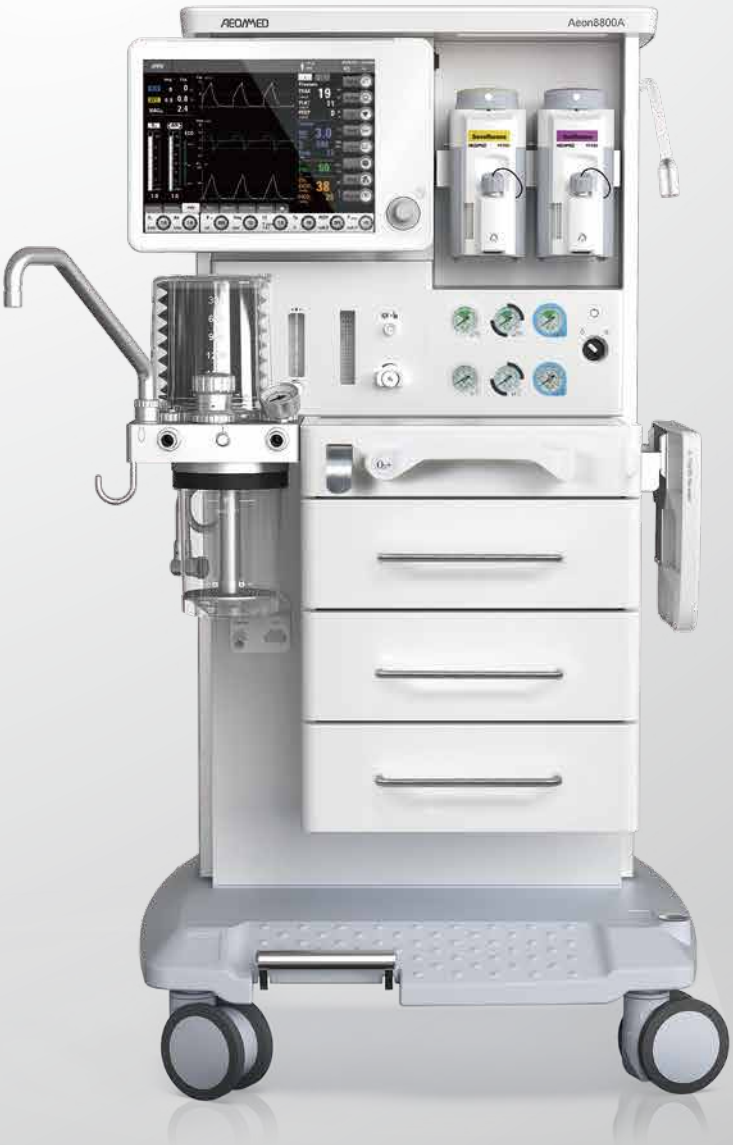



# Aeon8800A

## 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.

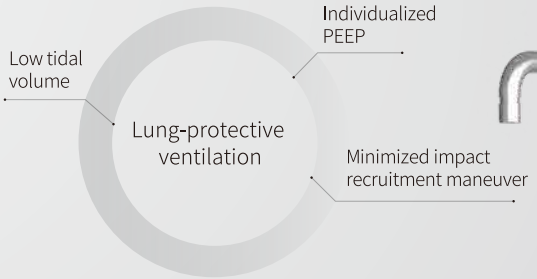
The integrated heating system with a better thermal conductivity of alloy help prevent condensation and make patients feel more comfortable.

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

The Breathing Ciucuit has $CO_2$ 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 $O_2$, $N_2O$ and Agent. And provide calculations of $CO_2$ 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 | $O_2$, $N_2O$, AIR; 280～600kPa |
| Cylinder yokes | Optional: $O_2$, $N_2O$, AIR |
| Fresh gas flow indicator | Electronically controlled mixer |
| Range of fresh gas flow indicators | 0~18L/min or set each gas independently: $O_2$, $N_2O$: 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 $cmH_2O$ |
| 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-VC) |
| | Synchronized Intermittent Mandatory Ventilation in Pressure (SIMV-PC) |
| | Synchronized Intermittent Mandatory Ventilation in PCV-VG (SIMV-VG) |
| | Pressure Support (PS) / Continuos 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 $cmH_2O$ |
| 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 $cmH_2O$ |
| Pressure support level (ΔP) | 3~60 $cmH_2O$ |
| Pressure limit (Pmax) | 10~100 $cmH_2O$ |
| Trigger | 0.5~15 L/min / -20~-1$cmH_2O$ |
| 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 preasure, 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 $O_2$, $N_2O$ 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, $F_iO_2$ high/low limit, Paw high/low limit, Pow er failure |
| | High Freq, Negative pressure, Continuous airway pressure, Apnea alarm, etc. |
| | Alarm (Silence ≤120 seconds) |
| Alarm logging | 500 items |

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

AEONMED
Reliable Quality Thoughtful Service

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AAM8800A-2022.03

# 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<br>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<br>Optional 10 to 1500 mL (Volume Control and SIMV modes)<br>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 $cmH_2O$)<br>(IPPV, SIMV-VC and PCV-VG vent modes) |
| Pressure ($P_{support}$) range | 3 to 60 $cmH_2O$ (increments of 1 $cmH_2O$)<br>(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( $P_{peak}$) | -20cm$H_2O$ to 99cm$H_2O$ |
| Mean pressure($P_{mean}$) | -20cm$H_2O$ to 99cm$H_2O$ |
| Plat pressure($P_{plat}$) | -20cm$H_2O$ to 99cm$H_2O$ |
| PEEP | -20cm$H_2O$ to 99cm$H_2O$ |
| Frequency | 0 to 110 breaths per minute |
| PAW | -20cm$H_2O$ to 110cm$H_2O$ |
| $FiCO_2$ | 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<br>> 100 mL = better than 15% |
| Pressure delivery | ±10% or ±3 cm $H_2O$ |
| PEEP delivery | ±2cm$H_2O$ or ±15% |
| Volume monitoring | < 100 mL = better than 10 mL<br>> 100 mL = better than15% |
| Pressure monitoring | ±5% |

## Alarm settings

| | |
|---|---|
| Minute volume (Mvexp) | Low: 0 to 20 L/min<br>High:1 to 25 L/min |
| Low airway pressure | 0 to 70 cm$H_2O$ |
| High pressure | 10 to 110cm$H_2O$ |
| High Breath Rate | 8 to 60 bpm |
| Inspired oxygen ($FiO_2$) | Low: 18 to 99%<br>High: 21 to 100% |
| exhalant $CO_2$($etCO_2$) | Low: OFF，0.1 to 9.8% or OFF，1 to 74 mmHg<br>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%<br>High: 0.1 to 8.4% |
| Insp. ISO | Low: OFF，0.1 to 8.3%<br>High: 0.1 to 8.4% |
| Insp. ENF | Low: OFF，0.1 to 9.8%<br>High: 0.1 to 9.9% |
| Insp. DES | Low: OFF，0.1 to 21.8%<br>High: 0.1 to 21.9% |
| Insp. SEV | Low: OFF，0.1 to 9.8%<br>High: 0.1 to 9.9% |
| Apnea alarm | Mechanical ventilation ON:<br>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<br>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<br>Manual mode:<br>Vt< 10 mL measured in 60 seconds |
| Sustained airway pressure | Mechanical ventilation ON:<br>Paw>PEEP add 10 cm $H_2O$ measured over 15 seconds Continuously<br>Mechanical ventilation OFF:<br>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<br>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<br>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);<br>RJ45 connector 100-Base-TX support HL7 communication license;<br>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 ± 1cm$H_2O$.

## 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<br>IRMA $CO_2$/ISA $CO_2$: < 10 sec |
| Rise Time | IRMA $CO_2$ / AX+:<br>$CO_2$≤90ms<br>$N_2O$≤300ms<br>HAL, ISO, ENF, SEV, DES≤300ms<br>ISA $CO_2$ :<br>$CO_2$ ≤200ms<br>ISA AX+ :<br>$CO_2$ ≤300ms<br>$N_2O$, $O_2$, ENF, ISO, SEV, DES ≤400ms<br>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.<br>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%<br>± (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%<br>$N_2O$: 0-100 vol%<br>HAL, ISO, ENF: 0-8 vol%<br>SEV: 0-10 vol%<br>DES: 0-22 vol% |

## Accuracy

| | |
|---|---|
| $CO_2$ | 0-15 vol%<br>± (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<br>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°)<br>30 to 70 cm $H_2O$ (180 to 288°) |
| Accuracy | ＜30 cm $H_2O$:±3 cm $H_2O$;<br>≥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)<br>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.**

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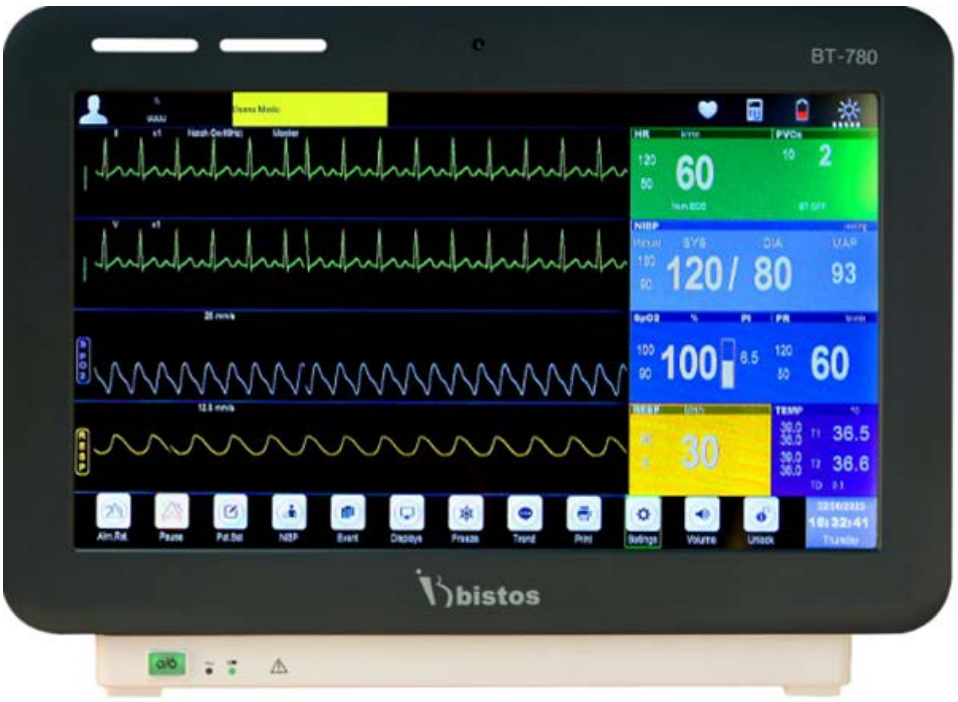
# BT-780 PATIENT MONITOR




## 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

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7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu,
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Tel : 82 31 750 0340 Fax : 82 31 750 0344

## 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)<br>Pressure setting range:140mmHg, 160mmHg, 180mmHg |
| | Pediatric : 140 (default)<br>Pressure setting range:140mmHg, 160mmHg |
| | Neonate : 100 (default)<br>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 | |

# BIO SIGNAL TOTAL SOLUTION

## Product

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

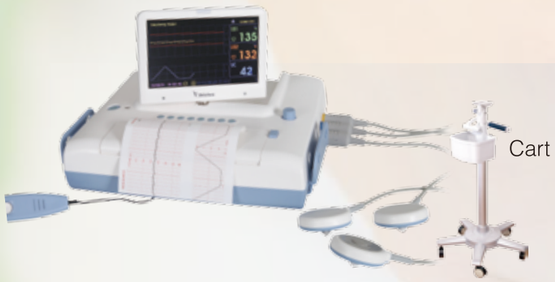
bistos
www.bistos.co.kr

# Fetal Monitor

## BT-350
LCD Monitor / LED Monitor

BT-350L

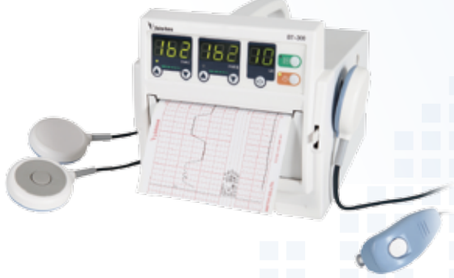
BT-350E



Cart

- 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



Cart

- 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 Rechageable (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 |

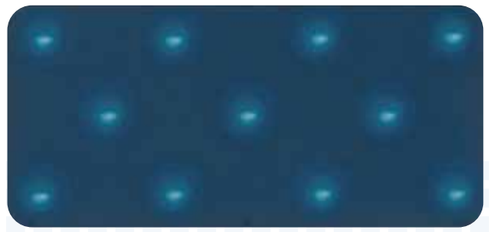
# Phototherapy

## 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 ㎝ |
| 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<br>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)

## 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)

| 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 |

# Electric Breast Pump

## Hi bebe plus

**Electric Breast Pump : BT-100**

- 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 | 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 |

MKT-ALL-1509

# BIO SIGNAL TOTAL SOLUTION

**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 E-mail : sales@bistos.co.kr www.bistos.co.kr



bistos
www.bistos.co.kr

# 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)<br>Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770)<br>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**<br>▪ BT-350<br>▪ FM-20<br>▪ Biocare FM-1 | IIa |
| Neonatal Phototherapy unit | ▪ BT-400 | IIa |
| Pulse Oximeter | ▪ BT-710 | IIb |
| Patient Monitor | ▪ BT-720<br>▪ BT-740<br>▪ BT-770<br>▪ 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

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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. 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

## 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)<br>Scope extension for pulse oximeter and patient monitor (BT-710, BT-720, BT-740, BT-770)<br>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** |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| Fetal monitor | ▪ BT-200<br>▪ BT-350<br>▪ FM-20<br>▪ Biocare FM-1 | IIa |
| Neonatal Phototherapy unit | ▪ BT-400 | IIa |
| Pulse Oximeter | ▪ BT-710 | IIb |
| Patient Monitor | ▪ BT-720<br>▪ BT-740<br>▪ BT-770<br>▪ **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**

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. |