Wearable Patient Monitor

EP30

Operator's Manual

CE 0123

Release time: 2023-01

Revision: 5.0

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this manual. This manual may refer to information protected by copyrights or patents and does not convey any license under the patent rights of Mindray, nor the rights of others.

Mindray intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

Release, amendment, reproduction, distribution, rental, adaption and translation of this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

mindray is the registered trademark owned by Mindray in China and other countries. All other trademarks that appear in this manual are used only for editorial purposes without the intention of improperly using them. They are the property of their respective owners.

Responsibility on the Manufacturer Party

Contents of this manual are subject to changes without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements;
- the product is used in accordance with the instructions for use.

WARNING

- This equipment must be operated by skilled/trained clinical professionals.
- It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

- This warranty shall not extend to
- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- 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, High-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:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

Notification of Adverse Events

As a health care provider, you may report the occurrence of certain events to SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD., and possibly to the competent authority of the Member state in which the user and / or patient is established.

These events, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. requests to be notified of device failures or malfunctions. This information is required to ensure that SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. provides only the highest quality products.

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 who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

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

Conventions

- *Italic text* is used in this manual to quote the referenced manuals, chapters, sections and formulas.
- **Bold text** is used to indicate the screen texts and names of hard keys.
- → is used to indicate operational procedures.

Contents

1 Safety ..... 1 - 1
1.1 Safety Information ..... 1 - 1
1.1.1 Warnings ..... 1 - 1
1.1.2 Cautions ..... 1 - 2
1.1.3 Notes ..... 1 - 3
1.2 Equipment Symbols ..... 1 - 4

2 Equipment Introduction ..... 2 - 1
2.1 Intended Use ..... 2 - 1
2.1.1 Intended Purpose Statement ..... 2 - 1
2.1.2 Indication for Use ..... 2 - 1
2.1.3 Intended Users ..... 2 - 1
2.1.4 Intended Patient Population ..... 2 - 1
2.1.5 Intended Medical conditions ..... 2 - 1
2.1.6 Contra-indications ..... 2 - 1
2.1.7 Side-effects ..... 2 - 2
2.2 Applied Parts ..... 2 - 2
2.3 Product Overview ..... 2 - 2
2.3.1 EP30 Main Unit Overview ..... 2 - 3
2.3.2 EP30 Docking Overview ..... 2 - 3
2.3.3 ES30 ECG Unit Overview ..... 2 - 4
2.3.4 ES30 Docking Overview ..... 2 - 4
2.3.5 Receiver (R20) Overview ..... 2 - 5
2.3.6 Charging Station (C20) ..... 2 - 6
2.3.7 Charging Pod (C25) ..... 2 - 7
2.3.8 NIBP Module (ePM BP20) ..... 2 - 8
2.4 Overview of Wireless Thermometer ..... 2 - 9

3 Getting Started ..... 3 - 1
3.1 Equipment Preparation Introduction ..... 3 - 1
3.2 Equipment Preparation Safety Information ..... 3 - 1

3.3 Unpacking and Checking ..... 3 - 2
3.4 Environmental Requirements ..... 3 - 3
3.5 Installing Batteries ..... 3 - 3
3.5.1 Installing Battery for the NIBP Module ..... 3 - 3
3.5.2 Installing Battery for the Wireless Thermometer ..... 3 - 4
3.6 Charging the Batteries ..... 3 - 5
3.6.1 Charging the Batteries of the EP30 Main Unit and ES30 ECG Unit with C20 Charging Station ..... 3 - 7
3.6.2 Charging the Batteries of the EP30 Main Unit and ES30 ECG Unit with C25 Charging Pod ..... 3 - 8
3.6.3 Charging the Battery of NIBP Module with C20 Charging Station ..... 3 - 9
3.6.4 Finishing Charging ..... 3 - 10
3.7 Setting the Work Mode of the NIBP Module ..... 3 - 10
3.8 Equipment Pairing and Network Connection ..... 3 - 11
3.8.1 Pairing the EP30 Monitor with an ECG Module ..... 3 - 12
3.8.2 Pairing the EP30 Monitor with an NIBP Module ..... 3 - 13
3.8.3 Pairing the EP30 Monitor with a Wireless thermometer ..... 3 - 14
3.8.4 Pairing the EP30 Monitor with an ePM Monitor ..... 3 - 14
3.8.5 Connecting the CMS ..... 3 - 15
3.8.6 Managing Physiological Data with mWear App ..... 3 - 16
3.8.7 Connecting Other Equipment ..... 3 - 19
3.9 Screen Display ..... 3 - 19
3.9.1 Display on the EP30 Monitor ..... 3 - 19
3.9.2 Display on the NIBP Module ..... 3 - 21
3.9.3 Display on the ePM Monitor ..... 3 - 22
3.9.4 Display on the CMS ..... 3 - 23

4 Patient Preparation ..... 4 - 1
4.1 Admitting a Patient ..... 4 - 1
4.2 Connection with Patient ..... 4 - 1
4.2.1 Patient Connection Overview ..... 4 - 1
4.2.2 Patient Connection Safety Information ..... 4 - 2

4.2.3 Wearing the Monitor ..... 4 - 2
4.2.4 Applying the SpO_2 Sensor ..... 4 - 3
4.2.5 Applying Electrodes ..... 4 - 4
4.2.6 Placing an NIBP Cuff ..... 4 - 6
4.2.7 Applying Temperature Sensor (Wireless Thermometer) ..... 4 - 9

5 Patient Monitoring ..... 5 - 1
5.1 Patient Monitoring Safety Information ..... 5 - 1
5.2 Work Modes ..... 5 - 1
5.2.1 Work Mode Introduction ..... 5 - 1
5.2.2 Changing of Work Mode ..... 5 - 2
5.2.3 Setting the Switch Monitor Mode Time ..... 5 - 2
5.2.4 Setting the Switch Monitoring Mode on EWS Score ..... 5 - 2
5.2.5 Setting the Conditions to Switch to Continuous Mode ..... 5 - 3
5.2.6 Setting the Display of EWS Score Area ..... 5 - 3
5.2.7 Changing Work Mode Manually ..... 5 - 3
5.3 Changing Patient Monitoring Settings ..... 5 - 4
5.3.1 Changing the SpO_2 Sensitivity ..... 5 - 4
5.3.2 Checking Paced Status ..... 5 - 4
5.3.3 Selecting NIBP Start Mode ..... 5 - 4
5.3.4 Setting NIBP Sequence ..... 5 - 5
5.3.5 Setting NIBP Measurement Prompt ..... 5 - 5
5.3.6 Setting the Initial Cuff Inflation Pressure ..... 5 - 6
5.4 View Monitoring Data ..... 5 - 7
5.4.1 SpO_2 Monitoring ..... 5 - 7
5.4.2 ECG Monitoring ..... 5 - 11
5.4.3 Resp Monitoring ..... 5 - 13
5.4.4 NIBP Monitoring ..... 5 - 15
5.4.5 Viewing Temp Data ..... 5 - 19
5.5 Performing Manual Measurements ..... 5 - 19
5.5.1 Performing Spot Check NIBP Measurement ..... 5 - 19
5.6 Measuring the Sleeping Time ..... 5 - 20

5.6.1 Sleeping Measurement Limitations ..... 5 - 20
5.6.2 Defining the Night Time ..... 5 - 20
5.7 Measuring the Exercise Time ..... 5 - 21
5.7.1 Viewing Exercise Time ..... 5 - 21
5.7.2 Exercise Measurement Limitations ..... 5 - 22
5.7.3 Setting the Exercise Goal ..... 5 - 22
5.8 Patient Fall Monitoring ..... 5 - 22
5.9 Assisting Venous Puncture ..... 5 - 23
5.10 Reviewing Monitoring Data ..... 5 - 23
5.11 Alarms ..... 5 - 23
5.12 Removing the Monitor from Use ..... 5 - 24

6 Troubleshooting ..... 6 - 1

7 Care and Cleaning ..... 7 - 1
7.1 Care and Cleaning Introduction ..... 7 - 1
7.2 Care and Cleaning Safety Information ..... 7 - 1
7.3 Cleaning ..... 7 - 2
7.3.1 Cleaning the EP30 Main Unit, ES30 ECG Unit, NIBP Module and Accessories 7 - 2
7.3.2 Cleaning the Charging Station and Charging Pod ..... 7 - 3
7.3.3 Cleaning the Receiver ..... 7 - 3
7.4 Disinfection ..... 7 - 4
7.4.1 Disinfectants for EP30 Main Unit, ES30 ECG Unit, NIBP Module and Receiver 7 - 4
7.4.2 Disinfectants for the Charging Station and Charging Pod ..... 7 - 6
7.4.3 Disinfectants for ES30 Docking and EP30 Docking (512ES) ..... 7 - 7
7.4.4 Disinfectants for EP30 Docking (512HS) ..... 7 - 8
7.5 Sterilization ..... 7 - 9
7.6 Impact of Improper Cleaning ..... 7 - 9

8 Maintenance ..... 8 - 1
8.1 Maintenance Introduction ..... 8 - 1

8.2 Maintenance Safety Information ..... 8 - 1
8.3 Maintenance and Testing Schedule ..... 8 - 2
8.4 Testing Methods and Procedures ..... 8 - 2
8.4.1 Performing Visual Inspection ..... 8 - 3
8.4.2 Maintaining the Battery ..... 8 - 3
8.4.3 Replacing the Battery of NIBP Module ..... 8 - 6
8.4.4 NIBP Leakage Test ..... 8 - 7
8.4.5 NIBP Accuracy Test ..... 8 - 7
8.5 Storing Batteries ..... 8 - 7
8.6 Disposing of EP30 Monitor ..... 8 - 8

9 Accessories ..... 9 - 1
9.1 SpO_2 Accessories ..... 9 - 2
9.2 ECG Accessories ..... 9 - 2
9.2.1 ECG Electrodes ..... 9 - 2
9.2.2 ES30 Docking ..... 9 - 3
9.3 NIBP Accessories ..... 9 - 3
9.4 Miscellaneous Accessories ..... 9 - 3

A Product Specifications ..... A - 1
A.1 Safety Specifications ..... A - 1
A.2 Environmental Specifications ..... A - 1
A.3 Power Supply Specifications ..... A - 2
A.3.1 Specification of EP30 Main Unit Battery ..... A - 2
A.3.2 Specification of ES30 ECG Unit Battery ..... A - 3
A.3.3 Specification of NIBP Module Battery ..... A - 4
A.3.4 Power Supply Specification of the Charging Station ..... A - 4
A.3.5 Power Supply Specification of the Charging Pod ..... A - 4
A.3.6 Power Supply Specification of the Receiver ..... A - 4
A.4 Physical Specifications ..... A - 4
A.4.1 Specifications of EP30 Main Unit Display ..... A - 5
A.4.2 Specifications of NIBP Module Display ..... A - 5

A.4.3 Interfaces ..... A - 5
A.4.4 Signal Outputs Specifications ..... A - 5
A.5 Data Storage ..... A - 5
A.6 Network Specifications ..... A - 5
A.6.1 Wi-Fi Technical Specifications ..... A - 5
A.6.2 Wi-Fi Performance Specifications ..... A - 6
A.6.3 Bluetooth Specification ..... A - 7
A.6.4 Bluetooth Performance Specifications ..... A - 7
A.6.5 NFC Specification ..... A - 9
A.7 Measurement Specifications ..... A - 9
A.7.1 ECG Specifications ..... A - 9
A.7.2 Resp Specifications ..... A - 12
A.7.3 SpO_2 Specifications ..... A - 12
A.7.4 PR Specification ..... A - 13
A.7.5 NIBP Specifications ..... A - 14
A.7.6 TEMP Specifications (Wireless Thermometer) ..... A - 15

B EMC and Radio Regulatory Compliance ..... B - 1
B.1 EMC ..... B - 1
B.2 Radio Regulatory Compliance ..... B - 7

C Default Settings ..... C - 1

D Messages and Solutions ..... D - 1
D.1 Technical Messages on the EP30 Main Unit ..... D - 1
D.2 Technical Messages on the NIBP Module ..... D - 2
D.3 Technical Messages on the ePM Monitor ..... D - 2

E Terminology ..... E - 1

F Declaration of Conformity ..... F - 1

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

- For continued safe use of the equipment, the instructions given in this manual must be followed. But instructions in this manual in no way supersede established medical procedures.
- This equipment is used for single patient at a time.
- To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.
- The equipment is not intended to be used within the Magnetic Resonance (MR) environment.

- 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.
- To avoid risk of electric shock, the charging station must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.
- Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.
- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- To reduce the hazard of burns during high-frequency surgical procedure, ensure that the monitor's cables and transducers never come into contact with the electrosurgery unit (ESU).
- Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.
- Set alarm volume and limits appropriate for the patient. Do not exclusively rely on audible alarms for patient monitoring. Adjusting alarm volume to a low level or turning off alarm sound may result in patient hazards.
- Physiological data and alarm messages provided by the monitor should not be used as the only basis for diagnosis or therapy decisions. They must be used in conjunction with clinical signs and symptoms. Misinterpreting measured values or other parameters may result in patient hazards.
- Place and secure cables and tubings carefully to prevent from stumbling, entanglement and patient strangulation.
- Do not press the touch button with wet hands.
- The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.

1.1.2 Cautions

CAUTION

- Use only parts and accessories specified in this manual.

- Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.
- 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.
- Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.
- Dry the equipment immediately in case of rain or water spray.
- Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.
- 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.

1.1.3 Notes

NOTE

- Put the equipment in a location where you can easily view and operate the equipment.
- In normal use, the operator is expected to be in front of the equipment.
- The software was developed in compliance with IEC62304.
- This manual includes information related to all features of the monitor. Some features may not be available on your monitor.
- The service life of the monitor is 10 years, and the service life of the accessories is 3 years. For the date of manufacture, refer to their labels.
- Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.

1.2 Equipment Symbols

Symbol	Description	Symbol	Description
	Caution		Serial number
	Direct current		Alternating current
	Not made with natural rubber latex		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
 (Yellow)	General warning sign	 (Blue)	Refer to instruction manual/ booklet
	NIBP Start/Stop key		Stand-by
IP24	Protected against solid foreign objects of 12.5 mm Ø and greater; Protected against splashing water	IP22	Protected against solid foreign objects of 12.5 mm Ø and greater; Protected against vertically falling water drops when enclosure tilted up to 15°
IPX1	Protected against vertically falling water drops	IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°
IPX4	Protected against splashing water	IPX7	Protected against the effects of temporary immersion in water
IP21	Protected against solid foreign objects of 12.5 mm Ø and greater; Protected against vertically falling water drops		
	Non-ionizing electromagnetic radiation		Temperature limit
	Atmospheric pressure limitations		Humidity limitations
	This way up		Keep away from rain
	Fragile, handle with care		Stacking limit by number

Symbol	Description	Symbol	Description
	Date of manufacture	MD	Medical Device
	Manufacturer		Dispose of in accordance to your country's requirements
LOT	Batch code	UDI	Unique device identifier
Rx ONLY	Federal law (USA) restricts this device to sale by or on the order of a physician.	EC REP	Authorised representative in the European Community
CE 0123 CE	The product bears CE mark indicating its conformity with the provisions of the REGULATION (EU) 2017/745 on medical devices and fulfills the general safety and performance requirements of Annex I of this regulation. Note: The product complies with the Council Directive 2011/65/EU.		

NOTE

- Some symbols may not appear on your equipment.

This page intentionally left blank.

2 Equipment Introduction

2.1 Intended Use

2.1.1 Intended Purpose Statement

The EP30 wearable patient monitor is intended for monitoring, displaying and transferring of multiple physiological parameters.

2.1.2 Indication for Use

It is intended for monitoring, displaying and transferring of multiple physiological parameters including ECG (3-lead, heart rate (HR)), Respiration Rate (Resp), Temperature (Temp), Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), and Non-invasive Blood Pressure (NIBP).

WARNING

- This monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.

2.1.3 Intended Users

It is to be used in healthcare facilities by clinical professionals or under their guidance.

2.1.4 Intended Patient Population

All the parameters can be monitored on single adult and pediatric over 12 years old.

2.1.5 Intended Medical conditions

It is expected to be used in medical institutions, and its application fields include: operating room, anesthesia induction and postoperative recovery, intensive care unit, emergency care, respiratory care, Cardiac Care Unit, neural care, dialysis care, elderly care, obstetric care, internal medicine and surgical care. The main unit is also intended for home use.

2.1.6 Contra-indications

None.

2.1.7 Side-effects

According to the conclusion of clinical evaluation and residual risk evaluation, for the intended patients, there is no known side effects that can occur during or after the use of the medical device. And there is no need for the operator to make extra preparations. Thus, no residual risk associated with using the medical device should be disclosed due to the risk management report.

2.2 Applied Parts

The applied parts of the monitor are:

- ECG electrodes and leadwires
- SpO_2 sensor
- NIBP cuff
- Temperature sensor

2.3 Product Overview

The wearable patient monitor consists of the following parts:

Model	Name on the label	Name in this manual
EP30	Wearable Patient Monitor	EP30 main unit, or EP30 monitor (if connected with an EP30 docking)
512ES/512HS/512RS	SpO_2 Sensor	EP30 docking
ES30	ECG Module	ES30 ECG unit, or ECG module (if connected with an ES30 docking)
EA6431B/EA6432B/ EA6433B/EA6434B	ECG Cable	ES30 docking
ePM BP20	NIBP Mobile Module	NIBP module
R20	Receiver	Receiver
C20	Central Charger	Charging station
C25	Charger	Charging pod

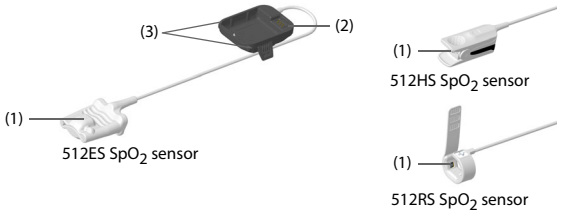
2.3.1 EP30 Main Unit Overview

(1) Display screen

(2) Touch button:
On a black screen, press the button to wake the screen up.
On a working screen, press the button to switch between different interfaces.

(3) Contacts: connects the EP30 docking

2.3.2 EP30 Docking Overview



(1) SpO_2 sensor

(2) Connector: used to connect the EP30 main unit

(3) Release button: press the button to unlock the connector and the EP30 main unit

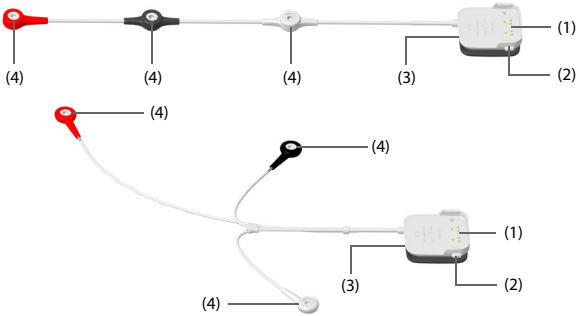
2.3.3 ES30 ECG Unit Overview

(1) Status indicator:

- When connected with an ES30 docking:
  - Lighting up in green and then off: the ECG module is paired successfully and starts working
  - Flashing green: the Central Monitoring System (hereinafter referred to as "CMS") is locating the ECG module
- When installed on the Charging station:
  - Flashing green: the battery is being charged
  - Green: the battery is fully charged
  - Yellow: error occurred during charging
  - Off: the Charging station is not connected to the AC power, or the Charging station is malfunctioning

(2) Contacts: connects ES30 docking

2.3.4 ES30 Docking Overview



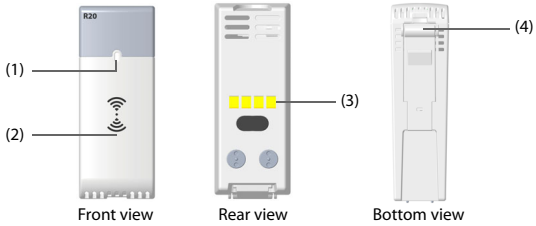
(1) Contacts

(2) Release button: press the button to unlock the connector and ES30 ECG unit

(3) Connector: connects the ECG lead set and ES30 ECG unit

(4) ECG electrodes

2.3.5 Receiver (R20) Overview



(1) Status indicator:

- On: the EP30 monitor has established bluetooth connection with the ePM series modular monitor (hereinafter referred to as "ePM monitor")
- Flashing: the receiver works properly but has no bluetooth connection with an EP30 monitor
- Off: the receiver is not properly installed or is malfunctioning

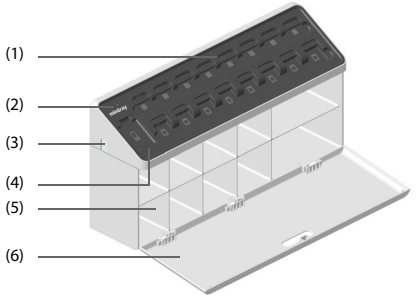
(2) Pairing area

(3) Contacts: used to transmit data or charge the battery. Avoid touching the contacts during operation.

(4) Release button: press the button to unlock and disconnect the receiver from the ePM monitor

2.3.6 Charging Station (C20)

2.3.6.1Charging Station Front View



(1) Charging slot

(2) Power indicator:
- Off: no AC power is connected
- Green: AC power is connected

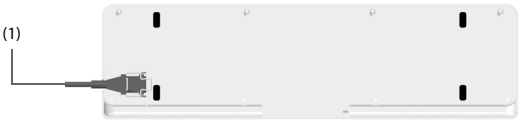
(3) Power cable outlet

(4) Status indicator for the batteries of NIBP modules
- Flashing green: the battery is being charged
- Green: the battery is fully charged
- Yellow: a charging failure occurs

(5) Storage box

(6) Storage box cover

2.3.6.2Charging Station Rear View



(1) AC power socket

2.3.7 Charging Pod (C25)

Top view

Front view

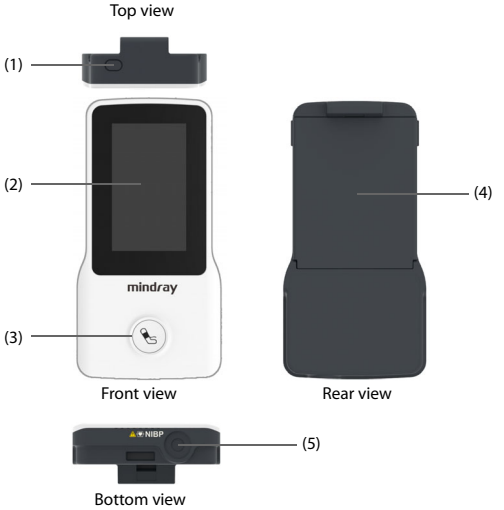
(1) USB Type-C connector: used to connect a USB Type-C cable for power input

(2) Contacts: used to charge the battery. Avoid touching the contacts during operation.

(3) Charing slot for ES30

(4) Charging slot for EP30

2.3.8 NIBP Module (ePM BP20)



(1) Power on/off key:

- After a battery is installed and when the NIBP module is off: press the key to turn on the NIBP module
- When the NIBP module is on: press and hold the key to turn off the NIBP module

(2) Display

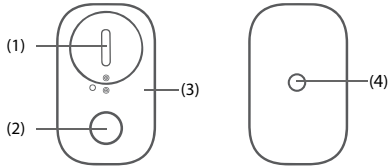
(3) NIBP Start/Stop key

(4) Battery

(5) NIBP cuff connector: used to connect an NIBP cuff

2.4 Overview of Wireless Thermometer

The wireless thermometer is a battery-operated electronic device with the intended use of measuring and monitoring human axillary temperature continuously and transmitting the results via wireless signal. It is suitable for adult and child temperature measurement. The wireless thermometer takes measurements in direct mode.



Front view Rear view

(1) Battery compartment

(2) On/Off button

(3) Power indicator

(4) Temperature sensor

This page intentionally left blank.

3 Getting Started

3.1 Equipment Preparation Introduction

This chapter describes the preparation and settings to be made before putting the monitor into use. Read the manual carefully before use, to understand the performance, operation steps, and safety messages for the operation of the equipment.

3.2 Equipment Preparation Safety Information

WARNING

- Use only installation accessories specified by Mindray.
- The equipment software copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Connect only approved devices to this equipment. Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port are responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Mindray.
- The monitor, ECG module, NIBP module and parameter monitoring accessories are suitable for use within the patient environment. The charging station is not for use in patient environment. For other equipment and accessories connected to the monitor, consult corresponding manufacturers for the suitability within the patient environment.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturer or an expert in the field. A determination must be made that the proposed

combination will not negatively affect the devices themselves or the patient's safety.

- If the accuracy of any value displayed on the monitor or central station is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working correctly.

CAUTION

- The equipment should be installed by authorized Mindray personnel.
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- Before use, verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.
- Use caution and avoid violent carrying in transport.
- Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

NOTE

- Put the equipment in a location where you can easily view and operate the equipment.
- Keep this manual in the vicinity of the equipment so that it can be conveniently referenced when needed.
- Save the packing case and packaging material as they can be used if the equipment must be reshipped.

3.3 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.

3.4 Environmental Requirements

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

CAUTION

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

3.5 Installing Batteries

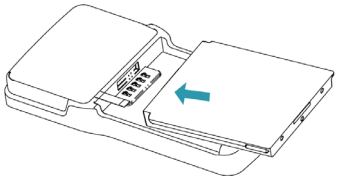
You may need to install batteries for the NIBP module or the Wireless Thermometer.

3.5.1 Installing Battery for the NIBP Module

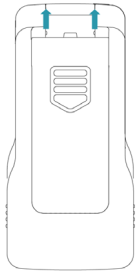
The NIBP module is powered by a rechargeable lithium-Ion battery. You may need to install a battery before use.

To install a battery, follow this procedure:

1. Place the mobile module with the battery compartment facing up.
2. Align the battery with the groove of the battery compartment.
3. Press down the battery until it clicks into the place.



4. Align the clip with the grooves on the back of the module, and push it as indicated in the following picture until you hear a click.



NOTE

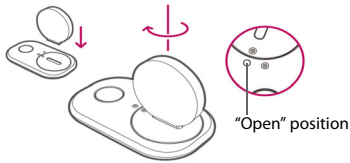
- Use only specified battery.

3.5.2 Installing Battery for the Wireless Thermometer

The wireless thermometer is powered by a non-rechargeable CR2025 battery. You may need to install a battery before use.

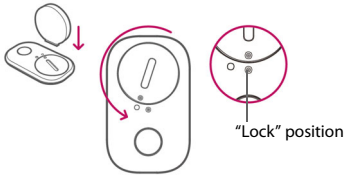
To install a battery, follow this procedure:

1. Place the wireless thermometer with the battery compartment facing up.
2. Use the supplied battery tool to rotate the battery compartment cover clockwise to the "Open" position



3. Insert the battery with the positive side facing up.

4. Rotate the battery compartment cover counterclockwise to the "Lock" position.



3.6 Charging the Batteries

The EP30 main unit and ES30 ECG unit are powered by embedded rechargeable lithium-Ion batteries. The NIBP module is powered by a rechargeable lithium-Ion battery. Charge the batteries with the charging station or charging pod before use.

WARNING

- Use only the charging station or charging pod supplied by Mindray to charge the batteries of the EP30 main unit, ES30 ECG units and NIBP modules from liquid.
- Use only the power cord delivered with the charging station.
- Operate the charging station or charging pod on a stable and flat surface.
- Keep the charging station, charging pod, the monitors, ES30 ECG units and batteries away from liquids. Use the charging station in dry and indoor environment.
- Do not disassemble, puncture or incinerate the charging station, charging pod or battery.
- Do not stack the charging station or charging pod.
- No modification of the charging station, charging pod or power plug is allowed.
- Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Insure that the sum of the individual ground leakage currents does not exceed the allowable limits.
- Before connecting the charging station to the AC mains, check that the voltage and frequency ratings of the power line are the same as those indicated beside the AC power input.

- Make sure the charging station or charging pod is intact and functioning well before charging.
- Do not cover the charging station, charging pod or batteries. Keep the charging station or charging pod in a cool and ventilated place while charging.
- Do not connect other devices to the power supply system.
- **The EP30 main unit and ES30 ECG unit are powered by embedded batteries that are not intended to be replaced. Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.**
- Extremely high ambient temperature may cause battery overheat protection and interrupt the charging. Do not charge the batteries at a temperature over 40°C.
- In the case of charger failure, disconnect the AC power, remove the batteries, and contact the service personnel.

CAUTION

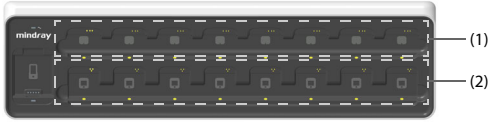
- Use the charging station and charging pod only in an environment as specified in this manual.
- Do not let a patient charge batteries with the charging station.
- Do not touch the contacts of the charging station, charging pod, monitor, ES30 ECG unit, NIBP module or batteries. Impaired contacts could affect the charging performance.
- Make sure the battery clicks into place for charging so the battery can be secured onto the charging slot.

NOTE

- The charging station uses a mains plug as isolation means to the mains power. Do not locate the charging station in a place difficult to operate the mains plug.
- After a battery is properly installed onto the charging station, check that the indicators light up as described in ***2.3.6 Charging Station (C20)***.
- Charge the battery at room temperature. The charging time may be prolonged at excessive high or low temperature.

3.6.1 Charging the Batteries of the EP30 Main Unit and ES30 ECG Unit with C20 Charging Station

The C20 charging station is powered by an external AC power supply. It has 8 charging slots for the EP30 main units and 8 charging slots for ES30 ECG units, as shown in the following picture:



(1) Charging slots for the ES30 ECG units

(2) Charging slots for the EP30 main units

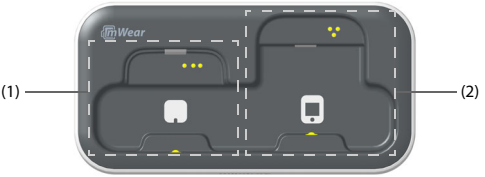
To charge the batteries of the EP30 main unit and ES30 ECG unit with the C20 charging station, follow this procedure:

1. Connect the power cord of the charging station to a wall AC outlet.
2. Make sure the power indicator of the charging station is on and green.
3. Put the EP30 main unit or ES30 ECG unit onto a correct charging slot. Make sure the contacts of the EP30 main unit or ES30 ECG unit are aligned with those on the charging station.
4. Push the EP30 main unit or ES30 ECG unit down until you hear a click.

After the EP30 main unit or ES30 ECG unit is properly installed on the charging station, the battery starts to be charged.

3.6.2 Charging the Batteries of the EP30 Main Unit and ES30 ECG Unit with C25 Charging Pod

The C25 charging pod is powered by an external DC power supply. It has a charging slot for the EP30 main unit and a charging slot for the ES30 ECG unit, as shown in the following picture:



(1) Charging slots for the ES30 ECG units

(2) Charging slots for the EP30 main units

To charge the batteries of the EP30 main unit and ES30 ECG unit with the C25 charging pod, follow this procedure:

1. Connect a USB Type-C cable to the USB Type-C connector on the charging pod and then the external DC power.
2. Put the EP30 main unit or ES30 ECG unit onto the correct charging slot. Make sure the contacts of the EP30 main unit or ES30 ECG unit are aligned with those on the charging pod.
3. Push the EP30 main unit or ES30 ECG unit down until you hear a click.

After the EP30 main unit or ES30 ECG unit is properly installed on the charging pod, the battery starts to be charged.

CAUTION

- **If you are using the EP30 monitor with mWear App, after charging, check the connection status of the EP30 monitor and the mWear App. For details, refer to *3.8.6 Managing Physiological Data with mWear App*.**

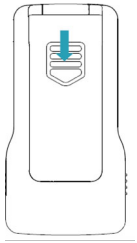
3.6.3 Charging the Battery of NIBP Module with C20 Charging Station

The C20 charging station is powered by an external AC power supply. It has a charging slot for the batteries of NIBP modules, as shown in the following picture:

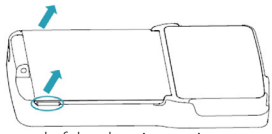
(1) Charging slot for NIBP module batteries

To charge the battery of the NIBP module with the C20 charging station, follow this procedure:

1. Follow the directions indicated in the following picture and remove the clip from the NIBP module.



2. Hold the protrusions on both sides of the battery and lift up the battery to remove it from the battery compartment.



3. Connect the power cord of the charging station to a wall AC outlet.
4. Make sure the power indicator of the charging station is on and green.
5. Put the battery to be charged onto the correct charging slot. Make sure the contacts of the battery are aligned with those on the charging station.

6. Push the battery down until you hear a click.

After the battery is properly installed on the charging station, it starts to be charged.

3.6.4 Finishing Charging

When the batteries are fully charged, take them out from the charging slots. Disconnect the power cord of the charging station from the AC power supply when the charger is not in use.

NOTE

- To completely disconnect the power supply, unplug the power cord.

3.7 Setting the Work Mode of the NIBP Module

The NIBP module works in **Continuous** mode or spot check (**Discrete**) mode.

- In **Continuous** mode, the NIBP module needs to be paired with the EP30 monitor to provide continuous NIBP monitoring for the patient. For details, refer to ***3.8.2 Pairing the EP30 Monitor with an NIBP Module***.
- In spot check (**Discrete**) mode, NIBP measurement is taken on demand and measurements be sent to the EP30 monitor via NFC (Near Field Communication). For details, refer to ***5.5.1 Performing Spot Check NIBP Measurement***.

To set the work mode of the NIBP module, follow this procedure:

1. Press the Power on/off key to start the NIBP module.
2. Press and hold the Power on/off key and NIBP Start/Stop key simultaneously until the screen displays **System Information**.
3. Press the NIBP Start/Stop key until screen displays **Config** on the top.
4. Check the setting of **Work Mode**. Press the Power on/off key to switch to the other option.
5. Press and hold the Power on/off key and NIBP Start/Stop key simultaneously to save the setting and exit.

NOTE

- If the work mode of the NIBP module is set to Discrete (spot check), the NIBP module cannot be paired with the EP30 monitor.

3.8 Equipment Pairing and Network Connection

Through wireless network, the EP30 monitor can be paired with an ePM monitor, an ECG module and an NIBP module, and be connected with the CMS. After the connection is established, you can view the measurements on the EP30 monitor, the ePM monitor and the CMS.

CAUTION

- Wireless network design, deployment, debugging, and maintenance should be executed by Mindray service personnel or authorized technicians.
- Always deploy the wireless network according to local wireless regulations.
- Mindray takes no responsibility for controlling the radio frequency environment in a hospital. If interference for the operating frequency of telemetry equipment exists, the telemetry equipment performance will be affected. Exercise caution when selecting the operating frequency of all the wireless equipment in a hospital as this is very important to avoid mutual interference among them.
- Using 5GHz frequency band is recommended whenever possible. There are more interference sources in 2.4GHz frequency band.
- Private APs and wireless routers are not allowed. These devices may cause radio interference and result in monitor and CMS data loss.
- To ensure network security and stability, data communication must be performed within a closed network or within a virtually isolated hospital network. The hospital is responsible for ensuring the security of the virtually isolated network.
- WPA2-PSK and WPA2-Enterprise verification and encryption should be used if possible. Otherwise, the equipment may not be able to work or patient information may be leaked. WPA2-Enterprise and a long password are recommended.
- Keep network authentication information, for example password, from being accessed by unauthorized users.
- Do not connect non-medical devices to the monitor network.
- If wireless network signal is poor, there may be a risk of CMS data loss.
- A maximum of 16 EP30 monitors can be connected to a single AP, on the condition that an ECG module is paired. Too many monitors connected to the same AP may result in network disconnection.

- RF interference may result in wireless network disconnection.
- Disconnecting from the network may result in CMS data loss and function failure. Check the patient in case of network disconnection and reconnect the network as soon as possible.
- Ensure that the monitor IP address setting is correct. Changing the network settings may result in network disconnection. Contact your service personnel if you have any problems on setting the IP address.
- After replacing the EP30 docking, ES30 docking, or NIBP module, re-pair them with the EP30 main unit. Otherwise patient data loss or errors may result.

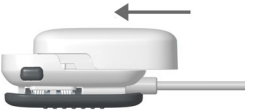
3.8.1 Pairing the EP30 Monitor with an ECG Module

The ECG module is used to obtain and transmit ECG, Resp and Temp related data. You need to pair the EP30 monitor with an ECG module before monitoring.

Follow this procedure:

1. Align the contacts on the EP30 main unit with the contacts on the connector of the EP30 docking. Then push the bottom edge of the EP30 main unit down as indicated below.

2. Put the ES30 ECG unit onto the connector of the ES30 docking with both sides aligned. Then slide the ES30 ECG unit up as indicated blow until the two click into place.



3. Place the front of the ECG module close to the screen of the EP30 monitor until you hear a beep.

4. Check the screen of the EP30 monitor immediately. If a confirmation screen is displayed, press the touch button to confirm the pairing. Failing to do so would cancel the pairing.

3.8.2 Pairing the EP30 Monitor with an NIBP Module

The NIBP module is used to perform NIBP measurements and transmit the data. To provide continuous NIBP monitoring for the patient, you need to pair the EP30 monitor with an NIBP module.

Follow this procedure:

1. Press the Power on/off key on the NIBP module to turn the module on.
2. Place the front of the NIBP module close to the screen of the EP30 monitor until you hear a beep.

3. Check the screen of the EP30 monitor immediately. If a confirmation screen is displayed, press the touch button to confirm the pairing. Failing to do so would cancel the pairing.

If the pairing keeps failing, the NIBP module may have been set to spot check mode. Set the module to continuous mode as described in ***3.7 Setting the Work Mode of the NIBP Module***.

3.8.3 Pairing the EP30 Monitor with a Wireless thermometer

To perform continuous temperature monitoring, you need to pair the EP30 monitor with a wireless thermometer. Follow this procedure:

1. Press and hold the On/off button on the wireless thermometer until the power indicator lights up.
2. Place the battery compartment part of the wireless thermometer close to the screen of the EP30 monitor until you hear a beep. This step has to be finished in 10 seconds after the indicator lights up, or the pairing will be canceled.
3. Check the screen of the EP30 monitor immediately. If a confirmation screen is displayed, press the touch button to confirm the pairing. Failing to do so would cancel the pairing.

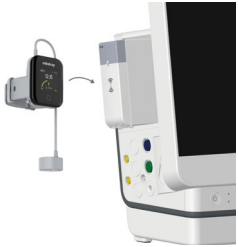
3.8.4 Pairing the EP30 Monitor with an ePM Monitor

To provide continuous realtime monitoring of a patient, you need to pair the EP30 monitor with an ePM monitor before monitoring. For details about **Wireless Monitoring** mode, refer to ***5.2.1 Work Mode Introduction***.

Follow this procedure:

1. Insert the receiver to the module rack of the ePM monitor.

2. Place the EP30 monitor close to the pairing area of the receiver until you hear a beep.



3. Check the screen of the EP30 monitor immediately. If a confirmation screen is displayed, press the touch button to confirm the pairing. Failing to do so would cancel the pairing.

If the pairing succeeds, the ᛒ icon is displayed on the screen of the EP30 monitor.

NOTE

- Not all ePM monitors support connection with the EP30 monitor. Before pairing, contact your service personnel to check the compatibility.

3.8.5 Connecting the CMS

The EP30 monitor can connect the CMS via an ePM monitor or by itself.

If you are using the EP30 monitor with an ePM monitor, connect the ePM monitor to the CMS via Wi-Fi network as instructed in the operator's manual of the ePM monitor. After pairing, the EP30 monitor obtains Wi-Fi connection with the CMS from the ePM monitor.

If you are using the EP30 monitor directly with the CMS, after connecting the EP30 main unit with an EP30 docking, the monitor automatically connects to the CMS. If the connection fails, contact your service personnel.

NOTE

- Not all CMSs support connection with the EP30 monitor. Before connection, contact your service personnel to check the compatibility.

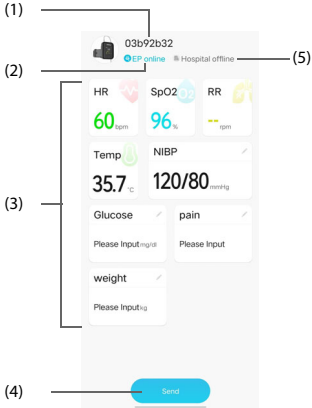
3.8.6 Managing Physiological Data with mWear App

mWear App is a mobile application that can be used to manage patient data from the patient end. With mWear, a patient can check the physiological data from the EP30 monitor on a mobile device, and update the data and send it back to the hospital.

CAUTION

- **Make sure that the equipment operating environment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **The monitor may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.**
- **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.**
- **Keep the equipment and accessories out of children's reach. For pediatric patients, the equipment should be used under adult supervision. Otherwise, product damage or patient injury may result.**
- **Make sure the patient has been adequately trained and fully familiar with the use of the equipment and finish all settings before delivering the equipment to the patient.**
- **If you need any help on the setting, operation or maintenance of the monitor, or any other support, contact the service personnel.**

Below is an example of the screen of mWear App:



(1) Name of the EP30 monitor

(2) EP30 connection status area: displays the connection status of this application with the EP30 monitor. Select this area to reconnect or unpair the device.

(3) Parameter area: displays parameter values. Parameters with an icon need to be input or selected manually. You can also add new parameters to this area. For details, refer to ***3.8.6.1 Adding a New Manual Parameter***.

(4) Select this button to send the current data back to the hospital.

(5) CMS connection status area: displays the connection status of this application with the hospital system.

3.8.6.1 Adding a New Manual Parameter

On the CMS, you can add manual parameters to the parameter area on mWear App, Follow this procedure:

1. On the CMS, select the system menu area in the upper left corner of the screen → select **System Setup** → select **ECG Pod** tab→ select **Manual Parameter** tab.
2. Select **Add**.
3. Select **Name** and input the name of the new parameter.

4. Set **Type** to **Numeric** or **Text**.
    - The type of a parameter cannot be changed after saving.
5. For **Numeric** type, continue to set the **Unit** and **Resolution** of the parameter. For **Text** type, you need to set the options to be selected. At least 2 options need to be set. If needed, you can select **Add** to set more options.
6. Select **Save**.
7. Check the box before the name of the parameter.

3.8.6.2Pairing the EP30 monitor with mWear App

To manage patient data with mWear App, you need to pair the EP30 monitor with the application. Follow this procedure:

1. Press and hold the touch button on the EP30 monitor for 3 seconds, and a QR code is displayed.
2. Select the icon on mWear App, and point the camera at the QR code on the EP30 monitor.
3. Select **Confirm**.

NOTE

- **Always enable bluetooth connection on the mobile device where mWear App is installed.**
- **Always keep the EP30 monitor close to the mobile device where mWear App is installed. Otherwise the bluetooth connection may be interrupted and data loss may occur.**

3.8.6.3Unpairing the EP30 Monitor and mWear App

After use, you need to unpair the EP30 monitor and the mWear App. Follow this procedure:

1. Make sure all patient data are properly stored.
2. Select the EP30 connection status area on the mWear App.
3. Select **Disconnect**.
4. Select **Confirm**.

3.8.7 Connecting Other Equipment

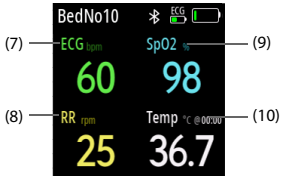
The EP30 monitor can be connected with more medical devices that support wireless network connection. Contact the service personnel to check the compatibility before connecting,

3.9 Screen Display

This section describes the contents displayed on the screens of the EP30 monitor, NIBP module, ePM monitor and CMS, after equipment and patient are properly connected.

3.9.1 Display on the EP30 Monitor

The following figures show some typical screens on the monitor.



(1) Patient bed number

(2) System time

(3) Exercise target and progress bar

(4) Network connection indicator:

- : The EP30 monitor is paired with an ePM monitor.
- : The EP30 monitor is unpaired with the ePM monitor.
- : The EP30 monitor is connected with an ePM monitor or CMS via Wi-Fi network.
- : The EP30 monitor is disconnected from Wi-Fi network.

(5) Battery status indicator: displays the battery status of the EP30 main unit.

- :The battery works correctly. The green portion represents the remaining charge.
- :The battery has low power and needs to be charged.
- : The battery has critically low charge and needs to be charged immediately. Otherwise, the monitor will soon automatically shut down.
- : The battery fails.
- (displays on the charging screen): The battery is being charged.

(6) Battery status indicator: displays the battery status of the ES30 ECG unit.

-  :The battery works correctly. The green portion represents the remaining charge.
-  :The battery has low power and needs to be charged.
-  : The battery has critically low charge and needs to be charged immediately. Otherwise, the ES30 ECG unit will soon automatically shut down.
-  : The battery fails.

(7) ECG parameter area: displays HR (heart rate) unit and value

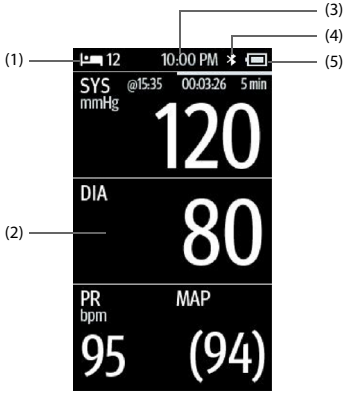
(8) RR (Respiration rate) parameter area: displays RR unit and value

(9) SpO_2 parameter area: displays SpO_2 unit and value

(10) Temp parameter area: displays Temp unit and value

3.9.2 Display on the NIBP Module

The following figure shows the display on the screen of the NIBP module.



(1) Patient bed number

(2) NIBP parameter area

(3) System time

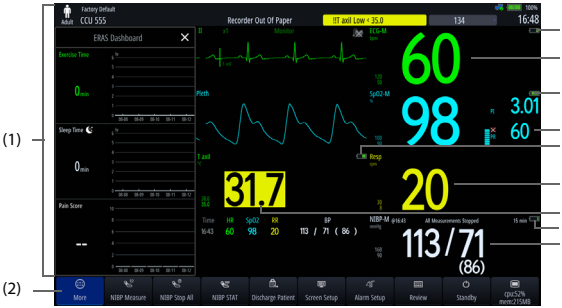
(4) Network connection status

(5) Battery status indicator: displays the current battery charge of the NIBP module.

- : The battery works correctly. The black portion represents the remaining charge.
- : The battery has low power and needs to be charged.
- : The battery has critically low charge and needs to be charged immediately. Otherwise, the NIBP module will soon automatically shut down.

3.9.3 Display on the ePM Monitor

Below is an example of the display on the ePM monitor under Wireless **Monitoring** mode.



(1) Parameter waveform and ERAS DashBoard area: displays waveforms and ERAS DashBoard. On the ERAS DashBoard screen, you can check the exercise time, sleep time and pain scores.

(2) Quick key area

(3) Battery status indicator*: displays the current battery charge of the ES30 ECG unit.

(4) ECG parameter area: displays the parameter value, unit, alarm limits and alarm status. "-M" indicates the measurement data are from the EP30 monitor.

(5) Battery status indicator*: displays the current battery charge of the EP30 main unit.

(6) SpO_2 parameter area: displays the parameter values, units, alarm limits and alarm status. "-M" indicates the measurement data are from the EP30 monitor.

(7) Battery status indicator*: displays the current battery charge of the wireless thermometer.

(8) Resp parameter area: displays the parameter value, unit, alarm limits and alarm status. The source displays as "ECG-M", in which "-M" indicates the measurement data are from the EP30 monitor.

(9) Temp parameter area: displays Temp unit and value

(10) Battery status indicator*: displays the current battery charge of the NIBP module.

(11) NIBP parameter area: displays the NIBP measurements, unit, alarm limits and alarm status.

*The symbols indicate the battery status as follows:

- : The battery works correctly. The green portion represents the remaining charge.
- : The battery has low power and needs to be charged.
- : The battery has critically low charge and needs to be charged immediately. Otherwise, the equipment will soon automatically shut down.

3.9.4 Display on the CMS

Below is an example of the display on the CMS under **Wearable** mode.

(1) Patient information area: displays patient information, including Bed No., name and so on.

(2) Patient status area: displays the current status of the patient*, including the remaining time to update physiological data, current exercising status and location. Below are symbols that indicate the patient status:

-  : indicates that the patient is sleeping at the set night time.
-  : indicates that the patient is walking.
-  : indicates that the patient is at rest, like sitting or lying quietly.
-  : indicates that the patient's ECG lead may have fallen off. Check the patient status.
-  : indicates that the patient may have fallen over. Check the patient status.

*: the patient status symbols display only when the ECG module is in connection with the EP30 monitor and ECG electrodes are properly applied.

(3) EWS area: displays the current EWS score. Select this area to display the EWS window. You can set whether to display this area on the main screen. For details, refer to ***5.2.6 Setting the Display of EWS Score Area***.

(4) ERAS DashBoard area: displays the exercise time and sleep time. Select this area to display the ERAS DashBoard screen.

(5) Enter 2min Continuous Mode: select to switch to Continuous Mode. For more information, refer to ***5.2.1 Work Mode Introduction***.

(6) ECG parameter area: displays the parameter value, unit, alarm limits and alarm status. "-M" indicates the measurement data are from the EP30 monitor.

(7) Battery status indicator*: displays the current battery charge of the ES30 ECG unit.

(8) Battery status indicator*: displays the current battery charge of the EP30 main unit.

(9) SpO_2 parameter area: displays the parameter values, units, alarm limits and alarm status. "-M" indicates the measurement data are from the EP30 monitor.

(10) Resp parameter area: displays the parameter value, unit, alarm limits and alarm status. The source displays as "ECG-M", in which "-M" indicates the measurement data are from the EP30 monitor.

(11) Temperature parameter area: displays the parameter value, unit, measurement site, alarm limits and alarm status.

(12) Battery status indicator*: displays the current battery charge of the NIBP module.

(13) NIBP parameter area: displays the NIBP measurements, unit, alarm limits and alarm status.

*The symbols indicate the battery status as follows:

-  : The battery works correctly. The green portion represents the remaining charge.
-  : The battery has low power and needs to be charged.
-  : The battery has critically low charge and needs to be charged immediately. Otherwise, the equipment will soon automatically shut down.

This page intentionally left blank.

4 Patient Preparation

This chapter describes patient related preparation to be made before monitoring, including managing patient information, applying accessories on a patient, etc.

4.1 Admitting a Patient

To make sure all patient data are properly saved, before starting monitoring, you need to admit the patient to be monitored.

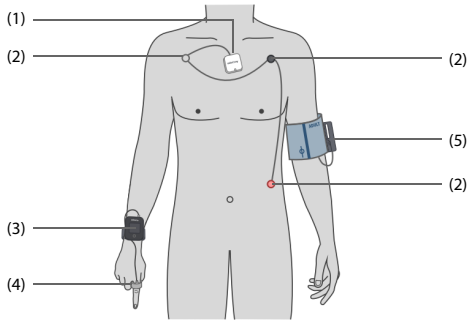
If your ePM monitor or CMS is equipped with a scanner, you can admit a patient following this procedure:

1. Press and hold the touch button on the EP30 monitor for 3 seconds, and a QR code is displayed.
2. Scan the barcode of the patient.
3. Scan the QR code displayed on the screen of the EP30 monitor.

You can also admit a patient, edit patient information, or discharge a patient on the ePM monitor or CMS. For details, refer to the operator's manual of the ePM monitor or CMS.

4.2 Connection with Patient

4.2.1 Patient Connection Overview



(1) ECG module

(2) ECG electrodes

(3) EP30 monitor

(4) SpO_2 sensor

(5) NIBP module and NIBP cuff

4.2.2 Patient Connection Safety Information

CAUTION

- Make sure the screen and touch button are not damaged or broken. If there is any sign of damage, remove the monitor from use and contact the service personnel.
- If the screen is loose, remove the monitor from use and contact the service personnel.
- Check the metal parts like contacts and pins on the equipment, accessories and charging station before use or on a regular basis. If needed, clean them with a soft cloth moistened with water or ethanol. Otherwise, the performance might be degraded because of poor contact.
- Attach the monitor and SpO_2 sensor on the same arm.

4.2.3 Wearing the Monitor

You can wear the monitor on either of the wrists of a patient. Make sure the fingers on the same side are suitable for applying the SpO_2 sensor.

To attach the monitor, follow this procedure:

1. Fit the EP30 main unit onto the connector of EP30 docking.
2. Wrap the wrist strap around the patient's wrist. Make sure the screen is facing out.
3. Accommodate the strap to the patient's wrist and buckle up.

CAUTION

- Always secure the wrist strap in case the monitor falls off and breaks.

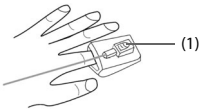
- Make sure the wrist strap fits the patient's wrist snugly but not too tight. Excessive tightness may cause discoloration and ischemia of the limb distal.

4.2.4 Applying the SpO_2 Sensor

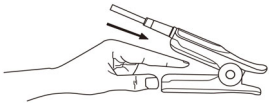
Apply the SpO_2 sensor on a finger on the same side of the wrist wearing the monitor.

Follow this procedure:

1. Wear the monitor as instructed in ***4.2.3 Wearing the Monitor***.
2. Select an application site. The index finger is the most recommended. Consider other fingers if the index finger is not available.
3. Clean the application site and contact surface of the sensor. Remove dyes in the measure site, such as nail polish, if needed.
4. Apply the sensor to the selected finger.
   - For 512ES sensors: insert the finger into the sensor until the finger nail aligns with nail mark on the outside. Make sure the fingertip is not exposed.
   - For 512HS sensors: clip the sensor on to the finger with the fingertip against the finger stop.



512ES



512HS

(1) Nail mark

   - For 512RS sensors, refer to the accompanying instructions for use.

5. Place the cable properly and secure it onto the back of the hand.

CAUTION

- Tight sensor application may cause venous pulsation, obstructed blood circulation, pressure marks, pressure necrosis, artifacts and inaccurate measurement. Loose sensor application may lead to erroneous optical alignment, or the sensor falling off.

- Do not bend the cable excessively for a prolonged time.
- After an EP30 docking is replaced, re-pair the EP30 monitor with the ECG module, NIBPmodule, ePM monitor or wireless thermometer as described in *3.8 Equipment Pairing and Network Connection*. Otherwise, patient data loss or errors may result.

4.2.5 Applying Electrodes

The ES30 ECG unit is for use with ES30 docking.

WARNING

- Use defibrillation-proof ECG cables during defibrillation.
- Make sure the conductive parts of electrodes and associated connectors, including the neutral electrode, do not contact any other conductive parts including earth.
- Do not touch the patient or metal devices connected to the patient during defibrillation.

4.2.5.1 Preparing the Patient Skin

Proper skin preparation is necessary to ensure good signal quality at the electrode sites, as the skin is a poor conductor of electricity. When applying the electrodes, avoid bony area, obvious layers of fat, and major muscles.

To properly prepare the skin, follow this procedure:

1. Shave hair from skin at chosen electrode sites.
2. Gently rub skin surface at sites to remove dead skin cells.
3. Thoroughly cleanse the site with a mild soap and water solution.
4. Dry the skin completely before applying electrodes.

4.2.5.2 Lead Wire Color Code

The following table lists the color coding of leadwires for both AHA and IEC standards:

Lead	IEC		AHA	
	Label	Color	Label	Color

Right arm	R	Red	RA	White
Left arm	L	Yellow	LA	Black
Left leg	F	Green	LL	Red

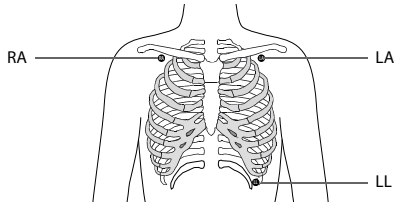
4.2.5.3ECG Electrode Placement

For lead placement, the ECG algorithm works best when the patient's R wave is significantly larger than the P wave or the T wave. On some patients, electrode placement and/or the viewed ECG lead may need to be adjusted in order to obtain a significant R wave.

For patients wearing pacemaker, do not place an ECG electrode directly over the pacemaker generator. Place the electrodes 5 cm to 7 cm away from the pacemaker generator area.

In this section, electrode placement is illustrated using the AHA naming convention.

The electrode placement is as follows:



- RA: just below the clavicle and near the right shoulder.
- LA: just below the clavicle and near the left shoulder.
- LL: below the lower left edge of the rib cage.

4.2.5.4Applying Electrodes to the Patient

You can use 3-lead leadwire for ECG monitoring. To apply the electrodes, follow this procedure:

1. Prepare the patient skin as described in ***4.2.5.1 Preparing the Patient Skin***.
2. Check that electrode packages are intact and the electrodes are not past the expiry date. Make sure the electrode gel is moist. Then attach the snaps to the electrodes before placing electrodes on the patient.

3. Place the electrodes on the prepared sites. Make sure that all electrodes have good skin contact.
4. Put on the patient's clothing.
5. Fit the ES30 ECG unit into the connector of the ES30 docking.

WARNING

- After all electrodes are placed, fit the ES30 ECG unit immediately into the connector of ES30 docking.

CAUTION

- After an ES30 docking being replaced, re-pair the ECG module with the EP30 monitor as described in *3.8.1 Pairing the EP30 Monitor with an ECG Module*. Otherwise, patient data loss or errors may result.

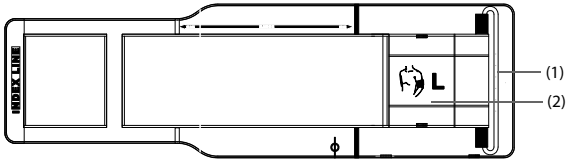
NOTE

- Store the electrodes at room temperature.
- Only open the electrode package immediately prior to use.
- Never mix patient electrode types or brands. This may lead to problem due to impedance mismatch.
- When applying the electrodes, avoid bony area, obvious layers of fat, and major muscles. Muscle movement can result in electrical interference.

4.2.6 Placing an NIBP Cuff

You can place an NIBP cuff on either arm of the patient. Select an appropriate cuff based on the limb circumference of the patient. The width of the cuff should be 40% of the limb circumference, or 2/3 of the length of the upper arm. The inflatable part of the cuff should be long enough to cover at least 50% to 80% of the limb.

The following figure is an overview of the cuff:



(1) Hanging bag

(2) Attached end

WARNING

- Do not perform NIBP measurements on patients with sickle-cell disease.
- To avoid further injury, do not apply the NIBP cuff on the limb with a wound.
- Use clinical judgment to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- To avoid the risk of patient injury, do not apply the NIBP cuff on a limb that has an intravenous infusion or catheter in place. Apply the cuff on another limb if possible.
- Do not apply cuff on the arm on the side of a mastectomy or lymph node clearance.
- Use care when placing the cuff on an extremity used for monitoring other patient parameters.
- Continuous cuff pressure due to connection tubing kinking may cause blood flow interference, and resulting in harmful injury to the patient.
- Taking NIBP measurements exert pressure on the patient's tissue. This can cause skin purpura, ischemia, and neuropathy. Periodically check the cuff site and the limb distal to the cuff for normal color, warmth and sensitivity. If there is a sign of skin change or poor distal circulation, move the cuff to another limb or stop NIBP measurements. Check more frequently when using the STAT mode or using the auto mode at short

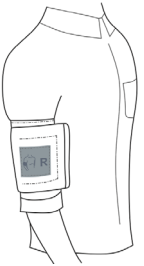
intervals. Auto NIBP measurements with one and two minute intervals are not recommended for extended periods of time.

CAUTION

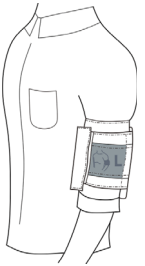
- Using a cuff of wrong size, or a cuff with twisted bladder and kinked air tubing, can cause inaccurate measurements.
- Do not touch or apply external pressure against the cuff and air tubing during NIBP measurement. This may cause inaccurate blood pressure values.

To place the NIBP cuff, follow this procedure:

1. Spread out the NIBP cuff, and then attach one end of NIBP cuff to the attached end.
2. Wear the NIBP cuff on the patient's arm.
3. Adjust the position of the cuff and make sure the middle of NIBP cuff is at the level of the right atrium of the heart.
4. Place the hanging bag with L (left arm) or R (right arm) mark facing up.



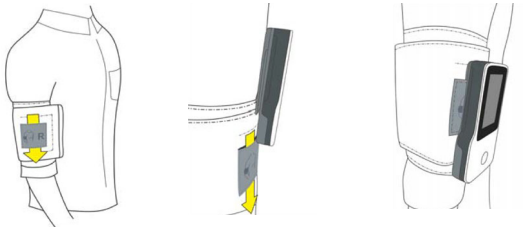
NIBP cuff on the right arm



NIBP cuff on the left arm

5. Make sure the ϕ marking on the cuff matches the artery location. The cuff should fit snugly, but with enough room for two fingers to be placed between the cuff and the patient's arm.
6. Adjust the cuff and make sure the cuff index line (INDEX LINE) falls within the range markings (RANGE) on the cuff.

7. Place the NIBP module onto the NIBP cuff with the NIBP Pod clip.



8. Connect the air tubing to the NIBP module. Make sure the air tubing is not compressed or twisted. Air must pass unrestricted through the tubing.

4.2.7 Applying Temperature Sensor (Wireless Thermometer)

The wireless thermometer is suitable for adult and child temperature measurement.

You can apply the wireless thermometer to the armpit of the patient.

To apply the Wireless Thermometer, follow this procedure:

1. Prepare the patient's skin. Clean the target application site or shave excessive hairs if necessary.
2. Clean the surface of the wireless thermometer with 75% medicinal alcohol.
3. Peel the patch cover off the supplied patch and then stick the wireless thermometer to the center of the patch with the temperature sensor facing out.

4. Lift the patient's arm and apply the temperature sensor to the selected site.

5. Ask the patient to hold the arm tight for at least 8 minutes.

CAUTION

- Sudden patient movement may lead to inaccurate measurements.
- Do not apply the temperature sensor to the same site for more than 24 consecutive hours.
- Check the wireless thermometer regularly and make sure it is in firm contact with the patient skin. Otherwise the measurements may be inaccurate.
- After a wireless thermometer is replaced, re-pair it with the EP30 monitor as described in *3.8 Equipment Pairing and Network Connection*. Otherwise, patient data loss or errors may result.

NOTE

- It is recommended to use the supplied patches. In the event of adverse effects, other full-cover patches or medical tapes can be used.
- Do not reuse the patches.

5 Patient Monitoring

This chapter introduces operation related information needed after starting patient monitoring.

5.1 Patient Monitoring Safety Information

WARNING

- Before start monitoring, make sure the monitor is paired or connected as intended with the correct device or system, and that the patient information is correct.
- Keep close observation on the equipment connection status during patient monitoring, in case patient data loss or errors occur.

CAUTION

- The patient should be required to move in a specified area. If the patient is at the edge of or outside the network coverage range, unstable network connection may compromise the monitoring performance.

5.2 Work Modes

5.2.1 Work Mode Introduction

The EP30 monitor supports the following work modes:

- Wireless Monitoring: the EP30 monitor provides continuous monitoring of the patient and updates patient data in real time.
  - This mode can be provided only when the EP30 monitor is in bluetooth connection with an ePM monitor.
  - This mode is for patients that require close observation, such as patients in critical or serious conditions or after surgery.
- Wearable: the EP30 monitor performs continuous ECG, Resp, NIBP and Temp monitoring, and sends all physiological data to the ePM monitor or CMS at a two-minute interval. This mode can be used for patients under observation that are in stable conditions and require normal mobility.

- **Continuous**: in **Wearable** mode, if a critical situations are detected, such as lethal arrhythmias and patient fall (configurable, see ***5.2.5 Setting the Conditions to Switch to Continuous Mode***), the system switches to **Continuous** mode and resumes real-time data acquisition and transmission. If the vital signs resume as normal for over 5 minutes, the system switches back to **Wearable** mode. You can also select **Enter 2min Continuous Mode** on the screen to enter the **Continuous** mode as needed. You can check the countdown clock on the screen for the remaining time to switch back to **Wearable** mode.

5.2.2 Changing of Work Mode

If your EP30 monitor is in bluetooth connection with an ePM monitor, the monitors enter **Wireless Monitoring** mode automatically after they are correctly paired via Bluetooth. In the following situations, the working mode switches from **Wireless Monitoring** to **Wearable** automatically:

- The system time has reached the set **Switch Monitor Mode Time**. For details, refer to ***5.2.3 Setting the Switch Monitor Mode Time***.
- The Bluetooth connection between EP30 monitor and the ePM monitor is disconnected.

In **Wearable** mode, if the **EWS** score on the ePM monitor has reached a set level, the work mode changes from **Wearable** to **Continuous** automatically. For details, refer to ***5.2.4 Setting the Switch Monitoring Mode on EWS Score***.

Besides, you can also change the work mode on the ePM monitor manually. For details, refer to ***5.2.7 Changing Work Mode Manually***.

5.2.3 Setting the Switch Monitor Mode Time

On the ePM monitor, you can set a time at which the working mode switches from **Wireless Monitoring** to **Wearable**. To do so, follow this procedure:

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.
2. Select **Other** tab.
3. Set **Switch Monitor Mode Time** to a time appropriate for the patient. If **Off** is selected, the monitors does not switch to **Wearable** mode based on time.

5.2.4 Setting the Switch Monitoring Mode on EWS Score

On the ePM monitor, you can set an EWS score as the threshold to change the work mode. After setting, if the EWS score of the patient is higher than the set threshold, the work mode switches from **Wearable** to **Continuous**.

To set the **Switch Monitoring Mode on EWS Score**, follow this procedure:

1. On the ePM monitor, select the **EWS** quick key.
2. From the **EWS** page, select **Setup** and then select the **Wearable mode** tab.
3. Select **Switch Monitoring Mode on EWS Score**.
4. Set **EWS Score Threshold** to a score appropriate for the patient. If you want to switch off **Switch Monitoring Mode on EWS Score**, select **Off**.

5.2.5 Setting the Conditions to Switch to Continuous Mode

To set the conditions to switch the work mode from **Wearable** to **Continuous**, follow this procedure:

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.
2. Select **ECG Pod** tab.
3. Select **SpO2 Desat** and **Patient Fall** as needed.

5.2.6 Setting the Display of EWS Score Area

You can choose whether or not to display the EWS score area on the main screen in **Wearable** mode. Follow this procedure:

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.
2. Select **ECG Pod** tab.
3. Select **EWS** as needed.

5.2.7 Changing Work Mode Manually

You can change the work mode manually in the following ways:

- On the ePM monitor, select the **Wearable mode** quick key to change the work mode from **Wireless Monitoring** to **Wearable**, and the ePM monitor displays the **Wearable mode** screen. And, in **Wearable** mode, select the **Exit Wearable mode** quick key to change the work mode from **Wearable** to **Wireless Monitoring**.
- On the ePM monitor, select the **UnPair** quick key → select **Use Patient in EP**, the ePM monitor enters Standby mode and the EP30 monitor connects the CMS automatically.
- In **Wearable** mode, select **Enter 2min Continuous Mode** on the screen to enter the **Continuous** mode for 2 minutes.

5.3 Changing Patient Monitoring Settings

Before starting patient monitoring, you can make preferential settings basing on the monitoring tasks.

5.3.1 Changing the SpO_2 Sensitivity

The SpO_2 value displayed on the monitor screen is the average of data collected within a specific time. The shorter the averaging time is, the quicker the monitor responds to changes in the patient's oxygen saturation level. Contrarily, the longer the averaging time is, the slower the monitor responds to changes in the patient's oxygen saturation level, but the SpO_2 measurement is more stable. For critically ill patients, selecting shorter averaging time will help understanding the patient's state.

To set the averaging time, follow this procedure:

1. On the ePM monitor or CMS, select the SpO_2 numeric area or waveform area to enter the **SpO2** menu.
2. Select the **Setup** tab.
3. Select **Sensitivity**, and then toggle between **High**, **Med** and **Low**, which respectively correspond to 7 s, 9 s and 11 s.

5.3.2 Checking Paced Status

It is important to correctly set the paced status before you start monitoring ECG. You can check the paced status on the ePM monitor. The paced symbol  is displayed when **Paced** is set to **Yes**. The pace pulse markers "|" are shown on each ECG waveform when the patient has a paced signal. If **Paced** is set to **No** or if the patient's paced status is not selected, the symbol  will be shown in the ECG waveform area.

To change the paced status, follow this procedure:

1. On the ePM monitor or CMS, select the ECG numeric area or waveform area to enter the **ECG** menu.
2. Select the **Pacer** tab.
3. Set **Paced** to **Yes** or **No**.

5.3.3 Selecting NIBP Start Mode

The monitor supports the following measurement modes:

- Manual mode: measurement is taken on demand. For more information, refer to ***5.5.1 Performing Spot Check NIBP Measurement***.
- Auto mode: repeated measurements are taken at set interval.

- STAT mode: continually rapid series of measurements are taken over a five-minute period.
- Sequence mode: continually automatic measurements are taken at set durations and intervals. For details, refer to ***5.3.4 Setting NIBP Sequence***.

To set the measurement mode, follow this procedure:

1. On the ePM monitor or CMS, select the NIBP numeric area to enter the **NIBP** menu.
2. Set **Start Mode**.
   - **Clock**: after the first measurement, the monitor automatically synchronizes NIBP automatic measurements with the real time clock. For example, if **Interval** is set to **20 min**, and you start NIBP auto measurement at 14: 03, the next measurement will be taken at 14: 20, and then at 14:40, 15:00, and so on.
   - **Interval**: after the first measurement, the monitor automatically repeats measurements at set interval. For example, if **Interval** is set to **20 min**, and you start NIBP auto measurement at 14:03, the next measurement will be taken at 14:23, and then at 14:43, 15:03, and so on.
3. Set **Interval** to an appropriate duration.

5.3.4 Setting NIBP Sequence

NIBP sequence measurement can have up to five phases: A, B, C, D, and E. You can individually set the duration and interval of each phase.

To set NIBP sequence, follow this procedure:

1. On the ePM monitor or CMS, select the NIBP numeric area to enter the **NIBP** menu.
2. Select the **Sequence** tab.
3. Set **Duration** and **Interval** of each phase.

5.3.5 Setting NIBP Measurement Prompt

For adult patients, you can switch on **NIBP Measurement Prompt** on the ePM monitor. If **NIBP Measurement Prompt** is on, the ePM monitor displays "**Recommended to take NIBP measurement**" when the detected patient data breaks the preset conditions. To switch on and set the **NIBP Measurement Prompt** function, follow this procedure

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.

2. Select **Module** tab→ **NIBP** Tab.
3. Switch on **NIBP Measurement Prompt**.
4. Set the **Duration of Prompt Message**. The prompt message is no longer displayed after being displayed for the set period.
5. Set the conditions to issue a prompt message:
   - HR: set the **HR value fluctuation** and **Duration of HR value fluctuation**.
   - PR: set the **PR value fluctuation** and **Duration of PR value fluctuation**.
6. Set the **PWTT Sensitivity**. The higher the sensitivity is, the more likely a prompt message will be issued when blood pressure change occurs.

The PWTT function is not applicable for patients in the following condition:

- On vasoactive medication
- Exercising or in excessive motion
- With severe arrhythmias
- Showing unstable pulse wave due to poor circulation
- Wearing SpO_2 sensor for excessively long time and thus causing a rising dicrotic pulse wave

NOTE

- **PWTT is applicable only for adult patients.**

5.3.6 Setting the Initial Cuff Inflation Pressure

To set initial cuff inflation pressure, follow this procedure:

1. On the ePM monitor, select the NIBP numeric area to enter the **NIBP** menu.
2. Select **Initial Pressure**, and then select the appropriate setting.

NOTE

- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**

5.4 View Monitoring Data

During patient monitoring, you can view the patient data on the EP30 monitor, ePM monitor, and CMS.

5.4.1 SpO_2 Monitoring

5.4.1.1 SpO_2 Introduction

Pulse Oxygen Saturation (SpO_2) monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the emitter side of the probe is partly absorbed when it passes through the monitored tissue. The amount of transmitted light is detected in the detector side of the probe. When the pulsative part of the light signal is examined, the amount of light absorbed by the haemoglobin is measured and the pulse oxygen saturation can be calculated. This device is calibrated to display functional oxygen saturation.

SpO_2 monitoring is intended for adult patients and pediatric patients over the age of 12.

WARNING

- If the patient has a trend of deoxygenation, analyze the blood samples with a laboratory CO-oximeter to completely understand the patient's condition.
- Do not use the monitor or EP30 docking during MRI scanning or in an MRI environment. Induced current could potentially causes burns. The monitor may affect the MRI image, and the MRI device may affect the accuracy of the SpO_2 measurements.
- SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- Avoid putting the SpO_2 sensor under direct sunlight. If the ambient light is too strong, move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
- Prolonged continuous monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. Change the application site every four hours. For

patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.

NOTE

- Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.
- A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.
- A functional tester or SpO_2 simulator cannot be used to assess the SpO_2 accuracy.
- Dye (e.g. Indocyanine Green) or other substances, containing dyes which usually modify the light absorption capacities, can lead to faulty measurement values of the oxygen saturation.
- The SpO_2 sensors and cables have been tested and validated for conformity with the standard IEC 60601-2-61 with the monitor.

5.4.1.2 SpO_2 Measurement Limitations

The following factors may influence the accuracy of SpO_2 measurement:

- Patient physiological characteristics:
  - Cardiac arrest
  - Hypotension
  - Darkly pigmented skin
  - Shock
  - Severe vasoconstriction
  - Hypothermia
  - Severe anemia
  - Ventricular septal defects (VSDs)
  - Venous pulsations
  - Poor perfusion

- Dysfunctional hemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Elevated levels of bilirubin
- Vasospastic disease, such as Raynaud's, and peripheral vascular disease
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Hypocapnic or hypercapnic conditions
- Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.

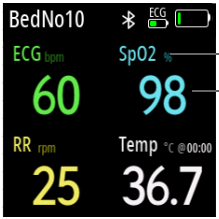
■ Interfering substances
- Intravascular dyes (such as indocyanine green, methylene blue, indigo carmine, etc.)
- Dyes in the measure site, such as nail polish.

■ Environmental conditions:
- Excessive ambient light
- Electrosurgery equipment
- Defibrillation (may cause inaccurate reading for a short amount of time)
- Excessive patient/sensor motion
- Electromagnetic field
- Arterial catheters and intra-aortic balloon

■ Others
- Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor
- Cuff or arterial blood pressure measurement device on the same limb as the SpO_2 sensor.

5.4.1.3Viewing SpO_2 Data on the EP30 Monitor

Press the touch button on the monitor and switch to the following screen:

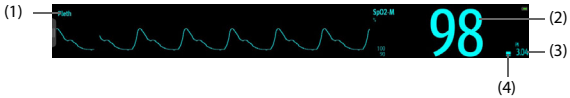


(1) SpO_2 unit

(2) SpO_2 value

5.4.1.4Viewing SpO_2 Data on the ePM Monitor

On the ePM monitor, the SpO_2 parameter area displays as follows:



(1) Pleth waveform (Pleth): indicates the blood pulsation at the measurement site. The waveform is not normalized.

(2) Arterial oxygen saturation (SpO_2): indicates the percentage of oxygenated hemoglobin relative to total hemoglobin.

(3) Perfusion index (PI): indicates the percentage of pulsatile signal to non pulsatile signal. PI is an indicator of the pulsatile strength. You can also use it to assess the SpO_2 signal strength.

- Above 1 is optimal.
- Between 0.3 and 1 is acceptable.
- Below 0.3 indicates low perfusion. Reposition the SpO2 sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible.

(4) Perfusion indicator: the pulsatile portion of the measured signal caused by arterial pulsation. The higher the bar, the better the perfusion quality.

5.4.1.5Viewing SpO_2 Data on the CMS

On the CMS, the SpO_2 parameter area displays as follows:

(1) SpO_2 unit

(2) SpO_2 value

5.4.2 ECG Monitoring

5.4.2.1 ECG Introduction

The electrocardiogram (ECG) measures and records the electrical activity of the heart. ECG monitoring provides 3-lead ECG monitoring.

WARNING

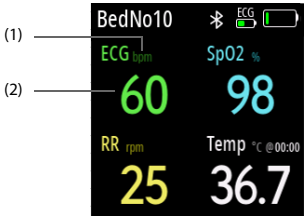
- The ECG waveforms displayed on the EP30 monitor and CMS cannot be used as the basis for diagnosis and therapy decisions.
- For paced patients, set Paced to Yes. Otherwise the monitor could mistake a pace pulse for a QRS complex and fail to generate alarms when the ECG signal is too weak. On ventricular paced patients, episodes of ventricular tachycardia may not always be detected.Do not rely entirely upon the system's automated arrhythmia detection algorithm.
- False low heart rate or false asystole alarms may result with certain pacemakers because of pacemaker artifacts, such as electrical overshoot of the pacemaker overlapping the true QRS complexes.
- Do not rely entirely on heart rate meter alarms when monitoring patients with pacemakers or arrhythmia. Always keep these patients under close surveillance.

CAUTION

- Implanted devices (for example cardiac pacemakers), other patient connected equipment, and other equipment near the patient can cause interference on the waveform.

5.4.2.2Viewing ECG Data on the EP30 Monitor

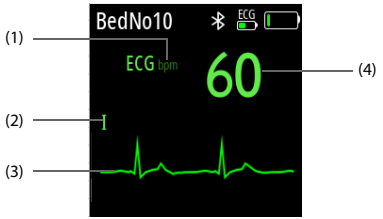
Press the touch button on the monitor and switch to the following screen:



(1) HR unit

(2) HR value

You can also continue to press the touch button and switch to the following screen for more ECG information.



(1) HR unit

(2) ECG lead label of the displayed waveform

(3) ECG waveform

(4) HR value

5.4.2.3Viewing ECG Data on the ePM Monitor and CMS

On the ePM monitor and CMS, the ECG parameter area displays as follows:

(1) HR unit

(2) HR value

5.4.3 Resp Monitoring

5.4.3.1Resp Introduction

The Respiration Rate (RR) on your monitor can be sourced from ECG module (ECG) or EP30 monitor (SpO_2).

When an ECG module is correctly paired with the EP30 monitor, it provides impedance respiration monitoring. Impedance respiration is measured across the thorax. When the patient is breathing or ventilated, the volume of air changes in the lungs, resulting in impedance changes between the electrodes. Respiration rate (RR) is calculated from these impedance changes.

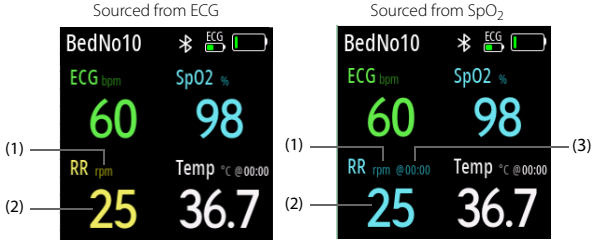
For adult patients, if the monitor is not paired with an ECG module, the monitor obtains RR from pulse wave signals collected by the SpO_2 sensor. In this case, the EP30 monitor takes RR measurements at a set interval. For details, refer to *5.4.3.6 Setting the RR Measurement Interval*.

CAUTION

- RR sourced from SpO_2 is available only for adult patients.
- Respiration monitoring is not for use on the patients who are very active, as this will cause false alarms.

5.4.3.2Viewing Resp Data on the EP30 Monitor

Press the touch button on the monitor and switch to the following screen:



(1) RR unit

(2) RR value

(3) Time of the last RR measurement (available when RR is sourced from SpO_2)

5.4.3.3Viewing Resp Data on the ePM Monitor and CMS

On the ePM monitor and CMS, the Resp parameter area displays as follows:

(1) RR unit

(2) RR value

(3) RR source

5.4.3.4Measurement Limitations of SpO_2-Sourced RR

The following factors may influence the accuracy of RR measurement sourced from SpO_2:

- Low perfusion
- Excessive motion on the measurement site
- Arrhythmia
- RR signal too weak to be detected in the pleth waveform

5.4.3.5Enabling the SpO_2 Source for RR Measurement

To provide RR measurement sourced from SpO_2 for adult patients, you need to enable the function. Follow this procedure:

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.
2. Select **Module** tab→ **SpO2** Tab.
3. Switch on **SpO2 Calc RR**.

5.4.3.6Setting the RR Measurement Interval

When the RR measurement is sourced from SpO_2, measurements are taken at the set interval. To change the measurement interval, follow this procedure:

1. On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵.
2. Select **Module** tab→ **SpO2** Tab.
3. Set **SpO2 Calc RR Frequency** to an appropriate interval.

5.4.4 NIBP Monitoring

5.4.4.1NIBP Introduction

The NIBP module uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The oscillometric device uses a blood pressure cuff to sense these oscillations that appear as tiny pulsations in cuff pressure. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

NIBP monitoring is intended for adult patients and pediatric patients over the age of 12.

WARNING

- NIBP reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition. If you doubt the NIBP measurements, determine the patient's vital signs by alternative means, and then verify that the monitor is working correctly.
- NIBP diagnostic significance must be decided by the physician.

NOTE

- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/

stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard: manual, electronic, or automated sphygmomanometers.

5.4.4.2NIBP Measurement Limitations

Measurement is impossible with heart rate extremes of less than 30 bpm or greater than 300 bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible in the following situations:

- The patient is connected to a heart lung machine.
- Regular arterial pressure pulses are hard to detect.
- The patient has cardiac arrhythmias.
- The patient's blood pressure changes dramatically.
- The patient has poor circulation due to severe shock or hypothermia.
- NIBP cuff is applied on an limb with edematous extremity.
- The NIBP cuff is compressed by excessive movement such as shivering, seizures, or convulsions.
- The patient's blood pressure is out of measurement range.

CAUTION

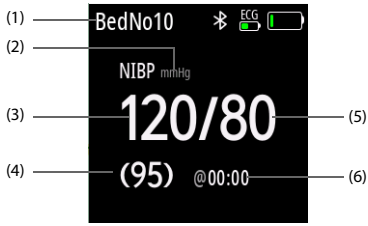
- In case the NIBP measurement is inaccurate or fails because of patient motion or external force being applied on the cuff, ask the patient to keep still and quiet during NIBP measurement.

NOTE

- The effectiveness of the sphygmomanometer has not been established in pregnant, including pre-eclamptic patients.
- Other factors that have been shown to result in an overestimation of blood pressure are labored breathing, full bladder, pain etc.

5.4.4.3Viewing NIBP Data on the EP30 Monitor

Press the touch button on the monitor and switch to the following screen:



(1) Patient bed number

(2) NIBP unit

(3) Systolic pressure

(4) Mean pressure (displayed after measurement completed) or cuff pressure (displayed during the measurement)

(5) Diastolic pressure

(6) Time of the last NIBP measurement

5.4.4.4Viewing NIBP Data on the ePM Monitor and CMS

On the ePM monitor and CMS, the NIBP parameter area displays as follows

(1) The last NIBP measurement time

(2) NIBP unit: mmHg or kPa

(3) Systolic pressure

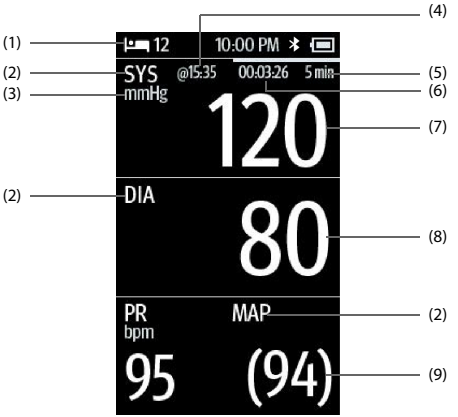
(4) Measurement mode: for Auto NIBP, interval is displayed; for Sequence mode, the current phase and interval are displayed

(5) Diastolic pressure

(6) Mean pressure (displayed after measurement completed) or cuff pressure (displayed during the measurement)

5.4.4.5Viewing NIBP Data on the NIBP Module

On the screen of the NIBP module, you can check the last NIBP measurements of the patient.



(1) Patient bed number

(2) NIBP parameter label

(3) NIBP unit: mmHg or kPa

(4) The last NIBP measurement time

(5) Measurement mode: for Auto NIBP, interval is displayed; for Sequence mode, the current phase and interval are displayed

(6) Time to the next measurement (for Auto mode and Sequence mode)

(7) Systolic pressure

(8) Diastolic pressure

(9) Mean pressure (displayed after measurement completed) or cuff pressure (displayed during the measurement)

5.4.4.6Correcting the NIBP Measurement

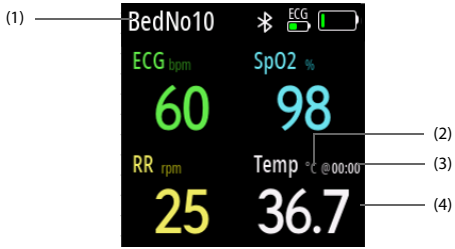
The middle of the cuff should be at the level of right atrium. If the limb is not at the heart level, you need to correct the measurement:

- Add 0.75 mmHg (0.10 kPa) to the displayed value for each centimeter higher.

- Deduct 0.75 mmHg (0.10 kPa) to the displayed value for each centimeter lower.

5.4.5 Viewing Temp Data

Press the touch button on the EP30 monitor and switch to the following screen:



(1) Patient bed number
(2) Temp unit
(3) Time of the last Temp measurement
(4) Temp value

5.5 Performing Manual Measurements

5.5.1 Performing Spot Check NIBP Measurement

NOTE

- It is recommended that the patient calms down and relaxes as much as possible before performing the measurement and that the patient do not talk during the measurement.
- It is recommended to have the patient sit quietly for five minutes before taking the measurement.

To start a spot check NIBP measurement, follow this procedure:

1. Prepare the patient. In normal use, perform NIBP measurement on a patient who is in the following position:
   - Comfortably seated
   - Legs uncrossed

- Feet flat on the floor
- Back, arm and feet supported

2. Press the NIBP Start/Stop key on the front of the NIBP module.
3. Wait till the measurement is finished. Then place the front of the NIBP module close to the screen of the EP30 monitor to send the measurements.

If the data transmission keeps failing, the NIBP module may have been set to continuous mode. Set the module to spot check mode as described in *3.7 Setting the Work Mode of the NIBP Module*.

5.6 Measuring the Sleeping Time

The monitor measures the sleeping time at night. It helps in knowing the patient's sleep state.

NOTE

- During sleeping time measurement, make sure the patient stays under network coverage and that the ECG leadwire is connected properly. Otherwise, the sleeping time measurement would fail.

5.6.1 Sleeping Measurement Limitations

The following factors may influence the measurement accuracy of the sleeping time:

- Patient with arrhythmias (atrial or ventricular)
- Patient with autonomic dysfunction
- Patient without self-controlling ability (paralysis or under sedation)
- Patient with pacemaker
- Electromagnetic field

5.6.2 Defining the Night Time

To define the nighttime for the sleeping time measurement, follow this procedure:

1. Access the **Time** tab in either of the following ways:
   - On the ePM monitor, select the **Main Menu** quick key → from the **System** column select **Maintenance** → input the required password → select ↵ → select the **Time** tab.

- On the CMS, select the system menu area in the upper left corner of the screen → select **System Setup** → select **Other Tab** → select the **Time** tab.

2. Select **From** and **To** under **Night time** to define the beginning and end of the nighttime.

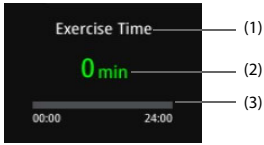
5.7 Measuring the Exercise Time

The monitor measures the patient's exercise time. Clip the ECG module on the patient's collar, and inform the patient to keep the ECG module stable during the measurement.

5.7.1 Viewing Exercise Time

You can view the exercise time in either of the following ways:

- In **Wearable** mode, check the exercise time area on the screen.

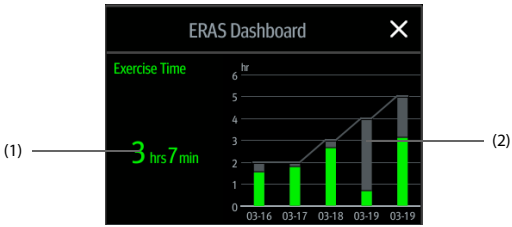


(1) Parameter label

(2) Current exercise time

(3) Exercise progress bar: the green portion represents the achieved exercise time.

- In **Wireless Monitoring** mode, on the ePM monitor, select the **Main Menu** quick key → from the **Display** column select **Choose Screen** → select **ERAS Dashboard**.



(1) Current exercise time: selecting this area enters the **Exercise Goal** menu.

(2) The trend of exercise time: each bar graph represents the exercise time measured every day. The color indicates the exercise progress.

- The green portion represents the achieved exercise time.
- The grey portion represents the exercise time not achieved.

Selecting this area enters the Exercise Goal menu.

5.7.2 Exercise Measurement Limitations

The following factors may influence the measurement accuracy of the exercise time:

- Walking too fast or too slowly (faster than 120 steps/minute or slower than 30 steps/minute)
- Walking time less than one minute
- Walking slowly with the help of a walker, or moving step by step
- Continuous interferences, such as coughing, shaking legs, patting on the back, and so on
- Electromagnetic interference
- The ECG module is not stably attached

5.7.3 Setting the Exercise Goal

On the ePM monitor and CMS, you can set the exercise goal for the patient. Through setting the exercise goal, the monitor assists the patient in taking exercise and helps the patient recovered from the surgery. If the patient does not achieve the exercise goal, the monitor will remind the patient.

To set the exercise goal, follow this procedure:

1. On the ePM monitor or CMS, select the exercise time area to enter the **Exercise Goal** menu.
2. Switch on **Exercise Goal**.
3. Separately set the **Exercise Goal** of each postoperative day.

5.8 Patient Fall Monitoring

The monitor provides patient fall monitoring. If a possible fall is detected, the system displays a patient fall icon on the ePM monitor and CMS. If the following icon is displayed, check the patient's status and provide help or further treatment if needed.

5.9 Assisting Venous Puncture

You can use the ePM monitor and NIBP cuff to cause sub-diastolic pressure to block the venous blood vessel and therefore help venous puncture. To assist venous puncture, follow this procedure:

1. On the ePM monitor, select the **Venipuncture** quick key or select the **NIBP** numeric area → **Setup** tab.
2. Set **Venipuncture Pressure**.
3. Select **Venipuncture** at the bottom of the menu.
4. Puncture vein and draw blood sample.
5. Select the **NIBP Start/Stop** quick key to deflate the cuff. If you do not deflate the cuff, the cuff automatically deflates after a period of time (170 seconds for adult and pediatric patient).

During venous puncture, pay attention to the cuff pressure and the remaining time displayed in the NIBP numerics area.

5.10 Reviewing Monitoring Data

You can view the history data of monitored patients on the ePM monitor and CMS. For details, refer to the operator's manuals of the ePM monitor and CMS.

5.11 Alarms

Alarms refer to audio and visual indication sent by the monitor when the vital signs of the patient appears abnormal or technical problems that may interrupt the monitoring are detected.

After the EP30 monitor being paired with an ePM monitor and connected with a CMS, alarms are issued on the ePM monitor and CMS. For details, refer to the operator's manuals of the ePM monitor and CMS.

All alarm related functions and messages are provided by the ePM monitor and CMS. For details, refer to the operators manuals of the ePM monitor and CMS.

5.12 Removing the Monitor from Use

When the patient monitoring is finished, you can remove the monitor from use following this procedure:

1. Make sure the patient monitoring data is saved or cleared as required. Then, discharge the patient.
2. Detach the SpO_2 sensor, ECG electrodes, NIBP cuff from the patient, and take off the EP30 monitor, ECG module and NIBP module.
3. Perform cleaning, disinfection and other maintenance as required by the local or your hospital's regulation.
4. Charge the batteries if needed.
5. Properly manage and store the equipment and accessories.

6 Troubleshooting

This chapter lists the problems that are likely to occur and possible solutions. If the problem persists after corrective actions have been taken, contact your service personnel.

CAUTION

- In case of any abnormity, remove the equipment from use immediately. Otherwise, injury to the patient or operator or damage to the equipment might result.

Symptom	Possible Cause	Attemptable Solution
The equipment cannot be paired.	The EP30 main unit is not connected with an EP30 docking. The ES30 ECG unit is not connected with an ES30 docking.	Connect the EP30 main unit with an EP30 docking. Then try and pair the equipment again. Connect the ES30 ECG unit with an ES30 docking. Then try and pair the equipment again.
The EP30 monitor cannot connect the CMS.	The network setting is incorrect. The EP30 main unit is disconnected with the EP30 docking.	Pair the EP30 monitor with an ePM monitor that has been correctly set and connected with the CMS. Connect the EP30 main unit with the EP30 docking.
ECG noise	ECG waveforms are overlapped with the noise interference.	Check the electrodes and make sure the electrodes are intact, and firmly stuck to the patient. Make sure the leadwire is properly secured. Check the patient and make sure the patient is not in contact with ungrounded electrical device.
SpO_2 No Pulse	The EP30 docking failed to obtain pulse signal.	Check the patient's condition and change the sensor application site. If the error persists, replace the sensor and re-pair the equipment.

Symptom	Possible Cause	Attemptable Solution
"SpO2 sensor off" is displayed when the sensor is properly applied.	The SpO_2 sensor or cable failed.	Contact the service personnel.
The EP30 monitor does not respond.	The battery is depleted.	Disconnect the EP30 main unit and the EP30 docking. Charge the battery of the main unit with the charging station.
SpO_2 data is not displayed on CMS.	The EP30 monitor failed.	Contact the service personnel.
The AC power indicator on the charging station is off.	The charging station is not properly connected to the AC power. The charging station fails.	Connect the AC power correctly. Make sure the AC power source works normally. If the problem persists, contact the service personnel.
Charging error	The EP30 main unit or charging station failed.	Take the EP30 main unit out from the charging slot. Then re-install the EP30 main unit onto the charging slot. If the problem persists, contact the service personnel.
"NIBP Cuff or Airway Leak" is displayed on ePM.	Check the NIBP cuff and pump is leaking.	Check the NIBP cuff and pump for leakages. If there is leakage, replace the cuff. If the alarm persists, contact your service personnel.
"NIBP Airway Error" is displayed on ePM	The air tubing may be occluded.	Check the air tubing for occlusion or kinking. If the alarm persists, contact your service personnel.

7 Care and Cleaning

7.1 Care and Cleaning Introduction

This chapter describes how to clean and disinfect the EP30 main unit, ES30 ECG unit, NIBP module, receiver, charging station, charging pod and accessories. For the cleaning and disinfection of other reusable accessories, see their instructions for use.

7.2 Care and Cleaning Safety Information

WARNING

- Use only Mindray approved cleaners, disinfectants and methods listed in this chapter to clean or disinfect your equipment or accessories. Warranty does not cover damage caused by unapproved substances or methods.
- Do not mix disinfecting solutions, as hazardous gases may result.
- We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's infection control officer or epidemiologist.
- The responsible hospital or institution shall carry out all cleaning and disinfection procedures specified in this chapter.

CAUTION

- Clean and disinfect the equipment and accessories before use on a new patient.
- Never immerse any part of the equipment or accessories in liquids or allow liquid to enter the interior.
- Any contact of cleaners or disinfectants with connectors or metal parts may cause corrosion.
- Do not pour or spray any liquid directly on the equipment or accessories or permit fluid to seep into connections or openings.
- If you spill liquid on the equipment or accessories, disconnect the power supply, dry the equipment, and contact your service personnel.

- Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).
- Dilute and use the cleaners or disinfectants according to the manufacturer's instructions.
- Check the equipment after cleaning and disinfecting. If there is any sign of damage, remove it from use.

7.3 Cleaning

Clean your equipment and accessories on a regular basis. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

7.3.1 Cleaning the EP30 Main Unit, ES30 ECG Unit, NIBP Module and Accessories

To clean the EP30 main unit, ES30 ECG unit, NIBP module, and accessories, follow this procedure:

1. Disconnect the ECG leadwire, the SpO_2 sensor and the NIBP cuff from the patient.
2. Take out the mobile module from the hanging bag of the NIBP cuff.
3. Dampen a soft lint-free cloth with water or ethanol (70%). Wring excess liquid from the cloth.
4. Wipe the screen of the EP30 main unit and NIBP module.
5. Wipe the external surface of the EP30 main unit, ES30 ECG unit, NIBP module and all accessories with the damp cloth, avoiding the connectors and metal parts.
6. Dry the surface with a clean cloth. Allow the equipment air dry in a ventilated and cool place.

CAUTION

- Any contact of cleaners or disinfectants with connectors or metal parts may cause corrosion. If necessary, you can clean the connectors and metal parts with a soft cloth moistened with water or ethanol.

NOTE

- When cleaning the EP30 monitor, ECG module, and NIBP module, it is not necessary to remove all accessories.

7.3.2 Cleaning the Charging Station and Charging Pod

To clean the charging station, follow this procedure:

1. Disconnect the charging station and charging pod from the power supply. Take out the EP30 main unit, ES30 ECG unit or battery of the NIBP module from the charging slot.
2. Wipe the external surface of the charging station with a soft cloth moistened with water or ethanol (70%).
3. For the charging station, open the storage box, and wipe the inside of the storage box.
4. Wipe off all the cleaner residue with a dry cloth. Then allow the charging station or charging pod to air dry.

WARNING

- Disconnect the charging station or charging pod from the power supply before cleaning.

7.3.3 Cleaning the Receiver

To clean the receiver, follow this procedure:

1. Remove the receiver from the module rack of the ePM monitor.
2. Dampen a soft lint-free cloth with water or ethanol (70%). Wring excess liquid from the cloth.
3. Wipe the external surface of the receiver with the damp cloth, avoiding the metal parts.
4. Wipe off all the cleaner residue with a dry cloth. Then allow the receiver to air dry.

7.4 Disinfection

Disinfect the equipment and accessories as required in your hospital's servicing schedule. Cleaning the equipment and accessories before disinfecting is recommended. Always dilute and use disinfectants according to the manufacturer's instructions.

7.4.1 Disinfectants for EP30 Main Unit, ES30 ECG Unit, NIBP Module and Receiver

The following table lists approved disinfectants for the EP30 main unit, ES30 ECG unit, NIBP module and receiver:

Product Name	Product Type	Manufacturer
1-Propanol, 50%	Liquid	/
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.
CIDEXR OPA Solution	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Bleach Germicidal Wipes	Wipes	Clorox professional products company
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Clorox professional products company
Diversey Oxivir® TB Wipes	Wipes	Diversey Inc
Hydrogen peroxide, 3%	Liquid	/
Isopropanol, 70%	Liquid	/
Metrex CaviCide1™	Liquid, spray	METERX® RESEARCH
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® HB Germicidal Disposable Wipe	Wipes	PDI Inc.

Product Name	Product Type	Manufacturer
PDI Sani-Cloth® Plus Germicidal Disposable Cloth	Wipes	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Perform® Classic Concentrate OXY, 0.5%	Powder	Schülke & Mayr GmbH
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd
Sodium hypochlorite bleach, 0.5%	Liquid	/
Virex® II 256 (1:256)	Liquid	Diversey Inc
Virex® TB	Liquid, spray	Diversey Inc
HEALTH ESSENCE Disinfecting Effervescent Tablets	Tablet	Beijing ChangJiangMai Medical Science Technology Co. Ltd
Environmental Surface of Health Essence brand Disinfectant	Liquid, spray	Beijing ChangJiangMai Medical Science Technology Co. Ltd
JIAN ZHI SU Disinfectant, Double-chain Quaternary Ammonium	Liquid	Beijing ChangJiangMai Medical Science Technology Co. Ltd
DIAN'ERKANG® Surface Wipes	Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
DIAN'ERKANG® Surface Disinfectant	Liquid	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
DIAN'ERKANG® Disinfectant Spray	Liquid, spray	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Clinell® Universal Wipes	Wipes	GAMA Healthcare Ltd
Clinell ® Sporicidal Wipes	Wipes	GAMA Healthcare Ltd
Tristel Duo™	Liquid, foam	Tristel solutions Limited
Tristel Jet	Liquid, spray	Tristel solutions Limited
Tristel Fuse For Surfaces, 196ppm	Liquid	Tristel solutions Limited
Surfanios Premium, 0.25%	Liquid	ANIOS LABORATORIES
Surfa 'safe	Liquid, spray	ANIOS LABORATORIES
Wip' Anios premium	Wipes	ANIOS LABORATORIES
Aniosurf ND premium, 0.25%	Liquid	ANIOS LABORATORIES
Mikrobac® Tissues	Wipes	BODE Chemie GmbH

Product Name	Product Type	Manufacturer
Cleanisept® Wipes	Wipes	Dr. Schumacher GmbH
mikrozid® PAA Wipes	Wipes	Schülke & Mayr GmbH
mikrozid® Sensitive Wipes	Wipes	Schülke & Mayr GmbH
Ethanol, 70%	Liquid	/
Glutaraldehyde, 2%	Liquid	/
Ecolab Incidin® OxyWipe S.	Wipes	Ecolab Deutschland GmbH
Descosept® forte	Liquid	Dr. Schumacher GmbH
Descosept® AF	Liquid	Dr. Schumacher GmbH
Dismozon® plus, 0.4%	Powder	BODE Chemie GmbH
mikrozid® AF Wipes	Wipes	Schülke & Mayr GmbH
Terralin® Liquid	Liquid	Schülke & Mayr GmbH

7.4.2 Disinfectants for the Charging Station and Charging Pod

The following table lists approved disinfectants for the charging station and charging pod:

Product Name	Product Type	Manufacturer
Ethanol, 70%	Liquid	/
1-Propanol, 50%	Liquid	/
Isopropanol, 70%	Liquid	/
Sodium hypochlorite bleach, 0.5%	Liquid	/
Hydrogen peroxide, 3%	Liquid	/
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd
Descosept® forte	Liquid	Dr. Schumacher GmbH
Dismozon® plus, 0.4%	Powder	BODE Chemie GmbH
mikrozid® AF Wipes	Wipes	Schülke & Mayr GmbH
Terralin® Liquid	Liquid	Schülke & Mayr GmbH
Perform® Classic Concentrate OXY, 0.5%	Powder	Schülke & Mayr GmbH

7.4.3 Disinfectants for ES30 Docking and EP30 Docking (512ES)

The following table lists approved disinfectants for the ES30 docking and 512ES-typeEP30 docking:

Product Name	Product Type	Manufacturer
1-Propanol, 50%	Liquid	/
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.
CIDEXR OPA Solution	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Bleach Germicidal Wipes	Wipes	Clorox professional products company
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Clorox professional products company
Diversey Oxivir® TB Wipes	Wipes	Diversey Inc
Hydrogen peroxide, 3%	Liquid	/
Isopropanol, 70%	Liquid	/
Metrex CaviCide1™	Liquid, spray	METERX® RESEARCH
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® AF3 Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Bleach Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® HB Germicidal Disposable Wipe	Wipes	PDI Inc.
PDI Sani-Cloth® Plus Germicidal Disposable Cloth	Wipes	PDI Inc.
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
Rely+On™ Virkon® High Level surface Disinfectant, 1%	Powder	Antec International Ltd
Sodium hypochlorite bleach, 0.5%	Liquid	/

Product Name	Product Type	Manufacturer
Virex® II 256 (1:256)	Liquid	Diversey Inc
Virex® TB	Liquid, spray	Diversey Inc
mikrozid® sensitive liquid	Liquid	Schülke & Mayr GmbH
anios surf	Liquid, spray	ANIOS LABORATORIES
anios Surfa 'safe	Liquid, spray	ANIOS LABORATORIES
Clinell® Universal Sanitising Wipes	Wipes	GAMA Healthcare Ltd
DIAN'ERKANG® Surface Wipes	Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Environmental Surface of Health Essence brand Disinfectant	Liquid, spray	Beijing ChangJiangMai Medical Science Technology Co. Ltd
Glutaraldehyde, 2%	Liquid	/
Ethanol, 70%	Liquid	/

7.4.4 Disinfectants for EP30 Docking (512HS)

The following table lists approved disinfectants for 512HS-type EP30 docking:

Product Name	Product Type	Manufacturer
1-Propanol, 50%	Liquid	/
Alpet® D2 Surface Sanitizing Wipes	Wipes	BEST SANITIZERS INC™.
CIDEXR OPA Solution	Liquid	Gilag GmbH International Advanced Sterilization products
Clorox Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	Wipes	Clorox professional products company
Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	Wipes	Clorox professional products company
Isopropanol, 70%	Liquid	/
Metrex CaviWipes™	Wipes	METERX® RESEARCH
PDI Sani-Cloth® Plus Germicidal Disposable Wipe	Wipes	PDI Inc.

Product Name	Product Type	Manufacturer
PDI Super Sani-Cloth® Germicidal Disposable Wipe	Wipes	PDI Inc.
mikrozid® sensitive liquid	Liquid	Schülke & Mayr GmbH
DIAN'ERKANG® Surface Wipes	Wipes	Shanghai Likang Disinfectant Hi-Tech Co., Ltd
Environmental Surface of Health Essence brand Disinfectant	Liquid, spray	Beijing ChangJiangMai Medical Science Technology Co. Ltd
Glutaraldehyde, 2%	Liquid	/
Ethanol, 70%	Liquid	/

7.5 Sterilization

Do not sterilize the monitor, ECG module, NIBP module, receiver, charging station, accessories, or supplies unless otherwise specified in the instructions for use delivered with the accessories and supplies.

7.6 Impact of Improper Cleaning

Using cleaners other than those recommended may have the following impact:

- Product discoloration
- Metal part corrosion
- Brittle and breaking wires, connectors, and equipment housing
- Reduced cable and leadwire life
- Overall system performance degradation
- Equipment malfunction or failure

This page intentionally left blank.

8 Maintenance

8.1 Maintenance Introduction

Regular maintenance is essential to ensure that the equipment functions properly. This chapter contains information on periodic testing and maintenance.

8.2 Maintenance Safety Information

WARNING

- To reduce the risk of interrupting patient monitoring because of equipment failure, remove the equipment from use if the housing is broken. Contact the service personnel for further advice.
- Follow the maintenance and testing schedule or local regulations to perform testing and maintenance. Not implementing the maintenance schedule may cause equipment failure and possible health hazards.
- No modification of this equipment is allowed.
- This equipment contains no user serviceable parts.
- The safety checks or maintenance involving any disassembly of the equipment should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result.
- The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.

CAUTION

- The equipment and accessories shall not be served or maintained while in use with a patient.
- If a problem occurs to the equipment, contact the service personnel.
- Use and store the equipment within the specified temperature, humidity, and altitude ranges.
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.

- 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 Mindray.

NOTE

- If needed, contact the manufacture for circuit diagrams, component part lists, descriptions, calibration instructions, or other information concerning the repair of the equipment.

8.3 Maintenance and Testing Schedule

Follow the maintenance and testing schedule or local regulations to perform testing and maintenance. Make sure to clean and disinfect the equipment before taking any tests and maintenance.

The following table lists the maintenance and testing schedule:

Test/Maintenance Item		Recommended Frequency
Performance Tests		
Visual inspection		Every day, before first use.
Measurement module performance test and calibration		1. If you suspect that the measurement values are incorrect. 2. Follow any repairs or replacement. 3. Once every two years.
Electrical Safety Tests		
Electrical safety tests		1. After the equipment drops. 2. Once every two years.
Other Tests		
Power-on test		Before use.
Battery check	Functionality test	1. When first installed. 2. When battery is replaced.
	Performance test	Every three months or if the battery runtime reduced significantly.

8.4 Testing Methods and Procedures

Except the following maintenance tasks, all other test and maintenance tasks should be performed by Mindray-qualified service personnel only.

- Visual inspection
- Battery check

If your monitor needs a safety test and performance test, contact the service personnel.

8.4.1 Performing Visual Inspection

Visually inspect the equipment and accessories before its first used every day. If you find any signs of damage, remove your monitor from use and contact the service personnel.

Verify that the equipment and accessories meet the following requirements:

- Environment and power supply specifications are met.
- The equipment housing and display screen are free from cracks or other damage.
- The power cord of the charging station is not damaged and the insulation is in good condition.
- Connectors, plugs, and cables are not damaged or kinked.
- The screen displays normally.
- The touch button functions properly.
- The indicator on the ES30 ECG unit works normally.

8.4.2 Maintaining the Battery

The battery has a service life of five years. The performance of a rechargeable battery deteriorates over time. You should condition the batteries every three months.

If the battery is not conditioned for a prolonged time, its charge indication may not be accurate and you may wrongly evaluate the remaining battery runtime.

The operating time of the battery reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, the battery may reach its service life or malfunction. If the battery performance meets the requirement, fully charge the battery again for use or charge it to 40 – 60% for storage.

WARNING

- Do not crush, drop or puncture the battery or equipment. Mechanical abuse can lead to internal damage and internal short circuits. If a battery has been dropped or banged against a hard surface, whether damage is

externally visible or not, remove the battery from use and dispose of it properly.

- Do not open batteries, heat batteries above 60 °C, incinerate batteries, or short battery terminals. They may ignite, explode, leak or heat up, causing personal injury.

NOTE

- Battery operating time depends on equipment configuration and operation. For example, high display brightness or measuring NIBP repeatedly will shorten the battery operating time.
- Do not interrupt battery conditioning.

8.4.2.1 Conditioning the Battery of EP30 Main Unit and ES30 ECG Unit

The EP30 main unit and ES30 ECG unit are powered by embedded rechargeable lithium-Ion batteries. The performance of batteries deteriorates over time. You should condition the batteries every three months.

To condition the batteries of the EP30 main unit and ES30 ECG unit, follow this procedure:

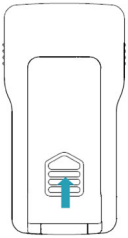
1. Disconnect the EP30 monitor and ECG module from the patient and stop all monitoring and measuring procedures.
2. Disconnect the EP30 main unit and EP30 docking, and the ES30 ECG unit and ES30 docking.
3. Install the EP30 main unit and ES30 ECG unit onto the charging slots of the charging station to charge the batteries uninterruptedly till they are fully charged.
4. Remove the EP30 main unit and ES30 ECG unit from the charging slots. Use the EP30 main unit and ES30 ECG unit till the batteries are completed depleted.
5. Fully charge the batteries again for use or charge the batteries to 40 – 60% for storage.

8.4.2.2 Conditioning the Battery of NIBP Module

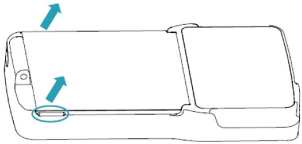
The NIBP module is powered by a replaceable rechargeable battery. The performance of batteries deteriorates over time. You should condition the batteries every three months.

To condition the battery of NIBP module, follow this procedure:

1. Disconnect the NIBP module from the patient and stop all monitoring and measuring procedures.
2. Follow the directions indicated in the following picture and remove the clip from the NIBP module.



3. Hold the protrusions on both sides of the battery and lift up the battery to remove it from the battery compartment.



4. Install the battery onto the correct charging slot of the charging station and charge the battery uninterruptedly till it is fully charged
5. Install the battery as instructed in *3.5 Installing Batteries*. Use the NIBP module till the battery is completely depleted and the NIBP module automatically shuts down.
6. Fully charge the battery again for use or charge it to 40 – 60% for storage.

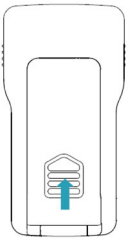
NOTE

- Do not use the monitor to monitor the patient during battery conditioning.
- Do not interrupt battery conditioning.

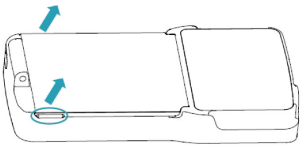
8.4.3 Replacing the Battery of NIBP Module

The battery of the NIBP module is replaceable. To replace the battery, follow this procedure:

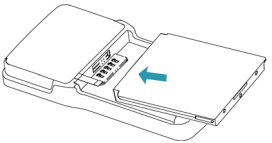
1. Follow the directions indicated in the following picture and remove the clip from the NIBP module.



2. Hold the protrusions on both sides of the battery and lift up the battery to remove it from the battery compartment.



3. Lay the NIBP module down with the battery compartment facing up.
4. Align the battery with the groove of the battery compartment.
5. Push the battery down until you hear a click.



6. Align the clip with the groove on the back of the NIBP module, and push the clip as indicated below until you hear a click.

8.4.4 NIBP Leakage Test

The NIBP leakage test checks the integrity of the system and of the valve. The NIBP leakage test should be performed once every two years or when you doubt the NIBP measurements. The NIBP leakage test should be performed by Mindray-qualified service personnel only.

8.4.5 NIBP Accuracy Test

The NIBP accuracy test should be performed once every two years or when you doubt the NIBP measurements. The NIBP accuracy test should be performed by Mindray-qualified service personnel only.

8.5 Storing Batteries

The EP30 main unit and ES30 ECG unit contain embedded batteries. The NIBP module is equipped with a replaceable battery. When storing the batteries, make sure that the battery terminals do not come into contact with metallic objects. If batteries are stored for an extended period of time, place the batteries in a cool place with a partial charge of 40% to 60% capacity.

Condition the stored batteries every three months. For more information, see *8.4.2.1 Conditioning the Battery of EP30 Main Unit and ES30 ECG Unit* and *8.4.2.2 Conditioning the Battery of NIBP Module*。

NOTE

- Storing batteries at high temperature for an extended period of time will significantly shorten their life expectancy.

- Storing batteries in a cool place can slow the aging process. Ideally the batteries should be stored at 15 °C.

8.6 Disposing of EP30 Monitor

Dispose of the monitor and its accessories when its service life is reached. Follow local regulations regarding the disposal of such products.

WARNING

- Unless otherwise specified, dispose of parts and accessories in accordance with local regulations regarding disposal of hospital waste.

9 Accessories

The accessories listed in this chapter comply with the requirements of IEC 60601-1-2 when in use with the patient monitor. The accessory material that contacts the patients has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1. For details about the accessories, refer to the instructions for use provided with the accessory.

WARNING

- Use accessories specified in this chapter. Using other accessories may cause damage to the monitor or not meet the claimed specifications.
- The accessories listed in this chapter must be used in connection with the specified equipment only. The user shall be responsible for ensuring the compatibility between the accessories and other equipment by either referring to the instructions for using the accessory or contacting us before use. Otherwise, product performance may be compromised or personal injury may occur.
- Single use accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.

CAUTION

- The accessories may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If accessory performance is degraded due to aging or environmental conditions, contact your service personnel.
- Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
- Use the accessories before the expiry date if their expiry date is indicated.
- The disposable accessories shall be disposed of according to hospital's regulations.

NOTE

- Use the accessories before the expiry date if their expiry date is indicated.

9.1 SpO_2 Accessories

Wavelength emitted by the sensors is between 600 nm and 1000 nm. The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians, for example, when photodynamic therapy is performed.

Model	Part No.	Description	Applicable patient	Application site
512RS	125-000246-00	Reusable SpO_2 sensor	Adult	Finger
512HS	125-000268-00		Pediatric	Finger
512ES	125-000269-00		Adult	Finger

9.2 ECG Accessories

9.2.1 ECG Electrodes

Model	Part No.	Description	Applicable patient
31499224	0010-10-12304	Disposable electrode, Kendall, 10 pieces/package	Adult
SF06	040-002711-00	Disposable electrode, 5 pieces/bag	Adult
SF07	040-002833-00	Disposable electrode (Intco)	Pediatric

9.2.2 ES30 Docking

Model	Part No.	Description	Length	Applicable patient
EA6431B	125-000270-00	Reusable ECG leadwires, 3-lead, AHA, snap, defibrillation-proof	1.2 m	Adult/ Pediatric
EA6433B	125-000272-00		0.42 m	
EA6432B	125-000271-00	Reusable ECG leadwires, 3-lead, IEC, snap, defibrillation-proof	1.2 m	
EA6434B	125-000273-00		0.42 m	

9.3 NIBP Accessories

Model	Part No.	Description	Limb circumference (cm)	Bladder width (cm)	Applicable patient
CM1702	115-052296-00	Reusable NIBP cuff	18 - 26	9.8	Pediatric
CM1703	115-052297-00		25 - 35	13.1	Adult
CM1704	115-052298-00		33 - 47	16.5	Large adult

9.4 Miscellaneous Accessories

Part No.	Description
115-092419-00	EP30 main unit
120-023169-00	ES30 ECG unit
120-013752-00	ePM BP20 NIBP module
120-023236-00	ePM BP20 NIBP module with CM1703 cuff (adult)
120-023237-00	ePM BP20 NIBP module with CM1704 cuff (large adult)
120-023238-00	ePM BP20 NIBP module with CM1702 cuff (pediatric)
115-092416-00	R20 receiver
125-000419-00	Wireless thermometer
115-062591-00	LP11I001E, Rechargeable lithium-Ion battery, 3.8 V, 1900 mAh, for NIBP module
DA8K-10-14454	Power cord, Europe

Part No.	Description
115-089345-00	C20 charging station (power cord, China)
115-089353-00	C20 charging station (power cord, Europe)
115-089356-00	C20 charging station (power cord, USA)
115-089361-00	C20 charging station (power cord, UK)
115-089362-00	C20 charging station (power cord, India)
115-089364-00	C20 charging station (power cord, Brazil)
115-089365-00	C20 charging station (power cord, South Africa)
115-089366-00	C20 charging station (power cord, Australia)
115-089367-00	C20 charging station (power cord, Switzerland)
115-092325-00	C25 charging pod

A Product Specifications

A.1 Safety Specifications

The monitor is classified, according to IEC 60601-1: 2020

Type of protection against electrical shock	EP30 main unit, ES30 ECG unit, NIBP module: internally powered ME equipment: Charging station: Class I Receiver: ME EQUIPMENT energized from a specific external electrical power source
Degree of protection against electrical shock	Type CF defibrillation proof for ECG, SpO_2, Resp, TEMP and NIBP
Degree of protection against harmful ingress of water	EP30 main unit: IP24 EP30 docking (512ES /512HS): IPX2 EP30 main unit connected with EP30 docking: IP22 ES30 ECG unit: IP24 NIBP module: IPX2 Charging station and Receiver: IPX1 Charging pod: IP21
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous

A.2 Environmental Specifications

Item	Temperature (°C)	Relative humidity (noncondensing) (%)	Barometric (kPa)
Operating Condition	0 to 40	15 to 95	57.0 to 107.4
Storage and transportation Condition* (EP30, ES30, R20, C20)	-20 to 60	10 to 95	16.0 to 107.4
Storage and transportation Condition (C25)	-25 to 70	10 to 95	16.0 to 107.4

*Further requirements for storage are as follows:
- Time of storage under a temperature of 45 - 60ºC: < a month at 30% of full charge.
- Time of storage under a temperature of 25 - 45ºC: < 3 months at 50% of full charge.
- Time of storage under a temperature of -20 - 25ºC: < 6 months at 50% of full charge.
- Never store the equipment under a temperature below -20ºC or above 60ºC.

NOTE

- For environmental specifications of the wireless thermometer, refer to the instructions for use of the thermometer.
- The monitor resumes normal performance in 30 minutes after being moved from storage environment to working environment in which the ambient temperature is 20 °C.
- The monitor may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges. If the performance of the equipment is degraded due to aging or environmental conditions, contact your service personnel.

A.3 Power Supply Specifications

A.3.1 Specification of EP30 Main Unit Battery

Battery type	Rechargeable lithium-Ion battery, model LI21S001G
Run time	At least 48 hours with a new and fully-charged battery when working continuously at a temperature of 25 ºC±5 ºC and at the following conditions: • The EP30 main unit is connected with an EP30 docking, and paired with an ES30 ECG unit that is connected with an ES30 docking. • The beeper is not beeping. • The screen is resting. • The EP30 monitor is in bluetooth connection with an ePM monitor and works under **Wireless Monitoring** mode in the first 8 hours and then switches to **Wearable** mode.

Run time	At least 48 hours with a new and fully-charged battery when working continuously at a temperature of 25 ºC±5 ºC and at the following conditions: • The EP30 main unit is connected with an EP30 docking, and paired with an ES30 ECG unit that is connected with an ES30 docking. • The beeper is not beeping. • The screen is resting. • The EP30 monitor is connected to CMS via Wi-Fi network and works under **Wearable** mode.
Run time	At least 36 hours with a new and fully-charged battery when working continuously at a temperature of 25 ºC±5 ºC and at the following conditions: • The EP30 main unit is connected with an EP30 docking, and paired with an ES30 ECG unit that is connected with an ES30 docking. • The beeper is not beeping. • The screen is resting. • The EP30 monitor is in bluetooth connection with an ePM monitor and works under **Wireless Monitoring** mode.
Run time	At least 48 hours with a new and fully-charged battery when working continuously at a temperature of 25 ºC±5 ºC and at the following conditions: • The EP30 main unit is connected with an EP30 docking • The beeper is not beeping. • The screen is resting. • The EP30 monitor is in bluetooth connection with mWear App • Resp measurement is sourced from SpO_2 and taken once every 30 minutes
Charge time	< 3 hours to 90% at 20 ºC±5 ºC
Shutdown delay	At least 30 minutes after the low battery indication first occurs

A.3.2 Specification of ES30 ECG Unit Battery

Battery type	Rechargeable lithium-Ion battery, model LI11S001G
Run time	At least 72 hours with a new and fully-charged battery when working at 25 ºC±5 ºC, with an ES30 docking connected, and sending data continuously to the EP30 monitor.
Charge time	< 3 hours to 90% at 20 ºC±5 ºC
Shutdown delay	At least 30 minutes after the low battery indication first occurs on EP30 monitor

A.3.3 Specification of NIBP Module Battery

Battery type	Rechargeable lithium-Ion battery, model LP11I001E
Run time	At least 600 NIBP measurements, when the NIBP module is powered by a new fully-charged battery at 25 ºC±5 ºC
Charge time	< 5 hours to 90% at 25 ºC±5 ºC
Shutdown delay	At least 30 minutes after the low battery indication first occurs

A.3.4 Power Supply Specification of the Charging Station

Input voltage	100 to 240 VAC (±10%)
Input current	1.2A to 0.6A
Frequency	50/60 Hz (± 3 Hz)

A.3.5 Power Supply Specification of the Charging Pod

Input voltage	4.5 V to 5.5 V
Input current	1 A
Output voltage	5 V ±5%

A.3.6 Power Supply Specification of the Receiver

The receiver is powered by the ePM monitor after being properly installed to the module rack.

A.4 Physical Specifications

Item	Model	Weight (g)	Dimension (H×L×D)(mm)
EP30 main unit	EP30	< 60	< 61.5 x 49 x 18
ES30 ECG unit	ES30	<31	< 46.5 x 46.5 x 12.5
NIBP module	ePM BP20	<165	< 119 x 60 x 19
Receiver	R20	<235g	< 150 x 50 x 120
Charging station	C20	<5800g	< 600 x 180 x 320
Charging pod	C25	<165g	< 154.5 x 78 x 26.5

A.4.1 Specifications of EP30 Main Unit Display

Screen type	LCD TFT screen
Screen size	1.54 inches
Resolution	240 pixels *240 pixels

A.4.2 Specifications of NIBP Module Display

Screen type	Black and white, untouchable
Screen size	2.4 inches
Resolution	208 pixels*360 pixels

A.4.3 Interfaces

Power input	Charging station: **1**, AC power input Charging pod: 1, standard USB Type-C connector
Data transmission interfaces	Bluetooth, Wi-Fi and NFC interface

A.4.4 Signal Outputs Specifications

Alarm output (on ePM monitor)	
Alarm delay time from the monitor to remote equipment	The alarm delay time measured at the monitor signal output connector from the monitor to the CMS and remote monitors: ≤2 seconds
Alarm signal sound pressure level range	45 db(A) to 85 db(A) within a range of one meter

For more information about alarms, refer to the operator's manuals of the ePM monitor and CMS.

A.5 Data Storage

Trends	Under Wi-Fi network: 8 hours Under bluetooth connection with mWear App: 24 hours

A.6 Network Specifications

A.6.1 Wi-Fi Technical Specifications

Protocol	IEEE 802.11a/b/g/n

Operating frequency	2412MHz - 2472MHz; 5180MHz - 5320MHz; 5500MHz - 5700MHz; 5745MHz - 5825MHz
Data security	Standards: WPA/WPA2-PSK, WPA/WPA2-Enterprise EAP method: EAP-TLS, PEAP-MsCHAPv2, EAP-TTLS Encryption: TKIP and AES
Modulation mode	BPSK, QPSK, 16-QAM, 64-QAM
Average output power	≤20 dBm

A.6.2 Wi-Fi Performance Specifications

WARNING

- All network functions of data communication are designed to operate on a private network.

The EP30 monitor communicates with the ePM monitor or CMS through Wi-Fi network under **Wearable** and **Continuous** modes. Via Wi-Fi network, it transmits physiological measurements and waveforms to the ePM monitor or CMS and synchronizes patient information and parameter settings from the ePM monitor or CMS.

A.6.2.1 System Capacity and Resistance to Wireless Interference

Meets the following requirements:

- None of the monitors encounter communication loss.
- The total delay of data transmission from the monitor to the ePM monitor or CMS under **Wearable** mode: ≤ 138 seconds.
- The total delay of data transmission from the monitor to the ePM monitor or CMS under **Wireless Monitoring** and **Continuous** mode: ≤ 3 seconds.
- Time to prompt upon Wi-Fi network interruption:
  - In **Wearable** mode: ≤ 150 seconds.
  - In **Wireless Monitoring** and **Continuous** mode: ≤ 14 seconds.

Testing conditions are as follows:

- Number of the EP30 monitors supported by a single AP: ≤ 16
- Each monitor can communicate with the ePM monitor or CMS.

- The weakest strength of the AP signal where the monitor is located cannot be less than -65 dBm.
- The distance between the interfering devices and the monitor is greater than 20 cm. A Wi-Fi interference (no greater than -85 dBm) in the same channel and a Wi-Fi interference (no greater than -50 dBm) in an adjacent-channel are presented synchronously. The interfering devices include, but are not limited to, 2.4GHz wireless devices, cellular mobile networks, microwave ovens, interphones, cordless phones, and ESU equipment.

A.6.2.2Wi-Fi Network Stability

There is no communication data loss when the EP30 monitor moves at a speed not higher than 3.75 m/s in a 15 meter obstacle-free linear range.

16 EP30 monitors are connected to the same AP and in any 12 of them, at least 3 monitors roam simultaneously with each roams for 30 times. The ratio of the communication data loss on the ePM monitor or CMS from any monitor does not exceed 0.1% over a 24-hour period.

A.6.2.3Line of Sight Distance

The line of sight distance between the EP30 monitor and the AP is no less than 50 meters.

A.6.3 Bluetooth Specification

Protocol	The EP30 monitor, ECG module, Receiver: Bluetooth 5 NIBP module: Bluetooth low energy 4.0
Operating frequency	2402MHz - 2480MHz
Modulation mode	GFSK
Output power	<10mW
Data security	Private

A.6.4 Bluetooth Performance Specifications

WARNING

- Keep the monitor away from interference sources.
- Do not use Bluetooth nodes to perform realtime vital signs monitoring.

A.6.4.1System Capacity and Resistance to Interference

Meets the following requirements:

- Data loss rate of bluetooth transmission: ≤ 0.1%
- Time to prompt upon bluetooth disconnection: ≤ 14 seconds
- The monitoring network must support bluetooth transmission without data loss.
- The total delay of data transmission meets the following requirements:

Work mode	From	To	Data transmission delay
Wireless Monitoring and Continuous	EP30 monitor	Receiver on ePM monitor	≤ 3 seconds
	ECG module	EP30 monitor	
Wearable	EP30 monitor	Receiver on ePM monitor	≤ 138 seconds
	ECG module	EP30 monitor	
/	NIBP module	EP30 monitor	≤ 3 seconds
	Wireless thermometer	EP30 monitor	≤ 3 seconds

Testing conditions are as follows:

- In a range of 100 m^2, there should be no more than 10 groups of paired EP30 monitors, ECG modules, NIBP modules, wireless thermometer, and receivers working simultaneously.
- The bluetooth signal strength around the EP30 monitor should be no less than -70dBm.
- The distance between the interfering devices and the EP30 monitor is greater than 20 cm. The interfering devices include 2.4 GHz Wi-Fi devices, cellular mobile networks, microwave ovens, intercoms, and cordless phones.

A.6.4.2Line of Sight Distance

Paired Devices	Line of Sight Distance
EP30 monitor and Receiver on ePM monitor	No less than 7 m
EP30 monitor and the ECG module	No less than 1.5 m
EP30 monitor and the NIBP module	No less than 1.5 m

Paired Devices	Line of Sight Distance
EP30 monitor and the wireless thermometer	No less than 1.5 m

A.6.5 NFC Specification

Protocol	The EP30 monitor, Receiver: ISO/IEC 14443 A; ISO/IEC 14443 B ECG module, NIBP module: ISO/IEC 14443 A
Working mode	The EP30 monitor, Receiver: READER, CARD, P2P ECG module, NIBP module: CARD
Operating frequency	13.56 MHz
Modulation mode	ASK (EP30 monitor, Receiver)
Data security	Private

A.7 Measurement Specifications

Items marked with an asterisk symbol "*" are applicable only when the EP30 monitor is in bluetooth connection with an ePM monitor. Items marked with two asterisk symbols "**" are applicable if the EP30 monitor is used with an ePM monitor or CMS or both.

A.7.1 ECG Specifications

ECG	
Standards*	Meet standard of IEC 60601-2-27: 2011
Lead set	I, II, III
ECG standard	AHA, IEC
Display sensitivity**	With ±800 mV direct current polarization voltage, the sensitivity change is within ±5% The sensitivity change is ≤3% after 1 minute and 1 hour since the monitor starts up. 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/mV (×4), Auto, less than 5% error
Sweep speed**	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s, less than 5% error
Bandwidth	ST mode*: 0.05 to 40 Hz (+0.4dB-3.0dB) Monitor mode**: 0.5 to 40 Hz Surgical mode*: 1 to 20 Hz (+0.4dB-3.0dB)

Notch filter	50/60 Hz, Monitor**, surgical*, and ST mode*: notch filter turns on Interference rejection: ≥ 20 dB
Common mode rejection ratio	ST mode*, Monitor mode**, Surgical mode*: >105 dB (with notch filter on)
Electrode offset potential tolerance	±800 mV
Lead-off detection current	Measuring electrode: < 0.1 μA Drive electrode: < 1 μA Sine wave <300 μA RMS, 32 kHz (±10%)
Input signal range**	±10 mV (peak-to-peak value)
Differential input impedance**	≥5 MΩ
Defibrillation protection**	Enduring 5000V (360 J) charge without data loss or corruption Baseline recovery time: <5 s (after defibrillation) Polarization recovery time: <10 s Defibrillation energy absorption: ≤10% (100Ω load)
Pace pulse rejection**	When tested in accordance with the IEC 60601-2-27: 2011: 201.12.1.101.13, the heart rate meter rejects all pulses meeting the following conditions. Amplitude: ±2 to ±700 mV Width: 0.1 to 2 ms Rise time: 10 to 100 μs No overshoot The slew rate of ES30 is 1.8 V/s±15%

HR	
Measurement range	Pediatric: 15 to 350 bpm Adult: 15 to 300 bpm
Accuracy	±1 bpm or ±1%, whichever is greater.
Resolution	1 bpm

HR averaging method	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 3) of IEC 60601-2-27: 2011, the following method is used: If the last 3 consecutive RR intervals are greater than 1200 ms, the 4 most recent RR intervals are averaged to compute the HR. Otherwise, heart rate is computed by subtracting the maximum and minimum ones from the most recent 12 RR intervals and then averaging them. The HR value displayed on the monitor screen is updated no more than one second.
Response to irregular rhythm	In compliance with the requirements in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27: 2011, the heart rate after 20 seconds of stabilization is displayed as follows: Ventricular bigeminy (waveform A1): 80±1 bpm Slow alternating ventricular bigeminy (waveform A2): 60±1 bpm Rapid alternating ventricular bigeminy (waveform A3): 120±1 bpm Bidirectional systoles (waveform A4): 90±2 bpm
Response time to heart rate change	Meets the requirements of IEC 60601-2-27: 2011: Clause 201.7.9.2.9.101 b) 5). From 80 to 120 bpm: less than 11 s From 80 to 40 bpm: less than 11 s
Time to alarm for tachycardia**	Meets the requirements in Clause 201.7.9.2.9.101 b) 6) of IEC 60601-2-27: 2011. Waveform B1h-range: <11 s B1-range: <11 s B1d-range: <11 s B2h-range: <11 s B2-range: <11 s B2d-range: <11 s
Tall T-wave rejection capability	When the test is performed based on Clause 201.12.1.101.17 of IEC 60601-2-27: 2011, the heart rate calculation is not affected for QRS of 1 mV amplitude and 100 ms duration, T-wave duration of 180 ms and amplitude lower than 1.2 mV, and QT interval of 350 ms.

Alarm limit (on ePM monitor or CMS)	**Range**	**Step**

HR High	HR ≤ 40 bpm: (low limit + 2 bpm) to 40 bpm HR > 40 bpm: (low limit + 5 bpm) to 295 bpm	HR ≤ 40bpm: 1 bpm HR > 40 bpm: 5 bpm
HR Low	HR ≤ 40 bpm: 16 bpm to (high limit - 2 bpm) HR > 40 bpm: 40 bpm to (high limit - 5 bpm)	

A.7.2 Resp Specifications

Lead**	Options are lead I and Lead II	
RR (Respiration Rate)		
Measurement range	0 to 200 rpm	
Accuracy	0 to 120 rpm: ±1 rpm 121 to 200 rpm: ±2 rpm	
Resolution	1 rpm	
Recovery time**	<15 s (after defibrillation)	
Alarm limit (on ePM monitor or CMS)	**Range (rpm)**	**Step (rpm)**
RR High	RR ≤ 20: (low limit + 2) to 20 RR > 20: (low limit + 5) to 100	RR ≤ 20: 1 RR > 20: 5
RR Low	RR ≤ 20: 0 to (high limit - 2) RR > 20: 20 to (high limit - 5)	

A.7.3 SpO_2 Specifications

Standards**	Meet standard of ISO 80601-2-61: 2017
*Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	
Measurement range	0 to 100%
Resolution	1%
Accuracy[1]	70% to 100%: • ±2% (measured without motion) • ±3% (measured with motion)[2] 0% to 69%: Not specified.

Refreshing rate	≤ 2 s (under **Wireless Monitoring** or **Continuous** mode)
Response time	< 30 s (normal perfusion, no disturbance, PR value at 75 bpm, SpO_2 value sudden changes from 70% to 100%)
Recovery time**	<15 s (after defibrillation)
PI (On ePM monitor or CMS)	
Measurement range	0.05% to 20%
Resolution	0.05% to 9.99% range: 0.01% 10.0% to 20.0% range: 0.1%

[1]. The SpO_2 accuracy has been verified in human experiments on healthy adult subjects of different skin colors (from dark to light) and genders (both male and female).

[2]. The SpO_2 accuracy under conditions of motion has been verified in hypoxia experiments on healthy adult subjects, using a pulse oximeter and ECG monitor and covering an SpO_2 measurement range of 70% to 100%. There are two modes of motion:

Mode I: Repetitive movements (rubbering and tapping) at the frequency of 2 to 4 Hz and amplitude of 1 to 2 cm;

Mode II: Irregular movements at the frequency of 1 to 5 Hz and amplitude of 2 to 3 cm.

Alarm limit (on ePM monitor or CMS)	**Range (%)**	**Step (%)**
SpO_2 High	(low limit + 2) to 100	1
SpO_2 Low	(Desat+1) to (high limit - 2)	
SpO_2 Desat Low	0 to (high limit - 1)	

A.7.4 PR Specification

PR from EP30 Monitor

Measurement range	20 bpm to 300 bpm
Resolution	1 bpm
Accuracy	±2 bpm (measured without motion) ±4 bpm (measured with motion)

Response time	<30 s (normal perfusion, no disturbance, SpO_2 value at 98%, PR value sudden changes from 25 to 220bpm)

PR from NIBP Module**

Measurement range	30 bpm to300 bpm
Resolution	1 bpm
Accuracy	±3bpm or ±3%, whichever is greater

Alarm limit (on ePM monitor or CMS)	**Range (bpm)**	**Step (bpm)**
PR High	PR≤ 40: (low limit + 2) to 40 PR > 40: (low limit + 5) to 295	PR≤ 40: 1 PR>40: 5
PR Low	PR≤ 40: 16 to (high limit - 2) PR > 40: 40 to (high limit - 5)	

A.7.5 NIBP Specifications

Standard*	Meet standard of IEC 80601-2-30: 2018		
Mode of operation**	Manual, Auto, STAT, Sequence		
Auto mode repetition intervals**	1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180, 240 or 480 min		
Static pressure measurement range	0 mmHg to 300 mmHg		
Static pressure measurement accuracy	±3 mmHg		
Measurement ranges (mmHg)		**Adult**	**Pediatric**
	Systolic:	25 to 290	25 to 240
	Diastolic:	10 to 250	10 to 200
	Mean:	15 to 260	15 to 215
Accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg		
Resolution	1mmHg		
Initial cuff inflation pressure range (mmHg)**	Adult: 80 to 280 Pediatric: 80 to 210		
Software overpressure protection	Adult/Pediatric: 297±3 mmHg		

Recovery time	<15 s (after defibrillation)

*Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the Standard for Non-invasive sphygmomanometers (ISO 81060-2) in terms of mean error and standard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5th Korotkoff sound was used to determine the diastolic pressure.

Alarm limit (on ePM monitor or CMS)	**Range (mmHg)**	**Step (mmHg)**
NIBP-S High	Adult: (low limit + 5) to 290 Pediatric: (low limit + 5) to 240	NIBP ≤ 50: 1 NIBP > 50: 5
NIBP-S Low	25 to (high limit - 5)	
NIBP-M High	Adult: (low limit + 5) to 260 Pediatric: (low limit + 5) to 215	
NIBP-M Low	15 to (high limit - 5)	
NIBP-D High	Adult: (low limit + 5) to 250 Pediatric: (low limit + 5) to 200	
NIBP-D Low	10 to (high limit - 5)	

A.7.6 TEMP Specifications (Wireless Thermometer)

Standard**	Meet the standard of ISO 80601-2-56: 2017/Amd 1: 2018
Measurement range	25 to 45 ℃ (77 to 113 ℉)
Resolution	0.1℃ (±0.2 ℉)
Accuracy	±0.1 ℃ or ±0.2 ℉
Minimum time for accurate measurement	<150s under rapid temperature change
Recovery time	<15 s (after defibrillation)

Alarm limit (on ePM monitor or CMS)	**Range (°C)**	**Step (°C)**
Temp High	(low limit +1.0) to 50.0	0.1
Temp Low	0.1 to (high limit - 1.0)	

This page intentionally left blank.

B EMC and Radio Regulatory Compliance

B.1 EMC

The device meets the requirements of IEC 60601-1-2: 2014.

WARNING

- Use of accessories, transducers, adapter and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM may be disrupted by the electromagnetic interference of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the non-ME EQUIPMENT or shielding the location.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- This device is intended for use in home healthcare environment and professional healthcare facility environment only. If it is used in special environment, such as magnetic resonance imaging environment, the equipment/system may be disrupted by the operation of nearby equipment.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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**
Conducted and radiated 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.
Conducted and radiated RF EMISSIONS CISPR 11	Class B	The devices (the EP30 monitor, ECG module, NIBP module, charging pod) are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Conducted and radiated RF EMISSIONS CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic distortion IEC 61000-3-2	Class A	The devices (the EP30 monitor, ECG module, NIBP module, charging pod) are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations/ Flicker EMISSIONS IEC 61000-3-3	Complies	

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:

- Display
- Operating mode
- Accuracy
- Accessories identification
- Alarm
- Data stored
- Network connection and data transmission

NOTE

- If the essential performance is lost or degraded, it may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location or stopping using the monitor and contact the service personnel.
- 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.
- The EMISSIONS characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the device.

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	±8 kV contact ±15 kV air	±8 kV contact ±15 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 (length greater than 3 m)	±2 kV for power supply lines ±1 kV for input/ output lines (length greater than 3 m)	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	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips and voltage interruptions IEC 61000-4-11	0% U_T for 0.5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles 0% U_T for 250/ 300 cycle	0% U_T for 0.5 cycle 0% U_T for 1 cycle and 70% U_T for 25/30 cycles: 0% U_T for 250/ 300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz	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 disturbances induced by RF fields 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: $d = 1.2\sqrt{P}$
	6 Vrms in ISM bands and amateur radio bands[a] between 0,15 MHz and 80 MHz	6 Vrms	
Radiated RF EM fields IEC61000-4-3	3 V/m 10V/m (EP30/ ECG module/ NIBP module/ charging pod) 80 MHz to 2.7 GHz	3V/m 10V/m (EP30/ ECG module/ NIBP module/ charging pod)	Recommended separation distances: 80 MHz to 800 MHz: $d = 1.2\sqrt{P}$ 800MHz - 2.7GHz: $d = 2.3\sqrt{P}$ 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]. 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]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment IEC61000- 4-3	27 V/m 380–390 MHz	27 V/m	
	28 V/m 430–470 MHz, 800–960 MHz, 1700–1990 MHz, 2400–2570 MHz	28 V/m	
	9 V/m 704–787 MHz, 5100–5800 MHz	9 V/m	

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.

EMC adapter information
Power adapter (Model: MANGO18SC-05; Cable length: 3.0m; Unshielded)
Note: Select the above typical accessories for EMC verification.

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.

WARNING

- The device is configured with a wireless network connector to receive wireless signal. Other devices may interfere with this device even though they meet the requirements of CISPR.

Recommended separation distances between portable and mobile RF communications equipment and this equipment

This equipment 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 of transmitter (W)	**Separation distance in meters (m) according to frequency of the transmitter**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 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.

B.2 Radio Regulatory Compliance

The radio device used in this product is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU.

This page intentionally left blank.

C Default Settings

Item		Default Setting
Unit	SpO2	%
	PR	bpm
	HR	bpm
	NIBP	mmHg
	RR	rpm
	Temp	℃
Patient Category		Adult
Lead (ECG)		II
Interval (NIBP)		60 min
Initial Pressure (NIBP)		160mmHg
Start Mode (NIBP)		Clock
NIBP Measurement Mode		Auto
Sensitivity (SpO_2)		Med
Resp Lead		Auto
Filter Mode		Monitor

This page intentionally left blank.

D Messages and Solutions

This chapter lists the technical messages that may occur on the EP30 monitor, NIBP module and ePM monitor. If you encounter problems when performing the mobile monitoring, check the table below before requesting for services. If the problem persists after you have taken corrective actions, contact your service personnel.

Alarm messages are displayed on the ePM monitor and CMS. For details, refer to the operator's manuals of the ePM monitor and CMS.

D.1 Technical Messages on the EP30 Main Unit

Message	Possible cause and solutions
Module Error	Error occurred on the EP30 main unit. Disconnect the monitor and the EP30 docking and then install it onto a correct charging slot on the charging station. Wait for a few minutes, remove the EP30 main unit from the charging station and connect it with the EP30 docking.
ES Module Error	Error occurred on the ES30 ECG unit. Disconnect the ES30 ECG unit and the ES30 docking and then install it onto a correct charging slot on the charging station. Wait for a few minutes, remove the ES30 ECG unit from the changing station and connect it with the ES30 docking.
IP Address Conflict	Wireless network IP network conflicts. Check the network settings.
	Pairing with the ePM monitor failed. Check the connection between the EP30 main unit and the EP30 docking and the installation of receiver. Reconnect them properly and try pairing again.
	Pairing with the ECG module failed. Check the connection between the EP30 main unit and the EP30 docking and between the ES30 ECG unit and ES30 docking. Reconnect them properly and try pairing again.
	Pairing with the NIBP module failed. Check the connection between the EP30 main unit and the EP30 docking. Reconnect them properly and try pairing again.

Message	Possible cause and solutions
	One or more of the electrodes have fallen off from the patient. Check the connection of the electrodes.
	The SpO_2 sensor has fallen off from the patient. Check the connection and application of the sensor. If the message persists, replace the EP30 docking.

D.2 Technical Messages on the NIBP Module

Message	Possible cause and solutions
Pair with ECG Pod	The NIBP module is not paired with an EP30 monitor. You need to pair the NIBP module with EP30 monitor. For details, refer to *3.8.2 Pairing the EP30 Monitor with an NIBP Module*.
Paired successfully	The NIBP module and the EP30 monitor are paired successfully.
NIBP Measure Failed	■ There is a leak in the cuff or air tubing. Use a cuff of correct type based on the patient size. Apply the cuff and connect the air tubing as instructed in the manual. ■ The measured NIBP value exceeds the measurement range. Check the patient's condition. ■ Check the patient's condition and reduce patient motion.
System is shutting down…	The NIBP module shuts down.

D.3 Technical Messages on the ePM Monitor

Message	Possible cause and solutions
Receiver Error	The receiver does not work properly. Replug the receiver.
mWear Disconnected	The EP30 monitor is powered off for depleting of battery charge or moved out of the network coverage. Charge the battery, or move the monitor back to network covered area.
Patient Left the Room	The patient wearing the EP30 monitor has moved out of allowable range for bluetooth connection. The EP30 monitor will connect with the ePM monitor via Wi-Fi network.

Message	Possible cause and solutions
EP Low Battery	The battery of EP30 main unit is low. Charge the battery.
EP Battery Depleted	The battery of EP30 main unit is almost depleted. Charge the battery immediately.
EP Battery Error	The battery of EP30 main unit failed. Contact the service personnel.
EP Battery Service Required	The battery of EP30 main unit reaches its lifetime. Contact the service personnel.
ES Disconnected	The ECG module lost bluetooth connection with the EP30 monitor. Check the monitor and ECG module. If needed, re-pair them.
mWear Module Error	Error occurred on the EP30 monitor. Disconnect the EP30 main unit and the EP30 docking and then install it onto a correct charging slot on the charging station. Wait for a few minutes, remove the EP30 main unit from the charging station and connect it with the EP30 docking.
ES Module Error	Error occurred on the ECG module. Disconnect the ES30 ECG unit and the ES30 docking and then install it onto a correct charging slot on the charging station. Wait for a few minutes, remove the ES30 ECG unit from the charging station and connect it with the ES30 docking.
Recommended to take NIBP measurement	The blood pressure measurements of the patient change irregularly. Take NIBP measurement on the patient promptly.
NIBP Pod Error	Error occurred on the NIBP module. Restart the module.
NIBP Pod Low Battery	The battery of the NIBP module is low. Replace the battery.
NIBP Pod Battery Depleted	The battery of the NIBP module is almost depleted. Replace the battery immediately.
NIBP Pod Battery Error	The battery of the NIBP module encounters communication error. Replace the battery.
NIBP Pod Battery Service Required	The battery of the NIBP module reaches its lifetime. Replace the battery.
NIBP Pod Battery Temperature Too High	The battery temperature of the NIBP module is high. Replace the battery.

Message	Possible cause and solutions
RR Interference	The SpO_2 signal has been interfered. Check the patient for excessive motion. Make sure the SpO_2 sensor is properly applied to the patient and that the patient is at rest state.
RR Weak Signal. Measurement Failed.	The SpO_2 sensor is not properly placed or the patient's perfusion index is too low. Check the sensor and make sure the SpO_2 sensor is properly applied to the patient. Reposition the sensor if necessary.

E Terminology

Abbreviation	In Full
℃	centigrade
℉	Fahrenheit
Ω	ohm
A	ampere
Ah	ampere hour
AC	alternating current
ADT	Admit/Discharge/Transfer
Adu	adult
bpm	beat per minute
CE	Conformité Européenne
cm	centimeter
CMS	central monitoring system
DC	direct current
Dia	diastolic
ECG	electrocardiograph
EEC	European Economic Community
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EMR	Electronic Medical Record
h	hour
Hz	hertz
IABP	intra-aortic balloon pump
ID	identification
IEC	International Electrotechnical Commission
ISO	International organization for standardization
IEEE	Institute of Electrical and Electronic Engineers

Abbreviation	In Full
IP	internet protocol
k	kilo
kg	kilogram
kPa	kilopascal
LA	left arm
LCD	liquid crystal display
LL	left leg
m	meter
mAh	milliampere hour
MDD	Medical Device Directive
MetHb	methemoglobin
min	minute
mm	millimeter
mmHg	millimeters of mercury
MRI	magnetic resonance imaging
ms	millisecond
mV	millivolt
NIBP	noninvasive blood pressure
NIBP-Dia	NIBP-diastolic pressure
NIBP-Mean	NIBP-mean pressure
NIBP-Sys	NIBP-systolic pressure
P	power
PD	photodetector
Ped	pediatric
Pleth	plethysmogram
PR	pulse rate
RA	right arm
s	second
SpO_2	arterial oxygen saturation from pulse oximetry
Sys	systolic pressure

Abbreviation	In Full
TEMP	temperature
V	volt
VA	volt ampere
VAC	volts alternating current
W	watt

This page intentionally left blank.

Declaration of Conformity V1.0

Declaration of Conformity

CE 0123

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
Manufacturer SRN:	/
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Wearable patient monitor
Model:	EP30
Basic UDI-DI:	69449040AB0100001235
Classification:	IIb (According to Rule 10 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
GMDN code:	33586
CND code:	Z120302
Intended purpose:	It is intended for monitoring, displaying, and transferring of multiple physiological parameters

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS:	/
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	/
Start of CE-Marking:	2022.09.07

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.

Place, Date of Issue: Shenzhen, 2022.9.7

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Deputy Director, Technical Regulation

This page intentionally left blank.

P/N: 046-024386-00 (5.0)