Anexa 3

Specificație tehnică completată

Model: Hamilton C6, Producător: Hamilton Medical AG, Tara: Elvetia

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Ventilator pulmonar adult, pediatric (caracteristici avansate) Cod 110330 Descriere Ventilatoarele mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menţinînd o ventilare adecvată. Parametrul Specificația Tip Mobil, pe suport cu rotile da Tip pacient adult, pediatric da Gama de control/setări Volum total 20-2,500 mL Flux inspir 6-180 L/min Presiune inspir 0-100 cm H2O Rata respiratorie 1-100 rpm Timp inspir 0.1 - 8 s. Rata I:E 1:8 to 4:1 FiO2, % 21-100 Buton pentru respirație manuală da PEEP/CPAP 0-50 cm H2O Suport presiune 0-50 cm H2O Inhalator da Mecanism triger Presiune Flux Ajustarea presiunii pantă/rampă da Funcția suspin da Buton 100 % O2 da Timpul maxim activ al butonului 100 % O2 2 min Blocarea panoului de control da Moduri de operare Modul A/C A/C Volum respirator da A/C presiune respiratorie da Modul SIMV SIMV volum respirator da SIMV presiune respiratorie da Modul CPAP CPAP, CPAP/suport presiune (PS) da Modul Apnea-backup da Moduri combinate da Ventilație neinvazivă da Modul Bilevel/APRV da Parametri monitorizați/afișați Presiunea inspiratorie maximă da	Ventilator pulmonar adult, pediatric (caracteristici avansate) **DA** Cod 110330 Descriere Ventilatoarele mecanice oferă suport ventilator temporar sau permanent pentru pacienţii care nu pot respira pe cont propriu sau care au nevoie de asistenţă, menţinînd o ventilare adecvată. **DA** Parametrul Specificația Tip Mobil, pe suport cu rotile **DA** Tip pacient adult, pediatric **DA optional neonat (dela 0.2 la 30 Kg)** Gama de control/setări Volum total 20-2000 mL Flux inspir **maxim 260 L/min DA** Presiune inspir 0-100 cm H2O **DA** Rata respiratorie 1-80 rpm **DA** Timp inspir 0.1 - **12 s. DA** Rata I:E 1:9 to 4:1 **DA** FiO2, % 21-100 **DA** Buton pentru respirație manuală **DA** PEEP/CPAP 0-50 cm H2O **DA** Suport presiune 0-100 cm H2O **DA** Inhalator **DA penumatic** Mecanism triger Presiune **DA** Flux **DA** Ajustarea presiunii pantă/rampă **DA** Funcția suspin **DA** Buton 100 % O2 **DA** Timpul maxim activ al butonului 100 % O2 2 min **DA** Blocarea panoului de control **DA** Moduri de operare Modul A/C A/C Volum respirator **DA** A/C presiune respiratorie **DA** Modul SIMV SIMV volum respirator **DA** SIMV presiune respiratorie **DA** Modul CPAP CPAP, CPAP/suport presiune (PS) **DA sa nu fie inurat cu nCPAP regim specilizat pentru neonat** Modul Apnea-backup **DA** Moduri combinate **DA** Ventilație neinvazivă **DA** Modul Bilevel/APRV **DA** Parametri monitorizați/afișați Presiunea inspiratorie maximă **DA**

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Reason: MoldSign Signature
Location: Moldova

Anexa 3

Presiunea medie în căile respiratorii da	Presiunea medie în căile respiratorii **DA**
Presiunea PEEP da	Presiunea PEEP **DA**
Volumul total da	Volumul total **DA**
Monitorizarea FiO2 da	Monitorizarea FiO2 **DA**
Rata respiratorie da	Rata respiratorie **DA**
Timp inspir da	Timp inspir **DA**
Timp expir da	Timp expir **DA**
Rata I:E da	Rata I:E **DA**
Volumul minutar spontan da	Volumul minutar spontan **DA**
Alarme pacient FiO2 mare/mic da	Alarme pacient FiO2 mare/mic **DA**
Volum minutar mare/mic da	Volum minutar mare/mic **DA**
Presiune inspir mare/mică da	Presiune inspir mare/mică **DA**
PIP mare da	PIP mare **DA**
PEEP mare da	PEEP mare **DA**
Lipsă PEEP da	Lipsă PEEP **DA**
Apnea da	Apnea d **DA**
Presiune/ocluzie continuă ridicată da	Presiune/ocluzie continuă ridicată **DA**
Inversare IE da	Inversare IE **DA**
Circuit respirator deconectat da	Circuit respirator deconectat **DA**
Alarme echipament Lipsă alimentare gaz da	Alarme echipament Lipsă alimentare gaz **DA**
Lipsă alimentare electrică da	Lipsă alimentare electrică **DA**
Baterie descărcată da	Baterie descărcată **DA**
Eroare de sistem Sensor decalibrat, scurgere prin valve	Eroare de sistem Sensor decalibrat, scurgere prin valve **DA**
Autodiagnostic da	Autodiagnostic **DA**
Interfața Interfața cu dispozitivele exterioare da	Interfața Interfața cu dispozitivele exterioare **DA**
Porturi pentru ieșirea datelor da	Porturi pentru ieșirea datelor **DA**
Port pentru alarmă la distanță da	Port pentru alarmă la distanță **DA**
Ieșire analogică da	Ieșire analogică **DA**
Raportarea alarmelor și starea pacientului afișare pe display da	Raportarea alarmelor și starea pacientului afișare pe display **DA**
Transmiterea rapoartelor la imprimată da	Transmiterea rapoartelor la imprimată **DA**
Posibilitatea conectării în rețea centralizată da	Posibilitatea conectării în rețea centralizată **DA**
Display LCD TFT da	Display LCD TFT **DA**
Mărimea ≥ 15 inch	Mărimea **17 inch DA**
Touchscreen da	Touchscreen **DA**
Compresor de aer Integrat în dispozitivului, tip turbină da	Compresor de aer Integrat în dispozitivului, tip turbină **DA**
Alimentare Pneumatică Gazele comprimate aer, O2	Alimentare Pneumatică, O2 **DA**
Presiunea în rețea 3-6 atm	Presiunea în rețea 3-6 atm **DA**
Electrică Rețea electrică 220 V, 50 Hz da	Electrică Rețea electrică 220 V, 50 Hz **DA**
Baterie internă reîncărcabilă da	Baterie internă reîncărcabilă **DA**
Timp operare baterie ≥ 1 h	Timp operare baterie **-1.5 h/90 min DA**
Accesorii	Accesorii
Circuite respiratorii pediatrice tip reutilizabil 2 set.	Circuite respiratorii pediatrice si adult tip reutilizabil 2 set. **DA PN 260188 model HAMILTON BC8022 A**
adult tip reutilizabil 2 set.	
Mască respiratorie pediatrice tip reutilizabil 1 set.	Mască respiratorie pediatrice tip reutilizabil 1 set. **DA (3 marimi)**
adult tip reutilizabil 1 set.	adult tip reutilizabil 1 set. **DA (Marimi)**
Umidificator Indicați modelul oferit model	Umidificator **H-900**

Anexa 3

Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul da	Umidificator cu mentinerea temperaturi si umidificarea aerului în regim automa, Compatibil cu ventilatorul **DA**
Minim două regimuri de funcționare: invaziv și neinvaziv da	Minim două regimuri de funcționare: invaziv și neinvaziv **DA**
Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc.	Cameră de umidificare adult/pediatrice tip reutilizabil 1 buc.**DA (este inclus si in setul cu PN 260188)**
Filtre antibacteriale pediatrice unică utilizare 100 buc.	Filtre antibacteriale pediatrice/adult unică utilizare 100 buc. **DA**
adult unică utilizare 100 buc.	
Senzor de debit adult/pediatrice tip reutilizabil 2 buc.	Senzor de debit (flux) adult/pediatrice tip reutilizabil 2 buc. **DA**
Plamăn de test adult tip reutilizabil 1 buc.	Plamăn de test adult tip reutilizabil 1 buc. **DA**
Suport pe rotile Indicați modelul oferit model	Suport pe rotile Indicați este integrat de ventilator
Min. 4 rotile da	Min. 4 rotile da
Min. 2 roți cu frînă da	Min. 2 roți cu frînă da
Braț articulat pentru fixarea furtunelor respiratorii da	Braț articulat pentru fixarea furtunelor respiratorii **DA**
Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare da	Suport pentru fixarea/atașarea cablurilor electrice, furtunul aer, oxigen pentru transportare, depozitare **DA**
Mîner pentru transportare da	Mîner pentru transportare **DA**

HAMILTON-C6

Technical specification for SW version 1.2.x

Ventilation modes

Standard: ✓ Option: O Not applicable: --

Mode form	Mode name	Mode	Adult/Ped	Neonatal
Volume-controlled modes, flow controlled	(S)CMV	Breaths are volume-controlled and mandatory, including patient-triggered breaths.	✓	--
	SIMV	Volume-controlled mandatory breaths can be alternated with pressure-supported breaths.	✓	--
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.	✓	✓
	APRV	Spontaneous breaths can be continuously triggered. The pressure release between the levels contributes to ventilation.	✓	✓
	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.	✓	✓
	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.	✓	✓
	nCPAP-PS	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
	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 ports: Three COM ports, two USB ports, DVI, Nurse call	✓	✓
Communication protocols: for details, see the *Connectivity* brochure	✓	✓
Distributed alarm system (DAS) compatible	✓	✓
Dynamic Lung (real-time visualization of the lungs)	✓	--
Event log (up to 10,000 events with date and time stamp)	✓	✓
HAMILTON-H900 humidifier integration	O	O
Inspiratory and expiratory hold maneuver	✓	✓
IntelliCuff® integrated cuff pressure controller	O	O
IntelliSync+ (inspiratory and expiratory trigger synchronization)	O	--
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)	✓	✓
Leakage compensation	✓	✓
Manual breath/prolonged inspiration	✓	✓
Nebulization (Aerogen§)	O	O
Nebulization (pneumatic)	✓	--
O2 enrichment	✓	✓
On-screen help	✓	✓
P/V Tool® Pro	O	O
Paramagnetic O2 sensor	O	O
Patient group	✓	O
Print screen	✓	✓
Screen lock	✓	✓
Second battery	O	O
SpO2 monitoring	O	O
Standby with timer	✓	✓
Suctioning tool	✓	✓
Transpulmonary pressure monitoring	✓	✓
TRC (tube resistance compensation)	✓	✓
Trends/Loops	✓	✓
Trigger, flow and pressure selectable	✓	✓
Vent Status (visual representation of patient's ventilator dependence)	✓	✓

Technical performance

Description	Specification
Automatic expiratory base flow	Fixed at 6 l/min
Inspiratory pressure	0 to 100 cmH2O
Maximum inspiratory flow	260 l/min
Means of inspiratory triggering	Flow trigger, pressure trigger, or optional IntelliSync+
Means of expiratory triggering	Flow cycling (ETS), or optional IntelliSync+
Minimum expiratory time	20% of cycle time; 0.2 to 0.8 seconds
O2 input flow	80 l/min (at 2.8 bar/ 280 kPa / 41 psi input pressure)
Oxygen mixer accuracy	± (Volume fraction of 2.5% + 2.5% of actual reading)
Preoperational checks	Leak test, Flow sensor/O2 sensor/CO2 sensor calibration
Tidal volume	*Adult/Ped:* 20 to 2000 ml *Neonatal:* 2 to 300 ml

Standards and approvals

Classification	Class IIb, continuously operating according to EC directive 93/42/EEC
Certification	EN 60601-1:2006/A1:2013, 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 80601-2-55:2018
Declaration	The HAMILTON-C6 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 I, Type B applied part (ventilator breathing system, VBS), type BF applied parts CO2 sensor including CO2 module connector, humidifier, Aerogen§ system, nebulizer, and SpO2 sensor including SpO2 adapter, continuous operation according to IEC 60601-1

Pneumatic performance

O2	Input pressure:	2.8 to 6 bar / 41 to 87 psi
	Connector:	DISS (CGA 1240) or NIST
Air supply	Integrated turbine with lifetime warranty	
Inspiratory outlet (*To patient* port)	Connector:	ISO 15 mm ID/22 mm OD conical
Expiratory outlet (*From patient* port)	Connector (on expiratory valve):	ISO 15 mm ID/22 mm OD conical

Electrical specifications

Input power	100 to 240 VAC ±10%, 50/60 Hz	
Power consumption	60 VA typical, 210 VA (510 VA with humidifier) maximum	
Battery	Electrical specifications:	14.4 V, 5.0 Ah, 72 Wh, 48 W typical, 288 W maximum
	Type:	Lithium-ion
	Normal operating time:	≥ 90 min with one battery / ≥ 180 min with two batteries

Graphical patient data

Graphic type/tab name	**Options**
Waveforms	Pressure, Flow, Volume, PCO2[1], FCO2[1], Plethysmogram[1], Ptrach, Pes, Ptranspulm, Off
Intelligent panels	Dynamic Lung[2], Vent Status, ASV Graph[3], SMPs (Secondary monitoring parameters)
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[1], Volume/FCO2[1], Pes/Volume, Ptranspulm/Volume

[1] CO2 + SpO2 option required
[2] Only for adult/pediatric patients
[3] Only in ASV mode

Alarms

Priority	Alarm
High priority	Apnea, Check for blockage, Minute volume high/low, Oxygen 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 Options not found, Self test failed, Blower fault, Device temperature high, Vent outlet temperature high, Panel connection lost Battery low, Battery power loss, Battery totally discharged, Battery temperature high, Battery communication error, Battery defective, No ventilation after power failure *SpO2*:[4] Low SpO2 *HAMILTON-H900:* Humidifier tilt, Humidifier chamber temp high, Humidifier Y-piece temp high, Humidifier water high, Humidifier error, Check humidifier *IntelliCuff:* Cuff leak, Check IntelliCuff
Medium priority	Aerogen nebulizer disconnected, Frequency high/low, Vt high/low, Inspiratory volume limitation, High PEEP, Loss of PEEP, Pressure limitation 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 Remote communication error, Remote communication timeout *CO2*:[5] PetCO2 high/low *SpO2*:[4] SpO2: Adapter missing, SpO2: Light interference, SpO2: Low perfusion index, SpO2: Poor signal, SpO2: Probe missing, SpO2: Patient disconnected, SpO2: Sensor error, PI high/low, PVI high/low, Pulse high/low, Low SpO2 *HAMILTON-H900:* Check breathing circuit limbs, Check humidifier, Humidifier chamber temp low, Humidifier Y-piece temp low, Humidifier water low, Humidifier check chamber, Humidifier check left/right tube *IntelliCuff:* Check IntelliCuff, Cuff deflated, Cuff pressure high, Cannot turn off IntelliCuff *INTELLiVENT-ASV:* FiO2 set to 100% due to low SpO2, Oscillation Oxygen, Oscillation %MinVol, Oscillation PEEP/CPAP, Oxygenation adjustment off, Oxygen control limit exceeded, Oxygen supply failed, Ventilation adjustment off
Low priority	ASV: Cannot meet target, Maximum leak compensation, Pressure limit has changed, Pressure high, Suctioning maneuver, Apnea ventilation, Apnea ventilation ended Flow sensor calibration needed, Replace HEPA filter, IRV (inverse ratio ventilation), Release valve defective, Touch not functional, Check settings, Settings file error, Language not loaded, Panel settings file error Continue charging battery, Battery calibration required, Battery replacement required, Wrong battery, Battery low, Loss of external power O2 sensor calibration needed, O2 sensor defective, O2 sensor missing, O2 sensor not system compatible Invalid communication board *CO2*:[5] 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 *SpO2*:[4] High SpO2 *HAMILTON-H900:* Check humidifier, Check humidifier communication *IntelliCuff:* Check IntelliCuff *INTELLiVENT-ASV*:[6] Oxygenation controller at limit, Recruitment in progress, Ventilation controller at limit

[4] If the SpO2 option is installed and enabled.
[5] If the CO2 option is installed and enabled.
[6] If INTELLiVENT-ASV is installed.

Control settings and ranges

Parameter (units)	Range Adult/Ped[7]	Range Neonatal[7]
%MinVol (%)	25 to 350	--
Apnea backup	On, Off	On, Off
Cuff pressure[8] (cmH2O)	0 to 50	0 to 50
End PEEP[9] (cmH2O)	0 to 35	0 to 35
Expiratory trigger sensitivity ETS (%)	5 to 80	5 to 80
Flow pattern	Square, decel. 50%, Sine, decel. 100%	--
Flow trigger (l/min)	0.5 to 20, Off	0.1 to 5.0, Off
Flow[10] (l/min)	2 to 100	2 to 30
Gender (sex)	Male, Female	--
I:E	1:9 to 4:1	1:9 to 4:1
Max. pressure[8] (cmH2O)	6 to 50	6 to 50
Min. pressure[8] (cmH2O)	5 to 49	5 to 49
Nebulizer Duration (min)	5 to 40, continuous	5 to 40, continuous
Nebulizer Synchronisation	Inspiration, Exhalation, Insp. and Exh.	Inspiration, Exhalation, Insp. and Exh.
Oxygen (%)	21 to 100	21 to 100
P high (cmH2O) (only in DuoPAP and APRV)	0 to 100	0 to 60
P low (cmH2O) (only in APRV)	0 to 50	0 to 25
Pat. height (cm) (in)	30 to 250 / 12 to 98	--
Pause (%)	0 to 70	--
Peak flow (l/min)	1 to 195	--
PEEP/CPAP (cmH2O)	0 to 50	0 to 25
Plimit (cmH2O)	5 to 100	--
P-ramp (ms)	0 to 2000	0 to 600
Pressure trigger (cmH2O)	-0.1 to -15.0, Off	-0.1 to -15.0, Off
Pstart[9] (cmH2O)	0 to 35	0 to 35
Ptop[9] (cmH2O)	25 to 60	25 to 60
Ramp speed[9] (s)	2 to 5	2 to 5
Rate (b/min)	1 to 80	1 to 150
Rel. pressure[8] (cmH2O)	-15 to 5	-15 to 5
Set temp[11] (°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

[7] Parameter settings and ranges can vary depending on the selected mode.
[8] If the IntelliCuff integrated cuff pressure controller option is installed.
[9] If the P/V Tool Pro option is installed.
[10] Only for high flow oxygen therapy.
[11] If the HAMILTON-H900 humidifier integration option is installed.

Parameter (units)	Range Adult/Ped[7]	Range Neonatal[7]
Sigh	On, Off	--
T gradient[11] (°C)	-2 to 3	-2 to 3
T high (s) (in DuoPAP and APRV)	0.1 to 40	0.1 to 40
T low (s) (in APRV)	0.2 to 40	0.2 to 40
TI (s)	0.1 to 12	0.1 to 12
TI max (s)	0.5 to 3	0.25 to 3.0
Tip (s)	0 to 8	--
Tpause[9] (s)	0 to 30	0 to 30
TRC compensation (%)	0 to 100	0 to 100
Vt (ml)	20 to 2000	2 to 300
Weight (kg)	--	0.2 to 30.0
ΔPcontrol (cmH2O)	5 to 100	3 to 60
ΔPinsp (cmH2O)	3 to 100	0 to 60
ΔPsupport (cmH2O)	0 to 100	0 to 60

Monitoring parameters

Parameter (units)		Description
Pressure	AutoPEEP (cmH2O)	Unintended positive end-expiratory pressure
	Paw (cmH2O)	Airway pressure
	ΔP (cmH2O)	Driving pressure
	PTP (cmH2O*s)	Inspiratory pressure time product
	Pcuff (cmH2O)	Cuff pressure
	Ptrans I (cmH2O)	The arithmetic mean value of Ptranspulm over the last 100 ms of the last inspiration.
	Ptrans E (cmH2O)	The arithmetic mean value of Ptranspulm over the last 100 ms of the last expiration.
	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
	Pprox (cmH2O)	Airway pressure at proximal patient interface
	Pes min (cmH2O)	See PEEP. The pressure is measured through the Pes port instead of using airway pressure.
	Pes max (cmH2O)	See Ppeak. The pressure is measured through the Pes port instead of using airway pressure.
	Pes plateau (cmH2O)	See Pplateau. The pressure is measured through the Pes port instead of using airway pressure.
	Pes PTP (cmH2O*s)	See PTP. The pressure is measured through the Pes port instead of using airway pressure.
	Pes P0.1 (cmH2O)	See P0.1. The pressure is measured through the Pes port instead of using airway pressure.
Flow	Control Flow (l/min)	The set flow of gas to the patient when using HiFlowO2
	Insp Flow (l/min)	Peak inspiratory flow, spontaneous or mandatory
	Exp Flow (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 or VTI NIV (ml)	Inspiratory tidal volume
	Vt/IBW Vt/Weight (ml/kg)	Tidal volume is calculated by ideal body weight (adult/pediatric patients) and according to the actual body weight for neonatal patients.
	VLeak (%) or MVLeak (l/min)	Leakage percent or total minute volume leakage

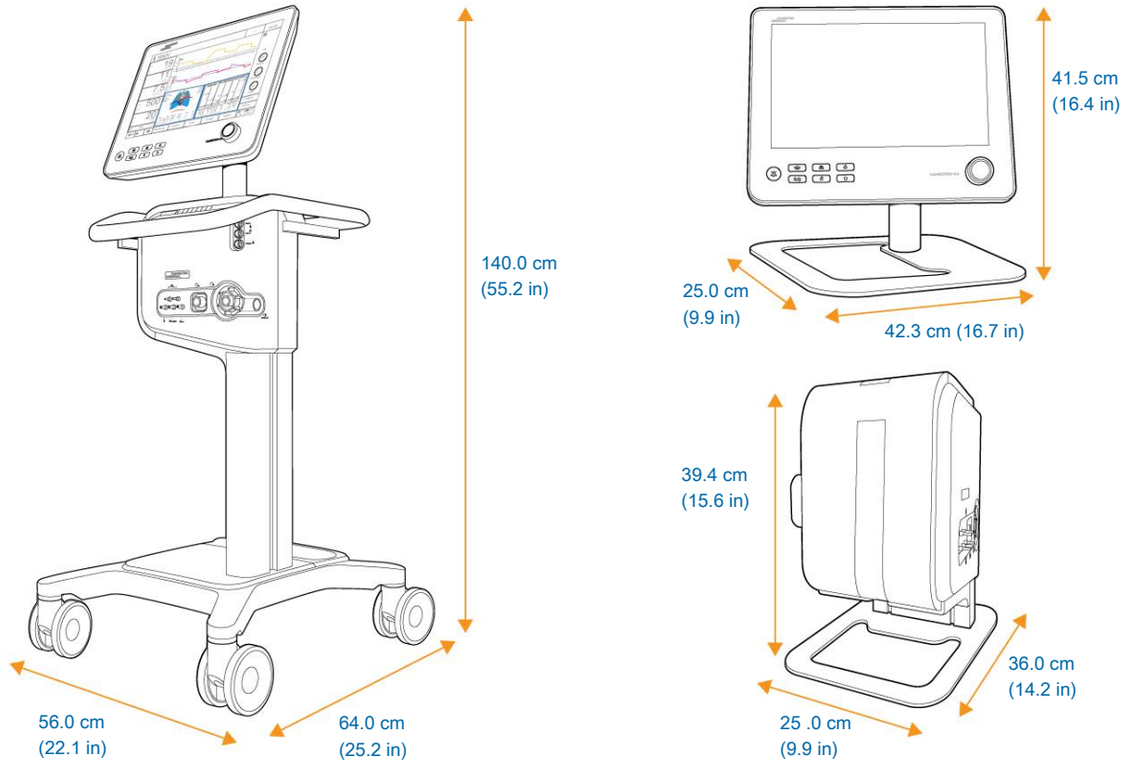
Parameter (units)		Description
CO2	FetCO2 (%)	Fractional end-tidal CO2 concentration
	PetCO2 (mmHg)	End-tidal CO2 pressure
	slopeCO2 (%CO2/l)	Slope of the alveolar plateau in the PetCO2 curve, indicating the volume/flow status of the lungs
	V'alv (l/min)	Alveolar minute ventilation
	Vtalv (ml)	Alveolar 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
	Plethysmogram	The waveform that visualizes the pulsating blood volume; it is delivered by the pulse oximeter.
	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
	SpCO (%)	Carboxyhemoglobin saturation
	SpMet (%)	Methemoglobin saturation
	SpHb (g/dl) (mmol/l)	Total hemoglobin
	SpOC (ml/dl)	Oxygen content
Oxygen	Oxygen (%)	Oxygen concentration of the delivered gas
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
	Pause (s)	Inspiratory pause or plateau
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
Humidifier related	T humidifier (°C)	Measured temperature at water chamber exit
	T Y-piece (°C)	Measured temperature at the Y-piece

Physical characteristics

Weight	Monitor (interaction panel) without shelf mount: 7.8 kg (17.2 lb) Monitor with shelf mount: 10 kg (22 lb) Ventilation unit with shelf mount: 10.5 kg (23.2 lb) Ventilation unit, monitor, and trolley: 46 kg (101 lb) The trolley can accommodate a maximum safe working load[12] of 80 kg (176 lb).
Dimensions, Trolley and shelf mount solutions	See figure below
Dimensions, Combined shelf mount solution, monitor tilt/swivel range	See next page
Monitor	Type: Color TFT, Size: 1920 x 1200 pixels, 17 in (431.8 mm) diagonal
Monitor mounting options	VESA, pole mount, rail mount, handle mount
Trolley accessories	Basket, O2 cylinder holders (two bottles), humidifier mounting system, additional standard rail, bed docking system

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

Figure 1. HAMILTON-C6 dimensions



Shelf mount dimensions	See the figures below
Monitor mounted to *left* of ventilator body, monitor tilt and swivel ranges (see top figure below)	Monitor tilt range: Forward = 30°; Backward = 37° Monitor swivel range: 34° to the left from neutral
Monitor mounted to *right* of ventilator body, monitor tilt and swivel ranges (see bottom figure below)	Monitor tilt range: Forward = 30°; Backward = 37° Monitor swivel range: 144° to the right from neutral to 22° to the left

Figure 2. Shelf mount dimensions, monitor mounted to the *left* of the ventilator body, monitor swivel and tilt ranges

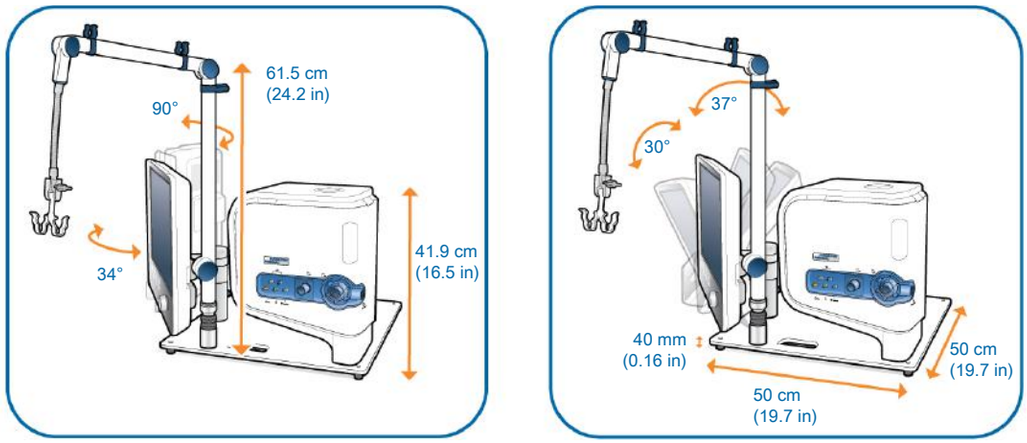
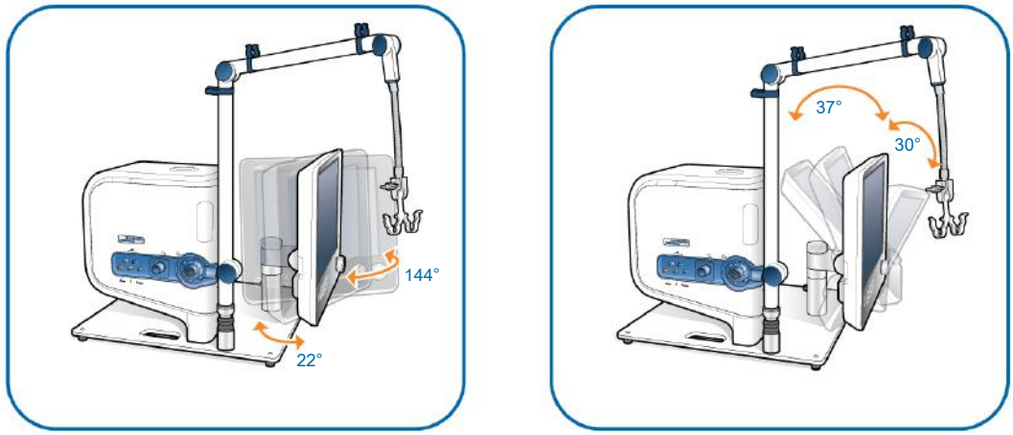


Figure 3. Shelf mount dimensions, monitor mounted to *right* of ventilator body, monitor swivel and tilt ranges



All angles in the figures above are relative to the monitor facing forward, with the bottom of the monitor parallel to the shelf plate, at a 90° angle relative to the floor. References to *left* and *right* refer to the reader's left and right, viewing the monitor from the front.

Manufacturer:

Hamilton Medical AG

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689596/04

HAMILTON-C6

The next generation of intelligent ICU ventilators

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-C6

The HAMILTON-C6 represents a new generation of high-end ventilators. The combination of modularity, ease of use, mobility, and advanced features allows you to individualize your patient's ventilation therapy:

- State-of-the-art ventilation modes for adult, pediatric, and neonatal patients
- Adaptive, lung-protective ventilation modes ASV® and INTELLiVENT®-ASV
- IntelliSync+ real-time patient synchronization
- High-performance noninvasive ventilation
- High flow oxygen therapy
- P/V Tool® Pro for lung assessment and recruitment
- Transpulmonary pressure measurement
- Integrated IntelliCuff® pressure controller
- Remote access to humdifier controls and status

Slender, flexible, convenient

Flexible device configuration

The HAMILTON-C6 adapts to your individual user environment. Mount it on a trolley, with the interaction panel on top or in front, or use the shelf-mounted version with the interaction panel on the side or mounted on the pendant system.

For intrahospital transport

Thanks to the slender frame, an integrated O2 cylinder carrier, and the high-performance turbine, the HAMILTON-C6 can stay at your patient's side for intrahospital transports.

Ergonomic maneuverability

With a compact footprint and high-quality trolley wheels the HAMILTON-C6 is designed for easy handling and maneuverability.


ASV
26
10.7
484
21
0.43
Modes
Controls
Alarms
Monitoring
Graphics
Trends
Events
System
HAMILTON MEDICAL

Ease of use

In close cooperation with users and ventilation experts, our engineers have designed a user interface that is particularly intuitive. Switching between the HAMILTON-C6 and all other Hamilton Medical ventilators is easy because they are all operated according to the same principles.

The Ventilation Cockpit on the HAMILTON-C6 consolidates the monitoring data and displays it as intuitive graphics. These provide a quick overview of the patient's current ventilation status and provide a reliable basis for therapy decisions.

“

The Hamilton operating platform actually made my job as an educator and a clinical specialist a lot easier. Because once we learn one platform it transfers over to all of the other platforms. To the MRI ventilators, to the transport ventilators, to the neonatal side, in the EC and ICU, it all transfers over.

Craig Jolly, Adult Clinical Education Coordinator
University Medical Center, Lubbock (TX), 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, resistance in real-time, cuff pressure, and pulse. The lungs expand and contract in synchrony with the actual breaths.

3 Vent Status

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

4 Direct access to main controls

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

Individualized, lung-protective ventilation

Adaptive, lung-protective ventilation with ASV

- ✓ Supports the earliest possible spontaneous breathing by the patient[1, 2]
- ✓ Shortens the ventilation time in various patient groups[1, 2]

Your bedside assistant INTELLiVENT-ASV

- ✓ Requires fewer manual adjustments than conventional ventilation, consequently reducing the work-load for the healthcare team[3]
- ✓ Follows the latest recommendations for lung-protective ventilation in terms of tidal volumes, driving pressure, and mechanical power[4, 5, 6]

Lung assessment and recruitment with the P/V Tool Pro

- ✓ Hysteresis of the pressure/volume curve can be used for assessing the recruitability of the lung at the bedside[7]
- ✓ May reduce the need for assessing recruitability with a CT scan, when using the PV loop in early on-set ARDS[8]

Synchronization based on waveform analysis with IntelliSync+

- ✓ Waveform analysis is a reliable, accurate, and reproducible method for assessing patient-ventilator interaction[9]
- ✓ In terms of cycling, IntelliSync+ performs at least as well as ETS optimized by clinicians[10]

Automatic cuff pressure control with IntelliCuff

- ✓ Continuous cuff pressure control can decrease microaspiration and VAP[11, 12]

Transpulmonary pressure measurement

- ✓ PEEP set based on transpulmonary pressure can improve compliance and oxygenation in ARDS patients[13]
- ✓ Transpulmonary pressure measurement can avoid the use of ECMO in the most severe patients[14]

---

[1] Kirakli C. Eur Respir J. 2011 Oct;38(4):774-80
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[3] Bialais, E., et al., Minerva Anestesiol, 2016. 82(6): p. 657-68
[4] Arnal JM. Intensive Care Med Exp 2016, 4(Suppl 1):A602
[5] Arnal, J.-M., M. Saoli, and A. Garnero, Heart & Lung: The Journal of Cardiopulmonary and Acute Care. 2019 Nov
[6] Buiteman-Kruizinga LA. Crit Care Explor. 2021 Feb 15;3(2):e0335
[7] Demory D. Intensive Care Med. 2008 Nov;34(11):2019-25
[8] Chiumello D. Crit Care Med. 2020 Oct;48(10):1494-1502
[9] Mojoli F. Intensive Care Med Exp 2016, 4(Suppl 1):A1168
[10] Mojoli F. Intensive Care Med Exp 2016, 4(Suppl 1):A1164
[11] Lorente L. Critical Care. 2014;18(2):R77
[12] Nseir S. American Journal of Respiratory and Critical Care Medicine. 2011;184(9):1041-1047
[13] Talmor D. N Engl J Med. 2008 Nov 13;359(20):2095-104
[14] Grasso S. Intensive Care Med. 2012 Mar;38(3):395-403

Adaptive Support Ventilation (ASV)

adjusts respiratory rate, tidal volume, and inspiratory pressure continuously, depending on the patient's lung mechanics and effort. ASV adapts ventilation breath-by-breath, 24 hours a day, and from intubation to extubation.

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.

P/V Tool Pro for lung assessment and recruitment

helps you assess recruitability and set PEEP based on respiratory mechanics. It also provides a repeatable method for quickly performing recruitment maneuvers.

IntelliSync+ keeps an eye on patient-ventilator synchrony

by continuously analyzing waveform shapes hundreds of times per second. This allows IntelliSync+ to detect patient efforts and cycling immediately, and initiate inspiration and expiration in real time. IntelliSync+ applies to invasive and noninvasive ventilation, regardless of the ventilation mode.

IntelliCuff pressure controller

continuously measures and automatically maintains the user-set cuff pressure of an endotracheal or tracheostomy tube in real time.

Transpulmonary pressure measurement

allows optimization of PEEP, tidal volume, and inspiratory pressure. Use it in combination with the P/V Tool Pro to assess lung recruitability more precisely and perform recruitment maneuvers.

Features and options

State-of-the-art ventilation modes

Adult, pediatric, and neonatal ventilation

Integrated high flow oxygen therapy

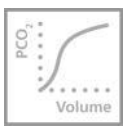
High-performance turbine with lifelong warranty

Integrated pneumatic and optional Aerogen nebulizer

Integrated control for IntelliCuff pressure controller

Pulse oximetry
(SpO2 and pulse measurement)

Remote access to HAMILTON-H900 controls and status



Mainstream (volumetric) and sidestream capnography

Serial interface for connection to PDMS or patient monitors

Continuous monitoring of driving pressure

On-screen help for alarm troubleshooting

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 and free simulation software:
www.hamilton-C6.com

Manufacturer:

Hamilton Medical AG

Via Crusch 8, 7402 Bonaduz, Switzerland

☎ +41 58 610 10 20

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www.hamilton-medical.com

689590.01

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-C6, 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, 06. DEZ. 2021

CEDCL-HAM-C6 Attachment

Product name	P/N	UDI-DI / GTIN	Basic UDI-DI / GMN
HAMILTON-C6	160021	07630002808590	76300028PN160021ZW

EC Certificate

TÜVRheinland®

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

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

Products: Ventilators and ventilator systems

Replaces certificate, registration no.: HD 60137935 0001

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

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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

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

EC Certificate

TÜVRheinland®

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

Registration No.: HD 1093044-1

Manufacturer: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification includes the following manufacturing sites:

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

Report No.: 3348226-90

Effective date: 2021-05-19

Expiry date: 2024-05-26

Issue date: 2021-05-19

TÜV Rheinland LGA Products GmbH TÜVRheinland

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1093044-1

Organization: Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

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

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

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

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

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1093044-1

Organization:
Hamilton Medical AG
Via Crusch 8
7402 Bonaduz
Switzerland

The scope of certification also covers the following locations:

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

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

TÜV Rheinland LGA Products GmbH

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

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

HAMILTON-BC8022-A - Adult dual limb heated breathing set, autoclavable, with integrated temperature probe, incl. chamber and water trap

HAMILTON-BC8022-A – Beheiztes Beatmungsschlauchset mit zwei Schenkeln für Erwachsene, autoklavierbar, mit integriertem Temperatursensor, inkl. Befeuchterkammer und Wasserfalle

HAMILTON-BC8022-A - Kit de circuit respiratoire chauffant à deux branches pour adulte, autoclavable, avec sonde de température intégrée, réservoir et piège à eau inclus

HAMILTON-BC8022-A: Equipo respiratorio para adultos con calefacción en las dos ramas, esterilizable en autoclave, con sensor de temperatura integrado, cámara y colector de agua incluidos

HAMILTON-BC8022-A - Kit de respiração aquecido de alça dupla para adulto, autoclavável, com sonda de temperatura integrada, incl. câmara e retentor de água

HAMILTON-BC8022-A - Set circuito paziente riscaldato con branca doppia per adulti, autoclavabile, con sonda termica integrata, camera e raccogli condensa inclusi

HAMILTON-BC8022-A - 集成温度探头并带有蒸发腔和集水杯的双肢加热、耐热压处理成人呼吸装置

HAMILTON-BC8022-A – 成人向けデュアルリム加熱呼吸セット、オートクレーブ可能、一体型温度センサー、チャンバーおよびウォータートラップ付属

HAMILTON-BC8022-A – Комплект взрослого автоклавируемого нагреваемого дыхательного контура с У-образным коннектором, встроенным температурным зондом, резервуаром увлажнителя и влагосборником

HAMILTON-BC8022-A - Yetişkin çift parçalı ısıtmalı solunum seti, otoklavlanabilir, entegre sıcaklık probu ile birlikte, hazne ve su kapanı dahil

Accessories

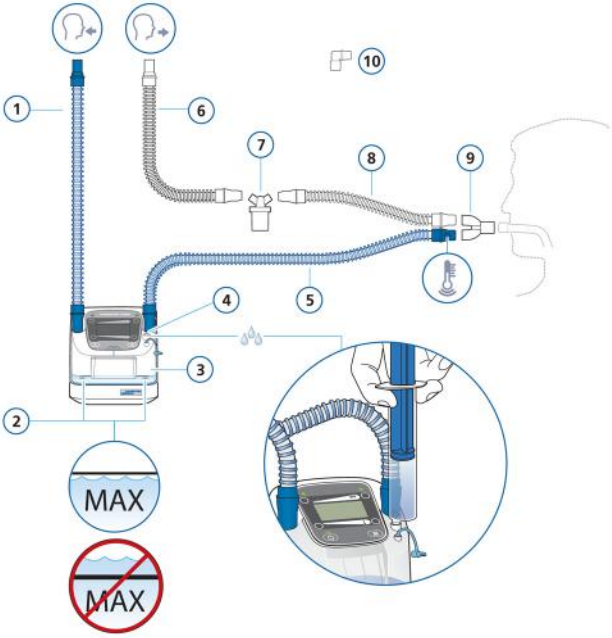
Instructions for use
Gebrauchsanweisung
Instructions d'utilisation
Instrucciones de uso
Istruzioni per l'uso
Instruções de uso
使用说明
使用説明書
Инструкции по эксплуатации
Kullanım talimatları

REF 260188

PN 624766/02 | 2015-10-23

CE 0197

HAMILTON MEDICAL
Intelligent Ventilation since 1983



1 Inspiratory limb (blue) to humidifier
Inspirationsschenkel (blau) zum Befeuchter
Branche inspiratoire (bleue) vers l'humidificateur
Rama inspiratoria (azul) hacia el humidificador
Alça inspiratória (azul) para umidificador
Branca inspiratoria (blu) all'umidificatore
连接至湿化器的吸气肢（蓝色）
吸気肢（青）を加湿器へ
Патрубок вдоха (голубой), подсоединяемый к увлажнителю.
Nemlendiriciye giden inspiratuvar parça (mavi)

2 MAX filling level mark. *Do not exceed this level.*
Füllstandsmarkierung (MAX). *Dieser Füllstand darf nicht überschritten werden.*
Repère du niveau de remplissage MAX. *Ne pas dépasser ce niveau.*
Marca de nivel de llenado MAX. *No superar este límite.*
Marca do nível de enchimento MAX. *Não exceder este nível.*
Simbolo del livello di riempimento MAX. *Non superare questo livello.*
最高水位标识。*不得超过该水位线。*
最高補充レベルマーク *このラインを超えないようにしてください。*
Отметка максимального уровня заполнения. *Не превышайте его.*
Dolum seviyesi işareti MAX. *Bu seviyeyi geçmeyin.*

3 Water chamber
Befeuchterkammer
Réservoir d'eau
Cámara de agua
Câmara de água
Camera dell'acqua
水箱
給水チャンバー
Водный резервуар
Su haznesi

4 Water fill port and stopper. *Ensure the cap is closed during operation.*
Wasserfüllanschluss und Stopfen. *Stellen Sie sicher, dass die Kappe während des Betriebs angebracht ist.*
Port et système de fermeture du réservoir d'eau. *Vérifier que le bouchon est fermé au cours de l'opération.*
Puerto de llenado de agua y tapón. *Compruebe que la tapa esté puesta durante el funcionamiento.*
Porta de enchimento de água e tampão. *Assegurar que a tampa está fechada durante a operação.*
Porta di riempimento dell'acqua e tappo. *Assicurarsi che il tappo sia chiuso durante il funzionamento.*
注水口和堵水塞。*请确保在设备运行过程中塞上盖帽。*
給水ポートとストッパー。*使用時はキャップを閉じてください。*
Канал заполнения водой и заглушка. *Во время работы устройства крышка должна быть закрыта.*
Su dolum portu ve tıkaç. *Cihaz çalışırken tıkaç kapağının kapalı olduğundan emin olun.*

5 Heated inspiratory limb (blue) with temperature probe to patient
Beheizter Inspirationsschenkel (blau) mit Temperatursensor zum Patienten
Branche inspiratoire chauffante (bleue) avec capteur de température vers le patient
Rama inspiratoria (azul) hacia el paciente, con calefacción y sensor de temperatura
Alça inspiratória aquecida (azul) com sonda de temperatura para o paciente
Branca inspiratoria riscaldata (blu) con sonda termica al paziente
带有温度探头的加热吸气肢（蓝色），连接至病人
加熱した吸気肢（青）と温度センサーを患者へ
Нагреваемый патрубок вдоха (голубой), подсоединяемый к пациенту стороной с температурным зондом.
Isıtmalı inspiratuvar parça (mavi), hastaya giden sıcaklık probu ile birlikte

6 Expiratory limb (short, white) to ventilator
Exspirationsschenkel (kurz, weiß) zum Beatmungsgerät
Branche expiratoire (courte, blanche) vers le ventilateur
Rama espiratoria (corta, blanca) hacia el respirador
Alça expiratória (curta, branca) para o respirador
Branca espiratoria (corta, bianca) al ventilatore
连接至呼吸机的呼气肢（短、白色）
呼気肢（ショート、白）を人工呼吸器へ
Патрубок выдоха (короткий, белый), подсоединяемый к аппарату ИВЛ
Ventilatöre giden ekspiratuvar parça (kısa, beyaz)

7 Water trap, 22M/22M
Wasserfalle, 22M/22M
Piège à eau, 22M/22M
Colector de agua, 22 M/22 M
Retentor de água, 22M/22M
Raccogli condensa, 22M/22M
集水杯，22M/22M
ウォータートラップ、22M/22M
Влагосборник, штекерные разъемы 22 мм / 22 мм.
Su kapanı, 22M/22M

8 Expiratory limb (long, white) from patient
Exspirationsschenkel (lang, weiß) vom Patienten
Branche expiratoire (longue, blanche) partant du patient
Rama espiratoria (larga, blanca) desde el paciente
Alça expiratória (longa, branca) do paciente
Branca espiratoria (lunga, bianca) dal paziente
连接自病人的呼气肢（长、白色）
呼気肢（ロング、白）を患者から
Патрубок выдоха (длинный, белый), подсоединяемый со стороны «от пациента»
Hastadan gelen ekspiratuvar parça (uzun, beyaz)

9 Y-piece, 22M/22M/15F
Y-Stück, 22M/22M/15F
Pièce en Y, 22M/22M/15F
Pieza en Y, 22 M/22 M/15 H
Peça em "Y", 22M/22M/15F
Raccordo a Y, 22M/22M/15F
Y 形管，22M/22M/15F
Y ピース、22M/22M/15F
У-образный коннектор, штекерный (22 мм) / штекерный (22 мм) / гнездовой (15 мм) разъемы.
Y parçası, 22M/22M/15F

10 Adapter, 90°, 22M/15F/22F (optional)
Adapter, 90°, 22M/15F/22F (optional)
Adaptateur, 90°, 22M/15F/22F (en option)
Adaptador, 90°, 22 M/15 H/22 H (opcional)
Adaptador, 90°, 22M/15F/22F (opcional)
Adattatore, 90 °, 22M/15F/22F (opzionale)
接口，90°，22M/15F/22F（选配件）
アダプター、90°、22M/15F/22F（オプション）
Адаптер, 90°, штекерный (22 мм) / гнездовой (15 мм) / гнездовой (22 мм) разъемы (дополнительный).
Adaptör, 90°, 22M/15F/22F (isteğe bağlı)

⚠ WARNING

- **The breathing set including the water chamber must be cleaned, disinfected, and autoclaved before use.**
- **Follow the instructions in the *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) to clean and sterilize the product.**
- **Inappropriate reprocessing may cause malfunction of the product. The use of ETO gas may lead to increased cancer rates in patients and users. Hamilton Medical does not warrant the proper functioning of breathing sets if they are cleaned or reused by the user in an inappropriate manner.**
- **The breathing set must be set up and used by trained medical professionals.**
- **The breathing set must not be covered by any objects, such as sheets, towels, etc.**
- **Route the breathing circuit without tension and without any kinks from the humidifier to the patient, and protect against unintended influences.**
- **Do not use heated breathing circuits without existing gas flow. If the gas supply is interrupted, the humidifier must be switched off or put into standby mode.**
- **Heated limbs must not be placed directly on the patient's skin. Attach breathing circuits or tubing holders appropriately to avoid mechanical forces on the ET tube.**
- **Only fill the humidifier chamber with sterile, demineralized water that meets the hospital's hygiene requirements.**
- **Do not operate the device if the water level in the humidifier chamber exceeds the marked maximum (MAX).**
- **Check the water level regularly and refill if needed.**
- **The humidifier must always be positioned below patient level. Do not operate the humidifier at an angle in excess of 10°.**
- **Do not use the breathing set with other humidifiers.**
- **Do not add any drugs or medication directly to the water in the water chamber. If the HAMILTON-H900 is used in combination with any medical gases or nebulized medications, follow the instruction for use of the supplied application and make sure that it is suitable for use with active humidification.**
- **Do not touch the hot plate or the bottom of the chamber. The surfaces can reach a temperature of over 85°C. These hot surfaces radiate heat.**

⚠ CAUTION

- *Check the breathing set for damage prior to use. Discard the breathing set if there is any sign of damage such as cracks or discoloration.*
- *Handle used breathing circuits and humidifier chambers as contaminated goods according to local laws and regulations or hospital internal procedures.*
- *If the ambient temperature is outside the recommended range (18°C to 26°C), physiological humidity levels may not be achieved. Humidification performance is not guaranteed outside of this range.*

NOTICE

- Read also the operating instructions of the HAMILTON-H900 humidifier.
- Before using the breathing set on the patient, a tightness test must be carried out. If this test fails, it may be repeated once. After two consecutive failed tests, the breathing set must be replaced by a new one.
- The refill water should be no warmer than 37°C.

- Check the stability of all connections prior to use.

Intended use

The HAMILTON-BC8022-A breathing set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of adult and pediatric patients.

Terminology

The *breathing circuit* comprises the tubing (connection limb, wall-heated inspiratory limb, short expiratory limb, long expiratory limb), water trap, and Y-piece.

The *breathing set* comprises the breathing circuit and the humidifier chamber.

Connecting the HAMILTON-BC8022-A breathing set to the HAMILTON-H900

Ventilator connection

Note that the limb connectors on the humidifier combine electrical connections with breathing circuit connectors. Ensure proper orientation of electrical contacts on the breathing circuit connectors to match the connecting element on the humidifier.

See the full setup on the front page of these *Instructions for use*.

To connect the breathing set

1 Insert the humidifier chamber completely into the humidifier until it clicks into place.
   To remove it, pull the humidifier chamber out of the humidifier.
2 Connect the inspiratory connection limb (short blue limb) first to the humidifier chamber, then to the ventilator at the inspiratory outlet.
3 Connect the expiratory limbs (white) to the water trap and connect the shorter limb to the ventilator expiratory valve.
4 Connect the inspiratory limb (long blue limb) first to the humidifier chamber, and then to the Y-piece.
5 Manually fill the humidification chamber using a syringe.
   Be sure not to fill the chamber above the marked MAX level.
6 Replace the blue water fill port cap. Be sure the cap is closed during humidifier operation.

Cleaning, disinfection, and reprocessing

For detailed reprocessing instructions, use the information provided in the *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767). The guide is available online at **www.hamilton-medical.ch**, in **MyHamilton**. Registration is free.

A printed copy can be sent to you upon request; contact your Hamilton Medical technical representative.

Disposal

Used breathing sets may be contaminated. Dispose of all parts according to your institution's protocol. Follow all local, state, and federal regulations with respect to environmental protection.

Technical data

Flow range	Up to 120 l/min
Connectors	Conical according to ISO 5356-1
Compliance of dual limb heated breathing sets	< 1 ml/cmH2O/m
Compressible volume	400 ml
Water volume (max)	220 ml
Flow resistance at 30 l/min (nominal flow) Inspiration Expiration	 0.3 cmH2O 0.3 cmH2O
Gas leakage	< 50 ml/min
Maximum operating pressure in humidifier chamber	10 kPa
Circuit length	1.50 m (approx. 5 ft)
Compatibility	HAMILTON-H900 humidifier
Operating conditions Atmospheric pressure	Recommended: 18°C to 26°C 61 to 106 kPa
Maximum operating duration	28 days

⚠ VORSICHT

- **Das Beatmungsschlauchset inkl. Befeuchterkammer muss vor dem Gebrauch gereinigt, desinfiziert und autoklaviert werden.**
- **Befolgen Sie die Anweisungen im *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A Aufbereitungsvorschrift), um das Produkt zu reinigen und zu sterilisieren.**
- **Eine unsachgemäße Aufbereitung kann zu einer Fehlfunktion des Produktes führen. Außerdem kann der Einsatz von ETO-Gas das Krebsrisiko von Patienten und Anwendern erhöhen. Hamilton Medical übernimmt keine Garantie für die ordnungsgemäße Funktion von Beatmungsschlauchsets, falls diese vom Anwender unsachgemäß gereinigt und wiederverwendet werden.**
- **Das Beatmungsschlauchset muss von ausgebildetem medizinischem Fachpersonal konfiguriert und verwendet werden.**
- **Das Beatmungsschlauchset darf nicht mit Gegenständen wie Laken, Handtüchern usw. abgedeckt werden.**
- **Führen Sie das Beatmungsschlauchsystem spannungsfrei und ohne Knicke vom Befeuchter zum Patienten und schützen Sie es gegen unerwünschte Einflüsse von Außen.**
- **Verwenden Sie beheizte Beatmungsschlauchsysteme nicht ohne vorliegenden Gasflow. Wenn die Gasversorgung unterbrochen ist, muss der Befeuchter abgeschaltet oder in den Standby-Modus versetzt werden.**
- **Beheizte Schenkel dürfen nicht direkt auf der Haut des Patienten platziert werden. Befestigen Sie die Beatmungsschlauchsysteme oder Schlauchhalterungen ordnungsgemäß, um eine mechanische Krafteinwirkung auf den ET-Tubus zu verhindern.**
- **Befüllen Sie die Befeuchterkammer nur mit sterilem, entmineralisiertem Wasser, das die Hygieneanforderungen des Krankenhauses erfüllt.**
- **Betreiben Sie das Gerät nicht, wenn der Wasserstand in der Befeuchterkammer den markierten maximalen Füllstand (MAX) übersteigt.**
- **Überprüfen Sie den Wasserstand regelmäßig und füllen Sie bei Bedarf Wasser nach.**
- **Der Befeuchter muss stets unter der Höhe des Patienten positioniert werden. Betreiben Sie den Befeuchter nicht in einem Winkel über 10°.**
- **Verwenden Sie das Beatmungsschlauchset nicht mit anderen Befeuchtern.**
- **Füllen Sie keine Arzneimittel oder Medikamente direkt in die Befeuchterkammer. Wenn der HAMILTON-H900 in Kombination mit medizinischen Gasen oder vernebelten Medikamenten verwendet wird, befolgen Sie die Gebrauchsanweisung der gelieferten Anwendung und stellen Sie sicher, dass sie für den Einsatz mit aktiver Befeuchtung geeignet ist.**
- **Berühren Sie weder die Heizplatte noch die Unterseite der Kammer. Die Oberflächen können eine Temperatur von über 85 °C erreichen. Diese heißen Oberflächen strahlen Wärme ab.**

⚠ VORSICHT

- *Untersuchen Sie das Beatmungsschlauchset vor dem Gebrauch auf Schäden. Entsorgen Sie das Beatmungsschlauchset, wenn es Anzeichen von Schäden wie Risse oder Verfärbungen aufweist.*
- *Gebrauchte Beatmungsschlauchsysteme und Befeuchterkammern sind gemäß den lokalen Gesetzen und Vor-*

schriften oder den krankenhausinternen Verfahren als kontaminierte Produkte zu behandeln.

- *Wenn die Umgebungstemperatur außerhalb des empfohlenen Bereichs (18 °C bis 26 °C) liegt, können die physiologischen Feuchtigkeitswerte möglicherweise nicht erreicht werden. Die Befeuchtungsleistung ist außerhalb dieses Bereichs nicht gewährleistet.*

HINWEIS

- Lesen Sie auch die Bedienungsanleitung zum HAMILTON-H900 Befeuchter.
- Vor der Verwendung des Beatmungsschlauchsets beim Patienten muss ein Dichtheitstest durchgeführt werden. Wird der Test nicht bestanden, kann er einmal wiederholt werden. Wenn der Test zweimal in Folge nicht bestanden wird, muss das Beatmungsschlauchset durch ein neues ersetzt werden.
- Das Wasser zum Nachfüllen darf maximal 37 °C warm sein.
- Überprüfen Sie die Stabilität aller Verbindungen vor der Verwendung.

Vorgesehener Verwendungszweck

Das HAMILTON-BC8022-A Beatmungsschlauchset ist für die Verwendung zusammen mit kompatiblen Atemgasbefeuchtern von Hamilton Medical bei der invasiven und nichtinvasiven maschinellen Beatmung von erwachsenen und pädiatrischen Patienten vorgesehen.

Terminologie

Das *Beatmungsschlauchsystem* umfasst die Schläuche (Verbindungsschenkel, wandbeheizter Inspirationsschenkel, kurzer Exspirationsschenkel, langer Exspirationsschenkel), die Wasserfalle und das Y-Stück.

Das *Beatmungsschlauchset* umfasst das Beatmungsschlauchsystem und die Befeuchterkammer.

Anschließen des HAMILTON-BC8022-A Beatmungsschlauchsets am HAMILTON-H900

Anschluss am Beatmungsgerät

Beachten Sie, dass alle Schenkelanschlüsse am Befeuchter elektrische Anschlüsse mit Anschlüssen am Beatmungsschlauchsystem kombinieren. Stellen Sie sicher, dass die elektrischen Kontakte der Anschlüsse am Beatmungsschlauchsystem korrekt ausgerichtet sind, so dass sie dem jeweiligen Anschlusselement am Befeuchter entsprechen.

Die vollständige Konfiguration ist auf der Vorderseite dieser *Gebrauchsanweisung* abgebildet.

So schließen Sie das Beatmungsschlauchset an

1 Setzen Sie die Befeuchterkammer vollständig in den Befeuchter ein, bis sie hörbar einrastet.

  Ziehen Sie die Befeuchterkammer aus dem Befeuchter, um sie zu entfernen.

2 Schließen Sie den Inspirationsverbindungsschenkel (kurzer blauer Schenkel) zuerst an der Befeuchterkammer und dann am Inspirationsauslass des Beatmungsgerätes an.

3 Schließen Sie die Exspirationsschenkel (weiß) an der Wasserfalle an und verbinden Sie den kürzeren Schenkel mit dem Exspirationsventil des Beatmungsgerätes.

4 Schließen Sie den Inspirationsschenkel (langer blauer Schenkel) zuerst an der Befeuchterkammer und dann am Y-Stück an.

5 Befüllen Sie die Befeuchterkammer manuell mit einer Spritze.

  Stellen Sie sicher, dass die Befeuchterkammer nicht über den markierten maximalen Füllstand (MAX) hinaus befüllt wird.

6 Bringen Sie die blaue Kappe wieder am Wasserfüllanschluss an. Stellen Sie sicher, dass die Kappe während des Befeuchterbetriebs angebracht ist.

Reinigung, Desinfektion und Aufbereitung

Detaillierte Anweisungen zur Aufbereitung finden Sie im *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A Aufbereitungsvorschrift). Die Vorschrift steht online auf der Website **www.hamilton-medical.ch** unter

„MyHamilton“ zur Verfügung. Die Registrierung ist kostenlos.

Auf Anfrage ist auch ein gedrucktes Exemplar erhältlich. Wenden Sie sich dazu an Ihren Ansprechpartner für technische Fragen bei Hamilton Medical.

Entsorgung

Gebrauchte Beatmungsschlauchsets können kontaminiert sein. Entsorgen Sie alle Teile gemäß den Richtlinien Ihres Krankenhauses. Befolgen Sie alle gesetzlichen Bestimmungen hinsichtlich des Umweltschutzes.

Technische Daten

Flowbereich	Bis zu 120 l/min
Anschlüsse	Konisch gemäß ISO 5356-1
Compliance von beheizten Beatmungsschlauchsets mit zwei Schenkeln	< 1 ml/cmH2O/m
Komprimierbares Volumen	400 ml
Wasservolumen (max.)	220 ml
Flow-Resistance bei 30 l/min (nomineller Flow) Inspiration Exspiration	 0,3 cmH2O 0,3 cmH2O
Gasleckage	< 50 ml/min
Maximaler Betriebsdruck in der Befeuchterkammer	10 kPa
Schlauchsystemlänge	1,50 m
Kompatibilität	HAMILTON-H900 Befeuchter
Betriebsbedingungen Luftdruck	Empfohlen: 18 °C bis 26 °C 61 bis 106 kPa
Maximale Betriebsdauer	28 Tage

⚠ PRÉCAUTION

- **Le kit de circuit respiratoire comprenant le réservoir d'eau doit être nettoyé, désinfecté et autoclavé avant utilisation.**
- **Suivez les instructions du *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guide de retraitement HAMILTON-BC8022-A) pour nettoyer et stériliser le produit.**
- **Un retraitement inapproprié peut provoquer un dysfonctionnement du produit. L'utilisation d'oxyde d'éthylène peut générer une augmentation des taux de cancer chez les patients et les utilisateurs. Hamilton Medical ne garantit pas le bon fonctionnement des kits de circuit respiratoire s'ils sont nettoyés ou réutilisés par l'utilisateur de manière inappropriée.**
- **Le kit de circuit respiratoire doit être configuré et utilisé par des professionnels de la santé qualifiés.**
- **Le kit de circuit respiratoire ne doit pas être recouvert par des draps, des serviettes, etc.**
- **Installer le circuit respiratoire en veillant à ne créer aucune tension ni torsion entre l'humidificateur et le patient, et le protéger de toute manipulation malencontreuse.**
- **Ne pas utiliser de circuits respiratoires chauffants sans débit de gaz. Si l'alimentation en gaz est interrompue, l'humidificateur doit être éteint ou mis en mode Veille.**
- **Les branches chauffantes ne doivent pas être mises en contact direct avec la peau du patient. Fixer les circuits respiratoires ou les supports de tubulures de manière à ne pas exercer de forces mécaniques sur la sonde d'intubation.**
- **Remplir le réservoir d'eau uniquement avec de l'eau stérile déminéralisée répondant aux exigences d'hygiène de l'hôpital.**
- **Ne pas faire fonctionner le dispositif si le niveau d'eau du réservoir d'eau dépasse le niveau maximum (MAX) indiqué.**
- **Vérifier régulièrement le niveau d'eau et ajouter de l'eau si nécessaire.**
- **L'humidificateur doit toujours être positionné en dessous du niveau du patient. Ne pas faire fonctionner l'humidificateur à un angle de plus de 10°.**
- **Ne pas utiliser le kit de circuit respiratoire avec d'autres humidificateurs.**
- **Ne pas ajouter de médicament directement dans l'eau du réservoir d'eau. Si le HAMILTON-H900 est utilisé avec des gaz de qualité médicale ou des médicaments nébulisés, respecter les instructions d'utilisation correspondantes et s'assurer que ces procédures sont compatibles avec une humidification active.**
- **Ne pas toucher la plaque chaude ou le fond du réservoir. Les surfaces peuvent atteindre une température de plus de 85 °C. Ces surfaces chaudes génèrent de la chaleur.**

⚠ PRÉCAUTION

- *Vérifier que le kit de circuit respiratoire n'est pas endommagé avant toute utilisation. Jeter le kit de circuit respiratoire s'il semble endommagé (fissures ou décoloration, par exemple).*
- *Manipuler les circuits respiratoires et les réservoirs d'eau usagés comme des produits contaminés, conformément à la législation et aux règlements locaux ou aux procédures internes de l'hôpital.*
- *Si la température ambiante se situe en dehors de la plage recommandée (18 °C à 26 °C), les niveaux d'humidité physiologique peuvent ne pas être atteints. Les performances d'humidification ne sont pas garanties en dehors de cette plage.*

REMARQUE

- Lire également les instructions d'utilisation de l'humidificateur HAMILTON-H900.
- Effectuer impérativement un test d'étanchéité avant d'utiliser le kit de circuit respiratoire sur le patient. Le test peut être répété une fois en cas d'échec. Après deux échecs consécutifs, le kit du circuit respiratoire doit être remplacé par un nouveau kit.
- L'eau de remplissage ne doit pas excéder une température de plus de 37 °C.
- Vérifier que tous les raccords sont stables avant toute utilisation.

Usage prévu

Le kit de circuit respiratoire HAMILTON-BC8022-A est destiné à être utilisé avec des humidificateurs de gaz respiratoire compatibles Hamilton Medical dans le cadre d'une ventilation mécanique invasive et non invasive chez les adultes et les enfants.

Terminologie

Le *circuit respiratoire* comprend la tubulure (branche de raccord, branche inspiratoire à paroi chauffante, branche expiratoire courte, branche expiratoire longue), le piège à eau et la pièce en Y.

Le *kit de circuit respiratoire* comprend le circuit respiratoire et le réservoir d'eau.

Raccord du kit de circuit respiratoire HAMILTON-BC8022-A à l'humidificateur HAMILTON-H900

Connexion du ventilateur

Noter que les connecteurs des branches de l'humidificateur combinent des connexions électriques avec des connecteurs du circuit respiratoire. Vérifier que les contacts électriques sont correctement orientés sur les connecteurs du circuit respiratoire pour correspondre à l'élément de connexion de l'humidificateur.

Voir la configuration globale sur la page de garde des présentes *instructions d'utilisation*.

Pour connecter le kit de circuit respiratoire

1. Insérez le réservoir d'eau entièrement dans l'humidificateur jusqu'à ce qu'il s'enclenche.
   Pour l'enlever, sortez le réservoir d'eau de l'humidificateur.
2. Connectez tout d'abord la branche de raccord inspiratoire (branche bleue et courte) au réservoir d'eau, puis au ventilateur au niveau du port inspiratoire.
3. Connectez les branches expiratoires (blanches) au piège à eau et connectez la branche plus courte à la valve expiratoire du ventilateur.
4. Connectez tout d'abord la branche inspiratoire (branche bleue et longue) au réservoir d'eau, puis à la pièce en Y.
5. Remplissez manuellement le réservoir d'eau à l'aide d'une seringue.
   Veillez à ne pas remplir le réservoir au-dessus du niveau MAX.
6. Remettez le bouchon bleu du port de remplissage d'eau. Vérifiez que le bouchon est fermé au cours du fonctionnement de l'humidificateur.

Nettoyage, désinfection et retraitement

Pour plus de détails sur les instructions de retraitement, reportez-vous aux informations fournies dans le *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guide de retraitement HAMILTON-BC8022-A). Le guide est disponible en ligne à l'adresse **www.hamilton-medical.ch**, dans la rubrique **MyHamilton**. L'inscription est gratuite.

Une copie imprimée peut être envoyée sur simple demande. Il vous suffit de contacter votre représentant technique Hamilton Medical.

Mise au rebut

Les kits de circuit respiratoire usagés peuvent être contaminés. La mise au rebut de toutes les pièces doit être conforme au protocole en vigueur dans votre établissement. Suivez toutes les réglementations locales et nationales en matière de protection de l'environnement.

Données techniques

Plage de débit	Jusqu'à 120 l/min
Connecteurs	Coniques en conformité avec la norme ISO 5356-1
Compliance des kits de circuit respiratoire chauffant à deux branches	< 1 ml/cmH2O/m
Volume compressible	400 ml
Volume d'eau (max)	220 ml
Résistance au débit à 30 l/min (débit nominal) Inspiration Expiration	 0,3 cmH2O 0,3 cmH2O
Fuite de gaz	< 50 ml/min
Pression de fonctionnement maximum dans le réservoir d'eau	10 kPa
Longueur du circuit	1,50 m
Compatibilité	Humidificateur HAMILTON-H900
Conditions de fonctionnement	Recommandée : 18 à 26 °C
Pression atmosphérique	61 à 106 kPa
Durée de fonctionnement maximum	28 jours

⚠ ADVERTENCIA

- **Antes del uso, el equipo respiratorio, cámara de agua incluida, debe limpiarse, desinfectarse y esterilizarse en autoclave.**
- **Para limpiar y esterilizar el producto, siga las instrucciones de la *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guía de reprocesamiento del HAMILTON-BC8022-A).**
- **El reprocesamiento inadecuado provoca fallos en el producto. El uso del gas ETO puede provocar un aumento de los casos de cáncer tanto en pacientes como en usuarios. Hamilton Medical no garantiza el correcto funcionamiento de los equipos respiratorios si el usuario los limpia o reprocesa inadecuadamente.**
- **El equipo respiratorio lo debe configurar y utilizar personal médico cualificado.**
- **No debe cubrirse el equipo respiratorio con ningún objeto, como sábanas o toallas.**
- **Asegúrese de que no se produzcan dobleces ni tensión en el circuito respiratorio al conectarlo del humidificador al paciente y protéjalo de efectos no intencionados.**
- **No utilice circuitos respiratorios con calefacción sin flujo de gas. Si se interrumpe el suministro de gas, el humidificador debe apagarse o pasar al modo standby.**
- **Las ramas con calefacción no deben colocarse directamente sobre la piel del paciente. Conecte los circuitos respiratorios o los soportes de los tubos correctamente para evitar que se produzcan fuerzas mecánicas en el tubo ET.**
- **La cámara de agua solo debe llenarse con agua estéril y desmineralizada que cumpla los requisitos de higiene del hospital.**
- **No ponga el dispositivo en funcionamiento si el nivel de agua de la cámara supera el máximo indicado (MAX).**
- **Compruebe habitualmente el nivel de agua y añada en caso necesario.**
- **El humidificador siempre debe colocarse por debajo del nivel del paciente. El humidificador no debe funcionar en un ángulo superior a 10°.**
- **No utilice el equipo respiratorio con otros humidificadores.**
- **No añada fármacos ni medicamentos directamente a la cámara de agua. Si se usa el HAMILTON-H900 en combinación con cualquier gas médico o medicamento nebulizado, siga las instrucciones de uso de la aplicación suministrada y asegúrese de que sea adecuada para el uso con humidificación activa.**
- **No toque la placa calefactora ni la parte inferior de la cámara. Estas superficies pueden alcanzar temperaturas superiores a 85 °C e irradian calor.**

AVISO

- *Compruebe si el equipo respiratorio presenta daños antes de utilizarlo. En caso de visualizar algún daño, como grietas o decoloración, deseche el equipo respiratorio.*
- *Manipule los circuitos respiratorios y las cámaras de agua usados como productos contaminados según la normativa y legislación locales o los procedimientos internos del hospital.*
- *Si la temperatura ambiente no se encuentra en el intervalo recomendado (de 18 °C a 26 °C), pueden no alcanzarse los niveles de humedad fisiológica. No se garantiza la eficacia de la humidificación fuera de este intervalo.*

AVISO

- Lea también las instrucciones de funcionamiento del humidificador HAMILTON-H900.
- Antes de utilizar el equipo respiratorio en el paciente, debe realizarse una prueba de estanqueidad. En caso de fallo, puede repetirse una vez. Si la prueba falla dos veces, debe cambiarse el equipo respiratorio por uno nuevo.
- El agua de recarga no debe superar los 37 °C.
- Compruebe la fijación de todas las conexiones antes de utilizar el equipo.

Uso previsto

El equipo respiratorio HAMILTON-BC8022-A está diseñado para su uso junto con humidificadores de gas respiratorio compatibles de Hamilton Medical durante la ventilación mecánica invasiva y no invasiva de pacientes adultos y pediátricos.

Terminología

El *circuito respiratorio* está formado por los tubos (rama de conexión, rama inspiratoria con calefacción en el tubo, rama espiratoria corta, rama espiratoria larga), el colector de agua y la pieza en Y.

El *equipo respiratorio* está formado por el circuito respiratorio y la cámara de agua.

Conexión del equipo respiratorio HAMILTON-BC8022-A al HAMILTON-H900

Conexión del respirador

Tenga en cuenta que todos los conectores de las ramas del humidificador combinan conexiones eléctricas con conectores del circuito respiratorio. Asegúrese de que orienta correctamente los contactos eléctricos de los conectores del circuito respiratorio de manera que coincidan con el elemento de conexión del humidificador.

En la portada de estas *instrucciones de uso* aparece todo el equipo.

Para conectar el equipo respiratorio

1. Inserte completamente la cámara en el humidificador hasta que suene un clic y quede fijada en su sitio.

   Para extraerla, tire de la cámara hacia fuera del humidificador.
2. Conecte la rama inspiratoria de conexión (corta y azul), primero a la cámara de agua y después al respirador por la salida inspiratoria.
3. Conecte las ramas espiratorias (blancas) al colector de agua y la rama más corta a la válvula espiratoria del respirador.
4. Conecte la rama inspiratoria (larga y azul), primero a la cámara de agua y después a la pieza en Y.
5. Llene manualmente la cámara de agua con una jeringa.

   Asegúrese de no llenar la cámara por encima del nivel denominado MAX.
6. Coloque la tapa del puerto de llenado de agua azul. Compruebe que la tapa esté puesta durante la humidificación.

Limpieza, desinfección y reprocesamiento

Si desea instrucciones detalladas sobre el reprocesamiento, consulte la *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guía de reprocesamiento del HAMILTON-BC8022-A). La encontrará en línea en **www.hamilton-medical.ch**, **MyHamilton**. El registro es gratuito.

Póngase en contacto con el servicio de asistencia técnica de Hamilton Medical para solicitar el envío de una copia impresa.

Eliminación

Los equipos respiratorios usados pueden estar contaminados. Deseche todos los componentes según el protocolo de su centro sanitario. Cumpla todas las normativas locales, estatales y federales referentes a la protección medioambiental.

Datos técnicos

Intervalo de flujo	Hasta 120 l/min
Conectores	Cónicos según la norma ISO 5356-1
Compliance de los equipos respiratorios con calefacción en las dos ramas	< 1 ml/cmH2O/m
Volumen comprimible	400 ml
Volumen de agua (máx.)	220 ml
Resistencia al flujo a 30 l/min (flujo nominal) Inspiración Espiración	 0,3 cmH2O 0,3 cmH2O
Fuga de gas	< 50 ml/min
Presión de funcionamiento máxima en la cámara de agua	10 kPa
Longitud del circuito	1,50 m
Compatibilidad	Humidificador HAMILTON-H900
Condiciones de funcionamiento	Recomendadas: de 18 °C a 26 °C
Presión atmosférica	De 61 a 106 kPa
Duración máxima en funcionamiento	28 días

⚠ AVISO

- **O kit de respiração, bem como a câmara de água, têm que ser limpos, desinfetados e autoclavados antes de serem utilizados.**
- **Siga as instruções no *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guia de reprocessamento HAMILTON-BC8022-A) para limpar e esterilizar o produto.**
- **Um reprocessamento inapropriado pode causar um mau funcionamento do produto. O uso de gás ETO pode levar ao aumento das taxas de câncer nos pacientes e usuários. A Hamilton Medical não garante o funcionamento adequado de kits de respiração se eles forem limpos e reutilizados pelo usuário de forma inapropriada.**
- **O kit de respiração deve ser configurado e utilizado por profissionais de saúde treinados.**
- **O kit de respiração não pode ser coberto por nenhum objeto como, por exemplo, lençóis, toalhas, etc.**
- **Encaminhe o circuito de respiração do umidificador para o paciente sem tensão nem dobras, e proteja contra influências não pretendidas.**
- **Não utilize circuitos de respiração aquecidos sem o fluxo do gás instalado. Se o fornecimento de gás for interrompido, o umidificador deve ser desligado ou colocado no modo standby.**
- **As alças aquecidas não devem ser colocadas diretamente sobre a pele do paciente. Fixe os circuitos de respiração ou os suportes de tubos de forma adequada para evitar forças mecânicas no tubo ET.**
- **Abasteça a câmara de água somente com água estéril, desmineralizada e em conformidade com as exigências do hospital em termos de higiene.**
- **Não opere o dispositivo se o nível de água na câmara de água exceder o máximo assinalado (MÁX).**
- **Verifique regularmente o nível de água e, se necessário, reabasteça.**
- **O umidificador deverá estar sempre posicionado abaixo do nível do paciente. Não opere o umidificador a um ângulo superior a 10°.**
- **Não utilize o kit de respiração com outros umidificadores.**
- **Não adicione drogas ou medicamentos diretamente à água na câmara de água. Se o HAMILTON-H900 for usado em conjunto com gases medicinais ou medicamentos nebulizados, siga as instruções de uso da aplicação fornecida e certifique-se de que se adequa à utilização em conjunto com umidificação ativa.**
- **Não toque a placa quente ou o fundo da câmara. As superfícies podem atingir uma temperatura superior a 85 °C. Estas superfícies quentes irradiam calor.**

⚠ ADVERTÊNCIA

- *Verifique o kit de respiração quanto a danos antes do uso. Descarte o kit de respiração se houver qualquer sinal de danos, tais como rachaduras ou descoloração.*
- *Manuseie os circuitos de respiração e as câmaras de água usados como produtos contaminados de acordo com as leis e regulamentos locais ou os procedimentos internos do hospital.*
- *Se a temperatura ambiente se encontrar fora do intervalo recomendado (18 °C a 26 °C) pode não ser possível alcançar os níveis de umidade fisiológica. Fora desse intervalo não é possível assegurar o desempenho de umidificação.*

OBSERVAÇÃO

- Leia também as instruções de operação do umidificador HAMILTON-H900.

- Antes de usar o kit de respiração no paciente, é necessário efetuar um teste de vazamento. Se esse teste falhar, ele poderá ser repetido uma vez. Se o teste falhar após duas tentativas consecutivas, o kit de respiração deverá ser substituído por um novo.
- A água de abastecimento não deverá estar a uma temperatura superior a 37 °C.
- Verifique a estabilidade de todas as conexões antes do uso.

Uso pretendido

O kit de respiração HAMILTON-BC8022-A deve ser utilizado juntamente com umidificadores do gás respiratório Hamilton Medical compatíveis durante a ventilação mecânica invasiva e não invasiva de pacientes adultos e pediátricos.

Terminologia

O *circuito de respiração* inclui o tubo (alça de conexão, alça inspiratória de parede aquecida, alça expiratória curta, alça expiratória longa), o retentor de água e a peça em "Y".

O *kit de respiração* inclui o circuito de respiração e a câmara de água.

Conexão do kit de respiração HAMILTON-BC8022-A ao HAMILTON-H900

Conexão do respirador

Observe que os conectores da alça no umidificador combinam conexões elétricas com conectores do circuito de respiração. Assegure a orientação adequada dos contatos elétricos nos conectores do circuito de respiração para que correspondam ao elemento de conexão no umidificador.

Veja a configuração completa na primeira página destas *Instruções de uso*.

Para conectar o kit de respiração

1 Insira a câmara de água completamente no umidificador até encaixar.
Para retirá-la, puxe a câmara de água para fora do umidificador.

2 Conecte a alça de conexão inspiratória (alça azul curta) primeiro à câmara de água e depois ao respirador na saída inspiratória.

3 Conecte as alças expiratórias (brancas) ao retentor de água e conecte a alça mais curta à válvula expiratória do respirador.

4 Conecte a alça inspiratória (alça azul longa) primeiro à câmara de água e depois à peça em "Y".

5 Encha a câmara de água manualmente, utilizando uma seringa.
Certifique-se que não enche a câmara acima do nível MÁX assinalado.

6 Substitua a tampa azul da porta do enchimento de água. Certifique-se que, durante a operação do umidificador, a tampa está fechada.

Limpeza, desinfecção e reprocessamento

Para instruções de reprocessamento detalhadas, consulte o *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guia de reprocessamento HAMILTON-BC8022-A). O guia está disponível online, em **www.hamilton-medical.ch**, em **MyHamilton**. O registro é gratuito.

Também pode solicitar uma cópia impressa; contate seu representante de assistência técnica da Hamilton Medical.

Descarte

Os kits de respiração usados podem estar contaminados. Descarte todas as peças de acordo com o protocolo de sua instituição. Siga todos os regulamentos locais, estaduais ou federais em relação à proteção ambiental.

Dados técnicos

Intervalo de fluxo	Até 120 l/min
Conectores	Cônicos segundo ISO 5356-1
Complacência dos kits de respiração aquecidos de alça dupla	< 1 ml/cmH2O/m
Volume comprimível	400 ml
Volume da água (máx)	220 ml
Resistência ao fluxo a 30 l/min (fluxo nominal) Inspiração Expiração	 0,3 cmH2O 0,3 cmH2O
Vazamento de gás	< 50 ml/min
Pressão operacional máxima na câmara de água	10 kPa
Comprimento do circuito	1,50 m (aprox. 5 pés)
Compatibilidade	Umidificador HAMILTON-H900
Condições de funcionamento	Recomendado: 18 °C a 26 °C
Pressão atmosférica	61 a 106 kPa
Duração de funcionamento máxima	28 dias

⚠ ATTENZIONE

- **Il set circuito paziente, compresa la camera dell'acqua, deve essere pulito, disinfettato e sterilizzato in autoclave prima dell'uso.**
- **Per la pulizia e la disinfezione del prodotto, attenersi alle istruzioni indicate nella *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guida alla risterilizzazione di HAMILTON-BC8022-A).**
- **La risterilizzazione non corretta può causare il malfunzionamento del prodotto. L'uso di gas ETO può portare a un aumento dei casi di tumore nei pazienti e negli operatori. Hamilton Medical non garantisce il corretto funzionamento dei set circuito paziente nel caso in cui vengano puliti o riutilizzati dall'operatore in modo non appropriato.**
- **Il set circuito paziente deve essere predisposto e utilizzato da professionisti medici qualificati.**
- **Il set circuito paziente non deve essere coperto da oggetti, quali lenzuola, asciugamani, ecc.**
- **Far passare il circuito paziente, senza tirarlo eccessivamente né attorcigliarlo, dall'umidificatore al paziente e proteggerlo da fattori di disturbo involontari.**
- **Non utilizzare circuiti paziente riscaldati senza flusso di gas esistente. Se viene interrotta l'alimentazione del gas, l'umidificatore deve essere spento o messo nella modalità standby.**
- **Le branche riscaldate non devono essere posizionate direttamente sulla pelle del paziente. Collegare in modo appropriato i circuiti paziente o i supporti per tubi per evitare forze meccaniche sul tubo ET.**
- **Riempire la camera dell'acqua solo con acqua sterile, demineralizzata, che soddisfa i requisiti igienici dell'ospedale.**
- **Non utilizzare il dispositivo se il livello dell'acqua nella camera dell'acqua supera il livello massimo (MAX) contrassegnato.**
- **Controllare regolarmente il livello dell'acqua e riempire la camera, se necessario.**
- **L'umidificatore deve sempre essere posizionato al di sotto del livello del paziente. Non utilizzare l'umidificatore a un angolo superiore a 10 °.**
- **Non utilizzare il set circuito paziente con altri umidificatori.**
- **Non aggiungere farmaci di nessun tipo direttamente nell'acqua della camera dell'acqua. Se si utilizza HAMILTON-H900 in combinazione con gas medicali o farmaci nebulizzati, attenersi alle istruzioni per l'uso dell'applicazione fornita e assicurarsi che sia idonea all'utilizzo con l'umidificazione attiva.**
- **Non toccare la piastra calda o il fondo della camera. La temperatura delle superfici può superare gli 85 °C. Queste superfici calde irradiano calore.**

⚠ CAUTION

- *Prima dell'uso, controllare che il set circuito paziente non sia danneggiato. Eliminare il set circuito paziente, se risulta danneggiato, in presenza di crepe o scolorimento.*
- *Maneggiare i circuiti paziente e le camere dell'acqua usati come articoli contaminati secondo le leggi e le normative locali o le procedure interne dell'ospedale.*
- *Se la temperatura ambiente è al di fuori dell'intervallo raccomandato (da 18 °C a 26 °C), i livelli di umidità fisiologica possono non essere raggiunti. La capacità di umidificazione non è garantita al di fuori di questo intervallo.*

NOTICE

- Leggere anche le istruzioni operative dell'umidificatore HAMILTON-H900.

- Prima di utilizzare il set circuito paziente sul paziente, deve essere eseguito un test di tenuta. Se questo test ha esito negativo, può essere ripetuto una volta. Dopo due test consecutivi con esito negativo, il set circuito paziente deve essere sostituito con uno nuovo.
- La temperatura dell'acqua di riempimento non deve essere superiore a 37 °C.
- Prima dell'uso, controllare la stabilità di tutte le connessioni.

Uso previsto

Il set circuito paziente HAMILTON-BC8022-A è destinato a essere utilizzato insieme agli umidificatori per gas respiratori Hamilton Medical compatibili durante la ventilazione meccanica invasiva e non invasiva di pazienti adulti e pediatrici.

Terminologia

Il *circuito paziente* comprende i tubi, (branca di connessione, branca inspiratoria riscaldata a parete, branca espiratoria corta, branca espiratoria lunga), il raccogli condensa e il raccordo a Y.

Il *set circuito paziente* comprende il circuito paziente e la camera dell'acqua.

Connessione del set circuito paziente HAMILTON-BC8022-A all'umidificatore HAMILTON-H900

Connessione dal ventilatore

Notare che i connettori della branca sull'umidificatore combinano le connessioni elettriche con i connettori del circuito paziente. Assicurarsi che i contatti elettrici sui connettori del circuito paziente siano orientati correttamente in modo che corrispondano all'elemento di connessione sull'umidificatore.

Vedere l'allestimento completo sulla prima pagina di queste *Istruzioni per l'uso*.

Per connettere il set circuito paziente

1. Inserire completamente la camera dell'acqua nell'umidificatore finché non scatta in posizione.

   Per rimuovere la camera dell'acqua, estrarla dall'umidificatore.
2. Prima connettere la branca di connessione inspiratoria (branca corta blu) alla camera dell'acqua, quindi al ventilatore sull'uscita inspiratoria.
3. Connettere le branche espiratorie (bianche) al raccogli condensa e connettere la branca più corta alla valvola espiratoria del ventilatore.
4. Prima connettere la branca inspiratoria (branca lunga blu) alla camera dell'acqua, quindi al raccordo a Y.
5. Riempire manualmente la camera dell'acqua con una siringa.

   Assicurarsi di non riempire la camera dell'acqua al di sopra del livello massimo (MAX) contrassegnato.
6. Rimettere il tappo blu della porta di riempimento dell'acqua. Assicurarsi che il tappo sia chiuso durante il funzionamento dell'umidificatore.

Pulizia, disinfezione e risterilizzazione

Per istruzioni dettagliate sulla risterilizzazione, utilizzare le informazioni fornite nella *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Guida alla risterilizzazione di HAMILTON-BC8022-A). La guida è disponibile online all'indirizzo **www.hamilton-medical.ch**, in **MyHamilton**. La registrazione è gratuita.

Su richiesta, è possibile inviare una copia stampata; contattare il rappresentante dell'assistenza tecnica Hamilton Medical.

Smaltimento

I set circuito paziente usati possono essere contaminati. Per lo smaltimento di tutti i componenti, attenersi ai protocolli ospedalieri. Lo smaltimento deve avvenire nell'osservanza di tutte le disposizioni di legge locali, regionali e nazionali in materia di tutela ambientale.

Dati tecnici

Intervallo di flusso	Fino a 120 l/min

Connettori	Conici secondo la normativa ISO 5356-1
Compliance dei set circuito paziente riscaldati con branca doppia	< 1 ml/cmH2O/m
Volume comprimibile	400 ml
Volume di acqua (max)	220 ml
Resistenza del flusso a 30 l/min (flusso nominale) Inspirazione Espirazione	 0,3 cmH2O 0,3 cmH2O
Perdita di gas	< 50 ml/min
Pressione operativa massima nella camera dell'acqua	10 kPa
Lunghezza del circuito	1,50 m
Compatibilità	Umidificatore HAMILTON-H900
Condizioni di funzionamento	Consigliato: da 18 °C a 26 °C
Pressione atmosferica	da 61 a 106 kPa
Durata di funzionamento massima	28 giorni

⚠ 警告

- **呼吸装置（包括水箱）在使用之前必须进行清洁、消毒和高压灭菌。**
- **为产品清洁和灭菌时请按照 *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767)《HAMILTON-BC8022-A 再处理指南》中的说明进行操作。**
- **再处理操作不当可能引发产品故障。环氧乙烷气体的使用可能会导致病人或使用者的癌症发病率增加。如果使用者以不恰当的方式清洁或重复使用呼吸装置，则 Hamilton Medical 哈美顿医疗公司无法保证其正常运行。**
- **呼吸装置必须由经过培训的专业医学人员设置和使用。**
- **呼吸装置不得覆盖任何物件，如床单、毛巾等。**
- **确保从湿化器连接至病人的呼吸管路无张力及任何扭结，并防止意外影响。**
- **如果没有气流，请勿使用加热的呼吸管路。如果气体供应中断，则必须关闭湿化器或让其进入待机模式。**
- **加热肢不能直接放置在病人皮肤上。请恰当地连接呼吸管路或管道支托，以免对气管内插管产生机械力。**
- **水箱只能灌注符合医院卫生要求的无菌软化水。**
- **若水箱中的水位超出标记的最高水位线 (MAX) 则不得运行设备。**
- **定期检查水位，在需要时注水。**
- **湿化器必须始终位于病人身体平面下方。湿化器倾斜角度超过 10° 时，切勿开机运行。**
- **切勿将本呼吸装置与其它厂商生产的湿化器搭配使用。**
- **请勿将任何药品或药物直接加入水箱的水中。如果 HAMILTON-H900 与医用气体或雾化药物结合使用，请遵照所供医用品的使用说明，并确保其适用于主动湿化。**
- **请勿接触热板或蒸发腔底部。其表面温度可超过 85 ℃。这些热表面会辐射热量。**

⚠ 小心

- *使用前检查呼吸装置是否有损坏。如果有任何损坏迹象（如裂痕或变色），请丢弃呼吸装置。*
- *根据当地的法律法规或医院的内部规定，将使用过的呼吸管路和水箱作为污染物品处理。*
- *如果环境温度超出推荐范围（18°C 至 26°C），可能无法达到生理湿度水平。此温度范围之外不能保证加湿性能。*

注意

- 另请阅读 HAMILTON-H900 湿化器操作说明。
- 给病人使用呼吸装置前，必须进行气密性测试。如果测试失败，可以重复一次。如果连续两次测试失败，则必须更换新的呼吸装置。
- 注水温度不应超过 37°C。
- 使用前请检查所有连接的稳定性。

预定用途

HAMILTON-BC8022-A 呼吸装置适合成年病人和儿童病人在有创和无创机械通气时，与相兼容的 Hamilton Medical 哈美顿医疗公司呼吸气体湿化器配合使用。

术语

*呼吸管路*由管道（连接肢、管壁加热吸气肢、短呼气肢、长呼气肢）、集水杯和 Y 形管组成。

*呼吸装置*由呼吸管路和水箱组成。

将 HAMILTON-BC8022-A 呼吸装置连接至 HAMILTON-H900

呼吸机连接

请注意，湿化器上的肢接头将电气连接与呼吸管路接头结合在一起。请确保呼吸管路接头上的电触头的方向正确，以匹配湿化器上的连接元件。

请参阅本 *《使用说明》* 首页的完整设置说明。

连接呼吸装置

1 将水箱完全插入湿化器，直至其卡入到位。
要取出水箱，只需将其拉出湿化器。

2 将吸气连接肢（蓝色短肢）首先连接至水箱，然后连接至呼吸机的吸气口。

3 将呼气肢（白色）连接至集水杯，然后将较短的呼气肢连接至呼吸机的呼气阀。

4 将吸气肢（蓝色长肢）首先连接至水箱，然后连接至 Y 形管。

5 用注射器为水箱人工注水。
为蒸发腔注水时切勿超过标记的最高水位线。

6 将蓝色的注水口盖帽放回原处。务必在湿化器运行过程中塞上盖帽。

清洁、消毒和再处理

欲了解再处理说明的详细信息，请阅读 *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767)《HAMILTON-BC8022-A 再处理指南》中介绍的内容。访问 www.hamilton-medical.ch 的 MyHamilton 可获取该指南。注册免费。

根据要求可将指南的印刷本发送给您；请联系您的 Hamilton Medical 哈美顿医疗公司技术代表。

废物处理

使用过的呼吸装置可能已被污染。根据您所在机构的相关规定处理所有部件。应遵守当地、省 / 市 / 自治区及国家对于环境保护的所有相关规定。

技术数据

流量范围	最高 120 l/min
接口	按照 ISO 5356-1 标准锥形
双肢加热呼吸装置的兼容性	< 1 ml/cmH2O/m
可压缩容积	400 ml
水容量（最大）	220 ml
30 l/min（额定流量）时的流动阻力 吸气 呼气	 0.3 cmH2O 0.3 cmH2O
气体泄漏	< 50 ml/min
水箱内的最大工作压力	10 kPa
管路长度	1.50 米（约 5 英尺）
兼容性	HAMILTON-H900 湿化器
工作条件	推荐：18°C 至 26°C
气压	61 至 106kPa
最长工作时间	28 天

⚠ 警告

- **呼吸セットと付属の給水チャンバーは、使用前に必ず洗浄、消毒、オートクレーブを行ってください。**
- ***HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A 再処理ガイド) の説明に従って、本製品を洗浄および殺菌してください。**
- **正しく再処理をしないと製品に不具合が生じることがあります。ETO ガスを使用すると、患者やユーザーの発がん率が高まることがあります。Hamilton Medical は、ユーザーが正しくない方法で洗浄して呼吸セットを再使用した場合、製品が正常に機能するかどうかを保証しません。**
- **呼吸セットは訓練を受けた医療専門家が設置、使用してください。**
- **呼吸セットは、シーツ、タオル等のもので覆われていてはなりません。**
- **呼吸回路は患者に対し、ゆるみをもたせ、加湿器とねじれることなく設置し、意図しない影響を防止ください。**
- **既存のガスフローなしで加熱された呼吸回路を使用しないでください。ガス供給が中断された場合は、加湿器をオフにするかスタンバイモードに入れてください。**
- **加熱されたチューブは患者の肌に直接当たらないようにして下さい。呼吸回路や配管ホルダーを適切に装げ、ET 管に機械的力がかからないようにして下さい。**
- **給水チャンバーには、病院の衛生要件を満たす無菌脱イオン水のみをご使用ください。**
- **給水チャンバー内の水位が記された最高水位 (MAX) を超える場合は、機器を操作しないでください。**
- **定期的に水量を点検し適宜補充してください。**
- **加湿器は必ず患者より低い位置に設置される必要があります。10 度以上傾けた状態で加湿器を使用しないでください。**
- **他の加湿器でこの呼吸セットを使用しないでください。**
- **給水チャンバーの水に薬剤を直接追加しないでください。HAMILTON-H900 を医療ガスまたはネブライザー薬剤とともに使用する場合は、付属アプリケーションの使用説明書に従い、それが加湿器での使用に適していることを確認してください。**
- **高温のプレートやチャンバーの底には触れないでください。これらの表面は 85° C 上に達する場合があります。これらの高温部は熱を放射します。**

⚠ 注意

- *使用前に呼吸セットに故障がないことを確かめてください。もし、ひびや変色等わずかでも故障が認められた場合は破棄してください。*
- *使用済みの呼吸回路や給水チャンバーは医療廃棄物として地域の条例または院内の規定に従って処理してください。*
- *周囲の室温が推奨される範囲 (18° C から 26° C) を超える場合、生理学上の湿度水準は達成できない場合があります。加湿器の性能はこの範囲外では保証されません。*

注:

- HAMILTON-H900 加湿器の使用説明書もお読みください。
- 患者に呼吸セットを使用する前に、必ず気密テスト実施してください。このテストが失敗した場合は、それをもう 1 回繰り返すことができます。テストが 2 回連続して失敗した場合は、呼吸セットを新しいものに交換する必要があります。
- 37° C 以下の水を補充してください。
- 使用前に全ての接続が確実に接続されていることを確かめてください。

使用目的

HAMILTON-BC8022 呼吸セットは、成人および小児患者の侵襲的 / 非侵襲的人工呼吸のために、互換性のある Hamilton Medical 呼吸ガス加湿器とともに使用することを目的としています。

用語

*呼吸回路*は、管（接続肢、壁加熱吸気肢、ショート呼気肢、ロング呼気肢）、ウォータートラップ、Y ピースで構成されています。

*呼吸セット*は、呼吸回路と給水チャンバーで構成されています。

HAMILTON-BC8022-A 呼吸セットを HAMILTON-H900 に接続する

人工呼吸器の接続

加湿器の肢コネクタは、呼吸回路コネクタと電気的接続を兼ね備えています。呼吸回路コネクタの電気接点の向きが加湿器の接続要素と一致するように正しく取り付けられていることを確認してください。

これらの*使用説明書*の表紙にある完全なセットアップを参照してください。

呼吸セットの接続方法

1. カチッと音がするまで給水チャンバーを加湿器に挿入します。
   取り外すには、加湿器から給水チャンバーを引き出します。
2. 先に吸気接続肢（ショート、青）を給水チャンバーに接続してから、吸気管の出口にある人工呼吸器に接続してください。
3. 呼気肢（白）をウォータートラップに接続し、短い方の肢を人工呼吸器呼気バルブに接続します。
4. 先に吸気肢（ロング、青）を給水チャンバーに接続してから、Y ピースに接続します。
5. シリンジを使って手動で給水チャンバーに給水します。
   最大レベルより上に給水しないでください。
6. 青の給水ポートキャップを交換します。加湿器使用時はキャップを閉じてください。

洗浄、殺菌、および再処理

詳細な再処理方法については、*HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A 再処理ガイド）に記載された情報を参照してください。ガイドは www.hamilton-medical.ch、MyHamilton よりオンラインで入手できます。登録は無料です。

ご希望に応じて印刷版をご送付します。Hamilton Medical の技術担当者までお問い合わせください。

廃棄

使用済み呼吸セットは汚染されていることがあります。すべてのパーツは各施設のプロトコルに従って廃棄してください。各地域、州、連邦の環境規制に従ってください。

技術データ

フローレンジ	最大 120 l/ 分
コネクタ	円錐コネクタ ISO 5356-1 規格に準拠
デュアルリム加熱呼吸セットの準拠	< 1 ml/cmH2O/m
圧縮量	400 ml
水量（最大）	220 ml
30 l/ 分毎のフロー抵抗（標準フロー） 吸気 呼気	 0.3 cmH2O 0.3 cmH2O
ガス漏れ	< 50 ml/min
給水チャンバーの最大動作圧	10 kPa
回路の長さ	1.50 m（約 5 ft）
互換性	HAMILTON-H900 加湿器
動作条件	推奨：18° C ～ 26° C
外気圧	61 ～ 106 kPa
最大動作時間	28 日

⚠ ПРЕДУПРЕЖДЕНИЕ

- **Перед использованием комплект дыхательного контура вместе с водным резервуаром необходимо очистить, продезинфицировать и простерилизовать в автоклаве.**
- **Следуйте инструкциям по очистке и стерилизации, приведенным в *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Руководстве по повторной обработке комплекта дыхательного контура HAMILTON-BC8022-A).**
- **Неправильная повторная обработка может стать причиной неисправности аппарата ИВЛ. Использование этиленоксида может повышать вероятность заболевания раком у пациентов и операторов. Компания Hamilton Medical не гарантирует правильное функционирование комплектов дыхательных контуров, очищенных или повторно используемых ненадлежащим образом.**
- **Комплект дыхательного контура могут подключать и использовать только квалифицированные медицинские специалисты.**
- **Запрещается накрывать комплект дыхательного контура какими-либо предметами (в том числе простынями, полотенцами и т. д.).**
- **Дыхательный контур нужно расположить так, чтобы исключить возможность непреднамеренного воздействия. Подключая контур, убедитесь, что патрубки не натянуты, а трубки, с помощью которых увлажнитель подсоединяется к пациенту, не перекручены.**
- **Не используйте нагреваемый дыхательный контур, когда газовая смесь не подается. Если подача газа прекратилась, отключите увлажнитель или переведите устройство в режим ожидания.**
- **Кожа пациента не должна непосредственно контактировать с нагреваемыми патрубками. Дыхательный контур или держатель трубок следует подсоединять так, чтобы исключить механическое воздействие на ЭТ-трубку.**
- **Резервуар увлажнителя можно наполнять только стерилизованной, обессоленной водой, соответствующей принятым в медицинском учреждении санитарно-гигиеническим требованиям.**
- **Не используйте изделие, если уровень воды в резервуаре увлажнителя превышает максимальный (отметка «MAX»).**
- **Регулярно проверяйте уровень воды и при необходимости доливайте ее в резервуар.**
- **Увлажнитель должен всегда находиться ниже уровня пациента. Не используйте увлажнитель, если уровень его наклона превышает 10°.**
- **Не используйте комплект дыхательного контура с другими увлажнителями.**
- **Не добавляйте никаких лекарственных смесей непосредственно в водный резервуар. Если HAMILTON-H900 используется с медицинскими газами или для распыления лекарственных препаратов, придерживайтесь соответствующих инструкций по эксплуатации и убедитесь, что газ/препарат может использоваться при активном увлажнении.**
- **Не прикасайтесь к горячей пластине и нижней части резервуара. Температура этих поверхностей может превышать 85 °C, и они излучают тепловую энергию.**

⚠ ВНИМАНИЕ

- *Прежде чем использовать комплект дыхательного контура, осмотрите его и убедитесь в отсутствии повреждений. При наличии таковых (трещины, обесцвечивание и т. д.) утилизируйте комплект.*
- *С использованными дыхательными контурами и резервуарами увлажнителей следует обращаться как с загрязненными предметами, соблюдая местные законы и нормы или внутренние процедуры медицинского учреждения.*
- *Если температура окружающей среды не соответствует требованиям (18–26 °C), устройство может не обеспечивать необходимый уровень влажности. В таких условиях нельзя гарантировать эффективность процедуры увлажнения.*

ПРИМЕЧАНИЕ

- Ознакомьтесь с инструкциями по эксплуатации увлажнителя для аппарата ИВЛ HAMILTON-H900.
- Прежде чем использовать комплект дыхательного контура, выполните проверку на герметичность. Если результаты проверки неудовлетворительны, ее можно повторить еще раз. Если и вторая попытка даст отрицательный результат, набор дыхательного контура следует заменить.
- Температура воды, доливаемой в резервуар, не должна превышать 37 °C.
- Прежде чем использовать комплект, проверьте надежность всех соединений.

Предполагаемое использование

Комплект дыхательного контура HAMILTON-BC8022-A предназначен для использования с совместимыми увлажнителями газовых дыхательных смесей Hamilton Medical при проведении инвазивной и неинвазивной искусственной вентиляции легких у взрослых и педиатрических пациентов.

Термины

Дыхательный контур состоит из трубок (соединительного патрубка, патрубка вдоха с нагреваемыми стенками, короткого патрубка выдоха, длинного патрубка выдоха), влагосборника и У-образного коннектора.

Комплект дыхательного контура включает дыхательный контур и резервуар увлажнителя.

Подсоединение комплекта дыхательного контура HAMILTON-BC8022-A к аппарату ИВЛ HAMILTON-H900

Подключение к аппарату ИВЛ

Обратите внимание: разъемы для присоединения патрубков на увлажнителе содержат как электрические контакты, так и разъемы дыхательного контура. Убедитесь, что электрические контакты правильно расположены по отношению к разъемам дыхательного контура (они должны соответствовать соединительному элементу увлажнителя).

Полная схема подключения приведена на первой странице этой *Инструкции по эксплуатации*.

Подключение комплекта дыхательного контура

1. Вставьте резервуар в увлажнитель до конца, чтобы он защелкнулся.

   Чтобы извлечь резервуар, просто вытащите его из увлажнителя.
2. Подключите соединительный патрубок вдоха (короткий, голубой) сначала к резервуару увлажнителя, а затем к выпускному отверстию патрубка вдоха на аппарате ИВЛ.
3. Подсоедините патрубки выдоха (белые) к влагосборнику и подключите короткий патрубок к клапану выдоха аппарата ИВЛ.
4. Подключите патрубок вдоха (длинный, голубой) сначала к резервуару

увлажнителя, а затем к У-образному коннектору.

5 Вручную наполните резервуар увлажнителя с помощью шприца, следя за тем, чтобы уровень воды не превысил максимальный (отметка «MAX»).

6 Закройте канал заполнения водой голубой крышкой. Во время работы увлажнителя крышка должна быть закрыта.

Очистка, дезинфекция и повторная обработка

Подробные инструкции по повторной обработке приведены в *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (Руководстве по повторной обработке комплекта дыхательного контура HAMILTON-BC8022-A). Электронная версия руководства доступна на веб-сайте www.hamilton-medical.ch (раздел MyHamilton). Регистрация бесплатна.

Чтобы получить печатную копию руководства, обратитесь к представителю отдела технической поддержки Hamilton Medical.

Утилизация

Использованные комплекты дыхательных контуров могут быть загрязнены. Утилизацию всех компонентов комплекта следует проводить согласно протоколу вашего учреждения. Соблюдайте все региональные, государственные и федеральные нормы по защите окружающей среды.

Технические данные

Диапазон потока	До 120 л/мин
Разъемы	Конусные согласно стандарту ISO 5356-1
Податливость комплектов нагреваемых дыхательных контуров с У-образным коннектором	< 1 мл/смH2O/м
Сжимаемый объем	400 мл
Объем воды (макс.)	220 мл
Сопротивление потоку при 30 л/мин (номинальная скорость потока) Вдох Выдох	 0,3 смH2O 0,3 смH2O
Утечка газовой смеси	< 50 мл/мин
Максимальное рабочее давление в резервуаре увлажнителя	10 кПа
Длина контура	1,50 м
Совместимость	Увлажнитель HAMILTON-H900
Условия эксплуатации Атмосферное давление	Рекомендуется: 18–26 °C 61–106 кПа
Максимальный срок работы	28 дней

⚠ UYARI

- **Su haznesinin bulunduğu solunum setinin kullanımdan önce temizlenmesi, dezenfekte edilmesi ve otoklavlanması gerekir.**
- **Ürünü temizlemek ve sterilize etmek için *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A Tekrar İşleme Kılavuzu)'ndaki talimatları izleyin.**
- **Tekrar işlemenin uygun şekilde yapılmaması ürünün arızalanmasına neden olabilir. ETO gazı kullanımı, hasta ve kullanıcılarda kansere yakalanma oranının artmasına sebebiyet verebilir. Hamilton Medical, kullanıcı tarafından uygun olmayan şekillerde temizlenen veya yeniden kullanılan solunum setlerinin doğru şekilde çalışmasıyla ilgili bir teminatta bulunmaz.**
- **Solunum seti eğitimli tıp uzmanları tarafından kurulmalı ve kullanılmalıdır.**
- **Solunum setinin üzeri, kağıt, havlu, vb. hiçbir nesneyle örtülmemelidir.**
- **Solunum devresini, nemlendiriciden hastaya giden devrede hiçbir gerilim ve kıvrılma oluşmayacak şekilde yerleştirin ve istenmeyen etkilere karşı koruyun.**
- **Isıtılan solunum devrelerini gaz akışı yoksa kullanmayın. Gaz beslemesinde kesinti oluşmuşsa, nemlendirici kapatılmalı veya bekleme moduna alınmalıdır.**
- **Isınan parçalar doğrudan hastanın cildi üzerine yerleştirilmemelidir. ET hortumu üzerinde mekanik kuvvet oluşmaması için, solunum devrelerini veya hortum tutucularını uygun şekilde takın.**
- **Su haznesini yalnızca hastanenin hijyen gerekliliklerini karşılayan steril, minerallerden arındırılmış suyla doldurun.**
- **Su haznesindeki su seviyesi işaretli en yüksek değeri (MAKS) geçiyorsa cihazı çalıştırmayın.**
- **Su seviyesini düzenli olarak kontrol edin ve gerekirse su takviye edin.**
- **Nemlendirici daima hastanın bulunduğu seviyenin altında konumlandırılmalıdır. Nemlendiriciyi 10°'nin üzerindeki açılarda çalıştırmayın.**
- **Solunum setini diğer nemlendirici cihazlarla birlikte kullanmayın.**
- **Su haznesi içindeki suya dogrudan herhangi bir ilaç eklemeyin. HAMILTON-H900'ün tibbi gaz veya nebulizasyon yoluyla verilen ilaçlar ile birlikte kullanilmasi durumunda verilen uygulamanin kullanim talimatlarina uyun ve cihazin aktif nemlendirme ile kullanim için uygun oldugundan emin olun.**
- **Sıcak plakaya veya haznenin alt kısmına dokunmayın. Yüzeylerdeki sıcaklık 85°C'ye ulaşabilir. Bu sıcak yüzeyler ısı yayar.**

⚠ DİKKAT

- *Kullanmadan önce solunum setini hasara karşı gözden geçirin. Çatlama veya renk değişimi gibi herhangi bir hasar belirtisi varsa solunum setini atın.*
- *Kullanılan solunum devreleri ve su haznelerine, yerel kanun ve düzenlemeler veya hastane içi prosedürlerine uygun olarak kontamine malzeme muamelesi yapın.*
- *Ortam sıcaklığı önerilen aralığın (18°C ila 26°C) dışındaysa, fizyolojik nemlilik seviyelerine ulaşılamayabilir. Bu aralığın dışındaki nemlendirme performansı garanti edilmemektedir.*

NOT

- Ayrıca bkz. HAMILTON-H900 nemlendirici çalışma talimatları.
- Solunum setini hastada kullanmadan önce bir kaçak testi yapılmalıdır. Bu test başarısız olursa işlem bir kez

daha tekrarlanabilir. Art arda iki başarısız testten sonra solunum seti yenisiyle değiştirilmelidir.

- Takviye edilen su 37°C'den sıcak olmamalıdır.
- Kullanımdan önce tüm bağlantıların sağlam olup olmadığını kontrol edin.

Kullanım amacı

HAMILTON-BC8022-A solunum seti, yetişkin ve pediyatrik hastaların invazif ve noninvazif mekanik ventilasyonu sırasında uyumlu Hamilton Medical respiratuvar gaz nemlendiricileri ile birlikte kullanılır.

Terminoloji

Solunum devresi; hortum (bağlantı parçası, duvar ısıtmalı inspiratuvar parça, kısa ekspiratuvar parça, uzun ekspiratuvar parça), su kapanı ve Y parçasından oluşur.

Solunum seti, solunum devresi ve su haznesinden oluşur.

HAMILTON-BC8022-A solunum setinin HAMILTON-H900'e bağlanması

Ventilatör bağlantısı

Nemlendirici üzerindeki parça konektörleri, elektrik bağlantılarını solunum devresi bağlantıları ile birleştirir. Solunum devresi konektörleri üzerindeki elektrik temas noktalarını, nemlendirici üzerindeki bağlantı ögesiyle doğru eşleşecekleri şekilde yerleştirin.

Kullanım talimatları'nın ön sayfasında yer alan tam kurulum bölümüne bakın.

Solunum setini bağlamak için

1. Su haznesini, hazne yerine oturup 'tık' sesi çıkartıncaya kadar nemlendiricinin içine sokun.
   Hazneyi ayırmak için, su haznesini nemlendiriciden çekip çıkarın.
2. İnspiratuvar bağlantı parçasını (kısa mavi parça) önce su haznesine, sonra inspiratuvar çıkıştaki ventilatör parçasına bağlayın.
3. Ekspiratuvar parçaları (beyaz) su kapanına, kısa parçayı ise ventilatör ekspiratuvar valfe bağlayın.
4. İnspiratuvar parçayı (uzun mavi parça) önce su haznesine, sonra Y parçasına bağlayın.
5. Su haznesini bir şırınga kullanarak manuel olarak doldurun.
   Hazneyi işaretli MAKS seviyesinin üzerinde doldurmadığınızdan emin olun.
6. Mavi su dolum portundaki tıkaç kapağını yenisiyle değiştirin. Nemlendirici çalışırken tıkaç kapağının kapalı olduğundan emin olun.

Temizlik, dezenfeksiyon ve tekrar işleme

Ayrıntılı tekrar işleme talimatları için *HAMILTON-BC8022-A Reprocessing Guide* (PN 624767) (HAMILTON-BC8022-A Tekrar İşleme Kılavuzu)'nda verilen bilgileri kullanın. Kılavuza www.hamilton-medical.ch adresindeki MyHamilton sekmesinden online olarak erişebilirsiniz. Kayıt ücretsizdir.

Basılı kopya talebiniz doğrultusunda adresinize gönderilebilir; Hamilton Medical teknik temsilcinize başvurun.

İmha etme

Kullanılan solunum setleri kontamine olmuş olabilir. Tüm parçaları kurumunuzun protokolüne uygun şekilde imha edin. Çevreyi korumaya yönelik tüm yerel, resmi ve federal yönetmelikleri izleyin.

Teknik veriler

Akış aralığı	En fazla 120 l/dk
Bağlantılar	ISO 5356-1'e uygun konik bağlantılar
Çift parçalı ısıtmalı solunum setlerinin uyumluluğu	< 1 ml/cmH2O/m
Sıkıştırılabilir hacim	400 ml
Su hacmi (maks)	220 ml
30 l/dk'daki akış direnci (nominal akış) İnspirasyon Ekspirasyon	 0,3 cmH2O 0,3 cmH2O
Gaz kaçağı	< 50 ml/dk
Su haznesindeki maksimum çalışma basıncı	10 kPa
Devre uzunluğu	1,50 m (yaklaşık 5 ft)
Uyumluluk	HAMILTON-H900 nemlendirici
Çalışma koşulları	Önerilen: 18°C ila 26°C
Atmosfer basıncı	61 ila 106 kPa
Maksimum çalışma süresi	28 gün

 Follow the Instructions for use. Gebrauchsanweisung beachten. Respecter les instructions d'utilisation. Siga las instrucciones de uso. Siga as Instruções de uso. Seguire le istruzioni per l'uso. 请按照说明使用。 使用説明書の説明に従ってください。 Следуйте инструкциям по эксплуатации. Kullanım talimatlarını izleyin.	 Do not use if the packaging is damaged. Bei beschädigter Verpackung nicht verwenden. Ne pas utiliser si l'emballage est endommagé. No utilizar si el envase está dañado. Não utilizar se a embalagem estiver danificada. Non utilizzare se la confezione è danneggiata. 如果包装损坏，请勿使用。 梱包が破損している場合は使用しないでください。 Не использовать при поврежденной упаковке. Ambalaj zarar görmüşse kullanmayın.
 To patient port. Connect the inspiratory limb to the inspiratory port on the ventilator. Anschluss zum Patienten. Schließen Sie den Inspirationsschenkel am Inspirationsanschluss des Beatmungsgerätes an. Vers port patient. Connecter la branche inspiratoire au port inspiratoire du ventilateur. Orificio hacia el paciente. Conecta la rama inspiratoria al puerto inspiratorio del respirador. Conexão inspiratória. Conectar a alça inspiratória na porta inspiratória do respirador. Porta Al paziente. Connettere la branca inspiratoria all'uscita inspiratoria sul ventilatore. 至病人端口。将吸气肢连接至呼吸机上的吸气端口。 患者ポートへ。吸気肢を人工呼吸器の吸気ポートに接続します。 Порт «к пациенту». Подсоедините патрубок вдоха к соответствующему отверстию аппарата ИВЛ. Hasta portuna. İnspiratuvar parçayı ventilatör üzerindeki inspiratuvar porta bağlayın.	 From patient port. Connect the expiratory limb to the expiratory port on the ventilator. Anschluss vom Patienten. Schließen Sie den Exspirationsschenkel am Exspirationsanschluss des Beatmungsgerätes an. À partir du port patient. Connecter la branche expiratoire au port expiratoire du ventilateur. Orificio desde el paciente. Conecta la rama espiratoria al puerto espiratorio del respirador. Conexão expiratória. Conectar a alça expiratória na porta expiratória do respirador. Porta Dal paziente. Connettere la branca espiratoria all'uscita espiratoria sul ventilatore. 自病人端口。将呼气肢连接至呼吸机上的呼气端口。 患者ポートから。呼気肢を人工呼吸器の呼気ポートに接続します。 Порт «от пациента». Подсоедините патрубок выдоха к соответствующему отверстию аппарата ИВЛ. Hasta portundan. Ekspiratuvar parçayı ventilatör üzerindeki ekspiratuvar porta bağlayın.

 Temperature probe; marks the location of the temperature probe on the breathing circuit. Temperatursensor; zeigt die Position des Temperatursensors im Beatmungsschlauchsystem an. Sonde de température ; indique l'emplacement de la sonde de température sur le circuit respiratoire. Sensor de temperatura; marca la ubicación del sensor de temperatura en el circuito respiratorio. Sonda de temperatura; marca a localização da sonda de temperatura no circuito de respiração. Sonda termica; segna la posizione della sonda termica sul circuito paziente. 温度探头；在呼吸管路上标注温度探头的位置。 温度プローブ。呼吸回路の温度プローブの位置をマークします。 Температурный зонд (указывает на расположение температурного зонда в дыхательном контуре). Sıcaklık probu; sıcaklık probunun solunum devresi üzerindeki konumunu gösterir.	 Do not use any blades, knives, or cutters to open; they can damage the product. Keine Klingen, Messer oder Cutter zum Öffnen verwenden; sie können das Produkt beschädigen. Ne pas utiliser de lames, de couteaux ou d'autres instruments de découpe pour ne pas endommager le produit. No utilice cuchillas, cuchillos o cúters para abrir el envase; estos pueden dañar el producto. Não utilizar lâminas, facas ou ferramentas de corte para abrir; estas podem causar danos no produto. Non utilizzare lame, coltelli o taglierini per l'apertura; possono danneggiare il prodotto. 切勿使用任何刀片、刀或刀具打开包装；它们可能会损坏产品。 刃物、ナイフ、カッター等で開けないでください。製品に傷がつくことがあります。 Не вскрывайте изделие с помощью лезвий, ножей или других режущих инструментов: они могут повредить устройство. Ambalajı açmak için bıçak veya kesici aletler kullanmayın; bunlar ürüne zarar verebilir.	 Filling level mark on humidifier chamber. Füllstandsmarkierung an der Befeuchterkammer. Repère du niveau de remplissage sur le réservoir d'eau. Marca de nivel de llenado en la cámara de agua. Marca do nível de enchimento na câmara de água. Simbolo del livello di riempimento sulla camera dell'acqua. 水箱上的水位标识。 給水チャンバーの補充レベルマーク。 Отметка уровня заполнения резервуара увлажнителя. Su haznesi üzerindeki dolum seviyesi işareti.  Quantity Menge Quantité Cantidad Quantità Quantidade 数量 数量 Количество Miktar

CAUTION:
(USA only) Federal law restricts this device to sale by or on the order of a physician.

Hamilton Medical AG
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Switzerland
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www.hamilton-medical.com

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Certificate

Standard **ISO 9001:2015**

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

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

including the locations according to annex

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

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

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

2021-01-08

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

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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

2021-01-08

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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.

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

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
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