HAMILTON-MR1

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.	✓	✓
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

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Standard configuration and options (in alphabetical order)

Standard: ✓ Option: O Not applicable: --

Functions	Adult/Ped	Neonatal
CPR ventilation	✓	✓
Dynamic Lung	✓	--
Event log (up to 10,000 events with date and time stamp)	✓	✓
Flow trigger	✓	✓
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	✓	O
Print screen	✓	✓
Screen lock	✓	✓
Standby with timer	✓	✓
Suctioning tool	✓	--
TeslaSpy: Integrated magnetic field navigator	✓	✓
Trends/Loops	O	O
USB port	✓	✓
Vent Status (visual representation of patient's ventilator dependence)	✓	✓

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
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)[1]	The range is 1 to 10. The default setting is 5.
Sound power level[2]	50 dB(A) ± 3dB(A)
Sound pressure level[2]	42 dB(A) ± 3dB(A)

[1] 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).
[2] 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, ASTM F2503-13:2013, CISPR 11:2009 + A1:2010
Declaration	The HAMILTON-MR1 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 1 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 I, Type B applied part (ventilator breathing system, VBS)

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
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, 50/60 Hz	
Power consumption	90 VA typical, 180 VA maximum	
Battery	Hamilton Medical provides two high-capacity batteries[3].	
	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:	Operating times are measured with two fully charged batteries, the blower in use, 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: • Display brightness = 80%: 8 h • 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.

MR Clearance

MR Conditional	1.5 and 3.0 T static magnetic field
Maximum proximity to MRI scanner	50 mT
Gaussmeter	TeslaSpy

[3] PN 369108, revision 4 and later.

Graphical patient data

Graphic type/tab name	Options
Waveforms	Pressure, Volume, Flow
Intelligent panels	Dynamic Lung[4], Vent Status, ASV Graph[5]
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

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, 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 TeslaSpy service required, TeslaSpy defective, Service required
Medium priority	High Flow, fTotal high/low, Frequency high/low, Vt high/low, Inspiratory volume limitation, High PEEP, Loss of PEEP, Pressure limitation Wrong expiratory valve, Circuit calibration needed, Flow sensor calibration needed, Flip the flow sensor, Check flow sensor for water (Neonatal) Fan failure, Function key not operational, Performance limited by high altitude, Real-time clock failure, Battery low Check TeslaSpy communication, Move away from MRI scanner
Low priority	Check Plimit, ASV: Cannot meet the target, Maximum leak compensation, Pressure limit has changed, CPR ON, 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

[4] Only for adult/pediatric patients.
[5] Only in ASV mode.

Control settings and ranges

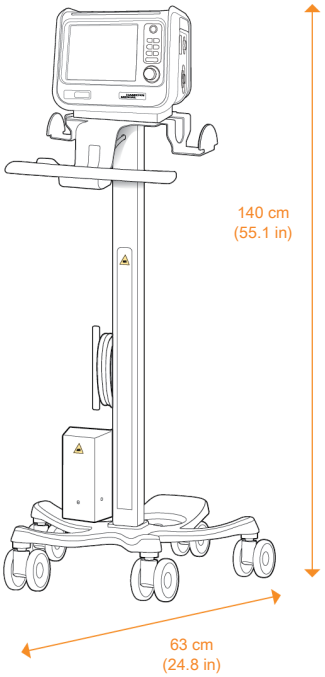
Parameter (units)	Range Adult/Ped[6]	Range Neonatal[6]
%MinVol (%)[7]	25 to 350	--
Apnea backup	On, Off	On, Off
ETS (%)	5 to 80	5 to 80
I:E[8]	1:9 to 4:1	1:9 to 4:1
IBW (kg) *(calculated)*	3 to 139	--
Oxygen (%)	21 to 100	21 to 100
P high (cmH20) (in APRV)	0 to 60	0 to 45
P high (cmH20) (in DuoPAP)	0 to 60	3 to 45
P low (cmH20) (in APRV)	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)[9]	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)[10]	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
Sex	Male, Female	--
Sigh	On, Off	--
T high (s) (in APRV and DuoPAP)[10]	0.1 to 40.0	0.1 to 40.0
T low (s) (in APRV)	0.2 to 40.0	0.2 to 40.0
TI (s)[8,10]	0.1 to 12.0	0.1 to 12.0
TI max (s)	0.5 to 3.0	0.25 to 3.0
Trigger, flow (l/min)[11]	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)[12]	5 to 12	5 to 12
Weight (kg)	--	0.2 to 30.0
ΔPcontrol (cmH2O)[13]	5 to 60	3 to 45 *nCPAP-PC:* 0 to 45
ΔPinsp (cmH2O)[13]	3 to 60	3 to 45
ΔPsupport (cmH2O)[13]	0 to 60	0 to 45

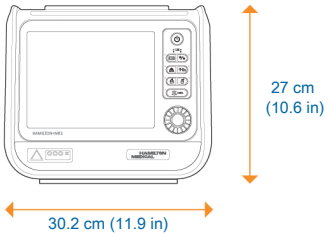
[6] Parameter settings and ranges can vary depending on the selected mode.
[7] Only in ASV mode.
[8] In PCV+, (S)CMV, and APVcmv modes, mandatory breath timing can be controlled by using a combination of inspiratory time (TI) and Rate, or by the I:E ratio; set the method in Configuration. All other modes are controlled by using a combination of inspiratory time (TI) and Rate.
[9] P-ramp is limited to one-third (1/3) of TI time. Adjustment of TI time can override the P-ramp setting.
[10] Startup setting derived from IBW (adult/pediatric), body weight setting (neonatal). Does not apply in ASV mode.
[11] Flow trigger is leak compensated.
[12] IBW is calculated using height and sex, for adult and pediatric patients. Actual body weight is used for neonates.
[13] *ΔPcontrol:* Control pressure, added to PEEP/CPAP. *ΔPinsp:* Inspiratory pressure, added to PEEP/CPAP. *ΔPsupport:* Pressure support, added to PEEP/CPAP.

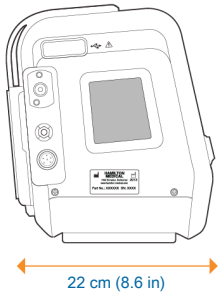
Monitoring parameters

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)	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

Physical characteristics







Weight	6.8 kg (15 lb) 21 kg (46.2 lb) with trolley The trolley can accommodate a maximum safe working load[14] of 44 kg (97 lb).
Dimensions	See graphic above
Monitor	**Type:** Color TFT **Size:** 640 x 480 pixels, 8.4 in (214 mm) diagonal
Trolley accessories	MR1 safety tether for trolley

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

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For devices manufactured in Switzerland

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