Neonatal Care System

Infant Incubator

Infant Warmer

Phototherapy

bistos

BT-500 Infant Incubator

Masimo Pulse oximeter*

Trend Display

External Monitor*

Environment designed for premature baby

- Double Wall and air curtain maintain constant temperature control in the hood and help the infant keep their temperature.
- Low operation noise and the part that makes noise is designed to make only minimal noise to ensure quiet environment
- In-built x-ray tray and weighing scale minimize the necessity for premature baby leave the incubator for additional care.

Double wall

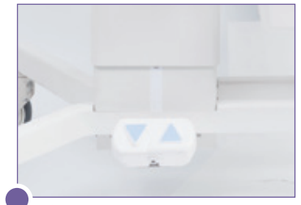
X-ray tray

Tilt

- Tilting of best enable Trendelenburg and reverse-Trendelenburg for faster recovery
- Built-in Masimo Pulse Oximeter provides most accurate measurement for SpO2.
- Water tank can be disinfected by autoclaving.
- O2 Servo control and measurement available

Convenience designed for medical staff

- Lifting stand adjust mattress height to optimized height for each staff
- Large 6 doors on every side of hood enable the premature baby can be accessible in every direction.
- CCD Camera shows the status of infant in additional display even if the incubator is covered. Even the video can be displayed on mobile phone or PC simultaneously by wireless connection.



Lifting Stand*

Basket*

Peripheral temperature

- Multi language support helps the staff operate the incubator properly with the instruction in their own languages.
- Large size basket and have enough inner space to store all necessaries for infant care.
- Two skin temperature measures both temperature from belly and peripheral.

*Option

BT-550 Infant Warmer

Swivel head

Tilting*

Removable wall

LED examination light

- Servo temperature control (Manual, Baby, Pre-warm mode)
- Swivel head and X-rays tray for other procedure
- Tilting mattress for Trendelenburg treatment
- Easy removable side walls for easy access and cleaning
- APGAR timer for 1, 5, 10 minutes
- LED Examination light for 3 level brightness

*Option

BT-400 Phototherapy

Adjustable position

8 Power LED

Mobile design

- Highly effective blue LED light
- Fan-less design for noiseless treatment
- Intensity control (high & low)
- Extensive long LED life time up to 100,000 hours
- Displays treatment time and total used timeb
- Built-in clamp provides various installation options

with Cart

with IV pole

with Incubator

Technical Specification

Model		BT-500
Category		Infant Incubator
Air Temp.	Control	Normal : 23 - 37℃
		Override : 37.1 - 39℃
	Measurement	20 - 45 ±0.5℃
Skin Temp.	Control	Normal : 35 - 37.5℃
		Override : 37.6 - 39℃
	Measurement	25 - 45 ±0.3℃
Humidity	Control	30 - 95%
	Measurement	15 - 99 ±5% RH
	System	Steam (Boiling at 100℃)
	Water Tank	1,000ml (Autoclavable)
Scale *	Measurement	0 - 10Kg ±10g
	Trend	216 Hour
O_2 *	Control	21 - 65 ±5%
	Measurement	18 - 100 ±5%
Masimo SpO_2 *	Measurement	1 - 100%
	Accuracy	± 3% (70-100%)
		Unspecified (0~69%)
	Pulse Rate Range	25 - 240bpm ±3bpm
CCD Camera *	Resolution	2.5M pixel
	Video Transfer	Wi-Fi
Hood	Hand Port	6 Door
	Tubing Port	2 x 6 Port
	Structure	Double wall
	Air Curtain	Support
	Noise	< 45dB
Bed	Tilt	< 12°
	Matress	72 x 39 x 2 cm
	X-ray tray	35 x 40 cm
Lifting Stand *	Height	65 - 85 cm
IV Plate *	Load limit	11 Kg
IV Pole *	Hook	2 Hook
Basket *	Load limit	10 Kg
Shelf *	Load limit	3 Kg
Air filter	Particle	0.3 Micron
	Efficiency	99.8%
General	Display	7″ TFC Color LCD
	Trend	72 Hour
	Alarm	27 Events (Visual & Sound)
	Warm up	< 30 Minute (Fast Mode)
	Self Test	Power On
	Multi Language	Support
	Quick Guide	In-built
Dimensions	Standard (HWD)	1,354 x 1,024 x 690 mm
	With Lifting (H)	1,244 - 1,444 mm
Weight	Standard	99.3 Kg
	Maximum	117.5 Kg
Warranty	Main unit	2 year

* Option

Model		BT-550
Category		Infant Warmer
Temp. Control Mode		Prewarm / Baby / Manual
Skin Temp.	Control	34 - 38 ℃
	Measurement	26 - 42 ±0.3℃
Heater	Type	Infrared
	Control	0 - 100% / 20 Level
	Power	600W
	Life Time	5,000 Hour
	Rotation	90°
APGA Timer	Setting	0 - 59 min. 59 sec.
	Beep	1, 5, 10 min.
Examination	Power	40W LED (10W x 4)
	Control	3 Level
	Illumination	> 7,000 lx
Scale *	Measurement	0 - 10Kg ±10g
Masimo SpO_2 *	Measurement	1 - 100%
	Accuracy	± 3% (70-100%)
		Unspecified (0~69%)
	Pulse Rate Range	25 - 240bpm ±3bpm
Bed	Tilt *	< 15°
	Matress	80 x 49 x 2cm
	X-ray tray	35 x 40 cm
Lifting Stand *	Height	65 - 85 cm
IV Plate *	Load limit	11 Kg
IV Pole *	Hook	2 Hook
Basket *	Load limit	10 Kg
Shelf *	Load limit	3 Kg
Oxygen Delivery *		Regulator, Humidifier, Bracket
General	Display	7″ TFC Color LCD
	Alarm	6 Events (Visual & Sound)
	Self Test	Power On
	Leveler	Bubble type
Dimensions	Standard (HWD)	1,890 x 1,027 x 690 mm
	With Lifting (H)	1,780 - 1,980 mm
Weight	Standard	83 Kg
	Maximum	98 Kg
Warranty	Main unit	2 year

Model		BT-400
Category		Phototherapy
Light Source		Blue LED
Wavelength		Peak Between 450 - 475 nm
Intensity	Low	25 - 35 μW/cm²/nm
	High	35 - 55 μW/cm²/nm
Intensity Variation (over 6 hrs)		±10%
LED Life Time		100,000 Hour
Effective Surface (at 40cm)		Approx. 40 x 20 cm
Heat output over 6hours		< 10 ℃ than ambient
Audible Noise		< 30 dB (Fanless)
Clamp		Max. diameter 3.5cm
Shade *		Covers Incubator and Warmer
Cart *		Height : 74 - 118cm
General	Display	2.4″ TFT Color LCD
	Time Display	Treatment time, Total used time
	Timer	30 min. - 999 hrs.
Dimensions(HWD)	Head	75 x 340 x 210 mm
	Cart	1000 x 430 x 520 mm
Weight	Main unit	3.6 Kg
	Main unit & Cart	13 Kg
Warranty	Main unit	2 year

BIO SIGNAL TOTAL SOLUTION

Bistos Co., Ltd. (Headquarter)

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302,
Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, Korea
Tel. +82 (31) 750 0340
Fax. +82 (31) 750 0344

bistos@bistos.co.kr
www.bistos.co.kr

Bistos America Inc. (US Branch)

11417 W Bernardo Ct Ste D, San Diego, CA 92117, USA
Tel. +1-868-433-6689
Fax. +1-888-391-5153

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.

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
215934-2017-CE-KOR-NA-PS Rev 3.0	**PRJC-533956-2015-MSL-KOR**	**30 May 2021**

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 13201, Korea

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

Electric Breast Pump, Infant warmer, Infant incubator

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, 13 April 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Villy Rønneberg

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.:	Project No.:	Valid Until:
215934-2017-CE-KOR-NA-PS Rev 3.0	**PRJC-533956-2015-MSL-KOR**	**30 May 2021**

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	Original Certificate	2017-04-18
1.0	New model (Milk Genie) added	2017-09-25
2.0	Product add (Infant incubator)	2018-01-03
3.0	EU Rep change	2018-04-13

Products covered by this Certificate:

Product Description	Product Name	Class
Electric Breast Pump	▪ Hi bebe^{plus} BT-100 ▪ Milk Genie	IIa
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, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do 13201, Korea

EU Representative

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
215934-2017-CE-KOR-NA-PS Rev 3.0	**PRJC-533956-2015-MSL-KOR**	**30 May 2021**

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