iT20

Telemetry Transmitter

Version 1.4

User Manual

CE 0123

EDAN

About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Upon request, EDAN may provide, with compensation, necessary circuit diagrams, and other information to help qualified technician to maintain and repair some parts, which EDAN may define as user serviceable.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

Telemetry transmitter (hereinafter called iT20) must work with central monitoring system (hereinafter called MFM-CMS) manufactured by EDAN.

Telemetry transmitter is intended to be used in clinical divisions of hospital environments, including CCU and general wards (as Cardiology Dept., Respiratory Dept.). It is intended to be used for adults and pediatrics. The monitored physiological parameters include: ECG, respiration (RESP), oxygen saturation of arterial blood (SpO_2) and pulse rate (PR).

1.2 Safety Guidance

Federal (U.S.) law restricts this device to sale by or on the order of a physician.

WARNING

1 Before using the device, the equipment, patient cable and electrodes etc. should be checked. Replacement shall be taken if there is any evident defect or signs of aging which may impair the safety or performance.

2 The electrodes expired are forbidden to be used.

3 Medical technical equipment such as telemetry monitoring system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly. The user should have access to, and fully read user manual (this book) before use. Harm to patient may occur if users' operating is not in accordance with user manual.

4 The Minors should be under supervision of their custodians to wear and use. Minors damaging/ biting the device, and minors taking batteries out or taking batteries into mouth, are prohibited.

5 ECG cables, SpO_2 sensors and cables are not intended to be contacted continuously with body over 24 Hours.

6 It is prohibited that the operator touches battery and patient simultaneously.

7 Do not use the device with electrosurgical unit simultaneously.

8 EXPLOSION HAZARD-Do not use the device in a flammable atmosphere where concentrations of flammable anesthetics or other materials may occur.

9 SHOCK HAZARD-To avoid the RISK of electric shock, MFM-CMS must only be connected to a SUPPLY MAINS with protective earth. Never adapt the three-prong plug from the MFM-CMS to fit a two-slot outlet.

10 Under simultaneous use of cardiac pacemaker and other patient-connected equipment, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected or could lead to false alarm of asystole.

WARNING

11 Do not come into contact with the patient, table, or the telemetry transmitter during defibrillation.

12 Extreme care must be exercised when applying medical electrical equipment. Many parts of the human/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

13 Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the telemetry transmitter comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

14 Route all cables away from patient’s throat to avoid possible strangulation.

15 Two batteries must be used as power supply.

16 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

17 Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards. Furthermore all configurations shall comply with the valid version of the standard IEC/EN 60601-1. Therefore anybody, who connects additional equipment to the signal input or output connector to configure a medical system, must make sure that it complies with the requirements of the valid version of the system standard IEC/EN60601-1. If in doubt, consult our technical service department or your local distributor.

18 Telemetry transmitter is connected to MFM-CMS via wireless network. Therefore, any other equipment complying with CISPR radiation requirements may also interfere with the wireless communication and make it interrupted.

19 Telemetry transmitter will sent technical alarm information of low battery power to MFM-CMS informing user of changing battery when battery power is 0-level. Meanwhile, telemetry transmitter gives out a periodic sound of “du-du-du” whose interval is 10 seconds till shutdown. After shutdown, module configuration and patient information can be saved. User should restart the device after changing battery.

20 Clinical decision making based on the output of the device is left to the discretion of the provider.

WARNING

21 Only use patient cable and other accessories supplied by EDAN. The performance and electric shock protection cannot be guaranteed, and the patient may be injured otherwise. Prior to use, check if the casing of a disposable or sterilized accessory is intact. Do not use it if its casing is damaged.

22 Wireless LAN equipment contains an intentional RF radiator that has the potential of interfering with other medical equipment, including patient implanted devices. Be sure to perform the electromagnetic compatibility test, as described in the Wireless LAN System Installation, before installation and any time new medical equipment is added to the Wireless LAN coverage area.

23 When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.

24 If multiple instruments are connected to a patient, the sum of the leakage currents must not exceed the limits; or it may result in shock hazard.

25 During monitoring, if the power supply is off and there is no battery for standby, the telemetry transmitter will be off. Last settings used will be recovered when the power is restored.

26 When leakage or foul odor is detected，stop using and keep away from fire immediately.

27 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. Inappropriate disposals of waste may contaminate the environment. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

28 The packaging is to be disposed of according to local or hospital’s regulations; otherwise, it may cause environmental contamination. Place the packaging at the place which is inaccessible to children.

29 After defibrillation, the ECG display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers’ instructions.

30 When deploying wireless network, hospital should make sure that clinicians have acknowledged and familiarized the coverage of wireless network signal. Patients’ activity must be within that range.

31 This equipment is not intended for home usage.

32 Do not service or maintain the telemetry transmitter or any accessories during patient monitoring.

WARNING

33 The 30-meter indoor barrier-free distance of distinct vision is the coverage of wireless network connecting telemetry transmitter and MFM-CMS. Telemetry transmitter is 30 meters (distinct vision) from wireless AP.

34 Only nurse call can be operated by user. Other functions are all prohibited for patient to operate.

35 Leather cover is used for wearing telemetry transmitter. There should be clothing between leather cover and skin. Direct contact between telemetry transmitter/ leather cover and body is prohibited.

36 Operation of the equipment exceeding the measurement range may cause inaccurate results.

37 Portable and mobile RF communications equipment can affect medical electrical equipment; Refer to the recommended separation distances provided in Appendix B EMC Information.

38 Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of telemetry transmitter.

39 Telemetry transmitter should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you must check that normal operation is possible in the necessary configuration before you start monitoring patients.

40 Assembly of the telemetry transmitter and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

41 Connecting any accessory (such as external printer) or other device (such as the computer) to MFM-CMS makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

42 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

43 Additional multiple socket-outlet or extension cord can’t be connected to the system.

44 Only items that have been specified as part of the system or specified as being compatible with the system can be connected to the system.

45 The appliance coupler or mains plug is used as isolation means from supply mains. Position the MFM-CMS in a location where the operator can easily access the disconnection device.

WARNING

46 Do not touch accessible parts of electrical equipment in the patient environment and the patient simultaneously.

47 SHOCK HAZARD - Don't connect electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer.

48 The telemetry transmitter is intended for use by trained healthcare professionals in hospital environments.

49 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.

50 Only use EDAN approved batteries for telemetry transmitter.

CAUTION

1 Electromagnetic Interference - Ensure that the environment in which the system is installed is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.

2 Keep the environment clean. Avoid vibration. Keep it far away from corrosive medicine, dust area, high temperature and humid environment.

3 Do not immerse transducers in liquid. When using solutions, use sterile wipes to avoid pouring fluids directly on the transducer.

4 Do not sterilize telemetry transmitter or any accessories.

5 The device and reusable accessories may be sent back to the manufacturer for recycling or proper disposal after their useful lives.

6 Remove a battery from the telemetry transmitter immediately if battery life cycle has expired or it is not used for a long time.

7 Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.

8 Avoid liquid splashing on the device.

9 To ensure patient safety, use only parts and accessories manufactured or recommended by EDAN.

10 Before connecting the system to the AC power, make sure the voltage and the power frequency are consistent with the requirements indicated on the device label or in this user manual.

11 Protect the device against mechanical damage resulting from gravitation, collision, powerful vibration and so on.

12 Do not touch the touch screen with a sharp object.

13 A drafty environment for system installation is required.

NOTE：

1 Position the device in a proper location that is stable and not easy to fall or shake.

2 The telemetry transmitter can only be used on one patient at a time.

3 If the telemetry transmitter gets damp or liquid pours on it, please contact the service personnel of EDAN.

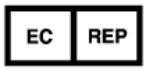
4 This telemetry transmitter is not a device for treatment purposes.

5 The pictures and interfaces in this manual are for reference only.

6 Regular preventive maintenance should be carried out every two years. You are responsible for any requirements specific to your country.

1.3 Explanation of Symbols on the Telemetry transmitter

1		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
2		Caution
3		Operating instructions
4		Refer to User Manual (Background: Blue; Symbol: White)
5		Non- ionizing electromagnetic radiation
6	IPX7	Ingress Protection: IPX7 (protected against ingress of water with harmful effects: temporary immersion)
7		Warning (Background: Yellow; Symbol & outline: black)
8		Power Supply switch
9	SN	SERIAL NUMBER
10		Trend
11		Picture freeze
12	CE 0123	CE marking

13		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
14		Date of manufacture
15		MANUFACTURER
16	P/N	Part Number
17		General symbol for recovery/recyclable
18		Disposal method
19	Rx Only	Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

NOTE:

The user manual is printed in black and white.

Chapter 2 Overview

2.1 System Introduction

Telemetry monitoring system (iT20&MFM-CMS) can realize an integrated monitoring for multiple mobile patients or bed patients via wireless network. It is easy for extending and net deploying. Among the system, telemetry transmitter owns small size, light weight and long battery life and works with MFM-CMS to form an integrated monitoring solution.

The detailed operation instructions of MFM-CMS refer to *MFM-CMS Central Monitoring System User Manual.*

You may frequently use the following functions:

- ECG monitoring (Refer to Chapter*Monitoring ECG* for details)
- SpO_2 monitoring (Refer to Chapter *Monitoring SpO_2* for details)
- PR monitoring (Refer to Chapter*Monitoring PR* for details)
- RESP monitoring (Refer to Chapter *Monitoring RESP* for details)
- Alarm Management (Refer to Chapter *Alarm Management* for details)

2.2 Display Screen of Telemetry Transmitter

The display screen of telemetry transmitter is associated with the parameters' configuration customer bought.

2.2.1 Default Interface

The default interface has two parts: Information Area and Parameter Value Area. Under parameters on, the symbol **?** will be displayed in parameter value area if measuring is not implemented or the measured value is invalid. The default interface with three parameters on is as follow:

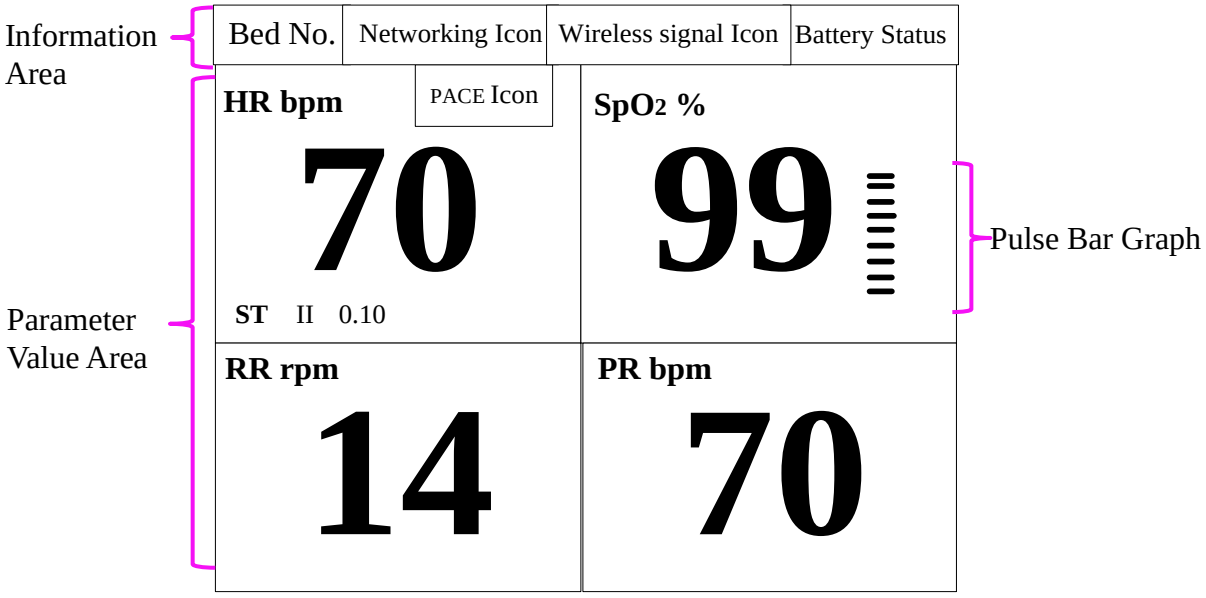


Figure 2-1 ECG + SpO_2 + RESP Default Interface (ST on)

2.2.2 Main Interface

Main interface has two kinds: Waveform Main Interface and Trend Graph Main Interface.

- Waveform Main Interface

1. ECG Interface: includes information area, ECG value of calculated lead and corresponding wave.

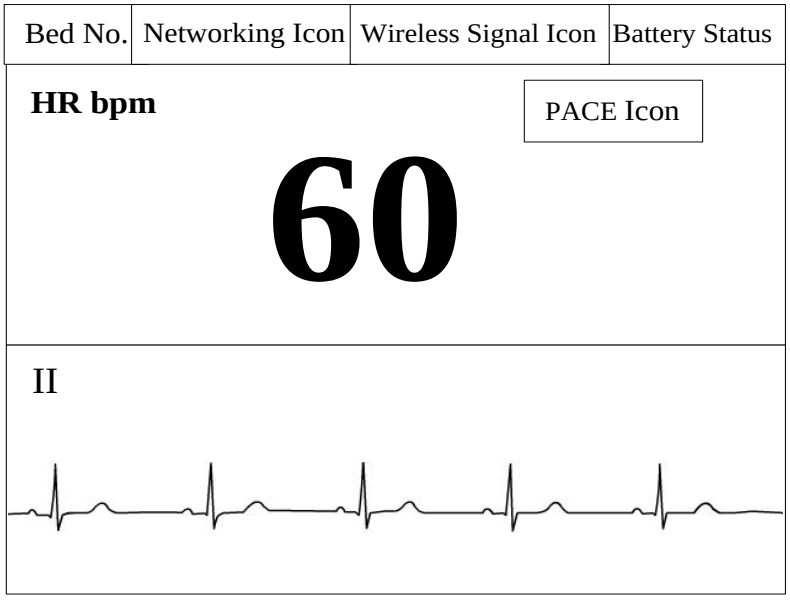


Figure 2-2 ECG Interface (ST off)

2. SpO_2 Interface: includes information area, SpO_2 value, PR value and PLETH wave.

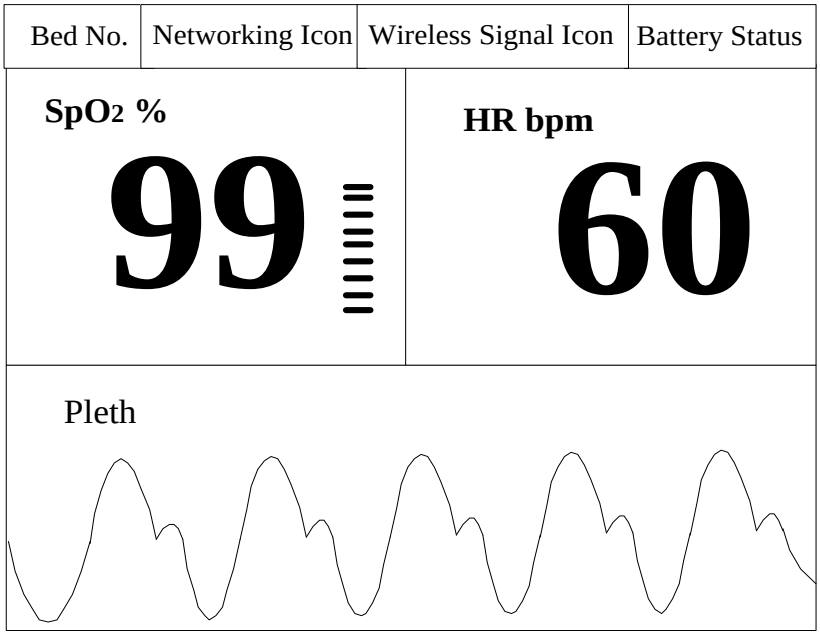


Figure 2-3 SpO_2 & PR Interface

3. ECG&SpO_2 Interface: includes information area, ECG value of calculated lead, SpO_2 value and ECG wave.

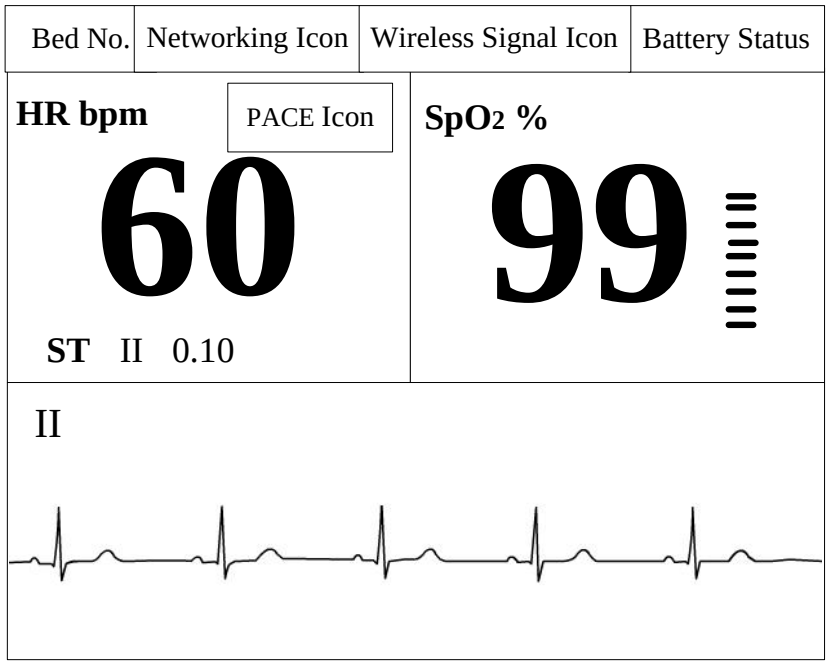


Figure 2-4 ECG & SpO_2 Interface (ST on)

4. ECG&RESP Interface: includes information area, ECG value of calculated lead, RR value and ECG wave.

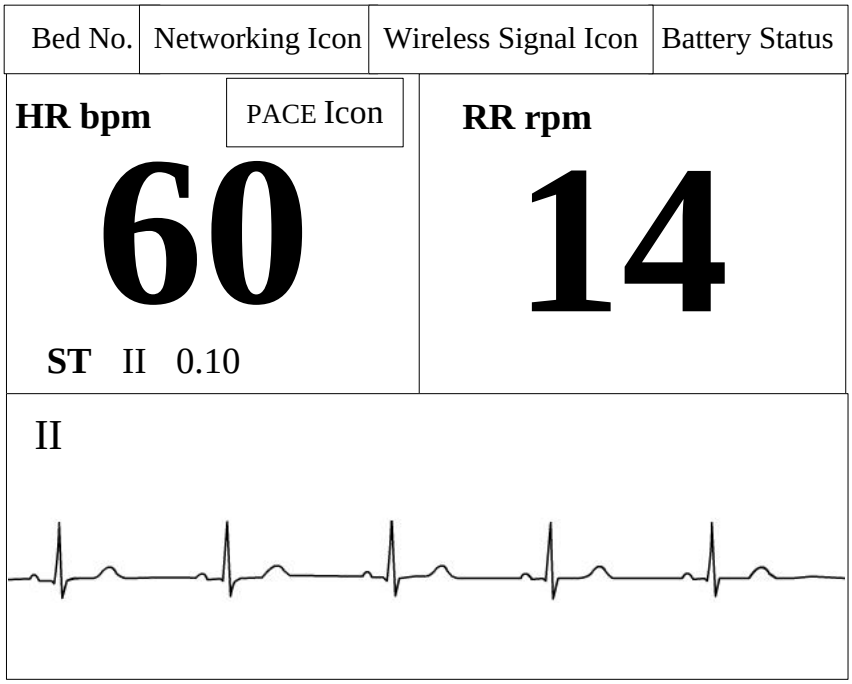


Figure 2-5 ECG & RESP Interface (ST ON)

5. ECG&SpO_2&RESP Interface: includes information area, ECG value of calculated lead, SpO_2 value, PR value and RR value. It's actually the same with default interface.

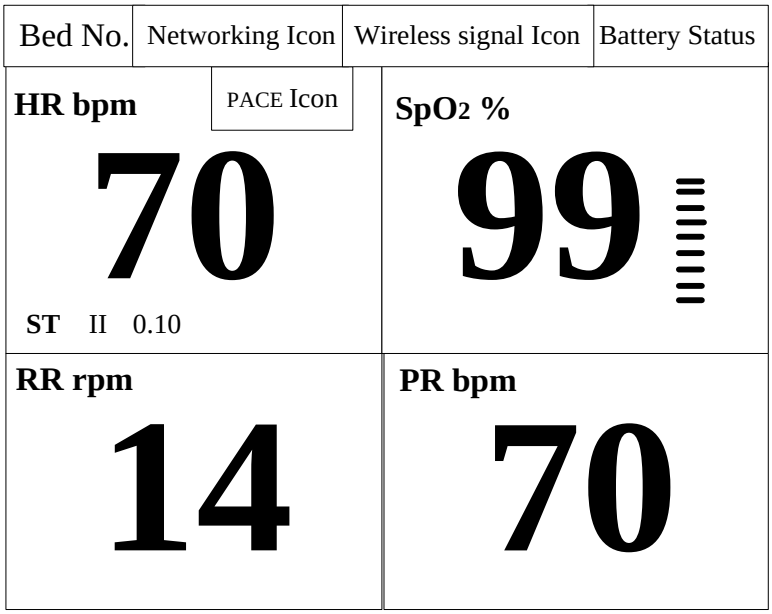


Figure 2-6 ECG & SpO_2 & PR & RESP Interface (ST ON)

■ Trend Graph Main Interface

Trend Graph Main Interface can be displayed when parameters are on. It includes current patient's data only, not the history patient's.

According to the parameters customer chosen, trend graph main interface has four kinds: ECG Trend Graph Main Interface, SpO_2 Trend Graph Main Interface, PR Trend Graph Main Interface and RESP Trend Graph Main Interface.

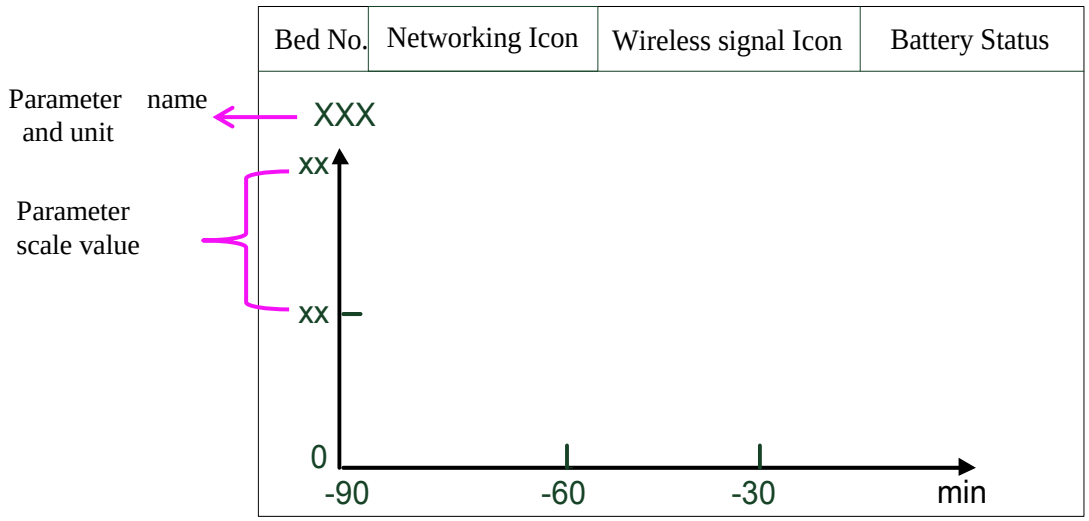


Figure 2-7 Trend Graph Main Interface

2.2.3 Setting Interface

Setting interface includes password inputting interface and function setting interface that will be displayed after confirm password. Under non-0-level of battery condition, when screen is in the setting interface, the screen can keep opened till level 0 of battery.

In setting interface, there are functions: choosing demo mode, choosing language of telemetry transmitter, checking network configuration, upgrading operation and checking related information of telemetry transmitter.

WARNING

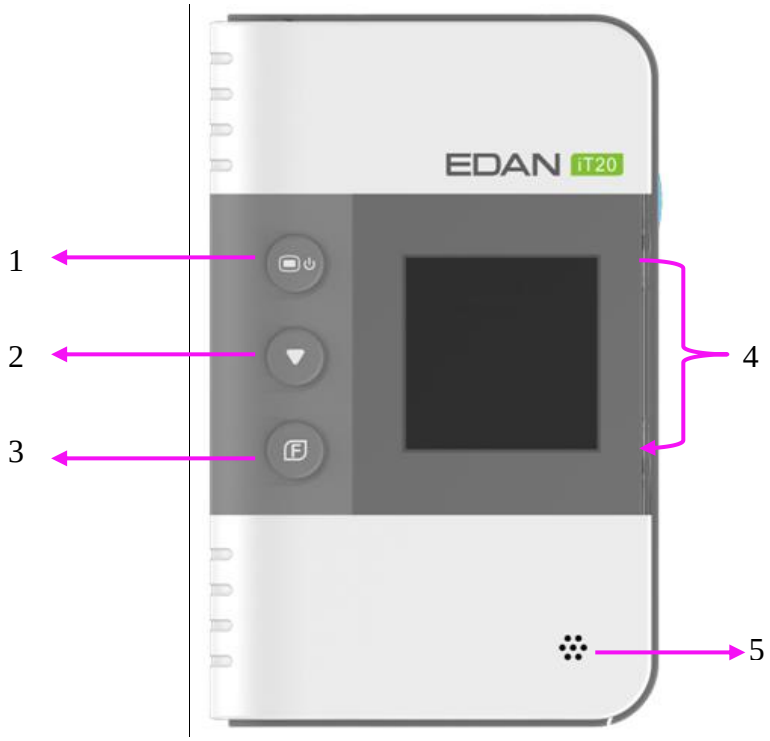
1. The functions in setting interface, such as checking network configuration and upgrading operation, are for service personnel only.
2. Demo Mode is for demonstration purposes only. You must not change into Demo Mode during monitoring. In Demo Mode, all stored trend information is deleted from the telemetry transmitter's memory.

NOTE:

Multiple languages are applicable to main interface. Setting interface supports English only.

2.3 Appearance of Telemetry Transmitter

2.3.1 Front View



Front View

Terms explanation

- Main Interface, Default Interface and Setting Interface: refer to *2.2 Display Screen of Telemetry Transmitter.*
- Control focus: means the cursor position triggered by shifting key.
- Focus acceptance: means user accept the position where the control focus is. It is triggered by function acceptance key.

1	Power supply switch ◆ Under telemetry transmitter off: Keep pressing at least for 2 seconds to turn on and the green light of power supply switch will occur. ◆ Under telemetry transmitter on: When power is in level 0 or screen is open, keep pressing at least for 3 seconds to turn off. ◆ Under telemetry transmitter on, press it to close or open the screen (low battery is an exception).
2	Shifting ◆ In main interface, press it to display between Waveform Main Interface and Trend Graph Main Interface. ◆ In setting interface, press it to switch control focus. ◆ When input password or choose language: ① press shifting to switch control focus; ② press function acceptance to accept focus; ③ press shifting to choose password or language. ◆ In ECG leads connection sketch interface (refer to *4.1.2 Switching On)*, press it to make the sketch disappear.
3	Function acceptance ◆ In main interface, press it to return to default interface. ◆ In setting interface, after control focus is switched to an icon, press function

	acceptance to accept this function. ◆ When input password or choose language: ① press shifting to switch control focus; ② press function acceptance to accept focus; ③ press shifting to choose password or language; ④ press function acceptance to exit focus acceptance.
1+3	Function group key (press power supply switch and function acceptance simultaneously at least for 1second) ◆ In main interface or in default interface, press it to display password window. ◆ In DEMO mode, press it to exit demo mode.
4	Display screen
5	Speaker

2.3.2 Rear View

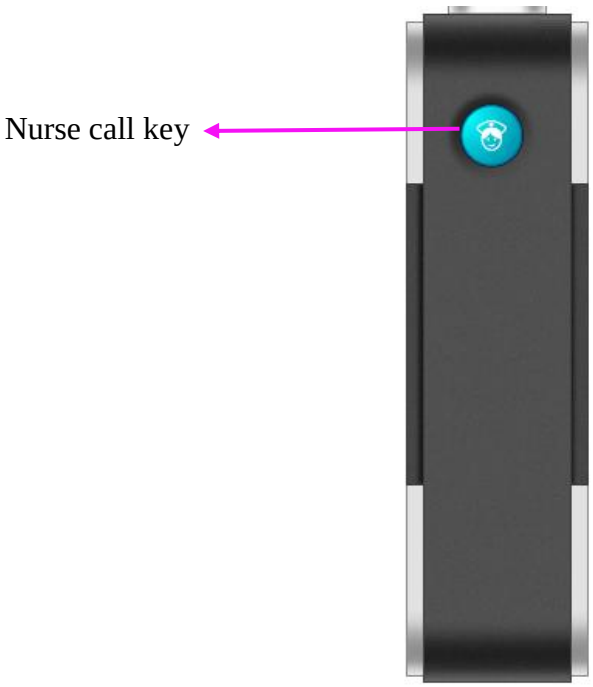
Rear View

Manufacturer's information is listed on this side. Detailed information please refers to the actual machine.

2.3.3 Left Side View

Left Side View

2.3.4 Right Side View



Right Side View

Nurse call key: press it to display calling nurse information on MFM-CMS.

2.3.5 Top View

Top View

1	ECG cable connector
2	SpO_2 sensor connector

2.3.6 Bottom View

Refer to *4.1.1 Battery Installing and Replacing.*

2.4 Configuration

The configuration of telemetry transmitter is listed below:

Function Configuration	ECG	SpO_2	PR	RESP
ECG	√	×	×	○
ECG & SpO_2	√	○	○	○

"√" means the parameter standardly configured is on by default after telemetry transmitter switches on. Changing status should be operated on MFM-CMS. The parameter status last used will be recovered when the device is switched on again.

"○" means the parameter standardly configured is off by default after telemetry transmitter switches on. Changing status should be operated on MFM-CMS. The parameter status last used will be recovered when the device is switched on again.

"×" means the parameter is not configured.

NOTE:

1. The parameters only standardly configured are applicable.
2. The parameters can be turned on/off on MFM-CMS.

Chapter 3 Installation of Telemetry Monitoring System

NOTE:

1. The entire system must be specified by the personnel authorized by EDAN.
2. To ensure that the system works properly, please read the user manual and follow the steps before using.

3.1 Initial Inspection

Before unpacking, check the packaging and ensure that there are no signs of mishandling or damage. If the shipping cartons are damaged, contact the carrier for compensation and package them again.

Open the package carefully and remove telemetry transmitter, MFM-CMS and accessories. Check that the contents are complete and that the correct options and accessories have been delivered.

If you have any question, please contact your local supplier.

3.2 Installation Environment

System working environment should be in consistent with the requirements in this user manual (refer to *A.2.2 Environmental Specifications).*

System working should avoid noise, shock environment and the environment where the concentrations of flammable anesthetics or other explosive materials may occur. The surrounding of device should have enough space (at least 5 cm) to maintain and transfer heat.

NOTE:

1. Please keep the system away from radio transmitters and high power electrical and mechanical device for those could affect monitoring.
2. Wireless transmission is applicable to the system. It’s normal that irregular waveform due to outside interference may occur. If you have any question on Electromagnetic environment, please contact service personnel.

3.3 Power Supply Requirement

Power supply should be in consistent with the requirements in this user manual (refer to *A.2.4 Battery*).

NOTE:

1 Connect the power cable of MFM-CMS to the socket specialized for hospital use.

2 Only use the power cable supplied by EDAN.

3.4 Wireless Network

Telemetry translator and MFM-CMS construct wireless network through AP. The qualified engineers specified by EDAN are responsible for installing wireless network and performance tests. For details, please refer to *Patient Monitor Wireless Network Installation Guide.*

NOTE:

1. Be aware that some network-based functions may be limited for telemetry transmitter on wireless networks in comparison with those on wired networks.
2. The obstacle may interfere with data transmission and even cause data loss.
3. When telemetry transmitter has been connected to a wireless network, to make the change of the Bed No. effective, you need to disconnect the wireless connection and then connect it again or reboot telemetry transmitter.

3.5 Installation Method

The personnel specified by EDAN are responsible for system installation, which includes surrounding verification, MFM-CMS installation, wireless device installation and telemetry transmitter installation, etc.

WARNING

1. When the system is required to connected with other electric devices, and those electric devices are not approved to be safe for connection with the system, such as current leakage may cause electronic shock, please contact specialists in hospital or our service personnel.
2. Upgrade operation is only for personnel authorized by EDAN.
3. Plugging three-pin into two-pin adaptor is prohibited.
4. To change installation environment or move system to another site, please contact our service personnel.
5. The medical electrical equipment needs to be installed and put into service according to the EMC Information provided in this user manual.

CAUTION

1. To avoid unpredictable results from sudden power interruption, please provide UPS (Uninterruptible power supplies) for the system.
2. Keeping battery bin dry is required.

NOTE:

Crossover Ethernet cable is connected with computer and parallel Ethernet cable is connected with HUB.

3.6 Checking the Printer

If an external printer is required, please confirm the printer is powered on and paper is properly installed in the slot. If it is not powered on or no paper exists, please power the printer on according to power requirements in *MFM-CMS Central Monitoring System User Manual* and put appropriate paper.

WARNING

External device connected with system, such as printer or speaker, should be in accordance with power requirements for system.

3.7 Checking the Telemetry Monitoring System

Make sure there is no damage on the measurement accessories and cables. Then turn on the telemetry and MFM-CMS, check whether the system can start normally. Make sure battery for telemetry transmitter has enough power, MFM-CMS can alarm normally and the alarm sound is heard.

WARNING

If any signs of damage are detected, or screen displays error messages, do not use it on any patient. Contact service center immediately.

NOTE:

1 Check all functions applicable and make sure that the system is in good status.

2 If telemetry transmitter is in low battery power status (level 0), replace battery to ensure the electric power is enough.

3.8 Setting Date and Time

Setting and displaying date and time is applicable to MFM-CMS only.

The user can set the correct date and time and their desired format. There are three kinds of date format: **yyyy-MM-dd**, **dd-MM-yyyy**, **MM-dd-yyyy**, two kinds of time format: **HH-mm-ss** (24 hours) and **hh-mm-ss tt** (12 hours), and three date separator: /, - and**.** To change the date and time setup, please select **Main Screen** > **System Setup** > **User Maintain** > **Date /Time Setup,** and select the desired settings from the menu**.** The time and date displayed on the main screen will also change after change the date and time setup and their format.

WARNING

During patient monitoring, a change in date and time will influence the storage of trend data.

NOTE:

1 The user must restart MFM-CMS to make the change effective.

2 If the system is not used for a longer period of time, its system time may be inaccurate. In this case, reset the system time after powering on.

3 If the system time cannot be saved and resumes the default value after restart, contact the service department of EDAN.

3.9 Handing Over the Central Monitoring Systerm

If you are handing over system to the end-users directly after installation and configuration, make sure that it is in the monitoring mode.

The users must be adequately trained to use the system before monitoring a patient. To achieve this, they should have access to, and read, the following documentation delivered with system:

- User Manual (this book) - for full operating instructions.
- Quick Reference Card - for quick reminders during use.

3.10 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

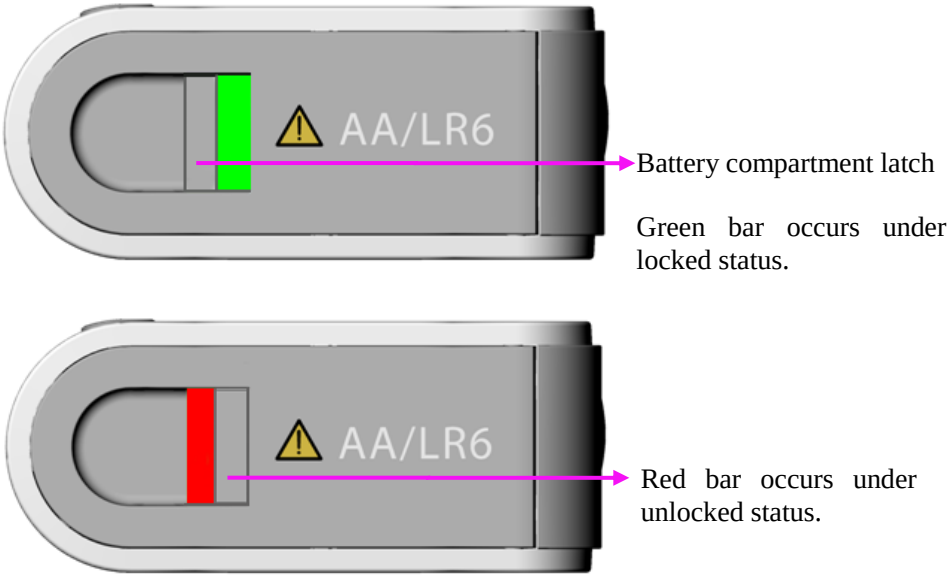
Chapter 4 Basic Operations

The general functions for telemetry transmitter are operated on MFM-CMS. Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

The following introduction is about the basic operations for telemetry transmitter.

4.1 Basic Operations for Telemetry Transmitter

4.1.1 Battery Installing and Replacing



Bottom View

Installing:

As pictured above, move the battery compartment latch right to open battery door. Install two AA alkaline batteries following "+" or "-" indication, and then press the door to close correctly with "ka-ka" sound.

Replacing:

Method is the same with installing.

Under the condition that telemetry transmitter continuously works at least for 15 minutes and moreover it has a good Wi-Fi communication (typical network environment with no interference), telemetry transmitter can keep power on up to 20 seconds after taking batteries out.

WARNING

It is prohibited for patient to install or replace battery.

4.1.2 Switching On

Under switch off condition, keep pressing power supply switch at least for 2 seconds to turn on. Then the green light of power supply switch will occur. At the same time, the following self-tests will be carried out:

- Read parameters configuration. Refer to *2.4 Configuration* for configuration information;
- Check ECG accessory compatibility.

When accessory is not compatible, the screen will display "**Check the ECG accessories**"; When compatible and ECG module is active, telemetry transmitter will check ECG leads connection. The screen will enter into main interface under condition of correct leads connection. Under leads off or wrong connection, the screen will display ECG leads connection sketch in which wrong leads position and correct leads position will be indicated. ECG leads connection sketch will disappear in these conditions, leads connection restoring normally, pressing shifting key or over 60 seconds.

- Distinguish automatically ECG leads type (3-lead or 5-lead) and ECG leads style (AHA or IEC).

NOTE:

During switch on, user should confirm the green light of power supply switch occurs and screen displays normally. Nurse call and patient call sounds should also be tested normally.

4.1.3 Switching Off

Under telemetry transmitter on:

When power is in level 0 or screen is open, keep pressing at least for 3 seconds to turn off..

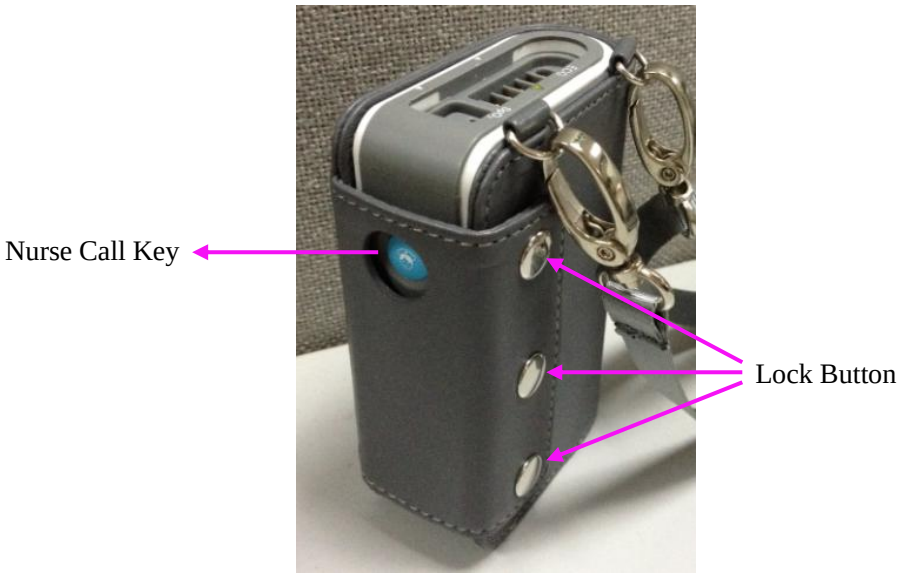
4.1.4 Open/Close Screen

- Under telemetry transmitter on, when screen is closed with non-0-level of battery, press is to open screen. The screen will be back to the interface last used after opening again.
- Under screen open condition, do one of the following method to close:
  1. Press power supply switch;
  2. Without any actions in 15 seconds, screen will close automatically.

After closing, monitoring and net connection keep working normally.

4.1.5 Leather Cover Wearing

Telemetry transmitter supports leather cover to wear, as pictured below:



WARNING

To avoid infection or other severe results, leather cover must not touch injured skin.

4.1.6 Nurse Call

Press nurse call key  on the right side. Information about nurse call will be sent to MFM-CMS on which a nurse call symbol  will be displayed to tell nurse patient's calling.

Chapter 5 Alarm Management

The contents related to this chapter are all operated on MFM-CMS.

5.1 Overview

Alarms, triggered by a physiological sign that appears abnormal or by technical problems of the telemetry transmitter, are sent to the MFM-CMS by the telemetry transmitters and then indicated to the users by the MFM-CMS. Alarms coming from the telemetry transmitters are displayed in the patient sectors and in the single bed view window.

The alarm and prompts coming from the MFM-CMS system are displayed in the system information area on the upper screen.

WARNING

1. A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room.
2. Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is recommended to use the default settings.

NOTE:

1. The alarm signal will be delayed for no more than 5 seconds.
2. If telemetry transmitter or MFM-CMS switches off, the alarm information stored by MFM-CMS will not be deleted. A maximum of 720 alarm information can be stored. If the storage space is full and there are new alarms occurring, the earliest alarm information will disappear.

5.1.1 Physiological Alarms

If one or several physiological parameters of the currently monitored patient exceed the predefined alarm limit, the telemetry transmitter will give an alarm, and this type of alarm is called physiological alarms. It includes parameter alarm and arrhythmia alarm. About the detailed alarm information, please refer to *Chapter 6 Alarm Information.*

Physiological information alarm arouses the doctors' attention by means of visual and audible methods specified in harmonized international standard. Visual method is realized basically by the way of lightening or flicking of the color light. Audible method is realized by the sound for different levels.

Physiological alarms are implemented by alarm limits, which define a range in which a certain physiological parameter is considered to be in the normal status. When a parameter value is beyond the range, the system will consider it to be in an abnormal status and consequently give an alarm.

5.1.2 Technical Alarms

If one or several technical status of the device is in abnormal status, the telemetry transmitter will send an alarm to MFM-CMS. And this type of alarm is called technical alarms. Technical alarms can't be disabled. Technical alarms of telemetry transmitter refer to alarms other than physiological alarms, including hardware failure, communication error, lead off, etc. About the detailed alarm information, please refer to *Chapter 6 Alarm Information.*

For these technical alarms, the system indicates by four different types of audible and visual prompts.

When a group of technical alarms (for example, transducer falls off) produced by telemetry transmitters, a piece of alarm prompt information in scrolling mode will appear on the main screen of MFM-CMS. In addition, the MFM-CMS will sound corresponding alarm (high, medium or low level alarm).

5.1.3 Prompts

Telemetry transmitter can send the character indication of monitoring process or other functions to MFM-CMS. This character, with black background, white font and with no alarm sound, is called prompts. The About the detailed alarm information, please refer to *Chapter 6 Alarm Information*.

5.2 Alarm Levels

Alarm level reflects the severity of an alarm. The alarms from telemetry transmitters are divided into three groups regarding the alarm levels.

1. High level alarms

A high level alarm intensively warns the operator of a high priority alarm condition which requires immediate operator response. Failure to respond to the cause of the alarm condition is likely to result in death or irreversible injury of the patient.

2. Medium level alarms

A medium level alarm warns the operator of a medium priority alarm condition which requires prompt operator response. Failure to respond to the cause of the alarm condition is likely to result in reversible injury of the patient.

3. Low level alarms

A low level alarm reminds the operator of a low priority alarm condition which requires response. And the response time for a low priority alarm condition can be greater than that for a medium priority alarm condition. Failure to respond to the cause of the alarm condition is likely to result in discomfort or reversible minor injury of the patient.

5.3 Parameters Alarm Setting

Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

5.4 Alarm Mute

Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

5.5 Audio Pause

Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

5.6 Alarm Prompt/Response

Alarm information can be prompted by means of visual and audible methods. Because the alarm information is very important and timely response to the alarm information is highly required, the MFM-CMS provides the following methods to indicate to the user the occurrence of the alarm.

- The alarm message will be displayed in the technical area or physiological area of the patient sector and of the single bed view window.

  High level alarm: displayed with red background

  Medium level alarm: displayed with yellow background

  Low level alarm: displayed with yellow background

- An asterisk or more will be displayed before the physiological alarm message to indicate the alarm level.

  High level alarm: ***

  Medium level alarm: **

  Low level alarm: *

- For limit alarms of the parameter, the relevant parameter value and alarm limit value will be respectively displayed with the color alternating between the parameter color and the alarm color.

  When physiological alarm exceeds the alarm limit, the icons for parameters exceeding the alarm limits will be displayed in parameter value area. The icon  is for high level alarm; Icon  is for medium and low level alarm.

- Alarm sound

If the system mute, alarm mute or alarm pause setup is deactivated, the system will warn the user about the alarm with the alarm sound. The sound pressure range for audible alarm signals is from 45 dB to 85 dB.

The alarm sound can be:

High level alarm: sound "DO-DO-DO DO-DO DO-DO-DO DO-DO"; The adjustable range of alarm sound interval is from 6 to 15 seconds.

Medium level alarm: sound "DO-DO-DO"; The adjustable range of alarm sound interval is from 6 to 30 seconds.

Low level alarm: sound "DO- ". The adjustable range of alarm sound interval is from 15 to 30 seconds.

WARNING

1 Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in patient danger. Please remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

2 Ensure the volume is properly set up. When the sound pressure of audible alarm is below or equivalent to the ambient noise, it may be difficult for the operator to distinguish the audible alarm.

5.7 Testing Alarms

When you switch the MFM-CMS on, a self-test is started. Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

The physiological alarms, technical alarms and prompts from telemetry transmitter are displayed on MFM-CMS. Before monitoring, user should perform the measurement on yourself or use a simulator to check the follows:

- System information area can normally display technical alarms and prompts of MFM-CMS system;
- Patient sector and single bed view can normally display physiological alarms, technical alarms and prompts of telemetry transmitter;
- Alarm sound can be heard clearly.

The correct checking above indicates that the visible and audible alarm are functioning correctly. For further alarm tests, please adjust the alarm limits to check whether the alarm response is correct.

5.8 Alarms for Networking Status

When telemetry transmitter is online or offline, the system will indicate it with a sound of “du”.

If telemetry transmitter is offline without being discharged (that is improper offline), and there are other patients online at the same time, system will indicate it with medium level alarm sound. The alarm sound for improper offline will be given out only once.

NOTE:

In good network status, if there are no patients online, MFM-CMS will give out a high level alarm sound with intervals of 20 s.

Chapter 6 Alarm Information

All alarm information will be displayed on MFM-CMS.

WARNING

During monitoring, the physiological alarms including ASYSTOLE, VFIB/VTAC, RESP APNEA and SpO_2 No Pulse are preset to be on. ASYSTOLE, RESP APNEA and SpO_2 No Pulse cannot be turned off.

6.1 Physiological Alarm Information

Message	**Cause**	**Alarm level**
HR High	HR measuring value is above the upper alarm limit.	User-selectable
HR Low	HR measuring value is below the lower alarm limit.	User-selectable
ST-X High	ST measuring value is above the upper alarm limit. (X stands for I, II, III, aVR, aVL, aVF, V)	User-selectable
ST-X Low	ST measuring value is below the lower alarm limit.(X stands for I, II, III, aVR, aVL, aVF, V)	User-selectable
PVCs High	PVCs measuring value is above the upper alarm limit.	User-selectable
ASYSTOLE	No QRS is detected for 4 consecutive seconds	High (user-unselectable)
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.	High (user-unselectable)
VT>2	3 ≤ the number of consecutive PVCs < 5	User-selectable
COUPLET	2 consecutive PVCs	User-selectable
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.	User-selectable
TRIGEMINY	A dominant rhythm of N, N, V, N, N,V	User-selectable
R ON T	A type of single PVC under the condition that HR<100，R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).	User-selectable
PVC	Single PVC detected in normal heartbeats.	User-selectable

Message	**Cause**	**Alarm level**
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.	User-selectable
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.	User-selectable
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.	User-selectable
IRR	Consistently irregular heart rhythm	User-selectable
PNC (with pacemaker)	PACE NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.	User-selectable
PNP (with pacemaker)	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.	User-selectable
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.	User-selectable
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.	User-selectable
RESP APNEA	RESP cannot be measured within the set apnea alarm delay time.	High (user-unselectable)
RR High	RR measuring value is above upper alarm limit.	User-selectable
RR Low	RR measuring value is below lower alarm limit.	User-selectable
SpO_2 High	SpO_2 measuring value is above upper alarm limit.	User-selectable
SpO_2 Low	SpO_2 measuring value is below lower alarm limit.	User-selectable
SpO_2 No Pulse	The signal of the measurement site is too weak, so the telemetry transmitter can’t detect the pulse signal.	High (user-unselectable)
PR High	PR measuring value is above upper alarm limit.	User-selectable
PR Low	PR measuring value is below lower alarm limit.	User-selectable

6.2 Technical Alarm Information

NOTE:

The ECG alarm information listed in the below table describes the lead names in America. For the corresponding lead names in Europe, please refer to the section *Installing Electrodes*.

Message	Cause	Alarm Level	Action Taken
ECG Lead Off	1) The drive electrode or more than one ECG limb electrode falls off the skin; 2) ECG cables fall off the telemetry transmitter.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LL Lead Off	ECG electrode LL falls off the skin or the ECG cable LL falls off the telemetry transmitter.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG LA Lead Off	ECG electrode LA falls off the skin or the ECG cable LA falls off the telemetry transmitter.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG RA Lead Off	ECG electrode RA falls off the skin or the ECG cable RA falls off the telemetry transmitter.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG V Lead Off	ECG electrode V falls off the skin or the ECG cable V falls off the telemetry transmitter.	Low	Make sure that all electrodes, leads and patient cables are properly connected.
ECG Signal Exceeded	ECG measuring signal is beyond measuring range.	Low	Check lead connection and patient condition
ECG Noise	ECG measuring signal is greatly interrupted.	Low	Check lead connection and patient condition

Message	Cause	Alarm Level	Action Taken
RESP Cardiac Artifact	No RESP waveform can be detected due to apnea or shallow breathing of the patient.	High	Check whether the patient is breathing normally. Take measures to help the patient breathe normally when necessary. If the patient is breathing normally, try to adjust the electrode position on the patient in order to reduce the interference of cardiogenic artifact.
RESP Noise	RR cannot be measured due to patient movement.	Low	Check whether the RESP leads are well connected. Keep the patient calm for better monitoring.
RR Exceed	RR measuring value is out of the measure range.	Medium	Check whether interference to the respiratory signal exists. And check whether the patient is breathing normally; breathing too rapidly or too slowly may endanger patient's life.
SpO_2 Sensor Off	SpO_2 sensor may be disconnected from the patient or the telemetry transmitter.	Low	Make sure the sensor is well connected to the patient's finger or other parts. Make sure the telemetry transmitter and cables are well connected.

Message	Cause	Alarm Level	Action Taken
SpO_2 No Sensor	SpO_2 sensor was not connected well or connected to the telemetry transmitter, or the connection is loose.	Low	Make sure the telemetry transmitter and sensor are well connected and reconnect the sensor.
SpO_2 Low Perfusion	The pulse signal is too weak or the perfusion of the measurement site is too low. The value displayed may not be correct.	Low	Reconnect the SpO_2 sensor and change the measurement site. If problem exists, please notify biomedical engineer or manufacturer's service staff.
SpO_2 Noisy Signal	There is interference with SpO_2 measurement signals and the waveform is abnormal.	Low	Check the condition of patient and avoid patient movement; make sure the cable is well connected.
SpO_2 Light Interference	Ambient light around the sensor is too strong.	Low	Reduce interference of the ambient light and avoid sensor's exposure to strong light.
Battery Low	Battery Low	High	Change the batteries or charge the batteries.
No signal for telemetry transmitter	Telemetry transmitter didn't connect to MFM-CMS.	Medium	Check whether network connection, MFM-CMS and wireless AP are work normally, or contact supplier.
Check the ECG accessories	ECG cables have connected to patient, and the valid authorized information for ECG accessories cannot be detected.	Medium	Use the specified ECG accessories.

6.3 Prompts

Message	**Cause**
ECG ARR Learning	The QRS template building required for Arr. Analysis is in process.
SpO_2 Search Pulse	SpO_2 module is analyzing the patient signal and searching for the pulse to compute the saturation, when sensor is connected with patient.
Weak Wi-Fi signal	The status that iT20 Wi-Fi signal is lower than level 1, means Wi-Fi signal is weak.
VFIB/VTAC Off	VFIB/VTAC alarm is set to **off**.

6.4 Adjustable Range of Alarm Limits

ECG alarm limits are listed as follows: unit (bpm)

	Patient Type	ALM HI	ALM LO
HR	ADU	300	15
	PED	350	15

ST analysis alarm limits are listed as follows: unit (mV)

	ALM HI	ALM LO
ST	2.0	-2.0

PVCs alarm upper limits are listed as follows:

	ALM HI	ALM LO
PVCs	10	0

RESP alarm limits are listed as follows: unit (rpm)

	Patient Type	ALM HI	ALM LO
RESP	ADU	120	6
	PED	150	6

SpO_2 alarm limits are listed as follows (unit %):

	ALM HI	ALM LO
SpO_2	100	20

PR alarm limits is listed as follows: unit (bpm)

	ALM HI	ALM LO
PR	300	30

Chapter 7 Printing

The contents related to this chapter are all operated on MFM-CMS. Please refer to *MFM-CMS Central Monitoring System User Manual* for details.

Chapter 8 Monitoring ECG

8.1 Overview

The electrocardiogram (ECG) measures the electrical activity of the heart and displays it on the telemetry transmitter as a waveform and a numeric. This chapter also tells you about arrhythmia monitoring and ST monitoring.

8.2 ECG Safety Information

WARNING

1 Only use the ECG leads supplied by the manufacturer when using telemetry transmitter for ECG monitoring.

2 When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient but not the conductive part or ground.

3 Check every day whether there is skin irritation resulted from the ECG electrodes. If yes, replace electrodes every 24 hours or change their sites.

4 Place the electrode carefully and ensure a good contact.

5 Check if the lead connection is correct before monitoring. If you unplug the ECG cable from the socket, the screen will display the error message “ECG LEAD OFF” and the audible alarm is activated.

6 If the ECG signal exceeds the measuring range, MFM-CMS will indicates it by a message “ECG Signal Exceeded”.

7 When using the telemetry transmitter with the defibrillator or other high-frequency equipment, please use defibrillator-proof ECG lead to avoid burn.

8 For patients with pacemakers, the pacing impulse analysis function must be switched ON. Otherwise, the pacing impulse may be counted as regular QRS complexes, which could prevent an asystole event from being detected or could lead to false alarm of asystole.

9 The electrodes should be made of the same metal materials.

10 ECG cables can be damaged when connected to a patient during defibrillation or using other high frequency equipment. Check cables for functionality before using them again. It is recommended to use the ECG cables which are defibrillator-proof.

11 ECG accessories are not suitable for DIRECT CARDIAC APPLICATION. (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION.)

12 Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Check lead wires for damage and ensure good skin contact prior to and during use. Always use fresh electrodes and follow proper skin preparation techniques.

NOTE:

1 Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

2 IEC/EN60601-1-2 (protection against radiation is 3 v/m) specifies that the electrical field density exceeding 3 v/m may cause measurement error in various frequencies. It is accordingly suggested that do not use equipment generating electrical radiation near ECG/RESP monitoring devices.

3 If the pacemaker signals are beyond the claimed range, the heart rate may be calculated incorrectly.

4 In the default settings of MFM-CMS, the ECG waveforms are the first two waveforms from top in the waveform area.

5 For measurements in or near the heart we recommend connecting the telemetry transmitter to the potential equalization system.

6 For protecting environment, the used electrodes must be recycled or disposed of properly.

7 The simultaneous use of cardiac pacemaker and other patient-connected equipment may cause safety hazard.

8.3 ECG Display

8.3.1 ECG Display on Telemetry Transmitter Screen

The figure below is the interface with ECG opened. It is for reference only. The display on your telemetry transmitter depends on the configuration you have chosen.

- Device Status Indicator: including bed number, network symbol, Wi-Fi signal intensity symbol, power symbol and PACE icon.
- Waveform Display: supports 1 channel at most; If ECG is configured and open, the calculated lead waveform is displayed by default. The waveforms of different leads can be switched. If the configuration has SpO_2 without ECG, Pleth waveform will be displayed.
- Parameter Value;
- Trend Graph (via pressing shifting key to display in turn)

I, II and III lead are optional for 3-lead.

I, II, III, aVR, aVF, aVL, and V lead are optional for 5-lead.

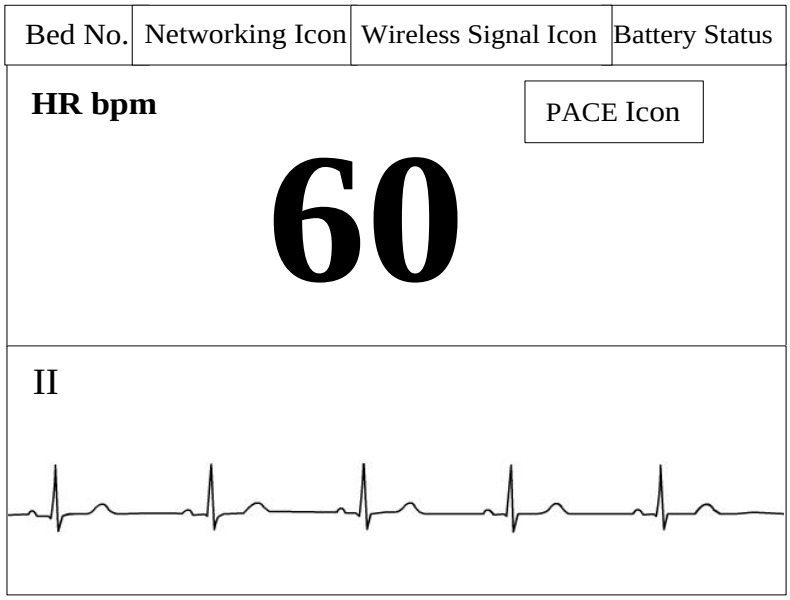


Figure 8-1

8.3.2 ECG Display on MFM-CMS

The figure below is ECG waveform for 5-lead. It is for reference only. The display on your MFM-CMS depends on the configuration you have chosen.

8.4 Selecting Calculation Lead

Selecting calculation lead is operated on MFM-CMS.

I, II and III lead are optional for 3-lead.

I, II, III, aVR, aVF, aVL, and V lead are optional for 5-lead.

Normal QRS complex should be:

- The normal QRS should be either completely above or below the baseline and it should not be biphasic. For paced patients, the QRS complexes should be at least twice the height of pace pulses.
- The QRS should be tall and narrow.
- The P-waves and the T-waves should be less than 0.2 mV.

8.5 Changing Size of ECG Waveform

Changing size of ECG waveform is operated on MFM-CMS.

X0.125 to make strength of ECG signal waveform of 1mV become 1.25 mm;

X0.25 to make strength of ECG signal waveform of 1mV become 2.5 mm;

X0.5 to make strength of ECG signal waveform of 1mV become 5 mm;

X1 to make strength of ECG signal waveform of 1mV become 10 mm;

X2 to make strength of ECG signal waveform of 1mV become 20 mm;

X4 to make strength of ECG signal waveform of 1mV become 40 mm;

Auto let the MFM-CMS choose the optimal adjustment factor for all the ECG waves.

NOTE:

The effect of ECG waveform gain is subject to the size of the waveform area. Whichever waveform gain is chosen, the ECG waveform has to be displayed within the waveform area.

8.6 Changing ECG Filter Settings

Changing ECG filter settings is operated on MFM-CMS.

– **Monitor**: Use this mode under normal measurement conditions.

– **Surgery**: The filter reduces interference to the signal. It should be used if the signal is distorted by high frequency or low frequency interference. High frequency interference usually results in large amplitude spikes making the ECG signal look irregular. Low frequency interference usually leads to a wandering or rough baseline. In the operating room, the Filter reduces artifacts. Under normal measurement conditions, selecting Surgery may suppress the QRS complexes too much and thus interfere with the clinical evaluation of the ECG displayed on the MFM-CMS.

–**Diagnosis**: Use when diagnostic quality is required. The unfiltered ECG waveform is displayed so that changes such as R-wave notching or discrete elevation or depression of the ST segments are visible.

8.7 ECG Alarm Settings

ECG alarm settings are operated on MFM-CMS. User can open or close the ECG alarm.

8.8 Monitoring Procedure

8.8.1 Preparation

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Select sites with intact skin, without impairment of any kind.
- Shave hair from sites, if necessary.
- Wash sites thoroughly with soap and water. (Never use ether or pure alcohol, because this increases skin impedance).
- Rub the skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.

8.8.2 Connecting ECG Cables

1. Attach clip or snap to electrodes prior to placement.
2. Put the electrodes on the patient. Before attaching, apply some conductive jelly on the electrodes if the electrodes are not electrolyte self-supplied.
3. Connect the electrode lead to the patient's cable.
4. Plug the patient cable into the ECG connector.

CAUTION

To protect the telemetry transmitter from damage during defibrillation, for accurate ECG information and to protect against noise and other interference, use only ECG electrodes and cables specified by EDAN.

8.9 Installing Electrodes

NOTE:

The following table gives the corresponding lead names used in Europe and America respectively. (Lead names are represented by R, L, F, N, C, C1-C6 in Europe, whose corresponding lead names in America are RA, LA, LL, RL, V, V1-V6.)

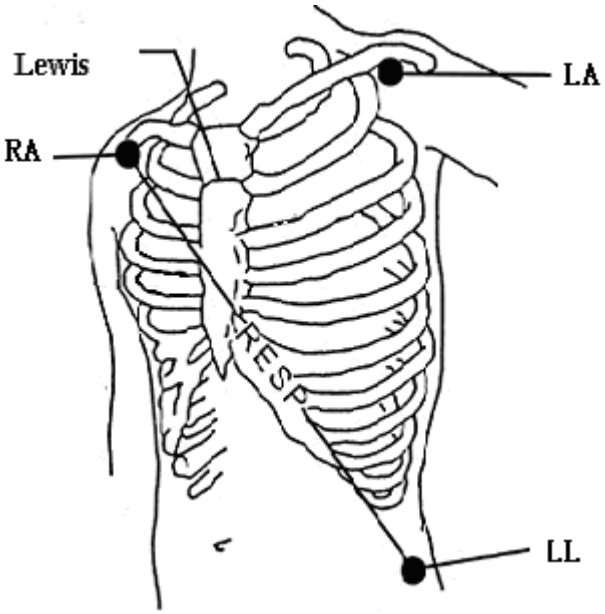
AHA (American Standard)		IEC (Europe Standard)	
Electrode Labels	Color	Electrode Labels	Color
RA	White	R	Red
LA	Black	L	Yellow
LL	Red	F	Green
RL	Green	N	Black
V	Brown	C	White
V1	Brown/ Red	C1	White/ Red
V2	Brown/ Yellow	C2	White/ Yellow
V3	Brown/ Green	C3	White/ Green
V4	Brown/Blue	C4	White/ Brown

AHA (American Standard)		IEC (Europe Standard)	
V5	Brown/Orange	C5	White/ Black
V6	Brown/Purple	C6	White/ Purple

8.9.1 Electrode Placement for 3-lead

Take the American standard for example, see the following figure:

- RA placement - directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- LL placement - on the left hypogastrium.

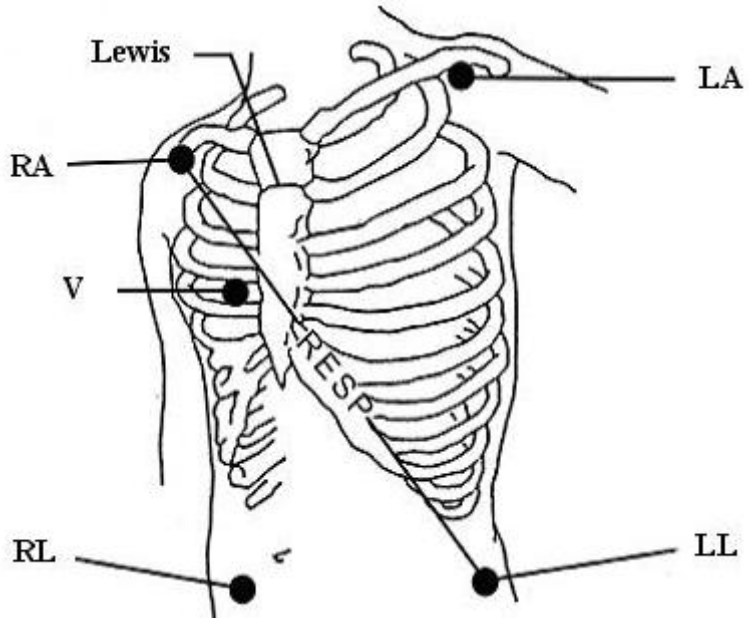


Electrode Placement for 3-lead

8.9.2 Electrode Placement for 5-lead

Take the American standard for example; see the following figure:

- RA placement: directly below the clavicle and near the right shoulder.
- LA placement: directly below the clavicle and near the left shoulder.
- RL placement: on the right hypogastrium.
- LL placement: on the left hypogastrium.
- V placement: on the chest, the position depends on your required lead selection.



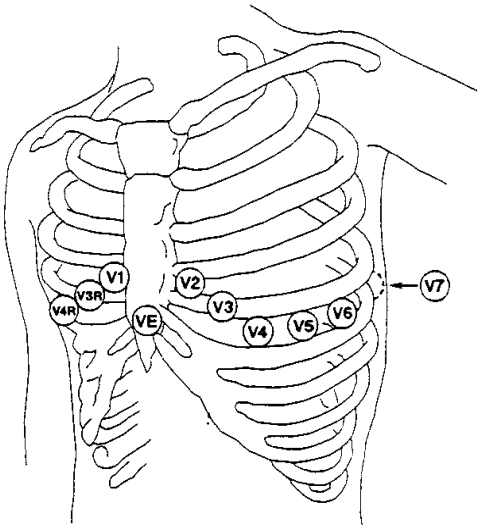
Electrode Placement for 5-lead

NOTE:

To ensure the patient safety, all leads must be attached to the patient.

For 5-lead, attach the V electrode to one of the indicated positions as below:

- V1 On the 4th intercostal space at the right sterna margin.
- V2 On the 4th intercostal space at the left sterna margin.
- V3 Midway between V2 and V4 electrodes.
- V4 On the 5th intercostal space at the left clavicular line.
- V5 On the left anterior axillary line, horizontal with V4 electrode.
- V6 On the left middle axillary line, horizontal with V4 electrode.
- V3R-V6R On the right side of the chest in positions corresponding to those on the left.
- VE Over the xiphoid position.
- V7 On the 5th intercostal space at the left posterior axillary line of back.
- V7R On the 5th intercostal space at the right posterior axillary line of back.



V-Electrode Placement for 5-lead

8.10 Setting Alarm Source

Setting alarm source is operated on MFM-CMS.

HR: the telemetry transmitter considers the HR as HR/PR alarm source;

PR: the telemetry transmitter considers the PR as HR/PR alarm source;

AUTO: If the Alarm Source is set to **Auto**, the telemetry transmitter will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical condition. The telemetry transmitter will automatically switch to Pulse as the alarm source if:

–a valid ECG lead can no longer be measured and

–a pulse source is switched on and available.

The telemetry transmitter then uses the pulse rate from the measurement currently active as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the telemetry transmitter automatically uses HR as alarm source.

8.11 Smart Lead Off

Choosing smart lead off is operated on MFM-CMS.

When Lead Type is 5 Leads and **Smart LeadOff** is set to **On**, if the selected ECG waveform cannot be measured because of lead-off or other reasons, it will automatically switch to another available lead channel via which a waveform can be measured. And the lead name above the display ECG waveform also automatically turns into the current one.

8.12 Setting Pace Status

Setting pace status is operated on MFM-CMS.

It is important to set the paced status correctly when you start monitoring ECG. When **Pace** is set to **On**:

- Pace Pulse Rejection is switched on. This means that pacemaker pulses are not counted as extra QRS complexes.

- Paced symbol is displayed as | on the main screen.

NOTE:

1 When monitoring a patient with a pacemaker, set **Pace** to **On**. If monitoring a patient without a pacemaker, set **Pace** to **Off**.

2 If **Pace** is set to **On**, the system will not perform some types of ARR analysis.

WARNING

Some pace pulses can be difficult to reject. When this happens, the pulses are counted as a QRS complex, and could result in an incorrect HR and failure to detect cardiac arrest or some arrhythmias. Keep pacemaker patients under close observation.

8.13 ECG Calibration

ECG calibration is operated on MFM-CMS. This item is used to calibrate ECG waveform.

NOTE:

The device can't be monitored during ECG calibration.

8.14 ECG Waveform Settings

ECG waveform setting is operated on MFM-CMS and is applicable to the wave on MFM-CMS.

User can select an appropriate setting. The bigger the value is, the wider the waveform is. **6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s** are optional.

8.15 ST Segment Monitoring

Telemetry transmitter performs ST segment analysis on normal and atrially paced beats and calculates ST segment elevations and depressions. This information can be displayed in the form of ST numerics on telemetry transmitter and MFM-CMS.

ST segment monitoring function is shut off by default. You can switch it to **On** in MFM-CMS when necessary.

NOTE:

1 ST-segment analysis is intended for use with adult patients only and is not clinically validated for use with pediatric patients.

2 The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician.

8.15.1 Open/ Close ST Analysis

Setting ST analysis is operated on MFM-CMS.

8.15.2 ST Display

The ST displayed on telemetry transmitter is as *figure 2-4 or figure 2-5*.

Please refer to *MFM-CMS Central Monitoring System User Manual* for ST displayed on MFM-CMS.

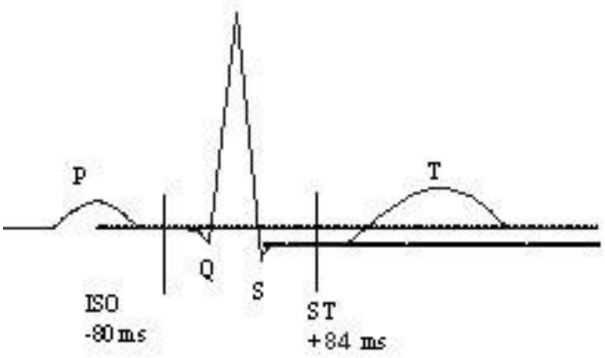
8.15.3 ST Alarm Settings

ST alarm settings are operated on MFM-CMS.

ST value range is from 2.0 mV to -2.0 mV. The minimum alarm high limit shall be 0.2 mV higher than the maximum alarm low limit.

8.15.4 About ST Measurement Points

The ST value for each beat complex is the vertical difference between the ISO point and the ST point, as shown in the diagram below. The isoelectric (ISO) point provides the baseline, and the ST point is at the midpoint of the ST segment. The J point is where the QRS complex changes its slope; as it is a fixed distance away from the ST point, it can be useful to help you position the ST point correctly.



DEF POINT

About ISO and ST measurement points:

For telemetry transmitters, the location of ISO and ST measurement points is not adjustable. Its initial value for ST testing points is +84ms by default. ST analysis takes no account of abnormal QRS wave.

8.16 Arr. Monitoring

8.16.1 Arrhythmia Analysis

The arrhythmia algorithm is used to monitor ECG of adult patients in clinics, and detect the changes of heart rate and ventricular rhythm, and also save arrhythmia events and generate

alarming information. The arrhythmia analysis is not clinically validated for use with neonatal and pediatric patients. Arrhythmia algorithm can monitor paced and non-paced patients. Qualified personnel can use arrhythmia analysis to evaluate patient's condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and decide the treatment. Besides detecting change of ECG, arrhythmia algorithm can also monitor patients and give proper alarm for arrhythmia.

Telemetry transmitter can support up to 16 different arrhythmia analyses.

ARR Types	Occurring Condition
ASYSTOLE	No QRS is detected for 4 consecutive seconds
VFIB/VTAC	4 consecutive seconds' fibrillation wave occurs, or each RR interval for 5 consecutive ventricular beats is less than 600 ms.
VT>2	3 ≤ the number of consecutive PVCs < 5
COUPLET	2 consecutive PVCs
BIGEMINY	A dominant rhythm of N, V, N, V (N = supraventricular beat, V = ventricular beat) was detected.
TRIGEMINY	A dominant rhythm of N, N, V, N, N,V.
R ON T	A type of single PVC under the condition that HR<100，R-R interval is less than 1/3 the average interval, followed by a compensating pause of 1.25X the average R-R interval (the next R wave advances onto the previous T wave).
PVC	Single PVC detected in normal heartbeats.
TACHY	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
BRADY	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.
MISSED BEATS	If HR < 120 bpm, no beats are detected for 1.75 times average RR interval; or if HR ≥ 120 bpm, no beats are detected for one second.
IRR	Consistently irregular heart rhythm
PNC	PACE NOT CAPTURE: no QRS complex detected in 300 ms after a pace pulse.
PNP	PACER NOT PACED: no pace pulse detected in 1.75 times RR interval after a QRS complex.
VBRADY	VENTRICULAR BRADYCARDIA: Each RR interval for 5 consecutive ventricular beats > 1000 ms.
VENT	VENTRICULAR RHYTHM: Each RR interval for 5 consecutive ventricular beats ranges from 600 ms to 1000 ms.

8.16.2 ARR Analysis Menu

8.16.2.1 Switching ARR Analysis On and Off

Switching ARR on or off is operated on MFM-CMS.

8.16.2.2 PVCs Alarm Settings

PVCs alarm settings are operated on MFM-CMS.

Select **On** in the menu to enable prompt message when an alarm occurs; select **Off** to disable the alarm function, and there will be a symbol  beside **PVCs**.

WARNING

When the PVCs Alarm is set to OFF, MFM-CMS won't give an alarm prompt even if an alarm occurs. In order to avoid endangering the patient's life, the user should use this function cautiously.

8.16.2.3 ARR Relearning

ARR relearning is operated on MFM-CMS.

Pick this item to start a learning procedure, and **ECG ARR LEARNING** is displayed on MFM-CMS screen. The ECG ARR LEARNING will start in the following status:

- Connecting leads;
- Starting ARR learning manually;
- Switching calculation leads.

8.16.2.4 ARR Alarm Settings

ARR alarm settings are operated on MFM-CMS.

Users can switch on or off all arrhythmia alarms by ARR alarm settings. And some arrhythmia alarms can be individually switched on or off. They are: **VFIB/VTAC**， **R-ON-T**, **VT>2**, **COUPLET**, **PVC**, **BIGEMINY**, **TRIGEMINY**, **TACHY**, **BRADY**, **MISSED BEATS, IRR, PNC, PNP, VBRADY** and **VENT**. **ASYSTOLE** is preset to be on and cannot be turned off.

Chapter 9 Monitoring RESP

9.1 Overview

Telemetry transmitter measures respiration from the amount of thoracic impedance between two ECG electrodes. The change of impedance between the two electrodes, (due to the thoracic movement), produces a respiratory waveform on the screen.

9.2 RESP Safety Information

WARNING

1 The respiration measurement does not recognize obstructive and mixed apneas - it only indicates an alarm when a pre-adjusted time has elapsed since the last detected breath.

2 If operating under conditions according to the EMC Standard EN 60601-1-2 (Radiated Immunity 3 V/m), field strengths above 3 V/m may cause erroneous measurements at various frequencies. Therefore it is recommended to avoid the use of electrically radiating equipment in close proximity to the respiration measurement unit.

3 Cardiogenic artifact in impedance respiration monitoring may make it difficult to detect breaths or may otherwise be counted as breaths. In some instances, the breath rate may also correspond to the heart rate making it difficult to determine if the signal is due to breathing or the cardiac cycle. Do not rely on RESP monitoring as the sole method for detecting cessation of breathing. Follow hospital guidelines and best clinical practices for apnea detection including monitoring additional parameters that indicate the patient's oxygenation status, such as $EtCO_2$ and SpO_2.

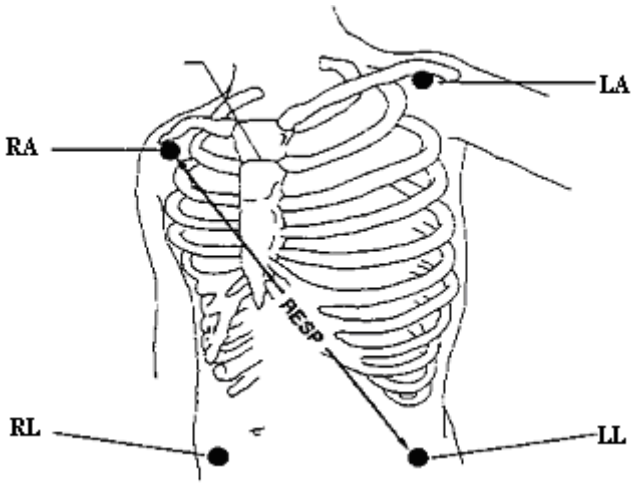
NOTE:

The RESP monitoring is not recommended to be used on patients who are very active, as this can cause false alarms.

9.3 Electrode Placement for Monitoring RESP

Correct patient skin preparation techniques for electrode placement are important for RESP measurement: you will find this information in the chapter on ECG.

The RESP signal is always measured between two of the ECG electrodes. There is only one standard ECG lead for telemetry transmitter: II lead (RA and LL).



Electrodes Placement for 5-lead

9.4 Cardiac Overlay

Cardiac activity that affects the RESP waveform is called cardiac overlay. It happens when the RESP electrodes pick up impedance changes caused by the rhythmic blood flow. Correct electrode placement can help to reduce cardiac overlay: avoid the liver area and the ventricles of the heart in the line between the respiratory electrodes.

9.5 Chest Expansion

Some patients, expand their chests laterally. In these cases it is best to place the two respiratory electrodes in the right midaxillary and left lateral chest areas at the patient's maximum point of breathing movement to optimize the respiratory wave.

9.6 Abdominal Breathing

Some patients with restricted chest movement breathe mainly abdominally. In these cases, you may need to place the left leg electrode on the left abdomen at the point of maximum abdominal expansion to optimize the respiratory wave.

NOTE:

Place the red and green electrodes diagonally to optimize the respiration waveform. Avoid the liver area and the ventricles of the heart in the line between the RESP electrodes so as to avoid cardiac overlay or artifacts from pulsating blood flow.

9.7 Selecting RESP Lead

II lead is constant as the RESP lead.

9.8 Changing the Apnea Time

Changing the apnea time is operated on MFM-CMS.

The apnea alarm is a high priority red alarm used to detect apneas. The apnea alarm delay time defines the time period between the point where the telemetry transmitter cannot detect any respiration activity and the indication of the apnea alarm.

NOTE:

Apnea time means the time period with no apnea alarm. If the actual apnea time of patient is over that that period, MFM-CMS will give apnea alarm. Please use it cautiously.

9.9 Changing the Size and Speed of the Respiration Waveform

RESP waveform setting is operated on MFM-CMS and is only applicable to the waveform on MFM-CMS.

9.10 RESP Alarm Settings

RESP alarm settings are operated on MFM-CMS. User can open or close the RESP alarm.

Chapter 10 Monitoring SpO_2

10.1 Overview

SpO_2 is based on the absorption of pulse blood oxygen to red and infrared light by means of finger sensor and SpO_2 measuring unit. SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% of the hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the telemetry transmitter will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

10.2 SpO_2 Safety Information

WARNING

1 If the SpO_2 sensor cannot work properly, please reconnect the sensor or change a new one.

2 Do not use the sterile supplied SpO_2 sensors if the packaging or the sensor is damaged and return them to the vendor.

3 Prolonged and continuous monitoring may increase the risk of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement for the patients of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. More frequent examinations may be required for different patients.

4 Tissue damage may be caused by incorrect application or prolonged measurement duration using the sensor (more than 4 hours). Inspect the sensor periodically according to the sensor user manual.

5 Use only EDAN permitted sensors and extension cables with the oximeter. Other sensors or extension cables may cause improper telemetry transmitter performance and/or minor personal injury.

NOTE:

1 Make sure the nail covers the light window. The wire should be on the backside of the hand.

2 SpO_2 waveform is not proportional to the pulse volume.

3 Avoid placing the sensor on extremities with an arterial catheter, or intravascular venous infusion line.

4 Don’t use the functional simulator to assess the SpO_2 accuracy.

5 The device is calibrated to display functional oxygen saturation.

6 The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1: 2009.

7 When the SpO_2 value is potentially incorrect, it will display “?”.

10.3 Measuring SpO_2

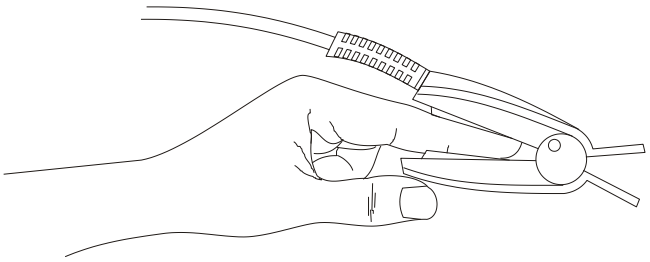
1. Select the correct **Type** in the patient management window (**Adult**/ **Pediat**) and click **Update Monitor** to confirm, as this is used to optimize the calculation of the SpO_2 and pulse numerics.
2. During measurement, ensure that the application site:

– has a pulsatile flow, ideally with a good circulation perfusion.

– has not changed in its thickness, causing an improper fit of the sensor.

10.4 Measurement Procedure

1. Switch on telemetry monitoring system.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO_2 socket on telemetry transmitter.



Mounting of the Sensor

WARNING

Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

NOTE:

Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

Interference can be caused by:

- High levels of ambient light or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material.)

- High-frequency electrical noise, including electro-surgical apparatus and defibrillators
- Intravascular dye injections
- Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin
- Excessive patient movement and vibration
- Improper sensor application
- Low perfusion or high signal attenuation
- Venous pulsation
- Placement of the sensor on an extremity that has a blood pressure cuff, arterial catheter, or intravascular line

10.5 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.

NOTE:

1. The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements. The volunteer population in the studies composed of local healthy men and women from age 19 to 37, with various skin pigmentations.
2. The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).

10.6 SpO_2 Alarm Delay

There is a delay between a physiological event at the measurement site and the corresponding alarm at the MFM-CMS. This delay has two components:

1. The time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing time and the sensitivity setting. The lower the sensitivity configured, the longer the time needed until the numerical values reflect the physiological event.
2. The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the MFM-CMS. This delay is the combination of the configured alarm delay time plus the general system delay time.

10.7 Setting Sensitivity

Setting sensitivity is operated on MFM-CMS.

The different sensitivity indicates different refresh frequency. **High** indicates the refresh frequency of SpO_2 value is the most frequent.

10.8 SpO_2 Alarm Settings

SpO_2 alarm settings are operated on MFM-CMS. User can open or close the ECG alarm.

Chapter 11 Monitoring PR

11.1 Overview

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart in beats per minute (bpm). You can display a pulse from any measured SpO_2 signal.

11.2 Selecting the Active Alarm Source

In most cases, the HR and Pulse numerics are identical. In order to avoid simultaneous alarms on HR and Pulse, the telemetry transmitter uses either ECG or Pulse as its active alarm source. Selecting active alarm source is operated on MFM-CMS.

- **HR**: if you want HR to be the alarm source for HR/Pulse.
- **PR**: if you select Pulse as the alarm source, ECG HR alarms are switched off.
- **AUTO**: If the Alarm Source is set to **Auto**, the telemetry transmitter will use the heart rate from the ECG measurement as the alarm source whenever the ECG measurement is switched on and at least one ECG lead can be measured without a technical condition. The telemetry transmitter will automatically switch to Pulse as the alarm source if:

  –a valid ECG lead can no longer be measured and

  –a pulse source is switched on and available.

  The telemetry transmitter then uses the pulse rate from the measurement currently active as system pulse. While PR is the alarm source, all arrhythmia and ECG HR alarms are switched off. If an ECG lead becomes available again, the telemetry transmitter automatically uses HR as alarm source.

NOTE:

Pulse alarms are only generated when the active alarm source is set to **PR**, a pulse source is set as system pulse and pulse alarms are switched on.

11.3 PR Alarm Settings

PR alarm settings are operated on MFM-CMS. User can open or close the ECG alarm.

Chapter 12 Using Battery

Telemetry transmitter supports 2 sections of AA batteries which cannot be charged directly in battery bin.

CAUTION

Remove the batteries from the telemetry transmitter if they are not used for a longer period of time.

12.1 Battery Status on Screen

The screen of telemetry transmitter as well as MFM-CMS displays battery status. Higher the battery surplus' level is, more power the battery has.

The following is the definition about the battery level under the typical testing environment.

Battery Level	Power Surplus
Level 0	near to using up
Level 1	work continuously no less than 6 mins
Level 2	work continuously no less than 20 hours
Level3	work continuously no less than 40 hours
Level 4	work continuously no less than 60 hours

The typical testing environment includes:

Temperature (25±2) ℃, SpO_2 module unconnected, continuously testing ECG of 3-lead （pace off and RESP off）, typical network environment with no interference, screen closed and at least 5 mins of continuous work.

In actual application, power surplus may be different with the table above due to batteries' performance.

Telemetry transmitter will sent technical alarm information of low battery power to MFM-CMS informing user of changing battery when battery power is 0-level. Meanwhile, telemetry transmitter gives out a periodic sound of "du-du-du" whose interval is 10 seconds till shutdown.

WARNING

1. Please use the specified battery and confirm its quality.
2. Before installing or replacing battery, be sure to read the user manual and safety precautions thoroughly.
3. The service life of the batteries depends on the service frequency and time. The service life of the batteries may shorten if they are used inappropriately.
4. Periodic checks on the battery performance are required. Change the batteries if necessary.
5. Do not place battery in telemetry transmitter with the (+) and (-) in the wrong way.
6. Do not connect the positive (+) and negative (-) terminals with metal objects, and do not put the batteries together with metal objects, which can result in short circuits.
7. Do not unplug the batteries when monitoring.
8. Do not heat or throw the batteries into a fire.
9. Do not use, leave the batteries close to fire or other places where temperature may be above 60 °C.
10. Do not immerse, throw, or wet the batteries in water/seawater.
11. Do not destroy the batteries: do not pierce the batteries with a sharp object such as a needle; do not hit with a hammer, step on or throw or drop to cause strong shock; do not disassemble or modify the batteries.
12. Do not disassemble the battery.
13. Do not use with new and old batteries at the same time, or use with alkaline and nickel-metal hydride battery.
14. Do not solder the leading wire and the battery terminal directly.
15. If liquid leaking from the batteries gets into your eyes, do not rub your eyes. Wash them well with clean water and go to see a doctor immediately. If liquid leaks of the batteries splash onto your skin or clothes, wash well with fresh water immediately.
16. Keep away from fire immediately when leakage or foul odor is detected.
17. Stop using the batteries if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage. Keep it away from the telemetry transmitter.
18. Do not use a battery with serious scar or deformation.
19. Use the batteries with similar performance, which can extend the service life of the batteries. If one of the two batteries is malfunctioning, it is recommended to change both of the two batteries.

12.2 Replacing the Battery

To install or replace the battery, please refer to *4.1.1 Battery Installing and Replacing*.

12.3 Recycling the Battery

When the battery no longer holds a charge, it should be replaced. Remove the old battery from the battery bin and recycle it properly.

WARNING

Do not disassemble the battery, put it into fire or cause it to short circuit. It may ignite, explode or leak, causing personal injury.

Chapter 13 Safety

13.1 Control and Safety Index

Windows XP/ Windows 7 workstation, printer, UPS (optional), Keyboard, display and mouse should accord with the corresponding safety requirements. They are not suitable for installing in the patients' environment.

13.2 Characteristics

The standard MFM-CMS includes the following characteristics:

- Up to 240 hours of trend data storage and review
- Storage of patients' history data
- 96-hour full disclosure physiological waveforms
- 12-hour short trend data
- Printing report
- Monitoring 64 patients simultaneously
- Transfer waveforms, parameters, alarms, etc.

Chapter 14 Care and Cleaning

Use only the EDAN-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

EDAN Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection

14.1 General Points

Keep your device, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the telemetry transmitter and reusable accessories after they are cleaned and disinfected.

CAUTION

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or EDAN service engineer.

14.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the telemetry transmitter and reusable accessories are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

14.2.1 Cleaning the Telemetry Transmitter

WARNING

Before cleaning the device, make sure that the telemetry transmitter is switched off and take the battery out.

To surface-clean the telemetry transmitter, follow these steps:

1. Switch off the telemetry transmitter and take the battery out.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain..
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains..
4. Dry the telemetry transmitter in a ventilated and cool place.

14.2.2 Cleaning the Reusable Accessories

14.2.2.1 Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains..
3. Wipe off with a dry cloth to remove residual moisture.
4. Leave the cable assembly to air dry.

14.2.2.2 Cleaning the SpO_2 Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution. until no visible contaminants remain
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the sensor to air dry.

14.2.2.3 Cleaning Leather Cover

1. Wipe leather cover with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains..

3. Wipe off with a dry cloth to remove residual moisture.
4. Leave leather cover to air dry.

14.3 Disinfection

For telemetry transmitter or accessories, low level disinfection is appropriate. Clean the telemetry transmitter and reusable accessories before they are disinfected. The validated disinfectants for cleaning the telemetry transmitter and reusable accessories are:

- Ethanol (75%)
- Isopropanol (70%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

WARNING

The telemetry transmitter and reusable accessories shall be disinfected regularly to avoid patient cross infection.

14.3.1 Disinfecting the Telemetry Transmitter

WARNING

Before disinfecting the telemetry transmitter, make sure that the telemetry transmitter is switched off and take batteries out.

To disinfect the telemetry transmitter, follow these steps:

1. Switch off the telemetry transmitter and take batteries out.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the telemetry transmitter for at least 30 minutes in a ventilated and cool place.

14.3.2 Disinfecting the Reusable Accessories

14.3.2.1 Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the cable assembly to air dry for at least 30 minutes.

14.3.2.2 Disinfecting the SpO_2 Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth after disinfection.
4. Leave the sensor to air dry for at least 30 minutes.

14.3.2.3 Cleaning Leather Cover

1. Wipe leather cover with a soft cloth dampened with the disinfectant solution.
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave leather cover to air dry for at least 30 minutes.

14.3.2.4 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the telemetry transmitter.

Chapter 15 Maintenance

WARNING

1 Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

2 If you discover a problem with any of the equipment, contact your service personnel, or your authorized supplier.

15.1 Inspecting

The overall check of the telemetry transmitter, including the safety check, should be performed only by qualified personnel every 24 months, and each time after fix up.

The following items should be checked:

- If the environment condition and power supply meet requirement.
- If the power supply cord has damage and insulativity meets requirement.
- If the device and accessories have damage.
- Specified accessories.
- If the alarm system can work properly.
- If the printer can work properly and the paper meets the requirement.
- Battery performance
- If all monitoring functions are in good conditions.
- If the grounding resistance and leakage current meet requirement.

If any damage or abnormality is found, please don't use the telemetry transmitter and contact local Customer Service Center.

15.2 Maintenance Task and Test Schedule

Maintenance shall be carried out at least once every two years, or as specified by local regulations. The following tasks are for EDAN-qualified service professionals only. Contact an EDAN-qualified service provider if your device needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	**Frequency**
Safety checks. Selected tests on the basis of IEC60601-1	At least once every two years, or as needed, after any repairs where the power supply is removed or replaced, or if the telemetry transmitter has been dropped.
Check all monitoring functions and measuring functions	At least once every two years, or as needed.

Chapter 16 Warranty and Service

16.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) damage caused by mishandling during shipping.

b) subsequent damage caused by improper use or maintenance.

c) damage caused by alteration or repair by anyone not authorized by EDAN.

d) damage caused by accidents.

e) replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

16.2 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Chapter 17 Accessories

You can order accessories from EDAN supplies at www.edan.com.cn or consult your local EDAN representative for details.

WARNING

1 Never reuse disposable transducers, sensors, accessories and their casing that are intended for single use; or only use them on a single patient. Reuse may compromise device functionality and system performance and cause a potential hazard.

2 Use only EDAN-approved accessories. Using non-EDAN-approved accessories may compromise device functionality and system performance and cause a potential hazard. It is not recommended to use accessories supplied by EDAN with patient monitors or telemetry transmitters by other manufacturers.

3 Do not use a sterilized accessory if its casing is damaged.

NOTE:

1. Transducers and sensors have a limited shelf life. Refer to the package labeling.
2. The part name may differ in documents, but the part number shall prevail for all purposes.

The following cables may not all be available in all countries. Please check availability with your local EDAN supplier.

17.1 ECG Accessories

Part Number	Accessories
02.04.241956	3-lead, IEC, snap, adult, limb wires for telemetry transmitter
02.04.241957	3-lead, AHA, snap, adult, limb wires for telemetry transmitter
02.04.241958	3-lead, IEC, clip, adult, limb wires for telemetry transmitter
02.04.241959	3-lead, AHA, clip, adult, limb wires for telemetry transmitter
02.04.241960	5-lead, IEC, snap, adult, limb wires for telemetry transmitter
02.04.241961	5-lead, AHA, snap, adult, limb wires for telemetry transmitter
02.04.241962	5-lead, IEC, clip, adult, limb wires for telemetry transmitter
02.04.241963	5-lead, AHA, clip, adult, limb wires for telemetry transmitter
01.57.471276	ECG CONDUCTIVE ADHESIVE ELECTRODES, TYCO KENDALL MEDI TRACE 210, 10PCS/package
01.57.471056	Adult Disposable Adhesive Electrodes, TYCO H99SG,30PCS/ package, CE
01.57.471057	Children Disposable Adhesive Electrodes, TYCO H124SG, 50PCS/package,CE
01.57.471060	Adult Disposable Adhesive Electrodes, TYCO Medi-Trace 200, 100PCS/ package, FDA

17.2 SpO_2 Accessories

Part Number	Accessories
For EDAN Module	
02.01.210120	EDAN SH1 Adult Reusable SpO_2 Sensor (DB9) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size>40kg)
02.01.210122	EDAN SH4 Adult Silicone Soft-tip SpO_2 Sensor (DB9) (Immersion Disinfection) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size>50kg)
02.01.210121	EDAN SH5 pediatric Silicone Soft-tip SpO_2 Sensor (DB9) (Only compatible with EDAN SpO_2 module and EDAN SpO_2 Extension cable), 1m (finger type, patient size: 10kg to 50kg)
01.57.471235	EDAN Adult Single-Patient SpO_2 sensor SHD-A (forefinger, for patients over 30kg)
01.57.471236	EDAN Pediatrics Single-Patient SpO_2 sensor SHD-P (forefinger, for patients between 10kg to 50kg)
01.57.471237	EDAN Infant Single-Patient SpO_2 sensor SHD-I (big toe, for patients between 3kg to 20kg)
01.57.471405	SpO_2 Extension cable for telemetry transmitter
01.57.040196	Adult Disposable SpO_2 Sensor (DB9)
01.57.040197	Pediatric Disposable SpO_2 Sensor (DB9)
01.57.040198	Infant Disposable SpO_2 Sensor (DB9)

NOTE:

The information about wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

17.3 Other Accessories

Part Number	Accessories
01.56.465787	Elastic Rope
01.56.465786	Leather Cover
01.21.064086	Alkaline LR6, 1.5V, 2600mAh, Nanfu

A Product Specifications

NOTE:
The performance of the equipment with ☆ mark was determined to be essential performance.

A.1 Classification of Telemetry Transmitter

Anti-electroshock type	Internally powered equipment
Anti-electroshock degree	ECG (RESP) CF SpO_2, CF
Ingress Protection	IPX7
Working system	Continuous operation equipment
Compliant with Standards	IEC 60601-1: 2005/ EN 60601-1: 2006 IEC 60601-1-2: 2007/ EN 60601-1-2: 2007 IEC 60601-2-49: 2011

A.2 Specifications of Telemetry Transmitter

A.2.1 Physical Specifications

Product	**Dimension**	**Max Weight**	**Comments**
iT20	100mm ±1mm *64mm ±1mm *26mm ±1mm	<140g	without battery and accessories

A.2.2 Environmental Specifications

Telemetry transmitter may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

When Telemetry transmitter and related products have differing environmental specifications, the effective range for the combined products is that range which is common to the specifications for all products.

Main unit	
Temperature	
Working	0 °C ~ +40 °C (32 ℉ ~ 104 ℉)
Transport and Storage	-20 °C ~ +55 °C (-4 ℉ ~ 131 ℉)
Humidity	
Working	15% RH ~ 95% RH (non-condensing)

Transport and Storage	15% RH ~ 95% RH (non-condensing)
Altitude	
Working	86 kPa to 106 kPa
Transport and Storage	70 kPa to 106 kPa

A.2.3 Display Specifications

Product	**Display**
iT20 (Telemetry Transmitter)	Display screen: 1.46-inch color screen Resolution: 128 x128

A.2.4 Battery

Battery Type	2 sections of AA batteries Batteries' model: (2 ∗1.5 V) AA IEC LR6
Power Supply Time	≥100 hrs. Temperature (25±2) ℃ for working environment, with fully new batteries, SpO_2 module unconnected, continuously testing ECG of 3-lead (pace off and RESP off), typical network environment with no interference, and screen closed ≥36 hrs. Temperature (25±2) ℃ for working environment, with fully new batteries, continuously testing SpO_2, continuously testing ECG of 5-lead (pace off), typical network environment with no interference, and screen closed
	Support alarm of low battery

A.3 Data Storage

Telemetry Transmitter:

Patient's Information	Bed number
Trend	1.5 hrs., at 1 min. resolution
Trend Display	Trend Graph (HR, SpO_2, RR, PR)

MFM-CMS:

Patient's Information	Department, MRN, Bed No, Last Name, First Name, Patient Type, Gender, BloodType, Date of Admission, Date of Birth, Height, weight, PACE, Doctor
Trend	240 hrs., at 1 second. resolution
Alarm review	720 sets

A.4 Specifications of MFM-CMS

A.4.1 Recommended Hardware Configuration

The minimum requirements of hardware configuration for the MFM-CMS are shown as below.

<table>
<tr><td>Components</td><td>Requirements</td></tr>
<tr><td>System</td><td>Meet the IEC/EN control requirements for ITE device</td></tr>
<tr><td>PC workstation</td><td>CPU: Intel Core 2 Duo 2.0GHz or above
Memory: 2G or above
Hard disk: 320GB or above
Display interface: 2
LAN port: 1 or above
USB port: more than one
OS: Windows XP (32 bit)
Windows 7 Pro 32/64bit/</td></tr>
<tr><td>Keyboard</td><td>PS/2 or USB keyboard</td></tr>
<tr><td>Mouse</td><td>PS/2 or USB mouse</td></tr>
<tr><td>Display</td><td>Specifications:
<table>
<tr><td>Dimensions (inch)</td><td>Resolution (pixel)</td></tr>
<tr><td>19 (widescreen)</td><td>1440X900</td></tr>
<tr><td>19 (regular-screen)</td><td>1280X1024</td></tr>
<tr><td>* 17 (regular-screen)</td><td>1280X1024</td></tr>
<tr><td colspan="2">*Recommended</td></tr>
</table>
Quantity:
For 1 to32 telemetry transmitters: one display
For 33 to 64 telemetry transmitters: two displays</td></tr>
<tr><td>Printer</td><td>LaserJet</td></tr>
</table>

UPS	1000 W	
Network device specifications	Structure	Ethernet 802.3
	Device	Network switch
	Transmission rate	10 M, 100 M
	Transmitted information	Waveforms, parameters and alarms of all networked telemetry transmitters
	Compatible telemetry transmitters	telemetry transmitters complying with EDAN network protocol
	Maximum number of networked telemetry transmitters	64
Speaker	Built-in speaker is recommended.	

CAUTION

Ensure that the computer hardware can meet the requirements of the software installation and running. Also, the video adapter, the audio adapter, the network adapter and their respective drivers should been installed well in the computer; otherwise, the software may not run normally.

NOTE:

1 The hardware specifications require the use of PC that complies with IEC/EN requirements for ITE equipment.

2 The configuration mentioned above is for reference and not permanent. EDAN preserves the right to change and upgrade system settings.

A.4.2 Software Performance

Trend	240-hour trend review for each telemetry transmitter; 12-hour short trend dynamic display for each telemetry transmitter;
Alarm events	720 pieces of parameter alarm events for each telemetry transmitter
Alarm type	Physiological Alarm Technical Alarm
Alarm mode	3 levels of audible and visual alarms

Nurse call records (from the telemetry transmitter are stored by MFM-CMS)	Store 100 groups
Patient call records (from the telemetry transmitter are stored by MFM-CMS)	Store 100 groups
Waveform storage and review	96-hour waveform for each telemetry transmitter

A.5 ECG

Complies with IEC 60601-2-27: 2011

Lead Mode	◆ Automatic identification for leads ◆ 3-Lead: I, II, III ◆ 5-Lead: I, II, III, aVR, aVL, aVF, V
	Support Smart Lead Off Check
	(Telemetry transmitter) cannot choose calculation lead; (MFM-CMS) supports choosing calculation lead.
Lead naming style	AHA, IEC
☆ Display Sensitivity (Gain Selection)	MFM-CMS: 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 gain Telemetry Transmitter: AUTO gain
☆ Sweep	MFM-CMS: 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s Telemetry Transmitter: 12.5 mm/s
☆ Bandwidth (-3 dB)	Diagnosis: 0.05 Hz to 150 Hz Monitor: 0.5 Hz to 40 Hz Surgery: 1 Hz to 20 Hz

☆ CMRR (Common Mode Rejection Ratio)	Diagnosis: >95 dB Monitor: >105 dB Surgery: >105 dB
Notch	In diagnosis, monitor and surgery modes: 50 Hz/60Hz (Notch filter can be turned on or off manually)
☆ Differential Input Impedance	>5 MΩ
☆ Input Signal Range	±10 mV PP
☆ Accuracy of Input Signal Reproduction	An error of ≤ ±20% of the nominal value of the output or ±100 μV, whichever is greater. The total error and frequency response comply with IEC 60601-2-27: 2011, Sect. 201.12.1.101.1.
☆ Electrode Offset Potential Tolerance	±500 mV
Auxiliary Current (Leads off detection)	Active electrode: <100 nA Reference electrode: <900 nA
☆ Recovery time after Defibrillation	<5 s
☆ Leakage current of patient	<10 μA
☆ Scale signal	1 mVPP, accuracy is ±5％
☆ System noise	<30 μVPP
Multichannel Crosstalk	≤ 5% of the input signal Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.5.

Frequency and Impulse Response	Frequency response: Input a 5 Hz, 1 mV sine wave signal, and the output signal amplitude remains within the range of 71% to 110% at 0.67 Hz and 40 Hz. Input a 1 Hz, 1.5 mV 200 ms triangular wave input signal, and the output shall be within 11.25 mm~15 mm. Impulse response: Displacement value: ≤ 0.1 mV Slope: ≤ 0.3 mV/s following the end of the pulse. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.8.
Pace Pulse	
Pulse indicator	Pulse is marked if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.12 are met: Amplitude: ±2 mV to ±700 mV Width: 0.2 ms to 2.0 ms Ascending time: 10 μs to 100 μs And Amplitude: ±3 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
Pulse Rejection	Pulse is rejected if the requirements of IEC 60601-2-27: 2011, Sect. 201.12.1.101.13 are met: Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to100 μs
Baseline Reset Time	< 3 s. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.11
Minimum input slew rate (Lead II)	>2.5 V/S
Heart Rate	
HR Calculation	

☆ Range	ADU: 15 bpm to 300 bpm PED: 15 bpm to 350 bpm
☆ Accuracy	±1% or ±1 bpm, whichever is greater
☆ Resolution	1 bpm
Sensitivity	≥300 μV PP
QRS	
QRS Detection Range	The detection range has exceeded the requirement described in the standard: Width: 70 ms~120 ms for adult, 40 ms~120 ms for Pediatric/neonate. Amplitude: 0.5 mv~5 mv In adult mode, these two signals are not responded: 1. when QRS amplitude of 0.15 mV or less is applied; 2. when QRS duration of 10 ms and QRS amplitude of 1 mV or less is applied. Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.15.
PVC	
☆ Range	ADU: 0 to 300 PVCs/ min PED: 0 to 350 PVCs/ min
☆ Resolution	1 PVCs/min
ST value	
☆ Range	-2.0 mV to +2.0 mV
☆ Accuracy	-0.8 mV to +0.8 mV: ±0.02 mV or 10%, whichever is greater. Beyond this range: not specified.
☆ Resolution	0.01 mV
HR Averaging Method	
Method 1	Heart rate is computed by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals.

Method 2	If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the HR.
Range of Sinus and SV Rhythm	
Tachy	Adult: RR interval for 5 consecutive QRS complex ≤ 0.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≤ 0.375 s.
Normal	Adult: 0.5 s < RR interval for 5 consecutive QRS complex < 1.5 s. Pediatric: 0.375 s < RR interval for 5 consecutive QRS complex < 1 s.
Brady	Adult: RR interval for 5 consecutive QRS complex ≥ 1.5 s. Pediatric: RR interval for 5 consecutive QRS complex ≥ 1 s.
Range of Ventricular Rhythm	
Ventricular Tachycardia	The interval of 5 consecutive ventricular beats is less than 600 ms
Ventricular Rhythm	The interval of 5 consecutive ventricular beats ranges from 600 ms to 1000 ms
Ventricular Bradycardia	The interval of 5 consecutive ventricular beats is more than 1000 ms
☆ Maximum start-up alarm time for Tachycardia	
Ventricular Tachycardia 1 mV 206bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s
Ventricular Tachycardia 2 mV 195bpm	Gain 1.0: 10 s Gain 0.5: 10 s Gain 2.0: 10 s

<table>
<tr><td>Response time of Heart Rate Meter to Change in HR</td><td colspan="3">HR range: 80 bpm to 120 bpm
Within 11 seconds
HR range: 80 bpm ~ 40 bpm
Within 11 seconds</td></tr>
<tr><td>Tall T-wave Rejection</td><td colspan="3">Complied with IEC 60601-2-27: 2011, Sect. 201.12.1.101.17 minimum recommended 1.2 mV T-Wave amplitude</td></tr>
<tr><td>Accuracy of Heart Rate Meter and Response to Irregular Rhythm</td><td colspan="3">Complied with IEC 60601-2-27: 2011, Sect. 201.7.9.2.9.101 b) 4), the HR value after 20 seconds of stabilization is displayed as follows:
Ventricular bigeminy: 80 bpm ±1 bpm
Slow alternating ventricular bigeminy: 60 bpm ±1 bpm
Rapid alternating ventricular bigeminy: 120 bpm ±1 bpm
Bidirectional systoles: 91 bpm ±1 bpm</td></tr>
<tr><td>Time to Alarm for Heart Rate alarm conditions</td><td colspan="3">Asystole alarm: ≤ 10 s
HR low alarm: ≤ 10 s
HR high alarm: ≤ 10 s
Complied with IEC 60601-2-27: 2011, Sect. 208.6.6.2.103.</td></tr>
<tr><td rowspan="6">Arrhythmia analyses</td><td>ASYSTOLE</td><td>VFIB/VTAC</td><td>COUPLET</td></tr>
<tr><td>VT>2</td><td>BIGEMINY</td><td>TRIGEMINY</td></tr>
<tr><td>VENT</td><td>R ON T</td><td>PVC</td></tr>
<tr><td>TACHY</td><td>BRADY</td><td>MISSED BEATS</td></tr>
<tr><td>IRR</td><td>VBRADY</td><td>PNC</td></tr>
<tr><td>PNP</td><td colspan="2"></td></tr>
</table>

A.6 RESP

Method	Impedance RA-LL
Measurement lead	lead II
Calculation Type	Automatic
Respiration excitation waveform	Square Wave, 64 kHz (± 10%), <500 μA

☆ Measuring Sensitivity	Within baseline impedance range: 0.3 Ω
☆ Waveform bandwidth	0.2 Hz to 2.5 Hz (-3 dB)
☆ Baseline Impedance Range	200 Ω to 2500 Ω (leads cables 1 KΩ resistance)
☆ RR Measuring Range	
Adult	0 rpm to 120 rpm
Ped	0 rpm to 150 rpm
Resolution	1 rpm
☆ Accuracy	
Adult	6 rpm to 120 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
Ped	6 rpm to 150 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
☆ Gain Selection	(MFM-CMS) ×0.25, ×0.5, ×1, ×2, ×3, ×4, ×5
Sweep	(MFM-CMS) 6.25 mm/s, 12.5 mm/s, 25 mm/s
Apnea Alarm Time Setup	10 s, 15 s, 20 s, 25 s, 30 s, 35 s, 40 s; default value is 20 s. ±3 seconds delayed is acceptable.

A.7 SpO_2

Complies with ISO 80601-2-61: 2011.

☆ Measuring Range	0% to 100%
☆ Adjustable Range of Alarm Limits	20% to 100%
☆ Resolution	1%
☆ Data update period	1 s
☆ Accuracy	
Adult /Pediatric	±2% (70% to 100% SpO_2)
	Undefined (0% to 69% SpO_2)

Pulse Rate		
☆ Measuring Range	25 bpm to 300 bpm	
☆ Adjustable Range of Alarm Limits	30 bpm to 300 bpm	
Resolution	1 bpm	
☆ Accuracy	±2 bpm	
Sensor		
Red light	(660±3) nm	
Infrared light	(905±10) nm	
Emitted light energy	< 15 mW	
Sweep	(MFM-CMS) 6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s	
Alarm signal	System delay	less than 3 s
	Pause duration	60 s, 120 s, 180 s

NOTE:

Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

A.8 Wi-Fi

IEEE	802.11b/g/n
Frequency	2.4 GHz ISM band
Modulation	OFDM（BPSK，QPSK，16-QAM，64-QAM） CCK/DSSS（802.11b）
Typical Transmit Power (±2 dBm)	13 dBm for 802.11b DSSS 13 dBm for 802.11b CCK 13 dBm for 802.11g/n OFDM

NOTE：

iT20 only works with EDAN MFM-CMS and network encryption is applied. The devices from other manufacturer have no access to the system.

B EMC Information

B.1 Electromagnetic Emissions

Electromagnetic emission		
iT20 is intended for use in the electromagnetic environment specified below. The customer or the user of the iT20 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	iT20 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	iT20 is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC/EN 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3	Not applicable	

B.2 Electromagnetic Immunity

Electromagnetic immunity			
iT20 is intended for use in the electromagnetic environment specified below. The customer or the user of the iT20 should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Not applicable

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

B.3 Electromagnetic Immunity

Electromagnetic immunity			
iT20 is intended for use in the electromagnetic environment specified below. The customer or the user of iT20 should assure that it is used in such an environment.			
Immunity test	**IEC/EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of iT20,

			including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC/EN 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC/EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m). 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: 

NOTE 1 At 80 MHz and 800 MHz, 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.

[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 iT20 is used exceeds the applicable RF compliance level above, iT20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating iT20.

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

B.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and iT20

iT20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of iT20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and iT20 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter(m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 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 and 800 MHz, the separation distance for the higher frequency range applies.

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

C Default Settings

This appendix documents the most important default settings of your telemetry transmitter as it is delivered from the factory.

NOTE:

If your telemetry transmitter has been ordered preconfigured to your requirements, the settings at delivery will be different from those listed here.

C.1 Patient Information Default Settings

Patient Information Settings	
Patient Type	Adult
Pace	Off

C.2 Alarm Default Settings (MFM-CMS)

Alarm Settings	
Pause Time	120s
Mute	Off
Alarm Latch	Off

C.3 ECG Default Settings

ECG Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	120	160
Alarm Low Limit	50	75
Pace	Off	
Lead Type	Distinguish automatically	
Calculation Lead	Lead II	
Filter Mode	Monitor	
Smart Lead Off	Off	
ST Alarm Level	Med.	
ST Analysis	Off	
Alarm Switch	Off	
Alarm Level	Medium	

X stands for I, II, III, aVR, aVL, aVF, V, V1, V2, V3, V4, V5 or V6.			
ARR Analysis			
ARR Analysis	On		
PVCs Alarm Level	Medium		
PVCs Alarm Switch	Off		
ARR Alarm Settings	Alarm Switch	Alarm Level	Alarm Record
ASYSTOLE	On	High	Off
VFIB/VTAC	On	High	Off
R ON T	On	Medium	Off
VT > 2	On	Medium	Off
COUPLET	On	Medium	Off
PVC	off	Low	Off
BIGEMINY	On	Medium	Off
TRIGEMINY	On	Medium	Off
TACHY	On	Medium	Off
BRADY	On	Medium	Off
MISSEDBEATS	On	Medium	Off
IRR	Off	Low	Off
PNC	On	Medium	Off
PNP	On	Medium	Off
VBRADY	On	Medium	Off
VENT	On	Medium	Off

C.4 RESP Default Settings

RESP Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	30	30
Alarm Low Limit	8	8
Apnea Time	20 s	
Sweep	12.5 mm/s	

C.5 SpO_2 Default Settings

SpO_2 Settings	ADU	PED
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	100	100
Alarm Low Limit	90	90
Sensitivity	Meddium	
Sweep	12.5 mm/s	

C.6 PR Default Settings

PR Settings	ADU	PED
PR Source	SpO_2	
Alarm Switch	On	
Alarm Level	Medium	
Alarm High Limit	120	160
Alarm Low Limit	50	75
Alarm Source	Auto	

D Abbreviation

Abbr	English Full Name/Description
AC	Alternating current
Adu	Adult
CISPR	International Special Committee on Radio Interference
CMS	Central monitoring system
DC	Direct current
ECG	Electrocardiogram
EEC	European Economic Community
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ESU	Electrosurgical unit
FCC	Federal Communication Commission
FDA	Food and Drug Administration
HR	Heart rate
ID	Identification
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronic Engineers
LA	Left arm
LCD	Liquid crystal display
LED	Light emitting diode
LL	Left leg
MDD	Medical Device Directive
MRI	Magnetic resonance imaging
N/A	Not applied
oxyCRG	Oxygen cardio-respirogram
Ped	Pediatric
Pleth	Plethysmogram
PR	Pulse rate
PVC	Premature ventricular complex
R	Right

RA	Right arm
Resp	Respiration
RL	Right leg
RR	Respiration Rate
SpO_2	Oxygen saturation of arterial blood
USB	Universal serial bus

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