

**uMEC10/uMEC12/uMEC15/uMEC6/
uMEC7/uMEC15S**

Patient Monitor

Operator's Manual

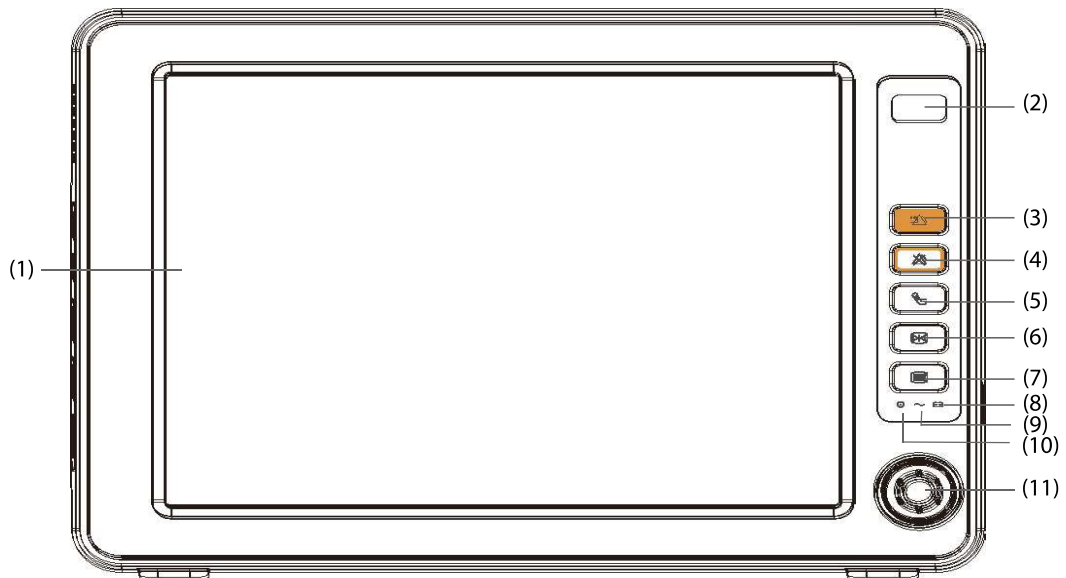


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2.2 Front View



- (1) Display Screen
- (2) Alarm lamp
When a physiological alarm or technical alarm occurs, this lamp will flash as defined below.
 - ◆ High level alarms: the lamp quickly flashes red.
 - ◆ Medium level alarms: the lamp slowly flashes yellow.
 - ◆ Low level physiological alarms: the lamp lights yellow without flashing.
 - ◆ Low level technical alarms: the lamp does not light.
- (3) Press to reset alarms.
- (4) Press to pause or restore alarms.
- (5) Press to start or stop NIBP measurements.
- (6) Press to freeze or unfreeze waveforms.
- (7) If no menu is displayed on the screen, pressing it will enter the main menu. If there is a menu displayed on the screen, pressing it will close that menu.
- (8) Battery LED
 - ◆ On: when the battery is installed and the AC source is connected.
 - ◆ Off: when no battery is installed or the installed battery is malfunction, or no AC source is connected when the patient monitor is power off.
 - ◆ Flash: when the patient monitor operates on battery power.
- (9) AC power LED
It turns on when AC power is connected.
- (10) Power On/Off LED
It turns on when the patient monitor is on and turns off when the patient monitor is off.
- (11) Knob
Rotate the Knob clockwise or anti-clockwise. With each click, the highlight jumps to the neighboring item. When you reach your desired item, press the Knob to select it.

3.9.6 Adjusting Volume

Alarm Volume

1. Select the **[Alarm Setup]** QuickKey → **[Others]**, or **[Main Menu]** → **[Alarm Setup >>]** → **[Others]**.
2. Select **[Alm Volume]** and then select the appropriate volume: X-10, in which X is the minimum volume, depending on the set minimum alarm volume (refer to **7 Alarms**), and 10 the maximum volume.

Key Volume

When you press the navigation knob or the touchscreen, or the hardkeys on the panel, the patient monitor prompts you by making a sound of the key volume you have set.

1. Select the **[Volume Setup]** QuickKey, or **[Main Menu]** → **[Screen Setup >>]**.
2. Select **[Key Volume]** and then select the appropriate volume. 0 means off, and 10 the maximum volume.

QRS Volume

The QRS tone is derived from either the HR or PR, depending on which is currently selected as the alarm source in **[ECG Setup]** or **[SpO2 Setup]**. When monitoring SpO₂, there is a variable pitch tone which changes as the patient's saturation level changes. The pitch of the tone rises as the saturation level increases and falls as the saturation level decreases. The volume of this tone is user adjustable.

1. Select the **[Volume Setup]** QuickKey, or the ECG parameter window → **[Others >>]**, or the SpO₂ parameter window.
2. Select **[QRS Volume]** or **[Beat Vol]** and then select the appropriate volume. 0 means off, and 10 the maximum volume.

3.10 Setting Parameters

3.10.1 Switching the Parameters On/Off

To switch the parameters on or off,

1. Select **[Main Menu]** → **[Maintenance >>]** → **[User Maintenance >>]** → enter the required password → **[Others]**.
2. Configure the **[Para Switch Authority]** to **[Unprotected]** or **[Protected]**.
 - ◆ If **[Para Switch Authority]** is configured to **[Unprotected]**, select **[Main Menu]** → **[Screen Setup >>]** → **[Screen Layout >>]** → **[Parameters Switch]** to switch the parameters on or off.
 - ◆ If **[Para Switch Authority]** is configured to **[Protected]**, the parameter switch is password protected. To switch the parameters on or off, select **[Main Menu]** → **[Maintenance >>]** → **[User Maintenance >>]** → enter the required password → **[Others >>]** → **[Parameters Switch Setup >>]**.

When a parameter is switched off, its corresponding parameter module stops working, and its parameter value and waveform are not shown on the monitor display.

NOTE

- **ECG is always selected, and you cannot switch it off.**

3.10.2 Accessing the Parameters Menu

Select **[Parameters >>]** from the main menu or select corresponding parameter area or waveform area to access a parameter setup menu.

3.11 Operating Modes

Your monitor has different operating modes. Some are password protected. This section lists the major operating modes.

5 Managing Configurations

5.1 Introduction

When performing continuous monitoring on a patient, the clinical professional often needs to adjust the monitor's settings according to the patient's condition. The collection of all these settings is called a configuration. Allowing you to configure the monitor more efficiently, the monitor offers different sets of configuration to suit different patient categories. You can change some settings from a certain set of configuration and then save the changed configuration as a user configuration.

WARNING

- **The configuration management function is password protected. The configuration management tasks must be performed by clinical professionals.**
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The system configuration items can be classified as:

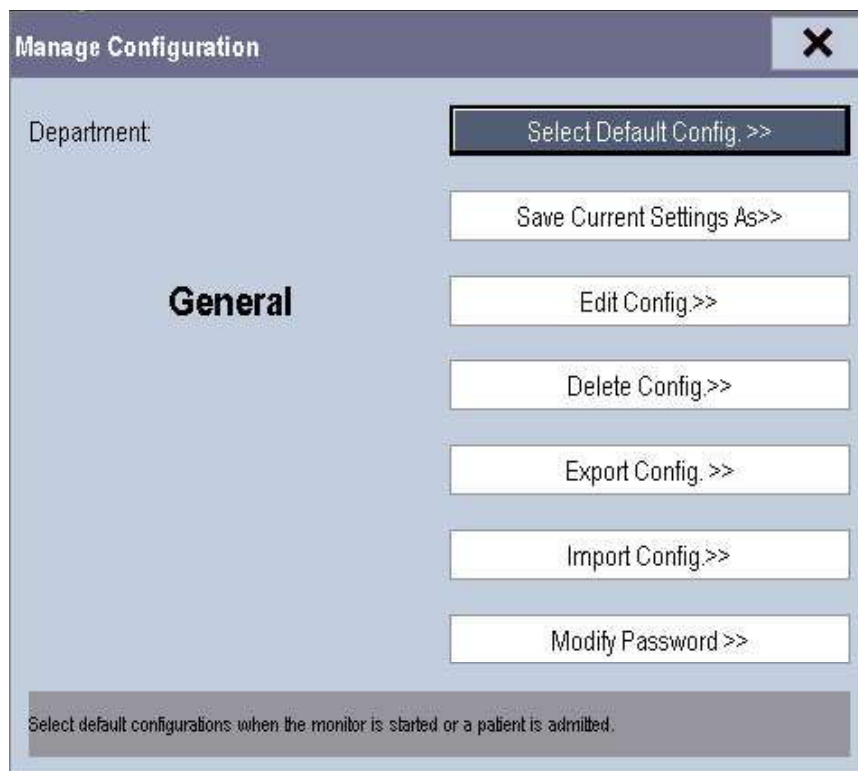
- Parameter configuration items
These items relate to parameters, e.g., waveform gain, alarm switch, alarm limits..
- Conventional configuration items
These items define how the monitor works, e.g., screen layout, record, print and alarm settings.
- User maintenance items
These items relate to user maintenance settings, e.g., unit setup, time format and data format.

For the important configuration items and their default values and user maintenance items, see appendix ***Configuration Default Information***.

5.2 Entering the [Manage Configuration] Menu

1. Press the  hardkey on the monitor's front to enter the main menu.

2. Select **[Maintenance >>]** → **[Manage Configuration >>]**. Enter the required password and then select **[Ok]**.



5.3 Setting Default Configuration

The monitor will load the pre-set default configuration in the following cases.

- The patient monitor restarts after quitting over 120 seconds.
- A patient is admitted.
- A patient is discharged.
- Patient data is cleared.
- Patient category is changed.

To set default configuration:

1. Select **[Select Default Config. >>]** in the **[Manage Configuration]** menu.
2. In the **[Select Default Config.]** menu, select **[Load the Latest Config.]** or **[Load Specified Config.]**.

When you select **[Load Specified Config.]**, the configuration (adult, pediatric or neonate) to be restored is subject to the patient category. This configuration can be either factory configuration or saved user configuration. Take adult as an example, select **[Default Adu Config.]** and toggle between **[Defaults]** or user configuration(s).

NOTE

- **To know what configuration is restored when the patient monitor starts, enter the main screen to check the prompt information at the lower part of the screen (displayed for about 10 seconds).**

5.4 Saving Current Settings

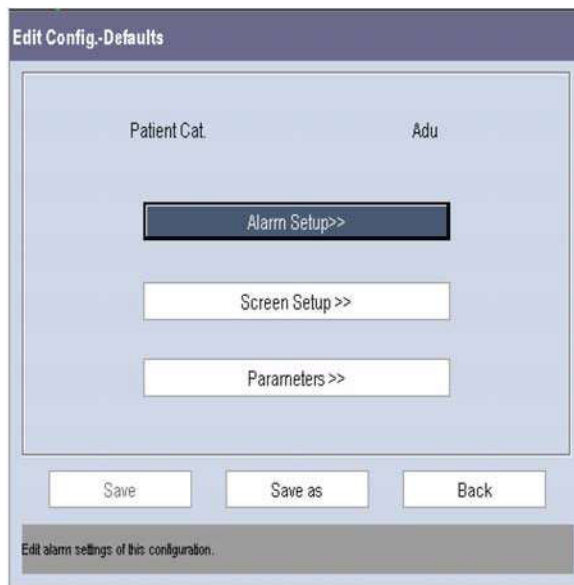
Current settings can be saved as user configuration. Up to 3 user configurations can be saved.

To save current settings:

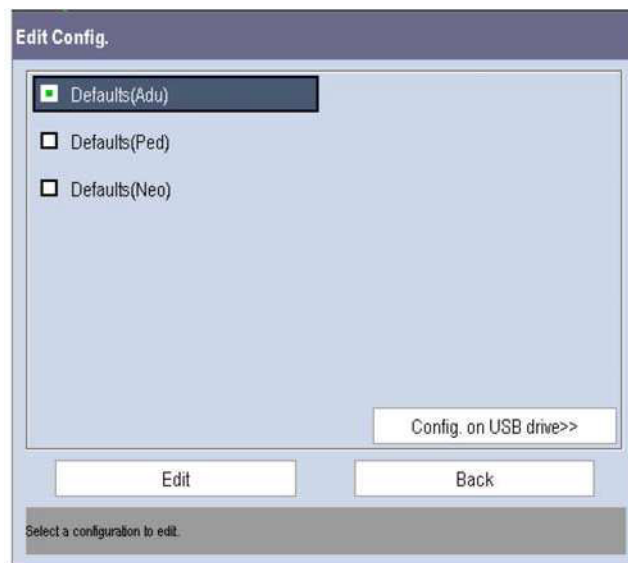
1. Select **[Save Current Settings As >>]** in the **[Manage Configuration]** menu.
2. In the popup dialog box, enter the configuration name and then select **[Ok]**.

5.5 Editing Configuration

1. Select **[Edit Config. >>]** in the **[Manage Configuration]** menu. The following menu appears.



2. The popup menu shows the existing configurations on the monitor. Selecting **[Config. on USB drive >>]** will show the existing configurations on the USB drive. Select the desired configuration and then select the **[Edit]** button. The following menu appears.



3. Select **[Alarm Setup >>]**, **[Screen Setup >>]** or **[Parameter >>]** to enter the corresponding menu in which settings can be changed. The changed items of alarm setup will be marked in red.
4. You can select **[Save]** or **[Save as]** to save the changed configuration. Select **[Save]** to overwrite the original configuration. Select **[Save as]** to save the changed configuration in another name.

5.6 Deleting a Configuration

1. Select **[Delete Config. >>]** in the **[Manage Configuration]** menu.
2. The popup menu shows the existing user configurations on the monitor. Selecting **[Config. on USB drive >>]** will show the existing user configurations on the USB drive. Select the user configurations you want to delete and then select **[Delete]**.
3. Select **[Yes]** in the popup.

5.7 Transferring a Configuration

When installing several monitors with identical user configuration it is not necessary to set each unit separately. An USB drive may be used to transfer the configuration from monitor to monitor.

To export the current monitor's configuration:

1. Connect the USB drive to the monitor's USB port.
2. Select [**Export Config. >>**] in the [**Manage Configuration**] menu.
3. In the [**Export Config.**] menu, select the configurations and [**User Maintenance Settings**] to export. Then select the [**Export**] button. A status message will report completion of the transfer.

To import the configuration on the USB drive to the monitor:

1. Connect the USB drive to the monitor's USB port.
2. Select [**Import Config. >>**] in the [**Manage Configuration**] menu.
3. In the [**Import Config.**] menu, select the configurations and [**User Maintenance Settings**] to import. Then select the [**Import**] button. A status message will report completion of the transfer.

5.8 Loading a Configuration

You may make changes to some settings during operation. However, these changes or the pre-selected configuration may not be appropriate for the newly admitted patient. Therefore, the monitor allows you to load a desired configuration so as to ensure that all the settings are appropriate for your patient.

To load a configuration,

1. Select [**Load Configuration >>**] from the main menu.
2. The popup menu shows the existing configurations on the monitor. Selecting [**Config. on USB drive >>**] will show the existing configurations on the USB drive.
3. Select a desired configuration.
4. Select [View] to view the configuration details. In the popup menu, you can select [**Alarm Setup >>**], [**Screen Setup >>**] or [**Parameter >>**] to view the corresponding contents. The alarm setup items which are different than those currently used are marked in red.
5. Select [**Load**] to load this configuration.

5.9 Restoring the Latest Configuration Automatically

During operation, you may make changes to some settings. However, these changes may not be saved as user configuration. To prevent the changes from losing in case of a sudden power failure, the patient monitor stores the configuration in real time. The saved configuration is the latest configuration.

The monitor restore the latest configuration if restarts within 60 seconds after the power failure. And it will restore the default configuration rather than the latest configuration if restarts 120 seconds later after the power failure. The monitor may load either the latest configuration or the default configuration if restarts from 60-120 seconds after the power failure.

5.10 Modifying Password

To modify the password for accessing the [**Manage Configuration**] menu,

1. Select [**Modify Password >>**] in the [**Manage Configuration**] menu.
2. Input a new password in the popup menu.
3. Select [**Ok**].



Lead Placement for Surgical Patients

The surgical site should be taken into consideration when placing electrodes on a surgical patient. e.g. for open-chest surgery, the chest electrodes can be placed on the lateral chest or back. To reduce artifacts and interference from electrosurgical units, you can place the limb electrodes close to the shoulders and lower abdomen and the chest electrodes on the left side of the mid-chest. Do not place the electrodes on the upper arm. Otherwise, the ECG waveform will be very small.

WARNING

- **When using electrosurgical units (ESU), patient leads should be placed in a position that is equal distance from the Electrosurgery electrotome and the grounding plate to avoid burns to the patient. Never entangle the ESU cable and the ECG cable together.**
 - **When using electrosurgical units (ESU), never place ECG electrodes near to the grounding plate of the ESU, as this can cause a lot of interference on the ECG signal.**
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8.3.4 Checking Paced Status

It is important to set the paced status correctly when you start monitoring ECG. The paced symbol  is displayed in the ECG waveform area when the **[Paced]** status is set to **[Yes]**. The pace pulse markers "I" are shown on the ECG wave when the patient has a paced signal. If **[Paced]** is set to **[No]** or the patient's paced status is not selected, the symbol  will be shown in the ECG waveform area.

To change the paced status, you can select either:

- the patient information area, or
- **[Main Menu]** → **[Patient Setup]** → **[Patient Demographics]**, or,
- the ECG parameter window or waveform area → **[Others >>]**,

and then, select **[Paced]** from the popup menu and toggle between **[Yes]** and **[No]**.

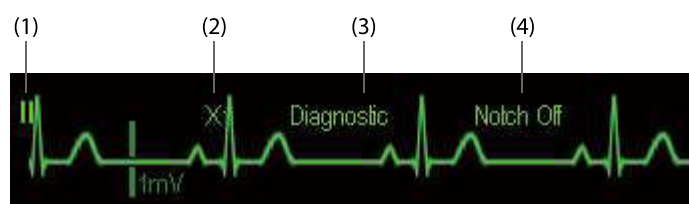
If you do not set the paced status, the patient monitor issues a prompt tone when pace pulse is detected. At the same time, the paced symbol flashes and the message **[Please confirm the pace of patient]** appears in the ECG waveform area. Then, please check and set the paced status of the patient.

WARNING

- **For paced patients, you must set [Paced] to [Yes]. If it is incorrectly set to [No], the patient monitor could mistake a pace pulse for a QRS and fail to alarm when the ECG signal is too weak. Do not rely entirely on rate meter alarms when monitoring patients with pacemakers. Always keep these patients under close surveillance.**
 - **For non-paced patients, you must set [Paced] to [No].**
 - **The auto pacer recognition function is not applicable to pediatric and neonatal patients.**
 - **False low heart rate indicators or false Asystole calls may result with certain pacemakers because of pacemaker artifact such as electrical overshoot of the pacemaker overlapping the true QRS complexes.**
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8.4 Understanding the ECG Display

Your display may be configured to look slightly different.

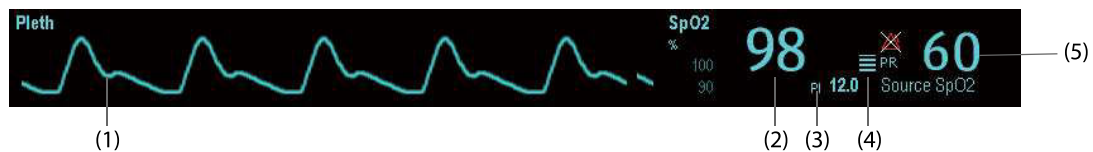


11 Monitoring SpO₂

11.1 Introduction

SpO₂ monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photodetector in the probe. The SpO₂ module processes the electrical signal and displays a waveform and digital values for SpO₂ and pulse rate.

This device is calibrated to display functional oxygen saturation. It provides four measurements:



- (1) Pleth waveform (Pleth): visual indication of patient's pulse. The waveform is not normalized.
- (2) Oxygen saturation of arterial blood (SpO₂): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
- (3) Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength. You can also use it to assess the quality of SpO₂ measurement.
 - ◆ Above 1 is optimal,
 - ◆ Between 0.3 and 1 is acceptable.
 - ◆ Below 0.3 indicates low perfusion. When PI is below 0.3, the low perfusion status indicator (a question mark) is displayed to the right of the SpO₂ value, indicating that the SpO₂ value may be inaccurate. Reposition the SpO₂ sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible. You can also disable the display of the low perfusion status indicator by referring to **11.4.9 Setting the Low Perfusion Status Indicator**.
 - ◆ PI value can be displayed under the PR value in larger characters if **[PI Zoom]** is enabled.
- (4) Perfusion indicator: the pulsatile portion of the measured signal caused by arterial pulsation.
- (5) Pulse rate (derived from pleth wave): detected pulsations per minute.

NOTE

- **A functional tester or SpO₂ simulator cannot be used to assess the accuracy of a SpO₂ module or a SpO₂ sensor.**
- **A functional tester or SpO₂ simulator can be used to determine the pulse rate accuracy.**

11.2 Safety

WARNING

- **Use only SpO₂ sensors specified in this manual. Follow the SpO₂ sensor's instructions for use and adhere to all warnings and cautions.**
- **When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.**

PR from SpO2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Response time	< 30 s (PI > 0.3, no disturbance, PR value sudden change within 25 – 240 bpm)
Accuracy	±3 bpm
Refreshing rate	≤2 s
SpO ₂ averaging time	7 s (when sensitivity is set to High) 9 s (when sensitivity is set to Medium) 11 s (when sensitivity is set to Low)

PR from NIBP Module

Measurement range	30 to 300 bpm
Resolution	1 bpm
Accuracy	±3 bpm or ±3%, whichever is greater
Refreshing rate	≤2 s

PR from IBP Module

Measurement range	25 to 350 bpm
Resolution	1 bpm
Accuracy	±1 bpm or ±1%, whichever is greater
Refreshing rate	≤2 s

A.7.5 NIBP

Standards	Meet standards of IEC80601-2-30,			
Technique	Oscillometry			
Mode of operation	Manual, Auto, STAT, Sequence			
Auto mode repetition intervals	1 min, 2 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, 2 h, 3 h, 4 h, 8 h			
STAT mode cycle time	5 min			
Max measurement time	Adult, pediatric: 120 s Neonate: 90 s			
Measurement ranges (mmHg)		Adult	Pediatric	Neonate
	Systolic:	25 to 290	25 to 240	25 to 140
	Diastolic:	10 to 250	10 to 200	10 to 115
	Mean:	15 to 260	15 to 215	15 to 125
Accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg			
Resolution	1mmHg			

Initial cuff inflation pressure range (mmHg)	Adult: 80 to 280 Pediatric: 80 to 210 Neonate: 60 to 140	
Default initial cuff inflation pressure (mmHg)	Adult: 160 Pediatric: 140 Neonate: 90	
Software overpressure protection	Adult, pediatric: 297±3 mmHg Neonate: 147±3 mmHg	
Static pressure measurement range	0 mmHg to 300 mmHg	
Static pressure measurement accuracy	±3 mmHg	
Alarm limit	Range (mmHg)	Step (mmHg)
Sys High	Adult: (low limit+5) to 290 Pediatric: (low limit+5) to 240 Neonate: (low limit+5) to 140	NIBP ≤ 50: 1 NIBP > 50: 5
Sys Low	25 to (high limit-5)	
Mean High	Adult: (low limit+5) to 260 Pediatric: (low limit+5) to 215 Neonate: (low limit+5) to 125	
Mean Low	15 to (high limit-5)	
Dia High	Adult: (low limit+5) to 250 Pediatric: (low limit+5) to 200 Neonate: (low limit+5) to 115	
Dia Low	10 to (high limit-5)	

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

In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Non-invasive sphygmomanometers (ISO 81060-2) in terms of mean error and standard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

A.7.6 Temp

Standards	Meet standard of ISO 80601-2-56
Technique	Thermal resistance
Operating mode	Direct mode
Measurement range	0 to 50 °C (32 to 122 °F)
Resolution	0.1 °C
Accuracy	±0.1 °C (without probe)
Refreshing rate	≤2 s
Minimum time for accurate measurement	Body surface: <100 s Body cavity: <80 s
Transient response time	Body surface probe: <45 s Body cavity probe: <45 s

D.1 Physiological Alarm Messages

Measurement	Alarm messages	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 Weak Signal	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/VTac	H	
	Vtac	H	
	Vent. Brady	H	
	Extreme Tachy	H	
	Extreme Brady	H	
	R on T	M*	
	Run PVCs	L*	
	PVCs	M*	
	Multif.PVC	M*	
	Bigeminy	M*	
	Trigeminy	M*	
	Tachy	M*	
	Brady	M*	
	Vent. Rhythm	M*	
Nonsus. Vtac	M*		
Pause	L*		
Resp	Resp Apnea	H	The respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's condition and the Resp connections.
	Resp Artifact	H	The patient's heartbeat has interfered with his respiration. Check the patient's condition and the Resp connections.
SpO ₂	SpO ₂ Desat	H	The SpO ₂ value has fallen below the desaturation alarm limit. Check the patient's condition and check if the alarm limit settings are correct.
	No Pulse	H	The pulse signal was so weak that the monitor cannot perform pulse analysis. Check the patient's condition, SpO ₂ sensor and measurement site.
CO ₂	CO ₂ Apnea	H	The patient stops breathing, or the respiration signal was so weak that the monitor cannot perform respiration analysis. Check the patient's condition and the RM connections.

D.2 Technical Alarm Messages

Measurement	Alarm message	L	I	Cause and solution	
XX	XX SelfTest Err	H	C	An error occurred to the XX module, or there is a problem with the communications between the module and the monitor. Re-plug the module and restart the monitor, or plug the module into another monitor.	
	XX Init Err	H	A		
	XX Init Err N	H	A		
	N is within 1 to 8				
	XX Comm Err	H	A		
	XX Comm Stop	H	C		
	XX Limit Err	L	C	XX parameter limit is accidentally changed. Contact your service personnel.	
	XX Overrange	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 adapter cable. Check the connections of the electrodes and leadwires.	
	ECG YY Lead Off	L*	B		
	Note: YY represents the leadwires, V, LL, LA, RA, as per AHA standard, or C, F, L and R as per IEC standard.				
	ECG Noisy	L	A	The ECG signal is noisy. Check for any possible sources of signal noise around the cable and electrode, and check the patient for great motion.	
	ECG Artifact	L	A	Artifacts are detected on the ECG analysis lead and as a result heart rate cannot be calculated and Asystole, Vfib and Vtac cannot be analyzed. Check the connections of the electrodes and leadwires and check for any possible source of interference around the cable and electrode. Check the patient's condition and check the patient for great motion.	
	ECG High Freq. Noise	L	A	High frequency signals are detected on the ECG analysis lead. Check for any possible source of interference around the cable and electrode.	
	ECG Low Freq. Noise	L	A	Low frequency signals are detected on the ECG analysis lead. Check for any possible source of interference around the cable and electrode.	
	ECG Amplitude Too Small	L	C	The ECG amplitude didn't reach the detected threshold. Check for any possible source of interference around the cable and electrode.	
	ECG Config. Err	L	C	ECG configuration is wrongly downloaded. Check the downloaded configuration and re-download the correct configuration.	
Resp	Resp Disturbed	L	A	The respiration circuit is disturbed. Restart the monitor.	
Temp	Temp Cal. Err	H	C	A calibration failed. Restart the monitor.	
	T1 Sensor Off	L	A	The Temp sensor has become detached from the patient or the module. Check the sensor connections.	
	T2 Sensor Off	L	A		

Measurement	Alarm message	L	I	Cause and solution
SpO ₂	SpO ₂ Sensor Off	L*	B	The SpO ₂ sensor has become detached from the patient or the module, or there is a fault with the SpO ₂ sensor, or an unspecified SpO ₂ sensor has been used. Check the sensor application site and the sensor type, and make sure if the sensor is damaged. Reconnect the sensor or use a new sensor.
	SpO ₂ Sensor Fault	L	C	
	SpO ₂ No Sensor	L	B	
	SpO ₂ Unknown Sensor	L	C	
	SpO ₂ Sensor Incompatible	L	C	
	SpO ₂ Too Much Light	L	C	There is too much light on the SpO ₂ sensor. Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
	SpO ₂ Low Signal	L	C	The SpO ₂ signal is too low or too weak. Check the patient's condition and change the sensor application site. If the error persists, replace the sensor.
	SpO ₂ Weak Pulse	L	C	
	SpO ₂ Interference	L	C	The SpO ₂ signal has been interfered. Check for any possible sources of signal noise around the sensor and check the patient for great motion.
	SpO ₂ Board Fault	L	C	There is a problem with the SpO ₂ measurement board. Do not use the module and contact your service personnel.
NIBP	NIBP Loose Cuff	L	A	The NIBP cuff is not properly connected, or there is a leak in the airway.
	NIBP Air Leak	L	A	
	NIBP Pneumatic Leak	L	A	Check the NIBP cuff and pump for leakages.
	NIBP Cuff Type Wrong	L	A	The cuff type applied mismatches the patient category. Verify the patient category and replace the cuff.
	NIBP Air Pressure Err	L	A	An error occurred to the air pressure. Verify that the monitor application site meets the environmental requirements and check if there is any source that affects the air pressure.
	NIBP Weak Signal	L	A	The patient's pulse is weak or the cuff is loose. Check the patient's condition and change the cuff application site. If the error persists, replace the cuff.
	NIBP Signal Saturated	L	A	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Overrange	L	A	The measured NIBP value exceeds the module measurement range.
	NIBP Excessive Motion	L	A	Check the patient's condition and reduce the patient motion.
	NIBP Cuff Overpress.	L	A	The NIBP airway may be occluded. Check the airway and measure again.
	NIBP Equip Err	H	A	An error occurred during NIBP measurement and therefore the monitor cannot perform analysis correctly. Check the patient's condition and NIBP connections, or replace the cuff.
	NIBP Timeout	L	A	
	NIBP Measure Failed	L	A	
	NIBP Illegally Reset	L	A	An illegal reset occurred during NIBP measurement. Check if the airway is occluded.

Measurement	Alarm message	L	I	Cause and solution
IBP	YY Sensor Off	L*	A	Check the sensor connection and reconnect the sensor.
	YY Disconnected	H	C	The liquid way is disconnected from the patient, or the three-way valve is open to the air. Check the connection of the liquid way, or check the valve is open to the patient. If the problem remains, contact the Customer Services Dept. for help.
	YY Non-Pulsatile	L	A	The catheter may be occluded. Please flush the catheter. YY represents an IBP label.
	YY represents an IBP label.			
C.O.	TB Sensor Off	L	A	Check the sensor connection and reconnect the sensor.
CO ₂	CO ₂ Sensor High Temp	L	C	Check, stop using or replace the sensor.
	CO ₂ Sensor Low Temp	L	C	
	CO ₂ FilterLine Occluded	L	C	The airway or watertrap was occluded. Check the airway and remove the occlusion.
	CO ₂ No Watertrap	L	B	Check the watertrap connections.
	CO ₂ Zero Failed	L	A	Check the CO ₂ connections. After the sensor's temperature becomes stabilized, perform a zero calibration again.
	CO ₂ System Err	L	A	Re-plug the module or restart the monitor.
	CO ₂ : Change Watertrap	L	C	Replace the watertrap.
	CO ₂ : Watertrap and Patient Mismatch	L	C	Check the patient category and use a correct watertrap.
Power	12V Too High	H	C	There is a problem with the system power supply. Restart the monitor.
	12V Too Low	H	C	
	5V Too High	H	C	
	5V Too Low	H	C	
	3.3V Too High	H	C	
	3.3V Too Low	H	C	
	Battery Too Low	H	C	Connect the monitor to an AC power source and allow the batteries to charge.
	Battery Overload	H	C	The power consumption of the equipment is too high. Power the monitor using an AC power source.
	RT Clock Not Exist	H	C	Contact your service personnel.

Measurement	Alarm message	L	I	Cause and solution
Recorder	Recorder Init Err N	L	A	Restart the monitor.
	N is within 1 to 8.			
	Recorder SelfTest Err	L	A	Stop the recording and restart the monitor.
	Recorder Comm Err	L	A	
	Recorder S. Comm Err	L	A	
	Recorder Unavailable	L	A	
	Recorder Vlt High	L	C	An error occurred to the system power supply. Restart the monitor.
	Recorder Vlt Low	L	C	
	Recorder Head Hot	L	C	The recorder has been working for too long time. Stop the recording and resume the recording till the recorder's printhead cools down.
	Rec Paper Wrong Pos.	L	A	Re-load the recorder paper.
System	System Watchdog Err	H	C	An error occurred to the system. Restart the monitor.
	System Software Err	H	C	
	System CMOS Full	H	C	
	System CMOS Err	H	C	
	System FPGA Err	H	C	
	System Err N	H	C	
	N is within 2 to 12.			
	Other Bed Disconnected	L	A	Check network connection.
	PWR interrupted. Check meas. state	L	A	Power supply failed accidentally. Check the measurements when the monitor restarts.
	No CMS	L	A	The monitor is disconnected from the CMS. Check network connection.

E Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed by using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe, such as Fluke, Metron, or Gerb, may require modifications to the procedure. Please follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed every two years. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

E.1 Power Cord Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

E.2 Device Enclosure and Accessories

E.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

E.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

E.3 Device Labelling

Check the labels provided by the manufacturer or the healthcare facilities are present and legible.

- Main unit label
- Integrated warning labels

E.4 Protective Earth Resistance

1. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
2. Test the earth resistance with a current of 25 A.
3. Verify the resistance is less than limits.

LIMITS

For all countries, $R = 0.2 \Omega$ Maximum

E.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test:

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)

LIMITS

For UL60601-1,

- ◆ 300 μ A in Normal Condition
- ◆ 1000 μ A in Single Fault Condition

For IEC60601-1,

- ◆ 500 μ A in Normal Condition
- ◆ 1000 μ A in Single Fault Condition

E.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition),
- normal polarity with open neutral (Single Fault Condition)

- reverse polarity with open neutral (Single Fault Condition)
- normal polarity with open earth (Single Fault Condition)
- reverse polarity with open earth (Single Fault Condition)

LIMITS

For CF  applied parts

- ◆ 10µA in Normal Condition
- ◆ 50µA in Single Fault Condition

For BF  applied parts

- ◆ 100µA in Normal Condition
- ◆ 500µA in Single Fault Condition

E.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity
- Reversed Polarity

LIMITS

- For CF  applied parts: 50 µA
- For BF  applied parts: 5000 µA

E.8 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connectors. All measurements may have a true RMS only response.

The following outlet conditions apply when performing the Patient Auxiliary Current test.

- normal polarity (Normal Condition)
- reverse polarity (Normal Condition)
- normal polarity with open neutral (Single Fault Condition)
- reverse polarity with open neutral (Single Fault Condition)
- normal polarity with open earth (Single Fault Condition)
- reverse polarity with open earth (Single Fault Condition)

LIMITS

For CF  applied parts,

- ◆ 10µA in Normal Condition
- ◆ 50µA in Single Fault Condition

For BF  applied parts,

- ◆ 100µA in Normal Condition
- ◆ 500µA in Single Fault Condition

NOTE

-
- **Make sure the safety analyzer is authorized comply with requirement of IEC60601-1.**
 - **Follow the instructions of the analyzer manufacturer.**
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F Symbols and Abbreviations

Symbols and abbreviations that you may encounter while reading this manual or using the monitor are listed below with their meanings.

F.1 Symbols

A	ampere
Ah	ampere hour
bpm	beats per minute
BrPM	breaths per minute
°C	centigrade
cc	cubic centimeter
cm	centimeter
dB	decibel
°F	fahrenheit
g	gram
GTT	gutta
hr	hour
hPa	hundred pascal
Hz	hertz
inch	inch
kg	kilogram
kPa	kilopascal
l	litre
lb	pound
m	meter
mcg	micrograms
mEq	milli-equivalents
mg	milligrams
min	minute
ml	milliliter
mm	millimeters
mmHg	millimeters of mercury
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
-	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

F.2 Abbreviations

AAMI	Association for Advancement of Medical Instrumentation
AC	alternating current
ADT	adult
AHA	American Heart Association
ANSI	American National Standard Institute
AP	access point
ARR	arrhythmia
ART	arterial
AUX	Auxiliary output
AwRR	Air way respiratory rate
BTPS	body temperature and pressure, saturated
CCU	critical care unit

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
D	diastolic
DC	direct current
DIA	diastolic
e.g.	for example
ECG	electrocardiograph
EEC	European Economic Community
EMC	electromagnetic compatibility
ERR	error
ES	electrosurgical
ESU	electrosurgical unit
Et	end-tidal
EURO	European
Fi	fraction of inspired
FiCO ₂	fraction of inspired carbon oxygen
FiN ₂ O	fraction of inspired nitrous oxide
FiO ₂	fraction of inspired oxygen
fpga	Field Programmable Gate Array
Hb-CO	Carbonmono-xide hemoglobin
HR	heart rate
HT	height
IEC	International Electrotechnical Commission
ID	invasive diastolic blood pressure
IM	invasive mean blood pressure
IS	invasive systolic blood pressure
Ins, INS	Inspired Minimum
InsCO ₂	Inspired Minimum carbon dioxide
ISO	International organization for standardization
LA (L)	left arm
LAP	left atria pressure
LCD	liquid crystal display
LED	light emitting diode
LL (F)	left leg

Loop	loop read-write test fail
M	mean
MAC	minimal alveolar concentration
MAP	mean arterial pressure
MDD	Medical Device Directive
MEAN	mean pressure
MetHb	methemoglobin
Mii	initialize MII registers fail
MRI	magnetic resonance imaging
N/A	not applied
NEO	neonate, neonatal
NIBP	noninvasive blood pressure
ND	non-invasive diastolic brood pressure
NM	non-invasive mean brood pressure
NS	non-invasive systolic brood pressure
O ₂	oxygen
OxyCRG	Oxygen Cardio-respirogram
P	power
PA	pulmonary artery
PAWP	pulmonary artery wedge pressure
PD	photodetector
PED	pediatric
PLETH	plethysmogram
PM	Patient Monitor
PPV	Pulse Pressure Variation
PR	pulse rate
PVC	premature ventricular complex
QRS	interval of ventricular depolarization
RA (R)	right arm
RAM	random access memory
RAP	right atrial pressure
Reg	test NE2000 registers fail
RESP	respiration
RL (N)	right leg
ROM	read-only memory
RR	respiration rate
S	systolic
SpO ₂	arterial oxygen saturation from pulse oximetry

SYNC	synchronization
SYS	systolic
TEMP	temperature
TFT	Thin-Film Technology
V (C)	precordial lead (chest)
VGA	Video Graphice Array

G Declaration of Conformity

Declaration of Conformity V2.0

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Patient Monitor (Including Accessories)

Model: uMEC6/uMEC7/uMEC10/uMEC12/uMEC15/uMEC15S

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2014/53/EU concerning radio equipment. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:

<input checked="" type="checkbox"/> EN 60601-1:2006/A1 :2013	<input checked="" type="checkbox"/> EN 60601-1-2:2015
<input checked="" type="checkbox"/> EN 62311:2008	<input checked="" type="checkbox"/> EN 50385:2002
<input checked="" type="checkbox"/> ETSI EN 301 489-1 V2.2.0	<input checked="" type="checkbox"/> ETSI EN 301 489-17 V3.1.1
<input checked="" type="checkbox"/> EN 300 328 V2.1.1	<input checked="" type="checkbox"/> ESTI EN 301 893 V2.1.1

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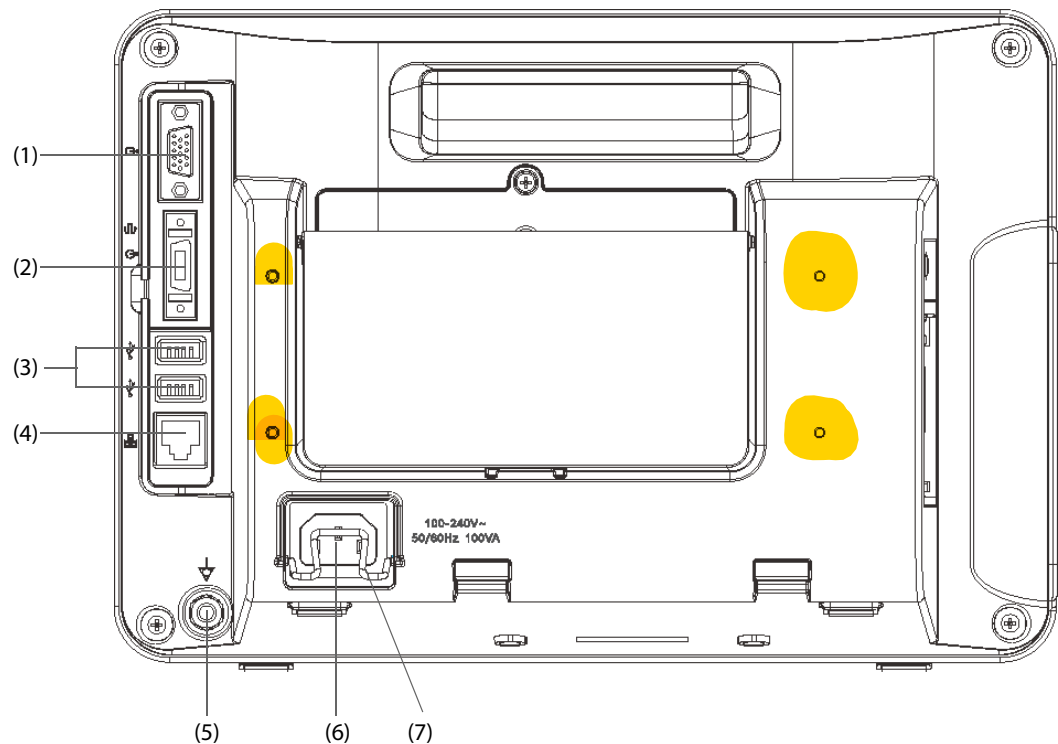
Signature: 

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

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2.4 Rear View



- (1) **VGA Connector**
It connects a secondary display, which extends the display capability of your monitor. The contents displayed on the secondary display screen accords with those displayed on the monitor screen.
- (2) **Multifunctional Connector**
It outputs defibrillator synchronization signals, nurse call signals and analogy output signals.
- (3) **USB Connector**
It connects the USB devices, such as a barcode scanner.
- (4) **Network Connector**
It is a standard RJ45 connector which connects the patient monitor to CMS or other patient monitor for remote view. It also connects the patient monitor to PC for system upgrade.
- (5) **Equipotential Grounding Terminal**
When the patient monitor and other devices are to be used together, their equipotential grounding terminals should be connected together, eliminating the potential difference between them.
- (6) **AC Power Input**
- (7) **Power mousing- hook**

2.5 Display Screen

This patient monitor adopts a high-resolution TFT LCD to display patient parameters and waveforms. A typical display screen is shown below.