



Bio Signal Total Solution

Fetal Monitor
Fetal & Vascular Doppler
Patient Monitor
Infant Incubator
Infant Warmer
Phototherapy
Breast Pump
Thermometer
Head Lamp

 **bistos**

Fetal Monitor



BT-380 Fetal & Maternal Monitor

- 1MHz Frequency with Twin Doppler
- 10.1" Color Touch Screen
- Fetal Monitoring : FHR, UC, DECG
Maternal Monitoring : ECG, NIBP, SpO2, TEMP
- Option: DECG, Rechargeable battery, Acoustic Stimulator, Wifi, Cart

BT-350 LCD Fetal Monitor

- 1MHz Frequency with Twin Doppler
- 7" color TFT LCD Display
- CTG Analysis
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart



BT-350 LED Fetal Monitor

- 1MHz Frequency with Twin Doppler
- Large 7 Segment LED Display
- Waterproof Probe (IPX 8)
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart

BT-300 LED Fetal Monitor

- 1MHz Frequency with Twin Doppler
- Waterproof Probe (IPX 8)
- Option : Rechargeable battery, Acoustic Stimulator, Carrying bag, Cart



Fetal & Vascular Doppler

BT-200 Fetal Doppler

- 2/3 MHz Frequency
- Various Display Type (Sound only, LCD, Color)
- Waterproof Probe
- FHR and Sound management



BT-220 Fetal Doppler

- 2/3 MHz Frequency
- 2.4" Color LCD Display with FHR Trend Display
- Acoustic Stimulator Function
- BMI and Body fat Analysis



BT-250 Fetal Doppler

- 2/3 MHz Frequency
- 3.2" color TFT LCD Display with FHR Trend Display
- Rechargeable Battery



BT-200 Vascular Doppler

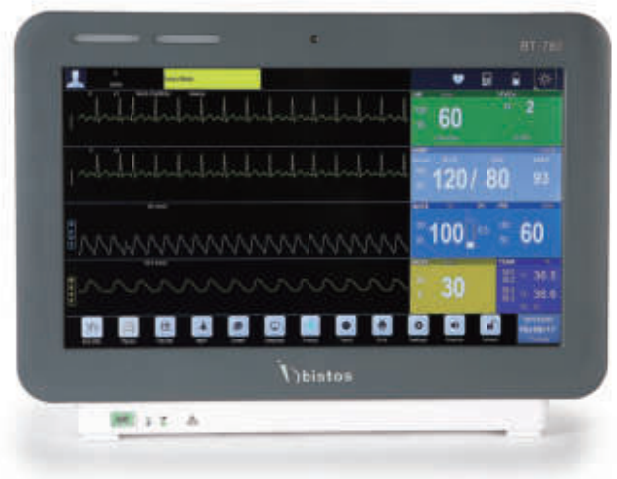
- 2, 4, 5, 8 MHz Frequency
- LCD Display
- Interchangeable Waterproof Probe
- Low Battery Indicator



Patient Monitor

BT-780 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO2, IBP, Multi-gas, C.O.
- 15.6" Color Touch Screen
- Ultra slim design
- 5 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO2, IBP, Multi-gas, C.O., Printer, Masimo SpO2, WIFI



BT-770 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO2, IBP, Multi-gas, C.O.
- 12.1" Color Touch Screen
- Ultra slim design
- 5 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO2, IBP, Multi-gas, C.O., Printer, Masimo SpO2, WIFI

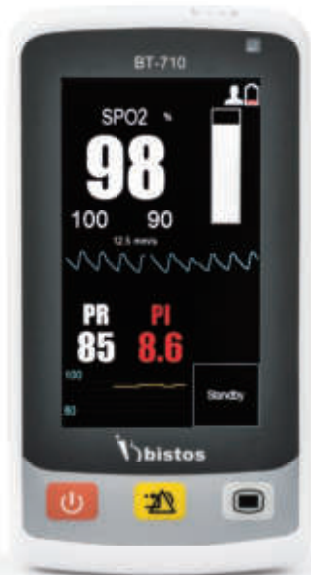


BT-740 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO2, IBP, Multi-gas, C.O.
- 8.4" Color Touch Screen
- Ultra slim design
- 6 hours operation on battery
- Smart Hook & stand
- HL 7 support
- Option : CO2, IBP, Multi-gas, CO, Printer, Masimo SpO2, WIFI

BT-720 Vital Sign Monitor

- SpO2, Pulse
- 4.3" Color Touch Screen
- 8 hours operation on battery
- Fan-less design
- Rechargeable by USB charger
- Option : NIBP, Temp



BT-710 Pulse Oximeter

- SpO2, Pulse
- Hand-held design
- 4.3" Color Touch Screen
- 8 hours operation on battery
- Fan-less design
- Rechargeable by USB charger
- Option : CO₂



BT-750 Patient Monitor

- ECG, Resp., SpO2, NIBP, Temp., CO₂, IBP
- 10.4" Color LCD Display
- 4 hours operation on battery
- Multi language support
- Option : CO₂, IBP, Printer, LAN, Cart, Wall mount

Neonate Care



BT-500 Infant Incubator

- Air / Skin Temperature servo control
- Humidity Servo Control
- Tilting bed
- Option : O2 Servo Control, O2 Monitoring, Masimo SpO2 & CCD Camera & External monitor, Lifting Stand, Weighing scale, Basket, IV Plate, IV Pole, Shelf

BT-550 Infant Warmer

- Infrared Heater
- Pre-warm / Baby / Manual Mode
- APGAR Timer
- Option : Tilting, Masimo SpO2, Lifting Stand, Weighing scale, Basket, IV Plate, IV Pole, Oxygen delivery, Suction



BT-400 Phototherapy

- Blue LED Lamp
- Intensity Control (High/Low)
- 100,000 hours LED lifetime
- Timer function

BT-450 Phototherapy

- Blue LED (455 nm to 465 nm)
- Intensity Control (High/Low)
- Blanket Type
- 10 hours operation on battery
- Alarm for High Temperature



BT-100 Breast Pump

- Portable Type with Dual Pumping
- Massage / Expression / Memory Mode
- Backflow Prevention
- BPA / Latex Free



BT-150 Breast Pump

- Desktop Type with Dual Pumping
- Massage / Expression / Program Mode
- Various Vacuum Level and Cycle Control
- Option : Carrying bag, Car charging cable, Nursing Night Lamp, Additional bottle set, Rechargeable battery, Bluetooth for mobile app

BT-35 Non-Contact Thermometer

- Fever Alert Function (Blue/Red Color)
- Measurement of Body and Object
- Quick & Infrared Measurement
- High Accuracy



BT-410A

BT-410F

BT-410 Head Lamp

- Power LED Light with 6,000K Color Temperature
- Adjustable illumination (BT-410F)
- Adjustable Light Spot (BT-410A)
- Option: Loupe, Astral Lamp, Additional battery

BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

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E-mail. info@bistosamericainc.com

Specifications : BT-200T Fetal Doppler

Functional Characteristics	
FHR	
Ultrasound frequency	3MHz
Ultrasound intensity	10mW/cm ² or less
Sensitivity	8~12 weeks onward
FHR range	50~240bpm ±2%
FHR resolution	1bpm
Display	
Mono LCD	
FHR quality (heart symbol)	Full(stable), empty(HR searching)
Low battery	2levels
Audio Output	
Output	1.2W
Earphone jack	3.5mm
Auto Shut Off	
Sound off	1min
Power off	5min
PC Interface	
Earphone jack to sound card	S/W : BCM-200
Others	
Waterproof probe	IPX7
Power	
Battery	1.5V x 2, AA type
Operating time	360min
Standard Configurations	
Operation manual	1ea
Battery (1.5V AA type)	2ea
Ultrasound Gel 60ml	1ea
Carrying pouch	1ea
Options	
Rechargeable battery	Ni-Cd AA, 1.2V, 800mA, KR14/49
Charger	Charging time 2hours for 1,000mAh 2pcs
Physical Characteristics	
Dimension	
Main unit	75(W) x 26(D) x 128(H)mm
Probe	25(W) x 25(D) x 131(H)mm
Packing (one unit)	110(W) x 70(D) x 200(H)mm
Carton box (10ea)	360(W) x 240(D) x 230(H)mm
Carton box (20ea)	360(W) x 440(D) x 230(H)mm
Weight	
Main unit & probe	190g
Packing (one unit)	400g
Carton box (10ea)	4.3Kg
Carton box (20ea)	8.4Kg
Environmental Conditions	
Operating temperature	5 ~ 40°C (41 ~ 104°F)
Operating humidity	5 ~ 85% non-condensing
Storage temperature	-20 ~ 60°C (-4 ~ 140°F)
Storage humidity	0 ~ 95% non-condensing
Warranty	
24 months	
Certificates	
KFDA, CE, FDA	

EC CERTIFICATE

Full Quality Assurance System

Certificate No.: 243267-2017-CE-KOR-NA-PS Rev. 2.0

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

Valid Until: 27 May 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

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

Ultrasound Doppler System with Foetal Doppler System Probes, Electric breast pump, Infant warmer, and Infant incubator

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, 17 March 2021

For the issuing office:

Notified Body 2460

DNV Product Assurance AS



Eugenie Winger Husebye
Technical Reviewer

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

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

ICP-4-5-11-MDD-f2, rev.0

Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1012401, Rev 3.0 (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	Recertification (Certificate no. 215934-2017-CE-KOR-NA-PS has been merged after the recertification audit completed)	17 March 2021

Products covered by this Certificate:

Product Description	Product Name	Class
Ultrasound Doppler system with Probes	<ul style="list-style-type: none"> ▪ BT-200L - AY-DOP-200L (2M) ▪ BT-200C - AY-DOP-200C (2M) ▪ BT-200S - AY-DOP-200S (2M) ▪ BT-200T - AY-DOP-200T (3M) ▪ BT-200V - AY-DOP-200V (2M) - AY-DOP-200V (4M) - AY-DOP-200V (5M) - AY-DOP-200V (8M) ▪ F-10 - AY-2MHZDOP-010 ▪ BT-220L - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-220C - AY-DOP-220 (2M) - AY-DOP-220 (3M) ▪ BT-250 - AY-DOP-250 (2M) 	Ila
Electric Breast Pump	<ul style="list-style-type: none"> ▪ BT-100 ▪ Milk Genie ▪ BT-150, BT-150L, BT-150B, BT-150S 	Ila

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

Infant warmer	▪ BT-550	IIb
Infant incubator	▪ BT-500	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, Galmachiro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EU Representative

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

Terms and conditions

The certificate is subject to the following terms and conditions:

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

The following may render this Certificate invalid:

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

Conformity declaration and marking of product

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

End of Certificate

EC 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 : Ultrasound Doppler System and probes

(See attachment 1)

GMDN Code: 34040, Foetal Doppler system and 41917, Foetal Doppler system

Classification: IIa (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.: 243267-2017-CE-KOR-NA-PS Rev. 2.0)
- 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.3.0

- 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: April 27, 2021

Signed for and behalf of Bistos Co., Ltd



Hyesun Jeong, RA manager

Attachment 1. Model list

Trade name	Model No.	Probes
HI-bebe	BT-200L	AY-DOP-200L(2M)
	BT-200C	AY-DOP-200C(2M)
	BT-200S	AY-DOP-200S(2M)
	BT-200T	AY-DOP-200T(3M)
HI-dop	BT-200V	AY-DOP-200V(2M) AY-DOP-200V(4M) AY-DOP-200V(5M) AY-DOP-200V(8M)

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 243275-2017-AQ-KOR-NA-PS Rev 3.0 Project No.: PRJC-533956-2015-MSL-KOR Initial Certification Date: 12 August 2004 Valid Until: 9 September 2021

This is to certify that the management system of:

Bistos Co., Ltd.

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

Complies with the requirements of:

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

The 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, 16 April 2020

For:
DNV GL PRESAFE AS



Eugenie Winger Husebye

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:
243275-2017-AQ-KOR-NA-PS Rev 3.0

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

Initial Certification Date:
12 August 2004

Valid Until:
9 September 2021

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.

End of Certificate