Presiune inspiratorie joasă **DA**
Presiune mare da	Presiune mare **DA**
Circuit respirator deconectat da	Circuit respirator deconectat **DA**
Alarme echipament Lipsă alimentare gaz da	Alarme echipament Lipsă alimentare gaz **DA**
Baterie descărcată da	Baterie descărcată **DA**
Display LCD sau LED da	Display LCD sau LED **DA tip touch screen**
Alimentare electrică Rețeaua electrică 12/24V DC, 220V da	Alimentare electrică Rețeaua electrică 12/24V DC, 220V **DA**
Baterie internă Timp de operare ≥ 3 h	Baterie internă Timp de operare **4 h DA**

HAMILTON-T1

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 CO_2 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

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HAMILTON MEDICAL

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, 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 date 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	✔	✔
Mounting options (trolley, carrying case, and a variety of wall, bed, ceiling, and shelf mounts)	O	O
NBC filter compatibility (only for HAMILTON-T1 MIL)	O	O
Nebulization, pneumatic	✔	--
Night vision compatibility (NVG)	O	O
O2 enrichment	✔	✔
On-screen help	✔	✔
Patient group	✔	O
Print screen	✔	✔
RJ-45 Ethernet port[3]	✔	✔
Screen lock	✔	✔
Second battery	O	O
Speak valve compatibility	O	--
SpO2 monitoring	O	O
Standby with timer	✔	✔
Suctioning tool	✔	--
Trends/Loops	O	O
USB port	✔	✔
Vent Status (visual representation of patient's ventilator dependence)	✔	✔

[1] Applies only to devices with serial number > 3000
[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%.
Brightness with NVG option	The range is 1 to 10. The default is 5.
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)

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[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, IEC 60601-1-12:2014, ISO 80601-2-12:2011 + Cor.:2011, ISO 80601-2-55:2018, EN ISO 5356-1:2015, EN 794-3:1998 + A2:2009, EN 1789:2007 + A1:2010, MIL-STD-461F, MIL-STD-810G, ISO 80601-2-61:2017, ISO 80601-2-49:2018
Declaration	The HAMILTON-T1 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 BF applied part (ventilator breathing system, VBS, CO2 sensor including CO2 module connector, and 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
	12 to 28 VDC (total range 10.2 to 30.3 VDC)
Power consumption	50 VA typical, 150 VA maximum
Battery	Hamilton Medical provides a high-capacity battery[7]. An optional second battery is available.
	Electrical specifications: 10.8 VDC, 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, approximately 6.25 h to fully recharge two batteries.
	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: Typically 4 hours with one battery, 8 hours with two batteries.
	Operating times are measured with one or two fully charged batteries, 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
	• Two batteries, display brightness = 80%: 8 h
	• Two batteries, display brightness = 20%: 9.25 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 index, 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

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[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) (cmH2O)	0 to 60	0 to 45
P high (in DuoPAP) (cmH2O)	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

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[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

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[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.
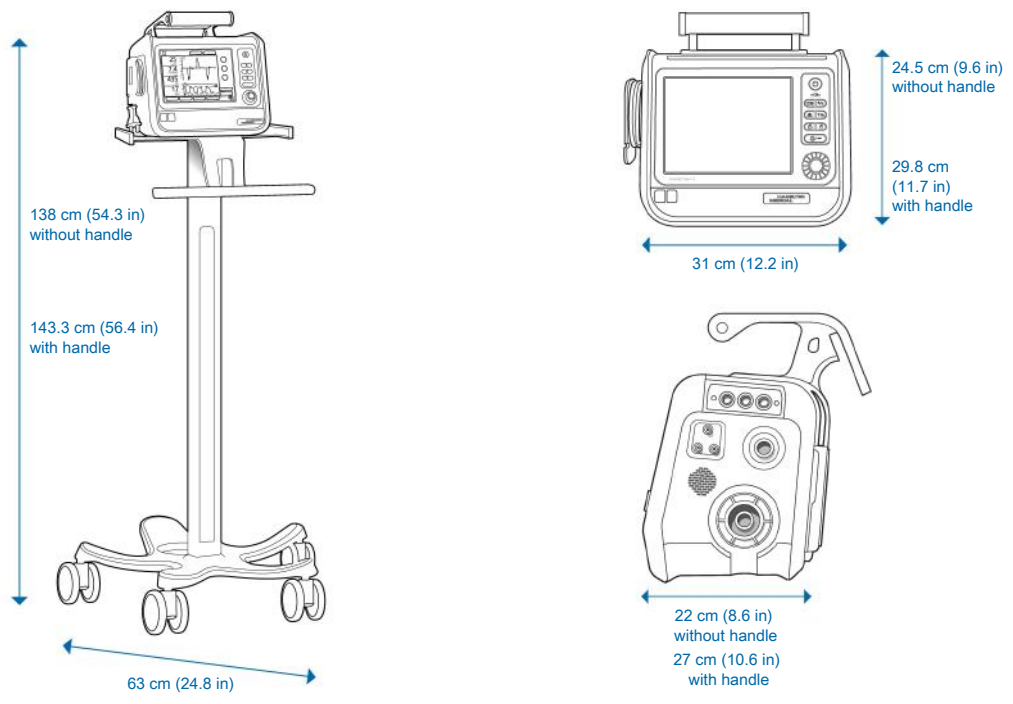
Monitoring parameters

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

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

Physical characteristics

138 cm (54.3 in)
without handle

143.3 cm (56.4 in)
with handle

63 cm (24.8 in)

24.5 cm (9.6 in)
without handle

29.8 cm
(11.7 in)
with handle

31 cm (12.2 in)

22 cm (8.6 in)
without handle
27 cm (10.6 in)
with handle

Weight	6.5 kg (14.3 lb)
	18.5 kg (40.8 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

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HAMILTON-T1

HAMILTON-T1

Intelligent transport ventilation

HAMILTON MEDICAL

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-T1

The HAMILTON-T1 is the first transport ventilator that combines the functionality of a fully featured ICU ventilator with the compactness and ruggedness required for transport. This combination enables you to provide optimal ventilation therapy to all patient groups during transport.

✓ Approvals and certificates for use in ambulances, helicopters and airplanes

✓ Adult, pediatric, and neonatal ventilation

✓ Independence from compressed air

✓ Up to 9 hours of battery operating time

✓ Noninvasive ventilation and integrated high flow oxygen therapy*

✓ Advanced ventilation modes, including ASV® and INTELLiVENT®-ASV

✓ CPR ventilation

✓ Digital solutions for respiratory care: Hamilton Connect Module and App

*Always use active humidification during high flow oxygen therapy.

Designed for mobility and convenient transport

Approved for all types of transport
The HAMILTON-T1 meets the transport standards EN 794-3 and ISO 10651-3 for emergency and transport ventilators, EN 1789 for ambulances, EN 13718-1 and RTCA/DO-160G for aircraft, as well as IEC 60601-1-12 for basic safety and essential performance. It reliably accompanies your patients to any destination either within or outside of the hospital, on the ground, at sea, and in the air.

Independent from compressed air
The integrated high-performance turbine enables the HAMILTON-T1 to be completely independent from compressed air, reducing weight and saving space. Even patients ventilated noninvasively can be transported successfully across greater distances.

Up to 9 hours of battery operating time
A battery operating time of up to 9 hours is provided by one integrated and one hot-swappable battery. The battery operating time can be extended as required with additional hot-swappable batteries.

Flexible mounting and system integration options
The wide range of system integration and mounting options allows you to tailor the HAMILTON-T1 to your needs and infrastructure. Various solutions are available for all the main types of helicopters and ambulances, as well as hospital beds, stretchers, surfaces, shelves, poles, rails, and ceilings.

The most popular ventilator for intensive care transport helicopters
According to the HOVER survey (Handover of ventilated Helicopter Emergency Services [HEMS] patients in the emergency room) conducted online amongst air rescue organizations in Germany, Austria, Switzerland, Italy, and Luxemburg, 71% of those organizations chose the HAMILTON-T1 as their intensive care transport ventilator[1].

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[1] Hilbert-Carius P. Notfall Rettungsmed 23, 106–112 (2020). https://doi.org/10.1007/s10049-019-0579-z
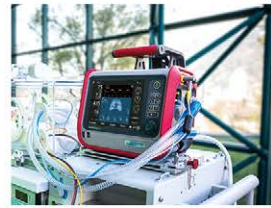
Ease of use

In close cooperation with users and ventilation experts, our engineers have designed the user interface to be particularly intuitive. Switching between the HAMILTON-T1 and all other Hamilton Medical ventilators is easy, because they are all operated according to the same principles.

The Ventilation Cockpit on the HAMILTON-T1 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.

"

About 50% of our patients go onto ASV mode. It is specifically advantageous in trauma. You have so many other fires to put out, that it is nice to just set up the ventilator and allow ASV to manage the patient from a lung standpoint.

Kyle Driesse, Critical Care Flight Paramedic
Life Link III
Minneapolis, USA

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 Customizable user interface

You can configure the display layout with different waveforms, loops, trends, or intelligent panel graphics to suit your institution's needs and protocols. Nurses and clinicians can have their own preferred layout.

4 Direct access to main controls

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

For transporting all patients, even the smallest

State-of-the-art ventilation therapy for newborns
- ✓ 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, including volume-targeted ventilation
- ✓ Leak compensation in every mode

Continuity of care for newborns from the delivery room to the NICU, as well as for transport
- ✓ In combination with a transport incubator, it represents an advanced solution for intra- and interhospital transport
- ✓ Monitoring parameters specific to neonates (SpO2 measurement with Oxygen Saturation Index, SpO2/FiO2-ratio, and CO2 measurement)

## Dedicated interfaces and consumables for neonates
- ✓ Interfaces for noninvasive ventilation specifically for neonates
- ✓ Robust proximal sensor for accurate flow measurement with low dead space
- ✓ Single-use consumables that may help in controlling infections

"

The HAMILTON-T1 transport ventilator is very small and compact, but still has all the features of a conventional ICU ventilator.

Thomas Burren, Chief Nurse Rega Jet
Rega - Swiss Air Rescue
Zurich, Switzerland
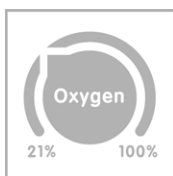
Oxygen adjustable from 21% to 100%
allows you to replicate the bedside settings one-to-one during transport. The adjustment to 21% even makes it possible to ventilate your patient with ambient air only.

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.

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.
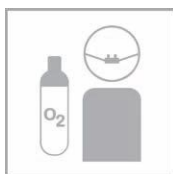
CPR ventilation
adapts ventilation settings to situations where CPR is being performed. It supports the CPR workflow with quick access to preconfigurable settings, adequate alarm and trigger adjustment, CPR-timer display, and display of the relevant main monitoring parameters and curves.

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

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.

Features and options

Adult, pediatric, and neonatal ventilation

Configurable loops and trends

High-performance turbine
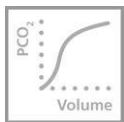
Dynamic Lung

Hot-swappable battery backup

Compatible with conventional speaking valves

Serial interface for connection to PDMS or patient monitors

Hamilton Connect App

Mainstream (volumetric) and sidestream capnography

Night vision goggles (NVG)

Pulse oximetry
(SpO2 and pulse measurement)

Approval for all types of transport

nCPAP modes

Quick startup

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-t1.com

HAMILTON MEDICAL

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 58 610 10 20

info@hamilton-medical.com

www.hamilton-medical.com

HAMILTON-T1

Declaration of Conformity

We,	Wir,	Nous,

Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland,
(SRN: CH-MF-000013790)

confirm under our sole responsibility that the following products	bestätigen, unter unserer alleinigen Verantwortung, dass die folgenden Produkte	confirmons sous notre seule responsibilité que les produits suivants

CEDCL-HAM-T1, Attachment on page 2

comply with:	konform sind mit:	sont conformes aux:

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

All listed products are classified as class IIb.	Alle aufgeführten Produkte sind der Klasse IIb zugeordnet.	Tous les produits répertoriés sont classés dans la classe IIb.

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany
Registration No: HD 1093044-1

EC REP

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

Validity:	**Gültigkeit:**	**Validité:**
This declaration is valid for products manufactured in 2022. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report.	Diese Konformitätserklärung gilt für Produkte, welche 2022 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 2022. 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, ...

0 6. DEZ. 2021

CEDCL-HAM-T1 Attachment

Product name	P/N	UDI-DI / GTIN	Basic UDI-DI / GMN
HAMILTON-T1	161006	07630002801850	76300028PN1610062C
	1610060	07630002813532	76300028PN16100605C
	161009	07630002806091	76300028PN1610092J
	1610090	07630002813549	76300028PN16100905M

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

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
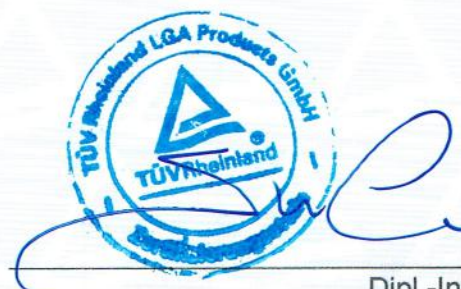
Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

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

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

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

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

2 / 2

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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

IAF
MEMBER OF MULTILATERAL
RECOGNITION ARRANGEMENT

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

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Certificate

Certificate No.:	MD 3321004-110
Manufacturer:	**Hamilton Medical AG**
	Via Crusch 8
	7402 Bonaduz
	Switzerland
D-U-N-S No.:	48-1492-312

Certification criteria:

ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Scope: Design and Development, Manufacturing, Distribution and Service of Ventilators and Ventilator Systems

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	3321004-50
Issue Date:	2020-12-14
Effective Date:	2020-12-14
Expiry Date:	2023-07-08

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087651?locale=en or calling 1-888-743-4652.

Page 1 of 2

Certificate

Certificate No.: MD 3321004-110

Manufacturer: **Hamilton Medical AG**

Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	Hamilton Medical AG Via Crusch 8 7402 Bonaduz Switzerland D-U-N-S No.: 48-1492-312	Design and Development, Distribution and Administration
/02	Hamilton Medical AG Parc Industrial Vial 10 7013 Domat/Ems Switzerland D-U-N-S No.: 48-1492-312	Manufacturing and Service

Project No.: 3321004-50

Issue Date: 2020-12-14

Effective Date: 2020-12-14

Expiry Date: 2023-07-08

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9105087651?locale=en
or calling 1-888-743-4652.

Page 2 of 2

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

Transport and storage solutions
for the HAMILTON-C1/T1/MR1

HAMILTON-T1 handles

1 UniversalMount handle
- ✔ Versatile solution allowing you to attach the device where it is most convenient for you
- ✔ For bed or rail attachment, or with a stretcher

2 3000Mount handle
- ✔ Suitable for ceiling installation
- ✔ Saves valuable space

3 EasyGrip handle
- ✔ Needs minimal space thanks to the slimline design

4 Foldaway handle
- ✔ Most compact solution available for the HAMILTON-T1
- ✔ Suitable for intrahospital transport only

HAMILTON MEDICAL

HAMILTON-T1 mounts

5 Shelf mount system
- ✔ For mounting the HAMILTON-T1 on surfaces and shelves using the quick-lock mechanism
- ✔ The sliding plate allows for easy attachment and removal
- ✔ Suitable for hospitals, ambulances and aircraft

6 Shelf mount plate with spacers
- ✔ Simple solution for mounting the HAMILTON-T1 on surfaces and shelves
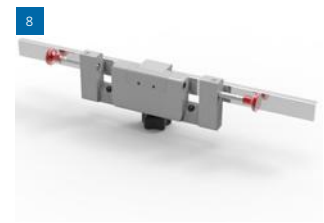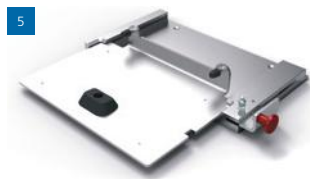- ✔ Suitable for hospitals and ambulances

7 Carrying device standard
- ✔ Space for a 2-liter oxygen cylinder
- ✔ For bed or stretcher mount

8 Rugged rail mount adapter
- ✔ Can be attached to standard rails
- ✔ Requires UniversalMount handle

9 Pole mount adapter
- ✔ Can be attached to pole mounts
- ✔ Equipped with a standard rail

#	Product	Part number
1	UniversalMount handle	161972
2	3000Mount handle	161971
3	EasyGrip handle	161973
4	Foldaway handle	161974
5	Shelf mount system	161449
6	Shelf mount plate with spacers	161920
7	Carrying device standard	161420
8	Rugged rail mount adapter	161146
9	Pole mount adapter	161145

HAMILTON-C1 mounts

10 Universal bed mount
✔ Used to ensure the HAMILTON-C1 is secured to the shelf, table or pendant system with the quick-lock mechanism

11 Shelf mount plate
✔ Simple solution for mounting the HAMILTON-C1 on surfaces and shelves

HAMILTON-MR1 handle and mounting plate

12 HAMILTON-MR1 transport kit
✔ Combines the UniversalMount handle and quick-lock mounting plate
✔ Quick-lock mechanism for easy attachment and removal
✔ Versatile solution that allows you to attach the device where it is most convenient for you
✔ For bed or rail attachment
✔ Designed to take up a mininum of space

#	Product	Part number
10	Universal bed mount	161148
11	Shelf mount plate	161439
12	Transport kit for HAMILTON-MR1	161140

Trolleys

13 Trolley for HAMILTON-C1/T1
- ✔ For intrahospital transport
- ✔ Mount for attaching a HAMILTON-H900 humidifier
- ✔ Space for two oxygen cylinders
- ✔ Standard rail
- ✔ 5 independent, high-quality wheels with brakes
- ✔ Robust basket available in two different sizes

14 Trolley for HAMILTON-MR1
- ✔ Nonferrous and MR-Compatible
- ✔ Auto-lock brake to prevent the trolley from accidentally moving toward the MRI scanner
- ✔ Storage for the power supply and cable
- ✔ Integrated hooks on the trolley's top plate to hold the breathing circuit
- ✔ Space for one medical gas cylinder (MR-Compatible oxygen E-cylinder)

#	Product	Part number
13	Trolley for HAMILTON-C1/T1	161150
	Small basket HAMILTON-C1/T1	10101016
	Large basket HAMILTON-C1/T1	10101017
14	Trolley for HAMILTON-MR1	161160

Manufacturer:

Hamilton Medical AG

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