



Fetal Doppler System Vascular Doppler System

Handheld Doppler
Desktop Doppler
Vascular Doppler

 **bistos**

Fetal Doppler



BT-200
Hi-bebe



Waterproof probe

Various Display type from low to medium budget



200S 200L/200T 200C

Various Frequency option

2MHz or 3MHz is available upon request.
(200T : 3MHz)

Waterproof probe

Even the most basic Doppler has waterproof probe suitable for water delivery. (IPX7)

Complimentary carrying pouch

All handheld Doppler comes with carrying pouch

FHR and sound management

Dedicated PC software enables save and manage FHR and heart sound data



Fetal Doppler



Interchangeable probe



BT-220
Hi-bebe S

Trend display

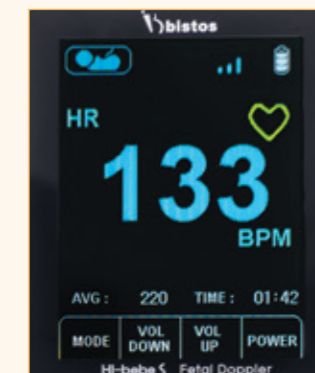
Large color LCD enables trend of FHR on screen.

Acoustic Stimulator

Stimulate sleeping fetus to acquire more accurate FHR.
High(100Hz) / Low(75Hz)

Interchangeable probe

2MHz or 3MHz probe can be used on one main unit



220C



220L

Recharging kit (Optional)

Just plug-in to microUSB cable recharge the battery and no need to change disposable battery.

Desktop Fetal Doppler



Vascular Doppler



BT-250

BT-200
Hi dop

Low Noise & Clear sound

Louder and better sound than handheld doppler. (5W)

Trend data save

Store data up to 4 hours and up to 15 patients.

Large display

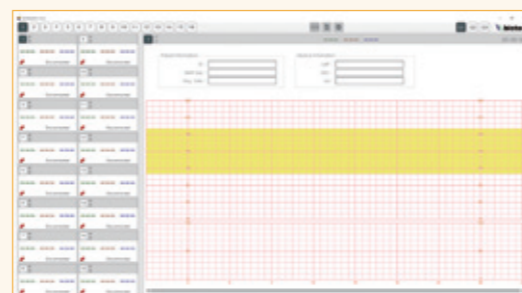
Lager dispaly than handheld Doppler enables to show more information on the screen.

Portability

Rechargeable battery and compact design makes portable use.

Central Monitoring Software

Works on BCM-350 software along with other Fetal monitors.



Interchangeable probes

4, 5, 8MHz probe is available for multiple application.

4~5 MHz : Femoral, popliteal, subclavian artery and deep vein

8Mhz : dorsal pedal, radial, orbital artery and vein close to surface

High sensitivity

Detect small vessel location and Sound very easy by even unskilled patient.

Diabetic foot application

Optimized vascular Doppler for constant monitoring diabetic foot.



BISTOS Fetal Dopplers and Vascular Doppler Technical Specification

● Standard ○ Option

Category	Fetal Doppler		
Model	BT-200		
Order code	200S	200L	200C
Frequency (MHz)	2	2	2
Detection Range (BPM)	50 - 240	50 - 240	30 - 240
Audio Output (W)	1.2	1.2	1.2
Headphone Output	●	●	●
Interchangeable probe			
Waterproof probe	IP X 7	IP X 7	IP X 7
Display type		Mono	Color
Trend display			
Trend saving			
Patient ID			
Event Mark			
Quick Guide			
Multi Language			
Acoustic Stimulator			
Adult Heart Rate (BPM)			
Body Fat Measurement			
Battery Type	2 X 1.5V AA	2 X 1.5V AA	2 X 1.5V AA
Battery Run Time (h)	5	5	5
Rechargeable Battery	○	○	○
BCM-200 Software	●	●	●
BCM-350 Central Monitoring Software			
Weight (g)	190	190	190
Dimensions (mm) Main Unit (HxWxD)	128 X 75 X 26		
Carrying Pouch	●	●	●
Optional Accessories			
Warranty (Main unit)	1year	1year	1year

Fetal Doppler			Vascular Doppler	
BT-200	BT-220		BT-250	BT-200
200T	220L	220C	250	200V
3	2 or 3	2 or 3	2	4, 5, 8
50 - 240	50 - 240	50 - 240	30 - 240	50 - 240
1.2	1.2	1.2	5	1.2
●	●	●	●	●
	●	●	●	●
IP X 7	IP X 7	IP X 7	IP X 7	IP X 2
Mono	Mono	2.4" Color	3.2" Color	Mono
		●	●	
			4 Hours	
			●	
			●	
			●	
	●	●		
		40-200		
		●		
2 X 1.5V AA	2 X 1.5V AA	2 X 1.5V AA	3.7V Li-ion	2 X 1.5V AA
5	5	4	5	5
○	○	○	●	○
●	●	●	●	
			●	
190	190	200	1,100	190
128 X 75 X 26	132 X 66 X 27		90 X 250 X 118	128 X 75 X 26
●	●	●	○	●
	Rechargeable kit	Rechargeable kit	Clamp	
1year	1year	1year	2year	1year



BIO SIGNAL TOTAL SOLUTION

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EC Certificate Full Quality Assurance System

Certificate No.: EU1012401

Date: 2016-07-01

Order No.: 293263

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Manufacturer:	Bistos Co., Ltd. 7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do Korea
Device categorie(s):	Ultrasound Doppler System with Foetal Doppler System Probes
GMDN code:	34040, 41917, 36462
Models:	See page 2 of this certificate
Risk class as defined by the manufacturer:	IIa
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.
Date of audit:	2015-07-07
End of the validity:	2021-01-01
Nemko EC notification No.:	0470
Remarks:	This certificate replaces the certificate EU1012401 issued 2016-01-01

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Sholeh Ghaisar

For Nemko AS

Nemko Norway

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ENTERPRISE NUMBER NO974404532

nemko.com/no



EC Certificate Full Quality Assurance System

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

Certificate History:

Revision	Description	Issue Date
0	Recertification	2010-12-01
1	Scope extension	2014-01-31
2	Recertification	2016-07-01

The certificate referred to above, includes the following devices/models:

Device Category	Model Name	GMDN Code
Ultrasound Doppler system:	BT-200	34040
Foetal Doppler system probe:	AY-2MHDOP-200L	41917
Foetal Doppler system probe:	AY-3MHDOP-200T	41917
Foetal Doppler system probe:	AY-4MHZDOP-200	41917
Foetal Doppler system probe:	AY-5MHZDOP-200	41917
Foetal Doppler system probe:	AY-8MHZDOP-200	41917
Ultrasound Doppler system:	BT-250	36462
Foetal Doppler system probe:	AY-2MHZDOP-250	41917
Ultrasound Doppler system:	BT-220C and BT-220L	34040
Foetal Doppler system probe:	AY-2MHZDOP-220C	41917
Foetal Doppler system probe:	AY-3MHZDOP-220C	41917

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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 Kolpus

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.