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,	APVcmv / (S)CMV+	Breaths are volume targeted and mandatory.	✓	✓
adaptive pressure controlled	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.	0	O
	APRV	Spontaneous breaths can be continuously triggered. The pressure release between the levels contributes to ventilation.	Ο	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.	0	0
	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.	0	0
	nCPAP	Demand flow nasal continuous positive airway pressure.		0
	nCPAP-PC	Breaths are pressure controlled and mandatory.		0



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	✓	✓
ntelliTrig (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	✓	
02 enrichment	✓	✓
On-screen help	✓	✓
Patient group	✓	0
Print screen	✓	✓
Screen lock	✓	✓
Standby with timer	✓	✓
Suctioning tool	✓	
TeslaSpy: Integrated magnetic field navigator	✓	✓
Trends/Loops	Ο	0
JSB 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	\pm (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 Ilb, 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 (<i>To patient</i> 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, \leq 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, Δ Pcontrol = 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 		
		Display brightness = 20 /0. 3.23 fr		
		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) <i>(calculated)</i>	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)	30 to 250	
(in)	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	0 to 600
	ASV, NIV, NIV-ST, SPONT, VS: max = 200	NIV, NIV-ST, SPONT, nCPAP-PC, VS: max = 200
Rate (b/min) ¹⁰	1 to 80	1 to 80
	APVcmv, PCV+: 4 to 80	PSIMV+: 5 to 80
	<i>PSIMV+, NIV-ST</i> : 5 to 80	APVcmv, PCV+, PSIMV+PSync, nCPAP-PC, NIV-ST, APVsimv + Apnea backup: 10 to 80
Sex	Male, Female	71 V3111V 171971Cd 20CKdp. 10 C0 C0
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 (I/min) ¹¹	0.5 to 20.0 <i>APVcmv</i> , <i>PCV</i> +: 0.5 to 20.0 / Off	0.1 to 5.0 <i>APVcmv</i> , <i>PCV</i> +: 0.1 to 5.0 / Off
Vt (ml)	20 to 2000	2 to 300
Vt/IBW	5 to 12	5 to 12
Vt/Weight (ml/kg) ¹²	3 (0 12	3 (0 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.

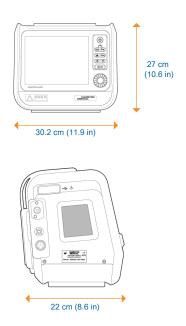
⁸ In PCV+, (S)CMV, and APVcmv modes, mandatory breath timing can be controlled by using a combination of inspiratory time (TI) and Rate, or by the I:E ratio; set the method in In PCV+, (S)CMV, and APVcmv modes, mandatory breath timing can be controlled by using a combination of inspiratory time (II)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

Monitoring parameters

AutoPEEP (cmH2O)	Unintended positive end-expiratory pressure	
DEED/CDAD / LIDC'		
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 (I/min)	nCPAP: The average flow updated every second	
	nCPAP-PC: The average flow during expiration, updated every breath	
Insp Flow (peak) (I/min)	Peak inspiratory flow, spontaneous or mandatory	
Exp Flow (peak) (I/min)	Peak expiratory flow	
ExpMinVol or MinVol NIV (I/min)	Expiratory minute volume	
MVSpont or MVSpont NIV (I/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 (I/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 weigh (neonatal patients)	
Oxygen (%)	Oxygen concentration of the delivered gas	
	The current oxygen consumption rate	
	MMP during CPR ventilation showing duration of CPR ventilation	
	Ratio of the patient's inspiratory time to expiratory time for every breath cycle	
	Mandatory breath frequency	
	Spontaneous breathing frequency	
	Total breathing frequency	
	Inspiratory time	
	Expiratory time	
	Airway occlusion pressure	
	Pressure time product	
	Expiratory time constant	
	Inspiratory flow resistance Rapid shallow breathing index	
	Pmean (cmH2O) Ppeak (cmH2O) Pplateau (cmH2O) Pprox (cmH2O) Pprox (cmH2O) Flow (l/min) Insp Flow (peak) (l/min) Exp Flow (peak) (l/min) Exp Flow (peak) (l/min) ExpMinVol or MinVol NIV (l/min) MVSpont or MVSpont NIV (l/min) VTE or VTE NIV (ml) VTI (ml) VLeak (%) MVLeak (l/min) Vt/IBW or Vt/Weight (ml/kg) Oxygen (%) O2 consumption (l/min) CPR timer I:E fControl (b/min) fSpont (b/min) fTotal (b/min) TI (s) TE (s) Cstat (ml/cmH2O) PO.1 (cmH2O) PTP (cmH2O*s) RCexp (s) Rinsp (cmH2O / (l/s))	

Physical characteristics





Weight 6.8 kg (15 lb)

21 kg (46.2 lb) with trolley

The trolley can accommodate a maximum safe working load¹⁴ 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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