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
Matrial	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_2O (increments of 1 cmH_2O) (IPPV, SIMV-VC and PCV-VG vent modes)
Pressure ($P_{support}$) range	3 to 60 cmH_2O (increments of 1 cmH_2O) (SIMV-VC/PC/VG,

	PS/CPAP, BIVENT and APRV vent modes)
Pressure (P_{TARGET}) range	5 to 70 cmH_2O (increments of 1 cmH_2O) (PCV and SIMV-PC vent modes)
Freq.	2 to 100 breaths per minute(SIMV-VC, SIMV-PC and SIMV-VG vent modes)
	2 to 60 breaths per minute for $Freq_{MIN}$ in PS/CPAP vent modes.
	4 to 100 breaths per minute(Other mode) (increments of 1 breath per minute)
Inspiratory/expiratory ratio	4:1 to 1:8 (increments of 0.5) (IPPV, PCV and PCV-VG vent modes)
Inspiratory time	0.2 to 5 seconds (increments of 0.1 seconds) (SIMV-VC/PC/VG vent modes)
Inspiratory Pause Time	OFF，5％ to 60％ (increments of 5%) (IPPV and SIMV-VC 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)
Pressure trigger (P_{SENS})	-20 to -1 cmH_2O (increments of 1 cmH_2O) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
E_{SENS}	5 to 70% (increments of 5%) (SIMV-VC/PC/VG, PS/CPAP, BIVENT and APRV vent modes)
I_{SENS}	5 to 70% (increments of 5%) (APRV vent modes)
P_{HIGH}	5 to 70 cmH_2O (increments of 1 cmH_2O) (BIVENT and APRV vent modes)
P_{LOW}	3 to 50 cmH_2O (increments of 1 cmH_2O) (BIVENT and APRV vent modes)
T_{HIGH}	0.2s to 30s (increments of 0.1s) (BIVENT and APRV vent modes)
T_{LOW}	0.2s to 30s (increments of 0.1s) (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)

Positive End Expiratory Pressure (PEEP)

Type	Integrated electronically controlled
Range	OFF, 3 to 50 cm H_2O (increments of 1 cm H_2O)

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_2O to 99cmH_2O
Mean pressure(P_{mean})	-20cmH_2O to 99cmH_2O
Plat pressure(P_{plat})	-20cmH_2O to 99cmH_2O
PEEP	-20cmH_2O to 99cmH_2O
Frequency	0 to 110 breaths per minute
PAW	-20cmH_2O to 110cmH_2O
$FiCO_2$	0 to 10 vol%
$EtCO_2$	0 to 10 vol%
DP (Driving airway pressure)	0 to 120 cmH2O
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 300cmH2O/(L/S)
Csys	0 to 300mL/(L/S)
VO2	Real time calculation
CO2-T	Real time calculation

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, FiO_2, $etCO_2$, $FiCO_2$, Agent1, Agent2, N_2O, MAC, FG-O_2, FG-Air and FG-N_2O.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,CO2, Agent, MV,VT,O2, The machine shall rememb the 72 hours trend chart

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,

Delivery/monitoring accuracy

Volume delivery	< 100 mL = better than 10 mL > 100 mL = better than 15%
Pressure delivery	±10% or ±3 cm H_2O
PEEP delivery	±2cmH_2O or ±15%
Volume monitoring	< 100 mL = better than 10 mL > 100 mL = better than15%
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_2O
High pressure	10 to 110cmH_2O
High Breath Rate	8 to 60 bpm
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
Inspired CO_2（$FiCO_2$）	High: 0.1 to 1.4% or 1 to 10 mmHg
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%
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 H2O or P_{mean}=1 cm H2O and PEEP≤0cmH2O measured in 30 seconds when Frequency⩾6 Vt < 10 mL breath or P_{mean}<1 cm H2O or P_{mean}=1 cm H2O and PEEP≤0cmH2O measured in 35 seconds when

	Frequency<6 Manual mode: Vt< 10 mL measured in 60 seconds
Sustained airway pressure	Mechanical ventilation ON: Paw>PEEP add 10 cm H_2O measured over 15 seconds Continuously Mechanical ventilation OFF: Paw>10 cm H_2O measured over 15 seconds Continuously
Subatmospheric pressure	Paw < -2 cm H_2O
Alarm silence countdown timer:	120 to 0 seconds

Ventilator components

Flow transducer

Type	Mass type Measure mass flow in bypass application
Location	Installed in breathing system

Oxygen Sensor

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

Ventilator Screen

Display type	Color active matrix TFT Touch screen
Display size	15 inches diagonal
Pixel format	1024×768
Color	LVDS 24 bit, 16777216 colors
Display parameters	All setting and alarm parameters(incluing 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
Display graphics	Wave of P-T, F-T, V-T, CO2-T(option), Paw-V Loop，V-Flow Loop, Paw -Flow Loop
Communication ports	RS-232C compatible serial interface(DB 9 connector); RJ45 connector 100-Base-TX support HL7 communication license; USB 2.0 interface

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 ± 1cmH_2O.

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℃
Accuracy	±20% of setting or ± 5% of the maximum scale
Agent setting range	Sevoflurance: : 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 mornitor(optional)

Type	main stream/side stream
Moudle	IRMA CO_2; IRMA AX+ ISA CO2; ISA AX+
Operating temperature	IRMA AX+: 10 to 40 °C (50 to 104 °F) IRMA CO2: 0 to 40 °C (32 to 104 °F) ISA CO2: 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 CO2: -40 to 75 °C (-40 to 167 °F) ISA CO2: -40 to 70 °C (-40 to 158 °F) ISA AX+: -40 to 70 °C (-40 to 158 °F)
Operating humidity	< 4 kPa H2O (non-

	condensing) (95 %RH at 30 °C)
Operating atmospheric pressure	525 - 1200 hPa (<4572 m)
Warm-up time	IRMA AX+/ISA AX+: < 20 sec IRMA CO_2/ISA CO_2: < 10 sec
Rise Time	IRMA CO_2 / AX+: CO_2≤90ms N_2O≤300ms HAL, ISO, ENF, SEV, DES≤300ms ISA CO_2 : CO_2 ≤200ms ISA AX+ : CO_2 ≤300ms N_2O, O_2, ENF, ISO, SEV, DES ≤400ms HAL ≤500ms
ISA sampling flow rate	50 ± 10 ml/min
Breath detect	Adaptive threshold, minimum 1 % CO_2 change.
Respiratory rate:	0 - 150 bpm ± 1 bpm
Compensation:	Automatic for atmospheric pressure, temperature and spectral interference

Airway adapters

IRMA Airway Adapter Adult/Paediatric	6 ml dead space
IRMA Airway Adapter Infant.	1 ml dead space
ISA Nomoline	Sampling line with proprietary water removal tubing. 2 m±0.1m versions

Carbon Dioxide (CO_2) Moudle (IRMA/ISA CO_2)

Monitor Gas	CO_2
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_2O;HAL;ISO;ENF;SEV;DES
Measurement range	CO_2: 0-15 vol% N_2O: 0-100 vol% HAL, ISO, ENF: 0-8 vol% SEV: 0-10 vol% DES: 0-22 vol%

Accuracy

CO_2	0-15 vol% ± (0.2 vol% + 2 % of reading)
N_2O	±(2 vol% + 2 % of reading)
HAL, ISO, ENF	±(0.15 vol% + 5 % of reading)

SEV	±(0.15 vol% + 5 % of reading)
DES	±(0.15 vol% + 5 % of reading)

Paramagnetic oxygen module

Range	0-100%
Accuracy	＜±0.2% O_2
Response Time (T10 –T90)	8 to 20 seconds dependent on application and filter selection (biological filter on request)
Operation Temperature	5 °C to 50 °C (41°F to 122°F)
Storage Temperature	-30°C to 70°C (-22°F to 158°F)
Storage Pressure	10kPa-200kPa(1.5psi-30psi)
Ambient Humidity	0 to 95% non-condensing
RoHS	ROHS Directive 2002/95/EC

Electrical specifications

Power and battery backup

Power input	100-240V,50/60Hz, Max. ≤8A
Battery type	Internal rechargeable sealed lead acid 24VDC,5.0AH
Backup power	Demonstrated battery backup time under typical operating conditions is 120 minutes when fully charged
Charge time	＜ 8 hours (in running status or standby mode)
Power code	5m/16.4ft
Outlets	4 outlets on back
Maximum output valve of auxiliary AC power plug	1.5A(single plug); 6A(in total)

Pneumatic specifications

Auxiliary common gas outlet(optional)

Connector:	ISO 22 mm OD and 15 mm ID
Security	Anti-misconnection switch and prominent prompts on the screen

Gas supply

Gas type	O_2,N_2O,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 nominal output	250 kPa/36psig

O_2 controls

Method	Proportionate decrease of N_2O with reduction in O_2 pressure
Supply failure alarm	Range: 185 to 215 kPa
O_2 flush	Range: 25 to 75 L/min

Electronic control Flowmeter (Electronic Mixer)

O_2 ranges	0 to 10 L/min
N_2O ranges	0 to 10 L/min
Air ranges	0 to 12 L/min
Total Flow Control Mode	Total flow range: 0.2 to 18 L/min O concentration range: 21% to 100%

Integrated safety functions

Guarantees a minimum O_2 concentration of 25% in an O_2/N_2O mixture.
N_2O cut-off if O_2 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
CO_2 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 H_20

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_2O
Tactile knob indication at	30 cm H_2O and above
Adjustment range of rotation	0 to 30 cm H_2O (0 to 180°) 30 to 70 cm H_2O (180 to 288°)
Accuracy	＜30 cm H_2O:±3 cm H_2O; ≥30 cm H_2O:±15% of set value;

Breathing circuit parameters

Compliance (Bag mode)	4.5ml/ cm H_2O
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℃

Materials

All materials in contact with exhaled patient gases are autoclavable, except mechanical pressure meter and O_2 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℃
Humidity	Less than 95% relative humidity, non-condensing.
Atmospheric pressure	70-106kPa

System storage

Temperature	－20 to 55℃
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 0123

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

Beijing Aeonmed Co., Ltd.
HQs Add: Building 9, No.26 Outer Ring West Road, Fengtai District, Beijing 100070, China
Operation Center Addr: No. 10, Chaobai Street, Yanjiao Development Zone, Sanhe City, Hebei Province, China 065201
Tel: +86-10-5841 1198 (Yanjiao) / +86-10-8368 1616 (Beijing)
E-Mail: service@aeonmed.com
Website: http://www.aeonmed.com

Edition 1.0
May.2021

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 tarchycardia : < 10s
	1/2/4mV, 195bpm ventricular tarchycardia : < 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 : ±2mV ~ ±700mV
	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	≤ 10sec
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/bradicardia, PVC frequent/couplet/singlr/bigeminy/trigeminy, Miss Beat
	Pacemaker not capture/work
	Signal weak, ST-I, II, II 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 ~ 2,000Ω
Sensitivity	1,2,3,4,5
Wave sweep speed	6.25mm/s, 12.5mm/s, 25mm/s
Measurement accuracy	±2rpm
Measurement range	0 ~ 120rpm
Alarm	RR high/low
	Apnea
	Respiration artifact
Temperature	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Measuring range	0℃ ~ 50.0℃ (32℉ ~ 122.0℉)
Resolution	0.1℃
Measurement accuracy	±0.1℃ or ±0.2℉ (without probe)
Number of channel	2
T1/T2 alarm upper limit	0.1℃ ~ 50.0℃, 0.1℃/℉ step
T1/T2 alarm lower limit	0℃ ~ 49.9℃, 0.1℃/℉ step
Temperature difference alarm upper limit	0℃ ~ 50.0℃, 0.1℃/℉ 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: ±5mmHg
	Maximum standard deviation: 8mmHg
Resolution	1mmHg

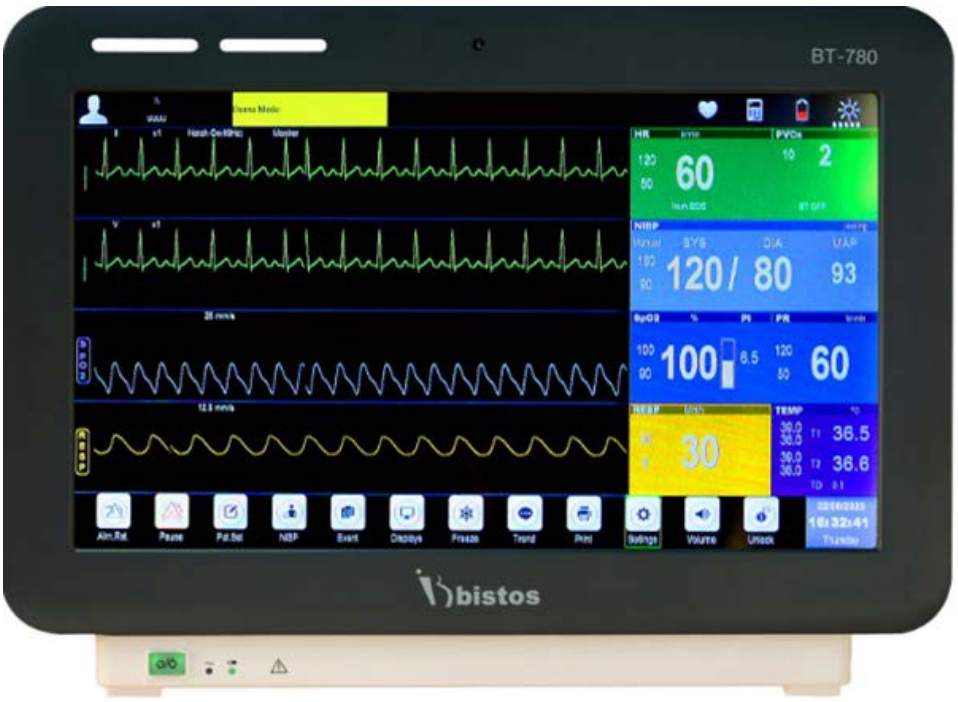
Initial inflation pressure (mmHg)	Adult : 160 (default) Pressure setting range:140mmHg, 160mmHg, 180mmHg
	Pediatric : 140 (default) Pressure setting range:140mmHg, 160mmHg
	Neonate : 100 (default) Pressure setting range:100mmHg, 120mmHg
Overpressure protection point (software)	Adult: 300mmHg
	Pediatric: 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	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℃±0.5 ℃
	IT : 0 ~ 20℃±0.5 ℃

Resolution factor	C.O. : 0.1L/min
	BT, IT : 0.1℃
Accuracy	C.O. : ±10%
	TB, TI : ±0.5℃
Scope of alarm limit	BT high limit : (Low limit +0.1) ~ 43℃
	BT low limit : 23.0 ~ (high limit -0.1) ℃
	Step size : 0.1℃
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	

BT-780 PATIENT MONITOR



15.6" Multi-Parameter Patient Monitor

ECG, Resp., SpO_2, NIBP, Temperature

Optional CO_2, IBP, Multi-gas, C.O., Masimo SpO_2

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
Resplration	Method		Trans-thoracic Impedance
	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%)		Unspecfied
	Perfusion Index		0.05-20 %
	Pulse Rate Range (bpm)		25-250
NIBP**	Method		Automatic Oscillometric
	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		Themal 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

bistos

Bistos Co., Ltd.
7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu,
Seongnam-si, Gyeonggi-do, Korea (zip. 462-739)
Tel : 82 31 750 0340 Fax : 82 31 750 0344

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD 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:G1 065725 0019 Rev. 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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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	▪ **BT-300** ▪ BT-350 ▪ FM-20 ▪ Biocare FM-1	IIa
Neonatal Phototherapy unit	▪ BT-400	IIa
Pulse Oximeter	▪ BT-710	IIb
Patient Monitor	▪ 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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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:

tuv-sud.com/ps-cert

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

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

.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

For the issuing office:
DNV Product Assurance AS

Tone Kolpus

Tone Elise Kolpus
Lead Auditor

Check Validity

NORWEGIAN ACCREDITATION

MSYS 018

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.