
Wearable ECG Monitor Operator's Manual



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Malfunction of the instrument or part whose serial number is not legible enough.

Others not caused by instrument or part itself.

Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address:	Mindray Building, Keji 12th Road South, Hi-tech industrial park, Nanshan, Shenzhen 518057, P.R. China
Website:	www.mindray.com
E-mail Address:	service@mindray.com
Tel:	+86 755 81888998
Fax:	+86 755 26582680

EC-Representative:	Shanghai International Holding Corp. GmbH(Europe)
Address:	Eiffestraße 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals and common people.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions

Italic text is used in this manual to quote the referenced chapters or sections.

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1. Safety

1.1 Safety Information

 **WARNING**

Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

 **CAUTION**

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

Provides application tips or other useful information to ensure that you get the most from your product.

1.1.1 Warnings

WARNING

- This equipment can not be used for infant whose weight is less than 10 Kg.
 - Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.
 - This equipment can not be used for the person whose skin is hypersusceptible to the the accessories.
 - To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline).
 - There is a battery inside. Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.
 - Please don't bend or reverse the ECG recorder. Otherwise the equipment may be damaged.
 - Remove the equipment from patients during defibrillation. Otherwise the equipment may be damaged.
 - Remove the equipment from patients during using the electro-surgery unit. Otherwise the equipment may be damaged.
 - When disposing of the package material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
 - Keep the equipment and accessories out of children's reach. Otherwise children may inadvertently damage the equipment and accessories or swallow the same small parts casuing apnea or other hazards.
 - The equipment is suit for violent sports such as football, basketball and volleyball. The balls hit the equipement that may hurt the user.
 - The equipment transmit wireless signal via sape. The signal may be interrupted by serval possible sources of interference. The transmission failure may happen sometime, although the equipment has some anti- interference capacity.
-

1.1.2 Cautions



CAUTION










-
- Make sure that the operating environment of the equipment meets the specific requirements.
 - To prolong the service life of the equipment, please don't put it under the sunshine for a long time.
 - To ensure patient safety, use only parts and accessories specified in this manual.
 - Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.
 - At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the equipment, please contact us.
 - Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.
-

1.1.3 Notes

NOTES

-
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.
-

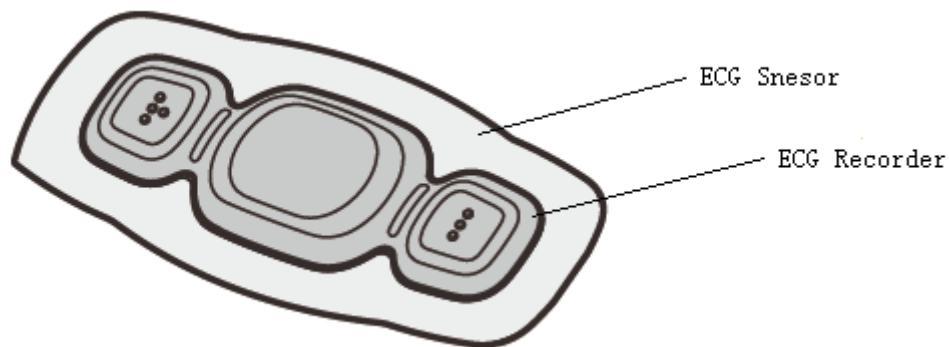
1.2 Equipment Symbols

	General warning sign
	DATE OF MANUFACTURE
	Serial number
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	<p>The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.</p> <p>Note: The product complies with the Council Directive 2011/65/EU.</p>
	Waterproof level 7
	Refer to instruction manual/booklet
	Type CF APPLIED PART
	Non-ionization radiation symbol

2. Safety

2.1 Product introduction

Wearable ECG monitor contain adhesive ECG recorder, ECG sensor. The adhesive ECG recorder collect ECG signal via ECG sensor. The data collected is stored in ECG recorder. It can be transmitted to protocol compatible device or APP.



2.1.1 Apply scope

Can be used for measuring, recording and storing human ECG data, for applications that require long continuous records of patients ECG data. Can be used in medical departments or in home environment.

WARNING

- This equipment is used for single user at a time.
 - The PATIENT is an intended OPERATOR.
 - The ECG recorder is suitable for use within the patient environment.
 - The waterproof level of the ECG recorder is IPX7. It can be used in the shower or in water for a short time.
 - Prohibit using the equioment in the hyperbaric oxygen chamber.
-

1.2.1 Applied Parts

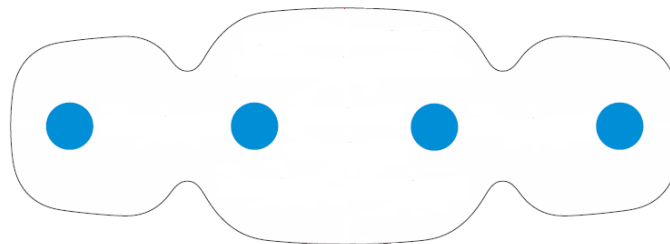
The applied parts of the wearable ECG monitor are:

- Shell of ECG recorder,
- ECG electrodes
- ECG sensor

2.2 Product appearance



Picture 错误！文档中没有指定样式的文字。-1 Adhesive ECG recorder front



Picture 错误！文档中没有指定样式的文字。-2 Adhesive ECG recorder back

3. Installation and Maintenance

3.1 Installation

WARNING

- **The software copyright of the equipment is solely owned by us. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
-
-

3.1.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us.

If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact us in case of any problem.

NOTE

- **Save the packing case and packaging material as they can be used if the equipment must be reshipped.**
-
-

WARNING

- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
 - **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients / users.**
-
-

1.2.2 Environmental Requirements

The operating environment of the equipment must meet the *Environmental Specification* in *Appendix B*.

3.1.2 Power requirements

The power used for this equipment must meet the *Power Specification* in *Appendix B*.

WARNING

- **Make sure that the operating environment and power of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
-

3.1.3 Installation method

Installation methods of adhesive ECG recorder, please refer chapter 4.

3.2 Cleaning and Disinfection

Only adhesive ECG recorder and changer need cleaning and disinfection. The accessories are single use products. So they need not cleaning and disinfection.

3.2.1 Cleaning

The ECG recorder should be cleaned before and after use. The charger should be cleaned before use.

Please use clean and soft cloth, sponge or tampon adsorb non-erosive cleaning agent and dry appropriately to clean the surface of the equipment. Recommended cleaning agents are:

- Water
- Ethanol (70%)
- Isopropyl alcohol (70%)

To clean your equipment, follow these rules:

1. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner, making sure that no cleanser is dripping from the cloth.
2. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
3. Dry your equipment in a ventilated, cool place.

 **WARNING**

- **Please clean the surface under the rules above. Otherwise, it may damage the shell or the print of the equipment**
-

3.2.2 Disinfection

Disinfect the equipment as required in your hospital's servicing schedule. Cleaning equipment before disinfecting is recommended.

4. Operations

4.1 Preparation before use

Please shake the ECG recorder and observe the LED light before use.

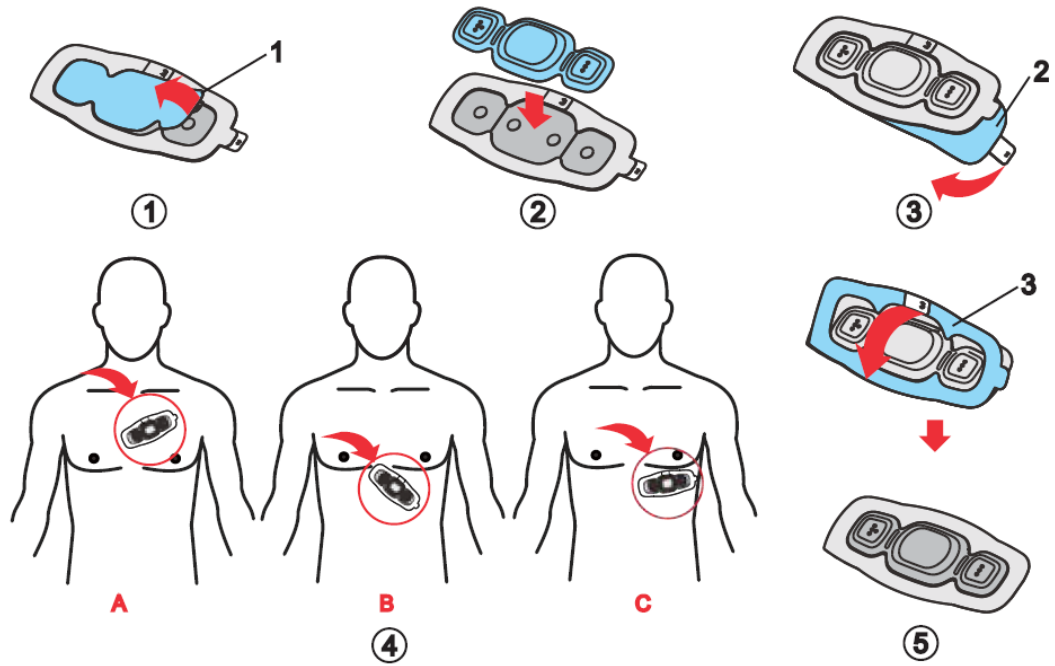
- The green light flicker means the ECG recorder is normal.
- The red light flicker every 3 seconds means the ECG recorder is malfunction.
- The red light flicker every 9 seconds means the ECG recorder is low power.
- No light flicker means the ECG recorder is mal function or its battery uses out.

NOTES

- **The ECG recorder need be waked up by charger before first use.**
 - **The battery will use out when the ECG recorder doesn't use for a long time. It can not be waked up by shaking. It needs be charged before use.**
 - **It is ready to use when it is waked up and flicker greens light. The time is less than 15 seconds.**
 - **The time required for me equipment to warm from the minimum storage temperature between uses until it is ready for intended use is less than 30 minutes.**
 - **The time required for me equipment to cool from the maximum storage temperature between uses until it is ready for intended use is less than 30 minutes.**
-

4.2 Wear the ECG recorder

Picture 4-1 shows how to install accessory and wear the equipment on human body.

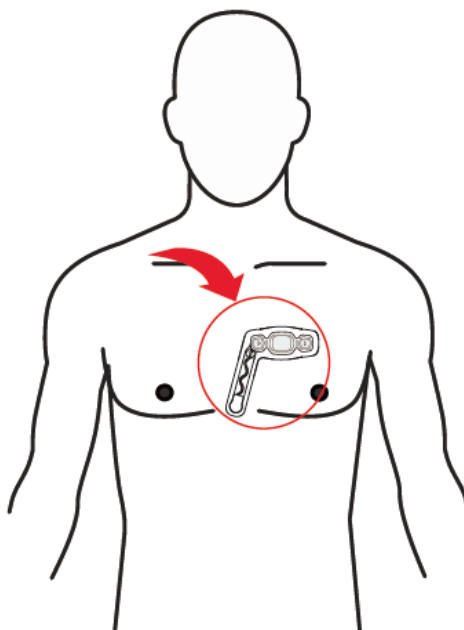


Picture 错误! 文档中没有指定样式的文字。-3 ECG recorder installatiosketch map with one channel ECG sensor

Installation process shows as below:

1. Tear off the tape marked ①.
2. Stick the ECG recorder to the accessory.
3. Tear off the tape marked ②.
4. Stick the ECG recorder with accessory nearby to heart such as A, B, C area in the picture.
5. Tear off the tape marked ③.

When use two channels ECG sensor, the operation is similar with one channel ECG sensor. The position shows as picture 4-2.



Picture 错误！文档中没有指定样式的文字。-4 ECG recorder installatiosketch map with two channel ECG sensor

NOTES

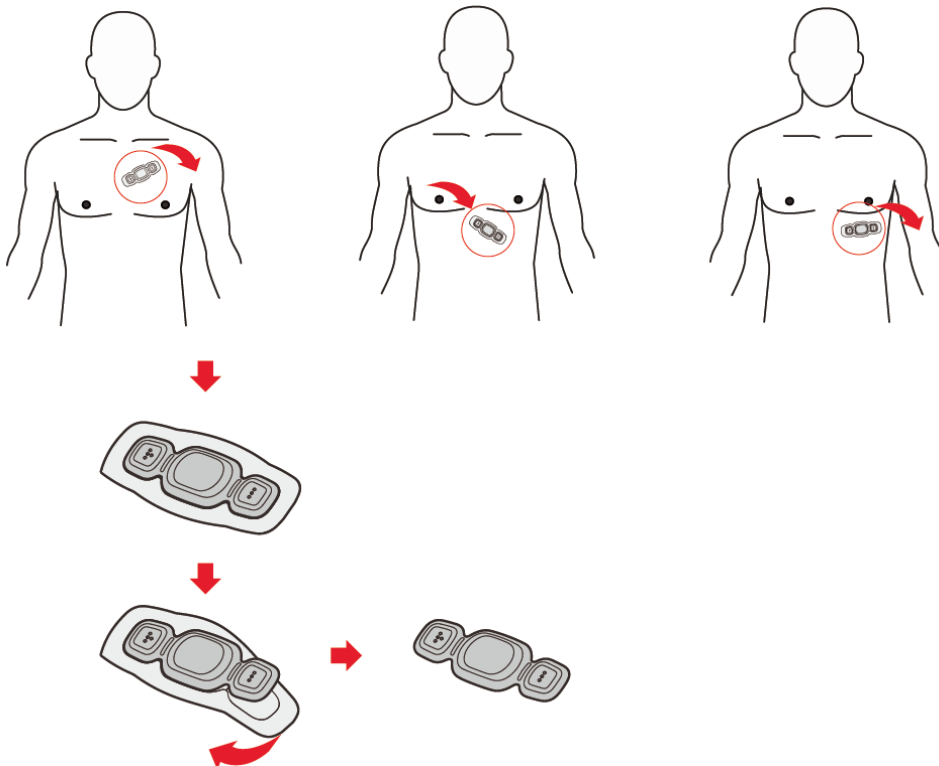
- The ECG recorder can work with one channel ECG sensor or two channel ECG sensor. Please use of accessories approved by Mindray.
 - Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
-

4.3 View ECG data

The ECG recorder can transmit data by Bluetooth. It can work with mobile equipment that is android 4.3 upwards, iOS 7.1 upwards, and Bluetooth 4.0 upwards. The ECG data can be read by protocol compatible APP's.

4.4 Take off the ECG recorder

- 1.Take off the ECG recorder with ECG sensor from human body.
- 2.Tear off the ECG recorder from the ECG sensor
- 3.Put the ECG recorder to the original box.



Picture 错误！文档中没有指定样式的文字。-5 Take off the ECG recorder

NOTES

- The ECG recorder will enter sleep mode. There is no need to power off it.
-

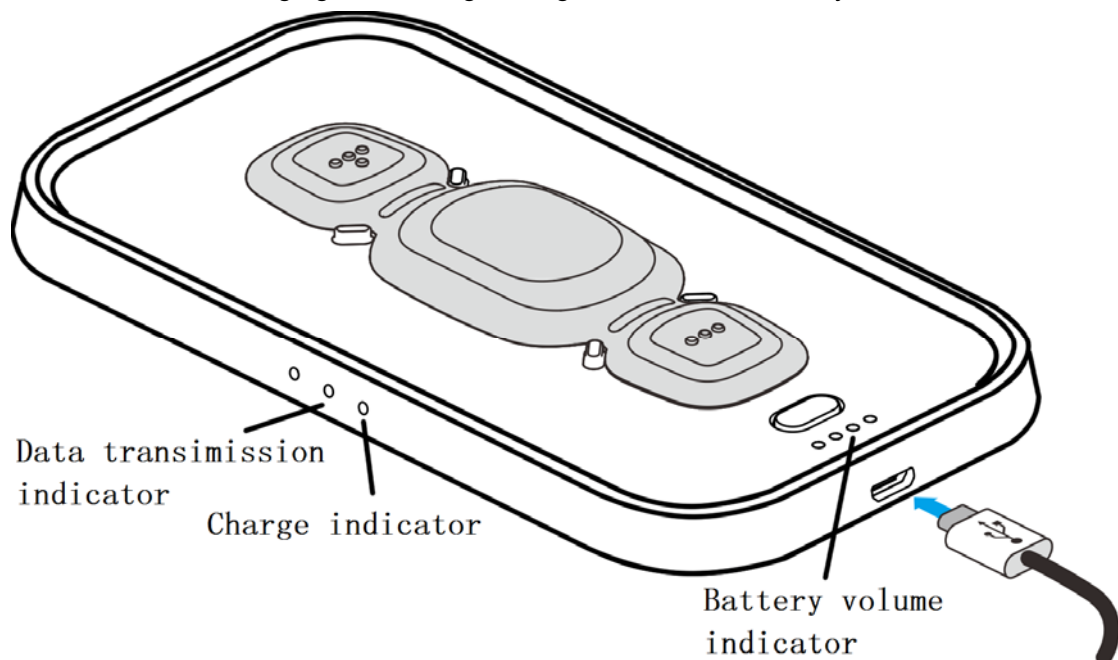
4.5 Charge the ECG recorder

Please charge the ECG recorder under following conditions:

- First use
- There is no light indicator when shake the ECG recorder.
- Reuse the ECG recorder over one month between last use.

Please charge it once every month to protect its battery, if it will not be used for a long time. Store it in a cool and dry place. You can check the battery volume on the APP and decide to charge or not basing on the intended using time. Recommend charging the ECG recorder when the battery volume is less than 10%.

Show as picture 4-4, put the ECG recorder on the charger and connect the cable to DC 5V 500mA out put power. The blue light of ECG recorder will be on and the red light will flicker, when it is charging. The red light will go out when the battery is full.



Picture 错误! 文档中没有指定样式的文字。-6 the indicators of charger

The charger indicator lights

- Battery volume indicator: Every light represents 25% volume.
- Charge indicator: This light turning on means the ECG recorder is charging.
- Data transmission indicator: This light flicker means the ECG recorder is sending data to the charger.

NOTES

- **The charger that model is EPC001 has no Battery volume indicator. Only can check the battery is full or not by ECG recorder's indicator.**
-

4.6 Offline data transmission

The data stored in ECG recorder can be exported by Bluetooth of charger. A computer and export software are needed as well. You can get the download link by scanning the picture below.



Connect the charger to the computer with the USB cable. Then open the software. Put the ECG recorder to the charger. Operate the software following the instruction on the software. The data can be exported to computer by Bluetooth of charger and upload to cloud by internet.

NOTES

- **The charger that model is EPC001 can not export data.**
-

5. Frequency Questions Management

5.1 Frequency Questions Management

Malfunction phenomena	Possible cause	resolvent
Battery low volume	Battery used out	Charge ECG recorder
Work time is short, only a couple of hours or minutes	1. Battery low volume 2. ECG recorder malfunction	1. Charge ECG recorder, then use. 2. Contact Manufacturer to fix it.
Bluetooth disconnection	1. Battery low volume 2. ECG recorder malfunction 3. Mobile equipment closed Bluetooth.	1. Charge ECG recorder, then use. 2. Contact Manufacturer to fix it. 3. Open bluetooth of mobile equipment.

6. Battery

Adhesive ECG recorder has a rechargeable Lithium-ion battery as work power.

The battery icon on Mindray health APP shows the volume status:

When the remaining volume of battery is less than 10%, the red light on the ECG recorder will flash. The ECG recorder should be charged at this time.



- **Inside rechargeable Lithium-ion battery can not be replaced.**
 - **When charge, keep it out of children's reach.**
 - **Only use the charger approved by Mindray.**
 - **To improve the life time of battery, please charge when indicating low volume.**
 - **Please charge to 80% upwards before longtime storage. And charge it once a month.**
 - **Please don't expose the battery to high temperature environment, such as warmer, oven, water heater and microwave oven. Battery overheating may explode.**
 - **Please don't disassemble or modify the battery. Otherwise it may cause battery leakage, overheating, fire or explosion.**
 - **Keep skin and eyes from the leakage liquid, if the battery leakage. Please flush the skin or eyes immediately and go to hospital for treatment, if skin or eyes touch the leakage liquid.**
 - **Please don't throw the battery into the fire. Otherwise it may cause explosion.**
 - **When a battery exceed lifetime, or no longer holds a charge, it should be disposed. To dispose of the batteries, follow local laws for proper disposal.**
 - **Please don't let children or pets swallow or bite the battery. Otherwise it may hurt them or cause explosion.**
-

7. Accessory

7.1 ECG Sensor

The accessories show as the table below. The lifetime of the accessories is 2years.

Part description	model	Type	Manufacturer
MR.Wear sigle channel ECG sensor	EPA001	Sigle use	Mindray
MR.Wear two channels ECG sensor	EPA002	Sigle use	

WARNING

- Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.
 - Single-use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.
 - Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
 - The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.
 - The accessory can not be pasted on the damaged skin. Otherwise it may cause dermatitis.
 - Don't stick the accessory in the same position time by time for a long time. It may cause dermatitis.
-

CAUTION

- Please store the ECG sensor in dark shade under the room temperature.
 - Please use the ECG sensor as soon as possible after the package is open. Otherwise the water evaporation of ECG sensor will impact its performance.
 - Check the ECG sensor is not expired before use.
-

-
- Please close the package after getting ECG sensor.
-

7.2 Charger

Part description	model	Type	Manufacturer
ECG Recorder Charger	EPC001	Repeat use	Mindray
ECG Recorder Charger (Professional)	EPC002	Repeat use	

 **WARNING**

- Please select a computer or adapter that fulfills IEC60950 or related industry safety standards to supply the charger.
 - Only use the charger approved by Mindray. The charger complies with the requirements of IEC60601-1.
 - The metal material stuff can not be placed on the charger. The charger can not use for other device except the ECG recorder.
 - Don't touch the user when touch the charger and USB cable during the charger connecting to the power.
-

A Product Specifications

A.1 Safety Specifications

The ECG recorder is classified, according to IEC60601-1:

Type of protection against electrical shock	Class I, equipment energized from an internal electrical power source.
Degree of protection against electrical shock	Type CF
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX7

A.2 Environmental Specifications



- The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.
-

Item	Operating conditions	Storage conditions
Temperature (°C)	0 to 45	-20 to 45
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (kPa)	86.0 to 106.0	57.0 to 107.0

A.3 Power Supply Specifications

Battery voltage range	3-4.2V
Battery Type	Chargeable Lithium-Ion, 11.1DVC, 4.5 Ah
Run time (type value)	≥ 30 hours

A.4 Physical Specifications

Size	Length: 87±5mm Width: 32±3mm Height: 6±1mm
Weight	≤10g
Interface	Standard interface, include ECG leads signals and Bluetooth signal

A.5 Display, Recorder and Storage Specification

Display	A least one lead ECG wave and equipment status information will be display on mobile phone or other mobile device.
Recorder mode	Real time record
Storage mode	Chip storage
Storage capacity	Storage 30 hours data

A.6 ECG Specification

ECG	
Lead set	3-lead: I, III
Sample rate	125Hz
Input signal range	±8 mV (peak-to-peak value)
Pace pulse markers	Pace pulses meeting the following conditions are labelled with a PACE marker: Amplitude: ±2 to ±200 mV Width: 0.1 to 2 ms Rise time: 10 to 100 µs
Common mode rejection ratio	≥96dB
Bandwidth (-3dB)	0.05~40Hz
Gain setting	error≤±5%
Display sensitivity	Accuracy: ±5%
Differential input impedance	≥20MΩ@10Hz

A.7 Charger Specification

Interface	Standard interface, micro USB
Input	DC 5V 200mA
Output	DC 5V 40mA

B EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2.

NOTE

- Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the device.
 - The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.
 - The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
 - Other devices may interfere with this device even though they meet the requirements of CISPR.
 - When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
 - Portable and mobile communication equipment may affect the performance of this monitor.
 - Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PADs, PCs with wireless function).
-

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	Compliance	Electromagnetic environment - guidance
Radio frequency (RF) emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class B	The device is suitable for use in all establishments , domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Not apply	/
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Not apply	

If the system is operated within the electromagnetic environment listed in Table **Guidance and Declaration —Electromagnetic Immunity**, the system will remain safe and provide the following essential performance,

- Operating mode
- Accuracy
- Function
- Accessories identification
- Data stored
- Alarm
- Detect for connection


Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not apply	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U _T (>95 % dip in U _T) for 0.5 cycle 40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 s	Not apply	/
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U _T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity

The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distances: 80 MHz~800 MHz $d = 1.2\sqrt{P}$ 800MHz-2.5GHz

		$d = 2.3\sqrt{P}$ <p>Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p>Interference may occur in the vicinity of equipment marked with the following</p> <div style="text-align: center;">  </div> <p>symbol:</p>
--	--	--

Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Note 3: The device that intentionally receives RF electromagnetic energy at the **exclusion band** (2400MHz-2483.5MHz) is exempt from the ESSENTIAL PERFORMANCE requirements, but remains safe.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power	Separation distance in meters (m) according to frequency of the transmitter		
		150 kHz ~ 80 MHz	80 MHz ~ 800 MHz

of transmitter (W)	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B.2 Radio Regulatory Compliance

RF parameters

Item	Description
	Bluetooth low energy 4.1
Operating Frequency Band (MHz)	2402 - 2480
Modulation	GFSK
Transmitter Output Power (dBm)	≤2.5

The device including Bluetooth module which complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

This Bluetooth device complies with Canadian ICES-001. Cet appareil ISM est conforme a la norme NMB-001 du Canada.

The device including Bluetooth module FCC and Industry Canada Radio Compliance: This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Mindray may cause harmful radio frequency interference and void your authority to operate this equipment.

The maximum antenna gain permitted complies with the e.i.r.p. limits as stated in RSS-210. The maximum antenna gain permitted complies with the e.i.r.p. limits specified for point-to-point operation, as stated in RSS-210.



The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC (Radio Equipment and Telecommunications Terminal Equipment Directive).

RF Exposure

The equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This device should be installed and operated with minimum distance 20cm between the radiator & your body.

C Symbols and Abbreviations

C.1 Symbols

A	ampere
dB	decibel
g	gram
Hz	hertz
k	kilo
kPa	kilopascal
m	meter
mm	millimeters
ms	millisecond
mV	millivolt
mW	milliwatt
s	second
V	volt
Ω	ohm
W	watt
—	minus
%	percent
/	per; divide; or
~	to
^	power
+	plus
=	equal to
<	less than
>	greater than
\leq	less than or equal to
\geq	greater than or equal to
\pm	plus or minus
\times	multiply
©	copyright

C.2 Abbreviations

ECG	electrocardiograph
MDD	Medical Device Directive
MRI	magnetic resonance imaging

