



Patient Monitoring Systems

Patient Monitor
Vital Sign Monitor
Pulse Oximeter

 **bistos**

Patient Monitor

BT-770

- 12.1" color TFT touch screen
- ECG, Resp., SpO₂, NIBP, Temp., CO₂, IBP, Multi-gas, C.O., Masimo SpO₂
- 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, CO₂, 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 (option)



Touch screen



Dual Screen Central monitoring station



Ultra Slim design



Smart hook/Stand



IBP, CO, Printer module

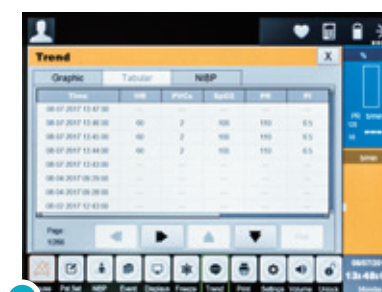
Patient Monitor

BT-740

- 8.4" color TFT touch screen
- ECG, Resp., SpO₂, NIBP, Temp., CO₂, Masimo SpO₂
- Ultra-low power consumption
- Fan-less design, super silent
- Accurate SpO₂ performance during motion and low perfusion
- Perfusion index display, pitch tone variation for pulse rate
- USB support for future upgrade and data transfer
- Over 6 hours continuous working on battery



Trend Graphic



Trend Tabular



BT-750

- 10.4" color TFT LCD
- ECG, Resp., SpO₂, NIBP, Temp., CO₂
- 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

Vital Sign Monitor



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
- HL7 export to clinical information systems



Portable design



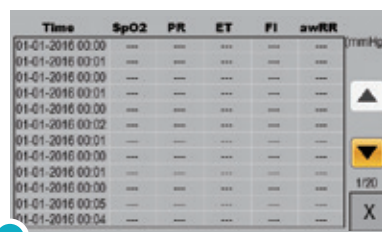
SpO2



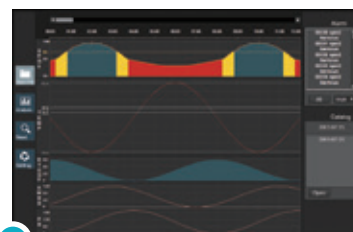
SpO2+NIBP



Trend Graphic



Trend Tabular



PC Viewer Software

Pulse Oximeter

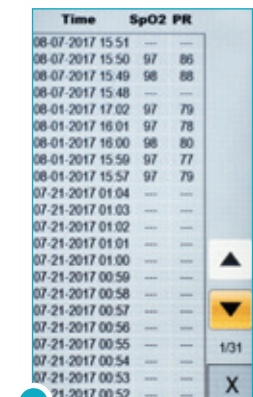


BT-710

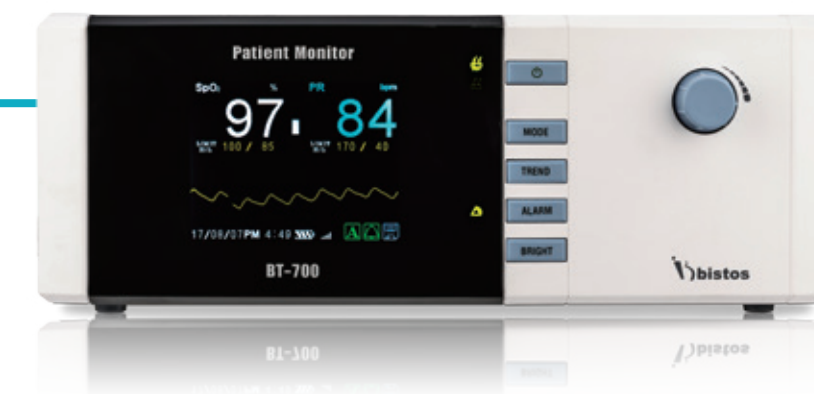
- 4.3" color touch screen
- Handheld style
- SpO2, Pulse
- Accurate SpO2 performance during motion and low perfusion
- Specialized PC software for data review and analysis
- Over 8 hours continuous working on rechargeable lithium-ion battery
- 5V DC input with convenient Micro-USB charger
- Battery can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



Handheld size



Trend Tabular



BT-700

- 3.2" color LCD
- Desktop Pulse Oximeter
- SpO2, Pulse
- Trend Graphic, Trend Tabular display
- Internal data saving
- Firmware upgrade by USB interface
- Apply nurse call state

BISTOS Patient Monitor Technical Specification

* Option ** Option (BT-720)

Model Category			BT-770	BT-750
			Patient Monitor	Patient Monitor
Display			12.1" Color Touch LCD	10.4" Color LCD
ECG	Lead Type		5 lead	3/5 lead
	Gain Selection		x0.125, x0.25, x0.5, x1,x 2,auto	5, 10, 20mm/mV
	Sweep Speed (mm/s)		12.5, 25, 50	12.5, 25, 50
	Bandwidth : Diagnostic Mode		0.05-130 Hz	
	Monitoring Mode		0.5-40 Hz	
	Surgery Mode		1-25 Hz	
	Strong Mode		5-20 Hz	
	Hert Rate Range (bpm)		Adult : 15-300 Pediatric/Neonate: 15-350	Adult : 20 - 250 Adult : 20 - 250
Respiration	Method		Trans-thoracic impedance	Trans-thoracic impedance
	Measurement Range		0-120 rpm	0-150 rpm
	Sweep Speed (mm/s)		6.25, 12.5, 25	6.25, 12.5, 25
SpO ₂	Measurement Range		0-100 %	0-100 %
	Accuracy (70-100%)	Adult/Pediatric	±2%	±2%
		Neonate	±3%	±3%
	Accuracy (0-69%)		unspecified	unspecified
	Perfusion Index		0.05-20%	0.05-20%
	Pulse Rate Range (bpm)		25-250	20-250
NIBP**	Method		Automatic Oscillometric	Automatic Oscillometric
	Operation Mode		Manual / Auto / STAT	Manual / Auto / STAT
	Parameter		Systolic, Diastolic, Mean	Systolic, Diastolic, Mean
	Systolic Range (mmHg)	Adult	40-270	50-255
		Pediatric	40-200	50-255
		Neonate	40-130	30-130
	Diastolic Range (mmHg)	Adult	10-210	30-220
		Pediatric	10-160	30-220
		Neonate	10-90	20-100
	Mean Range (mmHg)	Adult	20-230	40-235
		Pediatric	20-175	40-235
		Neonate	20-100	25-120
Temperature	Range		0-50℃ (41 to 122 ℉)	10-45℃ (50 to 113 ℉)
	Parameter		T1, T2 and TD	T1, T2
IBP *	Channel		2 Channel / 4 Channel	2 Channel
	Range (mmHg)		-50 to 400	-50 to 300
Printer *	Type		Thermal dot array	Thermal dot array
	Print Speed (mm/s)		12.5, 25, 50	50
	Paper size (mm)		50	50.8
CO ₂ *	Sidestream		Masimo ISA / Bistos	Respironics
	Mainstream		Masimo IRMA/ Bistos	
Multi-gas/O ₂ *			Masimo ISA	
SpO ₂ -Masimo *			Masimo SpO ₂	
C.O. *	Method		Thermodilution	
	Range		0.2 - 20 L/min	
Battery	Type (capacity)		Li-ion (4400mAh)	Li-ion (2200mAh)
	Run Time		5 hour	4 hour
	Charging Time		4 hour	4 hour
PC Software Interface			RJ45, USB, Nursing call	RJ45*, RS232C
Warranty			2 year	2 year

BT-740	BT-720	BT-710	BT-700
Patient Monitor	Vital Sign Monitor	Handheld Pulse Oximeter	Pulse Oximeter
8.4" Color Touch LCD	4.3" Touch LCD	4.3" Touch LCD	3.2" Color LCD
5 lead			
x0.25, x0.5, x1, x2, x4 auto			
12.5, 25, 50			
0.05-130Hz			
0.5-40Hz			
1-25Hz			
5-20Hz			
Adult : 15-300			
Pediatric/Neonate: 15-350			
Trans-thoracic impedance			
0-120 rpm			
6.25, 12.5, 25			
0-100 %	0-100 %	0-100 %	0-100 %
±2%	±2%	±2%	±2%
±3%	±3%	±3%	±3%
unspecified	unspecified	unspecified	unspecified
0.05-20%	0.05-20%	0.05-20%	
25-250	25-250	25-250	30-250
Automatic Oscillometric	Automatic Oscillometric		
Manual / Auto / STAT	Manual / Auto / STAT		
Systolic, Diastolic, Mean	Systolic, Diastolic, Mean		
40-270	40-270		
40-200	40-200		
40-130	40-130		
10-210	10-210		
10-160	10-160		
10-90	10-90		
20-230	20-230		
20-175	20-175		
20-100	20-100		
0-50℃ (41 to 122 ℉)			
T1, T2 and TD			
2 Channel / 4 Channel			
-50 to 400			
Thermal dot array			
12.5, 25, 50			
50			
Masimo ISA / Bistos			
Masimo IRMA/ Bistos			
Masimo ISA			
Masimo SpO ₂	Masimo SpO ₂		
Thermodilution			
0.2 - 20 L/min			
Li-ion (4400mAh)	Li-ion (4400mAh)	Li-ion (4400mAh)	Li-ion (2600mAh)
6 hour	8 hour	8 hour	3 hour
4 hour	8 hour	8 hour	8 hour
RJ45, USB, Nursing call	RJ45, SD card slot	SD card slot	RS232C, Nursing call
2 year	2 year	2 year	2 year



BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

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Fax. +82 (31) 750 0344

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Fax. +1-888-391-5153

EC Certificate

Full Quality Assurance System

Certificate No.:
243269-2017-CE-KOR-NA-PS Rev. 2.0

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 Article 11.3.a
and Annex II excluding section 4 (Module H2) 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, 30 August 2018



For:
DNV GL PRESAFE AS



Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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

EC Certificate

Full Quality Assurance System

Certificate No.:
243269-2017-CE-KOR-NA-PS Rev. 2.0

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

Valid Until:
01 September 2023

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)	2017-09-01
1.0	EU Rep change	2018-04-13
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, AU-UC-350)	2018-09-01

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	<ul style="list-style-type: none"> BT-300 BT-350 FM-20 Biocare FM-1 	Ila
Neonatal Phototherapy unit	<ul style="list-style-type: none"> BT-400 	Ila
Pulse Oximeter	<ul style="list-style-type: none"> BT-710 	IIb
Patient Monitor	<ul style="list-style-type: none"> BT-720 BT-740 BT-770 	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

EC Certificate

Full Quality Assurance System

Certificate No.:
243269-2017-CE-KOR-NA-PS Rev. 2.0

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

Valid Until:
01 September 2023

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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate

Management System Certificate

Certificate No.:
243275-2017-AQ-KOR-NA-PS Rev. 2.0

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

Initial Certification Date:
12 August 2004

Valid Until:
09 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, 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, 12 September 2018



For:
DNV GL PRESAFE AS



Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

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