Specifications : BT-710 Handheld Pulse Oximeter

Functional Characteristics	
SpO2	
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2%
	Neonate : 70 ~ 100% ±3%
	0 ~ 69% : unspecified
SpO2 alarm preset limits	Upper alarm limit : 86% ~ 100%
	Lower alarm limit : 85% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	No delay
SpO2 value refresh period	1s/time
SpO2 value refresh delay	< 10s
Average period	Low sensitivity : 7 ~ 8s
	Intermediate sensitivity : 4 ~ 6s
	Advanced sensitivity : 2 ~ 3s
Alarm condition delay period	Low sensitivity : < 8s
	Intermediate sensitivity : < 6s
	Advanced sensitivity : < 3s
Alarm sign generates delay period	0s
Pulse Rate	
Measuring range	25 ~ 250bpm
Resolution	±1bpm
Accuracy	±2% or ±2bpm, whichever is greater
Display	
Type	Color TFT touch screen LCD
Size	4.3"
Function	
Sleep mode	
Perfusion index	
Multi-language	
Trend	168hours
Alarm	
SpO2 alarms	SpO2 high/low
	PR high/low
	PI high/low
System alarms	Spo2 sensor no/off/error
	SpO2 search timeout/pulse
	SpO2 signal unstable
	SpO2 board failure
	Low perfusion
	Too much light
	Battery low
	System will shutdown
PC Interface	
SD card interface	S/W upgrade
Others	
Liquid Inlet Protection Grade	IPX2
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz)
	Output : DC 5V/2A
Rechargeable battery	3.7V Li-ion 3,800mA
	Operating time : 8hrs
	Charging time : 4hrs

Standard Configurations	
Adult SpO2 probe	1ea
Operation manual	1ea
Power adaptor	1ea
Physical Characteristics	
Dimension	
Main unit	84(W) x 34.5(D) x 158.5(H)mm
Packing (one unit)	201(W) x 106(D) x 69(H)mm
Carton box (10ea)	355(W) x 230(D) x 220H)mm
Weight	
Main unit	300g
Packing (one unit)	620g
Carton box (10ea)	6.6Kg
Environmental Conditions	
Operating temperature	10 ~ 40°C (50 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	

Specifications : BT-720 Vital Sign Monitor

Functional Characteristics	
SpO2	
Display range	0% ~ 100%
SpO2 display resolution	1%
SpO2 accuracy	Adult/Pediatric : 70 ~ 100% ±2%
	Neonate : 70 ~ 100% ±3%
	0 ~ 69% : unspecified
SpO2 alarm preset limits	Upper alarm limit : 86% ~ 100%
	Lower alarm limit : 85% ~ 99%
SpO2 alarm preset accuracy	±1%
SpO2 alerting signal generates delay	No delay
SpO2 value refresh period	1s/time
SpO2 value refresh delay	< 10s
Average period	Low sensitivity : 7 ~ 8s
	Intermediate sensitivity : 4 ~ 6s
	Advanced sensitivity : 2 ~ 3s
Alarm condition delay period	Low sensitivity : < 8s
	Intermediate sensitivity : < 6s
	Advanced sensitivity : < 3s
Alarm sign generates delay period	0s
Pulse Rate	
Measuring range	25 ~ 250bpm
Resolution	±1bpm
Accuracy	±2% or ±2bpm, whichever is greater
Display	
Type	Color TFT touch screen LCD
Size	4.3"
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	PR sound
	Alarm sound meets the IEC60601-1-8
Alarm	
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Data Storage	
Trend	168hours, resolution : 1min
Function	
Perfusion index	
Multi-language	English, Turkish
Trend	Graphic/tabular
Alarm	
SpO2 alarms	SpO2 high/low
	PR high/low
System alarms	Communication stop/error
	No sensor/ sensor off
	Search timeout
	Search pulse(weak)
	Battery low
PC Interface	
SD card interface	S/W upgrade
RJ45 (LAN)	CMS

NiBp (Option)	
Standard compliance	IEC80601-2-30
Measurement method	Automatic oscillometric method
Operating mode	Manual, automatic, continuous(STAT)
Useful life	100,000times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(40~270), Pediatric(40~200), Neonate(40~130)
	Mean : Adult(20~230), Pediatric(20~175), Neonate(20~100)
	Diastolic : Adult(10~210), Pediatric(10~162), Neonate(10~90)
Measurement accuracy	Maximum average error: ±5mmHg
	Maximum standard deviation: 8mmHg
Resolution	1mmHg
Initial inflation pressure (mmHg)	Adult : 150(default), 80~240(pressure setting range)
	Pediatric : 100(default), 80~200(pressure setting range)
	Neonate : 100(default), 60~120(pressure setting range)
Overpressure protection point (software)	Adult: 300mmHg
	Pediatric: 240mmHg
	Neonate: 150mmHg
Overpressure protection point (hardware)	Adult: 320~330mmHg
	Pediatric: 265~275mmHg
	Neonate: 160~165mmHg
Static Pressure accuracy	±3mmHg
Supply voltage	10V~14VDC
Maximum power consumption	3.6W
Quiescent current	50mA
Maximum current during measurement	180mA
Maximum current during inflation	300mA
Alarm	Communication, selfcheck error
	System error, measurement timeout
	Cuff loose, no, leak, type error
	Air pressure error
	Over range, signal weak/unstable/saturated
	Over pressure
	Systolic, mean, diastolic high/low
Temperature (Option)	
Standard compliance	ISO80601-2-56
Measurement method	Thermistor
Operating mode	Direct mode
Measuring range	0℃ ~ 50.0℃ (32℉ ~ 122.0℉)
Resolution	0.1℃
Measurement accuracy	±0.3℃
Number of channel	1
T1 alarm upper limit	0.1℃ ~ 50.0℃, 0.1℃/℉ step
T1 alarm lower limit	0℃ ~ 49.9℃, 0.1℃/℉ step
Temperature difference alarm upper limit	0℃ ~ 50.0℃, 0.1℃/℉ step
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz)
	Output : DC 15V/2.4A
Rechargeable battery	11.1V Li-ion 4,400mA
	Operating time : 8hrs
	Charging time : 4hrs

Standard Configurations	
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
Operation manual	1ea
Power adaptor	1ea
Options	
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Physical Characteristics	
Dimension	
Main unit	256(W) x 185(D) x 90(H)mm
Packing	335(W) x 245(D) x 210(H)mm
Weight	
Main unit	<1.5Kg
Packing	2.1Kg
Environmental Conditions	
Operating temperature	10 ~ 40°C (50 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	

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

Functional Characteristics	
Display	
Type	Color TFT touch screen LCD
Size and resolution	12.1", 800 x 600 pixels
LED	
Alarm indicator	Yellow & red
Adaptor power indicator	1 green
Battery status indicator	1 green
Audio	
Speaker	Alarm sound (45 ~ 85dB), key pressing sound
	QRS sound, PR sound
	Alarm sound meets the IEC60601-1-8
Data Storage	
Trend	168hours, resolution : 1min
Alarm event	200 physiological and 100 technical alarm events
NiBp measurement result	1,000 groups
Function	
Multi-language	English, France, Spanish, Turkey
Trend	Graphic/tabular
Alarm	
Mode	Visual, audible, information, parameter flashing
Alarm delay	Off, 1s, 2s, 3s, 4s, 5s, 6s, 7s, 8s
Pause duration	1, 2, 3, 4, 5, 10, 15min or permanent
System	Low battery
Interface	
Auxiliary	Nurse call
RJ45 (LAN)	CMS
USB	S/W upgrade
ECG	
Standard compliance	IEC60601-2-27
Lead type	3Lead : I, II, III
	5Lead : I, II, III, aVR, aVL, aVF, V
Display sensitivity (gain)	Auto, 1.25, 2.5, 5, 10, 20mm/mV
Wave sweep speed	12.5, 25, 50mm/s
Band width	Diagnostic mode : 0.05 ~ 130Hz
	Monitoring mode : 0.5 ~ 40Hz
	Surgery mode : 1 ~ 25Hz
	Strong filter mode : 5 ~ 20Hz
CMRR	> 100dB
Notch	50/60Hz (can be set on or off)
Differential input	> 5MΩ
Electrode polarization voltage range	±400mV
Baseline recovery time	< 5s after defibrillation (monitor and surgery mode)
Calibration signal	1mV (peak-peak), accuracy ±3%
Lead-off detection current	Measuring electrode : < 0.1μA
	Drive electrode : < 1μA
HR measuring range	Adult : 15 ~ 300bpm
	Pediatric/Neonate : 15 ~ 350bpm
HR measuring resolution	1bpm
HR measurement accuracy	±1bpm or ±1%, whichever is greater
HR accuracy & response to irregular rhythm	Ventricular bigeminy : 80±1bpm
	Slow alternating ventricular bigeminy : 60±1bpm
	Rapid alternating ventricular bigeminy : 120±1bpm
	Bidirectional systoles : 90±2bpm
HR time to alarm for tachycardia	0.5/1/2mV, 206bpm ventricular 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	Thoracic electrical bio impedance method
Measuring lead	Lead RA-LA, RA-LL
Wave gain	X0.5, x1, x2
Respiratory impedance range	0.2 ~ 3 Ω
Base line impedance	500 ~ 2,000Ω
Gain	10 grades
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	±0.3℃
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	100,000times
Measurement interval in automatic mode	1/2/3/4/5/10/15/30/60/90/120/180/240/480min
Typical measurement time	20~40s
Normal mode measuring range (mmHg)	Systolic : Adult(40~270), Pediatric(40~200), Neonate(40~130)
	Mean : Adult(20~230), Pediatric(20~175), Neonate(20~100)
	Diastolic : Adult(10~210), Pediatric(10~162), Neonate(10~90)
Measurement accuracy	Maximum average error: ±5mmHg
	Maximum standard deviation: 8mmHg
Resolution	1mmHg
Initial inflation pressure (mmHg)	Adult : 150(default), 80~240(pressure setting range)
	Pediatric : 100(default), 80~200(pressure setting range)
	Neonate : 100(default), 60~120(pressure setting range)

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

PR measurement accuracy	±3bpm
PR resolution	1bpm
Transducer sensitivity	5μV/V/mmHg
Transducer resistance range	300-5,000Ω
Supply voltage	+12VDC
Maximum power consumption	≤5W
Scan speed	12.5mm/s, 25mm/s
Alarm	IBP1, 2 communication stop/error
	IBP1, 2 sensor off
	Art-sys, PA-sys, P1-sys, P2-sys high
	Art-dia, PA-dia, P1-dia, P2-dia high
	Art-mean, PA-mean, CVP-mean, LAP-mean, RAP-mean, ICP-mean, P1-mean, P2-mean high
EtCO2 Mainstream & Sidestream (Option)	
Measurement parameters	EtCO2、FiCO2、AwRR
Measuring range	EtCO2 : 0~150mmHg, AwRR : 0~150rpm
Resolution	EtCO2/FiCO2 : 1mmHg, AwRR : 1rpm
Apnea delay	20s, 25s, 30s, 35s, 40s, 45s, 50s, 55s, 60s
Operating mode	Standby, measure
O2 compensation	Low, mid, high
N2O compensation	On, off
Alarm limit	EtCO2 lower limit : 0~149mmHg
	EtCO2/FiCO2 upper limit : 1~150mmHg
	AWRR lower limit : 0~119rpm
	AWRR upper limit : 1~120rpm
Alarm	Communication stop/error
	CO2 sensor off/error
	O2 sensor error/replace
	adaptor/sampling line no/check
	Parameter accuracy error
	O2, Air calibration error
	S/W, H/W error
	Motor accuracy error
	CO2 factory calibration error
	Adaptor, sampling line replace
	O2 port error
	CO2, O2, N2O out of accuracy
	CO2 temp., pressure out of accuracy
	CO2 zero required
	CO2 zeroing/sleeping
	CO2 module calibrating/calibration error
	EtCO2, FiCO2, AWRR high/low
	Apnea
C.O. (Cardiac Output : Option)	
Measurement range	C.O. : 0.2 ~ 20 L/min
	BT : 23 ~ 45℃±0.5 ℃
	IT : 0 ~ 20℃±0.5 ℃
Resolution factor	C.O. : 0.1L/min
	BT, IT : 0.1℃
Accuracy	C.O. : ±5% or ±0.1 L/min, subject to the bigger one
	BT, IT : ±0.1℃ (sensor exclusive)
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	58mm(W) x 42m
Power	
Adaptor	Input : AC 100 ~ 240V (50/60Hz)
	Output : DC 15V/2.4A
Consumption	13.5W
Rechargeable battery	11.1V Li-ion 4,400mA
	Operating Time : 5hrs
	Charging Time : 4hrs
Standard Configurations	
ECG cables and lead wire	1ea(5lead)
ECG electrode for adult	1pack(25pcs)
SpO2 adult reusable sensor	1ea
SpO2 extension cable	1ea
NiBp adult cuff	1ea
NiBp extension tube	1ea
Temperature sensor	1ea
Power adaptor	1ea
Bracket	1ea
Operation manual	1ea
Options (Function)	
IBP	Sensor cable & package
EtCO2 Mainstream (Bistos)	Airway adaptor & module
EtCO2 Sidestream (Bistos)	Sampling tube
EtCO2 IRMA Mainstream (Masimo)	Airway adaptor & module
EtCO2 ISA Sidestream (Masimo)	Sampling tube
C.O.	Sensor cable
Printer	Printer & paper
Cart	
Options (Accessory)	
ECG cables and lead wire	5/3 lead
ECG electrode	adult/neonate
SpO2 reusable sensor	adult/pediatric/neonate
SpO2 disposable sensor	adult/pediatric/neonate
Skin & rectal temperature sensor	adult/pediatric/neonate
NiBp cuff	adult(27~35cm)/pediatric(14~21.5cm)/neonate(4*9cm)
Physical Characteristics	
Dimension	
Main unit	320(W) x 65(D) x 250(H)mm
Packing	400(W) x 350(D) x 290(H)mm
Weight	
Main unit	< 2.8Kg
Packing	4.6Kg
Environmental Conditions	
Operating temperature	10 ~ 40°C (50 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	–20 ~ 60°C (–4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
Main unit	2 years
Optional sensor & accessory	1 year
Certificates	
KFDA, CE	

Patient Monitoring Systems

Patient Monitor

Vital Sign Monitor

Pulse Oximeter

bistos

Patient Monitor

BT-780
15.6“

BT-770
12.1“

BT-740
8.4“

Patient Monitor

- 15.6," 12.1," 8.4 "color TFT touch screen
- ECG, Resp., SpO_2, NIBP, Temp., CO_2, IBP, Multi-gas, C.O., Masimo SpO_2
- Precise ECG measurement with pacemaker detection
- ST segment and 16 types of arrhythmia analysis
- Double overpressure protection for NIBP
- Intelligent cuff inflation pressure adjustment
- Smart Hook/Stand design, provide multiple placement modes
- Plug & Play Modular IBP& C.O., Modular Printer
- Multiple configuration options: 4-channel IBP, CO_2, invasive C.O., Multi-gas
- Over 5 hours continuous working on battery
- 12-15V wide range DC input, suitable for ambulance
- Capable to connect with central monitoring system
- HL7 export to clinical information systems (UP TO MAX 30)
- Option for WIFI

CART

Touch screen

Dual Screen Central monitoring station

Ultra Slim design

Smart hook/Stand

IBP, CO, Printer module

Vital Sign Monitor

Portable design

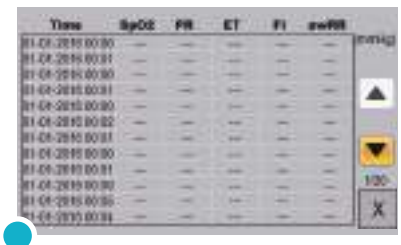
SpO2

SpO2+NIBP

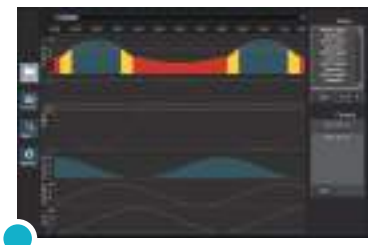
BT-720

- 4.3" color touch screen
- SpO2, Pulse, NIBP, Masimo SpO2
- Short/long trend graphic / trend table display
- Audio & visual alarm, adjustable alarm limit
- Automatic brightness adjustment
- Accurate SpO2 performance during motion and low perfusion
- Perfusion Index data / bar graph display
- Pitch tone variation for pulse rate
- Internal memory for data storage
- SD card for easy software upgradation
- Over 8 hours continuous working on rechargeable lithium-ion battery
- Specialized PC software for data review and analysis
- Option for Masimo SpO2, NIBP, Temp.
- HL7 export to clinical information systems

Trend Graphic



Trend Tabular



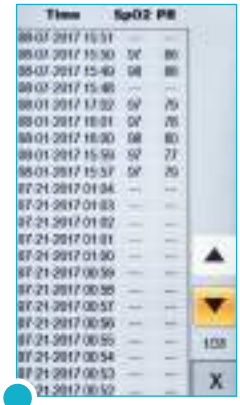
PC Viewer Software

Pulse Oximeter

BT-710

- 4.3" color touch screen
- Handheld style
- SpO2, Pulse
- Accurate SpO2 performance during motion and low perfusion
- Specialized PC software for data review and analysis
- Over 8 hours continuous working on rechargeable lithium-ion battery
- 5V DC input with convenient Micro-USB charger
- Battery can be charged by external USB battery
- Suitable for adult, pediatric and neonate
- Option for ETCO2

Handheld size



Trend Tabular

Protective case (option)

Wallmount Bracket

BT-750

- 10.4" color TFT LCD
- ECG, Resp., SpO_2, NIBP, Temp., CO_2
- Light weight for portable use (3kg)
- 72 hours of tabular and graphic trend data
- Multi Language Support
- Rolling stand and wall mount
- Central Monitoring System

BISTOS Patient Monitor Technical Specification

Model			BT780 / BT-770/ BT-740		
Category			Patient Monitor		
Dispaly			15.6"Color Touch Screen	12.1"Color Touch Screen	8.4"Color Touch Screen
ECG	Lead Type		3/5 Lead		
	Gain Selection		x0.125, x0.25, x0.5, x1, x2, auto		
	Sweep Speed (mm/s)		12.5, 25, 50		
	Bandwidth : Diagnostic Mode		0.05-100Hz		
	Monitoring Mode		0.5-40Hz		
	Surgery Mode		1-25 Hz		
	Hert Rate Range (bpm)		Adult: 15-300		
			Pediatric/Neonate: 15-350		
Respiration	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%)		unspecified		
	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	40-270		
		Pediatric	40-200		
		Neonate	40-130		
	Diastolic Range (mmHg)	Adult	10-210		
		Pediatric	10-162		
		Neonate	10-90		
	Mean Range (mmHg)	Adult	20-230		
		Pediatric	20-175		
		Neonate	20-100		
Temperature**	Range		0-50cC(41 to122 F°)		
	Parameter		T1, T2 and TD		
IBP *	Channel		2 Channel / 4 Channel		
	Range (mmHg)		-50 to 400		
Printer *	Type		Thermal dot array		
	Print Speed (mm/s)		12.5, 25, 50		
	Paper size (mm)		50mm x 2m		
CO_2 *	Sidestream		Masimo ISA/Bistos		
	Mainstream		Masimo IRMA/Bistos		
Multi-gas/O_2 *			Masimo ISA/Masimo IBMA/Bistos		
SpO_2-Masimo *			Masimo SPO_2		
C.O. *	Method		Thermodilution		
	Range		0.2- 20L/min		
Battery	Type (capacity)		Li-ion(4400mAh)		
	Run Time		5hour		
	Charging Time		4hour		
PC Software Interface			RJ45, USB, Nursing call		
Warranty			2year		

* Option ** Option (BT-720)

BT-750	BT-720	BT-710
Patient Monitor	Vital Sign Monitor	Handheld Pulse Oximeter
10.4" Color LCD	4.3" Touch LCD	4.3" Touch LCD
3/5 lead		
5, 10, 20mm/mV		
12.5, 25, 50		
Adult : 20 - 250		
Adult : 20 - 250		
Trans-thoracic impedance		
0-150 rpm		
6.25, 12.5, 25		
0-100 %	0-100 %	0-100 %
±2%	±2%	±2%
±3%	±3%	±3%
unspecified	unspecified	unspecified
0.05-20%	0.05-20%	0.05-20%
20-250	25-250	25-250
Automatic Oscillometric	Automatic Oscillometric	
Manual / Auto / STAT	Manual / Auto / STAT	
Systolic, Diastolic, Mean	Systolic, Diastolic, Mean	
50-255	30-280	
50-255	30-230	
30-130	30-145	
30-220	10-220	
30-220	10-165	
20-100	10-105	
40-235	10-240	
40-235	10-175	
25-120	10-115	
10-45℃ (50 to 113 ℉)	0-50℃ (41 to 122 ℉)	
T1, T2	T1, T2 and TD	
2 Channel		
-50 to 300		
Thermal dot array		
50		
50.8		
Respironics		
	Masimo SpO_2	
Li-ion (2200mAh)	Li-ion (4400mAh)	Li-ion (3000mAh)
4 hour	8 hour	8 hour
4 hour	4 hour	4 hour
RJ45*, RS232C	RJ45, SD card slot	SD card slot
2 year	2 year	2 year

BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

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Fax. +1-949-614-8745
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E-mail. info@bistosamericainc.com

No. DOC - 710 - 13

EC Declaration of Conformity

We, **Bistos Co., Ltd.**, (7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea) hereby declare that medical device described hereafter:

Product : Pulse Oximeter
Model No. : BT-710
GMDN code : 45607, Pulse oximeter, battery-powered
Accessories : SpO2 sensor (Model no. U403-01)
Classification: IIb (according to Rule 10 of Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC)
EC Representative : Obelis s.a. (Bd. Général Wahis 53 1030 Brussels / BELGIUM**)**

- is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.
- is subject to the procedures set out in Annex II excluding section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body 2460, DNV Product Assurance AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243269-2017-CE-KOR-NA-PS Rev. 5.0)
- is in conformity with the harmonized standards.

This declaration is supported by following Quality Management System certification:

Certification No. 243275-2017-AQ-KOR-NA-PS Rev.4.0
- is complies ISO 13485:2016/NS-EN ISO 13485:2016 requirements
- is issued by DNV Product Assurance AS (Veritasveien 3, N-1363 Høvik, Norway)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place of Issue: Gyeonggi-do, Korea
Date of Issue: August 23, 2021

Signed for and behalf of Bistos Co., Ltd

정혜선

Hyesun Jeong, RA

No. DOC - 700 – M16

EC Declaration of Conformity

We, **Bistos Co., Ltd.**, (7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea) hereby declare that medical device described hereafter:

Product : Patient monitor

Model No. : BT-720, BT-740 and BT-770

GMDN code : 33586, Single-patient physiologic monitoring system

Classification: IIb (according to Rule 10 of Annex IX of Council Directive 93/42/EEC as amended by 2007/47/EC)

EC Representative : Obelis s.a. (Bd. Général Wahis 53 1030 Brussels / BELGIUM**)**

- is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.
- is subject to the procedures set out in Annex II excluding section 4 of Council Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body 2460, DNV Product Assurance AS: Veritasveien 3 1363 Høvik Norway. (Certificate no.: 243269-2017-CE-KOR-NA-PS Rev. 5.0)
- is in conformity with the harmonized standards.

This declaration is supported by following Quality Management System certification:

Certification No. 243275-2017-AQ-KOR-NA-PS Rev.4.0

- is complies ISO 13485:2016/NS-EN ISO 13485:2016 requirements
- is issued by DNV Product Assurance AS (Veritasveien 3, N-1363 Høvik, Norway)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Place of Issue: Gyeonggi-do, Korea
Date of Issue: October 18, 2021

Signed for and behalf of Bistos Co., Ltd

Jonghyuk Park, PRRC

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

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.