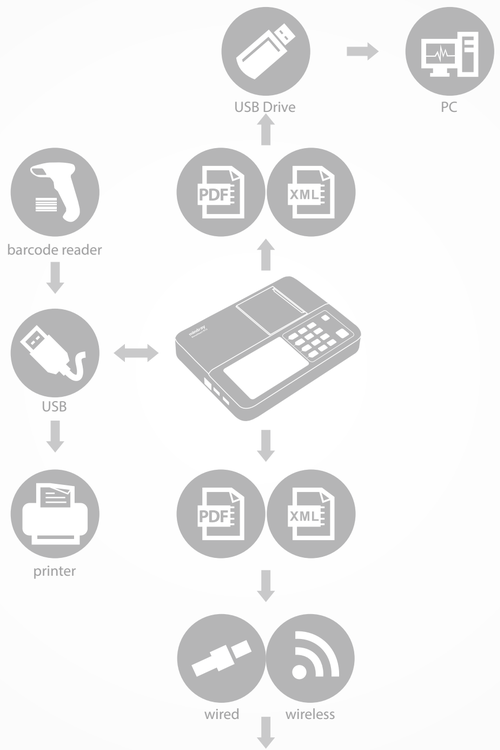
Peripherals and Communications



Digitally signed by Gorgan Vasile-Dan
Date: 2023.05.15 18:28:27 EEST
Reason: MoldSign Signature
Location: Moldova

BeneHeart R3

Electrocardiograph

Physical

Height:	56 mm
Width:	260 mm
Depth:	194 mm
Weight:	1.2 Kg including battery, internal AC power supply

Processing

Digital sampling rate:	1000 samples/second/channel
Pacer detection sampling rate:	16,000 samples/second/channel
ECG amplifier:	DC-coupled
Acquisition mode:	Pre- or post-acquisition, provide 10 seconds of instantaneous ECG acquisition
Dynamic range:	AC differential ±10 mV, DC offset ±600 mV
Resolution:	1 μV/LSB
Frequency response:	–3 dB @ 0.05 to 150 Hz
Baseline drift filter:	0.05 Hz, Baseline Drift Removal (BDR)
Artifact filter:	20 Hz, 35 Hz
AC filter:	50/60 Hz
Common mode rejection:	≥110 dB (with AC filter switched off)
ADC:	24 bits
Input impedance:	>50 MΩ @ 10 Hz, defibrillator protected
Time Constant	≥3.2 s
Noise Level	≤15 μV
Patient leakage:	<10 μA
Heart rate meter:	30 to 300 BPM ±10% or ±5 BPM, whichever is greater
Startup time:	≤5 second
Sensitivity/gain:	5,10,20 mm/mV, Auto

Display

Display type:	5-inch 24-bit color, TFT LCD with LED graphics backlit
Display resolution:	800*480 pixels
Display data:	Patient ID, gender, age, heart rate, clock, battery power indicator, waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, network, USB status

Power

Power supply:	AC input (without external power adaptor) or battery operation

AC Power

Input voltage:	100 to 240 VAC ±10%
Input power:	60 VA
AC frequency:	50/60 Hz ± 3 Hz

Battery

Battery type:	Rechargeable Lithium ion battery, 11.1 V, 2500 mAh
Battery capacity:	6 hours of continuous operation without recording or 500 ECGs in 2.5x4 format at 25 mm/s and 10 mm/mV
Battery charge time:	3.5 hours with power off

Writer

Writer technology:	Thermal dot array
Writer Width:	80 mm
Writer speed:	5, 12.5, 25, 50 mm/s
Number of traces:	3 leads + 1 rhythm or 3 leads; user selectable
Writer speed accuracy:	±5%
Writer amplitude accuracy:	±5%
Writer resolution:	Horizontal 32dots/mm @ 25mm/s, Vertical 8 dots/mm
Paper type:	Thermal roll paper (20 m) or Z-fold paper (80 mm width, 200 sheets/pack)

Software

Measurement and interpretation:	Supports the University of Glasgow 12-lead ECG analysis program for adults and pediatrics
Resting ECG mode:	Records and prints 12-lead resting ECG with 10-second duration as a standard feature
Supported patient information:	Name, patient ID, secondary ID, age, date of birth, gender, race, medication, class, V3 electrode Placement.
Internal storage:	800 ECGs in internal memory
ECG Storage format:	XML, PDF, Mindray
Multi-language support:	Supports 13 languages

Extensional Function

Reanalyze ECG automatically after changing patient's demographics
Connect to external printer directly (Optional)
Upload XML or PDF reports through FTP protocol (Optional)
Barcode scanner (Optional)
Wifi (Optional)
USB flash drive storage of PDF and XML outputs (Optional)

Report Formats

Thermal printer report formats:	4 by 2.5s (Sequential) 4 by 2.5s Compact 4 by 2.5s + 1 rhythm lead 4 by 2.5/5/7.5/10s (Simultaneous) Auto-rhythm (60-second ECG data for 1 rhythm lead) Continuous 1 or 3 channel manual rhythm
PDF report format (A4/Letter):	4 by 2.5s +1 rhythm lead 2 by 5s 2 by 5s + 1 rhythm lead 1 by 10s

Accessories

ECG patient cable with banana plugs, Limb Clamps, Chest Bulbs (IEC/AHA)
ECG cable with Electrode clips (IEC/AHA)
ECG patient cable with banana plugs, banana to tab lead adapters, ECG tab electrodes
Country-specific power cords
Z-fold and Roll paper
Trolley

Environmental Specification

Temperature	
Operating:	0°C to 40°C
Transport/storage:	-20°C to 60°C
Humidity	
Operating:	15% to 95% RH non-condensing
Transport/storage:	10% to 95% RH non-condensing
Pressure	
Operating:	57.0 kPa to 107.4 kPa
Transport/storage:	16.0 kPa to 107.4 kPa




Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com

P/N:ENG-BeneHeart R3-210285x4P-20160401

mindray

reddot design award
winner 2014

BeneHeart R3

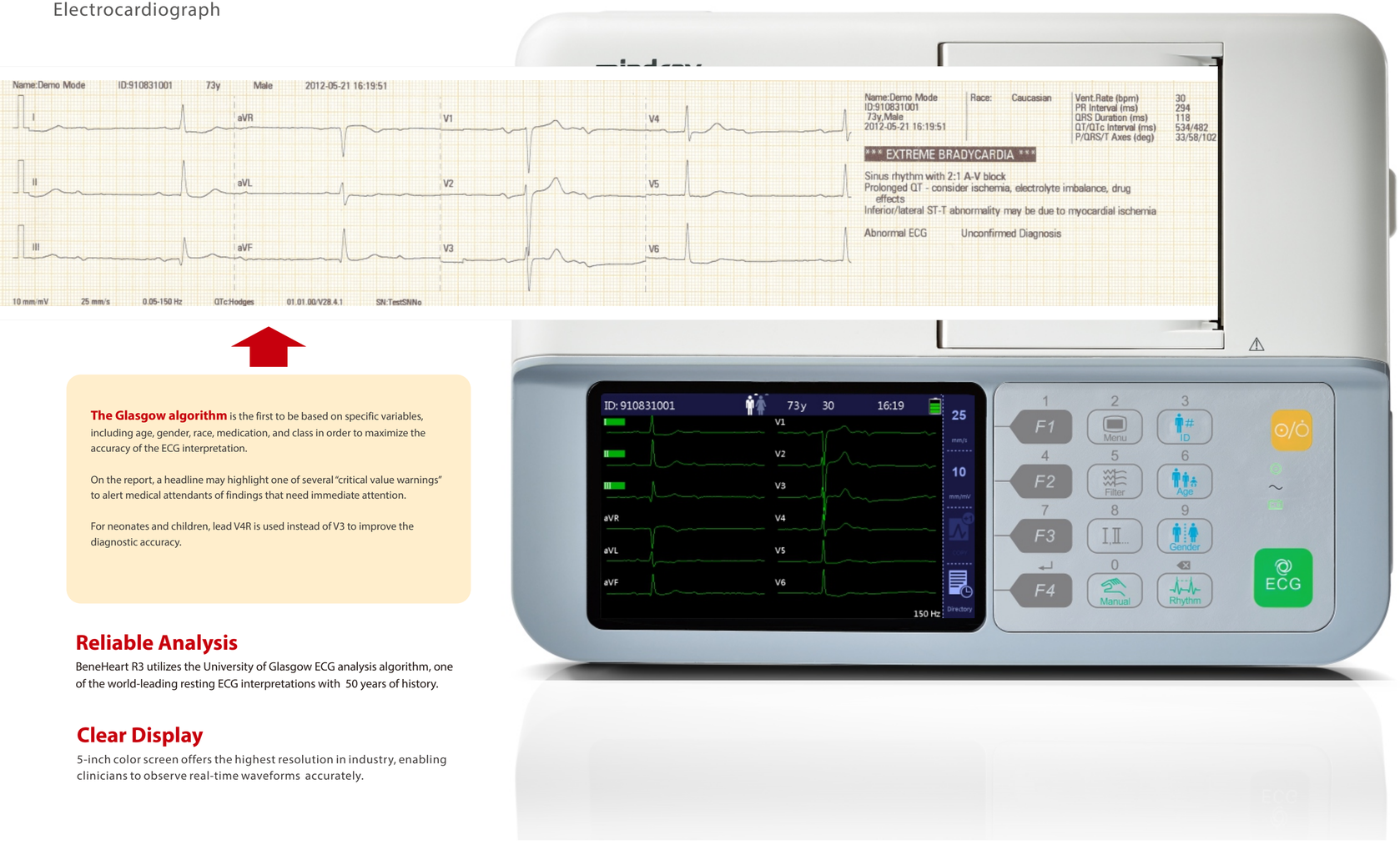
Electrocardiograph

Your Faithful Consultant for Resting ECG Diagnosis

mindray
healthcare within reach

BeneHeart R3

Electrocardiograph



The Glasgow algorithm is the first to be based on specific variables, including age, gender, race, medication, and class in order to maximize the accuracy of the ECG interpretation.

On the report, a headline may highlight one of several "critical value warnings" to alert medical attendants of findings that need immediate attention.

For neonates and children, lead V4R is used instead of V3 to improve the diagnostic accuracy.

Reliable Analysis

BeneHeart R3 utilizes the University of Glasgow ECG analysis algorithm, one of the world-leading resting ECG interpretations with 50 years of history.

Clear Display

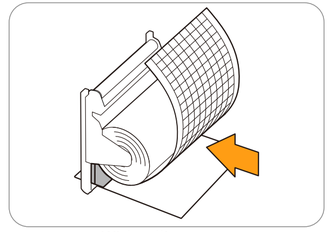
5-inch color screen offers the highest resolution in industry, enabling clinicians to observe real-time waveforms accurately.

Great Mobility

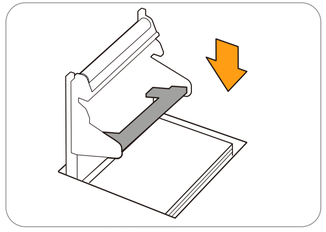
The BeneHeart R3 weighs only 1.2kg with battery, easy to carry. The trolley can makes BeneHeart R3 mobile to wherever it is needed.

Convenient Operation

The user-friendliness of BeneHeart R3's interface provides several paper-saving features, the report preview (before printed), re-analysis (if the patient information is modified) and E-report transmission.



With rolling paper



With Z-fold paper

Unique Recorder

Compatible with both rolling paper and Z-fold paper, you can easily switch between these two styles of papers without dismantling the pressure lever.

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

TÜV SÜD 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 044751 0167 Rev. 02

Manufacturer:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Patient Monitoring Devices,
Vital Signs Monitor,
Center Monitoring System,
Telemetry Monitoring System,
Ambulatory Blood Pressure Monitor,
Pulse Oximeter, Temperature Probe,
SPO2 Sensors, Electrocardiograph,
Ventilator, Anesthetic Vaporizer,
Air compressor,
Ultrasonic Diagnostic Equipment,
Ultrasonic Transducer,
Digital Radiography System,
Radiography System

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.: SH1905503

Valid from: 2019-11-13
Valid until: 2024-05-26

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

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

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD 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 044751 0167 Rev. 02

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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

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

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development,
production and distribution of
Active medical devices (intended) for monitoring,
diagnosis, anesthesia, breathing and intensive care;
In-vitro diagnostic instruments;
Non-active accessories
for breathing therapy and anesthesia;
In-vitro diagnostic reagents and kits (intended)
for hematology, clinical chemistry,
immunology and cell analysis
(For detail information see following pages)**

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.: SH2005501

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-07-24

Christoph Dicks
Head of Certification/Notified Body

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

Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Applied Standard(s):

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

Facility(ies):

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park,
Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor,
Center Monitoring System, Telemetry Monitoring System,
Pulse Oximeter, Temperature Probe, Flow Sensor,
Ambulatory Blood pressure Monitor,
Defibrillator/Monitor and Accessories, Electrocardiograph,
Anesthesia Machine and accessories, Ventilator,
Air compressor, Endoscope Camera System,
Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System,
Hematology Analyzer, Clinical Chemistry Analyzer,
Urine Analyzer, Microplate Reader,
Microplate Washer for invitro diagnostic use,
Chemiluminescence Immunoassay Analyzer,
Flow Cytometer, (Auto) Sample Processing System,
Auto Slide Maker&Stainer, Glycohemoglobin Analyzer,
Specific Protein Analyzer, Reagents for Hematology Analyzer,
Reagents for Clinical Chemistry Analyzer,
Chemiluminescence Immunoassay Reagents,
Chemiluminescence Immunoassay Calibrators and Controls,
Reagents for Flow Cytometer,
Reagents for Glycohemoglobin Analyzer,
Calibrators and Controls for Glycohemoglobin Analyzer,
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit,
Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag.

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Declaration of Conformity V2.0

Declaration of Conformity CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Electrocardiograph (Including Accessories)
Model:	BeneHeart R3、BeneHeart R3A
Classification:	IIa（According to Rule 10 of MDD Annex IX）
Conformity Assessment Route:	MDD Annex II excluding (4)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123

Place, Date of Issue: Shenzhen, 2015.3.20

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product:	**Electrocardiograph**
Model:	**BeneHeart R3、BeneHeart R3A**

Standards Applied:

EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 1041: 2008	Information supplied by the manufacturer with medical
EN ISO 15223-1: 2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 10993-1: 2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2: 2007/AC:2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2006+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-25:2011	Medical electrical equipment -- Part 2-25: Particular requirements for the safety of electrocardiographs
EN 62304: 2006/AC:2008	Medical device software - Software lifecycle processes
IEC 62366:2007+A1:2014	Medical devices - Application of usability engineering to medical devices