

TMS-6016 Telemetry Monitoring System

Operator's Manual

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 **WARNING**

-
- **Federal Law (USA) restricts this device to sale by or on the order of a physician.**
-

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- the product is used in accordance with the instructions for use.



WARNING

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

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Preface

Manual Purpose

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

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

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

Intended Audience

This manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practices and terminology as required for monitoring of critically ill patients.

Illustrations

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

Conventions

- Italic text is used in this manual to quote the referenced chapters or sections.
- The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness.

FOR YOUR NOTES

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1 Safety

1.1 Safety Information

The safety statements presented in this chapter refer to the basic safety information that the operator of the Telemetry monitoring system shall pay attention to and abide by. There are additional safety statements in other chapters or sections, which may be the same as or similar to the followings, or specific to the operations.

DANGER

- Indicates an imminent hazard situation that, if not avoided, will result in death, serious injury or property damage.
-
-

WARNING

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

CAUTION

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

NOTE

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

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific “Danger” statements may be given in the respective sections of this operation manual.

1.1.2 Warnings

 **WARNING**

- **The telemetry monitoring system is intended for use by trained clinical professionals in specific situations. Any operations of the system by unauthorized or untrained person are prohibited.**
 - **Check the system and accessories each time before use. Make sure they function properly and safely.**
 - **Possible fire or explosion hazard if used in the presence of flammable anesthetics.**
 - **Do not use this equipment in conjunction with electro-surgery unit (ESU).**
 - **Be sure to set the alarm according to the patient’s conditions. Make sure the system sounds when an alarm is present.**
 - **Opening the receiver housing may present a risk of electric shock. All servicing and future upgrades to this system must be performed by personnel trained and authorized by Mindray only.**
 - **Do not come into contact with patients or transmitter during defibrillation. Otherwise serious injury or death could result.**
 - **Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children’s reach.**
 - **The telemetry receiver must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect the receiver from the power line and operate it on battery power, if possible.**
 - **The equipment generates and uses RF energy. If it is not installed correctly or used by observing the manual, RF interference to other devices could result.**
 - **The telemetry system transmits through space wireless signals. During this process, signals may be interfered by multiple sources of RF interference. Although the telemetry system has certain capability against interference, occasional transmission failure could occur.**
 - **The telemetry transmitter is an IPX3 device. Never immerse the telemetry transmitter in water or other liquids such as cleaning solutions.**
-

 **WARNING**

- **The equipment is not capable of rejecting pacer pulse. Keep pacemaker patients under close observation.**
 - **After the first deploy of antenna array, or after hospital's building reconstruction or re-decoration, clinician shall confirm the coverage of antenna array, and shall require patients to move around within the confirmed area. Clinician should arrive on time within the area.**
-
-

1.1.3 Cautions

 **CAUTION**

- **To ensure patient safety, use only parts and accessories specified in this manual.**
 - **Remove the batteries if you do not intend to use the transmitter for a long period of time.**
 - **Disposable devices are intended for single use only. They should not be reused as performance could degrade or contamination could occur.**
 - **At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the product, please contact us.**
 - **Magnetic and electrical fields are capable of interfering with the proper performance of the system. For this reason make sure that all external devices operated in the vicinity of the system comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
 - **Before connecting the receiver to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label or in this manual.**
 - **Install or carry the transmitter properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
 - **Signal transmission can be disturbed when the patient passes concrete walls or elevator doors.**
 - **High quality alkali batteries are recommended. Remove the batteries when the transmitter is not in use.**
 - **Although the transmitter and receiver are chemically resistant to most common hospital cleaners and non-caustic cleaners, different cleaners are not**
-

 CAUTION

recommended and may stain the transmitter and receiver. Many cleaners must be diluted before use.

- Insert the silica gel plug into the programming port when the programming cable is not attached to the transmitter.
-

1.1.4 Notes

NOTE

- Keep this manual close to the Telemetry monitoring system so that it can be obtained conveniently when necessary.
 - For detailed introductions of the central monitoring system, refer to the operator's manual of the central monitoring system.
 - Choose a location that affords an unobstructed view of the system and easy access to the operating controls.
 - The instructions of this manual are based on the maximum configuration. Some of them may not apply to your system.
-

1.2 Equipment Symbols



Attention: Consult accompanying documents (this manual).



Power on



Power off



Alternating current (AC)



Type CF applied part. The unit displaying this symbol contains an F-type isolated (floating) patient part providing a high degree of protection against shock, and is suitable for use during defibrillation.



Equipotential terminal



Non-ionizing electromagnetic radiation



Network connector



Antenna interface



Communication status



Manufacture date



Serial number



European community representative

The following definition of the WEEE label applies to EU member states only.



This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it.

* For system products, this label may be attached to the main unit only.

The machine has only one of the certification labels below.

Please refer to the label attached to the machine to determine the applicable certification label.



The presence of this label indicates the machine was certified by ETL with the statement:

CONFORMS TO UL STD 60601-1, IEC 60601-2-49,
IEC60601-1-1

CERTIFIED TO CSA STD C22.2 NO 601.1, NO 60601-2-49,
CSA STD C22.2 NO 601-1-1



Classified by Underwriters Laboratories Inc. with respect to electric shock, fire and mechanical hazards, only in accordance with UL 60601-1, CAN/CSA C22.2 NO.601-1, IEC 60601-1-1, IEC 60601-2-49.

2 Overview

2.1 General

The telemetry monitoring system comprises several telemetry transmitters, a telemetry receiver, an antenna array, the central monitoring system software and certain accessories. It features:

- Compact size and light weight.
- Long battery life.
- Reliable signal reception.
- Easy expandability.
- Powerful central monitoring system software.

2.1.1 Intended Use

By using radiofrequency signal, the Telemetry Monitoring System (TMS) is intended to monitor Electrocardiogram (ECG), Heart Rate (HR), Arrhythmia Detection, ST Segment Analysis for adult and pediatric patients. Physical signals are collected by sensors and wirelessly transmitted by transmitters in WMTS band. Receivers get the signals and forward to the Central Monitoring System (CMS) for processing, displaying, storing, printing, etc. It can be used within a defined coverage area in hospitals or medical institutions.

WARNING

- **If the accuracy of any value displayed on the screen of the Telemetry monitoring system's screen is questionable, first determine the patient's vital signs by alternative means and then verify that the Telemetry monitoring system is working correctly.**
 - **The physiological waves, parameters and alarms displayed on the system screen are for doctor's reference only to make diagnoses. They can not be directly used as the basis for clinical treatment.**
 - **The system transmits data through wireless connection. Risk of data loss is possible. Keep a close eye on the critical patient.**
 - **One transmitter is to be used on one patient only.**
-
-

2.1.2 Contraindications

None.

2.1.3 Components

The system comprises several telemetry transmitters, a telemetry receiver, an antenna array, the central monitoring system software and ECG cable.

2.1.4 Functions

The system provides information on the following parameter.

- ECG Heart rate (HR)
 3-channel of ECG waveforms
 Arrhythmia and ST segment analysis
 Pace analysis (PACE)

In addition, the system provides such functions as alarms, freeze, review and recording.

2.2 Product Overview

2.2.1 Telemetry Transmitter

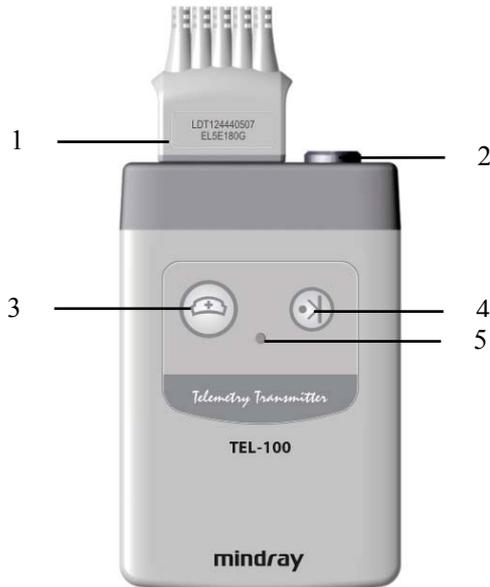


Figure 2-1 Transmitter – front view

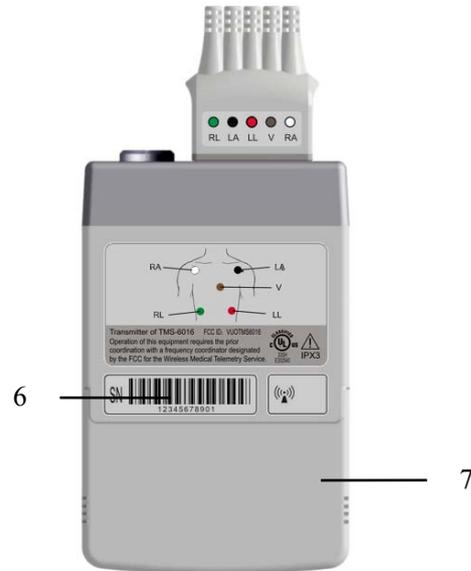


Figure 2-2 Transmitter – rear view



Figure 2-3 Transmitter – top view

1. ECG connector
Connects the designated ECG cable (3-lead or 5-lead).
2. Programming port
Connects the designated special configuration cable.
3. Nurse Call Button
To call a nurse during monitoring, press the Nurse Call Button on the transmitter. This sends the call to the Central Monitoring System (hereinafter called as CMS).
4. Event Button
Press the Event Button on the transmitter if the patient feels uncomfortable. This sends the event to the central monitoring system.

5. LED Indicator

- The LED flashes green when the transmitter works correctly.
- The green LED is on when instructions are in transmission.
- The LED flashes red if one of the patient leads has fallen off the patient;
- The LED flashes yellow when batteries in the transmitter are low.
- The red LED is on when the transmitter is conducting a self-test.

6. SN label

The last four digits of the serial number of the transmitter will be used as the transmitter ID to be displayed in the central monitoring system.

7. Battery door

It covers the battery compartment.

8. Hanging hole

If you want to hang the transmitter, hang it by this hole.

 **WARNING**

- **Do not use the patient cable to move or lift the transmitter. It might cause the transmitter to fall, which might damage the transmitter or injure the patient.**
-

2.2.2 Telemetry Receiver



Figure 2-4 Receiver – front view



Figure 2-5 Receiver – rear view

1. Communication indicator
A green LED that indicates the communication status.
 - It flashes frequently when the communication is normal.
 - It stops flashing when the communication is ceased.
 - It is off when the initialization failed or something is wrong with the hardware.

2. Power indicator
A green LED that indicates the power status.
 - It is on when the receiver is powered on.
 - It is off when the receiver is powered off.

3. AC power input connector

You can power on/off the receiver by pressing this button.

4. Power switch

Place the switch in “ | ” to switch on the power , in “ ○ ” to switch off the power.

5. Fuse holder

Open the cover to replace the fuse. The fuse shall be 5TT/1.6A.

6. Equipotential Grounding connector

When the telemetry receiver and other equipment are to be used together, their equipotential grounding terminals should be connected together, eliminating the potential difference between them.

7. Antenna connector

The receiver has two antenna connectors, respectively marked 1 and 2.

8. Network connector

Put network connection through an RJ45 connector.

 **WARNING**

-
- **Accessory equipment connected to this system must be certified according to the respective IEC standards (e.g. IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input port or signal output port is responsible to ensure that the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, contact our company or customer service.**
-
-

2.3 About The Central Monitoring System

By analyzing and calculating the ECG signals collected from the telemetry transmitter, the central monitoring system is intended to display the ECG waveforms and the HR value. Besides, the central monitoring system is intended to show status information for the transmitter and receiver as well as prompt information for the alarms coming from the transmitter and receiver.

2.3.1 Display

2.3.1.1 Single-Screen Mode

Main Screen in Single-Screen Mode

The central monitoring system supports the following display modes: single-screen, dual- and multi-screen. The figure below shows the main screen (default screen) under the single-screen mode.

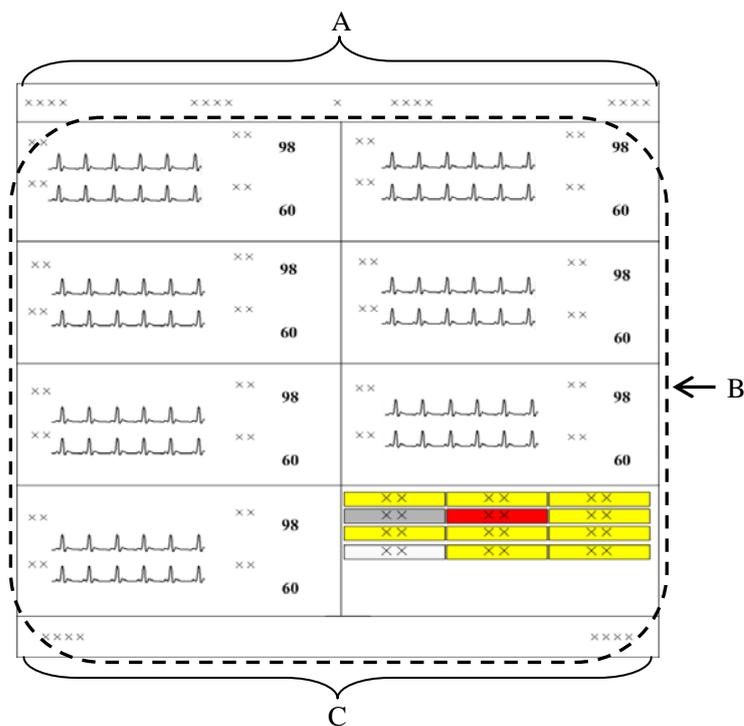


Figure 2-6 Main screen in Single-Screen Mode

- A. System information area
- B. Patient window area
- C. System buttons and icons area

System Information Area

In this area, the following information is displayed:

- 1 Hospital information: Displays the hospital and office where the central monitoring system is located.
- 2 System alarm icon area: Display system silence icon  or system alarm audio off icon .
- 3 System alarm area: Displays the prompts or alarms coming from the system itself. If more than one message occur, they will be displayed circularly. Please refer to the ***Hypervisor VI Central Monitoring System Operator's Manual*** for all the system alarms.
- 4 Current time: Displays the current time.

Patient Window Area

For details, refer to ***2.3.2 Multibed Screen***.

System Buttons and Icons Area

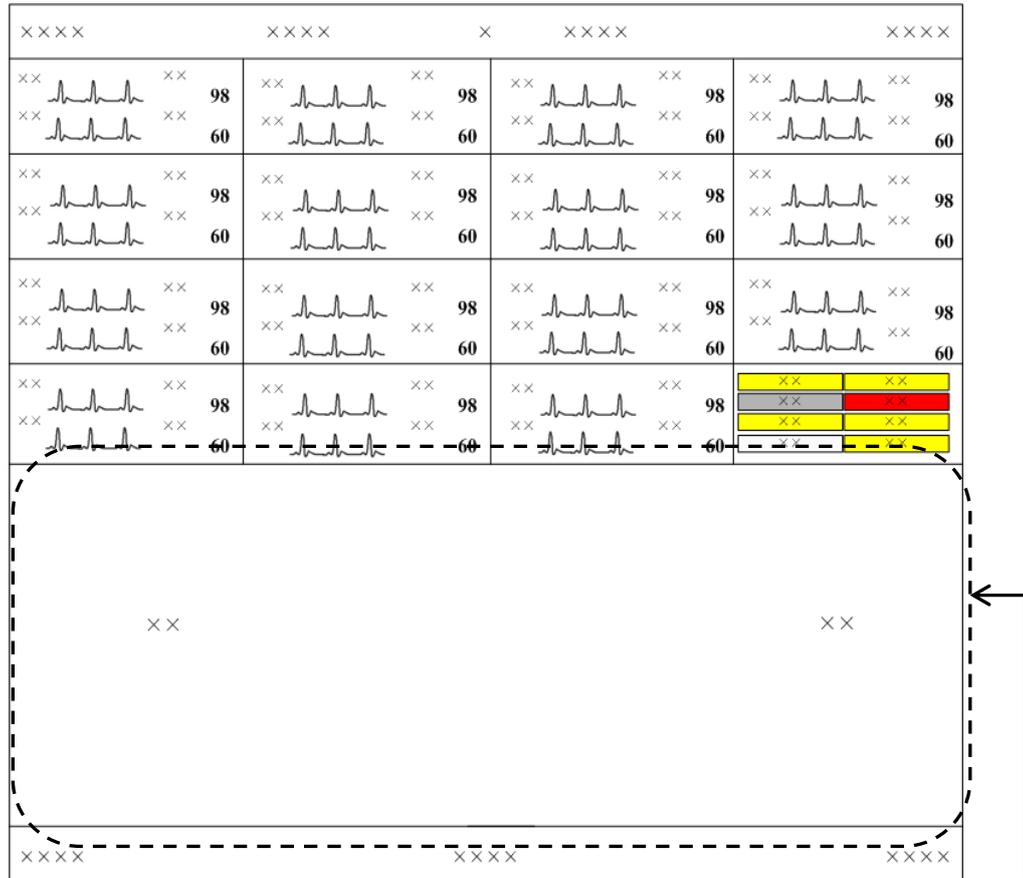
System buttons include:

- 1 Silence: Click to silence the central monitoring system.
- 2 Admit Patient: Click it to enter the “Connected patient list” screen.
- 3 System Setup: Click it to enter the “System Setup” tab sheet.
- 4 Discharged Pat.: Click it to enter the “Discharged Patients” tab sheet.
- 5 Remote CMS: Click it enter the “Remote CMS” tab sheet.
- 6 Main Screen/Viewbed: Click it to close the auxiliary screen and return to the main screen/ Click it to enter the “ViewBed” tab sheet.

System icons include:

No.	Icon name	Icon	Description
1	Alarm List		Show the alarms of all being monitored patients within the specified time range.
2	USB state		Indicates that the system connects other USB device besides the USB dongle.
3	Printer state		Indicates that the printer is normal.
			Indicates a printer error.
			Indicates that no printer is connected.
4	Recorder state		Indicates that the recorder is normal
			Indicates that the recorder is under test.
			Indicates a recorder error.
			Indicates that no recorder is connected.
5	Networking prompt		Flash: indicates new monitors log on.
			Not flash: indicates no new monitor logs on
6	Network status		Indicates that the network is normal
			Indicates that the network is disconnected.

Auxiliary Screen in Single-Screen Mode



Auxiliary Screen

Figure 2-7 Auxiliary Screen in Single-Screen Mode

In single-screen mode, you can enter an auxiliary screen by clicking the patient window, system buttons or icons area. As shown in the figure above, the auxiliary screen will occupy the lower half part of the main screen and the system will automatically adjust the size and number of patient windows.

You can:

- Click “Admit Patient” to enter the “Connected patient list” screen
- Click “System Setup” to enter the “System Setup” tab sheet.
- Click “Discharged Pat.” to enter the “Discharged Pat.” tab sheet.
- Click “Remote CMS” to enter the “Remote CMS” tab sheet.
- Click “ViewBed” to enter the “ViewBed” tab sheet.
- Click a patient window to enter the “Viewbed” tab sheet.

2.3.1.2 Dual-Screen Mode

For the dual-screen mode, a dual-link card is needed for connecting two displays to the host, respectively called primary display and secondary display. The dual-screen mode is classified into two main screens and one main screen.

■ Two Main Screens

As shown below, both displays have the main screen by default if the number of main screen is configured to 2. The primary display's screen is on the left and the secondary display's screen on the right. The system buttons and icons are located on the secondary display's screen.

Click a patient window, the secondary display will change to show the auxiliary screen of single bed window of this patient. To go back to the main screen, click the "Main Screen" button at the bottom of auxiliary screen.

In the mode of two main screens, a maximum of 32 patient windows can be viewed at one time.

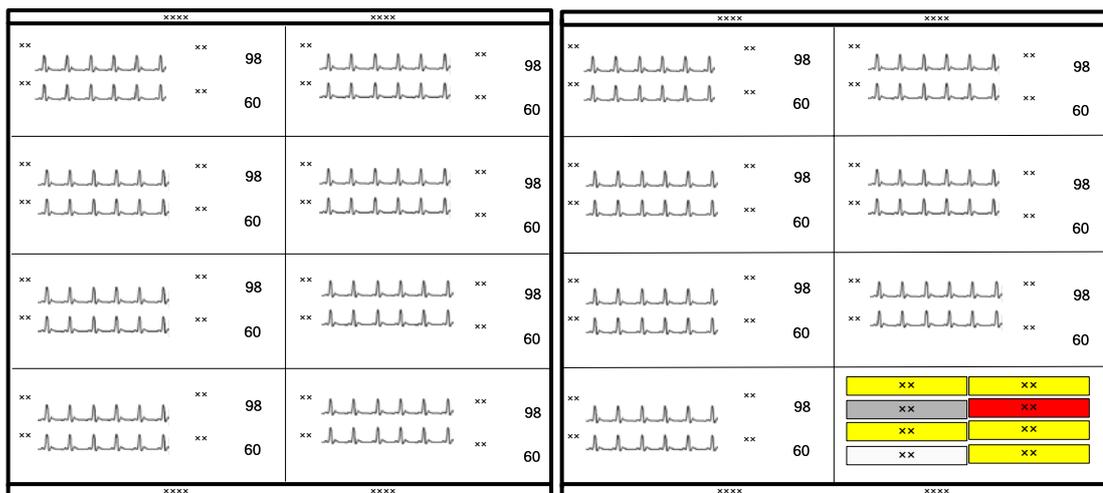


Figure 2-8 Two Main Screens (Default)

■ One Main Screen

As shown below, if the number of main screen is configured to 1, the primary display on the left always shows main screen and the secondary display on the right always shows auxiliary screen. In this mode, up to 16 patient windows can be viewed at one time.

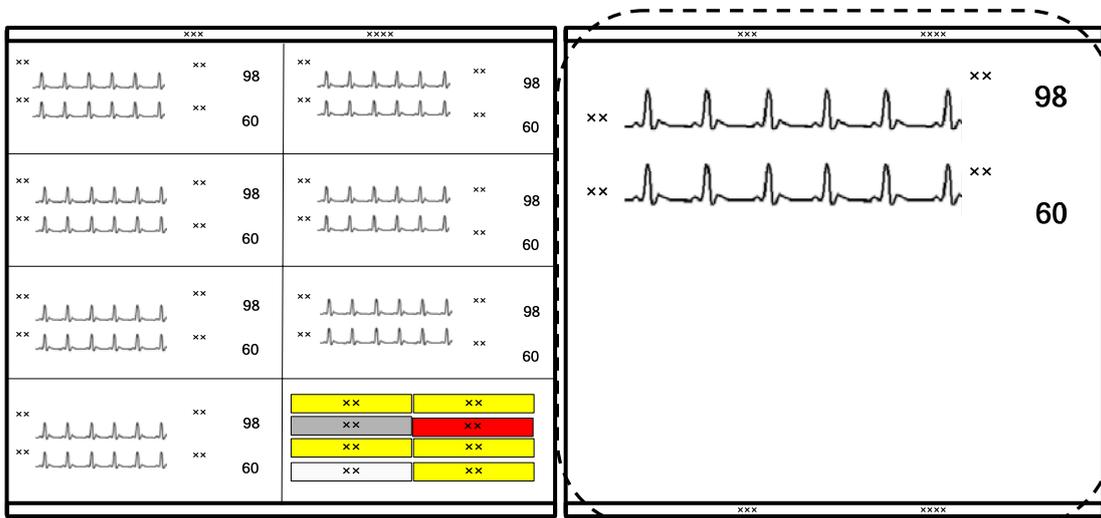


Figure 2-9 One Main Screen

2.3.1.3 Multi-Screen Mode

As to the CMS which supports tri-screen or quad-screen mode, three or four displays can be connected to the host. One display is set as secondary display, and others are primary displays

As shown below by the tri-screen mode, the two primary displays on the left always show main screen, and the secondary display on the right always for auxiliary screen. In the mode of tri-screen or quad-screen, a maximum of 16 patient windows can be viewed at one time on each primary display.

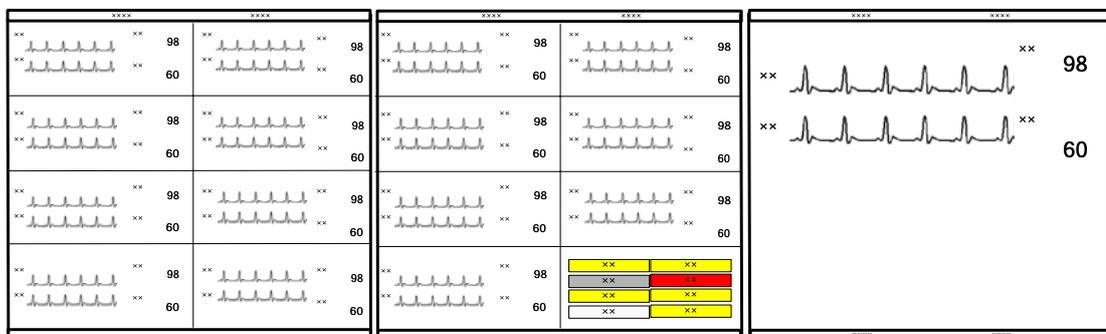


Figure 2-10 Tri-Screen Mode

2.3.2 Multibed Screen

The central monitoring system displays up to 16 patient windows in single-screen mode (32 patient windows in dual- or multi-screen mode) and you can therefore view 16 patients on the spot at one time. The number of the patient windows to be displayed depends on the display format defined for the multibed screen. For details, refer to the Central Monitoring System Operator's Manual.

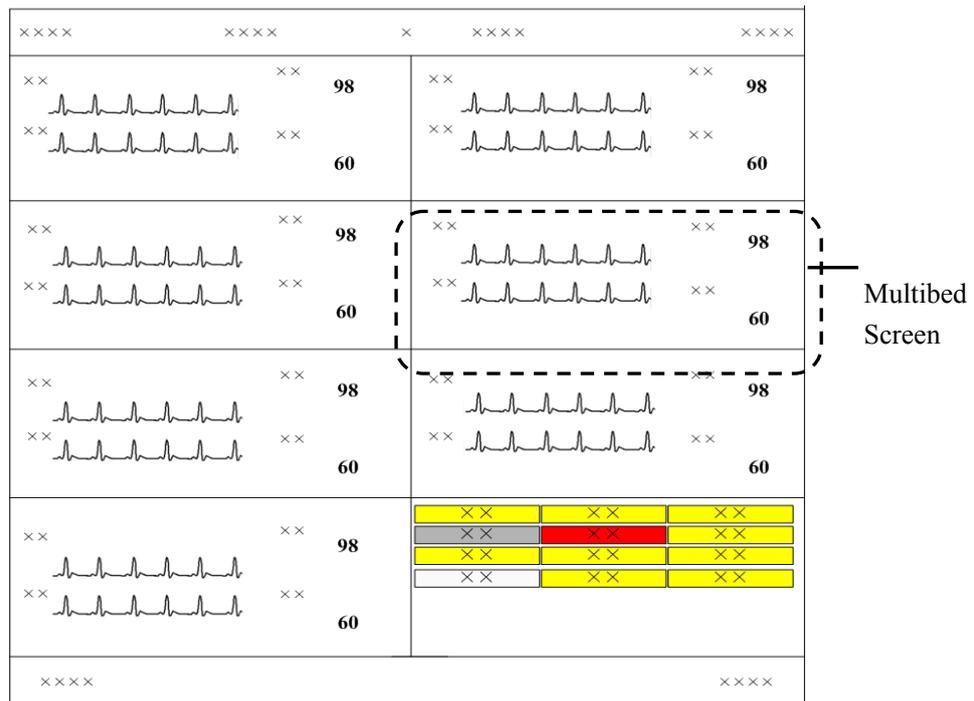


Figure 2-11 Multibed Screen

If the number of the transmitters connected to the central monitoring system is no more than the maximum of patient windows, all the patient windows can be used for spot observation; if not, the last patient window will be used for non-spot observation.

The patient windows used for spot observation will be hereinafter referred to as the spot patient windows, and their patients as spot patients. Likewise, the patient windows used for non-spot observation will be hereinafter referred to as the non-spot windows, and their patients as the non-spot patients.

2.3.2.1 Non-Spot Patient Window

The non-spot patient window shows information including bed number and status for each transmitter displayed in it. For the transmitters displayed in this window, different background colors represent different statuses.

xx	xx	xx

The following table shows each status of the non-spot transmitter and the corresponding block's indication.

Non-spot transmitter status	Corresponding block's indication
It is connected and no alarm is present.	Background is black.
It is connected and a low- or medium-priority alarm(s) is present.	Background is flashing yellow.
It is connected and a high-priority alarm(s) occurs.	Background is flashing red.
Disconnection alarm occurs.	 is displayed. Background is flashing yellow.
Disconnected	 is displayed. Background is black.
Standby	 is displayed. Background is black.
Nurse call occurs.	 is displayed. Background is flashing red.
Event occurs.	 is displayed. Background is flashing red.

NOTE

- Since a non-spot patient window presents neither waveform nor parameter to the clinician, it should not be used for monitoring patients.
- The user can adjust the display layout at any time so as to restore the non-spot patient windows to the spot ones and therefore view their realtime waveforms and parameters.

2.3.2.2 Spot Patient Windows

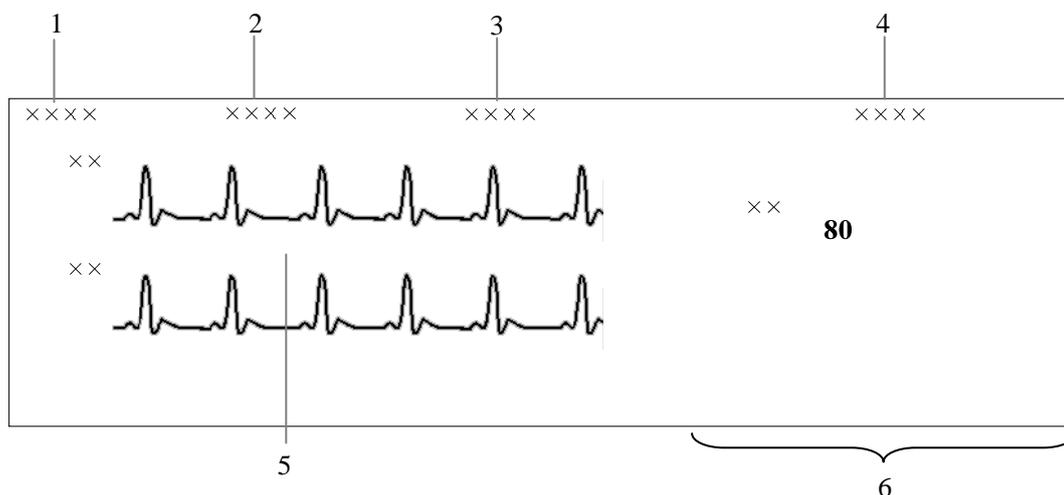
In the process of monitoring, the spot patient window may stay in one of the following statuses:

- “Not Patient Admitted” indicates that no patient is admitted to this patient window; namely, this patient window is left unused.
- “Offline” indicates that this patient window has admitted a patient but its corresponding monitor may be turned off or disconnected from the central monitoring system.
- Patient Window in Monitoring Status: This patient window indicates that the monitor has admitted a patient. The corresponding bedside monitor is monitoring the patient and transferring the data to the central monitoring system.
- “STANDBY” indicates that the monitor or telemetry transmitter enters the standby mode.
- Idle sector indicates “Idle sector. Click to admit a patient”.

The spot patient window may stay in other statuses. We will not introduce them in this manual.

2.3.2.3 Patient Window in Monitoring Status

In the monitoring status, a patient window displays real-time patient data transmitted from the monitor, as shown in the figure below. In an individual patient window, the number of waveforms and the layout of parameters are subject to the display format set for the multibed screen.



- 1. Drop-down menu button
- 2. Alarm icons
- 3. Technical alarm and patient information area
- 4. Physiological alarm area
- 5. Waveform area
- 6. Parameter area

Figure 2-12 Patient Window in Monitoring Status

When a telemetry system is connected, relevant telemetry icons will appear on this screen.

2.3.2.4 Telemetry Icons

No.	Icon name	Icon	Description	Location
1	Nurse Call		Continuous flashing indicates that this button is depressed.	Displayed in the waveform area.
2	Event		Continuous flashing indicates that this button is depressed.	Displayed in the waveform area.
3	Pace		Continuous flashing indicates that a pace pulse has been detected.	Displayed in the waveform area.

No.	Icon name	Icon	Description	Location
3	Battery capacity		<p>This icon tells the remaining battery capacity in the transmitter. With the battery wearing, the solid part and the color of the icon will change accordingly.</p> <ul style="list-style-type: none"> ■ White: indicates the battery is in normal condition. ■ Yellow: indicates the battery is low. ■ Red: indicates the battery is nearly used up. 	Displayed in the physiological alarm area when there is no physiological alarms.
4	Received Signal Strength		<p>This icon tells the received signal strength for corresponding channel. With the received signal strength changing, the number of the signal bars and the color of the icon will change accordingly.</p> <ul style="list-style-type: none"> ■ White: indicates the received signal strength is normal. ■ Yellow: indicates the received signal strength is weak. ■ Red: indicates no signal is received. 	Displayed in the alarm icon area and not displayed when alarm is paused.
5	Transmitter Number	TEL XXXX	Shows the transmitter number corresponding to this channel.	Displayed in the physiological alarm area when there is no physiological alarms.

NOTE

- **When the battery capacity icon indicates red, replace with a new battery for the transmitter in time. Continuing using low capacity battery may cause instable communication status or even communication failure.**

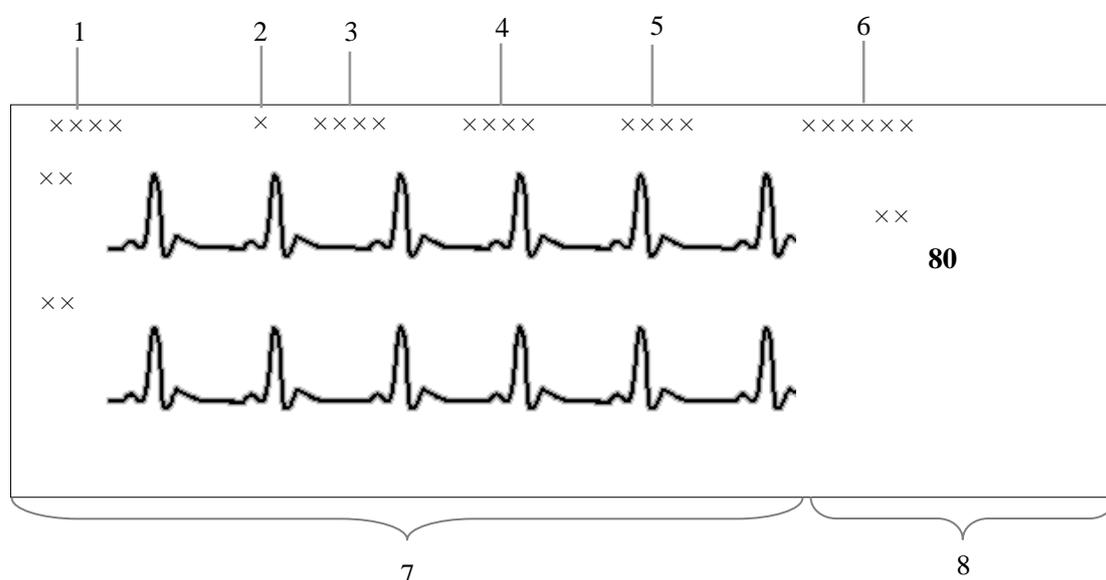
2.3.3 Viewbed Screen

The central monitoring system allows you to view a single patient through the “Viewbed” screen, in which you will have an enlarged view of that single patient’s information, parameter waveforms and values sent from the transmitter.

To access the “Viewbed” screen, follow the instructions below:

- For a spot patient, click the left mouse button in its corresponding patient window. The “Viewbed” screen for that patient will open.
- For a non-spot patient, click on its corresponding block in the non-spot patient window. The “Viewbed” screen for that patient will open.

The Viewbed screen is shown as below.



- | | | |
|-----------------------------|-----------------------------|--------------------|
| 1. Patient information area | 2. Alarm sound icons | 3. Telemetry icons |
| 4. Technical alarm area | 5. Physiological alarm area | 6. Button area |
| 7. Waveform area | 8. Parameter area | |

Figure 2-13 Viewbed Screen

2.3.3.1 Telemetry Icons

On the ViewBed screen, telemetry icons are displayed in the telemetry icons area as shown above. When alarm is paused, the received signal strength icon is not displayed. For details about telemetry icons, refer to **2.3.2 Multibed Screen**.

2.3.3.2 Button Area

Icon	Icon name	Description
	Alarm silence	Silence the alarms.
	Alarm pause	Pause the alarm for 2 minutes.
	STANDBY	Entering or exiting the STANDBY mode.
	Freeze	Used to freeze and unfreeze waveforms
	Show alarm high/low limits	Used to show/hide alarm high/low limits.
	Show Dynamic Short Trend	Used to show/hide dynamic short trend.
	Parameter Order	Used to open the “Parameter Order” window, in which, you can set the display order and switch status of modules.
	Record	Used to open the “Record” dialog box.
	Record	Used to stop recording.
	Print	Used to open the “Print” dialogue box.
	Show Multi-lead ECG	Used to show/hide multi-lead ECG.

FOR YOUR NOTES

3 Installation and Maintenance

3.1 Installation

WARNING

- **The Telemetry monitoring system should be installed by Mindray designated personnel. The copyright of the central monitoring system software is solely owned by Mindray. No organization or individual shall juggle, copy or exchange it in any form or by any means without due permission.**
-

3.1.1 Unpacking and Inspection

Before removing the system components from their packaging, inspect the packaging for signs of damage. In case of any damage, contact the carrier or our company immediately.

If the packaging is intact, remove the system and accessories from the packaging carefully and check if every item on the Packing List has been received without mechanical damage. If you have any question, contact Mindray Customer Service Department immediately.

CAUTION

- **Please save the packaging materials for future transport or storage use.**
-

WARNING

- **Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.**
 - **The system may be contaminated by microorganism during transport, storage and use. Verify the packaging, especially the packaging for the single use accessories, is intact. In case of any damage, contact the carrier or our company immediately.**
-
-

3.1.2 Environmental Requirements

The operating environment of this system must meet the requirements specified in the section A.2 Environmental Specifications.

The environment where the central monitoring system is installed should be reasonably free from noises, vibration, dust, and corrosive or flammable and explosive substances. Moreover, to maintain good ventilation, at least 2 inches clearance around the system should be left.

To ensure reliable communication, do not use radio equipment (e.g. walkie-talkies, radio controller) or large power electrical equipment (such as paper cutter) around the system. Keep the system away from the radio or television station. Contact us if you have any questions regarding the electromagnetic environment.

Before operation, make sure the receiver and transmitter are free from condensation. This can form when the system is moved from one place to another, and is exposed to moisture and differences in temperature.

NOTE

-
- **The system transmits data through wireless connection. External radio frequency interference may result in missing waveforms occasionally. Contact us for any questions regarding the electromagnetic environment.**
-

3.1.3 Power Requirements

The power applied to the system must meet the requirements specified in the section A.3 Power Specifications.

WARNING

- **Make sure the system works in the specified environment and powered by the required power supply. Incompliance with the environmental and power requirements may compromise the system performance and even damage the system.**
-
-

3.1.4 Installation

This system must be used in conjunction with our central monitoring system. For the hardware configuration requirements of the central monitoring system, refer to the Central Monitoring System Operator's Manual.

To ensure reliable performance, the system is to be installed by authorized personnel only. To relocate the system, be sure to contact us first.

WARNING

- **If the system is connected to another electrical instrument and the instrument specifications cannot tell whether the instrument combination is hazardous (e.g. due to summation of leakage currents), you should consult our company or experts in the field to ensure the required safety of all instruments concerned.**
 - **The equipment generates and uses RF energy. If it is not installed correctly or used by observing the manual, RF interference to other devices could result.**
 - **Do not use the three wire-to-two wire adaptor.**
 - **To avoid incidental power failure, do not use the outlet controlled by a wall switch.**
 - **The system can only be updated by the authorized personnel.**
-
-

CAUTION

- **To avoid sudden power failure, UPS is recommended.**
 - **Keep the battery compartment dry.**
-

NOTE

- **The provided network cable is for connection with the PC only. For connection with the hub, please use the parallel network cable.**
-

3.1.5 Starting the System

Follow the procedure below to start the system.

1. Switch on the UPS, if any.
2. Switch on the printer and speakers.
3. Switch on the computer and display.
4. The central monitoring system will run a self-test and beeps if the test result is normal. The central monitoring system will then enter the main screen.
5. Press the power switch on the back of the receiver to switch it on. The receiver will beep and the status indicator and power indicator will be lit.
6. Check the central monitoring system to make sure the receiver is on line.
7. Install batteries into the transmitters and connect the accessories (ECG cable). When data transmission begins, the status indicator on the receiver will flash.
8. Check the central monitoring system to make sure the transmitters are on line.

Now the system has been started and you can monitor the patients as instructed by this operation manual.

NOTE

-
- **If the computer beeps during the startup of the computer or the operating system, refer to the instructions for use of the computer for solutions.**
-

3.1.6 Shutting down the System

Follow the procedure below to shut down the system.

1. Make sure you do not want to monitor the patients any more
2. Save or delete the patient data as prompted by the central monitoring system.
3. Click on the “Shutdown” button from “General Setup”.
4. The system will check if any patient is being monitored
 - If no patients are being monitored, it enters the next step.
 - If there are still patients being monitored, it will pop up a message box to ask you to confirm the operation. You can either click on “Yes” to enter the next step, or click on “No” to save data and discharge the patients and then repeat the above procedures.
5. The system will pop up a message box to confirm the operation. Click on “Yes” and then enter the password, if any, to shut down the system.
6. Switch off the computer and the peripheral devices.
7. Switch off the transmitters and receiver.
8. Switch off the UPS, if any.

CAUTION

- **Hospitals without a stable power supply should use a UPS to provide power to the central monitoring system. The UPS must not be turned off. In case of a power failure, the system should be shut down by following the above shutdown procedure before the UPS is exhausted. If the system has a sudden power failure, system failure may occur and consequently the system will not work normally next time, or even have a serious result.**
-

3.2 Maintenance

WARNING

- **Failure on the part of the responsible hospital or institution employing the use of the central monitoring system to implement a satisfactory maintenance schedule may cause undue system failure and possible health hazard.**
-

3.2.1 Inspection

Regular maintenance

To ensure reliable system performance, the system shall be inspected by qualified personnel when the system

- Has not been used yet.
- Has been running continuously for 6 to 12 months
- Has been repaired or updated.

The inspection shall cover

- Whether the environment and power meet the requirements.
- Whether the power system is properly grounded.
- Whether the insulation of the power cable is fine.
- Whether the electromagnetic environment meets the requirements.
- Whether the battery contacts of the transmitters are fine.
- Whether there are physical damages on the housing, buttons, connectors and accessories.
- Whether only the specified accessories are being used.
- Whether the system clock is accurate.
- Whether the sound/visual alarms can function properly.
- Whether the transmitter frequency is accurate.
- Whether the antenna array is well connected.

If you find any damage or problem, do not use the system. Contact engineers of your hospital or our service engineers immediately.

3.2.2 Cleaning

WARNING

- **Be sure to shut down the system and disconnect all power cords from the outlet before cleaning the system.**
-

The system should be cleaned on a regular basis. If there is heavy pollution in your place or your place is very dusty and sandy, the system should be cleaned more frequently. Before cleaning the system, consult your hospital's regulations for cleaning, disinfecting and sterilizing system.

The exterior surfaces of the system may be cleaned with a clean and soft cloth, sponge or cotton ball, dampened with a non-erosive cleaning solution. Drying off excess cleaning solution before cleaning the system is recommended. Following are examples of cleaning solutions:

- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol.(70%)

NOTE

- **The above-recommended reagents are for general cleaning only. We make no guarantee of its effectiveness for use as a means to control contagious diseases.**
-

To avoid damage to the system, follow these rules:

- ALWAYS dilute the solutions according to the manufacturer's suggestions;
- ALWAYS wipe off all the cleaning solution with a dry cloth after cleaning;
- NEVER SUBMERGE the system into water or any cleaning solution, or POUR or SPRAY water or any cleaning solution on the system;
- NEVER permit fluid run into the casing, switches, connectors, or any ventilation openings in the system;
- NEVER use abrasive materials (such as steel wool or silverpolish) and strong solutions such as acetone and acetone-based cleaners.

 **CAUTION**

- **Failure to follow these rules may melt, distort, or dull the finish of the case, blur lettering on the labels, or cause system failures**

NOTE

- **Consult relevant instructions before cleaning the accessories.**

3.2.3 Disinfection and Sterilization

 **WARNING**

- **Disinfection or sterilization may cause damage to the system; therefore, when preparing to disinfect or sterilize the system, consult your hospital's infection controllers or professionals.**

Sterilization or disinfection may cause damage to the transmitter and receiver. We recommend that you sterilize and disinfect them only when necessary as determined by your hospital's policy. We also recommend that the products being sterilized and disinfected be cleaned first

The recommended disinfectants include: ethanol 70%, isopropanol 70%, Perform® classic concentrate OXY (KHSO₄ solution).

 **CAUTION**

- **ALWAYS dilute the solutions according to the manufacturer's suggestions or use the lowest possible concentration.**
- **NEVER pour liquid onto the system and its accessories during cleaning, or NEVER submerge any part of the system.**
- **NEVER allow any disinfecting agent to remain on the surfaces of the system and its accessories—wipe it off immediately with a dry cloth.**
- **NEVER use EtO or formaldehyde disinfecting agents.**
- **NEVER use the autoclave method or high-temperature disinfection of the system and its accessories.**

4 Using Transmitters

4.1 Installing and replacing batteries

The transmitter is powered by two AA batteries. To install the batteries:

1. Pull the battery door backwards until it clicks. Then lift the door to expose the battery compartment.
2. Follow the marked polarities to install two AA batteries.
3. Lower the battery door and push it forward until it clicks.
4. The transmitter will beep a moment later and the LED will be lit (first green and then red).

WARNING

- **Do not use batteries with physical damages.**
 - **Only use the AA alkaline battery.**
 - **Follow governmental requirements to dispose of batteries. Do not disassemble, burn or short circuit the batteries.**
 - **Remove the batteries from battery compartment if they are not to be used for a long time.**
-

NOTE

- **When the central monitoring system give alarms for low battery energy, install new batteries in time. Keeping using the old batteries may result in repeated re-start of the transmitter.**
-

4.2 Switching on/off the transmitter

Controlled by the software, the transmitter can be switched on/off automatically. When the batteries are installed, the transmitter runs a self test and gives one beep. The LED is illuminated green and red alternatively and then extinguished. Now the transmitter is ready for use.

If all ECG leads are off, the transmitter will be automatically shut down after 10 minutes. In such state, the transmitter sends no data and the operating time can be as long as over 10 days.

To return to normal operating state, you can do any of the following:

- Connect any ECG lead
- Press any key
- Reinstall the batteries

Be sure to remove the batteries if the transmitter is not to be used for a long time.

4.3 Wearing the transmitter

You can wear the transmitter using either a rope or a non-fabric cloth bag.

- To use the rope, make sure the rope can bear a continuous pulling force of 1 Kg.
- To use the non-fabric cloth bag, be sure to tie the bag to your body. Movement of the bag may result in lost connection of the ECG cable.

Be sure to disinfect the bag timely and adequately. A bag shall not be used for too many times.

WARNING

-
- **Do not tie the non-fabric cloth bag over broken skin.**
 - **The non-fabric cloth bag is intended for single patient use.**
-

5 CMS Operation

5.1 Nurse call

The central monitoring system shows graphic nurse call acknowledging buttons for individual patients. The Nurse Call acknowledging button is: 

- Once the “Nurse Call” button has been pressed, the icon will flash and the system will ring for a certain period.
- If you click on the icon, it will be cleared and the ring will be interrupted.
- If the record switch of “Nurse Call” at the “Alarm Setup” screen has been activated, the current call will be recorded by the recorder.
- If the print switch of “Nurse Call” at the “Alarm Setup” screen has been activated, the current call will be printed by the printer.
- Besides, this call will be stored in the “Event Review”. For details about event review, recording or printing refer to the central monitoring system Operator’s Manual.

5.2 Event

The central monitoring system shows graphic Event button for individual patients. The Event button is 

- Once the “Event” button has been pressed, the icon will flash and the system will sound a ring.
- If you click on the icon, it will be cleared.
- If the record switch of “Event” at the “Alarm Setup” screen has been activated, the event will be recorded by the recorder.
- If the print switch of “Event” at the “Alarm Setup” screen has been activated, the event will be printed by the printer.
- Besides, the event will be stored in the “Event Review”. For details about event review, recording or printing refer to the central monitoring system Operator’s Manual.

5.3 STANDBY

In case you want to replace the electrode, replace the batteries, or stop monitoring a patient for a moment, you may switch the transmitter to the STANDBY mode to avoid false alarms.

The central monitoring system provides independent STANDBY mode for each monitor. In the STANDBY mode, all the received patient information will still be saved and once you have exited the STANDBY mode, you can continue monitoring the patient without re-admitting the patient.

In the STANDBY mode, no waveforms or data will be displayed, analyzed, stored or recorded and all the audio/visual alarms will be paused. The screen will only display the nurse call icon, event icon, battery indicator and signal strength indicator. The waveform area will display “STANDBY”.

To enter the STANDBY mode, click on the dropdown button in the patient window and then select “STANDBY”, or click on  at the ViewBed screen. Repeat the step to exit the STANDBY mode.

5.4 Patient Management

5.4.1 Admitting a Patient

If the transmitter is already connected to the network, you can admit a patient either by:

- Clicking a patient window with no patient or an idle sector and selecting “Admit Patient” in the pop-up menu. This is applied to admit patient to a spot patient window. For detail, refer to **2.3.2 Multibed Screen**, or
- Clicking  in the icon area or the “Admit Patient” button in the button area and admitting the patient in the open window.

When icon  or the “Admit Patient” button is selected, a window is open, in which “Connected Patient List” is displayed at the left side and “Patient Info” at right side. The “Connected Patient List” includes the information of all the telemetry transmitters connected to the LAN. The information includes monitoring status, monitor name, unit, bed number, patient name, patient ID and details through which you can know more about monitoring status.

For the telemetry transmitter with the monitoring status of “No Patient Admitted” and the details of “The monitor is in this CMS monitor list”, the Patient Info area is enabled and you can click the “Admit Patient” button to admit a patient.

NOTE

- If you directly click on the “Admit Patient” button before inputting patient information, the patient information will be blank. In this case, you can modify the patient information by referring to *5.4.2 Modifying Patient Information*.
-

5.4.2 Modifying Patient Information

NOTE

- Check that the patient settings such as “Patient Type”, “Paced”, etc, are appropriate for your patient.
-

1. Enter the “Patient Management” tab sheet;

To enter the “Patient Management” tab sheet, you can click in the patient window for a spot patient or on the block in the non-spot patient window for a non-spot patient, and then select the “Patient Management” tab from the multiple tabs as shown below.

2. In this tab sheet, you can modify such information:

- Unit: Patient’s unit;
 - Bed NO: Patient bed number;
 - Patient ID: Patient medical ID;
 - Name: Patient name;
 - Gender: Patient gender (available options: MALE and FEMALE);
 - Patient Type: Patient type (available options: ADU and PED);
 - Date of Birthday: Date of birth (selected from the drop-down timetable);
 - Admit Date: Date when the patient is hospitalized;
 - PACED: Pacer status (available options: ON and OFF);
 - Address: Patient address;
 - Postal code: Patient address’s post code;
 - Phone: Patient’s phone number;
 - Height: Patient height;
 - Weight: Patient weight;
 - Blood Type: Patient blood type (available options: A, B, AB, O and NA. NA represents unknown);
 - Physician: Name of the doctor.
-

-
- Bed Mark: Mark patient bed with different color
 - Comment Physician's comment
 - Nurse Call (Optional): Nurse call status
 - Event(Optional): Event status

You can enable or disable "Nurse Call" and "Event" functions. Enter the central monitoring system's "System Setup"- "Admin Setup"- "Telemetry", you can make the following settings:

- If "Enable" is selected, the telemetry system will enable nurse call and event functions, and Patient Mgmt. screen will display the setting items of "Nurse Call" and "Event".
 - If "Nurse Call" is selected, the telemetry system will enable nurse call function, and the Patient Mgmt. screen will display the setting item of "Nurse Call".
 - If "Event" is selected, the telemetry system will enable event function, and the Patient Mgmt. screen will display the setting item of "Event".
 - If "Disable" is selected, the telemetry system will disable nurse call and event functions there are no setting items of "Nurse Call" and "Event" in the Patient Mgmt. screen.
3. Click on the "Modify" button after modifying the patient information. Additionally,
- ◆ If patient type has been changed, a message box will pop up. Select "OK" to save the change or "Cancel" to cancel the change.
 - ◆ If "Nurse Call" and/or "Event" in telemetry system is set to "Off", a message box will pop up. Select "OK" to save the changes or "Cancel" to cancel the changes

5.4.3 Discharging a Patient

Discharging a patient is to terminate monitoring a patient before admitting a new patient. You can discharge a patient from the central monitoring system as follows:

- Method 1 (applied to spot patients):
 1. Click the drop-down menu in corresponding patient window and select "Discharge".
 2. In the pop-up dialogue box, select either "Discharge patient and save data" or select "Discharge Without Saving Data". If "Discharge patient and save data" is selected, the system will automatically save all reviewing data of this patient. If "Discharge Without Saving Data" is selected, the system will delete all data about this patient after he is discharged.
 3. Click the "OK" button. The patient will be discharged automatically.

-
- Method 2 (applied to both spot patients and non-spot patients):
 1. Click the patient window for a spot patient or the block in the last patient window for a non-spot patient.
 2. Select “Patient Mgmt.” tab sheet.
 3. Click the “Discharge” button in the “Patient Mgmt.” tab sheet.
 4. Perform Steps 2 through 3 of Method 1.

5.5 Managing Parameter Settings

In the “Parameter Setup” screen, you can manage the parameter settings.

- Factory default is loaded when CMS runs for the first time.
- All the ECG settings can be changed and saved as user default. Password is needed before saving as default. User default will be loaded when new patient is admitted and corresponding message will appear in the technical alarm message area of CMS at the same time.
- Factory default (See *Appendix B*) or user default can be restored by clicking the corresponding button.

5.6 Review

You can review the dynamic short trends, waveforms, trends and events of a currently monitored patient from the central monitoring system.

5.6.1 Dynamic Short Trend

Clicking on the  button in the ViewBed screen will show graphic short trends for the parameter module. The colors and order are subject to their respective parameter modules.

5.6.2 Waveform Review

Click the “Waveform Review” tab sheet, you can review the latest 240 hours’ waveforms of the patient.

In the Waveform Review window, you can review compressed or normal waves as required. If normal waves are displayed, click the “Compressed” button to review the latest 240-hour waveforms of the patient.

If compressed waves are displayed, click the “Full Size” button to review the latest 240-hour waveforms of the patient.

In the Waveform Review window, you can perform operations like “Wave Save”, “Wave Select”, and “Sweep Speed”.

5.6.3 Trend Review

Clicking on the “Trend Review” tab will enter the following tab sheet, through which you can store and review up to 240 hours of trend data. Change of trends can be observed through the trend graph and trend table. You can switch between the trend table and trend graph by simply clicking on their buttons.

5.6.4 Event Review

Clicking the “Event Review” tab will enter the “Event Review” window, through which you can view all alarm parameters and waveforms of a patient.

The “Event Review” window displays:

1. Event list: alarm latching/unlatching, event time, message, priority and description.
2. The values of all parameters at the event occurrence time. The central monitoring system prompts if an alarm occurs to a specific parameter and indicates the alarm priority by using different background colors.
 - ◆ Black: no alarm generated;
 - ◆ Red: high level alarm generated;
 - ◆ Yellow: medium or low level alarm generated.
3. Waveform 16 seconds before and after the alarm occurrence time of the relevant parameter.

5.6.5 ST Review

Click “ST Review” to open the ST review window. In this window, you can view real-time ST segments and review historical ST segments. You can also record and print out ST segments.

In the ST review window, you can: View ST segment, Set reference ST segment, Select reference ST segment, Delete reference ST segment, Set waveform speed, Set trend parameter, Print and Record

5.7 Record

The central monitoring system can be equipped with a thermal recorder which, with a separate power supply, is connected with the host of the central monitoring system via the general interface.

The central monitoring system can print out the following information through the recorder:

5.7.1 Recording Patient Information

1. Enter the “Patient Mgmt.” tab sheet;
2. Make sure that the patient information is correct;
3. Click on the “Record” button. The patient information will be printed out through the recorder.

5.7.2 Recording Normal Waveforms

1. Enter the “Waveform Review” tab sheet;
2. Click the “Full Size” button;
3. Click on the “Record” button;
4. Select a maximum of 2 waveforms, waveform speed and grid from the pop-up dialog box;
5. Select “OK”. The selected waveforms will be printed out through the recorder.

5.7.3 Recording Events

1. Enter the “Event Review” tab sheet;
2. Select an event from the event list;
3. Click on the “Record” button. From the pop-up dialog box, you can select a maximum of 2 waveforms and grid;
4. Select “OK”. The selected waveforms will be printed out through the recorder.

5.7.4 Recording ST Segment Waveform

1. Enter the “ST Review” tab sheet.
2. Click the “Record” button.

5.7.5 Recording Real-time Waveforms

1. Enter the “ViewBed” tab sheet;
2. Click on the Record icon at the upper right corner;
3. Select a maximum of 2 waveforms, record time, waveform speed and grid from the pop-up dialog box;
4. Click on “OK”. The selected waveforms will be printed out through the recorder.

5.7.6 Recording Real-time Frozen Waveforms

1. Enter the “ViewBed” tab sheet.
2. Click the “Freeze” icon at the upper right corner.
3. Click the “Record” icon at the upper right corner.
4. Select a maximum of 2 waveforms from the pop-up dialog box.
5. Click “OK” to print out the selected waveforms.

5.7.7 Recording Real-time Alarms

If a parameter generates an alarm when its alarm switch and record switch are set to “ON”, the central monitoring system will automatically initiate a real-time alarm recording.

5.8 Print

For printing reports, the central monitoring system can be equipped with a laser printer, which with a separate power supply, is connected to the central monitoring system via the general interface. For instructions about the printer, refer to the accompanying documents provided with the printer.

5.8.1 Printing Patient Information

1. Enter the “Patient Mgmt.” tab sheet;
2. Make sure if the patient information is correct. If not, click on the “Modify” button to correct them;
3. Click the  icon on the “Print” button and select “Print Setup” to complete print setups as prompted;
4. Click the  icon on the “Print” button and select “Print Preview” to preview the printout;
5. Click on the “Print” button.

5.8.2 Printing Trend Graph or Trend Table

1. Enter the “Trend Review” tab sheet;
2. Set the resolution and start time;
3. Click the  icon on the “Print” button and select “Print Setup” to complete print setups as prompted;
4. Click the  icon on the “Print” button and select “Print Preview” to preview the printout;
5. Click on the “Print” button.

5.8.3 Printing Normal Waveforms

1. Click the “Waveform Review” tab sheet. If compressed waves are displayed, click the “Full Size” button.
2. Select the current review time.
3. Click the  icon on the “Print” button and select “Print Setup” to perform print setups as prompted.
4. Click the  icon on the “Print” button and select “Print Preview” to preview the printout.
5. Click the “Print” button.

5.8.4 Printing ECG Report

1. Click the “Waveform Review” tab sheet. If normal waves are displayed, click the “Compressed Wave” button in the lower right corner of the screen.
2. Select the desired waveforms by double-click to add them to one report. At most, six waveforms can be printed on each page. You can also deselect a waveform by double clicking it again. “Prev” and “Next” button can be used to toggle between the selected waveforms.
3. Select “Print Preview” to preview the printout.
4. Click the “Print All” button.

5.8.5 Printing Compressed Waveforms

1. Click the “Waveform Review” tab sheet. If normal waves are displayed, click the “Compressed Wave” button.
2. Click the  icon on the “Print” button and select “Print Preview” to preview the printout.
3. Click the “Print” button.

5.8.6 Printing ARR Statistic Result

1. Click the “Waveform Review” tab sheet. If normal waves are displayed, click the “Compressed Wave” button in the lower right corner of the screen.
2. Click the “ARR Statistic” button to enter the “ARR Statistic” menu where you can view the statistic about the HR value and the number of each arrhythmia type during a certain time range.
3. Click the “Print” button.

5.8.7 Printing Event List

1. Enter the “Event Review” tab sheet.
2. Click the  icon on the “Print” button under the event list and select “Print Setup” to perform print setups as prompted.
3. Click the  icon on the “Print” button and select “Print Preview” to preview the printout.
4. Click the “Print” button.

5.8.8 Printing an Event

1. Enter the “Event Review” tab sheet;
2. Select an event from the event list;
3. Click the  icon on the “Print” button and select “Print Preview” to preview the printout;
4. Click on the “Print” button.

5.8.9 Printing ST Segment Waveform

1. Enter the “ST Review” tab sheet.
2. Click the  icon on the right side of the “Print” button and select “Print Preview” to preview the printout.
3. Click the “Print” button.

5.8.10 Printing Multi-lead ECG

1. Enter the “ViewBed” tab sheet.
2. Click the “Multi-lead ECG” button to display the multi-lead ECG waveforms.
3. Click the “Print” button.

5.8.11 Printing in Real-time

1. Enter the “ViewBed” tab sheet.
2. Click the “Print” button.
3. Select the desired waveforms from the pop-up dialog box.
4. Click the “OK” button.

or

1. Enter the “Multibed” tab sheet.
2. Click the drop-down menu button.
3. Click the “Print” button to print the displayed waveforms

6 Alarm

Alarms, triggered by a vital sign that appears abnormal or by technical problems of the telemetry transmitter, are sent to the central monitoring system by the transmitter and then indicated to the user by the central monitoring system.

WARNING

- **In any single area (such as intensive care unit or cardiac operating theater), potential hazards may arise from using different alarm presets for same or similar devices.**
-

6.1 Alarm Categories

By nature, the patient monitor's alarms can be classified into three categories: physiological alarms, technical alarms and prompt messages.

1. Physiological alarms

Physiological alarms, also called patient status alarms, are triggered by a monitored parameter value that violates set alarm limits or an abnormal patient condition. Physiological alarm messages are displayed in the physiological alarm area.

2. Technical alarms

Technical alarms, also called system status alarms, are triggered by a device malfunction or a patient data distortion due to improper operation or mechanical problems. Technical alarm messages are displayed in the technical alarm area.

3. Prompt messages

As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the central monitor system will show some messages telling the system status. Messages of this kind are included into the prompt message category and usually displayed in physiological alarm area, technical alarm area and system information area.

6.2 Alarm Priorities

By severity, the patient monitor's alarms can be classified into three categories: high priority alarms, medium priority alarms and low priority alarms.

1. High priority alarms

Indicate that your patient is in a life threatening situation and an emergency treatment is demanded.

2. Medium priority alarms

Indicate that your patient's vital signs appear abnormal and an immediate treatment is required.

3. Low priority alarms

Indicate that you patient's vital signs appear abnormal and an immediate treatment may be required.

The priority for most technical alarms and some physiological alarms are predefined before the central monitoring system leaves the factory and cannot be changed. But for some technical and physiological alarms, the priority is user adjustable.

6.3 Alarm Indicators

The central monitoring system gives audible and visual alarms in compliance with international standards.

WARNING

-
- **The audible and visual alarms given by the central monitoring system comply with the IEC 60601-1-8 standard. The hospital or institution employing the use of the central monitoring system should give adequate training to the operators.**
-

6.3.1 Audible Alarms

This system has three choices of alarm tones and patterns: ISO, Mode 1 and Mode 2. For each pattern, the alarm tones identify the alarm priorities as follows:

- ISO pattern:
 - ◆ High priority alarms: triple+double+triple+double beep.
 - ◆ Medium priority alarms: triple beep.
 - ◆ Low priority alarms: single beep.
- Mode 1:
 - ◆ High priority alarms: high-pitched single beep.
 - ◆ Medium priority alarms: double beep.
 - ◆ Low priority alarms: low-pitched single beep.
- Mode 2:
 - ◆ High priority alarms: high-pitched triple beep.
 - ◆ Medium priority alarms: double beep.
 - ◆ Low priority alarms: low-pitched single beep.

NOTE

-
- **When multiple patients have alarms of different priorities at the same time, the system will select the alarms of highest priorities and give alarm tones accordingly.**
 - **When the system is set to “silence”, giving alarm tones is disabled. In case of a new alarm, the silenced state will be released automatically. You can also release the silenced state manually. For details, refer to *6.12 CMS System Silence*.**
 - **In the “General Setup” screen of “System Setup”, when the alarm volume is set to 0, the CMS alarm sound is turned off, and the CMS will switch off the alarm tone permanently and give no audible alarm even if a new alarm occurs. Be careful to configure the alarm volume to 0.**
-

6.3.2 Reminder Tone

In the status of CMS system silence or audio alarm off, the CMS can give a kind of reminder tone in case of an active alarm condition. The Reminder Tone is same as the highest alarm tone. You can set the reminder volume in the “General Setup” tab sheet. You can set the reminder interval and switch on/off the reminder tone in the “Admin Setup” menu.

6.3.3 Alarm Messages

The central monitoring system alerts the users by giving alarm messages in the physiological or technical alarm area. Before the alarm messages, asterisks are used to indicate different alarm priorities:

- High priority alarms: triple asterisks “***”.
- Medium priority alarms: double asterisks “**”.
- Low priority alarms: single asterisk “*”.

When alarms are latched, alarm time is displayed; otherwise, the alarm time is not displayed. The high priority alarm messages are in white font and medium/low priority alarm messages are in black font. Besides alarm messages, the technical alarm area also displays prompt messages coming from monitors. The prompts are in white font.

6.3.4 Color Changes

If a spot patient has an alarm, its corresponding patient window will give an alarm message, with different background colors indicating different alarm priorities:

- High priority alarms: red
- Medium priority alarms: yellow
- Low priority alarms: yellow

If a non-spot patient has an alarm, its corresponding block will appear in red indicating a high-priority alarm or yellow indicating a medium-or low-priority alarm.

6.3.5 Flashing Numeric

If a physiological parameter of the patient generates an alarm, the numeric of the parameter will flash in the parameter area. If the alarm high/low limits of the parameter are displayed in the “ViewBed” screen, either the alarm high or low limit will also flash indicating that the parameter exceeds the alarm high or low limit.

6.4 Alarm Status Symbols

Apart from the aforementioned alarm indicators, the patient monitor still uses the following symbols telling the alarm status:

-  indicates alarm is paused.
-  indicates alarm is silenced.
-  indicates system sound is silenced.
-  indicates alarm sound is turned off.
-  indicates alarm of an individual parameter is turned off.

6.5 Alarm Setup

Clicking the  button in the “ViewBed” screen will enter the “Alarm Setup” tab sheet, in which you can set parameter alarms, arrhythmia alarms, arrhythmia alarm threshold and other aspect of alarms.

Take the HR as an example; you can use the keyboard to modify its alarm high/low limits after clicking “HIGH LIMIT” or “LOW LIMIT”, as well as use the mouse to make a selection after clicking “Alarm Priority”, “Activation State”, “Record On Alarm” or “Print on Alarm”.

6.6 Alarm Volume

By clicking “System Setup” then “General Setup”, you can enter a tab sheet. The central monitoring system provides 11 volume levels, increasing from 0 to 10. You can drag the volume control key to your desired volume. While dragging the volume control key, the corresponding sound will also be played.

The alarm volume can be configured in the range from Minimum Alarm Volume to 10. The minimum alarm volume can be set from 0 to 10 at ”General Setup”-“Admin Setup”-“Alarm” tab sheet.

In the “General Setup” tab, you can set high alarm volume. High alarm volume can be set equal to or louder than the alarm volume. The options are “alarm volume +0”, “alarm volume+1”and “alarm volume+2”. When a high priority alarm occurs, the alarm will sound with the specified high alarm volume. For example, if the high alarm volume is set to “alarm volume+1”, and the current level of alarm volume is 5, then the high alarm volume is 6.

NOTE

-
- **If the alarm volume is set to 0, the system information area displays alarm audio off icon .**
 - **If high alarm volume level is greater than 10, the monitor will sound it in the volume of 10.**
-

6.7 Alarm Delay Setup

Click “System Setup” to enter “General Setup” tab sheet. Click the “Telemetry Alarm Delay Setup” button. You can set the “Alarm Delay” (6 s by default) and “ST Alarm Delay” (30 s by default). The alarms include: HR too high, HR too low, ST too high and ST too low.

6.8 Alarm Level Setup

Click the “Admin Setup” button in the “General Setup” tab sheet. The Input Password dialog box will pop up. After inputting the required password, select “OK” to enter a tab sheet. Then select the “Telemetry” tab. Click the “Alarm Level Setup” button. In the popup menu, you can set the “Alm Lev of ECG Lead Off” as “High”, “Med” or “Low”. The default setting is “Low”.

6.9 Alarm Pause

You can click the Alarm Pause icon  in the ViewBed screen or Alarm Pause in the drop-down menu in the multibed screen to pause the alarm of the telemetry transmitter for two minutes. After alarm pause time (two minutes) ends, the system will automatically release the alarm pause. You can also release the alarm pause by clicking the icon  or Alarm Pause in the drop-down menu again.

During alarm pause,

- The  icon is displayed in the alarm icon area.
- All alarms are not responded or stored.
- The remaining alarm pause time is displayed in the physiological alarm area.

6.10 Alarm Silencing

You can click the Silence icon  in the ViewBed screen or Silence in the drop-down menu in the multibed screen to acknowledge the ongoing alarms. The patient window on the system will enter the alarm silenced status. The alarm silenced status of system's patient window has the following features. After the physiological alarm is silenced, ✓ appears before the alarm message. For some technical alarms, ✓ appears before the alarm message after the alarm is silenced. For some technical alarms, the alarm message changes to prompt message after the alarm is silenced. For some other technical alarms, the alarm message is cleared after the alarm is silenced.

As for the classification of technical alarms, please refer to section **9.2 Common Technical Alarms and Troubleshooting**.

The alarm silenced status will be automatically cancelled when a new alarm occurs.

6.11 Alarm Latching

If an alarm is latched, the alarm message remains and the alarm start time is also displayed in the alarm area when the alarm condition ends.

Enter “Alarm Setup” window, select “Others” tab sheet and then set the “Alarm Latch” by the options of “Off”, “High”, “High & Med” and “All”:

- If “Off” is selected, no alarm will be latched
- If “High” is selected, the alarms in the high level will be latched
- If “High & Med” is selected, the alarms in the high and medium levels will be latched
- If “All” is selected, all the alarms will be latched.

You can enable or disable the alarm latch function on the CMS. When alarm latch is disabled, the “Alarm Latch” control in the “Alarm Setup” tab sheet is inactive.

NOTE

-
- **When “Alarm Pause” is selected, the latched alarm message will be cleared.**
-

6.12 CMS System Silence

System silence silences the central monitoring system sounds, which include alarm sound, nurse call, event, etc.

To silence or reactivate system sounds, click System Setup; then click Admin Setup; enter required password. In the Admin Setup tab sheet, select Alarm and select or deselect the “Silence Hotkey” check box as desired.

Clicking the “Silence” button on the main screen, or pressing the Silence hot key if the Silence Hotkey check box is selected will enter the system silenced status.

When the system sounds are silenced, the icon  will appear on the main screen.

In the system silenced status, the system gives no audible alarm, but other alarm indications, such as alarm message, remain being presented. If a new alarm occurs, the system silenced status will be automatically released.

In the system silenced status, clicking the “Silence” button on the main screen again, or pressing the Silence hot key again if the Silence Hotkey check box is selected will the exit system silenced status.

6.13 CMS Alarm Audio Off

Alarm Audio Off only switches off the central monitoring system audible alarms.

To switch on or off central monitoring system audible alarms, click Admin Setup and then click Alarm; in the “Alarm” tab sheet, deselect or select the “Alarm Audio Off” check box.

In “General Setup”, when the alarm volume is set to 0, the CMS audio is turned off. Refer to *6.6 Alarm Volume*.

When audible alarms are switched off, the icon  will appear on the main screen. In this case, the CMS gives no audible alarm, but other alarm indications and audible signals remain being presented.

NOTE

- **Be careful to use this function. If Alarm Audio Off is selected, the central monitoring system will switch off the alarm tone permanently and give no audible alarm even if a new alarm occurs.**
 - **When the central monitoring system is restarted, the “Audio Alm Off” check box turns to be deselected again.**
-

The central monitoring system can be in either system silenced or alarm audio off status at one time.

NOTE

- The  icon will appear on the main screen if the central monitoring system is in the system silenced status.
 - The  icon will appear on the main screen if the central monitoring system is in the alarm audio off status.
-

FOR YOUR NOTES

7 ECG Monitoring

7.1 Preparation

1. Skin preparation

The quality of ECG information displayed on the monitor is a direct result of the quality of the electrical signal received at the electrode. Proper skin preparation is necessary for good signal quality at the electrode. A good signal at the electrode provides the monitor with valid information for processing the ECG data. Choose flat, non-muscular areas to place electrodes. Following is a suggested guideline for skin preparation:

- Shave hair from sites, if necessary.
 - Gently rub skin surfaces at sites to remove dead skin cells
 - Wash sites with soap and water (never use ether or pure alcohol, because this increases skin resistance).
 - Dry the skin completely before applying the electrodes.
2. Attach the ECG lead to the electrodes prior to placement;
 3. Place the electrodes on the patient. Use electrode gel prior to placement only if pre-gelled electrodes are not used
 4. Make sure the monitor is turned on and is ready for monitoring.

7.2 Electrode Placement

WARNING

- Use only the specified ECG cable and electrodes for monitoring.
 - When applying electrodes or connecting cables, make sure they are not connected to any conductive part or the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.
 - Do not use this equipment in conjunction with electro-surgery unit (ESU).
 - Skin irritation may result from the continuous application of the ECG electrodes. These should be checked each day. If there is an indication of excess skin irritation, replace the electrodes or change the location of the electrodes.
 - Do not touch the patient, bed or instrument during defibrillation.
 - After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied in accordance with the manufacturer's instructions for use.
 - Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the ECG waveform.
 - Always dispose of, or recycle electrodes properly to prevent from environment contamination.
 - Verify the lead fault detection prior to the start of monitoring. Unplug the ECG cable from the ECG connector and the screen should display the error message "ECG LEAD OFF" and an audible alarm should be activated.
-

NOTE

- The conductive ointment coatings should be isolated, and the electrodes should have no contact with each other to avoid short-circuit.
 - Do not use physiological saline instead of electrode gel to prevent eroding the electrodes.
-

7.2.1 3-Leadwire Electrode Placement

Following is the configuration per the American standard (AHA) when using three leadwires:

- 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 lower abdomen.

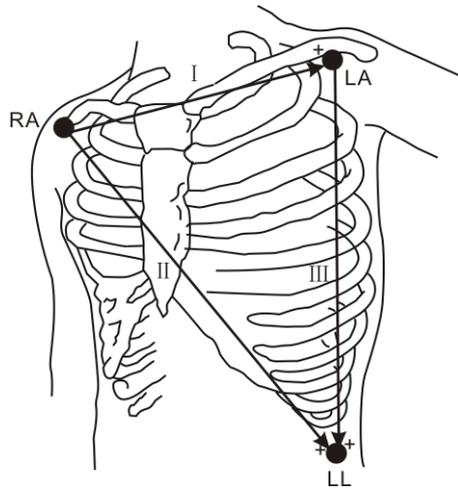


Figure 7-1 3-lead electrode placement

The chart below shows the label used to identify each leadwire. Included also is its associated color code per American (AHA) standards.

American Standard	
Label	Color
RA	White
LA	Black
LL	Red

7.2.2 5-Leadwire Electrode Placement

Following is the configuration per the American standard (AHA) when using five leadwires:

- RA (right arm) electrode — directly below the clavicle and near the right shoulder;
- LA (left arm) electrode — directly below the clavicle and near the left shoulder;
- RL (right leg) electrode — on the right lower abdomen;
- LL (left leg) electrode — on the left lower abdomen;
- V (precordial) electrode — on the chest.

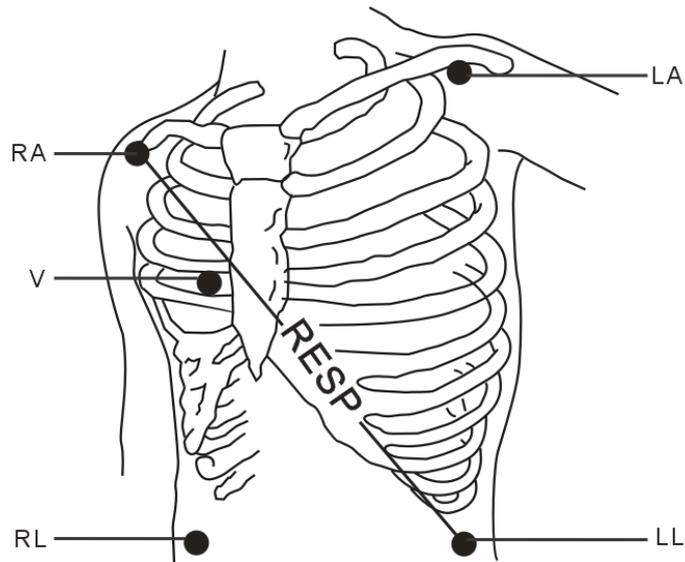


Figure 7-2 5-lead electrode placement

For a 5-lead configuration, place the V electrode at one of the locations shown in Figure 7-3

- V1: On the 4th intercostal space at the right sternal border;
- V2: On the 4th intercostal space at the left sternal border;
- V3: Midway between V2 and V4 electrodes;
- V4: On the 5th intercostal space at the mid-clavicular line;
- V5: On the left anterior axillary line, horizontal with V4;
- V6: On the left mid-axillary line, horizontal with V4;
- V3R-V6R: On the right side of the chest in positions corresponding to those on the left;
- VE: Over the xiphoid process;

For posterior V electrode placement, place the V electrode at one of the following locations

- V7: On posterior chest at the left posterior axillary line in the fifth intercostal space;
- V7R: On posterior chest at the right posterior axillary line in the fifth intercostal space.

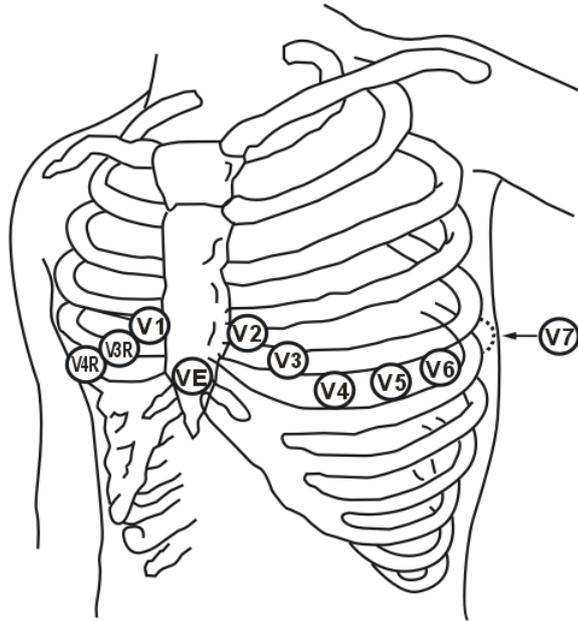


Figure 7-3 V Electrode placement

The chart below shows the label used to identify each leadwire. Included also is its associated color code per American (AHA) standards.

American Standard	
Label	Color
RA	White
LA	Black
LL	Red
RL	Green
V	Brown

7.2.3 Characteristics of a Good Signal

As shown in Figure 7-4, the normal QRS complex should exhibit the following characteristics.

- Tall and narrow with no notches.
- R-wave should be tall, completely above or below the baseline.
- Pacer pulses should be smaller than the R-wave height.
- T-wave should be less than 1/3 of the R-wave height.
- P-wave should be much smaller than the T-wave.



Figure 7-4 Standard ECG waveform

To display a 1-millivolt calibration pulse on the ECG wave, re-install the transmitter batteries and then the transmitter will automatically generate the square waveforms for calibration.

NOTE

-
- **If the ECG waveform is too small, or not accurate, and the electrodes are secure and firmly attached to the patient, change the display to a different lead.**
 - **To obtain accurate calibrate waveform, set the filter mode to “ST”. See 7.3.8 *Filter Mode* for more information regarding the filter mode.**
 - **When calibrating the system, do not count the overshoot on the waveform edge.**
-

7.3 ECG Monitoring

7.3.1 ECG Waveform Area

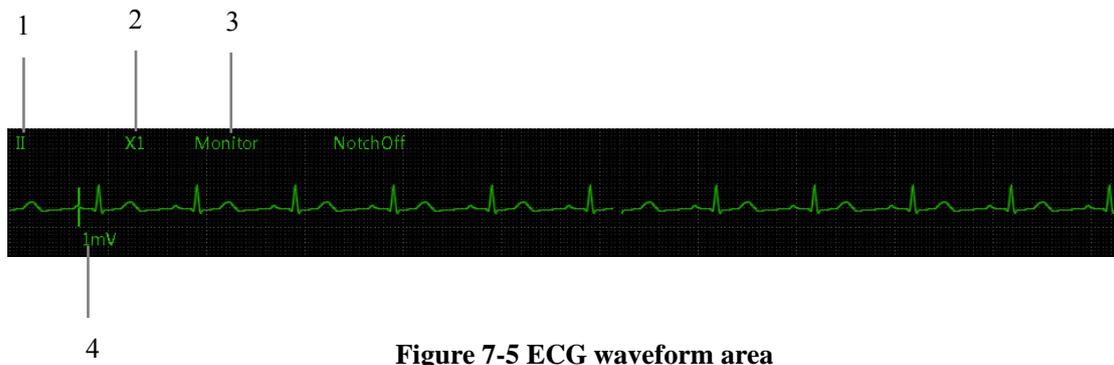


Figure 7-5 ECG waveform area

1. Lead
2. Gain
3. Filter
4. Scale

7.3.2 ECG Parameter Area

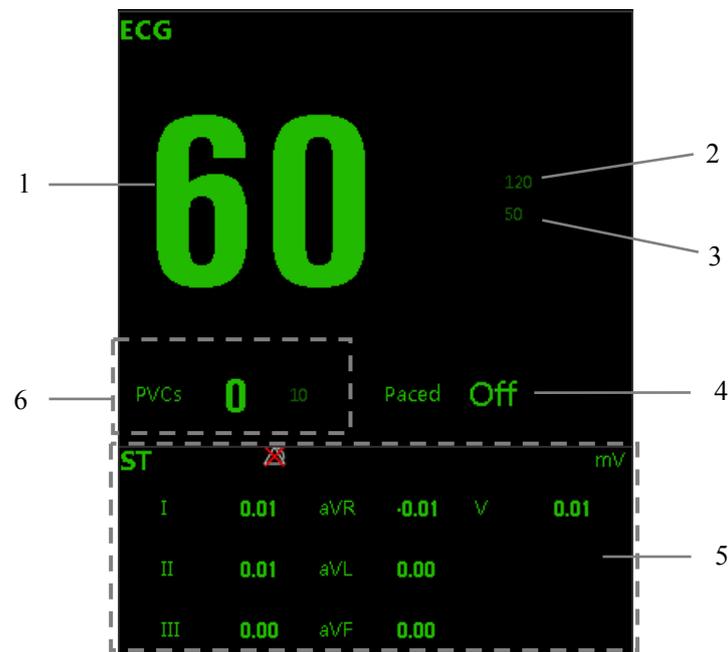


Figure 7-6 ECG parameter area

1. Heart rate (HR)
2. HR high limit. The high limit is generally located in the upper right of the parameter value.
3. HR low limit. The low limit is generally located in the lower right of the parameter value.
4. PACE indicator
5. ST value and alarm limits
6. PVCs value and alarm limits

The  icon in the figure represents alarm off.

7.3.3 ECG Setup Screen

Click on the ECG parameter area of the ViewBed screen to enter the “Parameter Setup” screen.

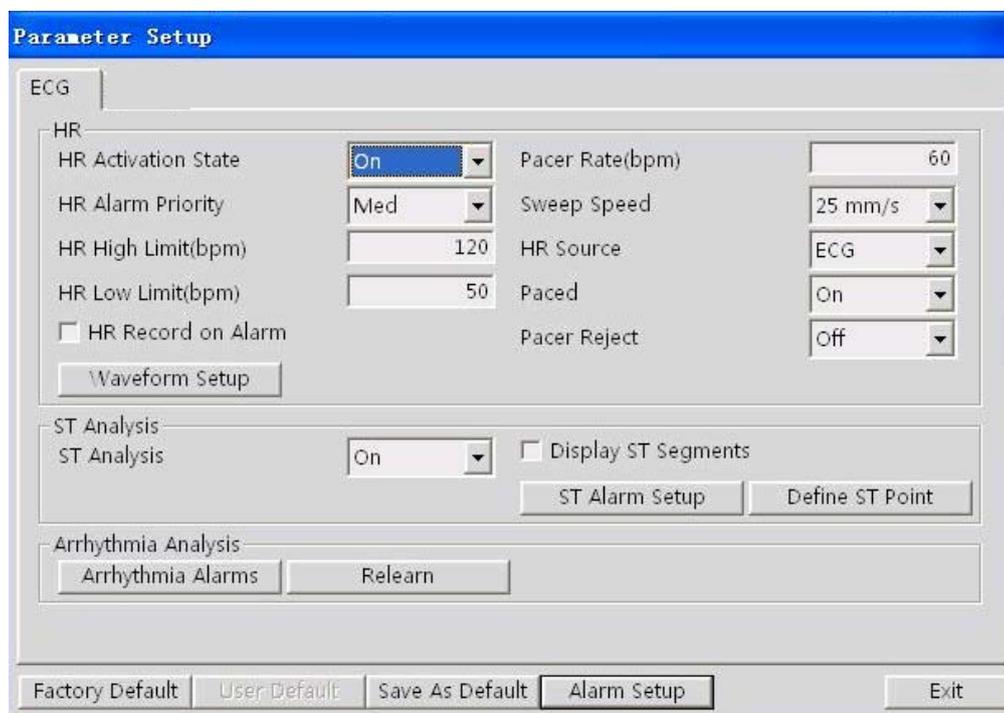


Figure 7-7 ECG Setup screen

7.3.4 ECG Lead Type

The system can automatically recognize the connected ECG cable and the central monitoring system can display the type accordingly.

When a 3 leadwire cable is connected, the central monitoring system will display the waveform of lead II.

When a 5 leadwire cable is connected, the central monitoring system will display the waveforms of leads II, I and V by default. To view the waveform of leads III, aVR, aVL and aVF, click on  to switch to the 7 lead display mode, as the figure below shows. To exit the 7 lead display mode, click on  again.

7.3.5 Wave Speed

The system provides three options for wave speed: 12.5mm/s, 25mm/s and 50mm/s. In the 7-lead display mode, the wave speed is fixed to 25mm/s.

7.3.6 HR Source

The system provides for a HR source of ECG and AUTO.

1. ECG: HR is calculated from ECG.
2. AUTO: The system determines the heart rate source depending on the signal quality.

7.3.7 Wave Gain

Click the “Waveform Setup” button and select “Wave Gain”.

The system provides six options for ECG wave gain: $\times 0.125$ (1.25 mm/mV), $\times 0.25$ (2.5 mm/mV), $\times 0.5$ (5 mm/mV), $\times 1$ (10 mm/mV), $\times 2$ (20 mm/mV) and $\times 4$ (40 mm/mV). If you want to view the details of the displayed waveforms, select a large gain; if you find incomplete waveform, select a small gain.

7.3.8 Filter Mode

The system provides 3 filter modes: ST, Monitor, and Surg. You can select the desired filter mode on the “Waveform Setup” window of the “Parameter Setup” screen. The selected filter mode applies to all channels.

You should select the filter mode according to your own needs.

Patient movement will disturb the waveform signals. To obtain a stable and clear waveform, you can select the Monitor or Surg mode. However, certain significant diagnostic information may be lost during the filtering process.

When “ST Analysis” is set to “ON”, “Filter” is automatically set to “ST” mode to obtain effective low frequency responses and ensure ST analysis accuracy.

When Filter is set to “Monitor” or “Surg”, “ST Analysis” is automatically set to “OFF”.

7.3.9 Pacer Pulse Detection

When a patient's pacer pulse is detected, the  icon will flash in the middle of the waveform area. Click the icon, the "Patient Mgmt." sheet will pop up. The item of "Pace" can be configured there.

When "Paced" is set to "On" and the pacer pulse is detected, a pacer pulse will be indicated by white "P" among the ECG waveform.

7.3.10 Pacer Reject on Waveform

Pacer Reject can be set to display the detected pacer pulse on the ECG wave or not.

- When "Pacer Reject" is set to "ON", the system will filter out pacer pulse when displaying the ECG wave.
- When "Pacer Reject" is set to "OFF", the pacer pulse will be displayed on the ECG wave.

WARNING

- **The pacer pulses may be counted as QRS complex, hence leading to wrong HR readings or failure to diagnose certain arrhythmia symptoms. Be sure to keep a close eye on the patient wearing a pace-maker.**
- **The output power of the transmitters and other sources of radio frequency energy, when used in the proximity of a pacemaker, can be sufficient to interfere with pacemaker performance. Due to the shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring any paced patient.**
- **In order to minimize the possibility of the interference, place electrodes, cables and transmitters as far away from the pacemaker as possible.**

NOTE

- **When "PACED" is set to "ON", the system does not detect PVC-related arrhythmia (including PVCs) resulting from pacemaker but still analyzes the normal QRS complex.**
 - **When the patient is not wearing a pacemaker, set "PACED" to "OFF".**
 - **When PACE is set to "ON", missed beat (MIS) alarm is reported as pacer not captured (PNC) or pacer not paced (PNP).**
-

7.3.11 Pacer Rate

Some pace pulses may be difficult to suppress. In this case, the pace pulse may be counted as a QRS complex, and could result in incorrect HR measurements and failure to detect some arrhythmias. You can access the ECG Parameter Setup window to set Pacer Rate to the heart rate of the pacer, so that the system can calculate the HR and detect the arrhythmias more accurately. When Paced in the central monitoring system Patient Mgmt window is set to “OFF”, setting of “Pacer Rate” is disabled.

7.3.12 HR Alarm

In the HR area of the ECG Parameter Setup screen, you can set alarm switch, alarm level, HR high limit, HR low limit etc. HR alarm limits can be changed as described in the following table.

Alarm limit	Range	Step
HR high limit	(low limit+ 2) to 300 bpm	1 bpm
HR low limit	15 to (high limit – 2) bpm	

7.4 ST Analysis

7.4.1 General

- ST analysis is deactivated by default.
- When ST analysis is activated, “Filter” is automatically switched to “ST”. When “Filter” is set to “Monitor” or “Surg”, ST analysis is deactivated.
- ST analysis can be conducted by measuring the rising or falling part of the ST segment. The ST numerics are displayed in the parameter areas.
- You can view the trend graph and data of the ST analysis through the trend review function.
- Options for ST measurement unit: mV (milivolt) or mm (millimeter).
- ST numeric: positive numeric means rising and negative numeric means falling.
- ST measurement range: -2.0 mV to +2.0 mV.

NOTE

-
- **When ST analysis is activated, “Filter” is set to “ST” automatically to obtain effective low-frequency response and ensure the accuracy of ST segment measurement.**
 - **When “Filter” is set to “Monitor” or “Surg”, ST analysis is disabled.**
-

7.4.2 Switching on/off ST Analysis

Enter the ECG Parameter Setup window to set “ST Analysis” to “ON” or “OFF”.

Reliable ST monitoring can hardly be ensured if:

- You are unable to get a lead that is not noisy.
- Arrhythmias such as atrial fib/flutter cause irregular baseline.
- The patient is continuously ventricularly paced.
- The patient has left bundle branch block.

In these cases, you should consider switching off ST monitoring.

7.4.3 Setting ST Parameter Display

Click the dropdown menu button of central monitoring system Multibed tab sheet and select “ST Select” from the pop-up menu. You can then select to show or hide the desired parameter by clicking the check box before the parameter.

7.4.4 Setting ST Alarm

In the ST analysis area of the Parameter Setup screen, you can click “ST Alarm Setup” button to set ST alarm switch, ST alarm priority, ST high limit, ST low limit etc. ST alarm limits can be changed as described in the following table.

Alarm limit	Range	Step
ST high limit	(low limit+ 0.2) to 2.00 mV	0.1 mV
ST low limit	-2.00 to (high limit – 0.2) mV	

7.4.5 Defining ST Point

As shown in the figure below, the ST measured for each beat complex is the vertical difference between two measurement points with the R-wave peak as the baseline for the measurement.

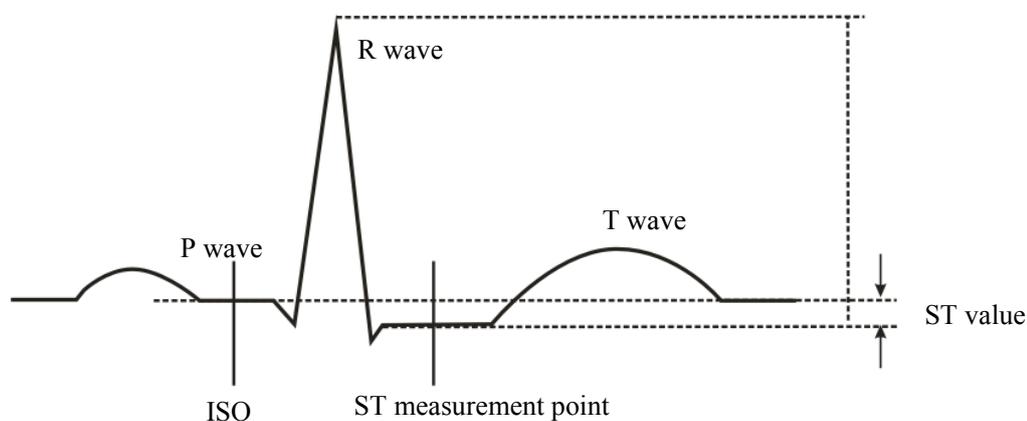


Figure 7-8 ST measurement points

The ISO and ST points need to be adjusted if the patient’s heart rate or ECG morphology changes significantly.

NOTE

-
- Abnormal QRS complex is not considered in ST analysis.
-

To adjust the ST measurement points:

1. Select “Define ST Point” to access the window as shown below. The Define ST Point window displays QRS complex template. The three vertical lines represent the positions of the ISO, J and ST points.

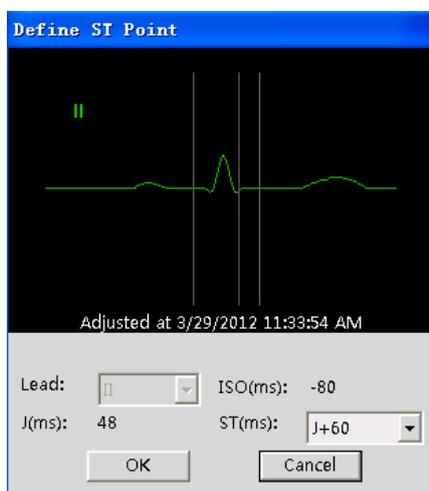


Figure 7-9 Define ST point

2. Click the Lead dropdown menu and select an ECG lead with obvious J point and R wave.
3. Drag the mouse to move the two vertical lines representing ISO and J points to adjust ST point.
 - The ISO-point (isoelectric) position is given relative to the R-wave peak. Position the ISO-point in the middle of the flattest part of the baseline (between the P and Q waves or in front of the P wave).
 - The J-point position is given relative to the R-wave peak and helps locating the ST-point. Position the J-point at the end of the QRS complex and the beginning of the ST segment.
4. Click the dropdown menu of ST(ms) and select the desired value to let the ST point at the middle of ST segment.

7.5 Arrhythmia Analysis

7.5.1 Overview

In clinical application, arrhythmia analysis is used to:

- Detect the change of heart rate and premature ventricular beat.
- Store the arrhythmia events and the alarm information generated.

The medical professionals can use the arrhythmia analysis to evaluate patients' condition (such as heart rate, PVCs frequency, rhythm and ectopic beat) and give proper treatment.

The arrhythmia analysis of the system has the following characteristics:

- Applicable to the monitoring of either a patient with a pacemaker or without.
- Activated by default.
- Capability of raising the doctor's attention to the patient's heart rate, by measuring and classifying the arrhythmia and the abnormal heartbeat and triggering the alarm.

WARNING

- **Arrhythmia analysis program is intended to detect ventricular arrhythmias. It is not designed to detect atrial or supraventricular arrhythmias. It may incorrectly identify the presence or absence of an arrhythmia. Therefore, a physician must analyze the arrhythmia information with other clinical findings.**
-
-

7.5.2 Arrhythmia Events

Arrhythmia message	Description
Asystole	No QRS complex within the preset threshold time (in absence of ventricular fibrillation or chaotic signals).
Vfib	Ventricular fibrillation occurs and persists for 6 seconds.
Vtac	Ventricular HR is greater or equal to the preset threshold value and the number of consecutive PVCs is greater than or equal to the preset threshold value.
PVCs/min	PVCs/min exceeds high limit.
VT > 2	Ventricular HR is greater than or equal to the preset threshold value and the number of consecutive PVCs is greater than or equal to 3 and less than the preset threshold value.
Vent. Rhythm	Ventricular HR is less than the preset threshold value and the number of consecutive PVCs is greater than or equal to 3.
R ON T	R on T is detected in normal heartbeats.
Couplet	Two consecutive PVCs occur.
Bigeminy	A dominant rhythm of N, V,N, V, N, V.
Trigeminy	A dominant rhythm of N, N, V,N, N, V, N, N, V.
Multif. PVC	More than 2 PVCs of different forms occur in the preset search window (3-31).
Missed Beats	No QRS complex is detected for more than 180% average R-R interval.
Brady	HR is less than or equal to the preset threshold value.
Tachy	HR is greater than or equal to the preset threshold value.
Irr. Rhythm	Consecutive irregular rhythm.
PNP	No pace pulse is detected for (60*1000/pace rate +90) milliseconds following a QRS complex or a pacer pulse (for paced patients only)
PNC	No QRS complex is detected for 300 milliseconds following a pace pulse (for paced patients only).

7.5.3 Arrhythmia Alarm Setup

Select “Arrhythmia Alarms” button to access “Arrhythmia Alarms” tab sheet to change arrhythmia alarm priority, activation state, record switch and print switch.

Asystole, Vfib and Vtac are fixed to high level alarms, whose alarm levels cannot be changed. These alarms are triggered when alarm conditions are met and the alarms are set to “On”.

7.5.4 Arrhythmia Threshold Setup

You can change arrhythmia alarm threshold settings in “Arrh. Threshold Setup” tab sheet on the alarm setup screen. When an arrhythmia violates the threshold, an alarm is triggered.

The setting of asystole delay is related to arrhythmia relearn. When HR is less than 30 bpm, it is recommended to set asystole delay to 10 s.

Arrh. Event	Range	Default	Unit
PVCs High	1 to 100	10	/min
Asys. Delay	2 to 10	4	s
Vtac Rate	100 to 200	130	bpm
Vtac PVC	3 to 12	6	beats
Multif. PVC's Window	3 to 15	15	beats
Tachy	Adult: 100 to 300 Pediatric: 160 to 300	Adult: 120 Pediatric: 160	bpm
Brady	Adult: 15 to 60 Pediatric: 15 to 80	Adult: 50 Pediatric: 75	bpm

7.5.5 Arrhythmia Alarm Review

You can view the arrhythmia alarm information on the event review screen. On the auxiliary screen, click the event review tab sheet to open an event review window. Then you can review all alarm parameters and waveforms of the patient.

By selecting arrhythmia for alarm type and all levels for alarm level, you can view the arrhythmia alarm information of the patient.

7.5.6 Arrhythmia Relearn

NOTE

-
- **Arrhythmia relearn can be activated automatically under certain circumstances.**
-

During ECG monitoring, you may need to start an arrhythmia relearn when a dramatic change in the patient's ECG pattern has occurred. A change in the ECG pattern could result in:

- Incorrect arrhythmia alarms,
- Loss of ST measurements, and/or
- Inaccurate heart rate.

Arrhythmia relearn allows the telemetry monitoring system to learn the new ECG pattern to correct arrhythmia alarms and heart rate value, and to restore ST measurements.

To start arrhythmia relearn manually, click the Relearn button. During relearn, the technical alarm area displays "ARR Learning", which disappears automatically when the learning finishes.

Arrhythmia relearn is activated automatically when:

- ECG monitoring is switched on.
- Lead type is changed.
- Patient type is changed
- Paced setting is changed
- A new patient is admitted.
- Lead off ends.
- The telemetry transmitter is networked to the central monitoring system.

7.5.7 Arrhythmia Troubleshooting

In the case of false heart rate, asystole, and ventricular fibrillation, do the following to troubleshoot the problems:

- Check the site where the electrode is placed.
- Check whether the patient skin is well prepared.
- Check the amplitude of the ECG signal. If the signal amplitude is too low, replace the electrode or adjust the position to place the electrode.
- Start arrhythmia relearn if necessary.

7.6 Maintenance and Cleaning

WARNING

- **Before cleaning the ECG cable, be sure to disconnect the monitor from the ECG cable, or shut down the system and disconnect all power cords from the outlet.**
 - **If the ECG cable is damaged or aged, replace with a new one.**
-

■ Cleaning

The exterior surfaces of the ECG cable may be cleaned with a soft cloth, dampened with the alcohol, and then be air-dried or dried with a clean dry cloth.

■ Disinfection

Disinfection may cause damage to the system. We recommend the disinfection be contained in the hospital's servicing schedule only when necessary. The system should be cleaned prior to disinfection.

8 Troubleshooting

This chapter lists only the most important physiological and technical alarm messages. Some messages appearing on your equipment may not be included.

In this chapter:

- The “I” field indicates how alarm indications are cleared: “A” means all alarm indications are cleared after the  icon is pressed, “B” indicates alarm lamp flashing and alarm tones are cleared and the alarm messages change to prompt messages after the  icon is pressed, and “C” indicates alarm lamp flashing and alarm tones are cleared and  appears before the alarm message after the  icon is pressed.
- The “L” column indicates alarm level: H means high, M means medium, L means low and Mesg. means message.. “*” means the alarm level is user-adjustable.
- XX represents a measurement or parameter label, such as HR, ST-I, PVCs etc. For the American Standard, YY represents V, LL, LA and RA.

In the “Cause and Solution” column, corresponding solutions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

8.1 Common Physiological Alarms and Troubleshooting

Measurement	Alarm message	L	Cause and solution
XX	XX Too High	M*	XX value has risen above the high alarm limit or fallen below the low alarm limit. Check the patient's condition and check if the patient category and alarm limit settings are correct.
	XX Too Low	M*	
ECG	ECG Lost	H	The ECG signal is so weak that the monitor can't perform ECG analysis. Check the patient's condition and the ECG connections.
	Asystole	H	Arrhythmia has occurred to the patient. Check the patient's condition and the ECG connections.
	VFib	H	
	VTac	H	
	R on T	M*	
	VT>2	L*	
	Couplet	Mesg.*	
	Bigeminy	M*	
	Trigeminy	M*	
	Tachy	M*	
	Brady	M*	
	Missed Beat	Mesg.*	
	Irr. Rhythm	Mesg.*	
	VRT	M*	
	Multif. PVC	M*	
	PNP	Mesg.*	
PNC	Mesg.*		

Common Technical Alarms and Troubleshooting

Measurement	Alarm message	L	I	Cause and solution
System	Low Battery	H	C	The transmitter's battery capacity is to be depleted. Replace the transmitter's battery.
	No RF Signal	M	C	The receiver did not receive valid data for consecutive 5 seconds. Check if the transmitter's battery capacity is depleted already. Check if the corresponding transmitter is in dormant status. Check if the patient is out of the coverage. Check if the antenna array cables are connected properly. Check if the corresponding transmitter is equipped with leadwires acting as antennas.
	Wrong Channel	H	C	The receiver received data sent from the transmitter. But the ID code does not belong to the system. Check if there is another telemetry system in the vicinity. Contact your service personnel to re-configure the frequency points.
	Receiver Fault	H	C	An error occurred to the receiver. Restart the receiver.
	Offline	L	A	The receiver cannot be connected to the central monitoring system. Check if the receiver is powered on. Check if the network cable is properly connected.
XX	XX Out of Range	L	C	The measured XX value is not within the specified range for XX measurement. Contact your service personnel.
ECG	ECG Lead Off	L*	B	The electrode has become detached from the patient or the lead wire has become disconnected from the transmitter. Check the connections of the electrodes and leadwires.
	ECG YY Lead Off	L*	B	

8.2 Common Problems and Troubleshooting

Alarm message	Cause and solution
RF Interference	The receiver has received 3 consecutive wrong frames. Check if the patient is at the edge of the coverage or in an elevator or behind a reinforced concrete wall. Check if there is strong RF interference.
Wrong transmitter button pressed.	The transmitter detected that a button has been depressed for consecutive 10 seconds. Check if the button is depressed by a foreign object or jammed.
ECG Signal Saturated	The transmitter detected ECG signal saturation or overload. Check the electrodes of the ECG cable. Check if the electrodes are in good contact with the skin.
Transmitter restarting repeatedly.	The transmitter's battery capacity is to be depleted. Replace the transmitter's battery.

9 Accessories

WARNING

- Use the accessories specified in this chapter. Use of accessories other than the specified may lower system performance or damage the system.
 - Disposable accessories are designed for single-patient use only. Reuse of them may cause a risk of contamination and affect the measurement accuracy.
 - Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.
-

9.1 ECG

9.1.1 ECG Electrodes

Model	Quantity	Patient Category	PN
210	10 pieces	Adult	0010-10-12304
2245	50 pieces	Pediatric	9000-10-07469

9.1.2 Cable Sets

3-Electrode Cable Sets			
Type	Compatible with	Model	PN
Snap	AHA	EY6302B	0010-20-12441
Clip	AHA	EY6302A	040-000303-00
5-Electrode Cable Sets			
Type	Compatible with	Model	PN
Snap	AHA	EY6502B	0010-20-12443
Clip	AHA	EY6502A	040-000305-00

9.2 Others

Accessory	PN
Power cord (American standard)	DA8K-10-14452
Configuration cable	009-000014-00
Transmitter bag	0152-10-39878
Crossover cable	0000-10-11009
Silica gel plug	0152-20-39707

A Product Specifications

A.1 Safety Specifications

Type of protection against electric shock	Transmitter: Internal power source Receiver: I
Degree of protection against electric shock	ECG: CF (defibrillation proof)
Mode of operation	Continuous
Degree of protection against hazards of ignition of flammable anesthetic mixtures	Not protected (ordinary)
Degree of protection against harmful ingress of water	Transmitter: IPX3 (IEC 529) Receiver: IPX0 (IEC 529)
Equipment type	Transmitter: handheld Receiver: mobile

A.2 Environmental Specifications

Operating temperature	0 to 40°C
Operating humidity	15 to 95%, non-condensing
Operating altitude	70.0 to 106.0kP
Storage temperature	-20 to 60°C
Storage humidity	10 to 95%, non-condensing
Storage altitude	22.0 to 107.4kPa

A.3 Power Specifications

A.3.1 Transmitter

Battery voltage range	2 to 3.4VDC
Power type	Two AA size, 1.5V alkaline batteries
Power ON/OFF	The transmitter is switched on when the batteries are installed, and switched off when the batteries are removed.
Transmitter automatic in sleep state	The transmitter is switched on when the batteries are installed. If all ECG leads are off for 10 minutes, the transmitter will automatically sleep. To return to normal operating state, you can do any of the following: <ul style="list-style-type: none">■ Connect any ECG lead■ Press any key■ Reinstall the batteries
Battery life (typical)	ECG: 96h Dormant: 240 hours

A.3.2 Receiver

Input voltage	100 - 240 VAC
Input current	0.6 - 0.3 A
Frequency	50/60 Hz
Fuse	T 1.6AL, 250V

A.4 Physical Specifications

A.4.1 Transmitter

Size	Width: 62 ± 3 mm, Height: 96 ± 3 mm Depth: 26 ± 3 mm
Weight	<140g (excluding the batteries, ECG leads)
Buttons	Nurse call, Event mark
Battery compartment	Battery door installed; polarity protected.

A.4.2 Receiver

Size	Width: 278 ± 3 mm Height: 116 ± 3 mm Depth: 300 ± 3 mm
Weight	<7 kg
Cooling	Natural cooling by convection
Antenna connector	Quantity: 2 Impedance: 50 ohm Connector type: TNC, female
Ethernet interface	Protocol: IEEE 802.3 Speed: 10M/100M (self-adaptive) Connector type: RJ45

A.5 Data Display, Recording and Storage

Maximal monitoring beds	32 beds
Recorder/printer	Thermal recorder WINDOWS compatible printer
Recording type	Real-time recording Alarm-triggered recording Remotely triggered recording (transmitter buttons)
Waveforms	240 hours of full-disclosure waveform for each patient
Trends	240 hours for each patient
Events	720 events for each patient.

A.6 Alarms and Indicators

Alarms	ECG, ST, ARR, signal quality, battery capacity, system failure.
Alarm type	High priority, medium priority, low priority, error message, alarm sound (45dB to 85dB); in compliance with IEC 60601-1-8.
Alarm pause	2 minutes; independent for each patient.
Alarm recording	Automatic
Battery indicator	Graphic indicator; independent for each patient.
Signal strength indicator	Independent for each patient.
Transmitter status indicator	Operating/power-saving mode, lead-off, low-battery, button response, transmitter failure.
Speaker	Give alarm tones (45 to 85 dB), alarm tones comply with IEC60601-1-8.

A.7 Wireless Transmission

Frequency range	608 to 614MHz (WMTS band) , Programmable
RF Output Power	1 mW ERP, typical
Frequency error	+/-3 PPM
Modulation type	GFSK
Occupied Bandwidth	<16 kHz
Transmitting antenna	ECG cable
Receiver sensitivity	-110 dbm
Antenna diversity	Two antennae array space diversity, automatic selection per signal strength
Channel spacing	25 KHz

To ensure sufficient coverage, TMS antenna system is customized.

A.8 ECG Specifications

ECG	
Lead type	3-lead: II 5-lead: I, II, III, aVR, aVF, aVL, V Automatic 3/5 lead recognition
Dynamic range	$\pm 5\text{mV}$ (peak to peak)
Polarization voltage	$\pm 300\text{mV}$
Differential input impedance	$>20\text{Mohm}$ (10Hz)
Sweep speed	12.5mm/s, 25mm/s, 50mm/s, error less than $\pm 10\%$
ECG gain	1.25 mm/mV, 2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40 mm/mV
Frequency response	ST: 0.05 to 40Hz Monitor:0.5 to 40Hz Surgery:1 to 20Hz
Common mode rejection ratio	105dB (50HZ/60HZ)
Sensitivity	200uV
Noise	$<30\text{ uV p-p}$
Lead-off detection current	Measure electrode: $<0.1\text{uA}$ Drive electrode: $<1\text{uA}$
Defibrillation proof	5000V/360J
Baseline recovery time	Auto discharge; fast recovery. $<5\text{s}$ (after defibrillation)
ECG calibration	Calibration waveform: 1Hz/1mV, square waveform, 5% accuracy, and automatic generation by the transmitter.
HR	
HR measurement/alarm range	Pediatric/adult: 15 to 300 bpm
HR resolution	1 bpm
HR accuracy	$\pm 1\text{ bpm}$ or $\pm 1\%$, whichever is greater.
HR averaging	In compliance with the requirements in Clause 4.1.2.1 d) of ANSI/AAMI EC13-2002, the following method is used: Heart rate is computed by averaging the most recent 16 RR intervals, unless the HR by averaging the most recent 4 heart beats is less than or

	<p>equals to 48.</p> <p>The HR value displayed on the monitor screen is updated every second.</p>
Tall T-wave rejection capability	<p>When the test is performed based on part 4.1.2.1 c) of ANSI/AAMI EC 13-2002, the heart rate meter will reject all 100 ms QRS complexes with less than 1.2 mV of amplitude, and T waves with T-wave interval of 180 ms and those with Q-T interval of 350 ms.</p>
Response to irregular rhythm	<p>In compliance with the requirements in Clause 4.1.2.1 e) of ANSI/AAMI EC13-2002, the heart rate after 20 seconds of stabilization is displayed as follows:</p> <p>Ventricular bigeminy (3a): -80 ± 1 bpm</p> <p>Slow alternating ventricular bigeminy (3b): -60 ± 1 bpm</p> <p>Rapid alternating ventricular bigeminy (3c): -120 ± 1 bpm</p> <p>Bidirectional systoles (3d): -90 ± 2 bpm</p>
Response time to heart rate change	<p>Meets the requirements of ANSI/AAMI EC13-2002: Section 4.1.2.1 f)</p> <p>Rise from 80 to 120 bpm: less than 11 s</p> <p>Fall from 80 to 40 bpm: less than 11 s</p>
Time to alarm for tachycardia	<p>Meets the requirements of ANSI/AAMI EC13-2002: section 4.1.2.1 g).</p> <p>Waveform</p> <p>4ah – range: < 11 s</p> <p>4a – range: < 11 s</p> <p>4ad – range: < 11 s</p> <p>4bh – range: < 11 s</p> <p>4b – range: < 11 s</p> <p>4bd – range: < 11 s</p>
Arrhythmia analysis	<p>ASYSTOLE, VFIB, VTAC, PVCs/min, Irr.Rhythm, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, TACHY, R ON T, BRADY, MISSED BEATS, Vent. Rhythm, Multif. PVC, PNC, PNP.</p>
Paced	
Pace mark	<p>Detects and marks pace pulse. The mark should be not lower than 2 mm.</p> <p>Amplitude: ± 10 to ± 700 mV</p> <p>Duration: 0.1 to 2 ms</p> <p>Rise time: 10 to 100 μs</p>
Pacer pulse detector rejection of fast ECG signals	<p>8V/s RTI when measured in accordance with ANSI/AAMI EC13-2002 Section 4.1.4.3.</p>
ST Measurement	
Range	<p>-2.0~2.0mV</p>

Accuracy	$\pm 0.02\text{mV}$ or $\pm 10\%$, whichever is greater, in the range of -0.8mV to $+0.8\text{mV}$; not specified in other range
Data refreshing cycle	Every 16 beats

FOR YOUR NOTES

B Factory Defaults

ECG Setup		
HR	Adult	Pediatric
HR Alarm	On	
HR Alarm Priority	Med	
HR High Limit	120	160
HR Low Limit	50	75
HR Alarm on Record	Off	
Sweep Speed	25mm/s	
HR Source	ECG	
Filter	Monitor	
Channel 1 waveform gain	× 1	
Channel 2 waveform gain	× 1	
Channel 3 waveform gain	× 1	
Pacer Rate	60	
ST analysis		
ST Analysis	Off	
ST Alarm	Off	
ST Alarm Priority	Med	
ST Record on Alarm	Off	
Lead	II	
ST	J+60	
ST Alarm Limit	High Limit	Low Limit
ST I	0.2	-0.2
ST II	0.2	-0.2
ST III	0.2	-0.2
ST aVR	0.2	-0.2
ST aVL	0.2	-0.2
ST aVF	0.2	-0.2
ST V	0.2	-0.2
All	0.2	-0.2

Arrhythmia Threshold	Adult	Pediatric	
Tachy High	120	160	
Brady Low	50	75	
PVCs High	10		
Asystole Delay	4		
Vtac Rate	130		
Vtac PVC	6		
Multif. PVC's Window	15		
Arrhythmia Event	Alarm Activation State	Alarm Priority	Record on Alarm
Asystole	On	High	Off
Vfib	On	High	Off
VTac	On	High	Off
PVCs/min	On	Med	Off
R ON T	On	Med	Off
VT>2	Off	Low	Off
Couplet	Off	Message	Off
Multif. PVC	Off	Med	Off
Vent.Rhythm	On	Med	Off
Bigeminy	On	Med	Off
Trigeminy	On	Med	Off
Tachy	Off	Med	Off
Brady	Off	Med	Off
Irr. Rhythm	Off	Message	Off
PNC	Off	Message	Off
PNP	Off	Message	Off
Missed Beats	Off	Message	Off

Alarm Setup	Factory Default Settings
Alarm Volume	5
Alarm Latched	Off
Alarm Audio Off	On
Silence Hotkey	None
Alarm Off Reminder Tone	Off
Alarm Off Reminder Vol.	Low
Alarm Off Reminder Interval(min)	1
High Alarm Interval(s)	10
Med Alarm Interval(s)	20
Low Alarm Interval(s)	20
Alm Lev of ECG Lead Off	Low
Alarm Delay(s)	6
ST Alarm Delay(s)	30

FOR YOUR NOTES

The system meets the requirements of IEC 60601-1-2:2007.

WARNING

- **Use of accessories and cables other than those specified may result in increased emission and/or decreased immunity of the system.**
- **Devices too close or stacked may interfere with each other. Do not put devices too close or stack them together. Keep a close eye on the system in case there are other devices around it.**
- **Devices even in compliance with CISPR transmitting requirements may interfere with the system.**
- **If the input signal is lower than the specified threshold, measurements may be inaccurate.**

Guidance and declaration — electromagnetic emissions		
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment — guidance
RF emissions CISPR 11	Group 1	The system generates electromagnetic energy that may interfere with operation of other electronic devices nearby.
RF emissions CISPR 11	Class B	The system is suitable for use in all electrical installations.
Harmonic Emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Compliance	

Guidance and declaration — electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The user of the system should assure that it is used in such an environment.			
sImmunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power cord ±1 kV for I/O cables		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV different mode ±2 kV common mode		
Voltage dips, Short interruptions and voltage variation on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5 sec		Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and declaration — electromagnetic immunity

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80M to 800MHz $d = 2.3\sqrt{P}$ 800M to 2.5GHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). 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 — At 80 MHz and 800 MHz, the higher frequency range applies.

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

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

Recommended separation distances between portable and mobile RF communication and the system			
The system is intended for use in an electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the system as recommended below, according to the maximum output power of the communication equipment.			
Rated Maximum Output power of Transmitter W (Watts)	Separation Distance According to Frequency of Transmitter M (Meters)		
	150kHz -80MHz $d = \left[\frac{3.5}{3} \right] \sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{3} \right] \sqrt{P}$	800MHz to 2.5GHz $d = \left[\frac{7}{3} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34
<p>For transmitters at a maximum output power not listed above, the recommended separation distanced in meters (m) can be determined 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.</p> <p>Note — At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note — These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

D FCC Compliance

TMS-6016 complies with the requirements of FCC Part 95:

Authorized health care providers, in conjunction with the equipment manufacturers, must cooperate in the selection and use of frequencies in order to reduce the potential for interference with other wireless medical telemetry devices, or other co-primary users. Operations in the 608–614 MHz band (television channel 37) are not protected from adjacent band interference from broadcast television operating on channels 36 and 38.

As the RF range of the TMS-6016 is 608-614Mhz, if located near the radio astronomy observatories, the two parties will interfere with each other.

Therefore, we don't suggest that the equipment can be installed or operated
Within 80 kilometers of:

1. National Astronomy and Ionosphere Center, Arecibo, Puerto Rico: $18^{\circ} 20' 38.28''$ North Latitude, $66^{\circ} 45' 09.42''$ West Longitude.
2. National Radio Astronomy Observatory, Socorro, New Mexico: $34^{\circ} 04' 43''$ North Latitude, $107^{\circ} 37' 04''$ West Longitude.
3. National Radio Astronomy Observatory, Green Bank, West Virginia: $38^{\circ} 26' 08''$ North Latitude, $79^{\circ} 49' 42''$ West Longitude.

Within 32 kilometers of the National Radio Astronomy Observatory centered on:

Very long baseline array stations	Latitude (north)	Longitude (west)
Pie Town, NM	34° 18'	108° 07'
Kitt Peak, AZ	31° 57'	111° 37'
Los Alamos, NM	35° 47'	106° 15'
Fort Davis, TX	30° 38'	103° 57'
North Liberty, IA	41° 46'	91° 34'
Brewster, WA	48° 08'	119° 41'
Owens Valley, CA	37° 14'	118° 17'
Saint Croix, VI	17° 46'	64° 35'
Mauna Kea, HI	19° 49'	155° 28'
Hancock, NH	42° 56'	71° 59'

If the installation distance is not enough, obtain the written concurrence of the Director of the affected radio astronomy station before the equipment can be installed or operated.

E Symbols and Abbreviations

E.1 Units

A	ampere
Ah	ampere hour
bpm	beats per minute
°C	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
DS	dyne. second
°F	fahrenheit
g	gram
hr	hour
hPa	hundred pascal
Hz	hertz
inch	inch
k	kilo
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
ms	millisecond
mV	millivolt
mW	milliwatt
nm	nanometer
ppm	part per million
s	second

V	volt
VA	volt ampere
Ω	ohm
μA	microampere
μm	micron
μV	microvolt
W	watt

E.2 Symbols

-	minus
%	percent
/	per; divide; or
^	power
+	plus
=	equal to
<	less than
>	greater than
\leq	less than or equal to
\geq	greater than or equal to
\pm	plus or minus
\times	multiply
©	copyright

E.3 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
ADT	adult
AHA	American Heart Association
ANSI	American National Standard Institute
ARR	arrhythmia
ART	arterial
AUX	Auxiliary output
aVF	left foot augmented lead
aVL	left arm augmented lead
aVR	right arm augmented lead
CH	channel
CISPR	International Special Committee on Radio Interference
CMS	central monitoring system
cmos	Complementary Metal Oxide Semiconductor
CPU	central processing unit
CVP	central venous pressure
DC	direct current
D, DIA	diastolic
ECG	electrocardiograph
EEC	European Economic Community
EMC	electromagnetic compatibility
err	error
ES	electrosurgical
ESU	electrosurgical unit
EURO	European
fpga	Field Programmable Gate Array
Hb-CO	Carbonmono-xide hemoglobin
HR	heart rate
HT	height
IEC	International Electrotechnical Commission

ID	
IM	——
IS	
ISO	International organization for standardization
LA(L)	left arm
LAP	left atria pressure
LED	light emitting diode
LL(F)	left leg
Loop	loop read-write test fail
M, MEAN	mean pressure
MDD	Medical Device Directive
MetHb	methemoglobin
MII	initialize MII registers fail
MRI	magnetic resonance imaging
N/A	not applied
O ₂	oxygen
P	power
PA	pulmonary artery
PD	photodetector
PM	Patient Monitor
PVCs	——
QRS	interval of ventricular depolarization (QRS complex)
RA(R)	right arm
RAM	random access memory
Reg	test NE2000 registers fail
RL(N)	right leg
ROM	read-only memory
S, SYS	systolic pressure
TD	temperature difference
TEMP	temperature
TFT	Thin-Film Technology
V(C)	precordial lead(Chest)
VGA	Video Graphics Array
