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℃ (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	

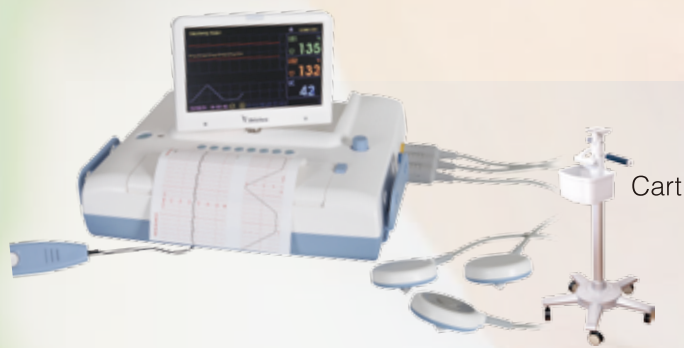# Bio Signal TOtal Solution

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

Fetal Doppler

BT-350
LCD Monitor / LED Monitor

BT-350L   BT-350E

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

Cart

BT-300
LED Monitor

Cart

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

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	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)		

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

Vascular Doppler & LED Head Lamp

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 Operating hours, Total operating hours, Timer, Intensit Intensity
Option	Cart, Eye shield, Shade

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

· 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

BT-410A   BT-410F

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)	

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)

Hi bebe *plus*
Electric Breast Pump : BT-100

BT-750
Multi-parameter Patient Monitor

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

Memory customized expression sequence	Rechargeable battery (2.5hour operation)
Vacuum control in 10 levels	Convenient and graceful design
Auto switch off after 30 minutes	3 operating mode (express , massage, memory)
Sufficient vacuum for dual expression	Operating time display
Backflow prevention	Silent

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

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

Bio Signal TOtal Solution

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DNV

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

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com   ICP-4-5-i1-MDD-f2, rev.0

Page   2 of 4

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

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NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com   ICP-4-5-i1-MDD-f2, rev.0

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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

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

NOTIFIED BODY 2460: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com   ICP-4-5-i1-MDD-f2, rev.0

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DNV

Management System Certificate

Certificate No.: 243275-2017-AQ-KOR-NA-PS Rev 4.0   Initial Certification Date: 12 August 2004   Valid Until: 09 September 2024

This is to certify that the quality system of:

Bistos Co., Ltd.

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

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

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

This certificate is valid for the following scope:

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

Place and date:
Høvik, 23 June 2021

Check Validity

For the issuing office:
DNV Product Assurance AS

Tone Elise Kolpus
Lead Auditor

NORWEGIAN
ACCREDITATION

MSYS 018

ICP-4-5-i1-ISO13485-f1,
rev.0

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

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

rev.0