iE 300

Technical Specifications

Signal processing specification:

ECG interpretation	Biocare CardioPro ECG analysis program for adults and pediatrics
Acquisition mode	Simultaneous standard 12-lead acquisition
A/D conversion	24 bit
Sampling rate	8,000 samples/s
Frequency response	0.05 Hz ~ 250 Hz
Signal measurement range	-5mV ~ +5mV
Common mode rejection ratio	>115dB
Polarization voltage	± 500 mV
Input circuit	Floating circuit input
Input impedance	≥50 MΩ
Input CIR current	≤0.1 μA
Patient leakage current	<10 μA
Time constant	≥3.2 s
Noise level	≤12.5 μV_{p-p}
Sensitivity threshold	≤20 μV
Calibration voltage	1 mV±3 %
Sensitivity	(0.625, 1.25, 2.5, 5, 10, 20, 40, 10/5, 20/10) mm/mV, Auto Gain
Filter setting	EMG filter: 25/35/75/100/150/250Hz Baseline wander filter: 0.01/0.02/0.05/0.35/0.5/0.8Hz
AC filter	50Hz, 60Hz
Heart rate range	30~300 bpm
Special acquisition functions	Lead-off detection, lead overflow, AC interference, baseline wander interference, EMG interference
Acquisition time	10~24 seconds

Display and keyboard specifications:

Display type	5 inch TFT LCD
Display resolution	800×480
Display data	Waveforms, heart rate, clock, printing mode, filters, sensitivity, paper speed, system prompt, alarming messages, battery, power indicator, tone level
Waveform display mode	1) Same screen display: 3*4, 3*4+1R, 6*2, 6*2+1R, 12*1 2) Split-screen display: 3*4 , 3*4+1R
Keyboard type	Silicon quick-access function keys

Recorder specifications:

Recorder technology	Thermal dot matrix word printing system
Recorder resolution	8 points/mm (perpendicular) 40 points/mm (horizontal, 25 mm/s)
Recorder speed	（5, 6.25, 10, 12.5, 25, 50） mm/s±5 %
Recording paper	80 mm, roll paper

Standard software specifications:

Measurement and interpretation	Supports measurement and interpretation with Biocare CardioPro ECG analysis program for adults and pediatrics
Measurement values	HR, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 amplitude, RV5+SV1

	amplitude
Minnesota code	With newest Minnesota code
Working mode	Automatic mode, Manual mode, Rhythm mode, Upload mode
DEMO mode	Normal ECG, Arrhythmia ECG
QTC formula	Bazett, Fridercia, Framingham, Hodges
Rhythm analysis	Single rhythm mode: 30-300 seconds
Extended printing in arrhythmia	Supports extended arrhythmia waveform printing in automatic mode
Waveform frozen	Supports 300 seconds of waveform frozen
Pacemaker detection	Weak, Normal, Enhance
Report auto-saved	Selectable auto-saved file
Interpretation printout	Selectable interpretation printing
Report preview	Preview the report before printing
Data format	ECG, DICOM, XML, JPEG, PDF
Patient information setting	Record No., Name, Gender, D.O.B, Height, Weight, BP, Race, Pacemaker, Medication, Accession No., Ref-physician, Technician, Physician, Room No., User-define
Language	Chinese, English, Spanish, Portuguese, Russian, Polish, German, Czech, French, Italian, Ukrainian, Turkish
Local memory capacity	More than 3000 files

Report specifications:

Report type	Manual report, Simple report, MVB report(Median beat report)
Record format	3*4, 3*4+1R; 1*12, 1*12+1R; 3/2

External peripheral use:

Patient cable socket	Connect to the patient cable
Two USB port	Support USB flash disk and barcode scanner
LAN port	Communication with ECG-1000 workstation software on PC

Power supply

Power supply	AC / DC
AC power supply	100 V~240 V, 50 Hz /60 Hz, 80 VA
Battery power supply	Rechargeable lithium battery, 11.1V, 2600mAh
Battery capacity	Supports about 3 hours for continuous operation, no less than 350 pcs 3 channels ECG exams and reports recording
Battery charge time	Approximately 4 hours for total charge

Dimensions and weight

Length × width × height	281 mm×191 mm×59 mm
Weight:	About 1.3 kg

Standard accessories

ECG Cable	10 lead wires,TPU, banana plug, defi, IEC
Chest Electrode	Adult chest electrode,Φ4mm,6pcs/set
Limb Electrode	Adult limb electrode, Φ4mm, 4pcs/set, no

	LOGO, light blue color
Thermal Recording Paper	Roll paper,80mmx20m,no LOGO
Paper roller	ABS fire-proof UL94V-0
Power Cord	L=1900±100mm H05VV-F/3G*0.75 AP24/AC24, black, European standard
Grounding Cable	L=4mm UL1015 14AWG
Battery	HYLB-1994,11.1V 2600mAh

Environment requirements

1	Transportation	
	Environment temperature	-20℃~+55 ℃
	Relative humidity	≤95% (No condensation)
	Air pressure	70 kPa~106 kPa
	In accordance with the requirements stipulated in the contract order, the transport process to prevent rain and sun.	
2	Storage	
	Environment temperature	-20℃~+55℃
	Relative humidity:	≤95%(No condensation)
	Air pressure	70 kPa~106 kPa
	The packaging of ECG stored in the non-corrosive gases and well-ventilated room.	
3	Using	
	Environment temperature	+5 ℃~+40
	Relative humidity:	≤95%(No condensation)
	Air pressure	86 kPa~106 kPa

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

SHENZHEN BIOCARE BIO-MEDICAL EQUIPMENT CO., LTD.
#16-1，JINHUI ROAD, JINSHA COMMUNITY, KENGZI SUB-DISTRICT, PINGSHAN NEW DISTRICT, 518122 SHENZHEN, PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:	*DIGITAL ELECTROCARDIOGRAPH* *TYPE: iE 101, iE 300* *GMDN CODE: 16231*
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE 10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II EXCLUDING(4)*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH Ridlerstraße 65 · 80339 Munich · Germany
IDENTIFICATION NUMBER	CE 0123
(EC) CERTIFICATE(S):	*G1 065758 0004 REV.01*
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP. GMBH (EUROPE)* *Eiffestraße 80, 20537 Hamburg, GERMANY*

START OF CE-MARKING: *2017-05-20*

PLACE, DATE OF DECLARATION:	*SHENZHEN P.R.C., 2019-09-19*
SIGNATURE:	_____ *NAME:CHENJUN* *POSITION: GENERAL MANAGER*

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065758 0004 Rev. 01

Manufacturer:

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#16-1 Jinhui Road,Jinsha Community,Kengzi Sub-District
Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#16-1 Jinhui Road,Jinsha Community,Kengzi Sub-District,
Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Digital Electrocardiograph, Patient Monitor, B-Ultrasonic Diagnostic Equipment, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Fetal/Maternal Monitor, Fetal Monitor, Color Doppler Ultrasound System, Central Monitoring System, Ambulatory Electrocardiographs, Ambulatory blood pressure recorders, and associated software.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:	BJ1989607
Valid from:	2019-09-11
Valid until:	2024-05-26

Date, 2019-09-11

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 065758 0005 Rev. 01

Holder of Certificate: **Shenzhen Biocare Bio-Medical Equipment Co., Ltd.**
#16-1 Jinhui Road,Jinsha Community,Kengzi Sub-District
Pingshan New District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
#16-1 Jinhui Road,Jinsha Community,Kengzi Sub-District,
Pingshan New District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Digital Electrocardiograph, B-Ultrasonic Diagnostic Equipment, Patient Monitor, Fetal Monitor, Doppler Fetal Heart Rate Detector, Infusion Pump, Syringe Pump, Fingertip Pulse Oximeter, Handheld Pulse Oximeter, Ambulatory electrocardiographs, Ambulatory blood pressure recorder and associated software, Fetal/Maternal Monitor, Color Doppler Ultrasound System, Central Monitoring System.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: BJ20089601
Valid from: 2020-04-01
Valid until: 2023-03-31

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

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