

Aeon8800A

Anesthesia Workstation

CE 0123

AEOMED
Reliable Quality Thoughtful Service

Aeon8800A

Anesthesia Workstation

The Aeon8800A Anesthesia Workstation is a high-level device from AEONMED, engineered based on clinical input and feedback.

The workstation has a user-friendly design, incorporates innovative technology, and provides the clinician with safe and effective treatment options for patients.

Modern Breathing Circuit

Safe, stable and efficient anesthesia management.

The characteristic breathing circuit is made of alloy, resistant to corrosion and can withstand repeated high temperature and high pressure sterilization.

Adjustable angle, easy to install, many user-friendly designs make maintenance easier.

The integrated heating system with a better thermal conductivity of alloy help prevent condensation and make patients feel more comfortable.

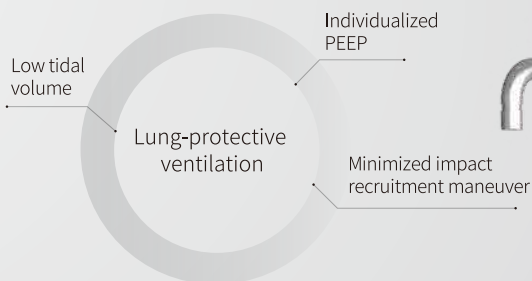
APL with fast release pressure, the upper pressure limit is accurately adjustable, avoiding repeated operations and improving anesthesia efficiency.

The Breathing Circuit has CO₂ bypass function.



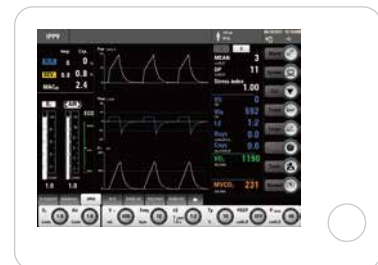
Lung-Protective Ventilation

Lung-protective ventilation is the current standard of care for mechanical ventilation. The risk of Postoperative Pulmonary Complications (PPCs) can be effectively reduced through Lung-protective ventilation strategy



Low tidal volume

The 8800A has a minimum tidal volume of 10ml in volume control mode, in addition to possessing the PCV-VG and BIVENT ventilation mode, helping to achieve the precise low tidal volume required during lung protective ventilation.



Individualized PEEP titration tool

Stress index (SI) monitoring helps with Individualized PEEP titration. Through the guidance of the Static PV loop tool, the appropriate setting of PEEP value and tidal volume are realized.

Minimized impact recruitment maneuver

Two types recruitment maneuvers: stepwise PEEP or sustained inflation. Automate repetitive tasks used during lung ventilation procedures.



Enhanced monitoring and clinical tools

In addition to traditional monitoring parameters, special monitoring parameters, such as Driving Pressure(DP), are provided to guide clinicians in adjusting ventilation parameters.

Spirometry loops can be stored for future reference, allowing clinicians the ability to better understand changes in the patient's response to therapy.

Provide multiple of cardiopulmonary bypass modes (CBP) to assist in the implementation of cardiopulmonary bypass surgery.

Continuous trend information together with time discrete events are stored and shown in the table or chart.

Provides medical gas consumption calculations: including O₂, N₂O and Agent. And provide calculations of CO₂ production.

International standard data protocol support to connect to internet center of hospitals.

Ventilator-level ventilation modes

Aeon8800A is always your professional guard for lives, offering comprehensive and accurate respiratory care for all the patient types from infant to adult, helping clinicians to have more solutions for different clinical situations.

PPV | PCV | PCV-VG

SIMV-VC | SIMV-PC | SIMV-VG

PS / CPAP | BIVENT | APRV

PCV-VG

Combines the advantages of VCV and PCV, providing better oxygenation with lower peak inspiratory pressure.

SIMV-VG

Guarantees patients can breathe spontaneously between mandatory breaths with pressure support as a backup. It offers flexible respiratory solutions when anesthesia steps into different phases.

BIVENT / APRV

Pressure controlled breaths are provided by switching between a high and low airway pressure in an adjustable time sequence. Spontaneous breaths can be pressure supported at the high and low pressure levels.





Intelligent operations bring cost-efficient management

Digital Flowmeter with ECO-Optimizer

- Digital Flowmeter makes fresh gas flow setting easier and more precise.
- The ECO-Optimizer indicates the recommended fresh gas flow setting according to the setting value and the minimum O_2 needed of the patient. It enables a safe Low Flow, and reduces the waste of anesthetic agents and medical gases.

Necessity of Low Flow



-  **Economical**
Agents and Medical Gases in FGF
-  **Pollution**
Operating room, environment
-  **Patient**
Temperature and humidity

Driven Gas Auto-Switch

- By first using compressed air as the drive gas, Driven Gas Auto-Switch to reduce oxygen consumption, also ensure the patient is ventilated uninterruptedly.
- When the compressed air supply is disrupted, the Aeon8800A will automatically switch to O_2 driving gas.

Technical Specifications

BASE UNIT	
Dimensions (H x W x D)	
Trolley version (with breathing circuit)	1420×770×760 mm
Weight and load	
Trolley (without vaporizer and backup cylinder)	135 kg
Top shelf load	25 kg
Caster locking	
Braking Types	Central brake system
Power and battery backup	
Power input	AC 100~240 V, 50/60 Hz
Power outlets	4 sockets on back, 1.5A individual
Batteries and Operation time with fully charged	DC 24V, 4.0AH, Minimum 120 minutes
Environmental requirements	
Operation temperature	10~40 °C (50~104 °F)
Operation humidity	≤95% (non-condensing)
Storage temperature	-20~60 °C (-4~131 °F)
Storage humidity	≤95% (non-condensing)
ANESTHESIA GAS SUPPLY MODULE	
Gas supply	O ₂ , N ₂ O, AIR; 280~600kPa
Cylinder yokes	Optional: O ₂ , N ₂ O, AIR
Fresh gas flow indicator	Electronically controlled mixer
Range of fresh gas flow indicators	0~18L/min or set each gas independently: O ₂ , N ₂ O: 0~10L/min; AIR: 0~12L/min
O ₂ flush	25~75 L/min
Auxiliary common gas outlet (ACGO)	Optional
Anesthetic Gas Scavenging System (AGSS)	Optional
Vaporizer	
Agent	Sevoflurane, Halothane, Enflurane, Isoflurane
Installation mode	Selectatec® with interlock, optional standby vaporizer parking holder
Filling type	Pour-Fill, Key-Fill, Quik-Fil®
Breathing system	
Volume of CO ₂ absorber	1.5 L for single canister
APL Range	Spontaneous breathing (SP) -70 cmH ₂ O
Material	Autoclavable (except O ₂ cell and airway pressure gauge)
Heating system	32~40 °C
CO ₂ bypass	Optional
VENTILATOR OPERATING SPECIFICATIONS	
Ventilator	Pneumatically driven, Electronically controlled
Ventilation modes – standard	Manual/Spontaneous Volume control (IPPV) Pressure control (PCV)
Ventilation modes - options	Pressure Controlled Ventilation Volume Guaranteed (PCV-VG) Synchronized Intermittent Mandatory Ventilation in Volume (SIMV-VG) Synchronized Intermittent Mandatory Ventilation in Pressure (SIMV-PC) Synchronized Intermittent Mandatory Ventilation in PCV-VG (SIMV-VG) Pressure Support (PS) / Continuous Positive Airway Pressure (CPAP) Bilevel Positive Airway Pressure Ventilation (BIVENT) Airway Pressure Release Ventilation (APRV)
Control input ranges	
Breathing frequency (Freq)	2~100 bpm
Positive end expiratory pressure (PEEP)	OFF, 3~50 cmH ₂ O
Inspiration/expiration ratio (I:E)	4:1~1:8
Tidal volume (Vt)	10~1500 ml
Inspiration pause	OFF, 5%~60%
Inspiratory time	0.2~5.0 s
Inspiratory pressure (P _{TARGET})	5~70 cmH ₂ O
Pressure support level (ΔP)	3~60 cmH ₂ O
Pressure limit (Pmax)	10~100 cmH ₂ O
Trigger	0.5~15 L/min / -20~-1cmH ₂ O
Inspiratory Slope Time (T _{SLOPE})	0~2s
Compensation	Compliance and Leak compensation, fresh gas compensation, altitude compensation
Ventilator monitoring & alarm	
Monitoring	Continuous monitoring of inspiratory O ₂ concentration, breathing frequency, tidal volume, minute volume, peak airway pressure, PEEP, mean or plateau pressure, I:E ratio, resistance, compliance. Option: driving pressure, stress index, CO ₂ concentration, paramagnetic oxygen analyzer, anesthetic gas concentration with MAC
Trend storage	Maximum 720 hours of trend data table, 72 hours of trend chart
Medical gas calculations	Consumption of O ₂ , N ₂ O and Agent. Calculations of CO ₂ production. require relevant gas monitoring
Control screen	15" TFT color touch screen
Graph Display	Waveforms of P-t, F-t, V-t, CO ₂ -t (option), P-V Loop, V-F Loop, P-F Loop
Alarm	MV high/low limit, FIO ₂ high/low limit, Paw high/low limit, Power failure High Freq, Negative pressure, Continuous airway pressure, Apnea alarm, etc.
Alarm logging	Alarm (Silence ≤120 seconds) 500 items

Remark: Above configurations include standard and option. Please check price with your Aeonmed sales representative.



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AAM8800A-2022.03



Aeon8600A

Anesthesia Machine

CE 0123

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- PCV and SIMV+PS modes ensure flexibility in ventilation, suitable for both pediatric and adult operations
- Flowmeter with backlight, suitable for endoscopy surgery etc.
- Breathing system heater to avoid condensation build-up during low-flow anesthesia
- Enhances usability with auxiliary oxygen, suction, auxiliary power source, monitor arm (optional) etc.
- Optional CO₂ and anesthetic gas analyzer
- With CE certificate, meets EU clinical requirements

Technical Specification

Physical & Environment Specifications

- Dimensions (W×H×D): 704 mm × 1403 mm × 750 mm
- Weight: 115kg (including trolley base and 2 vaporizers, without cylinder)
- Operation Temperature: 10 ~ 40 ° C
- Operation Humidity: ≤80% (non-condensing)
- Storage Temperature: -20 ~ 55 ° C
- Storage Humidity: ≤93% (non-condensing)

Electrical Specifications

- Mains: 100 ~ 240 V AC, 50/60 Hz
- Battery: 24V DC, minimum 120 min
- Outlets: 4 on back, 1.5A individual

Pneumatic Specifications

- Gas Supply: Air, O₂, N₂O; 280 kPa ~ 600 kPa
- Flowmeters: O₂ Range: 0~1 L/min; 1 ~ 10 L/min
N₂O Range: 0~1 L/min; 1 ~ 10 L/min
Air Range: 0~1 L/min; 1 ~ 12 L/min
Auxiliary O₂ Range: 0 ~ 15 L/min
- Gas System: Flowmeter backlight
Oxygen supply failure alarm
N₂O cut-off system
O₂ flush: 25 ~ 75 L/min
- ACGO: Optional auxiliary common gas outlet
- AGSS: Optional anesthetic gas scavenging system

Breathing System Specifications

- Operational Modes: Closed, Semi-closed, Semi-open
- CO₂ Canister: 2 Loose fill (3 L) or 2 prepacks, optional single canister (1.5 L)
- APL Range: Spontaneous breathing (SP) -70 cmH₂O
- Material: Autoclavable (except O₂ cell and airway pressure gauge)
- CO₂ bypass: Optional

Ventilator Specifications

- Driven Mode: Pneumatically driven and electronically controlled
- Patient Types: Adult, Pediatric
- Ventilation Modes: IPPV, PCV, SIMV+PS, PS and Manual
- Setting Modes: Touch key & navigator wheel knob
- Tidal Volume: 20 ~ 1500 ml
- Ventilation Frequency: 4 ~ 100 bpm
- I:E Ratio: 4:1 ~ 1:8
- Pressure (inspired) Range: 5 ~ 70 cmH₂O
- Pressure (support) Range: 3 ~ 50 cmH₂O
- PEEP: Off, 3 ~ 30 cmH₂O
- Tslope: 0 ~ 2 s
- Inspiratory Plateau: Off, 5% ~ 60% Ti
- Trigger Sensitivity: 1 ~ 15 L/min
- Compensation: Compliance and leakage compensation, fresh gas compensation and altitude compensation

Ventilator Monitoring

- Display: 10.4" TFT color screen
- Pressure: P_{peak}, P_{plat}, P_{mean}, PEEP
- Volumes: MV, Vt, Freq
- Gas: O₂ Concentration, optional CO₂, Agent and MAC
- Graph Display: P-t, F-t, P-V, F-V loops (can be saved), optional CO₂-t
- Alarm: High Airway Pressure/Low Airway Pressure
Continuous airway pressure
High Minute Volume/Low Minute Volume
High FiO₂/Low FiO₂
High Breath Rate
O₂ Supply failure
Power failure
Apnea Alarm
Alarm Silence: 110 s

Vaporizer

- Supports two vaporizers
- Agent: Halothane, Enflurane, Isoflurane, Sevoflurane
- Installation Mode: Selectatec® with interlock, optional standby vaporizer parking holder
- Filling Type: Pour Fill, Key Fill, Quik-Fil®

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AAM8600A-1902

Physical Specifications

Dimensions

Height	1420mm
Width	770mm
Depth (without YOKE)	760mm
Weight (basic unit)	135kg

Top Shelf

Weight limit	25kg
Width	650mm
Depth	380mm

Work surface

Height	850mm
Width	440mm
Depth	300mm
Material	stainless steel

Flip-up side tray

Height	850mm
Weight limit	12kg
Width	265mm
Depth	330mm

Drawers (internal dimensions)

Quantity	3
Height	120mm
Width	355mm
Depth	340mm

Casters

Diameter	125mm
Brakes	Central control brake

Cylinder YOKE(optional)

Interface	Pin Index Safety System (PISS)
Type	E
Number	Optional 2 cylinders Maximum 4 cylinders

Ventilator Operating Specifications

Modes of ventilation – standard

Manual; IPPV PCV
STANDBY; Demo

Modes of ventilation – Options

SIMV-VC, SIMV-PC
PCV-VG, SIMV-VG
PS/CPAP
BIVENT, APRV

Ventilator parameter ranges

Tidal volume range	20 to 1500 mL Optional 10 to 1500 mL (Volume Control and SIMV modes) 5 to 1500 mL (Pressure Control Vent Mode)
Tidal volume Incremental settings	increments of 5mL(Set Vt below 100mL) or 10mL(when set Vt between 100 and 1000mL) or 50mL(when set Vt bigger than 1000mL)
Pressure (P _{MAX}) range	10 to 100 cmH ₂ O (increments of 1 cmH ₂ O) (IPPV, SIMV-VC and PCV-VG vent modes)
Pressure (P _{support}) range	3 to 60 cmH ₂ O (increments of 1 cmH ₂ O) (SIMV-VC/PC/VG,

	PS/CPAP, BIVENT and APRV vent modes)	Pressure trigger (P_{SENS})	-20 to -1 cmH ₂ O (increments of 1 cmH ₂ O)
Pressure (P_{TARGET}) range	5 to 70 cmH ₂ O (increments of 1 cmH ₂ O) (PCV and SIMV-PC vent modes)	E_{SENS}	(SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
Freq.	2 to 100 breaths per minute (SIMV-VC, SIMV-PC and SIMV-VG vent modes)		5 to 70% (increments of 5%) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
	2 to 60 breaths per minute for Freq _{MIN} in PS/CPAP vent modes.	I_{SENS}	5 to 70% (increments of 5%) (APRV vent modes)
	4 to 100 breaths per minute (Other mode) (increments of 1 breath per minute)	P_{HIGH}	5 to 70 cmH ₂ O (increments of 1 cmH ₂ O) (BIVENT and APRV vent modes)
Inspiratory/expiratory ratio	4:1 to 1:8 (increments of 0.5) (IPPV, PCV and PCV-VG vent modes)	P_{LOW}	3 to 50 cmH ₂ O (increments of 1 cmH ₂ O) (BIVENT and APRV vent modes)
Inspiratory time	0.2 to 5 seconds (increments of 0.1 seconds) (SIMV-VC/PC/VG vent modes)	T_{HIGH}	0.2s to 30s (increments of 0.1s) (BIVENT and APRV vent modes)
Inspiratory Pause Time	OFF, 5% to 60% (increments of 5%) (IPPV and SIMV-VC vent modes)	T_{LOW}	0.2s to 30s (increments of 0.1s) (BIVENT and APRV vent modes)
Flow trigger (V_{SENS})	0.5 L/min to 15L/min (increments of 1L/min) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)	T_{SLOPE} (Inspiratory Slope Time)	0.2s to 2.0 seconds (increments of 0.1 seconds)

	(PCV,PCV-VG, SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)	PAW	minute	-20cmH ₂ O to 110cmH ₂ O
		FiCO ₂		0 to 10 vol%
		EtCO ₂		0 to 10 vol%
Positive (PEEP) End Expiratory Pressure	Type Integrated electronically controlled	DP (Driving airway pressure)		0 to 120 cmH ₂ O
	Range OFF, 3 to 50 cm H ₂ O (increments of 1 cm H ₂ O)	SI (Stress index)		0.1 to 5
		V _{Ti}		0 to 3000mL
		V _{TE}		0 to 3000mL
		I:E		4:1 to 1:8
		Rsys		0 to 300cmH ₂ O/(L/S)
		Csys		0 to 300mL/(L/S)
		VO ₂		Real time calculation
		CO ₂ -T		Real time calculation
Ventilator performance				
Pressure range at inlet	280 kPa to 600kPa			
Peak gas flow	≥90 L/min + fresh gas flow			
Ventilator monitoring				
Minute volume range	0 to 30L			
Tidal volume range	0 to 3000mL			
FiO ₂	18% to 100%			
Peak pressure(P _{peak})	-20cmH ₂ O to 99cmH ₂ O			
Mean pressure(P _{mean})	-20cmH ₂ O to 99cmH ₂ O			
Plat pressure(P _{plat})	-20cmH ₂ O to 99cmH ₂ O			
PEEP	-20cmH ₂ O to 99cmH ₂ O			
Frequency	0 to 110 breaths per			

Trend table

Continuous trend information together with time discrete events are stored and shown in the table, including P_{peak}, P_{plat}, P_{mean}, PEEP, Freq, V_T, MV, FiO₂, etCO₂, FiCO₂, Agent1, Agent2, N₂O, MAC, FG-O₂, FG-Air and FG-N₂O. The left page shall include the 10 parameters and the remains shall be in the right page.

The machine shall remember maximum 30 days trend data, and the interval shall be 5 minutes, the interval is adjustable

Trend chart		Inspired oxygen (FiO ₂)	Low: 18 to 99% High: 21 to 100%
Continuous trend information are stored and shown in the chart, including Pressure, CO ₂ , Agent, MV, VT, O ₂ . The machine shall remember the 72 hours trend chart		exhalant CO ₂ (etCO ₂)	Low: OFF, 0.1 to 9.8% or OFF, 1 to 74 mmHg High: 0.1 to 9.9% or 1 to 75mmHg
Stories alarms		Inspired CO ₂ (FiCO ₂)	High: 0.1 to 1.4% or 1 to 10 mmHg
All the alarm messages can be viewed from the log menu. Click on the alarm message bar the detail information of the corresponding alarm appears on the screen.		Insp. HAL	Low: OFF, 0.1 to 8.3% High: 0.1 to 8.4%
The machine shall remember the lastest 500 alarm messages,		Insp. ISO	Low: OFF, 0.1 to 8.3% High: 0.1 to 8.4%
Delivery/monitoring accuracy		Insp. ENF	Low: OFF, 0.1 to 9.8% High: 0.1 to 9.9%
Volume delivery	< 100 mL = better than 10 mL > 100 mL = better than 15%	Insp. DES	Low: OFF, 0.1 to 21.8% High: 0.1 to 21.9%
Pressure delivery	± 10% or ± 3 cm H ₂ O	Insp. SEV	Low: OFF, 0.1 to 9.8% High: 0.1 to 9.9%
PEEP delivery	± 2cmH ₂ O or ± 15%	Apnea alarm	Mechanical ventilation ON: Vt < 10 mL breath or P _{mean} < 1 cm H ₂ O or P _{mean} = 1 cm H ₂ O and PEEP ≤ 0cmH ₂ O measured in 30 seconds when Frequency ≥ 6 Vt < 10 mL breath or P _{mean} < 1 cm H ₂ O or P _{mean} = 1 cm H ₂ O and PEEP ≤ 0cmH ₂ O measured in 35 seconds when
Volume monitoring	< 100 mL = better than 10 mL > 100 mL = better than 15%		
Pressure monitoring	± 5%		
Alarm settings			
Minute volume (Mvexp)	Low: 0 to 20 L/min High: 1 to 25 L/min		
Low airway pressure	0 to 70 cmH ₂ O		
High pressure	10 to 110cmH ₂ O		
High Breath Rate	8 to 60 bpm		

	Frequency<6		
	Manual mode:		
	Vt< 10 mL measured in 60 seconds	Ventilator Screen	
		Display type	Color active matrix TFT
			Touch screen
Sustained airway pressure	Mechanical ventilation ON:	Display size	15 inches diagonal
	Paw>PEEP add 10 cm H ₂ O measured over 15 seconds	Pixel format	1024×768
	Continuously		
	Mechanical ventilation OFF:	Color	LVDS 24 bit, 16777216 colors
	Paw>10 cm H ₂ O measured over 15 seconds	Display parameters	All setting and alarm parameters(including Vt, Freq., I:E, T _{INSP} , PEEP, Freq _{MIN} , T _P , Trigger, P _{TARGET} , ΔP, T _{SLOPE} , PEAK, MEAN, PLAT, FIO ₂ , DP, SI, VTI, VTE, I:E, Rsys, Csys VO2, CO2-T
	Continuously		
Subatmospheric pressure	Paw < -2 cm H ₂ O		
Alarm silence countdown timer:	120 to 0 seconds		

Ventilator components

Flow transducer

Type	Mass type	Display graphics	Wave of P-T, F-T, V-T, CO2-T(option), Paw-V Loop, V-Flow Loop, Paw -Flow Loop
	Measure mass flow in bypass application		
Location	Installed in breathing system	Communication ports	RS-232C compatible serial interface(DB 9 connector); RJ45 connector 100-Base-TX support HL7 communication license; USB 2.0 interface

Oxygen Sensor

Type1	Galvanic fuel cell		
Life Cycle	proximately 12 months (Dependent on usage)		
Type2	Paramagnetic oxygen		
Life Cycle	8 years		

Integrated safety functions

In case of electricity and battery failure, manual ventilation, gas delivery and agent delivery are possible.

Positive pressure relief valve opens at $110 \pm 1 \text{ cmH}_2\text{O}$.

Anesthetic agent delivery

Delivery

Vaporizer	VP300
Type	Halothane, Enflurane, Isoflurane, Sevoflurane,
Number of positions	2
Mounting	Selectatec ^R manifold interlocks

Dimensions

Height	23 cm
Width	12 cm
Depth	21 cm
Weight	6.2 kg
Agent capacity	250ml

Accuracy

Flow range	0.2-15L/min
Operation temperature	15-35°C
Accuracy	$\pm 20\%$ of setting or $\pm 5\%$ of the maximum scale

Agent setting range

Sevoflurane: :
 OFF , 0.2% , 0.5% ,
 1% , 2% , 3% , 4% ,
 5% , 6% , 7% , 8% ;
 Halothane, Enflurane,
 Isoflurane: OFF ,
 0.2% , 0.5% , 1% ,
 2% , 3% , 4% , 5% ;

Gas monitor(optional)

Type	main stream/side stream
Module	IRMA CO ₂ ; IRMA AX+ ISA CO ₂ ; ISA AX+
Operating temperature	IRMA AX+: 10 to 40 °C (50 to 104 °F) IRMA CO ₂ : 0 to 40 °C (32 to 104 °F) ISA CO ₂ : 0 to 50 °C (32 to 122 °F) ISA AX+: 5 to 50 °C (41 to 122 °F)
Storage temperature	IRMA AX+: -20 to 75 °C (-4 to 167 °F) IRMA CO ₂ : -40 to 75 °C (-40 to 167 °F) ISA CO ₂ : -40 to 70 °C (-40 to 158 °F) ISA AX+: -40 to 70 °C (-40 to 158 °F)
Operating humidity	< 4 kPa H ₂ O (non-

	condensing) (95 %RH at 30 °C)	Infant.	
Operating atmospheric pressure	525 - 1200 hPa (<4572 m)	ISA Nomoline	Sampling line with proprietary water removal tubing. 2 m±0.1m versions
Warm-up time	IRMA AX+/ISA AX+: < 20 sec IRMA CO ₂ /ISA CO ₂ : < 10 sec	Carbon Dioxide (CO₂) Moudle (IRMA/ISA CO₂)	
		Monitor Gas	CO ₂
Rise Time	IRMA CO ₂ / AX+: CO ₂ ≤90ms N ₂ O≤300ms HAL, ISO, ENF, SEV, DES≤300ms ISA CO ₂ : CO ₂ ≤200ms ISA AX+ : CO ₂ ≤300ms N ₂ O, O ₂ , ENF, ISO, SEV, DES ≤400ms HAL ≤500ms	Measurement range	0-15 vol%
		Accuracy	0-15 vol% ± (0.2 vol% + 2 % of reading)
		Anaesthesia Gas Moudle(IRMA/ISA AX+)	
		Monitor Gases	CO ₂ ;N ₂ O;HAL;ISO;EN F;SEV;DES
ISA sampling flow rate	50 ± 10 ml/min	Measurement range	CO ₂ : 0-15 vol% N ₂ O: 0-100 vol% HAL, ISO, ENF: 0-8 vol% SEV: 0-10 vol% DES: 0-22 vol%
Breath detect	Adaptive threshold, minimum 1 % CO ₂ change.		
Respiratory rate:	0 - 150 bpm ± 1 bpm	Accuracy	
		CO ₂	0-15 vol% ± (0.2 vol% + 2 % of reading)
Compensation:	Automatic for atmospheric pressure, temperature and spectral interference		
		N ₂ O	±(2 vol% + 2 % of reading)
Airway adapters			
IRMA Airway Adapter Adult/Paediatric	6 ml dead space	HAL, ISO, ENF	±(0.15 vol% + 5 % of reading)
IRMA Airway Adapter	1 ml dead space		

SEV	$\pm(0.15 \text{ vol\%} + 5 \% \text{ of reading})$	Battery type	Internal rechargeable sealed lead acid 24VDC,5.0AH
DES	$\pm(0.15 \text{ vol\%} + 5 \% \text{ of reading})$	Backup power	Demonstrated battery backup time under typical operating conditions is 120 minutes when fully charged
Paramagnetic oxygen module			
Range	0-100%	Charge time	< 8 hours (in running status or standby mode)
Accuracy	$< \pm 0.2\% \text{ O}_2$	Power code	5m/16.4ft
Response Time (T10 –T90)	8 to 20 seconds dependent on application and filter selection (biological filter on request)	Outlets	4 outlets on back
Operation Temperature	5 °C to 50 °C (41°F to 122°F)	Maximum output valve of auxiliary AC power plug	1.5A(single plug); 6A(in total)
Storage Temperature	-30°C to 70°C (-22°F to 158°F)	Pneumatic specifications	
Storage Pressure	10kPa-200kPa(1.5psi-30psi)		
Ambient Humidity	0 to 95% non-condensing		
RoHS	ROHS Directive 2002/95/EC	Auxiliary common gas outlet(optional) Connector:	ISO 22 mm OD and 15 mm ID
		Security	Anti-misconnection switch and prominent prompts on the screen

Electrical specifications

Power and battery backup

Power input	100-240V,50/60Hz, Max. $\leq 8\text{A}$
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Gas supply

Gas type	O ₂ ,N ₂ O,Air
Pipeline input range	280 kPa to 600 kPa/41 psi to 87 psi
Pipeline connections	NIST/DISS

Cylinder input Pin-index yokes

Primary regulator 250 kPa/36psig
nominal output

O₂ controls

Method Proportionate
decrease of N₂O with
reduction in O₂
pressure

Supply failure alarm Range: 185 to 215
kPa

O₂ flush Range: 25 to 75 L/min

Electronic control Flowmeter (Electronic Mixer)

O₂ ranges 0 to 10 L/min

N₂O ranges 0 to 10 L/min

Air ranges 0 to 12 L/min

Total Flow Control Total flow range: 0.2
Mode to 18 L/min
O concentration
range: 21% to 100%

Integrated safety functions

Guarantees a minimum O₂ concentration of 25%
in an O₂/N₂O mixture.

N₂O cut-off if O₂ pressure is less than 200kPa

Driven gas auto-switch(optional)

Use compressed air as the driving gas.

When the compressed air supply is disrupted,
the machine will automatically switch to O₂
driving gas.

Auxiliary oxygen inhalation

Range 1-15L/min

Pressure 400kPa

Flow indicator Flow tube

Auxiliary gas output

Gas Oxygen

Pressure 280-600kPa

Flow rate Max.90L/min

Breathing circuit specifications

Carbon dioxide absorbent canister

Absorbent capacity 1500ml

CO₂ bypass Optional

Ports and connectors

Exhalation 22 mm OD ISO 15
mm ID taper

Inhalation 22 mm OD ISO 15
mm ID taper

Bag port 22 mm OD

Pressure gauge

Scale range -20 to 100 cm H₂O

Bag-to-Ventilator switch

Type Key switch

Control Controls ventilator and
direction of
breathing gas within
the circuit

Integrated Adjustable Pressure Limiting (APL) valve

Range	0 to 70 cm H ₂ O
Tactile knob indication at	30 cm H ₂ O and above
Adjustment range of rotation	0 to 30 cm H ₂ O (0 to 180°) 30 to 70 cm H ₂ O (180 to 288°)
Accuracy	< 30 cm H ₂ O: ±3 cm H ₂ O; ≥30 cm H ₂ O: ±15% of set value;

Breathing circuit parameters

Compliance (Bag mode)	4.5ml/ cm H ₂ O
Compliance (Mechanical Mode)	Automatically compensates for compression losses within the absorber and bellows assembly
Circuit volume	3.9 L Vent Mode (including absorber; bellow) 2.4 L Bag Mode

Expiratory resistance under manual condition	0.51 kPa
Inpiratory resistance under manual condition	0.39 kPa

Expiratory resistance under automatic	0.57 kPa
Inpiratory resistance under automatic	0.22 kPa

Note: According to ISO 80601-2-13, test under peak flow 60L/min, fresh gas 10L/min.

Heating system(optional)

Temperature	32 - 40°C
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Materials

All materials in contact with exhaled patient gases are autoclavable, except mechanical pressure meter and O₂ cell.

All materials in contact with patient gas are free of natural rubber latex.

Anesthetic gas scavenging System(AGSS)

Size	445×142×95 (height x width x depth)
Weight	2.25Kg
Type of disposal system	Low-flow disposal system
extract Flow	35L/Min~50L/Min
Pressure relief device	Pressure compensation opening to the atmosphere
Filter	Stainless screen with hole diameter of

150µm

Spillage <100mL/min

Maximum constant flow 50L/Min

Maximum intermittent flow 35L/Min

Environmental specifications

System operation

Temperature 10 to 40°C

Humidity Less than 95% relative humidity, non-condensing.

Atmospheric pressure 70-106kPa

System storage

Temperature - 20 to 55°C

Humidity Less than 95% relative humidity, non-condensing.

Barometric 70-106kPa

Electromagnetic compatibility

Immunity Complies with all requirements of EN 60601-1-2

Emissions CISPR 11 group 1 class A



CE mark in this manual apply only to product with CE mark.

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Edition 1.0

May.2021

Physical Specifications

Dimensions

Height	1410mm
Width	740mm
Depth (without YOKE)	730mm
Weight (basic unit)	110kg

Top Shelf

Weight limit	25kg
Width	650mm
Depth	380mm

Work surface

Height	850mm
Width	440mm
Depth	300mm
Material	stainless steel

Flip-up side tray

Height	850mm
Weight limit	12kg
Width	265mm
Depth	330mm

Drawers (internal dimensions)

Quantity	3
Height	120mm
Width	355mm
Depth	340mm

Casters

Diameter	125mm
Brakes	Central control brake

Cylinder YOKE(optional)

Interface	Pin Index Safety System (PISS)
Type	E
Number	Optional 2 cylinders Maximum 4 cylinders

Ventilator Operating Specifications

Modes of ventilation – standard

Manual; IPPV PCV
STANDBY; Demo

Modes of ventilation – Options

SIMV-VC, SIMV-PC
PCV-VG, SIMV-VG
PS/CPAP
BIVENT, APRV

Ventilator parameter ranges

Tidal volume range	20 to 1500 mL Optional 10 to 1500 mL (Volume Control and SIMV modes) 5 to 1500 mL (Pressure Control Vent Mode)
Tidal volume Incremental settings	increments of 5mL(Set Vt below 100mL) or 10mL(when set Vt between 100 and 1000mL) or 50mL(when set Vt bigger than 1000mL)
Pressure (P _{MAX}) range	10 to 100 cmH ₂ O (increments of 1 cmH ₂ O) (IPPV, SIMV-VC and PCV-VG vent modes)
Pressure (P _{support}) range	3 to 60 cmH ₂ O (increments of 1 cmH ₂ O) (SIMV-VC/PC/VG,

	PS/CPAP, BIVENT and APRV vent modes)	Pressure trigger (P_{SENS})	-20 to -1 cmH ₂ O (increments of 1 cmH ₂ O)
Pressure (P_{TARGET}) range	5 to 70 cmH ₂ O (increments of 1 cmH ₂ O) (PCV and SIMV-PC vent modes)	E_{SENS}	(SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
Freq.	2 to 100 breaths per minute (SIMV-VC, SIMV-PC and SIMV-VG vent modes)		5 to 70% (increments of 5%) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
	2 to 60 breaths per minute for Freq _{MIN} in PS/CPAP vent modes.	I_{SENS}	5 to 70% (increments of 5%) (APRV vent modes)
	4 to 100 breaths per minute (Other mode) (increments of 1 breath per minute)	P_{HIGH}	5 to 70 cmH ₂ O (increments of 1 cmH ₂ O) (BIVENT and APRV vent modes)
Inspiratory/expiratory ratio	4:1 to 1:8 (increments of 0.5) (IPPV, PCV and PCV-VG vent modes)	P_{LOW}	3 to 50 cmH ₂ O (increments of 1 cmH ₂ O) (BIVENT and APRV vent modes)
Inspiratory time	0.2 to 5 seconds (increments of 0.1 seconds) (SIMV-VC/PC/VG vent modes)	T_{HIGH}	0.2s to 30s (increments of 0.1s) (BIVENT and APRV vent modes)
Inspiratory Pause Time	OFF, 5% to 60% (increments of 5%) (IPPV and SIMV-VC vent modes)	T_{LOW}	0.2s to 30s (increments of 0.1s) (BIVENT and APRV vent modes)
Flow trigger (V_{SENS})	0.5 L/min to 15L/min (increments of 1L/min) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)	T_{SLOPE} (Inspiratory Slope Time)	0.2s to 2.0 seconds (increments of 0.1 seconds)

	(PCV,PCV-VG, SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)	PAW	minute -20cmH ₂ O to 110cmH ₂ O
		FiCO ₂	0 to 10 vol%
		EtCO ₂	0 to 10 vol%
Positive (PEEP) End Expiratory Pressure	Type Integrated electronically controlled	DP (Driving airway pressure)	0 to 120 cmH ₂ O
	Range OFF, 3 to 50 cm H ₂ O (increments of 1 cm H ₂ O)	SI (Stress index)	0.1 to 5
		V _{Ti}	0 to 3000mL
		V _{TE}	0 to 3000mL
		I:E	4:1 to 1:8
		Rsys	0 to 300cmH ₂ O/(L/S)
		Csys	0 to 300mL/(L/S)
		VO ₂	Real time calculation
		CO ₂ -T	Real time calculation
Ventilator performance			
Pressure range at inlet	280 kPa to 600kPa		
Peak gas flow	≥90 L/min + fresh gas flow		
Ventilator monitoring			
Minute volume range	0 to 30L		
Tidal volume range	0 to 3000mL		
FiO ₂	18% to 100%		
Peak pressure(P _{peak})	-20cmH ₂ O to 99cmH ₂ O		
Mean pressure(P _{mean})	-20cmH ₂ O to 99cmH ₂ O		
Plat pressure(P _{plat})	-20cmH ₂ O to 99cmH ₂ O		
PEEP	-20cmH ₂ O to 99cmH ₂ O		
Frequency	0 to 110 breaths per		

Trend table

Continuous trend information together with time discrete events are stored and shown in the table, including P_{peak}, P_{plat}, P_{mean}, PEEP, Freq, V_T, MV, FiO₂, etCO₂, FiCO₂, Agent1, Agent2, N₂O, MAC, FG-O₂, FG-Air and FG-N₂O. The left page shall include the 10 parameters and the remains shall be in the right page.

The machine shall remember maximum 30 days trend data, and the interval shall be 5 minutes, the interval is adjustable

Trend chart Continuous trend information are stored and shown in the chart, including Pressure, CO ₂ , Agent, MV, VT, O ₂ . The machine shall remember the 72 hours trend chart	Inspired oxygen (FiO ₂)	Low: 18 to 99% High: 21 to 100%
	exhalant CO ₂ (etCO ₂)	Low: OFF, 0.1 to 9.8% or OFF, 1 to 74 mmHg High: 0.1 to 9.9% or 1 to 75mmHg
Stories alarms All the alarm messages can be viewed from the log menu. Click on the alarm message bar the detail information of the corresponding alarm appears on the screen. The machine shall remember the lastest 500 alarm messages,	Inspired CO ₂ (FiCO ₂)	High: 0.1 to 1.4% or 1 to 10 mmHg
Delivery/monitoring accuracy Volume delivery < 100 mL = better than 10 mL > 100 mL = better than 15% Pressure delivery ± 10% or ± 3 cm H ₂ O PEEP delivery ± 2cmH ₂ O or ± 15% Volume monitoring < 100 mL = better than 10 mL > 100 mL = better than 15% Pressure monitoring ± 5%	Insp. HAL	Low: OFF, 0.1 to 8.3% High: 0.1 to 8.4%
	Insp. ISO	Low: OFF, 0.1 to 8.3% High: 0.1 to 8.4%
Alarm settings Minute volume (Mvexp) Low: 0 to 20 L/min High: 1 to 25 L/min Low airway pressure 0 to 70 cmH ₂ O High pressure 10 to 110cmH ₂ O High Breath Rate 8 to 60 bpm	Insp. ENF	Low: OFF, 0.1 to 9.8% High: 0.1 to 9.9%
	Insp. DES	Low: OFF, 0.1 to 21.8% High: 0.1 to 21.9%
	Insp. SEV	Low: OFF, 0.1 to 9.8% High: 0.1 to 9.9%
	Apnea alarm	Mechanical ventilation ON: Vt < 10 mL breath or P _{mean} < 1 cm H ₂ O or P _{mean} = 1 cm H ₂ O and PEEP ≤ 0 cmH ₂ O measured in 30 seconds when Frequency ≥ 6 Vt < 10 mL breath or P _{mean} < 1 cm H ₂ O or P _{mean} = 1 cm H ₂ O and PEEP ≤ 0 cmH ₂ O measured in 35 seconds when

	Frequency<6		
	Manual mode:		
	Vt< 10 mL measured in 60 seconds	Ventilator Screen	
		Display type	Color active matrix TFT
Sustained airway pressure	Mechanical ventilation ON:		Touch screen
	Paw>PEEP add 10 cm H ₂ O measured over 15 seconds	Display size	12.1 inches diagonal
	Continuously Mechanical ventilation OFF:	Pixel format	1024×768
	Paw>10 cm H ₂ O measured over 15 seconds Continuously	Color	LVDS 24 bit, 16777216 colors
Subatmospheric pressure	Paw < -2 cm H ₂ O	Display parameters	All setting and alarm parameters(including Vt, Freq., I:E, T _{INSP} , PEEP, Freq _{MIN} , T _P , Trigger, P _{TARGET} , ΔP, T _{SLOPE} , PEAK, MEAN, PLAT, FIO ₂ , DP, SI, VTI, VTE, I:E, Rsys, Csys VO2, CO2-T
Alarm silence countdown timer:	120 to 0 seconds		

Ventilator components

Flow transducer

Type	Mass type	Display graphics	Wave of P-T, F-T, V-T, CO2-T(option), Paw-V Loop, V-Flow Loop, Paw -Flow Loop
	Measure mass flow in bypass application		
Location	Installed in breathing system	Communication ports	RS-232C compatible serial interface(DB 9 connector);

Oxygen Sensor

Type1	Galvanic fuel cell		RJ45 connector 100-Base-TX support HL7 communication license;
Life Cycle	proximately 12 months (Dependent on usage)		USB 2.0 interface
Type2	Paramagnetic oxygen		
Life Cycle	8 years		

Integrated safety functions

In case of electricity and battery failure, manual ventilation, gas delivery and agent delivery are possible.

Positive pressure relief valve opens at $110 \pm 1 \text{ cmH}_2\text{O}$.

Anesthetic agent delivery

Delivery

Vaporizer	VP300
Type	Halothane, Enflurane, Isoflurane, Sevoflurane,
Number of positions	2
Mounting	Selectatec ^R manifold interlocks

Dimensions

Height	23 cm
Width	12 cm
Depth	21 cm
Weight	6.2 kg
Agent capacity	250ml

Accuracy

Flow range	0.2-15L/min
Operation temperature	15-35°C
Accuracy	$\pm 20\%$ of setting or $\pm 5\%$ of the maximum scale

Agent setting range

Sevoflurane: :
 OFF , 0.2% , 0.5% ,
 1% , 2% , 3% , 4% ,
 5% , 6% , 7% , 8% ;
 Halothane, Enflurane,
 Isoflurane: OFF ,
 0.2% , 0.5% , 1% ,
 2% , 3% , 4% , 5% ;

Gas monitor(optional)

Type	main stream/side stream
Module	IRMA CO ₂ ; IRMA AX+ ISA CO ₂ ; ISA AX+
Operating temperature	IRMA AX+: 10 to 40 °C (50 to 104 °F) IRMA CO ₂ : 0 to 40 °C (32 to 104 °F) ISA CO ₂ : 0 to 50 °C (32 to 122 °F) ISA AX+: 5 to 50 °C (41 to 122 °F)
Storage temperature	IRMA AX+: -20 to 75 °C (-4 to 167 °F) IRMA CO ₂ : -40 to 75 °C (-40 to 167 °F) ISA CO ₂ : -40 to 70 °C (-40 to 158 °F) ISA AX+: -40 to 70 °C (-40 to 158 °F)
Operating humidity	< 4 kPa H ₂ O (non-

	condensing) (95 %RH at 30 °C)	Infant.	
Operating atmospheric pressure	525 - 1200 hPa (<4572 m)	ISA Nomoline	Sampling line with proprietary water removal tubing. 2 m±0.1m versions
Warm-up time	IRMA AX+/ISA AX+: < 20 sec IRMA CO ₂ /ISA CO ₂ : < 10 sec	Carbon Dioxide (CO₂) Moudle (IRMA/ISA CO₂) Monitor Gas	CO ₂
Rise Time	IRMA CO ₂ / AX+: CO ₂ ≤90ms N ₂ O≤300ms HAL, ISO, ENF, SEV, DES≤300ms ISA CO ₂ : CO ₂ ≤200ms ISA AX+ : CO ₂ ≤300ms N ₂ O, O ₂ , ENF, ISO, SEV, DES ≤400ms HAL ≤500ms	Measurement range Accuracy	0-15 vol% 0-15 vol% ± (0.2 vol% + 2 % of reading)
ISA sampling flow rate	50 ± 10 ml/min	Anaesthesia Gas Moudle(IRMA/ISA AX+) Monitor Gases	CO ₂ ;N ₂ O;HAL;ISO;EN F;SEV;DES
Breath detect	Adaptive threshold, minimum 1 % CO ₂ change.	Measurement range	CO ₂ : 0-15 vol% N ₂ O: 0-100 vol% HAL, ISO, ENF: 0-8 vol% SEV: 0-10 vol% DES: 0-22 vol%
Respiratory rate:	0 - 150 bpm ± 1 bpm	Accuracy CO ₂	0-15 vol% ± (0.2 vol% + 2 % of reading)
Compensation:	Automatic for atmospheric pressure, temperature and spectral interference	N ₂ O	±(2 vol% + 2 % of reading)
Airway adapters			
IRMA Airway Adapter Adult/Paediatric	6 ml dead space	HAL, ISO, ENF	±(0.15 vol% + 5 % of reading)
IRMA Airway Adapter	1 ml dead space		reading)

SEV	$\pm(0.15 \text{ vol\%} + 5 \% \text{ of reading})$	Battery type	Internal rechargeable sealed lead acid 24VDC,5.0AH
DES	$\pm(0.15 \text{ vol\%} + 5 \% \text{ of reading})$	Backup power	Demonstrated battery backup time under typical operating conditions is 120 minutes when fully charged
Paramagnetic oxygen module			
Range	0-100%	Charge time	< 8 hours (in running status or standby mode)
Accuracy	$< \pm 0.2\% \text{ O}_2$	Power code	5m/16.4ft
Response Time (T10 –T90)	8 to 20 seconds dependent on application and filter selection (biological filter on request)	Outlets	4 outlets on back
Operation Temperature	5 °C to 50 °C (41°F to 122°F)	Maximum output valve of auxiliary AC power plug	1.5A(single plug); 6A(in total)
Storage Temperature	-30°C to 70°C (-22°F to 158°F)	Pneumatic specifications	
Storage Pressure	10kPa-200kPa(1.5psi-30psi)		
Ambient Humidity	0 to 95% non-condensing		
RoHS	ROHS Directive 2002/95/EC	Auxiliary common gas outlet(optional) Connector:	ISO 22 mm OD and 15 mm ID
		Security	Anti-misconnection switch and prominent prompts on the screen

Electrical specifications

Power and battery backup

Power input	100-240V,50/60Hz, Max. $\leq 8\text{A}$
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Gas supply

Gas type	O ₂ ,N ₂ O,Air
Pipeline input range	280 kPa to 600 kPa/41 psi to 87 psi
Pipeline connections	NIST/DISS

Cylinder input Pin-index yokes

Primary regulator 250 kPa/36psig
nominal output

O₂ controls

Method Proportionate
decrease of N₂O with
reduction in O₂
pressure

Supply failure alarm Range: 185 to 215
kPa

O₂ flush Range: 25 to 75 L/min

Electronic Display Flowmeter

O₂ ranges 0.05 to 0.95 L/min
and 1.0 to 10.0 L/min;

N₂O ranges 0.05 to 0.95 L/min
and 1.0 to 10.0 L/min;

Air ranges 0.05 to 0.95 L/min
and 1.0 to 12.0 L/min;

Integrated safety functions

Guarantees a minimum O₂ concentration of 25%
in an O₂/N₂O mixture.

N₂O cut-off if O₂ pressure is less than 200kPa

Driven gas auto-switch(optional)

Use compressed air as the driving gas.
When the compressed air supply is disrupted,
the machine will automatically switch to O₂
driving gas.

Auxiliary oxygen inhalation

Range 1-15L/min

Pressure 400kPa

Flow indicator

Flow tube

Auxiliary gas output

Gas Oxygen

Pressure 280-600kPa

Flow rate Max.90L/min

Breathing circuit specifications

Carbon dioxide absorbent canister

Absorbent capacity 1500ml

CO₂ bypass Optional

Ports and connectors

Exhalation 22 mm OD ISO 15
mm ID taper

Inhalation 22 mm OD ISO 15
mm ID taper

Bag port 22 mm OD

Pressure gauge

Scale range -20 to 100 cm H₂O

Bag-to-Ventilator switch

Type Key switch

Control Controls ventilator and
direction of
breathing gas within
the circuit

Integrated Adjustable Pressure Limiting (APL) valve

Range 0 to 70 cm H₂O

Tactile knob indication at 30 cm H₂O and above

Adjustment range of rotation 0 to 30 cm H₂O (0 to 180°)
30 to 70 cm H₂O (180 to 288°)

Accuracy < 30 cm H₂O: ±3 cm H₂O;
≥30 cm H₂O: ±15% of set value;

Breathing circuit parameters

Compliance (Bag mode) 4.5ml/ cm H₂O

Compliance (Mechanical Mode) Automatically compensates for compression losses within the absorber and bellows assembly

Circuit volume 3.9 L Vent Mode (including absorber; bellow)
2.4 L Bag Mode

Expiratory resistance under manual condition 0.51 kPa

Inpiratory resistance under manual condition 0.39 kPa

Expiratory resistance 0.57 kPa

under automatic

Inpiratory resistance 0.22 kPa under automatic

Note: According to ISO 80601-2-13, test under peak flow 60L/min, fresh gas 10L/min.

Heating system(optional)

Temperature 32 - 40°C

Materials

All materials in contact with exhaled patient gases are autoclavable, except mechanical pressure meter and O₂ cell.

All materials in contact with patient gas are free of natural rubber latex.

Anesthetic gas scavenging System(AGSS)

Size 445×142×95 (height x width x depth)

Weight 2.25Kg

Type of disposal system Low-flow disposal system

extract Flow 35L/Min~50L/Min

Pressure relief device Pressure compensation opening to the atmosphere

Filter Stainless screen with hole diameter of 150µm

Spillage <100mL/min

Maximum constant flow 50L/Min

Maximum intermittent flow 35L/Min

Environmental specifications

System operation

Temperature 10 to 40°C

Humidity Less than 95% relative humidity, non-condensing.

Atmospheric pressure 70-106kPa

System storage

Temperature - 20 to 55°C

Humidity Less than 95% relative humidity, non-condensing.

Barometric 70-106kPa

Electromagnetic compatibility

Immunity Complies with all requirements of EN 60601-1-2

Emissions CISPR 11 group 1 class A



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Edition 1.0

May.2021



BIO SIGNAL TOTAL SOLUTION

Product

- Fetal Monitor · Fetal Doppler · Infant Incubator · Infant Warmer · Phototherapy
- Electric Breast Pump · Patient Monitor · Vascular Doppler · Head Lamp

Fetal Monitor

BT-350

LCD Monitor / LED Monitor



BT-350L



BT-350E

- 7" TFT color LCD / Large size LED
- Display mode variation
 - Graph mode, Number mode, Trend mode
- Multi language support
- Trend : 450 hours (3 hours/patient)
- Desktop & Wall mount
- CTG Analysis (BT-350L)
- USB Data Saving
- CCV (Cross-Channel Verification) Function

BT-300

LED Monitor



- Clear display & Sound
- Compact & Light Design
- Easy to use each function
- High sensitivity ultrasound probe

Specifications	BT300	BT350E	BT350L
Ultrasound Frequency	0.985MHz		
FHR Range	Twin / 30 ~ 240 bpm		
Fetal Movement	Auto-detection & print		
UC	0 ~ 99 units		
Print Function	1, 2, 3cm/min speed & Auto print (Off, 10, 20, 30, 40, 50, 60min) & FHR II offset		
Display	Medium 7-segment LED	Large 7-segment LED	7" TFT color LCD
Diagnosis	No	No	Yes
Trend(Data Save)	No	No	Yes(450 hours)
USB Function (data transfer)	No	Yes	Yes
Central Monitoring System	BCM350 (RS-232C / Bluetooth or WiFi)		
Warranty	2 years (Accessory Excluded)		
Options	Rechargeable battery, Acoustic stimulator, Cart, Wall mounted bracket (BT-350)		

Fetal Doppler

BT-200 (Hi-bebe)

Sound / Mono / Color



BT-200S



BT-200L / 200T



BT-200C

- LCD / OLED display
- High quality sound
- High sensitivity probe (2,3MHz)
- Hand-held style
- Low battery indicator
- Waterproof Probe

BT-220 (Hi-bebe S)

Sound / Mono / Color



BT-220C



BT-220L

- 2.4" Color LCD display
- Acoustic stimulator (BT-220C,L)
- Body fat analysis (BT-220C)
- Mother HR function (BT-220C)
- USB Rechargeable (BT-220C,L)
- Waterproof Probe

BT-250

Desktop Doppler



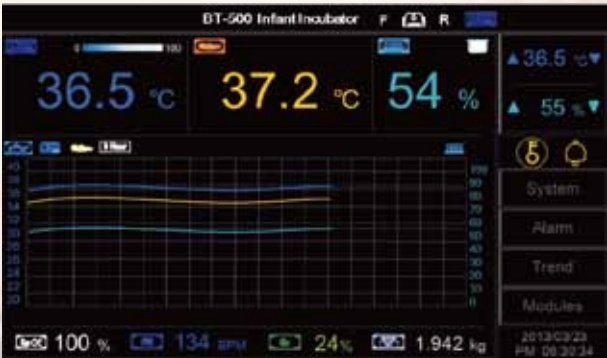
- 3.2" Color LCD display
- Data Save : 4 Hours
- Multi languages support
- Built-in rechargeable battery
- High quality sound
- High sensitivity(2MHz)
- Compact & Light
- Waterproof probe

Specifications	BT200S	BT200L	BT200C	BT200T	BT220L	BT220C	BT250
Ultrasound Frequency	2MHz			3MHz	2, 3MHz		2MHz
FHR Range	50 ~ 240 bpm					30 ~ 240 bpm	
Display	No	Mono LCD	Color LED	Mono LCD	Mono LCD	2.4" TFT color	3.2" TFT Color
Battery Time (hours)	5					4	5
Power	1.5V AA battery x 2						100~240V / rechargeable
Rechargeable Battery	-						Yes
PC Interface	BCM200 (Sound card)						RS-232C
Trend (Data Save)	No	No	No	No	No	No	4 hours
Acoustic Stimulate Function	No	No	No	No	Yes	Yes	No
Options	-					USB cable	
							Cramp

Infant Incubator

BT-500

- Accurate humidity control
- Comfortable & soft tilting structure
- 7" Color LCD Display
- Powerful Lifting Stand (option)
- O2 Monitoring / O2 Servo Control (option)
- MASIMO SpO2 & CCD Camera (option)
- Correct Weighting Scale (option)
- Various Alarm Functions
- Low Noise Hood



Air / Skin temperature
Humidity Servo control



MASIMO SpO2 & CCD
Camera & External Monitor
(Option)



Mattress tilt



Built-in x-ray tray

Specifications	BT500
Display	7" TFT color LCD
Dimension / Weight	1,024mm(W) x 690mm(D) x 1,354mm(H) / 99.3kg
Air / Skin Temperature Control Range	23.0 ~ 37.0℃±0.5℃ / 35 ~ 37.5℃±0.5℃ (override < 39.0℃)
Humidity Control / Measurement Range	40 ~ 95%±5% RH / 15 ~ 99%±5% RH
Humidity Control System	Steam
Water Tank Capacity	1,000 ml
Mattress Size & Tilt	730(L) x 27(H) x 380(D) mm / 12°
Noise Level	< 45dB
Options	Lifting Stand : 651(min) ~ 851(max)mm
	Drawer
	Plate
	IV pole
	O2 monitoring : 18 ~ 100% ±5%
	O2 servo control : 21% ~ 65%
	Weighing scale : 0 ~ 10Kg ±50g
	Shelf
MASIMO Spo2 & CCD camera & external monitor	

Infant Warmer

BT-550

- Far Infrared Heater
- 7 inch LCD Display
- Apgar Timer
- Swivel Head
- LED Examination Lamp
- Good design
- Wide Rnge of Accessories



Swivel Head (Left90° & Right90°)



LED Examination Lamp



Heat Source



Tilting (option)
(15°±2° to backward or forward)



7 inch TFT LCD Display



Tripod water level



Both sides Drawers (option)



Three sides open protective barriers



Lifting Stand (option)

Specifications	BT550
Display	7 inch TFT color LCD
Dimension / Weight	1,184(L) x 1,890(H) x 846(D)mm / 98Kg
Control Mode	Pre warm / Baby / Manual
Skin Temperature Display / Control Range	26 ~ 42℃±0.5℃ / 34 ~ 38℃±0.5℃
Heater Output Setting Range / Power	0 ~ 100% (5%p resolution) / 26mW/cm2 (±20%)
LED Examination Lamp	40W(10W x 4, <3,000lm) 3 steps control
Alarm	Visual and Sound Alarms
APGAR Timer	0min ~ 59min 59sec (1, 5, 10min Beep)
Mattress Size	495(L) x 27(H) x 810(D) mm
Options	Tilt : ±15°
	Drawer
	Plate
	IV pole
	Lifting Stand : 615 ~ 815mm
	Weighting scale : 0 ~ 10Kg ±50g
	MASIMO Spo2

Phototherapy

BT-400

- Lamp : Blue LED
- High Intensity of Radiation
- Compact design
- Flexible neck
- Wide effective area
- Time counter & Setting
- Easy to Use
- Various installation



Adjustable head



Timer & adjustable intensity



Power 11 LED

Light Source	11 Blue LEDs
Wave length	Peak between 450 – 475 nm
Intensity	20 ~ 100 uW/cm²/nm
Effective Area	40 x 20 cm
Life Time	About 20,000 hours
Variation in Intensity Over 6 Hours	< 10%
Power	AC 100 ~ 240V (50/60Hz)
Display	2.4" TFT color LCD Operating hours, Total operating hours, Timer, Intensit Intensity
Option	Cart, Eye shield, Shade

Vascular Doppler & LED Head Lamp

BT-200 (Hi-dop)

Vascular Doppler



- hand held style
- clear Sound
- compact and light
- High-Sensitive Doppler Probe
- 4 Ranges of probes
- Easy to use
- Low power consumption
- Long time continuous use (6 hours)

Specifications	Specifications
Ultrasound Frequency	2, 4, 5, 8MHz
HR Range	50 ~ 240 bpm
Display	Mono LCD
Battery Time (hours)	5 hours
Power	1.5V AA battery x 2
Options	-

BT-410

LED Head Lamp



BT-410A

BT-410F

- Light & comfortable
- Low battery display
- Quick battery recharge
- Ultra bright LED
- Easy to adjust Head band
- More than 50,000 hours LED life
- Removable battery module

Specifications		BT410A	BT410F
Mode		Adjustable focus	Fixed focus
Illumination		30,000lx / 50,000lx (Astral)	15,000 ~ 30,000lx (Adjustable)
LED Life Time		50,000 hours	
Color Temperature		6,000 Kelvin	
Battery Module	Operating Time	4 hours	
	Recharge	800 times	
	Output	3.7 V	
Charger	Input	AC 100 ~ 240 V (50/60Hz)	
	Charging Time	4 hours	
Options		X 3.5 Loupe, Battery module, Astral lamp (BT-410A)	

Patient Monitor

BT-700

Vital Sign Monitor



- 3.2" LCD display
- SpO2, Temp.
- Trend : 4 hours
- Compact and light
- Easy F/W upgrade (USB)
- Apply nurse call state
- Temperature - (optional)

Electric Breast Pump

Hi bebe *plus*

Electric Breast Pump : BT-100



BT-750

Multi-parameter Patient Monitor



- 10.4" Color LCD display
- ECG(2ch), SpO2, NIBP, Temp.(2ch), IBP, RESP.
- PVC and ST level display Pacemaker detection
- Detection of 12 kinds of arrhythmia
- Trend : 72 hours
- Central monitoring system (LAN)



Memory customized expression sequence



Vacuum control in 10 levels



Auto switch off after 30 minutes



Sufficient vacuum for dual expression



Backflow prevention



Rechargeable battery (2,5hour operation)



Convenient and graceful design



3 operating mode (express , massage, memory)



Operating time display



Silent

Specifications		BT700	BT750
Display		3.2" color LCD	Ultrasound 10.4" color LCD
Battery Operating Time		3 hours	3 hours
SpO2	Measuring Range	1% ~ 100%	
	Pulse Rate	30 ~ 250 bpm	20 ~ 300 bpm
NiBp	Mode	Auto, Manual, STAT	
	Auto Mode(min)	1,2,3,4,5,10,15,30,45,60,90,120,240	1,3,5,10,30,60,90,120,240
	Neonate/Adult Systolic	20/30 ~ 120/250 mmHg	30/50 ~ 130/255 mmHg
	Neonate/Adult Diastolic	10/20 ~ 110/210 mmHg	20/30 ~ 100/220 mmHg
ECG	Lead	-	3/5 Leads
	Sweep Speed	-	12.5, 25, 50 mm/s
Resp	Resp	-	0 ~ 150 breaths/min
	Sweep Speed	-	6.25, 12.5, 25 mm/s
Temp	Range	20 ~ 45℃	30 ~ 45℃
Options		NiBp, Temp	Printer, IBP, EtCO2

Specifications	BT100 Hello Mom
Type of Pump	Personal Use (Dual Express)
Adjustable Speed / Vacuum	Yes
Size / Weight	110(H) x 70(W) x 45(D) mm / 370g
Boot up & Shut down Time	< 1sec
Pumping Session	Timer & Memory
Automatic Turn Off	30minutes
Backflow Prevention	Yes
Memory Function	Yes
Vacuum Pressure	270mmHg
Expression Pressure Variation	10 steps
Massage Pressure Variation	10 steps



BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd.

** All specifications are subject to change without notice.*

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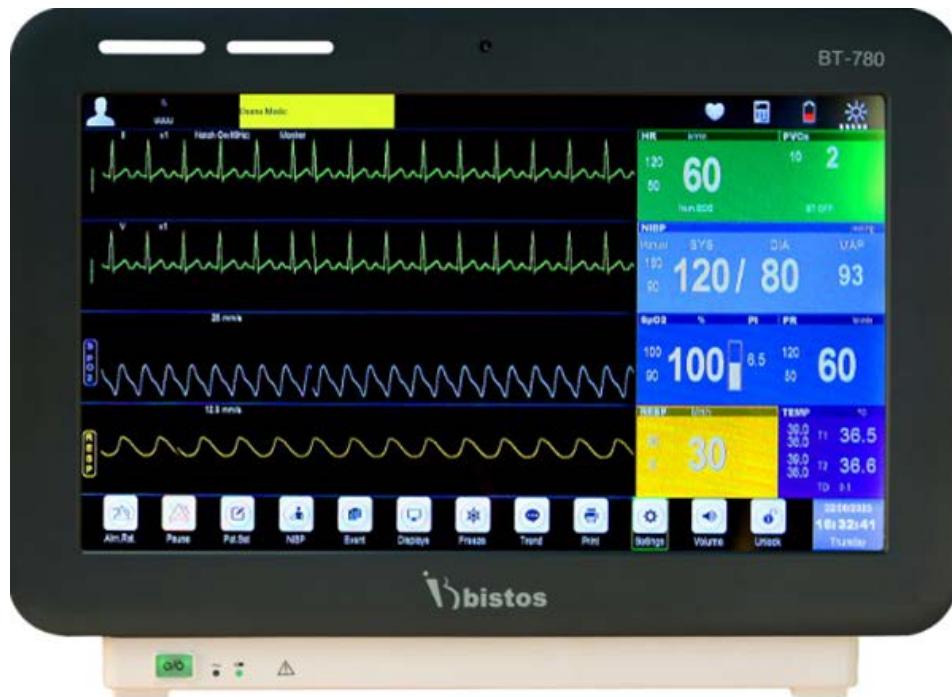
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BT-780 PATIENT MONITOR



15.6" Multi-Parameter Patient Monitor

ECG, Resp., SpO₂, NIBP, Temperature

Optional CO₂, IBP, Multi-gas, C.O., Masimo SpO₂

Touch screen

Central station / Ultra slim design / Over 5 hours battery use



Dual Screen Central monitoring station

:: Technical Specification

Model			BT-780
Category			Patient Monitor
Display			15.6" Color Touch LCD
ECG	Lead Type		3/5 lead
	Gain Selection		x0.125, x0.25, x0.5, x1, x2, x4, auto
	Sweep Speed (mm/s)		12.5, 25, 50
	Bandwidth : Diagnostic Mode		0.05-100 Hz
	Monitoring Mode		0.5-40 Hz
	Surgery Mode		1-25 Hz
	Strong Mode		5-20 Hz
	Heart Rate Range (bpm)		Adult : 15-300 Pediat / Neonate : 15-350
	Respiration	Method	
Measurement Range		0-120 rpm	
Sweep Speed (mm/s)		6.25, 12.5, 25	
SpO ₂	Measurement Range		0-100 %
	Accuracy (70-100%)	Adult / Pediatric	±2 %
		Neonate	±3 %
	Accuracy (0-69%)		Unspecified
	Perfusion Index		0.05-20 %
	Pulse Rate Range (bpm)		25-250
	NIBP**	Method	
Operation Mode		Manual / Auto / STAT	
Parameter		Systolic, Diastolic, Mean	
Systolic Range (mmHg)		Adult	30-280
		Pediatric	30-230
		Neonate	30-145
Diastolic Range (mmHg)		Adult	10-220
		Pediatric	10-165
		Neonate	10-105
Mean Range (mmHg)		Adult	10-240
		Pediatric	10-175
		Neonate	10-115
Temperature	Range		0-50 °C (41 to 122 °F)
	Parameter		T1, T2, and TD
IBP*	Channel		2 Channel / 4 Channel
	Range (mmHg)		-50 to 400
Printer*	Type		Thermal dot array
	Print Speed (mm/s)		12.5, 25, 50
	Paper size (mm)		50
CO ₂ *	Method		Masimo ISA / Bistos
	Range		Masimo IRMA / Bistos
Multi-gas/O ₂ *			Masimo ISA
SpO ₂ -Masimo*			Masimo SpO ₂
CO ₂ *	Method		Thermodilution
	Range		0.2-20 L/min
Battery	Type (capacity)		Li-ion (4400 mAh)
	Run Time		5 hour
	Charging Time		4 hour
PC Software Interface			RJ45, USB, Nursing call
Warranty			2 year

Specifications : BT-770 12.1" Multi-parameter Patient Monitor

Functional Characteristics	
Display	
Type	Color TFT touch screen LCD
Size and resolution	12.1", 800 x 600 pixels
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meets the IEC60601-1-8
Data Storage	
Trend	168hours, resolution : 1min
Alarm event	200 physiological and 100 technical alarm events
NiBp measurement result	1,000 groups
Function	
Multi-language	English, France, Spanish, Turkey
Trend	Graphic/tabular
Alarm	
Mode	Visual, audible, information, parameter flashing
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Pause duration	1, 2, 3, 4, 5, 10, 15min or permanent
System	Low battery
Interface	
Auxiliary	Nurse call
RJ45 (LAN)	CMS
USB	S/W upgrade
ECG	
Standard compliance	IEC60601-2-27
Lead type	3Lead : I, II, III
	5Lead : I, II, III, aVR, aVL, aVF, V
Display sensitivity (gain)	Auto, 1.25, 2.5, 5, 10, 20mm/mV
Wave sweep speed	12.5, 25, 50mm/s
Band width	Diagnostic mode : 0.05 ~ 130Hz
	Monitoring mode : 0.5 ~ 40Hz
	Surgery mode : 1 ~ 25Hz
	Strong filter mode : 5 ~ 20Hz
CMRR	> 100dB
Notch	50/60Hz (can be set on or off)
Differential input	> 5MΩ
Electrode polarization voltage range	±400mV
Baseline recovery time	< 5s after defibrillation (monitor and surgery mode)
Calibration signal	1mV (peak-peak), accuracy ±3%
Lead-off detection current	Measuring electrode : < 0.1μA
	Drive electrode : < 1μA
HR measuring range	Adult : 15 ~ 300bpm
	Pediatric/Neonate : 15 ~ 350bpm
HR measuring resolution	1bpm
HR measurement accuracy	±1bpm or ±1%, whichever is greater
HR accuracy & response to irregular rhythm	Ventricular bigeminy : 80±1bpm
	Slow alternating ventricular bigeminy : 60±1bpm
	Rapid alternating ventricular bigeminy : 120±1bpm
	Bidirectional systoles : 90±2bpm
HR time to alarm for tachycardia	0.5/1/2mV, 206bpm ventricular tachycardia : < 10s
	1/2/4mV, 195bpm ventricular tachycardia : < 5s

HR alarm upper limit (bpm)	Adult : 16 ~ 300, 1bpm step Pediatric/Neonate : 16 ~ 350, 1bpm step
HR alarm lower limit (bpm)	Adult : 15 ~ 299, 1bpm step Pediatric/Neonate : 15 ~ 349, 1bpm step
Pacing pulse identification	Detection range : $\pm 2\text{mV}$ ~ $\pm 700\text{mV}$ Pulse width : 0.2ms ~ 2.0ms
Pacing pulse average HR	15s data
Pacing pulse interval of HR Refreshing	Every second
Pacing pulse HR change response time	$\leq 10\text{sec}$
Pacing pulse tall T-wave suppression	2mV
Alarm	Communication, configuration, selfcheck error Lead off HR high/low, PVCs high Asystole, VF/VTA, R on T, Tachycardia/bradycardia, PVC frequent/couplet/singlr/bigeminy/trigeminy, Miss Beat Pacemaker not capture/work Signal weak, ST-I, II, III high/low
Respiration	
Measurement method	Thoracic electrical bio impedance method
Measuring lead	Lead RA-LA, RA-LL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2,000 Ω
Gain	10 grades
Wave sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement accuracy	$\pm 2\text{rpm}$
Measurement range	0 ~ 120rpm
Alarm	RR high/low Apnea Respiration artifact
Temperature	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Measuring range	0°C ~ 50.0°C (32°F ~ 122.0°F)
Resolution	0.1°C
Measurement accuracy	$\pm 0.3^\circ\text{C}$
Number of channel	2
T1/T2 alarm upper limit	0.1°C ~ 50.0°C, 0.1°C/°F step
T1/T2 alarm lower limit	0°C ~ 49.9°C, 0.1°C/°F step
Temperature difference alarm upper limit	0°C ~ 50.0°C, 0.1°C/°F step
Alarm	T1, T2 Sensor off T1/T2 high/low, TD high
NiBp	
Standard compliance	IEC80601-2-30
Measurement method	Automatic oscillometric method
Operating mode	Manual, automatic, continuous(STAT)
Useful life	100,000times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(40~270), Pediatric(40~200), Neonate(40~130) Mean : Adult(20~230), Pediatric(20~175), Neonate(20~100) Diastolic : Adult(10~210), Pediatric(10~162), Neonate(10~90)
Measurement accuracy	Maximum average error: $\pm 5\text{mmHg}$ Maximum standard deviation: 8mmHg
Resolution	1mmHg
Initial inflation pressure (mmHg)	Adult : 150(default), 80~240(pressure setting range) Pediatric : 100(default), 80~200(pressure setting range) Neonate : 100(default), 60~120(pressure setting range)

Overpressure protection point (software)	Adult: 300mmHg Pediatric: 240mmHg Neonate: 150mmHg
Overpressure protection point (hardware)	Adult: 320~330mmHg Pediatric: 265~275mmHg Neonate: 160~165mmHg
Static Pressure accuracy	±3mmHg
Supply voltage	10V~14VDC
Maximum power consumption	3.6W
Quiescent current	50mA
Maximum current during measurement	180mA
Maximum current during inflation	300mA
Alarm	Communication, selfcheck, CFG error System error, measurement timeout Cuff loose, no, leak, type error Air pressure error Over range, signal weak/unstable/saturated Over pressure Module reset failed Systolic, mean, diastolic high/low
SpO2	
Standard compliance	ISO80601-2-61
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2% Neonate : 70 ~ 100% ±3% 0 ~ 69% : Unspecified
Wave sweep speed	12.5mm/s, 25mm/s
Wave mode	Scan, fill
Pulse volume	0, 1, 2, 3, 4, 5, 6, 7, 8, 9 level
SpO2 alarm preset limits	Upper Alarm Limit : 86% ~ 100% Lower Alarm Limit : 85% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	No Delay
SpO2 value refresh period	1s/time
SpO2 value refresh delay	< 10s
Average period	Low Sensitivity : 7 ~ 8s Intermediate Sensitivity : 4 ~ 6s Advanced Sensitivity : 2 ~ 3s
Alarm condition delay period	Low Sensitivity : < 8s Intermediate Sensitivity : < 6s Advanced Sensitivity : < 3s
Alarm sign generates delay period	0s
Perfusion index	0.05 ~ 20%
PR Measurement Range	25 ~ 254bpm
PR Resolution	±1bpm
PR Measurement accuracy	±2% or ±2bpm, whichever is greater
Alarm	Communication stop/error No sensor/ sensor off Search timeout Search pulse(weak) SpO2, RR high/low
IBP (Option)	
Standards compliant	IEC60601-2-34
Pressure measurement range	-50 ~ 400 mmHg
Pressure measurement accuracy	±3 mmHg or ±2%, whichever is greater
Pressure resolution	1 mmHg
PR measurement range	35 ~ 250 bpm

PR measurement accuracy	±3bpm
PR resolution	1bpm
Transducer sensitivity	5µV/V/mmHg
Transducer resistance range	300-5,000Ω
Supply voltage	+12VDC
Maximum power consumption	≤5W
Scan speed	12.5mm/s, 25mm/s
Alarm	IBP1, 2 communication stop/error
	IBP1, 2 sensor off
	Art-sys, PA-sys, P1-sys, P2-sys high
	Art-dia, PA-dia, P1-dia, P2-dia high
	Art-mean, PA-mean, CVP-mean, LAP-mean, RAP-mean, ICP-mean, P1-mean, P2-mean high
EtCO2 Mainstream & Sidestream (Option)	
Measurement parameters	EtCO2、FiCO2、AwRR
Measuring range	EtCO2 : 0~150mmHg, AwRR : 0~150rpm
Resolution	EtCO2/FiCO2 : 1mmHg, AwRR : 1rpm
Apnea delay	20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Operating mode	Standby, measure
O2 compensation	Low, mid, high
N2O compensation	On, off
Alarm limit	EtCO2 lower limit : 0~149mmHg
	EtCO2/FiCO2 upper limit : 1~150mmHg
	AWRR lower limit : 0~119rpm
	AWRR upper limit : 1~120rpm
Alarm	Communication stop/error
	CO2 sensor off/error
	O2 sensor error/replace
	adaptor/sampling line no/check
	Parameter accuracy error
	O2, Air calibration error
	S/W, H/W error
	Motor accuracy error
	CO2 factory calibration error
	Adaptor, sampling line replace
	O2 port error
	CO2, O2, N2O out of accuracy
	CO2 temp., pressure out of accuracy
	CO2 zero required
	CO2 zeroing/sleeping
	CO2 module calibrating/calibration error
	EtCO2, FiCO2, AWRR high/low
	Apnea
C.O. (Cardiac Output : Option)	
Measurement range	C.O. : 0.2 ~ 20 L/min
	BT : 23 ~ 45°C±0.5 °C
	IT : 0 ~ 20°C±0.5 °C
Resolution factor	C.O. : 0.1L/min
	BT, IT : 0.1°C
Accuracy	C.O. : ±5% or ±0.1 L/min, subject to the bigger one BT, IT : ±0.1°C (sensor exclusive)
Scope of alarm limit	BT high limit : (Low limit +0.1) ~ 43°C
	BT low limit : 23.0 ~ (high limit -0.1) °C
	Step size : 0.1°C
Alarm	BT sensor off
	BT high/low
	C.O. high

Printer (Option)	
Type	Thermal dot array
Print speed	12.5, 25, 50mm/s
Paper size	58mm(W) x 42m
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz) Output : DC 15V/2.4A
Consumption	13.5W
Rechargeable battery	11.1V Li-ion 4,400mA Operating Time : 5hrs Charging Time : 4hrs
Standard Configurations	
ECG cables and lead wire	1ea(5lead)
ECG electrode for adult	1pack(25pcs)
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Power adaptor	1ea
Bracket	1ea
Operation manual	1ea
Options (Function)	
IBP	Sensor cable & package
EtCO2 Mainstream (Bistos)	Airway adaptor & module
EtCO2 Sidestream (Bistos)	Sampling tube
EtCO2 IRMA Mainstream (Masimo)	Airway adaptor & module
EtCO2 ISA Sidestream (Masimo)	Sampling tube
C.O.	Sensor cable
Printer	Printer & paper
Cart	
Options (Accessory)	
ECG cables and lead wire	5/3 lead
ECG electrode	adult/neonate
SpO2 reusable sensor	adult/pediatric/neonate
SpO2 disposable sensor	adult/pediatric/neonate
Skin & rectal temperature sensor	adult/pediatric/neonate
NiBp cuff	adult(27~35cm)/pediatric(14~21.5cm)/neonate(4*9cm)
Physical Characteristics	
Dimension	
Main unit	320(W) x 65(D) x 250(H)mm
Packing	400(W) x 350(D) x 290(H)mm
Weight	
Main unit	< 2.8Kg
Packing	4.6Kg
Environmental Conditions	
Operating temperature	10 ~ 40°C (50 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	-20 ~ 60°C (-4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	

Specifications : BT-780 15.6" Multi-parameter Patient Monitor

Functional Characteristics	
Display	
Type	Color TFT touch screen LCD
Size and resolution	15.6", 1366 x 768 pixels
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meets the IEC60601-1-8
Data Storage	
Trend	168hours, resolution : 1min
Alarm event	200 physiological and 100 technical alarm events
NiBp measurement result	1,000 groups
Function	
Multi-language	English, Turkish, Spanish, French, Polish, German, Italian, Hungarian
Trend	Graphic/tabular
Alarm	
Mode	Visual, audible, information, parameter flashing
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Pause duration	1, 2, 3, 4, 5, 10, 15min or permanent
System	Low battery
Interface	
Auxiliary	Nurse call
RJ45 (LAN)	CMS
USB	S/W upgrade
ECG	
Standard compliance	IEC60601-2-27
Lead type	3Lead : I, II, III
	5Lead : I, II, III, aVR, aVL, aVF, V
Display sensitivity (gain)	Auto, 1.25, 2.5, 5, 10, 20mm/mV
Wave sweep speed	12.5, 25, 50mm/s
Band width	Diagnostic mode : 0.05 ~ 130Hz
	Monitoring mode : 0.5 ~ 40Hz
	Surgery mode : 1 ~ 25Hz
	Strong filter mode : 5 ~ 20Hz
CMRR	> 100dB
Notch	50/60Hz (can be set on or off)
Differential input	> 5MΩ
Electrode polarization voltage range	±400mV
Baseline recovery time	< 5s after defibrillation (monitor and surgery mode)
Calibration signal	1mV (peak-peak), accuracy ±3%
Lead-off detection current	Measuring electrode : < 0.1μA
	Drive electrode : < 1μA
HR measuring range	Adult : 15 ~ 300bpm
	Pediatric/Neonate : 15 ~ 350bpm
HR measuring resolution	1bpm
HR measurement accuracy	±1bpm or ±1%, whichever is greater
HR accuracy & response to irregular rhythm	Ventricular bigeminy : 80±1bpm
	Slow alternating ventricular bigeminy : 60±1bpm
	Rapid alternating ventricular bigeminy : 120±1bpm
	Bidirectional systoles : 90±2bpm

HR time to alarm for tachycardia	0.5/1/2mV, 206bpm ventricular tachycardia : < 10s 1/2/4mV, 195bpm ventricular tachycardia : < 5s
HR alarm upper limit (bpm)	Adult : 16 ~ 300, 1bpm step Pediatric/Neonate : 16 ~ 350, 1bpm step
HR alarm lower limit (bpm)	Adult : 15 ~ 299, 1bpm step Pediatric/Neonate : 15 ~ 349, 1bpm step
Pacing pulse identification	Detection range : $\pm 2\text{mV}$ ~ $\pm 700\text{mV}$ Pulse width : 0.2ms ~ 2.0ms
Pacing pulse average HR	15s data
Pacing pulse interval of HR Refreshing	Every second
Pacing pulse HR change response time	$\leq 10\text{sec}$
Pacing pulse tall T-wave suppression	2mV
Alarm	Communication, configuration, selfcheck error Lead off HR high/low, PVCs high Asystole, VF/VTA, R on T, Tachycardia/bradycardia, PVC frequent/couplet/singlr/bigeminy/trigeminy, Miss Beat Pacemaker not capture/work Signal weak, ST-I, II, III high/low
Respiration	
Measurement method	Trans-Thoracic impedance
Operation modes	Auto
Measuring lead	Lead RA-LA, RA-LL, LA-RL, LL-RL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2,000 Ω
Sensitivity	1,2,3,4,5
Wave sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement accuracy	$\pm 2\text{rpm}$
Measurement range	0 ~ 120rpm
Alarm	RR high/low Apnea Respiration artifact
Temperature	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Measuring range	0°C ~ 50.0°C (32°F ~ 122.0°F)
Resolution	0.1°C
Measurement accuracy	$\pm 0.1^\circ\text{C}$ or $\pm 0.2^\circ\text{F}$ (without probe)
Number of channel	2
T1/T2 alarm upper limit	0.1°C ~ 50.0°C, 0.1°C/°F step
T1/T2 alarm lower limit	0°C ~ 49.9°C, 0.1°C/°F step
Temperature difference alarm upper limit	0°C ~ 50.0°C, 0.1°C/°F step
Alarm	T1, T2 Sensor off T1/T2 high/low, TD high
NiBp	
Standard compliance	IEC80601-2-30
Measurement method	Automatic oscillometric method
Operating mode	Manual, automatic, continuous(STAT)
Useful life	100,000 times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(30~280), Pediatric(30~230), Neonate(30~145) Mean : Adult(10~240), Pediatric(10~175), Neonate(10~115) Diastolic : Adult(10~220), Pediatric(10~165), Neonate(10~105)
Measurement accuracy	Maximum average error: $\pm 5\text{mmHg}$ Maximum standard deviation: 8mmHg
Resolution	1mmHg

Initial inflation pressure (mmHg)	Adult : 160 (default)
	Pressure setting range:140mmHg, 160mmHg, 180mmHg
	Pediatric : 140 (default)
	Pressure setting range:140mmHg, 160mmHg
	Neonate : 100 (default)
Overpressure protection point (software)	Pressure setting range:100mmHg, 120mmHg
	Adult: 300mmHg
	Pediatric: 240mmHg
Overpressure protection point (hardware)	Neonate: 150mmHg
	Adult: 320~330mmHg
	Pediatric: 265~275mmHg
Static Pressure accuracy	Neonate: 160~165mmHg
Supply voltage	±3mmHg
Maximum power consumption	10V~14VDC
Quiescent current	3.6W
Maximum current during measurement	50mA
Maximum current during inflation	180mA
Alarm	300mA
	Communication, selfcheck, CFG error
	System error, measurement timeout
	Cuff loose, no, leak, type error
	Air pressure error
	Over range, signal weak/unstable/saturated
	Over pressure
	Module reset failed
	Systolic, mean, diastolic high/low
SpO2	
Standard compliance	ISO80601-2-61
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2%
	Neonate : 70 ~ 100% ±3%
	0 ~ 69% : Unspecified
Wave sweep speed	12.5mm/s, 25mm/s
Wave mode	Scan, fill
Pulse volume	0, 1, 2, 3, 4, 5, 6, 7, 8, 9 level
SpO2 alarm preset limits	Upper Alarm Limit : 86% ~ 100%
	Lower Alarm Limit : 85% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	Off,1s,2s,3s,4s,5s,6s,7s,8s
SpO2 value refresh period	1s/time
SpO2 value refresh delay	< 10s
Average period	Low Sensitivity : 7 ~ 8s
	Intermediate Sensitivity : 4 ~ 6s
	Advanced Sensitivity : 2 ~ 3s
Perfusion index	0.05 ~ 20%
PR Measurement Range	25 ~ 250 bpm
PR Resolution	±1 bpm
PR Measurement accuracy	±2% or ±2bpm, whichever is greater
Alarm	Communication stop/error
	No sensor/ sensor off
	Search timeout
	Search pulse(weak)
	SpO2, RR high/low
IBP (Option)	
Standards compliant	IEC60601-2-34
Channel	2-ch, 4-ch
Pressure measurement range	-50 ~ 400 mmHg

Pressure measurement accuracy	±3 mmHg or±2%, whichever is greater
Pressure resolution	1 mmHg
PR measurement range	35 ~ 250 bpm
PR measurement accuracy	±3bpm
PR resolution	1bpm
Transducer sensitivity	5μV/V/mmHg
Transducer resistance range	300-3,000Ω
Supply voltage	+12VDC
Maximum power consumption	≤5W
Scan speed	12.5mm/s, 25mm/s
Alarm	IBP1, 2 communication stop/error
	IBP1, 2 sensor off
	Art-sys, PA-sys, P1-sys, P2-sys high
	Art-dia, PA-dia, P1-dia, P2-dia high
	Art-mean, PA-mean, CVP-mean, LAP-mean, RAP-mean, ICP-mean, P1-mean, P2-mean high
EtCO2 Mainstream & Sidestream (Option)	
Measurement parameters	EtCO2、FiCO2、AwRR
Measuring range	0-15%
Accuracy	±0.2%+2% of the reading
Resolution	EtCO2/FiCO2 : 1mmHg, AwRR : 1rpm
Rise time	200ms, typical at 50ml/min flow rate
Total response time	within 3 seconds(within 2m Nomoline sampling)
AWRR range	0-150bpm
AWRR Accuracy	±1 breath
Apnea delay	20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Warm-up time	Full accuracy within 10 seconds
Sampling flow rate	50ml/min(+/-10ml/min)
Operating mode	Standby, measure
O2 compensation	Low, mid, high
N2O compensation	On, off
Alarm limit	EtCO2 lower limit : 0~149mmHg
	EtCO2/FiCO2 upper limit : 1~150mmHg
	AWRR lower limit : 0~119rpm
	AWRR upper limit : 1~120rpm
Alarm	Communication stop/error
	CO2 sensor off/error
	O2 sensor error/replace
	adaptor/sampling line no/check
	Parameter accuracy error
	O2, Air calibration error
	S/W, H/W error
	Motor accuracy error
	CO2 factory calibration error
	Adaptor, sampling line replace
	O2 port error
	CO2, O2, N2O out of accuracy
	CO2 temp., pressure out of accuracy
	CO2 zero required
	CO2 zeroing/sleeping
	CO2 module calibrating/calibration error
	EtCO2, FiCO2, AWRR high/low
	Apnea
C.O. (Cardiac Output : Option)	
Method	Thermodilution
Measurement range	C.O. : 0.2 ~ 20 L/min
	BT : 23 ~ 45°C±0.5 °C
	IT : 0 ~ 20°C±0.5 °C

Resolution factor	C.O. : 0.1L/min BT, IT : 0.1°C
Accuracy	C.O. : ±10% TB, TI : ±0.5°C
Scope of alarm limit	BT high limit : (Low limit +0.1) ~ 43°C BT low limit : 23.0 ~ (high limit -0.1) °C Step size : 0.1°C
Alarm	BT sensor off BT high/low C.O. high
Printer (Option)	
Type	Thermal dot array
Print speed	12.5, 25, 50mm/s
Paper size	50mm(W) x 2m
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz) Input Current: 1.6-0.6A
Consumption	13.5W
Rechargeable battery	11.1V Li-ion 4,400mA Operating Time : 5hrs Charging Time : 4hrs
Standard Configurations	
ECG cables and lead wire	1ea (5lead)
ECG electrode for adult	1pack (25pcs)
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Power adaptor	1ea
Bracket	1ea
Operation manual	1ea
Options (Function)	
IBP	Sensor cable & package
EtCO2 Mainstream (Bistos)	Airway adaptor & module
EtCO2 Sidestream (Bistos)	Sampling tube
EtCO2 IRMA Mainstream (Masimo)	Airway adaptor & module
EtCO2 ISA Sidestream (Masimo)	Sampling tube
C.O.	Sensor cable
Printer	Printer & paper
Cart	
Options (Accessory)	
ECG cables and lead wire	5/3 lead
ECG electrode	adult/neonate
SpO2 reusable sensor	adult/pediatric/neonate
SpO2 disposable sensor	adult/pediatric/neonate
Skin & rectal temperature sensor	adult/pediatric/neonate
NiBp cuff	adult(27~35cm)/pediatric(14~21.5cm)/neonate(4*9cm)
Physical Characteristics	
Dimension	
Main unit	410(W) X 298(H) X 120(D)
Packing	495(W) x 295(D) x 385(H)mm
Weight	
Main unit	< 4.9Kg
Packing	7kg
Environmental Conditions	
Operating temperature	5 ~ 40°C (41 ~ 104°F)
Operating humidity	30 ~ 85% non-condensing

Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	



Product Service

Certificate

No. Q5 065725 0022 Rev. 02

Holder of Certificate: **Beijing Aeonmed Co., Ltd.**
Room 405
Basement 1 to 4th Floor of 901 Unit
Building 9, No.26 Outer Ring West Road
Fengtai District
100070 Beijing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, Installation and Servicing of Anaesthetic Workstation, Vaporizer, Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendent, Operating Table, Surgical Light, Multi-Parameter Patient Monitor, Syringe Pump, Patient Warming System, Videoscope System.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ1985904

Valid from: 2020-03-23

Valid until: 2022-12-31

Date, 2020-03-23

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 065725 0022 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Beijing Aeonmed Co., Ltd.
Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26
Outer Ring West Road, Fengtai District, 100070 Beijing, PEOPLE'S
REPUBLIC OF CHINA

Beijing Aeonmed Co., Ltd.
No. 10 Chaobai Street, Yingbin Road West, Yanjiao Development
Zone, 065201 Langfang City, Hebei Province, PEOPLE'S
REPUBLIC OF CHINA



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 065725 0019 Rev. 04

Manufacturer:

Beijing Aeonmed Co., Ltd.

Room 405

Basement 1 to 4th Floor of 901 Unit

Building 9, No.26 Outer Ring West Road

Fengtai District

100070 Beijing

PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies): Anaesthetic Workstation, Vaporizer,
Ventilator, Medical Air Compressor,
Infusion Pump, Ceiling Pendant,
Multi-Parameter Patient Monitor,
Videoscope System, Patient Warming System.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10657250019Rev.04

Report No.:

BJ19859071

Valid from:

2021-05-21

Valid until:

2024-05-26

Date,

2021-05-21

Christoph Dicks

Head of Certification/Notified Body

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 5.0

Project No.: PRJC-533956-2015-MSL-KOR

Valid Until: 01 September 2023

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Monitoring devices of vital physiological parameters and Utilising non-ionizing radiation

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Place and date:
Høvik, 30th April 2021

Check Validity

For the issuing office:
Notified Body 2460
DNV Product Assurance AS



Hazem Tinawi
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Further details of the product(s) and conditions for certification are given overleaf.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit (BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770) The accessories (Feotal Doppler system probe and Cardiotocograph transducers) are removed (AY-DOP-300, AY-DOP-350, AY-UC-300, AY-UC-350)	01 September 2018
3.0	Editorial change	13 February 2020
4.0	Scope extension to new model (BT-780)	26 April 2021
5.0	Editorial change in model name (typo error)	30th April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	<ul style="list-style-type: none"> BT-300 BT-350 FM-20 Biocare FM-1 	Ila
Neonatal Phototherapy unit	<ul style="list-style-type: none"> BT-400 	Ila
Pulse Oximeter	<ul style="list-style-type: none"> BT-710 	IIb
Patient Monitor	<ul style="list-style-type: none"> BT-720 BT-740 BT-770 BT-780 	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 243269-2017-CE-KOR-NA-PS Rev. 4.0

Project No.: PRJC-533956-2015-MSL-KOR

Valid Until: 01 September 2023

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

**Monitoring devices of vital physiological parameters and Utilising
non-ionizing radiation**

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply

Further details of the product(s) and conditions for certification are given overleaf

Place and date:
Høvik, 26 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Check Validity




Eugenie Winger Husebye
Technical Reviewer

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-MDD-f2, rev.0

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	01 September 2017
1.0	EU Rep change	13 April 2018
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit (BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770) The accessories (Fetal Doppler system probe and Cardiotocograph transducers) are removed (AY-DOP-300, AY-DOP-350, AY-UC-300, AY-UC-350)	01 September 2018
3.0	Editorial change	13 February 2020
4.0	Scope extension to new model (BT-780)	26 April 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	<ul style="list-style-type: none"> BT-200 BT-350 FM-20 Biocare FM-1 	Ila
Neonatal Phototherapy unit	<ul style="list-style-type: none"> BT-400 	Ila
Pulse Oximeter	<ul style="list-style-type: none"> BT-710 	IIb
Patient Monitor	<ul style="list-style-type: none"> BT-720 BT-740 BT-770 BT-780 	IIb

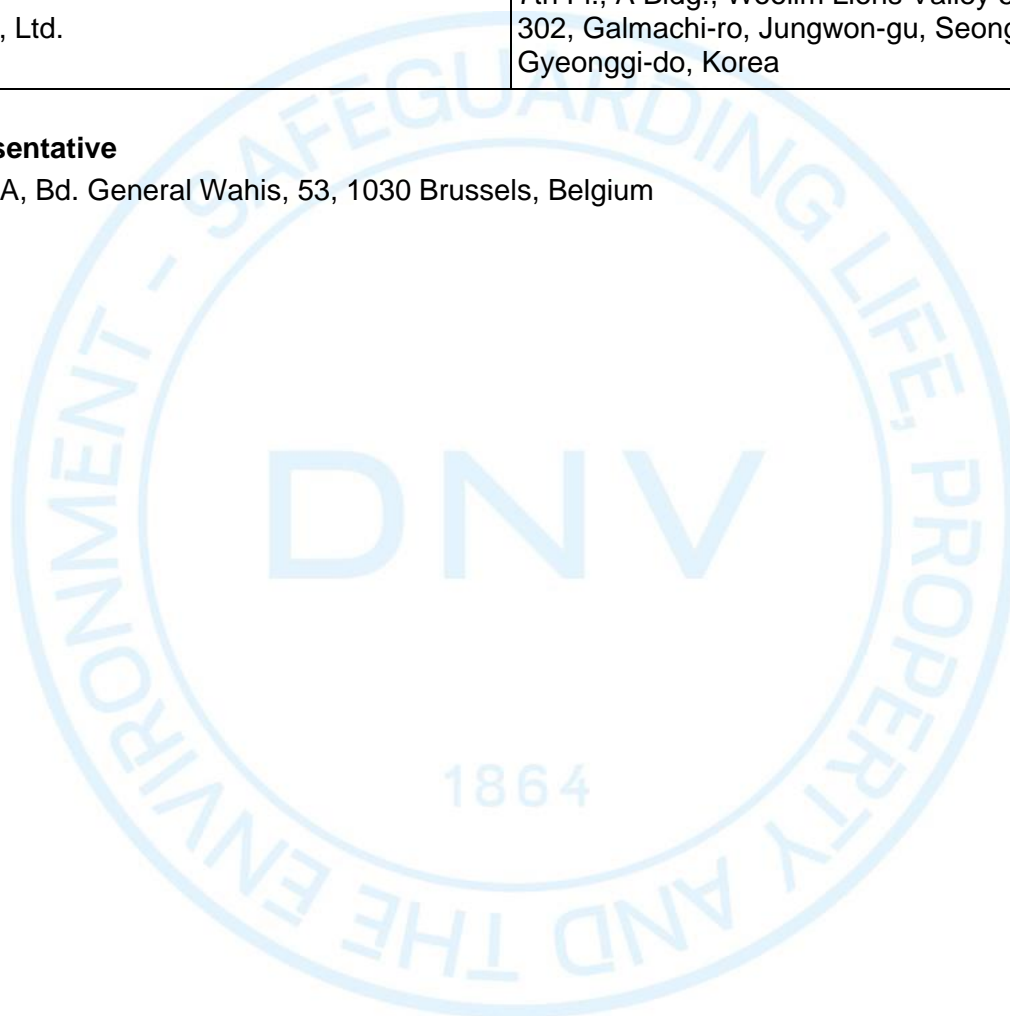
The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium



Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. the Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate

Management System Certificate

Certificate No.: 243275-2017-AQ-KOR-NA-PS Rev 4.0

Initial Certification Date: 12 August 2004

Valid Until: 09 September 2024

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Korea

has been found to conform to the Quality Management System standard:

ISO 13485:2016/NS-EN ISO 13485:2016

This certificate is valid for the following scope:

Design and Development, Manufacturing, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.

Place and date:
Høvik, 23 June 2021

Check Validity



For the issuing office:
DNV Product Assurance AS

Tone Kolpus
Tone Elise Kolpus
Lead Auditor

Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

Accredited Body: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

ICP-4-5-i1-ISO13485-f1,

rev.0

Site Name	Address	Site Specific Scope
Head Office	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Design and Development, Sales, Distribution, and Servicing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.
Factory	116~122ho, Jungang Induspia 3, 27, Sagimakgol-ro 105beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea	Manufacturing of Ultrasound Doppler system, Fetal monitor, Phototherapy, Patient Monitor, Pulse Oximeter, Incubator, Head-worn light, Infant Warmer and Electric Breast Pump.