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

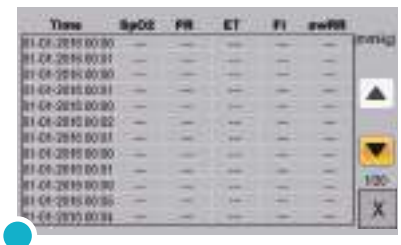
SpO2

SpO2+NIBP

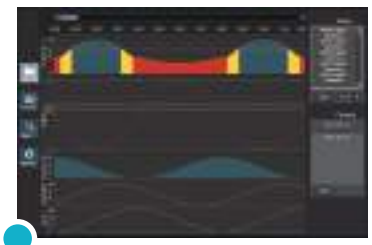
BT-720

- 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



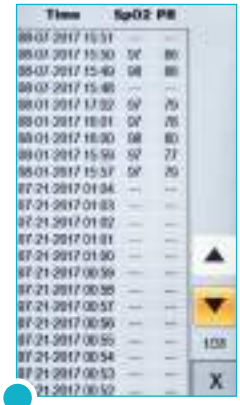
PC Viewer Software

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 5 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	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		0-50cC(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	5 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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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.