Basic Information

Product Name: Defibrillator Monitor

Product Model: S30/S30A/S30B/S30C/S50/S50A/S50B/S50C

Manufacturer: Shenzhen Comen Medical Instruments Co., Ltd.

Address: Floor 10, Floor 11 and Section C of Floor 12 of Building 1A & Floor 1 to Floor 5 of Building 2, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Introduction

This document summarizes the product's safety and performance information.

Chapter 1 Safety Information

1.1 Safety

Sign	Description
⚠ Danger	To indicate the dangers which would result in death or severe personal injury.
⚠ Warning	Alerts you to the situations that may result in serious consequences or endanger personal safety. Failure to observe the warning information may cause severe injury or even death of the user or patient.
⚠ Caution	Alerts you to potential dangers or unsafe operations, which, if not avoided, may result in minor injury, product failure or damage, or property damage, or cause more serious injury in the future.
⚠ Note	Emphasizes important precautions and provides instructions or explanations for better use of the product.

⚠ **Danger**

- **Do not use the monitor in an environment rich in oxygen, or in an environment with anesthetic and other flammable and explosive materials, to prevent explosion or fire. The monitor and its surrounding area should also be kept clean and dry.**
- **The defibrillator monitor generates high voltage during defibrillation, which may cause major injury or death due to inappropriate operations. Therefore, the defibrillator monitor should be used by or under the guidance of professional clinicians. Personnel using this defibrillator monitor should receive adequate training. Any unauthorized personnel or personnel without training shall not perform any operations.**
- **During defibrillation the operator should not come into contact with the patient, the monitor or the supporting table; otherwise this may result in serious injury or death.**
- **Do not open the housing of the monitor to avoid the potential risk of electric shock. The monitor must be maintained and upgraded by service technician trained and authorized by Comen. Non-professional operation can cause the monitor damage or cause a security risk, and human health may be endangered.**

⚠ Warning

- **Before use, you must check the monitor and its accessories to ensure that they can work normally and safely.**
- **Do not conduct therapy on patients lying on wet ground.**
- **When conducting therapy on patients with a pacemaker, the electrodes or paddles should be placed away from the pacemaker.**
- **Do not position the device so that it is difficult to operate the disconnection device of the supply mains.**
- **Do not rely only on the audible alarm. Otherwise, patient safety may be at risk if the alarm volume is low. Pay close attention to the patient's actual clinical conditions.**
- **Before monitoring the patient, the alarm limit should be appropriately set for the current patient to ensure timely and accurate alarm conditions. Pay close attention to the patient's actual clinical conditions and set the alarm limits accordingly.**
- **The monitor can only be connected to a power outlet with protective ground. If the power socket is not connected to a ground conductor, use the rechargeable battery to supply power to the monitor instead of using the power outlet.**
- **You should always check whether the power plug is loose or falling off, so as to prevent the device from suddenly shutting down and causing potential harm to the patient, when the battery is not installed or the battery is damaged.**
- **Observe the local laws and regulations or the waste disposal rules of the hospital when disposing of packaging materials. Keep the packaging materials out of the reach of children.**
- **Do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.**
- **To ensure safety, avoid stacking multiple equipment or placing anything on the monitor during operation.**
- **Carefully place the monitor power cord and accessories cables to avoid entanglement, potential strangulation, and electrical interference to the patient.**
- **To protect you from electric shock, always remove the sensor and completely disconnect the monitor before cleaning the device.**
- **For patients with pacemakers, the cardiotachometer may be used to record pacemaker pulse in the event of asystole or arrhythmia. Do not completely rely on the alarm function of the cardiotachometer. Patients with pacemakers must be closely monitored. For the pacemaker inhibiting function of the monitor, please refer to relevant section in this Manual.**
- **Keep patient under close surveillance when using this monitor to conduct therapy. If the shock is delayed, the shockable rhythm may change to non-shockable rhythm, leading to delivering an incorrect shock.**
- **Any equipment without defibrillation protection shall be disconnected from the patient during defibrillation.**
- **Any equipment connected to the monitor shall form an equipotential circuit (effective connection of protective ground).**
- **In order to avoid burns resulted from electric leakage to the patient, ensure that the monitor's sensors and sensor cables never come into contact with any high-frequency electrosurgical**

equipment.

- **The physiological waveform and parameter, alarm message and other information displayed by the monitor are only for reference by physicians, and not directly used as a basis for clinical treatment.**
- **Electromagnetic field can affect the performance of the monitor. Therefore, equipment used near the monitor should conform to the applicable EMC requirements. For example, mobile phones and X-ray machines are potential sources of interference, since they transmit high-intensity electromagnetic radiation.**
- **Do not use the monitor in an MRI environment.**
- **The operator should verify that the synchronous input equipment is applicable to this monitor and the input signals are valid.**
- **In normal use, the operator should not touch the signal I/O ports, other live equipment and the patient simultaneously. This action may result in injury to the patient.**
- **After defibrillation, the electrocardiogram (ECG) waveform will recover within 2.5s; other parameters will recover within 10s.**
- **The user must not make any modifications to the equipment.**
- **The operating environment and transport and storage environment of the monitor must meet the environmental specification in this manual, otherwise the accuracy of the monitor may be affected.**
- **During the proper use of the device, if the device cannot work properly, such as in the event of a power failure or equipment failure, stop using the malfunctioning device immediately and activate a back-up device. Simultaneously, close attention shall be paid to the patient's actual clinical conditions.**
- **Please implement CPR treatment for the patient first, if the use of the equipment is delayed or interrupted during a first aid process.**
- **Defibrillation may cause myocardial injury. Select an appropriate energy for the patient.**
- **No functional examination should be performed while the defibrillator monitor is connected to the patient, lest the patient receive an accidental electric shock.**
- **If the defibrillator monitor is used in conjunction with high frequency (HF) electrosurgical equipment, after the removal of HF signals and HF electromagnetic fields, within 10s the device shall resume normal operation in the previous operating mode, without loss of any permanently stored data.**
- **When disassembling or assembling components, place them out of reach of children to avoid the risk of suffocation.**
- **During the continuous monitoring of the device through the Central Monitoring System (CMS), close attention shall be paid to the network status to avoid delayed treatment to the patient caused by data loss.**
- **Make sure that the bedside patient monitor being used has the required specification that when performing remote synchronized cardioversion, the bedside patient monitor and defibrillator monitor used together can deliver a synchronous shock within 60ms of detecting the next R wave peak. Otherwise, the patient's treatment may be delayed.**
- **Any serious incident that has occurred in relation to the device should be reported to Comen and the competent authority of the Member State in which the user and/or patient is established.**

⚠ Caution

- **To avoid damage to the monitor and ensure the patient's safety, only use accessories and consumables specified in this manual.**
- **Handle the monitor carefully to avoid damage caused by dropping, collision, strong oscillation or other external mechanical forces.**
- **Before powering on the monitor, verify that the supply voltage and frequency conform to the requirements specified on the monitor nameplate or in this manual.**
- **At the end of the monitor and accessories service life, they must be disposed of in accordance with the local laws and hospital's regulations.**
- **Dry the equipment immediately if it is exposed to rain or water spray.**
- **Check the cables, paddle handles and functional accessories periodically for possible defects or aging.**
- **When the monitor is in normal use, do not repair or maintain the monitor and its accessories.**
- **The defibrillator monitor should not be used in environments with excessively bright or dim lighting, as this may impair the operator's ability to view the display. When necessary, set the device to high-contrast display mode to ensure clear screen visibility.**
- **Ingress of excessive lint or dust may cause equipment malfunction. Keep the device away from sources of lint or dust. Clean the equipment if required.**

⚠ Note

- **The device is not intended for home use.**
- **The device can only be used for one patient at a time.**
- **Place the device at a position where observation, operation and maintenance are convenient and not obstructed.**
- **This manual is based on the maximum configuration; therefore, some contents may not be applicable to your monitor.**
- **Keep this manual available for ease of use and convenient reference.**
- **The format of the data stored in the monitor is the private format of the manufacturer.**
- **In normal use, the operator's position should be within one meter of the monitor.**
- **If required, the way to obtain accompanying files will be provided by the company in an electronic file.**
- **The illustrations in the user manual are for reference only. In the event of any discrepancies between the illustration and the device, the device shall prevail.**
- **The signal input and output parts of the device are adequately isolated. The ME equipment remains affected when an external voltage is applied to the input/output interfaces.**
- **The symbols on the device and carton may not be exactly the same as above.**

1.2 Overview

Note

- **The product appearance varies according the product model and configuration. If there is any doubt, please contact the company.**
- **Paddles trays are only available to S50/S50A/S50B/S50C.**

Warning

- **Only approved medical device in accordance with the specified IEC standards (like IEC 60950 safety standards for Information Technology Equipment, IEC 60601-1 safety standards for medical electrical equipment, etc.) are allowed to be connected to the monitor. All configurations should comply with the standard IEC 60601-1. Personnel who connect external equipment to the monitor should verify that medical system complies with IEC 60601-1 requirements, before configuring the medical system. If there is any doubt, contact the company.**
- **In normal use, the operator should not touch the signal I/O ports, other live equipment and the patient simultaneously. This action may result in injury to the patient.**
- **If more than one piece of external equipment is connected to the monitor at one time through the signal ports (such as multi-function port and network port), the total leakage current should be in accordance with the requirement specified in IEC 60601-1.**

1.3 Installation

Warning

- **The defibrillator monitor must only be installed by personnel specified by Comen.**
- **With copyright reserved, any person shall not falsify, photocopy or exchange the software in any manner whatsoever without the prior written permission of Comen.**
- **When the defibrillator monitor is connected with other electrical equipment for a specific function, if users cannot confirm the combination is without risk (for example, the electric shock hazard caused by the accumulated leakage current) from the specifications of each equipment, please contact a specialist from Comen or the hospital to ensure the combination is safe.**
- **This equipment may suffer from microbial contamination during transport, storage or use. Please check whether the packaging is intact, especially for the disposable accessories, and do not use accessories whose packing appears damaged.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. Keep the packaging material out of the reach of children.**

- **Place the monitor in a location where external power can be easily disconnected.**
- **Use only power cords and inverters provided by the company.**
- **Before powering on the monitor, verify that the supply voltage and frequency conform to the requirements specified on the monitor nameplate or in this manual.**
- **If a battery is equipped with the device, after transport, storage or use, be sure to charge the battery. If the device is turned on without connecting the power supply, the device may not operate properly due to insufficient battery power. The battery will be charged automatically once the monitor is connected to the power supply, regardless of whether the monitor is turned on or turned off.**
- **Do not come into contact with the power cord with wet hands. Otherwise, electric shock may occur.**
- **Damaged metal contacts on the defibrillator monitor or docking station may affect performance. Avoid touching the contacts.**
- **When powering the defibrillator monitor via the docking station, make sure that the protective earth connection of the external power supply system is securely established.**
- **Avoid pinching when installing the docking station.**
- **During use, place the docking station on a stable flat surface to avoid damage from falling.**
- **Do not stack other equipment on the defibrillator monitor when connecting to the docking station.**
- **The monitor can only be connected to a power outlet with a protective ground. If the power socket is not connected to a ground conductor, use the rechargeable battery to supply power to the monitor instead of using the power outlet.**
- **The monitor installation, including a correct protective earth connection, must only be carried out by a qualified service technician.**
- **When the fixed base is installed, it should be verified that its protective ground terminal is reliably connected to the protective ground of the external power supply system.**
- **If there is any evidence of failure or any error messages are displayed, do not use this monitor. Contact a service technician of Comen or a biomedical engineer in your hospital.**

Note

- **To avoid accidental disconnection of the power cord, ensure that the power cord is securely plugged into the power port of the defibrillator monitor.**
- **When connected to an external power supply, the power cord plug can serve as a disconnection device of the supply mains. Pull the plug out to disconnect the device from the supply mains.**
- **When connecting the AC power cord, only connect the power cord to a specific hospital AC power outlet. Connect the equipotential conductor when necessary. Please refer to the content about equipotential grounding in *Chapter 4 Patient Safety*.**
- **It takes less than 2s to turn on the defibrillator monitor.**
- **An alarm will be triggered if a major error is detected during self-test.**
- **Check all monitoring functions to ensure that the monitor is operating correctly.**
- **To extend the service life of the monitor, after shut-down, wait for at least 1 minute before**

restarting the monitor.

- The time required for the device to warm from the minimum storage temperature or cool from the maximum storage temperature between uses until the device is ready for its intended use when the ambient temperature is 20℃ is 60 min.

1.4 Patient Safety

Warning

- It is NOT recommended to connect the 3-wire power cord to a 2-wire power outlet.
- If the protective grounding system is not stable, use the built-in battery to supply power to the monitor.

Note

- If the use of the equipment is affected by the equipotential grounding, contact the Company's After-Sales Service Department or agents.

1.5 Basic Operations

Note

- The first line of the standard screen layout displays ECG waveform and parameter, which cannot be set up by default.
- The ECG parameter cannot be turned off.
- Parameter color cannot be modified in high contrast mode or in NVG mode.
- For field operations, the NVG mode should be activated to minimize power consumption.
- In the NVG mode, auditory alarms will not be sounded.
- If [Brightness] is set to [Auto], the defibrillator monitor can adjust the brightness in accordance with the ambient light.
- Screen brightness cannot be adjusted in the NVG mode.
- The button backlight cannot be adjusted in the NVG mode.
- When set to [Permanent], manual unlocking is required.
- Upon returning to Monitor Mode after switching work mode, the device automatically reverts to

standard screen.

- **If the lead type is 3-lead, [ECG Full-Screen] and [ECG Half-Screen] are not available in the [Switch Screen] list.**
- **If the TBI function is not activated, TBI screen is not available in the [Switch Screen] list.**
- **If 12-lead ECG analysis is not configured, the [ECG 12-Lead] option will not appear.**
- **If you switch screen mode in a non-Monitor Mode, the system will automatically switch the work mode to Monitor Mode and display the set screen mode.**
- **If [Unfixed] is selected, the room number and bed number will be cleared after the patient is discharged.**
- **Temperature unit settings are available only when the EWS function is activated.**
- **The Network bed number must be unique in the Central Monitoring System (CMS).**

Warning

- **Demo waveforms and values are used to simulate the actual monitoring process. Do not enter mode during patient monitoring to avoid delayed diagnosis and treatment.**

1.6 Patient Management

Note

- **After patient discharge, the previous configurations are still applied. Modify configurations (via *Chapter 7 Configuration Management*) as required.**
- **If the patient type is changed, the device will load the latest configurations. Verify the configurations before monitoring to ensure that these configurations are applicable to the patient.**
- **Maximum 300 patient files can be stored.**
- **Access requires local password if [Discharged Patients] is set to [Local Password] in [Access Control] as mentioned in *Section 5.4.9 Access Control*.**
- **The data of the current patient data cannot be deleted.**

Warning

- **Regardless of whether or not a patient is admitted, make sure the settings in [Current Patient] are consistent with the patient's actual conditions before monitoring.**

- **When the patient type is changed, the device loads the latest configurations. If the patient type is not changed, the configurations will not be changed.**
- **For the patient without pacemaker, [Pacer] must be set to [No]. Otherwise, the device cannot detect arrhythmia related to ventricular premature beats (including PVCs count), and ST segment analysis will not be performed.**
- **For the patient with a pacemaker, [Pacer] should be set to [Yes]. Otherwise, pacemaker pulse may be counted as normal QRS waves.**

1.7 Configuration Management

Warning

- **Configuration management function is protected by password and must be accessed and modified by authorized personnel.**

Caution

- **A hazard can exist if different configurations are used for the same or similar equipment in any single area (e.g., ICU or CCU).**
- **Make sure the configuration you select is appropriate for the patient being monitored.**

Note

- **After department change, the corresponding default configurations for the new department will be automatically loaded.**
- **After loading the target configuration, the current alarm preset displays in the parameter area.**

1.8 Monitor Screen

Note

- **The ECG half screen is unavailable for 3-lead.**
- **The ECG full screen is unavailable for 3-lead.**

1.9 Alarms

Warning

- **A hazard can exist if different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.**
- **If restarted within 30 min after power loss, the device will automatically restore configurations (excluding defibrillation and pacing settings) prior to the power loss for the same patient type. If restarted after 30 min, the device boots normally without data restoration.**
- **Critical alarm settings (e.g., minimum alarm volume) require user password authentication and unauthorized access is not allowed.**
- **When the device is connected to the central monitoring system (CMS), the same alarm limits can be applied for the monitor and CMS. If you enable alarm delay on this monitor, the monitor will not display an alarm when the CMS indicates an alarm.**
- **Some physiological alarms are of exclusive type. They share identical audible and visual characteristics with high-level alarms but display in exclusive mode, i.e., only the exclusive-type alarm message is displayed when a normal alarm and an exclusive-type alarm are generated simultaneously.**
- **When the alarm volume is set to 0, the  icon is shown in the message prompt area of the screen and the monitor cannot sound an alarm even if a new alarm is generated. Therefore, you should consider this when setting the alarm volume to 0.**
- **Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions.**
- **Do not rely only on the audible alarm. Otherwise, patient safety may be at risk if the alarm volume is low. Pay close attention to the patient's actual clinical conditions.**
- **Before monitoring, make sure that the alarm limits are applicable to the current patient.**
- **When setting alarm limits, make sure the patient type is correct.**
- **If you have set the alarm limits manually, the monitor will display the alarm limits instead of the default alarm limits of the system.**
- **If the alarm is turned off, no physiological alarms will be triggered. The user should activate alarm off with caution.**
- **Risk may exist if the alarm audio is paused or turned off. The user should pay close attention to the actual clinical conditions of patients.**
- **Risk may exist if the apnea alarm is turned off. The user should pay close attention to the actual clinical conditions of patients.**

Note

- **All technical alarms (excluding ECG and SpO_2) are preconfigured with fixed priority levels, alarm messages and indicators. User access and modifications are prohibited. Some physiological alarm levels are user-adjustable according to clinical requirements.**

- **Both the device and the CMS are provided with audible alarm function.**
- **The device provides an independent dual-color alarm indicator.**
- **When multiple alarms of different levels are generated simultaneously, the device will activate the alarm sound and light for the highest-priority alarms. The alarm messages are displayed in turn.**
- **This section describes the alarm signals in normal display mode. They may differ in other display modes.**
- **The minimum alarm volume should be set to be higher than local environmental noise.**
- **The pressure level of alarm sound generated by this monitor is 45-85db.**
- **When applying factory default configurations, alarm limits of the parameters will also change. See *Appendix V Factory Default Configuration* for details.**
- **If [Alarm Setup] is set to [Local Password] in [Access Control], modifying parameter alarm limits or alarm switches requires entering the local password. Refer to *Section 5.4.9 Access Control* for details.**
- **Alarm pause settings can be applied to both the defibrillator monitor and CMS. If the device is connected to CMS, selecting the alarm pause button for the corresponding bed in the real-time monitoring page of CMS will enable the defibrillator monitor and the corresponding bed of CMS to enter the alarm pause state simultaneously. The user can set the alarm pause time in the alarm setting page of CMS. When the preset pause time expires, the system will automatically cancel the alarm pause state, or the user can exit this state by clicking the Alarm Paused button again. Similarly, the user can control the alarm pause state of the corresponding bed on the CMS by operating the alarm pause of the defibrillator monitor.**
- **If a new alarm is generated when the monitor is in alarm reset state, the alarm reset icon will disappear and the sound/light of the new alarm will function normally.**
- **Alarm reset settings can be applied to both the defibrillator monitor and CMS. If the device is connected to CMS, selecting the alarm reset button for the corresponding bed in the real-time monitoring page of CMS will cause the defibrillator monitor and the corresponding bed of CMS to enter the alarm rest state simultaneously. Similarly, the user can control the alarm reset state of the corresponding bed on the CMS by operating the alarm reset of the defibrillator monitor.**

1.10 12-Lead Resting ECG Analysis

Note

- **Prior to 12-lead resting ECG analysis, please first check whether the patient information is complete and correct.**
- **The median complex uses fixed amplitude, speed, and layout, unaffected by above settings.**
- **See *Section 12.4.2.5 Place 12-lead Monitoring Electrodes* for placement. For pediatric patients below 16 years old, it is recommended to place chest leads at V4R, V1, V2, V4-V6.**
- **The device stores up to 20 12-lead reports. If exceeded, the oldest report will be automatically**

overwritten by the newest.

- **The real-time recording time for a 12-lead report is 10s.**

1.11 ECG Monitoring

⚠ Warning

- **During defibrillation the operator should not come into contact with the patient, the monitor or the supporting table.**
- **Before monitoring, ensure that the ECG cable is properly connected. If the ECG cable is disconnected from the port when the heart rate can be displayed on the monitor normally, the monitor displays the prompt message [ECG Lead Off] and sounds an alarm.**
- **Use only ECG electrodes and cables specified by Comen.**
- **An ECG cable with defibrillation-proof protection should be used when conducting defibrillation.**
- **Different metal materials cannot be used for the electrodes.**
- **Do not use if the electrode package or electrode has signs of damage or has passed its service life date.**
- **Please do not mix electrodes of different types and brands. Mixing the electrodes may result in a large baseline drift or a longer recovery time after defibrillation.**
- **When connecting the electrodes or patient cable, ensure that the patient does not come into contact with any other conductive parts or the ground. Confirm that all ECG electrodes (including the neutral electrode) are attached to the patient's body. Inadvertent connection between an electrode (including pacing electrodes) and conductive components may lead leakage current to the patient's heart, which may result in patient death.**
- **Check every day whether the ECG electrode patch or paddle has caused irritation to the skin. If there is any sign of an allergic reaction, replace the electrode or paddle or change its position.**
- **Pacemaker fault: When cardiac conduction is completely blocked, or the pacemaker cannot be moved away, P wave (> 1/5 of the mean height of R wave) may be incorrectly recorded by the monitor, causing failure to monitor an asystole.**
- **Equipment such as a defibrillator and a remote measurement unit can generate a filtered ECG signal. When this signal is used as the input signal for the monitor, it is filtered again. If after the second filtering, this signal is transmitted to the arrhythmia algorithm, it may cause a failure to detect such conditions as pacemaker pulse, pacemaker capture failure or asystole. This failure degrades the performance of the equipment when it is used for monitoring patients with pacemakers.**
- **During defibrillation, the ECG cable connected to the patient may get damaged. When reusing such cables, the user should check that they function correctly.**
- **If electrodes are used correctly and attached according to the manufacturer's instructions, the ECG parameter on monitor screen recovers within 5s after defibrillation. For electro-surgery or defibrillation, the measurement accuracy may be reduced temporarily, but this accuracy will not affect the safety of the patient or the equipment.**
- **When the monitor is connected to an electrosurgical unit (ESU), in order to protect the patient**

from injury caused by leakage current, do not put the sensors and cables of the equipment in contact with the ESU.

- **Do not expose the monitor to X-ray and high-intensity magnetic fields.**
- **Do not use expired electrodes.**
- **Transients from isolating the monitor from the supply mains may be similar to the actual ECG waveform, thus inhibiting the cardiac alarms.**
- **Particular attention must be paid to the type of electrodes used, as some may exhibit significant potential offset due to polarization. This must be especially considered regarding the recovery time after a defibrillation pulse. This effect is more pronounced with suction ball electrodes, which are commonly used in diagnostic ECG recording.**
- **When using an electrosurgical unit (ESU), never place electrodes close to the ground plate of the ESU; otherwise there is too much interference which will affect the ECG signal.**
- **When the monitor is connected to an electrosurgical unit (ESU), in order to protect the patient from injury caused by leakage current, do not put the sensors and cables of the equipment in contact with the ESU.**
- **Do not use the electrode if the electrode package or the electrode shows signs of damage.**
- **For a patient without pacemaker, [Pacer] must be set to [No]. Otherwise, the system cannot detect arrhythmia related to ventricular premature beats (including PVCs count), and ST segment analysis will not be carried out.**
- **If the patient is admitted with a pacemaker, [Pacer] should be set to [Yes]. Otherwise, a pacemaker pulse may be counted as normal QRS wave.**
- **The system provides raw signals only in the diagnosis mode. In the [Monitor] and [Therapy] filter modes, the ECG wave distorts to different degrees. In this case, the system only provides the basic ECG information, which greatly affects the result of ST segment analysis.**
- **The following conditions may affect ST-segment measurements:**
  - **Administration of cardiac-affecting medications**
  - **Significant heart rate fluctuations**
  - **Conduction abnormalities or metabolic imbalances**
- **ST segment analysis data serve as reference information only. Definitive diagnoses and therapeutic decisions must be establish based on the clinical conditions of the patient.**
- **This monitor provides information about changes in ST levels, the clinical significance of which should be determined by a health care professional.**
- **The atrial fibrillation detection is not intended for pediatric and neonatal patients.**
- **Arrhythmia may affect the heart rate. During monitoring of patients with arrhythmia, do not completely rely on the alarm function of the cardiotachometer, and patients with arrhythmia should be closely monitored.**
- **Arrhythmia analysis data serve as reference information only. Definitive diagnoses and therapeutic decisions must be establish based on the clinical conditions of the patient.**

⚠ **Note**

- **Interference from ungrounded equipment near the patient, as well as ESU interference may result in waveform irregularities. If the monitor is operated under conditions specified in EN60601-1-2 (radiation resistance: 3V/m), electric field intensity over 1V/m may cause measurement errors at different frequencies. Therefore, it is suggested not to use any electric radiation equipment near the monitor if ECG/respiration is being measured.**
- **If the ECG electrode is correctly placed but the ECG waveform is still inaccurate, replace the ECG leads.**
- **To protect the environment, recycle and dispose of used electrode patches appropriately.**
- **Dot not to use external paddles to conduct ECG monitoring.**
- **If the source of the selected ECG signal is not available, the ECG waveform will be shown as a dotted line.**
- **ECG monitoring must be performed using the same type of lead electrode.**
- **Use the electrodes immediately when the unit package is opened.**
- **The ECG display varies with lead type and settings. The following is for reference only.**
- **The pacing signal detected will be shown as ▌in the ECG waveform area.**
- **When conducting ECG monitoring, the external paddles and defibrillation electrodes can only be placed in the anterior-lateral position.**
- **If the lead type is set to 3-lead, the [Smart Lead] switch will be unavailable.**
- **If [ECG] is set to [Pads] or [Paddles], settings of ST, QT, Notch Filter, Smart Lead, Beat and ECG Delay Record will be unavailable.**
- **When the input signal is excessive, waveform peaks may be clipped. Manually adjust the ECG gain according to the actual wave to avoid an incomplete wave display.**
- **The [Pacer Rejection] setting does not affect the pacer rejection function of the heart rate monitors.**
- **If [Beat] is turned on, [Delayed Wave] will be displayed in the waveform area.**
- **[Extreme Tachy] and [Extreme Brady] can be turned on or off only if [Lethal Arrhy. Alm Off] is set to [Enabled]. See Section *9.11.2 Lethal Arrhythmia Alarm On/Off for details*.**
- **If the HR value or ECG wave of the patient has noticeably changed, you should adjust the position of the ISO and ST points. Abnormal QRS complex is not considered for ST segment analysis.**
- **ST segment Analysis is applicable to adult, pediatric and neonatal patients under monitoring with ECG lead.**
- **Ensure that the position of the ST measuring point is suitable for the patient.**
- **The alarm level of lethal arrhythmia is fixed to high, which cannot be modified by the user.**
- **Lethal arrhythmia alarms can be turned on or off only if [Lethal Arrhy. Alm Off] is set to [Enabled]. See *Section 9.11.2 Lethal Arrhythmia Alarm On/Off* for details. If a lethal arrhythmia alarm is turned off, the message prompt [Lethal Arrhythmia Alarm Off] will be displayed in ECG waveform area.**
- **If [Arrhythmia] is set to [Local Password] in [Access Control], modifying alarm priority, alarm switch or alarm thresholds requires entering the local password. Refer to *Section 5.4.9 Access Control* for details.**
- **The setting of [Asystole Delay] is associated with ECG relearning. When the HR is less than 30bpm,**

it is recommended to set the Asystole Delay to 10 seconds.

- Heart rate variability function provides clinical reference only; not intended for direct diagnostic use.
- HRV analysis must be activated to enable monitoring.
- QT/QTc monitoring is intended for adult, pediatric and neonatal patients under monitoring with ECG leads.
- QTc value is calculated based on QT-HR which can be view via QT View.
- When acquired lead waveforms fail to meet analysis criteria, the device may be unable to calculate QT value. In such cases, the QT View window displays the specific reason for failure and [Cannot Analyze QT] is shown in the technical alarm area.

⚠ Caution

- Select the optimal ECG waveform to ensure accurate identification of heart beats and ventricular fibrillation (VF).
- The amplitude of the ECG waveform and the setting of QRS threshold will affect the sensitivity of arrhythmia detection and heart rate calculation.
- If the QRS amplitude is too low the monitor may fail to calculate the heart rate, or detect incorrect asystole.
- During arrhythmia analysis, the device may occasionally generate missed or false detections, particularly when the ECG signal experiences significant interference
- During ECG relearning the arrhythmia defection function may not be available. Therefore, the patient should be closely monitored during and within a few minutes after the ECG relearning.
- Start the ECG Relearn during normal rhythm and when the ECG signal is not noisy. If you start an ECG Relearn during an arrhythmia period, the monitor may collect the wrong QRS complex as the ECG template.

1.12 Manual Defibrillation

⚠ Danger

- Do not conduct defibrillation in an oxygen rich environment to avoid fire and explosion. When conducting defibrillation on a patient with an oxygen catheter, place the oxygen catheter away from the pads.
- During defibrillation, do not allow defibrillation electrodes to touch each other or touch the ECG electrodes, lead wires, dressings, etc. Otherwise electrical arcing and patient skin burns could occur.
- Before shock, make sure that no one is in contact with the patient and any equipment (including a

bed or stretcher) connected with the patient to avoid potential injury and death.

- Before shock, make sure that the patient is in a shockable rhythm.
- During defibrillation, do not touch the patient, conductive liquid or any metal to avoid forming a current path.
- Hold paddle handles with completely dry hands and avoid contact with conductive gel, to prevent accidental shocks.

⚠ Warning

- Before defibrillation, confirm whether the patient is with a pacemaker. If so, place the defibrillation electrodes at least 10cm away from the pacemaker.
- Poor contact between the defibrillation electrodes and the patient's skin may result in skin burns. Before defibrillation, prepare the patient's skin as specified in *Section 12.4.1 Prepare Skin*.
- Do not use a liquid conductive agent.
- To ensure the defibrillation effect and the patient's safety, only the conductive gel specified by Comen can be used.
- To ensure personal safety, do not attach the paddles to your body to verify whether the paddles are correctly connected.
- Do not use the electrode if the electrode package or the electrode shows signs of damage or the electrode service life has expired.
- Before defibrillation, confirm that the energy selected is applicable to the current patient, especially to the pediatric patients who shall be defibrillated with an appropriate energy level.
- When using the paddles, put the paddles flat on the patient and push them down with equal strength. Do not push the paddles with too much strength.
- During charging, or during the process of administering the electric shock, do not touch the bottom of the electrode paddle or any non-insulated part, otherwise the operator may receive an electric shock.
- During synchronized cardioversion, if an ECG waveform is obtained through external paddles, the artifacts caused by the paddles' movement may be similar to an R wave and trigger a defibrillation shock.
- ECG signals acquired through internal paddles are noisy. It is advised that you do not use internal paddles to obtain ECG signals for synchronized cardioversion.

⚠ Caution

- After therapy, the conductive gel on the paddles should be cleaned off immediately to prevent the paddles from becoming corroded.
- Any non-defibrillation-proof medical device shall be disconnected from the patient during defibrillation.

Note

- **The defibrillator monitor can detect and indicate the impedance in real-time.**
- **Feedback and guidance will be provided if CPR is performed in manual defibrillation mode. See *Chapter 20 CPR Guidance* for details.**
- **High levels of impedance could have a great impact on the patient's therapy. If a prompt message [High Impedance Shock Canceled] appears, please check whether the patient's skin is prepared correctly. If the prompt message is still present, please replace the pads or the pads cable.**
- **Alarms are disabled by default when entering asynchronous defibrillation mode and the text message [Alarm Off] is also displayed in the physiological alarm message area. You can enable alarms by one of the following ways:**
- **Press the alarm paused or alarm off hotkey**
- **Enter the synchronized cardioversion mode;**
- **Switch to the monitoring mode or pacing mode.**
- **Access to the manual defibrillation mode from other work modes requires password if [Access Method] is set to [Password] as mentioned in *Section 5.4.13.1 Manual Defibrillation Setup*.**
- **Before defibrillation, pay close attention to the patient's current impedance. The defibrillation can be conducted when the contact impedance is high. To achieve better therapy, it is recommended to conduct defibrillation when the contact impedance is normal.**
- **A 200J energy level is recommended for defibrillation for an adult.**
- **When using external paddles, the Shock button on the front panel is not available. If a shock is required, press both Shock buttons on the paddles simultaneously.**
- **Please conduct defibrillation with pads or paddles. The user can choose defibrillation-proof ECG lead wires to conduct ECG monitoring during defibrillation and any available lead can be selected to display.**
- **Clean the internal paddles after each use.**
- **To avoid serious patient infections, sterilize the internal paddles before each use.**
- **During internal defibrillation, to avoid damage to the patient's heart, the maximum selected energy is limited to 50J.**
- **If [Remote Sync Input] is turned off, local synchronized cardioversion will be conducted by default and remote synchronized cardioversion will be disabled.**
- **The alarms will be enabled automatically after entering synchronized cardioversion.**
- **Make sure that the bedside Patient monitor being used has the required specification that when performing remote synchronized cardioversion, the bedside Patient monitor and defibrillator monitor used together can deliver a synchronous shock within 60ms of detecting the next R wave peak.**
- **When giving a shock, you should press and hold the Shock button (or Shock buttons on external paddles) until the shock is delivered. The defibrillator monitor will deliver the shock when the next**

R wave is detected.

- When delivering electric shocks with external paddles, press both Shock buttons on the paddles simultaneously.
- If ECG signal is disturbed during analysis, check electrode connections and eliminate noise or motion artifact.
- Smart analysis stops when the device enters synchronized cardioversion mode.

1.13 Noninvasive Pacing

⚠ Warning

- Do not conduct pacing in an oxygen rich environment to avoid fire and explosion. For conducting pacing therapy on a patient with an oxygen catheter, please place the oxygen catheter away from the pads.
- During pacing, keep the patient under close surveillance and do not rely entirely on the heart rate displayed on the screen.
- When operating the monitor on battery in pacing mode, if the [Low Battery] alarm is triggered, please connect the monitor to an AC power supply or replace the battery with a fully charged one immediately.
- Exercise extreme caution when pacing with defibrillation electrodes to avoid shock hazards.
- Change the pacing rate with caution. Any rate adjustment must be performed under continuous real-time ECG monitoring to ensure patient safety.

⚠ Caution

- If pacing needs to be conducted for a long period, you should check the skin in contact with ECG electrodes and pads and replace ECG electrodes and pads periodically as specified in the instruction manual of accessories.
- For conducting therapy on a patient with an implanted device (like a permanent pacemaker or cardioverter-defibrillator), please consult the doctors or refer to the user manual of the implanted device.
- The patient's cardiac output shall be routinely evaluated.

⚠ Note

- Pacing mode supports arrhythmia analysis and provides arrhythmia alarms including Asystole, Ventricular Fibrillation/Ventricular Tachycardia and Ventricular Tachycardia.
- If pacing gets interrupted for any reason, select the [Start Pace] button to continue pacing.

- **In pacing mode, the pacing state of the patient cannot be changed.**
- **If the pads are in poor contact with the patient, [Pace Stopped Abnormally] and [Pads/Paddles Off] will be displayed.**
- **In pacing mode, the pads and paddles cannot be used as ECG waveform source.**
- **Access to the pacing mode requires password if [Access Method] is set to [Password] as mentioned in *Section 5.4.13.1 Manual Defibrillation Setup*.**
- **Use demand pacing for most patients. Use fixed pacing only when there is no reliable R wave detected due to interference or when there are no available monitoring electrodes.**
- **Pacing mode cannot be switched during overdrive pacing.**
- **In demand pacing mode, the monitor will detect the connection of the pads cable, pads, ECG cable and ECG electrodes. If any connection error is detected, the pacing will stop and the relevant prompt message will appear in the pacing message area until the connection is good.**
- **Concurrent use of electrosurgical units or other electronic devices may cause unstable monitoring or pacing.**

1.14 AED

Note

- **The defibrillator monitor completes analysis within 5s after the analysis starts.**
- **Do not place the pads in the anterior-posterior position. The AED algorithm of the defibrillator monitor has not been verified under the anterior-posterior placement.**
- **Keep the patient still during cardiac rhythm analysis in order to prevent misdiagnosis and delayed diagnosis.**
- **The monitor will not deliver shocks automatically. Shocks will only be delivered by pressing the Shock button.**
- **High levels of impedance could have a great impact on the patient's therapy. If a prompt message [High Impedance Shock Canceled] appears, please check whether the patient's skin is prepared correctly. If the prompt message is still present, please replace the pads or the pads cable.**
- **The initial shock energy recommended for an adult patient is 200J.**
- **Feedback and guidance will be provided if CPR is performed in AED mode. See *Chapter 20 CPR Guidance* for details.**

Danger

- **Do not conduct defibrillation in an oxygen rich environment to avoid fire or explosion. When conducting defibrillation on a patient with an oxygen catheter, place the oxygen catheter away**

from the pads.

- During defibrillation, do not allow the pads to touch each other or touch the ECG electrodes, lead wires, dressings, etc. Otherwise electrical arcing and patient skin burns could occur.
- Before shock, make sure that no one is in contact with the patient and any equipment (including the bed or stretcher) connected with the patient to avoid potential injury and death.
- During defibrillation, do not touch the patient, conductive liquid or any metal to avoid forming a current path.

Warning

- During defibrillation, any bubbles in the conductive gel between the pads and the patient's skin will cause patient skin burns. Make sure that the pads are tightly placed against the patient's skin to avoid bubbles.
- Do not use the pads if they are dry. Use the pads immediately after unpacking them.
- Do not use expired pads.
- AED is only applicable to patients aged 29 days or older. Only conduct defibrillation on patients below 29 days of age in manual defibrillation mode.
- In AED mode, during ECG analysis or auto-charging, do not come into contact with the patient or perform CPR compressions, to avoid delayed diagnosis, misdiagnosis, incorrect rhythm identification or automatic energy discharge.

Caution

- For the patients with pacemaker, the sensitivity and specificity of AED analysis may be lower.
- The defibrillation electrodes may be damaged due to improper operation during storage or before use. Do not use damaged electrodes.
- Dispose of expired or damaged accessories in accordance with local laws or relevant regulations of the hospital.

1.15 Resp Monitoring

Note

- Place the green and red electrodes diagonally for the best respiratory wave. The respiratory electrodes should not be put at the liver region and ventricle, so as to avoid the false difference of cardiac coverage or pulsating blood flow, which is especially important for neonates.
- Respiratory monitoring is not appropriate for patients with a high range of activity because it can lead to false alarms.
- The Apnea alarm can be turned on or off only if [Apnea Alarm Off] is set to [Enabled]. See *Section 9.11.4 Apnea Alarm On/Off* for details.

1.16 SpO_2 Monitoring

Warning

- **If there is any carboxyhemoglobin (COHb), methemoglobin (MetHb) or dye dilution chemical, the SpO_2 value will be unreliable.**
- **The monitor can automatically recognize the SpO_2 sensor type. However, the monitor is configured with a specific internal SpO_2 hardware before delivery, the monitor cannot measure SpO_2 if using an incompatible sensor.**
- **The monitor is compatible with the SpO_2 sensor designated by Comen only.**
- **The SpO_2 probe and its extension cord are designed for specified monitors. Before monitoring the patient, check the probe and extension cord are compatible with the monitor. Incompatible accessories reduce the performance of the monitor.**
- **Before monitoring the patient, check the sensor cable works properly. Remove the SpO_2 sensor cable from the sensor interface and the monitor displays the prompt message [SpO_2 No Sensor] and triggers the alarm sound.**
- **If the SpO_2 sensor or its package seems damaged, do not use it. Return the damaged product to the manufacturer.**
- **Prolonged, continuous monitoring may increase the risk of undesirable skin changes, such as irritation, erythema, blistering, or pressure necrosis. This risk is heightened in neonates or in patients with impaired perfusion or altered/immature skin integrity. Pay particular attention to the sensor site by checking for proper optical alignment and adhesion based on skin condition. Inspect the sensor site periodically and reposition it if skin quality deteriorates. More frequent inspections may be required depending on individual patient conditions.**
- **Make sure the sensor cable and the electrosurgical equipment cable are not intertwined.**
- **Do not place the sensor on a limb with an arterial catheter or intravenous line.**
- **Setting the high SpO_2 alarm limit to 100% disables the high-limit alarm. High oxygen concentrations can cause premature infants to develop retinopathy. Therefore the high alarm limit for oxygen saturation must be carefully chosen according to accepted clinical standards.**
- **The pulse oximeter is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.**
- **As with all medical equipment, carefully route patient cables to reduce the possibility of patient entanglement or strangulation.**
- **Do not place the pulse oximeter or accessories in any position where they might fall on the patient.**
- **Do not start or operate the pulse oximeter unless the setup was verified to be correct.**

- **Do not use the pulse oximeter during magnetic resonance imaging (MRI) or in an MRI environment.**
- **Do not use the pulse oximeter if it appears or is suspected to be damaged.**
- **Explosion hazard: Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substances in combination with air or nitrous oxide or in an oxygen-enriched environment.**
- **To ensure safety, avoid stacking multiple equipment or placing anything on the equipment during its operation.**
- **To protect against injury, follow the directions below:**
- **Do not soak or immerse the equipment in liquids.**
- **Do not attempt to sterilize the equipment.**
- **Use cleaning solutions only as instructed in this operator's manual.**
- **Do not attempt to clean the equipment while monitoring a patient.**
- **To protect from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.**
- **If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.**
- **Inaccurate SpO_2 readings may be caused by:**
- **Improper sensor application and placement.**
- **Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.**
- **Elevated levels of bilirubin.**
- **Elevated levels of dyshemoglobin.**
- **Vasospastic disease, such as Raynaud's, and peripheral vascular disease.**
- **Hemoglobinopathies and synthesis disorders such as thalassemias, such as thalassemias, Hbs, Hbc, sickle cell, etc.**
- **Hypocapnic or hypercapnic conditions.**
- **Severe anemia.**
- **Very low arterial perfusion.**
- **Extreme motion artifact.**
- **Abnormal venous pulsation or venous constriction.**
- **Severe vasoconstriction or hypothermia.**
- **Arterial catheters and intra-aortic balloons.**
- **Intravascular dyes, such as indocyanine green or methylene blue.**
- **Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.**

- **Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.**
- **Skin pigment disorders.**
- **Interfering Substances: Dyes or any coloring substance that can change usual blood pigmentation may cause erroneous readings.**
- **The pulse oximeter should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.**
- **The pulse oximeter is not an apnea monitor.**
- **The pulse oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.**
- **The pulse oximeter should not be used for arrhythmia analysis.**
- **SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).**
- **Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximeter for service if necessary.**
- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another location. Change the location of the sensor at least every four hours.**
- **When the SpO_2 has no value, the waveform at this time has no reference meaning.**
- **Functional testers or patient simulators must not be used to assess the accuracy of pulse oximetry sensors and pulse oximetry equipment. The accuracy of pulse oximeters and pulse oximetry sensors must be evaluated through clinical data.**
- **Place the SpO_2 sensor correctly based on the SpO_2 sensor type. This is especially important for neonates.**
- **Check the patient's skin every two hours to ensure good skin quality and lighting. In case of any skin change, move the sensor to another location. Change the sensor location at least every four hours.**

Note

- **The SpO_2 sensor and SpO_2 extension cable used together with the monitor have been confirmed and tested in compliance with ISO 80601-2-61.**
- **High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor may not allow the pulse oximeter to provide vital sign readings.**
- **The pulse oximeter is calibrated to measure and display saturation.**
- **Make sure the fingernail covers the lights from the sensor. Place the sensor cable on the back of the hand.**

- **DO NOT place the SpO_2 sensor on a limb with blood pressure cuff, or the blood flow occlusion in blood pressure measurement will affect the SpO_2 reading.**
- **The displayed SpO_2 waveform is normalized.**
- **When the measured value is invalid, the corresponding parameter value area of the monitor will display "---".**
- **Confirmation of the accuracy of SpO_2 measurement: The accuracy of Masimo SpO_2 has been confirmed in comparison with the reference value of arterial blood samples measured by CO-oxygen manometers in human experiments. The pulsation oximeter measurement results conform to the statistical distribution. Compared with the CO-oximeter measurement results, it is expected that about two-thirds of the measurement results will fall within the specified accuracy range.**
- **Masimo SpO_2 has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population weight.**
- **Masimo SpO_2 has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation.**
- **The injectable dyes, like methylene blue, and the dysfunctional hemoglobin in blood vessels will lead to inaccurate measurement results.**
- **The SpO_2 accuracy of the device shall be a root-mean-square difference of less than or equal to 4.0 % SpO_2 over the range of 70 % to 100 % SaO_2. The SpO_2 shall be indicated as functional oxygen saturation.**
- **In the clinical study evaluating SpO_2 accuracy, subjects were healthy adult males and females aged 18–60 years, including Black and Asian populations.**
- **When using the Maximum Sensitivity setting, the detection of "Sensor Off" may be compromised. If the equipment is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.**
- **Do not loop the patient cabling into a tight coil or wrap them around the equipment, as this can damage the patient cabling.**
- **Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).**
- **Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.**
- **If the SpO_2 measurement exceeds the alarm limits three times within 1 minute, an [SpO_2 High] or [SpO_2 Low] alarm will be triggered, even if the set Sat-Seconds duration has not been reached.**
- **When the device reboots, the Masimo SpO_2 sensitivity setting will revert to default configurations.**
- **[SpO_2 Desat.] can be turned on or off only if [SpO_2 Desat. Alm Off] is set to [Enabled]. See *Section***

9.11.3 SpO_2 Desaturation Alarm On/Off **for details.**

⚠ Caution

- **Do not place the pulse oximeter where the patient can control it.**
- **Electrical shock and flammability hazard: Before cleaning, always turn off the equipment and disconnect from any power supply.**
- **When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximeter may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.**
- **Do not place the pulse oximeter on electrical equipment that may affect the normal work of the oximeter equipment.**
- **If SpO_2 values indicate the possibility of hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.**
- **If using the pulse oximeter during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or be shown as zero for the duration of the active irradiation period.**
- **To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximeter is used.**
- **Variation in measurements may be profound and may be affected by the sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to any clinical decision made to completely understand the patient's condition.**
- **Do not submerge the pulse oximeter in any cleaning solution or attempt to sterilize it by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximeter.**
- **Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.**
- **Disposal of product - Comply with local laws in the disposal of the equipment and/or its accessories.**
- **To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximeter.**

- **If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.**
- **When a low SIQ message is displayed in the process of consistently monitoring patients, complete the troubleshooting steps listed in this manual and replace the cable or sensor if the message is still displayed.**

1.17 NIBP Monitoring

⚠ Warning

- **Before the NIBP measurement, make sure the selected monitoring mode is appropriate for the patient (adult, pediatrics or neonate). It is dangerous to select a non-neonatal mode for neonatal patients.**
- **Do not place the cuff on a limb with either an intravenous infusion or a cannula in place, or the tissues around the cannula may be damaged when the infusion is slowed or blocked in the cuff inflation process.**
- **Make sure the inflation tube connecting the blood pressure cuff to the monitor is not obstructed or entangled, otherwise it will cause harm to the patient.**
- **Do not perform the NIBP measurement on a patient with sickle cell disease or existing or expected skin lesions.**
- **For a patient with severe disturbances of blood coagulation, please determine the applicability of automatic NIBP measurement based on clinical evaluation, or the limb contacting the cuff may suffer from hematoma due to friction.**
- **Frequent measurements could cause blood flow disturbance and injure the patient.**
- **To prevent further injury, do not place the cuff on any wound.**
- **Do not place the blood pressure cuff on a limb under intravenous infusion, intravenous therapy or arteriovenous shunt, or the transient blood flow disturbance will injure the patient.**
- **Do not place the cuff on the arm at the same side as a mastectomy or lymph node dissection.**
- **The increasing cuff pressure could cause transient function failure to other monitoring equipment used on the same limb.**
- **If the measurement time is too long (such as repeated use of interval and continuous measurement mode), friction between the cuff and the limb may cause purpura, Ischemia and nerve damage. When monitoring patients, always check the color, temperature, and sensitivity of the distal limbs. Once any abnormality is found, the cuff placement position should be changed or the blood pressure measurement should be stopped**
- **When clinicians get unexpected readings, they should take corresponding measures based on the**

actual clinical conditions of the patient, such as retesting or adjusting the cuff position.

- NIBP measurements may be affected by extreme temperature, humidity, and altitude conditions.
- The measurement location may affect the NIBP measurement value.

Note

- If you have any doubt about the accuracy of the readings, check the patient's vital signs first before checking the monitor functions.
- The effectiveness of NIBP on pregnant women, including patients with pre-eclampsia, has not been established.
- The monitor operates the [Clock] function only if the [Interval] is set to 5min or greater.
- The sequence measurement is not intended for neonatal patients.
- The initial pressure setting will be hidden if [Rapid NIBP] is enabled.

1.18 CO_2 Monitoring

Warning

- Try to avoid dropping, knocking or vibrating the CO_2 module.
- Check the airway adapter before use. Replace it if the airway adapter suffers from any exterior damage or breakage.
- Make sure all connections are firm and reliable. Any leakage may allow ambient air to be mixed into the patient's respiratory gas, resulting in incorrect readings.
- Check the CO_2 sensor regularly for excessive humidity or secretion accumulations.
- This device must not be used with gases supplied from oxygen concentrators, as this may compromise the accuracy of CO_2 measurements.
- Hang the external CO_2 analyzer onto the CO_2 sensor holder on the back housing of the device reliably to prevent it from falling and becoming damaged.
- Place the IRMA sensor, if not protected by HME, with the status LED pointing up.
- Do not stretch the cable of the ISA sidestream gas analyzer.
- Operate the ISA sidestream gas analyzer in the specified working temperature environment only.
- Make sure all connections are firm and reliable. Any leakage will cause the respiratory gas of the patient to include the ambient air, resulting in incorrect readings.
- If the alarm message [CO_2 Need Zero] appears directly after zeroing, please re-zero the sensor.
- Set O_2 compensation and N_2O compensation based on the actual conditions, or the measurement results could differ greatly from the actual values which can cause misdiagnosis.

- **If the CO_2 module equipped with this device does not have an automatic atmospheric pressure compensation function, set the correct altitude before using the CO_2 measurement function for the first time. Incorrect altitude causes incorrect CO_2 readings (5% CO_2 error per 1,000m altitude difference).**
- **Anesthetics: If you measure the parameter of a patient who is using or recently has used an anesthetic, the gas discharging port on the module must be connected to a scavenging system or the patient circuit (on the anesthesia machine or the ventilator), so as to prevent medical personnel from inhaling the anesthetic.**
- **The exhaust port of the CO_2 module should be connected to a discharging system for disposal of calibration gases and sampled gases.**
- **If the sampled gas return to the respiratory system, cross-contamination may be caused.**
- **The ISA sidestream gas analyzer is intended for use only by authorized healthcare professionals.**
- **Use the Masimo Nomoline sampling line only.**
- **Never use the sidestream gas analyzer in the presence of any flammable anesthetic gas.**
- **Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.**
- **Do not reuse the disposable sampling tube.**
- **Do not lift the ISA gas analyzer by the sampling line as it could disconnect from the ISA, causing the ISA gas analyzer to fall on the patient.**
- **Dispose of the used disposable sampling line according to the local medical waste disposal regulations.**
- **Never apply the sampling line designed for adults/pediatrics to an infant, or the dead space in the patient circuit will be increased.**
- **Do not use the infant sampling line for an adult; otherwise excessive flow resistance will be caused.**
- **Only use airway T-adapters with the sampling point in the center of the adapter.**
- **Do only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.**
- **Do not use a T-adapter with infants, as this adds 7 ml dead space to the patient circuit.**
- **Do not use the ISA gas analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.**
- **Check if the sample gas flow rate is too high for the given patient type.**
- **Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.**
- **The Nomoline sampling line is not a piece of sterile equipment. In order to prevent the sampling line from causing damages, do not carry out high-pressure sterilization on any part of the sampling line.**
- **Never sterilize or immerse the ISA sidestream gas analyzer in liquid.**
- **The ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream gas analyzer is used in the electromagnetic environment specified in this**

manual.

- **The sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Replace the sampling line if the sampling line input connector starts flashing red, or the monitor displays a "Check sampling line" message.**
- **No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.**
- **The ISA sidestream gas analyzers are not designed for MRI environments.**
- **During MRI scanning, the ISA must be placed outside the MRI suite.**
- **Use of high frequency electrosurgical equipment in the vicinity of the ISA/monitor may produce interference and cause incorrect measurements.**
- **Do not use the external natural heat dissipation function of the ISA.**
- **The condensed water should not be removed by exerting a negative pressure on the Nomoline sampling tube (for example, use a syringe).**
- **An excess positive or negative pressure in the patient circuit may affect the sample gas flow rate.**
- **An excess exhaust suction pressure may affect the sample gas flow rate.**
- **The exhaust gas should be transferred to the exhaust system or returned to the patient circuit.**
- **If the acquired gas sample is used for respiration purpose, always use a biofilter on the exhaust side**
- **When placing the ISA gas analyzer, avoid placing it in a position where it may fall on the patient.**
- **Never apply the IRMA airway adapters designed for adults/pediatrics to neonates, as this adds 6 ml dead space to the patient circuit.**
- **Replace the airway adapter if there is any water drop or condensed water in the airway adapter.**
- **Use only Masimo manufactured IRMA airway adapters.**
- **Do not use the neonate airway adapters for an adult, otherwise excessive flow resistance will be caused.**
- **The main unit should be protected adequately when contacting a live part.**
- **Use the adapter cable approved by Masimo AB only.**
- **A warning instruction must be provided by the main unit when the demo data is displayed.**
- **The main unit should have an appropriate alarm system, which will trigger an alarm when it is possible to cause death or severe health damage to the patient.**
- **The main unit should provide the alarm message corresponding to the IRMA status summary field.**
- **The IRMA sensor is not intended to be in contact with the patient.**
- **Incorrect sensor zeroing will result in false gas readings.**
- **Only the authorized or trained medical workers are allowed to operate the IRMA sensor.**
- **Never use the IRMA sensor in the presence of any flammable anesthetic gas.**
- **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
- **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**
- **Use the Masimo O_2 sensor only. The O_2 sensor with depleted O_2 should be disposed of according to the local battery disposal regulations.**

- **Never try to disassemble the disposable O_2 sensor of the IRMA sensor, because it contains corrosive electrolyte and Pb.**
- **The IRMA sensor is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
- **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**
- **To prevent the secretions and tidal gas gathering at the sight glass and O_2 sensor interface, always place the IRMA sensor vertically with the LED pointing up.**
- **Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
- **The mobile and RF communication equipment will affect the measurement. Please use the IRMA sensor in the electromagnetic environment specified herein only.**
- **Never sterilize the IRMA sensor or immerse it in liquid.**
- **The IRMA O_2 battery and IRMA airway adapters are non-sterile equipment. Do not autoclave the equipment to avoid equipment damage.**
- **Do not install the O_2 battery with depleted O_2 onto the IRMA sensor, whether working or idle.**
- **Do not apply tension to the sensor cable.**
- **Do not operate the equipment outside the specified operating environment.**
- **Warning (U.S.): Federal law restricts this equipment to sale by or on the order of a physician.**
- **Do not use the ISA gas analyzer together with a quantitative spraying agent or pulverization treatment; otherwise it may result in the clogging of the germ filter.**
- **If water/ condensation accumulates in the airway adapter, replace the airway adapter.**
- **Do not use the IRMA Adu/Ped Airway Adapter for infants, as the adapter will add 6ml dead space in the patient circuit.**
- **Do not use the IRMA Neo Airway Adapter for adults as it may cause excessive flow resistance.**
- **The Nomoline sampling line is not a sterile piece of equipment. In order to prevent the sampling line from becoming damaged, do not carry out high-pressure sterilization on any part of the sampling line.**
- **Do not sterilize the ISA sidestream gas analyzer and the IRMA probe or soak them into a liquid.**

Note

- **Do not use the monitor in an environment with any flammable anesthetic gas.**
- **Only trained professionals familiar with this manual are allowed to operate the monitor.**
- **Only S30/S30A/S50/S50A can be equipped with Sidestream CO_2 module.**
- **Only S30/S30B/S50/S50B can be equipped with Mainstream CO_2 module.**
- **In order to prevent the condensed water dropping into the gas sampling line and blocking it, the gas sampling line connection end of the airway adapter should point up.**
- **For the best zeroing result, please zero the Respironics CO_2 sensor after preheating it for 5min.**
- **For the Masimo CO_2 module, 10s is not included in the options.**

- **Using sample tubes or cannulas with an inner diameter larger than 1 mm will increase the response time of the ISA system.**

⚠ Caution

- **The Water Filter Assembly of the Respironics Sidestream CO_2 sensor will last up to 12 hours when used without the Dehumidification Tubing in a non-humidified environment.**
- **The Water Filter Assembly of the Respironics Sidestream CO_2 sensor will last up to 120 hours when used with the Dehumidification Tubing under the conditions of ISO 80601-2-55 § 201.7.9.2.9.101b.**
- **The life of the Water Filter Assembly of the Respironics Sidestream CO_2 sensor will be significantly reduced if used in a humidified circuit without dehumidification tubing.**
- **The Dehumidification Tubing is a replaceable part and is attached directly to the Water Filter Assembly. The Dehumidification tubing should be regularly examined for cracks or visual contaminates on its walls. If these conditions exist, the Dehumidification Tubing should be discarded in accordance with clinical protocol and replaced with a new part.**
- **Based on a sample gas temperature of 37°C, a room temperature of 23°C, a sample relative humidity of 100% and flow rate of 50ml/min, the sampling tube can be used continuously for 120 hours with the dehumidification tubing and for 12 hours without the dehumidification tubing.**
- **The ISA analyzers should be securely mounted in order to avoid the risk of damage to the ISA.**
- **Do not operate the ISA sidestream gas analyzer outside the specified operating environment.**
- **(US Only) Caution: Federal law restricts this equipment to sale by or on the order of a physician.**
- **For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

1.19 CPR Guidance

⚠ Warning

- **During CPR compressions, closely monitor the patient's clinical conditions to assess compression efficacy.**
- **During CPR, position the patient supine on a backboard or other rigid surface.**
- **Do not perform CPR on spring mattresses or elastic surfaces, as this may compromise compression efficacy.**
- **High-frequency chest wall motion from gasping or mechanical ventilation may cause inaccurate compression rate measurements. In such cases, manually count compression rate and do not rely solely on device feedback.**
- **Using CPR feedback functions in mobile environments (e.g., ambulances) may cause unreliable data. Avoid usage when possible; if essential, do not rely solely on device feedback.**
- **Do not perform CPR on patients who are responsive with normal breathing.**
- **CPR metronome doesn't indicate the current condition of the patient. The operators should assess the patient's condition constantly because the patient's condition may vary in a very short period.**

- **Only use SpO_2 sensors specified by the company.**
- **Place the SpO_2 sensor at an appropriate site.**
- **During measurement, avoid movement of the measurement site to prevent interference with the reading.**
- **The CPR-QI monitoring is subject to the limitations on SpO_2 measurement.**

Note

- **The settings of [Voice Prompt] and [Voice Volume] in AED mode also determine the CPR metronome function.**
- **A slight display delay exists between CPR-filtered and raw ECG waveforms.**
- **Refer to the user manual of the CPR sensor for details.**

Caution

- **The CPR filter is only applicable when a CPR sensor is connected.**
- **The filter cannot eliminate all compression artifacts so residual artifacts may persist. Filtered ECG should only be a reference of true ECG rhythms during CPR. If a filtered ECG waveform suggests a shockable rhythm (e.g., ventricular fibrillation), pause chest compressions immediately to allow for another assessment of the patient's rhythm without compression. A decision on whether to deliver a shock should be made only after confirming the rhythm type.**

1.20 Clinical Assistant Assessment (CST)

Warning

- **The Early Warning Score is not intended for neonatal and pediatric patients.**
- **The Early Warning Score results and the suggested measures are provided for reference only, and should not be served as a direct basis for clinical treatment.**
- **The Early Warning Score is not intended for patients with Chronic Obstructive Pulmonary Disease (COPD), pregnant patients or patients under 16 years of age.**
- **The Early Warning Score is not a precise predictor of disease development and prognosis. It cannot be used as the sole tool for clinical judgement for replacing comprehensive assessment based on professional experience from a doctor.**

Note

- **The EWS function must be activated prior to use.**
- **Select [Reset] before initiating a new EWS assessment to clear previous results.**
- **Calculation is only possible when all parameter values for scoring are valid.**
- **GCS scoring is not intended for patients with language barriers, deaf-mute individuals, or those with psychiatric disorders.**
- **GCS scores may be deviated when assessing children under 5 years of age and elderly individuals with delayed responses.**
- **GCS results are for reference only; actual diagnosis must integrate other clinical evidence.**
- **GCS is not intended for patients under sedation or neuromuscular blocking agents, patients with artificial airways, patients with alcohol intoxication-induced altered consciousness or patients in status epilepticus causing altered consciousness.**
- **The GCS function must be activated prior to use.**
- **The HEART score function must be activated prior to use.**
- **The TBI score function must be activated prior to use.**
- **In non-monitoring mode, open the TBI window and the work mode will be switched to monitoring mode.**

1.21 Data Review

Note

- **The defibrillator monitor can store up to 1500 physiological alarms and 1500 technical alarms.**
- **Alarm messages in the event log are not categorized by patient.**
- **When event storage is full, the oldest events are overwritten by new events.**
- **In the event of power failure, the device automatically stores event logs prior to shutdown and the power-off time is not recorded in the event log. After reboot, saved logs remain accessible and are not cleared.**
- **See *Section 5.4.14.2 Event Review Display Setup* to select items to be displayed on the event review page.**
- **The defibrillator monitor supports 180 hours of storage for a single ECG waveform or 90 hours for 2 ECG waveforms. Selecting excessive waveforms reduces total storage duration due to memory limitations.**
- **The ST baseline is the reference template in the default configuration.**

1.22 Record

Note

- The three waveforms to be recorded simultaneously should not be the same.
- Load the paper carefully to avoid contact with the thermal print head.
- When the recorder is printing, do not pull the recorder paper with force; otherwise the recorder may be damaged. Do not use the recorder with no recorder paper loaded.
- Only use the recorder paper provided by the company.
- Do not keep the recorder door open unless the recorder paper should be changed or troubleshooting is required.
- Do not use any materials (such as abrasive paper) that can damage the thermal print head.
- Do not squeeze the thermal print head with force.

1.23 Other Functions

Note

- The Network bed number must be unique in the Central Monitoring System (CMS).
- See the User Manual for the Comen Central Monitoring System for more information about CMS.
- After the monitor is connected to the CMS, the time setting becomes grayed out and unavailable for editing.
- The delay time from the onset of the alarm condition to the point that the representation of the alarm condition leaves the signal input/output part is within 1s.
- The maximum alarm signal generation delay of the distributed alarm system is within 3s.
- The update can only be conducted by the personnel authorized by the manufacturer.

1.24 Battery

Warning

- Check the battery periodically to ensure there is adequate battery power.
- Improper replacement of the lithium battery will result in unacceptable risks.
- Replacement by unprofessional personnel could result in a hazard.
- Battery electrolyte is hazardous. In the event that battery electrolyte comes into contact with your skin or enters your eyes, wash it with clean water immediately and seek medical help.

- **Keep the battery out of the reach of children.**
- **When the battery is being used operationally, the device powers off automatically when the battery is low. To avoid patient injury, connect the device to an external power source before the battery is depleted.**
- **Only use the battery specified by the manufacturer.**
- **Do not throw the battery into water or into fire.**
- **Only the battery specified by the manufacturer can be used.**
- **The installation of the battery should be performed by the personnel authorized by the company.**
- **Avoid pinching your fingers or hands when installing the battery.**
- **Do not remove the battery during device operation.**
- **Do not transport or store batteries with necklaces, hairpins, or other metal objects to avoid short-circuiting the terminals.**
- **Deep discharge causes cell capacity degradation and permanent function failure.**
- **Do not squeeze, puncture, disassemble or short-circuit the battery; otherwise the battery may cause fire or explosion.**

Note

- **If the battery is not to be used for a long period of time, please remove the battery.**
- **If the monitor is provided with a built-in battery, the battery must be charged after each use to ensure sufficient charge.**
- **As the battery is used and becomes aged, the remaining battery power displayed by the battery icon may deviate from the actual power. Please refer to the system alarm information.**
- **After the alarm [Low Battery] is triggered, device can conduct vital signs monitoring for 20 minutes and simultaneously perform minimum 6 shocks at 360J or minimum 10 shocks at 200J.**
- **It is recommended to use the defibrillator monitor and the charger to charge the battery. Refer to the user manual of defibrillator battery charger for details.**
- **In order to prolong the service life of the rechargeable battery, if the battery is to be stored for a long period of time, it is suggested that the battery is charged every 6 months to prevent excessive discharging.**
- **The power supply time of the battery depends on the configuration and operation of the equipment. For example, frequent NIBP measurement reduces the power supply time of the battery.**
- **The battery life depends on the frequency and time of use. If the battery is properly stored, the service life of the lithium battery is about 2 years. If the battery is used improperly, its life may be shortened. We recommend replacing the battery every 2 years.**

1.25 Cleaning, Disinfection and Sterilization

⚠ Warning

- **Only use detergents and disinfectants recommended in this manual. Using other detergents and disinfectants may result in damage to the equipment or other risks.**
- **When performing cleaning procedures, adhere to the hospital safety regulations and wear appropriate personal protective equipment, such as protective clothing, gloves and safety goggles.**
- **Disinfection may cause damage to the device. It is recommended only when deemed necessary by the hospital or institutional maintenance schedule. The device must be cleaned before disinfection.**
- **Before cleaning the monitor, power it off and disconnect it from the AC power supply.**
- **Do not use EtO (ethylene oxide) to disinfect the monitor.**
- **Do not leave any disinfectant residue on the surface and accessory of the monitor. Use a wet cloth to clean it immediately.**
- **It is not allowed to use a detergent mixture; otherwise hazardous gases may be generated.**
- **This chapter only introduces the methods for cleaning reusable accessories. Disposable accessories should not be reused after cleaning and disinfection to avoid cross infection.**
- **To protect the environment, disposable accessories must be recycled or disposed of properly.**
- **After cleaning, if the sensor cable is damaged or shows any evidence of ageing, it should be replaced with a new cable.**
- **High-temperature sterilization of the monitor and all accessories is not allowed.**
- **Do not use any cleaning solution that is not recommended in this manual; failure to do so may result in permanent damage to the equipment, sensor or cable.**
- **Do not soak the sensor or connector in any solution for cleaning or disinfection.**
- **In order to prevent the entry of cleaning solution and dust into the ISA gas analyzer via the LEGI port, the Nomoline sampling line should always be connected when cleaning the ISA analyzer. Do not soak the ISA Sidestream gas analyzer in any liquid for disinfection.**
- **The Nomoline sampling line is not sterile equipment. In order to avoid damage, do not sterilize any part of the sampling line under high pressure.**
- **Do not use the following detergents unless otherwise stated:**
  - **Detergents containing acetone**
  - **Detergents containing trichloroethylene**
  - **Detergents containing cresol soap (Lysol water)**
  - **Detergents containing phenolic compound base**
  - **Alkaline detergents**
  - **Acid detergents**
- **Do not use the following disinfectants unless otherwise stated:**
  - **Disinfectant containing chlorine dioxide**
  - **Disinfectant containing trichloroisocyanuric acid**
  - **Disinfectant containing peracetic acid**
  - **Disinfectant containing benzalkonium bromide or benzalkonium chloride**

- Disinfectant containing chlorhexidine gluconate or chlorhexidine acetate
- Disinfectant containing quaternary ammonium salt
- Disinfectant containing potassium persulfate
- Disinfectant containing potassium permanganate
- Iodophor or tincture of iodine
- Ozone disinfection

- **Except for internal defibrillation paddles, do not sterilize any accessory unless otherwise stated.**
- **Do not use a chlorine-containing disinfectant such as sodium hypochlorite solution, bleach, or chlorhexidine gluconate to wipe the metal parts of the defibrillation paddles. Chlorine disinfectants and or other oxidizing disinfectants can corrode the defibrillation paddles.**
- **Before each use of the internal defibrillation paddles, the complete reprocessing cycle—Cleaning → Disinfection → Drying → Packaging → Sterilization—must be strictly followed in the correct, non-interchangeable sequence. Missing any step or altering the order may lead to sterilization failure and cause severe patient infection.**
- **Do not immerse internal defibrillation paddles in liquid.**
- **Do not squeeze the rubber tube on the cuff.**
- **During cleaning, only wipe the external surface of the connector. Do not wipe its inner surface.**
- **Carefully clean the air bladder. Do not allow any liquid to flow into the air bladder.**
- **Do not dry-clean the cuff.**
- **The disposable cuff must be disposed of in accordance with the local laws.**
- **Make sure that the patient is not connected to the defibrillator monitor when conducting a user test.**
- **The ECG cable test can only be conducted by personnel authorized by the manufacturer.**
- **The manual defibrillation test can only be conducted by personnel authorized by the manufacturer.**
- **The pacing test can only be conducted by personnel authorized by the manufacturer.**
- **The NIBP pressure verification can only be conducted by personnel authorized by the manufacturer.**
- **The calibration of NIBP measurement should be performed once every two years (or according to the maintenance rules of your hospital). Check its performance according to the following details.**
- **This leakage test is different from those described in EN 1060-1. This is simply for the user to test whether there is air leakage during NIBP inflation. If the system shows NIBP air leakage at the end of the test, contact Comen's service personnel.**
- **The NIBP overpressure protection test can only be conducted by personnel authorized by the manufacturer.**

Note

- **To avoid damage to the insulating coating, the internal defibrillation paddles can only be cleaned and disinfected manually. Do not subject them to mechanical or ultrasonic washing and disinfection.**
- **Replace internal defibrillation paddles after 50 high-temperature sterilization cycles. Medical**

institutions can establish a sterilization cycle management log with the serial number on the paddles. Update the cumulative count promptly after each sterilization, and replace the paddles upon reaching 50 cycles.

- When sterilizing the internal defibrillation paddles, the recommended drying time is 15 minutes.
- If the defibrillator monitor is switched off, it will perform an auto test at the specified time only when it is connected to an external power supply or is installed with a battery with sufficient power.
- During an auto test, install the battery in the device, maintain clean defibrillation paddles and ensure paddles are correctly placed in the paddle tray and firmly contacting conductive surfaces, or connect defibrillation electrode cable with a 50Ω test load to the device. Failure to meet these conditions will result in test failure.
- During a user test, install the battery in the device, maintain clean defibrillation paddles and ensure paddles are correctly placed in the paddle tray and firmly contacting conductive surfaces, or connect defibrillation electrode cable with a 50Ω test load to the device. Failure to meet these conditions will result in test failure.
- The audio test volume is dependent on the prompt volume. Set an appropriate prompt volume before performing the button test.
-

1.26 Accessories

Warning

- Please use the accessory models specified by the manufacturer. Using other models of accessories may damage the monitor or affect its performance.
- Disposable accessories can only be used once. Repeated use may result in reduced performance or cross-infection.
- Please check the packaging of the accessories before using the accessories. Do not use the accessory if it is found to be damaged.
- Expired and damaged accessories may cause environmental pollution and must be disposed of in accordance with relevant local laws and regulations or hospital systems.
- When using accessories, refer to the accessory manual to ensure compliance with operational temperature requirements.
- This monitor and its supporting accessories have been tested for compliance with relevant standards.
- Before monitoring the patient, check the accessories are compatible with the monitor. Incompatible accessories reduce the performance of the monitor.
- The accessories provided in this manual are used in conjunction with this monitor.
- Electrodes, the metal end of defibrillation paddles, the surface of the SpO_2 probe in contact with the measurement site, the blood pressure cuff and CO_2 sampling tube are all applied parts.

1.27 EMC

Warning

- **Use of the S30/S30A/S30B/S30C/S50/S50A/S50B/S50C adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the S30/S30A/S30B/S30C/S50/S50A/S50B/S50C and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories and cables other than those specified or provided by the manufacturer of the S30/S30A/S30B/S30C/S50/S50A/S50B/S50C could result in increased electromagnetic emissions or decreased electromagnetic immunity of the S30/S30A/S30B/S30C/S50/S50A/S50B/S50C and result in improper operation.**
- **Running the device with the value below the minimum amplitude or minimum value specified in this manual may lead to inaccurate results. The minimum amplitude or minimum value for physiological signals is 200μv.**
- **Although other equipment conforms to relevant requirements on transmission, the defibrillator monitor may interfered by other equipment.**

Note

- **The S30/S30A/S30B/S30C/S50/S50A/S50B/S50C defibrillator monitor complies with the applicable EMC requirements in IEC 60601-1-2, IEC 60601-2-4, ISO 80601-2-55, IEC 80601-2-30, IEC 80601-2-49, IEC 60601-2-34, ISO 80601-2-56, IEC 60601-1-12 and ISO 80601-2-61.**
- **Please follow the EMC instructions in the User's Manual to install and use the defibrillator monitor.**
- **Portable and mobile RF communication equipment may affect the performance of the device. To protect the device against strong electromagnetic interference, please keep it away from mobile phones, microwave ovens, etc.**
- **Refer to the attached guide and manufacturer's statement.**

1.28 Shift Change Checklist

Note

- **Remove the test load immediately after the test to avoid delayed treatment.**

1.29 Cybersecurity

Warning

- **Improper use of the defibrillator monitor could cause hazards to patients and device performance.**
- **For embedded device, the security update is integrated with the software application program update. The update is only allowed locally by authorized users.**
- **The device supports change of user passwords with strong password policy enforcement. It also supports a reminder to change the default passwords during the first access.**
- **When the defibrillator monitor reaches the end of service, do erase patient data and configuration data before enforcing disposal policy.**
- **Before connecting the defibrillator monitor to other instruments, ensure that any connected device is free of malware.**

Note

- **The defibrillator monitor is intended to be used in professional healthcare facilities by professional healthcare personnel.**
- **The defibrillator monitor is intended for use with Comen Central Monitoring System for distributed monitoring. It's responsible for an authorized user to set the network configuration according to the local area network.**
- **When the device is connected to open IT Network (that is Comen specific Central Monitoring System Station), it is required that the host server be installed with anti-virus software. See Instruction Manual for Use of Comen Central Monitoring System for details.**
- **No software installation required for the embedded device.**
- **We will make available on request of software bill of materials.**

Steps that can be taken to safeguard this information and the general security of the defibrillator monitor:

- **Physical Access: Limit use of the defibrillator monitor to authorized users. Keep the device under physical control.**
- **Active Use: Users of the defibrillator monitor should take measures to limit patient data storage. Patient data should be removed from the defibrillator monitor after a patient is discharged and patient monitoring has ended.**
- **Network Security: The facility must take measures to ensure the security of any shared network to which the defibrillator monitor may be connected to.**
- **Device Security: Only connect the device to the manufacturer indicate compatible and ensure that any connected device is free of malware.**
- **Keep the device updated.**
- **Use good password.**

- **Act on or follow-up on alerts, inconsistencies, strange behavior of a device and let the responsible organization (Health Delivery Organizations, HDOs) knows.**

Chapter 2 Performance Information

1. Product Type

Classified by	Type
Type of protection against electric shock	Class I equipment with internal power supply
Level of protection against electric shock	Defibrillation-proof CF: ECG, RESP, SpO_2, NIBP, internal defibrillation Defibrillation-proof BF: external defibrillation, CO_2
Degree of protection by enclosure	IP55: Dust-protected and water jetting-protected
Degree of safety for flammable anaesthetic mixture with air or oxygen or nitrous oxide	Non category AP/APG
Mode of operation	Continuous operation equipment
Mobility	Portable When used on road ambulance: Fixed

2. Environmental Specifications

Item	Specification	
Operating conditions	Ambient temperature	Main unit: -20℃ - 55℃ (ECG, manual defibrillation) 0-50℃ (other functions) Mainstream CO_2 module: 10℃ - 40℃ Sidestream CO_2 module: 5℃ - 40℃
	Relative humidity	0% ~ 95%, non-condensation (Mainstream CO_2 module: 10% - 90%, no condensation)
	Barometric pressure	57.0kPa – 106.2kPa (CO_2 module: 57.3kPa – 105.3kPa)
Transport and Storage conditions	Ambient temperature	-40℃ - 75℃ (CO_2 module: -20℃ - 60℃)
	Relative humidity	0% ~ 95%, non-condensation (Mainstream CO_2 module: 10% - 90%, no condensation)
	Barometric pressure	57.0kPa – 106.2kPa (CO_2 module: 57.3kPa – 105.3kPa)
	Protect the monitor against violent impact, vibration, rain and snow in transport.	

Note: The defibrillator monitor complies with the requirements of Clause 10.1.3 of IEC 60601-1-12 and meets the requirements for protection against shock, vibration, bump and drop under the following test conditions:

Item	Test conditions
Shock	Pulse shape: half-sine Peak acceleration: 1000 m/s^2 Pulse duration: 11 ms

	Shock direction and number of times: 3 shocks on each of ±X, ±Y, ±Z axes, with a total of 18 shocks
Vibration	Vibration spectrum: 10 Hz~100 Hz, 1 m^2/s^3 100 Hz~200 Hz, -3 dB/oct 200 Hz~2000 Hz, 0.5 m^2/s^3 Vibration direction: X, Y, Z axes Vibration duration: 30 min per axis
Bump	Pulse shape: half-sine Peak acceleration: 15 g Pulse duration: 6 ms Impact direction and number of times: 1000 impacts on Z-axis
Drop	Main unit: fall height 1.5 m, 1 drop on each of the 6 surfaces. Main unit with carrying case: fall height 3 m, 1 drop in the normal operating orientation.

3. Power Specifications

AC power supply	
Input voltage	100V-240VAC
Input frequency	50Hz/60Hz
Input current	1.8A - 0.8A
DC power supply	
Power voltage	12V DC
Rated power	200W
Built-in battery	
Battery type	One intelligent rechargeable lithium battery (14.4V/4700mAh, maintenance-free) can be equipped.
Battery charging time	Charging the batteries in the monitor: When the monitor is turned off, it takes less than 2 hours to charge each battery to 90% and less than 2.5 hours to charge each battery to 100%. When the monitor is turned on, it takes less than 4 hours to charge each battery to 90% and less than 5 hours to charge each battery to 100%. Charging the batteries with the compatible charger: It takes less than 2.5 hours to charge each battery to 90% and less than 3 hours to charge each battery to 100%.
Battery operating time	The operating time of a new battery at an ambient temperature of 20 ° C is as follows: ◆ Monitoring mode: A new fully charged battery (when the device is configured as follows: 3/5-lead ECG, lowest screen brightness, the recorder not printing and lowest volume) operates for not less than 6.5 hours. ◆ Defibrillation mode: With a new fully charged battery (and when the device is configured as follows: 3/5-lead ECG, lowest screen brightness, the recorder not printing and lowest volume), the device

	can perform not less than 220 discharges of 360J energy; not less than 300 discharges of 200J energy (3 charges and discharges in every minute with an interval of one minute). ◆ Pacing mode: A new fully charged battery (when the device is configured as follows: 3/5-lead ECG, lowest screen brightness, the recorder not printing and lowest volume) operates for not less than 4.5 hours (load of 50Ω, frequency of 80bpm, current of 60mA).
Low battery alarm	The defibrillator monitor can trigger light and sound alarm for low battery. After the alarm has occurred, the device can perform continuous vital signs monitoring for 20 minutes, and a minimum of 6 discharges of 360J or 10 discharges of 200J.

Defibrillator battery charger	
Function	Charges the rechargeable lithium batteries
AC input	100-240V, 50Hz/60Hz, 1.0-0.5A
DC input	11.1V-14.5V DC, <6A

Docking station	
Function	Charges the defibrillator monitor
AC input	100-240V~, 50Hz/60Hz, 1.8-0.8A
DC input	12-30.3V, 15.5-6.5A

4. Physical Specifications

Size & Weight	
Dimension	≤255.5mm (height, including the handle) × 164mm (length) × 281mm (width), excluding the external defibrillation paddles
Weight	4.2±0.3kg (3/5-lead ECG, configured with manual defibrillation function, with a battery)
Display	
Resolution	1024*768
Size	8.0 inch
Touchscreen	
Type	Capacitive touchscreen
Recorder	
Recording method	High resolution thermal array printing
Recording channel	Not less than 3 waveforms can be output simultaneously.
Paper width	50mm
Effective paper width	48mm
Paper speed	6.25/12.5/25/50 mm/s, error not greater than ±5%
Real-time recording time	3s, 5s, 8s, 16s, 32s, or continuous
Delayed ECG printing	The delayed ECG printing function is provided and the delayed print time is 10s.

Interface & Network	
Network interface	One RJ45 interface, compatible with the 100BASE-TX standard
Wi-Fi interface	Protocol: IEEE802.11 a/b/g/n
	Transmission frequency: IEEE 802.11a/b/g/n (2.4G): 2412MHz ~ 2472MHz IEEE 802.11 a/b/g/n (5G): 5180MHz ~ 5320MHz, 5500MHz ~ 5700MHz, 5745MHz ~ 5825MHz
	Data security: Standard: WPA/WPA2-PSK, WPA/WPA2-Enterprise EAP: EAP-TTLS, EAP-TLS, PEAP-MsGhapV2 Encryption: TKIP.AES
Cellular mobile network interface	Supports 4G/5G network
Bluetooth interface	Protocol: bluetooth5.0
	Transmission frequency: 2402-2480MHz
	Data security: AES128
USB interface	Quantity:1 Protocol: supports USB 2.0 protocol
HDMI interface	Quantity: 1 Protocol: supports HDMI 1.4a
Multifunction interface	Supports defibrillation synchronous signal input, ECG analog signal output and connection to a CPR sensor

5. Defibrillation Specification

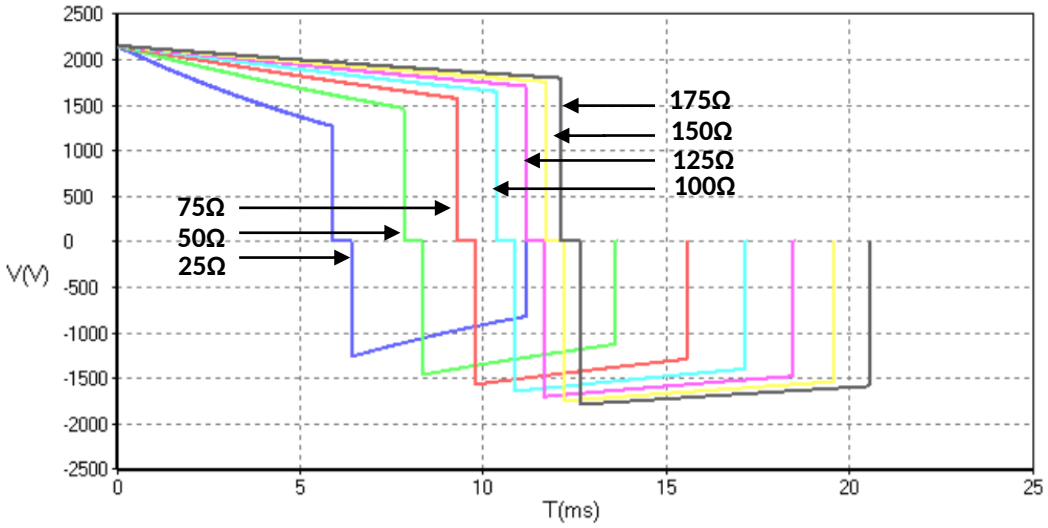
Item	Specification
Defibrillation mode	Manual asynchronous defibrillation, synchronous defibrillation, and AED defibrillation modes
Defibrillation waveform	BTE waveform, and waveform parameters can be automatically compensated according to patient impedance
Defibrillation method	External and internal defibrillation
Supported electrode type	External defibrillation paddles, multi-function defibrillation electrodes and internal defibrillation paddles, wherein the external electrode paddle is adult/pediatric multi-function type
Control and indication of external electrode paddle	The external defibrillation paddle has functions such as charging, discharging, energy selection, a charging completion indicator and patient contact impedance indicator. The grips of internal paddles can perform discharge.

Manual defibrillation energy selection range	
Range	1J – 360J
Options	26 options for external defibrillation: 1J, 2J, 3J, 4J, 5J, 6J, 7J, 8J, 9J, 10J, 15J, 20J, 25J, 30J, 50J, 70J, 100J, 120J, 150J, 170J, 200J, 220J, 250J, 270J, 300J, 360J

	15 options for internal defibrillation: 1J, 2J, 3J, 4J, 5J, 6J, 7J, 8J, 9J, 10J, 15J, 20J, 25J, 30J, 50J
Energy output accuracy	Under 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, and 175Ω loads, the deviation between the delivered energy level and the rated delivered energy value of the defibrillator monitor does not exceed ±1.5J or ±10% (whichever is greater).

Patient impedance range	
External defibrillation	20Ω ~ 300Ω
Internal defibrillation	15Ω ~ 300Ω

360J defibrillation waveform (load impedance is 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω and 175Ω, respectively)



Defibrillation energy								
Impedance / Energy	**25Ω**	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**	**Accuracy**
1J	1	1	1.1	1	1	0.9	0.8	±1.5J or ±10%, whichever is greater
2J	2	2	2	2	2	1.8	1.8	
3J	2.8	3	3	2.8	3	2.7	2.5	
4J	3.8	4	4.1	3.8	4	3.6	3.5	
5J	4.8	5	5.0	4.8	4	4.5	4.2	
6J	5.8	6	5.9	5.9	5	5.4	5.3	
7J	6.8	7	6.9	6.9	6.8	6.3	6	
8J	7.8	8	8	8	7.5	7.2	7	
9J	8.8	9	9	8.6	8.5	8.1	7.7	
10J	9.6	10	9.9	9.6	9.3	9	8.4	
15J	15	15	15	14	14	13	13	
20J	19	20	20	19	18	17	17	
25J	24	25	24	23	22	21	20	
30J	29	30	30	29	27	26	25	

50J	49	50	49	48	45	44	42	
70J	68	70	69	66	63	60	58	
100J	98	101	98	95	90	86	83	
120J	118	122	119	114	109	104	100	
150J	148	152	148	142	136	130	124	
170J	167	172	168	160	151	147	140	
200J	197	203	198	189	180	173	165	
220J	217	224	218	209	199	190	182	
250J	245	254	247	237	226	216	207	
270J	267	275	267	256	244	233	223	
300J	297	305	296	284	270	258	247	
360J	356	363	354	339	324	310	296	

Charging Time (at an ambient temperature of 20 ℃ ±5℃)								
	Manual defibrillation				AED			
	Charging time		From initial power on to ready for discharge		From initiation of rhythm analysis to ready for discharge		From initial power on to ready for discharge	
	200J	360J	200J	360J	200J	360J	200J	360J
With a new, fully charged battery	≤3s	≤6s	<10s	<15s	<10s	<12s	<12s	<13s
With a new, fully charged battery, depleted by 15 times of 360J discharge	<3s	<7s	<10s	<15s	<10s	<12s	<15s	<17s
With 90% to 100% rated mains voltage	≤3s	≤7s	<11s	<15s	<8s	<11s	<15s	<17s
AC mains: 100 to 240 VAC (±10%)								

Synchronous discharge delay	
Local synchronous discharge delay	Less than 60ms (from the R wave spike)
Remote synchronous discharge delay	Less than 25ms (from the rising edge of the synchronous signal)

Synchronous input signal	
Input limit	Vih≥2.4V，Vil≤0.4V
Input signal range	0 – 5V
Input impedance	≥ 10kΩ
Pulse width	>5ms

CPR	
Compression rate	Display range: 30cpm – 200cpm, accuracy: ±3cpm
Voice guide	Voice prompts are provided to guide CPR operations.
CPR filter	The filtered ECG waveforms are displayed.
Compression Rate	-When derived from multifunction electrode pads: Display range: 30–200 cpm, measurement accuracy: ±3 cpm. -When derived from CPR sensor: Display range: 30–200 cpm, resolution: 1 cpm, measurement accuracy: ±2 cpm. -When derived from SpO_2 sensor (COMEN): Display range: 20–300 cpm, resolution: 1 cpm, measurement accuracy: ±2 cpm.
Compression Depth	-When derived from CPR sensor: Display range: 0.0–8.5 cm, display accuracy: ±0.5 cm or ±10%, whichever is greater.

AED defibrillation	
Shock series	Electric shock energy: Adult: 100J, 150J, 170J, 200J, 300J, 360J Pediatric: 10J, 15J, 20J, 30J, 50J, 70J, 100J Number of electric shocks: once, twice, and 3 times can be set The default configuration complies with the AHA2015/ERC2015 First Aid Guide.
The 1st shock energy	Adult: 100J/150J/170J/200J/300J/360J Pediatric: 10J/15J/20J/30J/50J/70J/100J
The 2nd shock energy	Adult: the 1st shock energy – 360J Pediatric: the 1st shock energy – 100J
The 3rd shock energy	Adult: the 2nd shock energy – 360J Pediatric: the 2nd shock energy – 100J
Shockable rhythm	VF and VT

AED algorithm performance		
Cardiac rhythm type	Performance requirement	Remark
Shockable cardiac rhythm VF	Sensitivity >90%	Meet IEC60601-2-4, AAMI DF 39-93 requirements and AHA recommendations (sensitivity > 90%)
Shockable cardiac rhythm VT	Sensitivity >75%	Meet IEC60601-2-4, AAMI DF 39-93 requirements and AHA recommendations (sensitivity > 75%)
Non-shockable cardiac rhythm	Specificity >95%	Meet IEC60601-2-4, AAMI DF 39-93 requirements and AHA recommendations (specificity > 95%)

6. Pacing Specification

Item	Specification

Pacing mode	Fixed pacing, demand pacing and overdrive pacing
Pacing waveform	One-way square wave pulse
Pacing rate	Fixed and demand pacing: 30ppm - 210ppm; Overdrive pacing: 30ppm – 250ppm Accuracy：±1ppm or ±1.5% (whichever is greater)
Pacing current	0mA~200mA, accuracy: ±5% or ±5mA (whichever is greater)
Pacing pulse width	20ms or 40ms; error: ±5%
Slow-down pacing	When this function is activated, the pacing frequency is reduced to 1/4 of the original value.

7. Monitoring ECG Specifications (applicable to ECG lead)

Item	Specification	
Meet the requirement of IEC 60601-2-27:2011/IEC 60601-2-25:2011		
ECG input	Support 3-lead ECG cable, 5-lead ECG cable, 6-lead ECG cable, 12-lead ECG cable and automatic selection of lead.	
Screen Display	Support cascading display function. It can show single or multiple waveforms. 3-lead measurement: 1 waveform 5-lead measurement: 7 waveforms 6-lead measurement: 8 waveforms 12-lead measurement: 12 waveforms	
Sensitivity (gain) and error	Support at least 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/ mV (×4) and automatic gain, and the error is less than ± 5%.	
Electrode polarization voltage range	With a DC polarization voltage of ±850 mV, the sensitivity varies by ±5%.	
Sweep speed	50mm/s, 25mm/s, 12.5mm/s, and 6.25mm/s, accuracy: not greater than ±10%	
Time bases	Non-permanent display	6.25 mm/s, 12.5mm/s, 25mm/s, 50mm/s, accuracy: not greater than ±10%
	Permanent display	6.25 mm/s, 12.5mm/s, 25mm/s, 50mm/s, accuracy: not greater than ±5%
ECG wave display time	Not less than 34s	
Frequency characteristic (display and record)	Therapy mode: 1 Hz～20 Hz (-3.0dB～+0.4dB); Monitoring Mode: 0.5 Hz～40 Hz (-3.0dB～+0.4dB); Diagnosis mode: 0.05Hz～150 Hz (-3.0dB～+0.4dB); ST mode : 0.05Hz～40Hz (-3.0dB～+0.4dB)	
Power frequency notch	a) Power frequency interference suppression capability: ≥ 20dB; b) Monitoring, therapy and ST modes: Support the 50/60Hz notch function; c) Diagnosis mode: Support the 50/60Hz notch manual setting and manual selection of strong / weak notch.	
Common mode rejection	Diagnosis mode	>90dB
	Monitoring mode	>106dB

	Therapy mode	>106dB
	ST mode	>106dB
Differential input impedance	≥5MΩ	
Input signal range	For a QRS wave signal of ±10 mV (peak-to-peak), the HR measurement shall meet the requirements specified in the table "HR measuring range and accuracy".	
Level trigger threshold for HR detection	The HR detection level trigger threshold is 200 μV. For a QRS wave signal of 200 μV, the HR measurement shall meet the requirements specified in the table "HR measuring range and accuracy".	
Tall T-wave ability rejection	Maximum T-wave amplitude (a_T) 1.2 mV per IEC 60601-2-27 Clause 201.12.1.101.17.	
Input dynamic range	DC bias voltage up to ±850mV	
Lead off detection current (Respiration, lead off detection and noise suppression)	Current of Measurement electrode <0.1μA Current of drive electrode <900nA	
Analog output signal	Analog output function outputs analog ECG signals, magnified by 1:1000 times, and the accuracy is ±5%	
	Bandwidth	Diagnosis mode: 0.05Hz～150Hz (-3.0dB～+0.4dB) Monitoring mode: 0.5Hz～40Hz (-3.0dB～+0.4dB) Therapy mode: 1Hz～20Hz (-3.0dB～+0.4dB) ST mode: 0.05Hz～40Hz (-3.0dB～+0.4dB)
	Maximum delay	≤35ms
	Provides PACE enhanced signal	Signal amplitude: Voh≥2.5V Pulse width: 10ms±5% Signal rise and fall time: ≤100us
ST segment detection	Measuring range	-2.5mV - +2.5mV
	Measurement accuracy	The measurement error in the range of -0.8 mV to +0.8 mV is ±0.02 mV or ±10% (whichever is greater); the other ranges are not defined.
	Resolution	0.01 mV
	ST alarm range	Upper limit: (lower limit +0.1mV)～2.5mV Lower limit: -2.5 mV～ (upper limit -0.1 mV) Step size: 0.05mV
	ST reference segment	Save ST reference segment
System noise (p-v RTI)	The noise level converted to the input shall be no more than 25μV (peak-to-peak value)	
Calibration voltage	±5% error at 1mV	

Baseline recovery time	Less than 2.5s after defibrillation	
HR measurement range and accuracy	Range	Adult: 15bpm～300bpm
		Neonate/pediatric: 15bpm～350bpm
	Accuracy	±1% or ±1 bpm, whichever is greater
	Resolution	1bpm
HR alarm setting range	Adult	Upper limit: (lower limit +2bpm) ~ 300bpm
		Lower limit: 15bpm ~ (upper limit – 2bpm)
	Neonate/pediatric	Upper limit: (lower limit +2bpm) ~ 350bpm
		Lower limit: 15bpm ~ (upper limit – 2bpm)
	Accuracy	±1 bpm
HR alarm setting range	Adjustment Step: 15 ~ 40 bpm: 1 bpm per step 41 ~ 300 bpm: 5 bpm per step	
	HR Upper Limit: 17bpm~295bpm HR Lower Limit: 16bpm~290bpm Extreme Tachycardia: 65bpm~300bpm Extreme Bradycardia: 15bpm~115bpm	
Arrhythmia type	This monitor can analyze 38 types of arrhythmia: Asystole, Vfib/VT, PVCs/min too high, R on T, Run PVCs, PVC, Couplet, Bigeminy, Trigeminy, Tachycardia, Bradycardia, Extreme Tachycardia, Extreme Bradycardia, Missed beats, multiform PVC, V-Tach, NSVT, Ventricular Rhythm, Pause, Pauses/min high, Irregular Rhythm, Ventricular Bradycardia, Irregular Rhythm Stopped, AF, AF Stopped, Pacer Not Capture, Pacer Not Pacing, SVCs/min high, SVT, PAC Bigeminy, PAC Trigeminy, IPVC, VEB, Nonsus S-Tach, Atrial Rhythm, Run SVCs, PAC Couplet, Wide QRS Tachy	
Arrhythmia alarm	This monitor can provide 38 arrhythmia alarms: Asystole, Vfib/VT, PVCs/min too high, R on T, Run PVCs, PVC, Couplet, Bigeminy, Trigeminy, Tachycardia, Bradycardia, Extreme Tachycardia, Extreme Bradycardia, Missed beats, multiform PVC, V-Tach, NSVT, Ventricular Rhythm, Pause, Pauses/min high, Irregular Rhythm, Ventricular Bradycardia, Irregular Rhythm Stopped, AF, AF Stopped, Pacer Not Capture, Pacer Not Pacing, SVCs/min high, SVT, PAC Bigeminy, PAC Trigeminy, IPVC, VEB, Nonsus S-Tach, Atrial Rhythm, Run SVCs, PAC Couplet, Wide QRS Tachy	
Threshold for arrhythmia analysis	The following arrhythmia analysis threshold shall be provided: PVCs/min: 1~100 Asystole Delay: 3s~10s Tachycardia (HR high limit): 60 bpm~295 bpm Bradycardia (HR low limit): 16 bpm~120 bpm Extreme Tachycardia: 65 bpm~300 bpm Extreme Bradycardia: 15 bpm~115 bpm Ventricular Bradycardia Heart Rate: 15 bpm~60 bpm Multi-PVCs Window: 3 beats ~31 beats	

	Ventricular Tachycardia Heart Rate: 100 bpm~200 bpm Ventricular Tachycardia PVCs: 3 beats ~99 beats Heart Rate Stop Time: 1.5s, 2.0s, 2.5s, 3.0s,3.5s Ventricular Bradycardia PVCs: 3 beats ~99 beats Pauses/min: 1~15 AF/Irr Rhy End Time: 0min, 1min, 2min, 3min, 4min, 5min, 10min, 15min, 30min SVT SVCs: 3 beats ~99 beats SVT: 100 bpm ~300 bpm SVCs/min too High: 1 ~100	
Multi-lead simultaneous analysis function	Should have multi-lead ECG simultaneous analysis function	
Noise suppression of electrotome	ECG lead wire conforming to the standard is used, relative to ECG baseline, peak-to-peak noise ≤ 2mV	
Slew rate	2.2V/s	
QT/QTc Analysis	When the HR is at 15bpm – 150bpm (for adults) or 15bpm – 180bpm (for neonatal or pediatric patients): Measurement range: 200ms – 800ms Measurement accuracy: QT: ±30ms; QTc: not defined Measurement resolution: QT: 4ms, QTc: 1ms	
Overload protection	Loaded with differential input-circuit voltages of 1 V peak-to-valley, no damage	
Rejection of pacemaker pulses	The ME equipment rejects all pacemaker pulses having amplitudes from ±2mV to ±700mV, pluses widths from 0.1ms to 2.0ms and rise time from 10μs to 100μs.	
Rejection of pacemaker pulses without overshoot	Amplitude: ±2mV~±700mV; width: 0.1ms~2.0ms; if overshoot < 0.05αp, settling time < 5μs; start time, end time, rise time and fall time of pulse: ≤ 100μs; start time of pulse: 40ms or earlier before the start time of QRS wave; There is an identical pulse 150ms~250ms before the above pacemaker pulse.	
Pacemaker pulse display capability	Amplitude: ±2mV~±700mV; width: 0.5ms~2ms; maximum rise time: 100μs; the ECG display when the pacemaker pulse appears at 100/min.	≥0.2mV
Minimum Working Time	After the monitor applies a new fully charged 4700mAH battery, the normal operating time shall be not less than 3 hours under the following status: 1. Input a 1mV 10Hz sine wave signal (or ECG calibration signal CAL20002) without baseline drift to all channels of the ECG device; 2.Record this signal continuously at a rate of 25mm/s under standard sensitivity.	
Sampling and amplitude	ECG signals sampling rate: ≥500 samples/s	

quantisation during acquisition	Skew between channels: ≤100 μs Amplitude quantisation: ≤5 μV/LSB

HR algorithm	
Heart rate averaging	As required in Section 201.7.9.2.9.101 b) 3) of IEC 60601-2-27, the HR is calculated as follows. If all of the last 3 RR intervals are longer than 1200ms, the average of the last 4 RR intervals is the HR. Otherwise, the average of the last 12 RR intervals (with the longest interval and shortest interval excluded) is the HR.
Heart rate meter accuracy and response to irregular rhythm	As required in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the HR is displayed as follows after the 20s of stabilization period: Waveform A1(Ventricular bigeminy): 80±1bpm Waveform A2(Slow alternating ventricular bigeminy): 60±1bpm Waveform A3(Rapid alternating ventricular bigeminy): 120±1bpm Waveform A4(Bidirectional systoles): 90±2bpm
HR change response time	As required in Clause 201.7.9.2.9.101 b) 5) of IEC 60601-2-27: the response time for a HR change: from 80bpm to 120bpm: less than 11s. from 80bpm to 40bpm: less than 11s.
Time to alarm for Tachycardia	As required in Section 201.7.9.2.9.101 b) 6) of IEC 60601-2-27, the waveform: Waveform B1(1mVpp, 206 bpm): 11s Waveform B1(0.5mVpp, 206 bpm): 11s Waveform B1(2mVpp, 206 bpm) - range: 11s Waveform B2(2mVpp, 195bpm): 11s Waveform B2(1mVpp, 195 bpm): 11s Waveform B2(4mVpp, 195 bpm): 11s

8. Defibrillation ECG specification

Item	Specification
Input source	External defibrillation paddles, internal defibrillation paddles and multi-function defibrillation electrodes as the ECG input sources
Screen display	Support cascading display function
Sensitivity (gain) and error	Support at least 1.25 mm/mV (×0.125), 2.5 mm/mV (×0.25), 5 mm/mV (×0.5), 10 mm/mV (×1), 20 mm/mV (×2), 40 mm/ mV (×4) and automatic gain, and the deviation is less than ± 5%.
Electrode polarization voltage	With a DC polarization voltage of 850 mV, the sensitivity varies by ±5%.
Sweep speed	50mm/s, 25mm/s, 12.5mm/s, and 6.25mm/s, and the error is no more than ±10%
Frequency characteristic	Defibrillation electrode: 1Hz ~ 20Hz (-3.0dB ~ +0.4dB)
Common mode suppression ability	Therapy mode (notch filter on): >106dB

Power frequency notch	Therapy mode: Support the 50/60Hz notch function Power frequency interference suppression capability: ≥ 20dB
Differential input impedance	Defibrillation electrode: ≥5MΩ
Input signal range	For a QRS wave signal of ±10 mV (peak-to-peak), the HR measurement shall meet the requirements specified in the table "HR measuring range and accuracy".
HR detection level trigger threshold	The HR detection level trigger threshold is 200 μV. For a QRS wave signal of 200 μV, the HR measurement shall meet the requirements specified in the table "HR measuring range and accuracy".
Input dynamic range	DC bias voltage up to ±850mV
System noise	The noise level converted to the input shall be no more than 25μV (peak-to-peak value)
Calibration voltage	1 mV, with an error range of ±5%
Arrhythmia type	This monitor can analyze 5 types of arrhythmia: Asystole, V-fib/VT, VT, Pacer Not Capture, Pacer Not Pacing
Arrhythmia alarm	This monitor can provide 5 arrhythmia alarms: Asystole, V-fib/VT, VT, Pacer Not Capture, Pacer Not Pacing
Threshold for arrhythmia analysis	The following arrhythmia analysis threshold shall be provided: Asystole time and V-fib threshold.
HR meter accuracy and response to irregular rhythm	As required in Clause 201.7.9.2.9.101 b) 4) of IEC 60601-2-27, the HR is displayed as follows after the 20s of stabilization period: Waveform A1(Ventricular bigeminy): 80±1bpm Waveform A2(Slow alternating ventricular bigeminy): 60±1bpm Waveform A3(Rapid alternating ventricular bigeminy): 120±1bpm Waveform A4(Bidirectional systoles): 90±2bpm
HR alarm setting range and accuracy	Adjustment Step: 15 ~ 40 bpm: 1 bpm per step 41 ~ 300 bpm: 5 bpm per step
	HR Upper Limit: 17bpm~295bpm HR Lower Limit: 16bpm~290bpm Extreme Tachycardia: 65bpm~300bpm Extreme Bradycardia: 15bpm~115bpm
HR alarm setting range and accuracy	Adult: upper limit: (lower limit + 2bpm) ~ 300bpm, lower limit: 15bpm ~ (upper limit - 2bpm); Neonatal/Pediatric: upper limit: (lower limit + 2bpm) ~ 350bpm, lower limit: 15bpm ~ (upper limit - 2bpm) HR alarm accuracy: ±1bpm
Pacing detection	The device can detect external pacing signals and display them with markers.
Pacing rejection	The device can reject external pacing signals to avoid misinterpretation of pacing pulses as heartbeats.

Baseline recovery time	Less than 2.5s after defibrillation

9. Respiration Specifications

Item	Specification	
Display	Respiratory waveform and respiration rate	
Measuring lead	Leads I and II are optional and the default is lead II. Automatic lead is optional. Support manual and automatic measurement methods.	
Respiratory excitation waveform	<300 μA RMS, 56.9kHz (±10%)	
Respiration rate	From ECG lead: Measurement range: 0rpm-200rpm Measurement accuracy: 0rpm~120rpm: ±1rpm; 121rpm~200rpm: ±2rpm Resolution: 1rpm	
	From Comen SpO_2 module: Measurement range:4rpm-70rpm Measurement accuracy: ±3rpm Resolution: 1rpm	
RR alarm setup range	Step	0rpm – 20rpm: 1rpm 21rpm - 200rpm: 5rpm
	Upper limit	RR≤20rpm: (lower limit + step)~20rpm RR>20rpm: (lower limit + step)~200rpm
	Lower limit	RR≤20rpm: 0rpm~(upper limit - step) RR>20rpm: 20rpm~(upper limit - step)
No breath alarm time setup range	No RESP alarm setting time for adults shall be in the range of 10s ~ 60s, step size: 5s; setting range for neonates and pediatrics: 10s～40s, step size: 5s.	
CVA identification	The monitor will display the relevant alarm message when the HR is identical with the RR.	

10. NIBP Specifications

Item	Specification		
Meets the requirement of IEC 80601-2-30.			
Measurement range	Adult	SYS	25mmHg ~ 290mmHg (3.3kPa ~ 38.7kPa)
		MAP	15mmHg ~ 260mmHg (2.0kPa ~ 34.7kPa)
		DIA	10mmHg ~ 250mmHg (1.3kPa ~ 33.3kPa)
	Pediatric	SYS	25mmHg ~ 250mmHg (3.3kPa ~ 33.3kPa)
		MAP	15mmHg ~ 225mmHg (2.0kPa ~ 30.0kPa)
		DIA	10mmHg ~ 210mmHg (1.3kPa ~ 28.0kPa)
	Neonatal	SYS	25mmHg ~ 140mmHg (3.3kPa ~ 18.7kPa)
		MAP	15mmHg ~ 125mmHg (2.0kPa ~ 16.7kPa)
		DIA	10mmHg ~ 115mmHg (1.3kPa ~ 15.3kPa)
Static measurement	Range: 0mmHg ~300mmHg (0kPa ~ 40.0kPa) Accuracy: ± 3mmHg (± 0.4kPa)		

<table>
<tr><td>range and accuracy</td><td colspan="3"></td></tr>
<tr><td rowspan="11">Alarm limit range</td><td rowspan="3">Adult</td><td>SYS</td><td>Extreme high alarm limit: 28mmHg~290mmHg
Upper alarm limit: 27mmHg ~ 285mmHg
Lower alarm limit: 26mmHg ~ 280mmHg
Extreme low alarm limit: 25mmHg ~275mmHg</td></tr>
<tr><td>DIA</td><td>Extreme high alarm limit: 13mmHg ~ 250mmHg
Upper alarm limit: 12mmHg ~ 245mmHg
Lower alarm limit: 11mmHg ~ 240mmHg
Extreme low alarm limit: 10mmHg ~ 235mmHg</td></tr>
<tr><td>MAP</td><td>Extreme high alarm limit: 18mmHg ~ 260mmHg
Upper alarm limit: 17mmHg ~ 255mmHg
Lower alarm limit: 16mmHg ~ 250mmHg
Extreme low alarm limit: 15mmHg ~ 245mmHg</td></tr>
<tr><td rowspan="3">Pediatric</td><td>SYS</td><td>Extreme high alarm limit: 28mmHg ~ 250mmHg
Upper alarm limit: 27mmHg ~ 245mmHg
Lower alarm limit: 26mmHg ~ 240mmHg
Extreme low alarm limit: 25mmHg ~ 235mmHg</td></tr>
<tr><td>DIA</td><td>Extreme high alarm limit: 13mmHg ~ 210mmHg
Upper alarm limit: 12mmHg ~ 205mmHg
Lower alarm limit: 11mmHg ~ 200mmHg
Extreme low alarm limit: 10mmHg ~ 195mmHg</td></tr>
<tr><td>MAP</td><td>Extreme high alarm limit: 18mmHg ~ 225mmHg
Upper alarm limit: 17mmHg ~ 220mmHg
Lower alarm limit: 16mmHg ~ 215mmHg
Extreme low alarm limit: 15mmHg ~ 210mmHg</td></tr>
<tr><td rowspan="3">Neonate</td><td>SYS</td><td>Extreme high alarm limit: 28mmHg ~ 140mmHg
Upper alarm limit: 27mmHg ~ 135mmHg
Lower alarm limit:26mmHg ~ 130 mmHg
Extreme low alarm limit: 25mmHg ~ 125mmHg</td></tr>
<tr><td>DIA</td><td>Extreme high alarm limit: 13mmHg ~ 115mmHg
Upper alarm limit: 12mmHg ~ 110mmHg
Lower alarm limit: 11mmHg ~ 105mmHg
Extreme low alarm limit: 10mmHg ~ 100mmHg</td></tr>
<tr><td>MAP</td><td>Extreme high alarm limit: 18mmHg~ 125mmHg
Upper alarm limit: 17 mmHg ~ 120 mmHg
Lower alarm limit: 16mmHg ~115 mmHg
Extreme low alarm limit: 15mmHg ~110mmHg</td></tr>
<tr><td rowspan="2">Step size</td><td colspan="2">10mmHg ~50mmHg: 1mmHg</td></tr>
<tr><td colspan="2">51mmHg ~290mmHg: 5mmHg</td></tr>
<tr><td>NIBP</td><td colspan="3">Manual, auto (cyclic), sequence, clock and continuous measurement modes</td></tr>
</table>

measurement mode	Interval for auto mode	1min, 2min, 2.5min, 3min, 4min, 5min, 10min, 15min, 30min, 60min, 90min, 120min, 180min, 240min, 480min, 720min
	Continual measurement mode	Optional for adult, pediatric and neonate
Setting range of initial inflation pressure	Adult: 80mmHg ~ 290mmHg (10.7kPa ~ 38.7kPa); Pediatric: 80mmHg ~ 240mmHg (10.7kPa ~ 32.0kPa); Neonate: 60mmHg ~ 140mmHg (8.0kPa ~ 18.7kPa).	
Software overpressure protection	Adult/Pediatric: 297mmHg±3mmHg (39.6kPa±0.4kPa); Neonate: 147mmHg±3mmHg (19.6kPa±0.4kPa)	
Maximum measurement cycle	Adult/Pediatric: 120s; Neonate: 85s	
Auxiliary venipuncture (only for Comen NIBP)	Maximum auxiliary venipuncture time: Adult/Pediatric: 125s Neonatal: 87s Error: ±5s	
	Pressure range& Error: Adult: 20mmHg ~ 120mmHg (2.7kPa ~ 16.0kPa) Pediatric: 20mmHg ~ 80mmHg (2.7kPa ~ 10.7kPa) Neonatal: 20mmHg ~ 50mmHg (2.7kPa ~ 6.7kPa) Error: ±5mmHg (±0.7kPa)	
Rapid NIBP	The device supports non-invasive blood pressure measurement via inflation, providing a reading within 15 seconds.	

11. SpO_2 Specifications

Item	Specification
Meets the requirements of ISO 80601-2-61	
Displayed measurement	Pulse rate (PR) waveform and SpO_2
Display resolution	1%
Measurement range and accuracy	Comen SpO_2: SpO_2 Measurement range: 0%~100%; Measurement accuracy: When measurement range is 70%~100%, the accuracy is ±2% (adult/ pediatric, in non-motion state) or ±3% (neonate, in non-motion state); when measurement range is 0%~69%, the measurement accuracy is not defined. Masimo SpO_2: (a) SpO_2 Measurement range: 1%~100%; Measurement accuracy: When measurement range is 70%~100%, the accuracy is ±2% (adult/

	pediatric, in non-motion state), ±3% (in motion state), or ±3% (neonate, in non-motion state); when measurement range is 1%~69%, the measurement accuracy is not defined. (b) SpMet Measurement range: 0.0% ~ 99.9% Resolution: 0.1% Measurement accuracy: When measurement range is 1.0%~15.0%, the accuracy is 1.0%; the measurement accuracy of other measurement range is not defined. (c) SpCO Measurement range: 0.0% ~ 99.9% Resolution: 0.1% Measurement accuracy: When measurement range is 1.0%~40%, the accuracy (for adult/pediatric/neonate) is 3%; the measurement accuracy of other measurement range is not defined. (d) SpHb Measurement range: 0g/dL ~ 25.0g/dL Resolution: 0.1g/dL Measurement accuracy: When measurement range is 8g/dL ~ 17g/dL, the accuracy (for adult/pediatric) is ±1g/dL; the measurement accuracy of other measurement range is not defined (e) SPOC Measurement range: 0ml/dl ~ 35ml/dl Resolution: 1.0ml/dl (f) PVI Measurement range: 0%~100% Nellcor SpO_2: SpO_2 Measurement range: 0%~100% Measurement accuracy: When measurement range is 70%~100%, the accuracy is ±2% (adult/ pediatric, in non-motion state) or ±3% (neonate, in non-motion state); when measurement range is 0%~69%, the measurement accuracy is not defined.
Alarm limit range	Comen SpO_2: Upper alarm limit: (lower limit+2%) ~ 100% Lower alarm limit: (extreme low limit+2%) ~ (upper limit-2%); Extreme low alarm limit: 0% ~ (lower limit-2%) Step: 1% Masimo SpO_2: (a) SpO_2 Upper alarm limit: (lower limit+2%) ~ 100% Lower alarm limit: (extreme low limit+2%) ~ (upper limit-2%);

	Extreme low alarm limit: 1% ~ (lower limit-2%) Step: 1% (b) SpMet Upper limit: 1.0%~2.0%, step: 0.1%; 2.5%~99.5%, step: 0.5%; or turned off Lower limit: 1.0%~2.0%, step: 0.1%; 2.5%~99.0%, step: 0.5%; or turned off (c) SpCO Upper limit: 2%~98%, step: 1%; or turned off, when it is off, alarms are disabled. Lower limit: 1%~97%, step: 1%; or turned off, when it is off, alarms are disabled. (d) SpHb Upper limit: 2.0g/dL~24.5g/dL, step: 0.1g/dL; or turned off, when it is off, alarms are disabled. Lower limit: 1.0g/dL~23.5g/dL, step: 0.1g/dL; or turned off, when it is off, alarms are disabled. (e) SpOC Upper limit: 2ml/dl~34ml/dl, step: 1ml/dl; or turned off Lower limit: 1ml/dl~33ml/dl, step: 1ml/dl; or turned off (f) PVI Upper limit: 2~99, step: 1; or turned off, when it is off, alarms are disabled. Lower limit: 1~98, step: 1; or turned off, when it is off, alarms are disabled. Nellcor SpO_2: Upper alarm limit: (lower limit+2%)~100% Lower alarm limit: (extreme low limit+2% or 20, whichever is greater) ~ (upper limit-2%) Extreme low alarm limit: 0% ~ (lower limit-2%) Step: 1%
Data update period	≤1s
Perfusion index (PI) Measurement Range	Masimo: 0.02 % ~20 %, the accuracy is not defined; Comen: 0.05 % ~20 %, the accuracy is not defined
Perfusion index (PI) Resolution	Masimo: 0.02%~9.99%: 0.01%; 10.0% ~20.0%: 0.1%. Comen: 0.05%～9.99%: 0.01%. 10.0%～20.0%: 0.1%
Signal IQ	Comen and Masimo SpO_2 shall have SIQ function.
Pitch Tone function	With Pitch Tone function; the tone of the pulse sound can change with the change of pulse SpO_2.
CPR Quality Index (CPR-QI) (only for Comen SpO_2)	
Measurement range	0 ~ 100
Resolution	1
Compression Rate (Rate)	Display range: 20cpm ~ 300cpm Resolution: 1cpm

	Accuracy: ±2cpm

Masimo Accuracy Footnotes:

1 The Masimo SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

2 The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population.

3 The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68%of the population.

4 The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates.

5 The Masimo SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25 -240 bpm in bench top testing against a Biotek Index 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

6 Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO_2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm.

7 Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.

12. PR Specifications

Item	Specification
Measurement range and accuracy	Comen SpO_2: Measurement range: 20bpm~300bpm; Resolution: 1bpm; Accuracy: ±2bpm. Masimo SpO_2: Measurement range: 25bpm~240bpm; Resolution: 1bpm; Accuracy: ±3bpm (in non-motion state) and ±5bpm (in motion state) Nellcor SpO_2: Measurement range: 20bpm~300bpm; Resolution: 1bpm; Accuracy: ±3bpm within 20bpm~250bpm range. The measurement accuracy within 251bpm~300bpm range is not defined. NIBP: Measurement range: 30bpm～310bpm; Resolution: 1bpm Accuracy: ±3bpm or ±3%, whichever is greater.
PR alarm limit range	Adult: Upper limit (HR upper limit & Extreme Tachy): ≤40bpm, (HR lower limit + step size) ~ 40bpm >40bpm, (HR lower limit+ step size) ~ 300bpm Lower limit (HR lower limit & Extreme Brady): ≤40bpm, 15bpm ~ (HR upper limit - step size) >40bpm, 40bpm ~ (HR upper limit - step size) Pediatric/Neonatal: Upper limit (HR upper limit & Extreme Tachy): ≤40bpm, (HR lower limit + step size) ~ 40bpm >40bpm, (HR lower limit+ step size) ~ 300bpm Lower limit (HR lower limit & Extreme Brady): ≤40bpm, 15bpm ~ (HR upper limit - step size) >40bpm, 40bpm ~ (HR upper limit - step size)
	Step size: 15bpm ~ 40 bpm: 1bpm; 41bpm ~ 300 bpm: 5bpm
Pulse rate derived from the average time setting of oxygen saturation	For the Comen SpO_2 module, the sensitivity of oxygen saturation can be set to high, medium and low, and the corresponding pulse rate average time is short, medium and long.

13. CO_2 Specifications

Item	Specification
Meets the requirements of ISO 80601-2-55	

$EtCO_2$ display	CO_2 waveform and parameter
CO_2 measurement range	a) Comen mainstream CO_2 / Comen sidestream CO_2 / Comen Capno sidestream CO_2: 0mmHg～150mmHg, 0%～19.7% (at 760mmHg), 0kPa～20kPa; b) Masimo mainstream CO_2 / Masimo sidestream CO_2: 0mmHg～190mmHg, 0%～25% (at 760mmHg) c) Respironics mainstream CO_2 / Respironics LoFlo sidestream CO_2: 0mmHg～150mmHg, 0%～19.7% (at 760mmHg), 0kPa～20kPa; d) Respironics CapnoTrak sidestream CO_2: 0mmHg～99mmHg, 0%～13.03% (at 760mmHg), 0kPa～13.20kPa.
CO_2 accuracy	a) Comen mainstream CO_2/Comen sidestream CO_2 / Comen Capno sidestream CO_2: 0mmHg～40mmHg: ±2mmHg; 41mmHg～70mmHg: ±5%×reading; 71mmHg～100mmHg: ±8%×reading; 101mmHg～150mmHg: ±10%×reading; b) Masimo mainstream CO_2 (in all conditions): 0 mmHg ～114 mmHg: ±（2.25mmHg+4%×reading） 115mmHg～190 mmHg unspecified; c) Masimo sidestream CO_2 (in all conditions): 0 mmHg ～150 mmHg: ±（2.25mmHg+4%×reading）; 151mmHg ～190 mmHg unspecified; d) Respironics mainstream CO_2/Respironics LoFlo sidestream CO_2: 0mmHg～40mmHg: ±2mmHg; 41mmHg～70mmHg: ±5%×reading; 71mmHg～100mmHg: ±8%×reading; 101mmHg～150mmHg: ±10%×reading; e) Respironics CapnoTrak sidestream CO_2: 0mmHg～38mmHg: ±2mmHg; 39mmHg～99mmHg: ±10%×reading.
awRR measurement range	a) Comen mainstream CO_2 /Comen sidestream CO_2/Comen Capno sidestream/Masimo mainstream CO_2: 0rpm～150rpm b) Masimo sidestream CO_2: 0rpm～150rpm c) Respironics mainstream/Respironics LoFlo sidestream CO_2: 0rpm, 2rpm～150rpm d) Respironics CapnoTrak sidestream CO_2: 0rpm, 2rpm～100rpm
awRR measurement accuracy	±1rpm
$EtCO_2$ alarm preset range	a) Comen CO_2: Upper limit: (lower limit +2mmHg)～150mmHg, Lower limit: 0mmHg～(upper limit -2mmHg); b) Masimo CO_2:

	Upper limit: (lower limit +2mmHg)～190mmHg, Lower limit: 0mmHg～(upper limit -2mmHg); c) Respironics CO_2: Upper limit: (lower limit +2mmHg)～150mmHg, Lower limit: 0mmHg～(upper limit -2mmHg); Step size: 1 mmHg.
awRR alarm preset range	a) Comen CO_2: Upper limit: (lower limit +2rpm)～150rpm Lower limit: 0rpm～(upper limit -2rpm) b) Masimo CO_2: Upper limit: (lower limit +2rpm)～150rpm Lower limit: 0rpm～(upper limit -2rpm) c) Respironics CO_2: Upper limit: (lower limit +2rpm)～150rpm Lower limit: 0rpm～(upper limit -2rpm) Step size: 1 rpm.
$FiCO_2$ alarm preset range	a) Comen CO_2: Upper limit: 1mmHg～76mmHg, no lower limit; b) Masimo CO_2: Upper limit: 1mmHg～99mmHg, no lower limit; c) Respironics CO_2: Upper limit:1mmHg～76mmHg, no lower limit; Step size: 1 mmHg.
CO_2 resolution	Respironics CapnoTrak sidestream CO_2: 0mmHg~99mmHg: 0.01mmHg Masimo mainstream/sidestream CO_2: 0.01 vol% Comen mainstream/Comen sidetream/Respironics LoFlo sidestream/Respironics mainstream CO_2: 0mmHg~69mmHg: 0.1mmHg 70mmHg~150mmHg: 0.25mmHg
Sampling velocity	Comen/Comen Capno/Masimo/ Respironics sidestream CO_2: 50ml/min
Sampling rate control accuracy	Comen/Comen Capno/Masimo/ Respironics sidestream CO_2: ±10 ml/min
Data sampling rate	Masimo maisntream CO_2: 20Hz/channel Comen/Comen Capno/Respironics LoFlo/Respironics CapnoTrak sidetream CO_2: 50Hz/channel
Total system response time	Masimo/Comen/Respironics mainstream CO_2: ≤ 2s; Masimo/Comen/Respironics sidestream CO_2: ≤ 5s
10%-90% Rise time	Masimo sidetream: ≤340ms Respironics LoFlo sidestream: ≤300ms Respironics CapnoTrak sidestream: ≤400ms Comen sidestream: ≤600ms Comen Capno Sidestream: ≤430ms
I:E Ratio Effects	a) I:E ratios <2:1 have no effect on stated $EtCO_2$ accuracy stated above.

	b) For I:E ratios >2:1 the EtCO2 accuracy specification is as follows: IE2:1: -7% + -4% × every 10bpm (bpm > 40) IE3:1: -7% + -5% × every 10 bpm (bpm > 30) IE4:1: -12% + -6% × every 10 bpm (bpm > 30)
CO_2 Stability	The measurement accuracy can be met within 6 hours.
Warm-up time	Masimo mainstream CO_2: <10s; Masimo sidestream CO_2: <10s (Note: If stored at -40℃, use it immediately, the preheating time is 10min) Comen/Respironics mainstream CO_2: obtain waveform: <15s; achieve full accuracy specification: ≤2min, (Note: at 25 ℃). Respironics CapnoTraksidestream CO_2: obtain waveform: <10s; achieve full accuracy specification: ≤3min (Note: at 25℃). Respironics LoFlo sidestream CO_2/Comen sidestream CO_2: obtain waveform: <20s; achieve full accuracy specification: ≤2min (Note: at 25℃).

14. Data Management

Item	Specification
Storage capacity	Supports 4GByte storage
Storage during power loss	The defibrillator monitor shall support data storage during losses of power.
Event mark	The defibrillator monitor shall have the function of marking user events.
Event storage	The defibrillator monitor shall support event storage of 1500 records each for physiological alarms and technical alarms.
Waveform storage	The defibrillator monitor shall store waveforms up to 180 hours for 1 channel or 90 hours for 2 channels.
Audio recording	The defibrillator monitor shall record audio for 12 hours.
Trend	The defibrillator monitor shall store and review trends for 200 hours (resolution: 1 minute).
Self-test report	The defibrillator monitor shall store 1500 self-test reports.
Patient file	The defibrillator monitor shall support up to 300 patient files.
Data storage and transfer	The defibrillator monitor shall store and transfer data. Data shall be transferred through removable storage media.

15. Network Specifications

Item	Specification
WI-FI	
Modulation type	IEEE802.11 a/b/g/n
Transmission frequency	IEEE 802.11b/g/n (2.4G): 2.412GHz ~ 2.472GHz IEEE 802.11a (5G): 5.18GHz ~ 5.24GHz, 5.745GHz ~ 5.825GHz
Frequency characteristic	IEEE 802.11b/g/n (2.4G) :2400 MHz~2500 MHz

	IEEE 802.11a (5G): 4900 MHz~5845 MHz
Cellular mobile network (4G)	
Modulation type	3GPP E-UTRA Release 11: LTE-FDD/LTE-TDD/WCDMA/TD-SCDMA/CDMA/GSM
Transmission frequency	LTE-FDD B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz LTE-FDD B3: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz LTE-FDD B5: 824MHz ~ 849MHz, 869MHz ~ 894MHz LTE-FDD B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz LTE-TDD B38: 2570MHz ~ 2620MHz LTE-TDD B39: 1880MHz ~ 1920MHz LTE-TDD B40: 2300MHz ~ 2400MHz LTE-TDD B41: 2555MHz ~ 2655MHz CDMA BC0: 824MHz ~ 849MHz, 869MHz ~ 894MHz WCDMA B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz WCDMA B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz TD-SCDMA B34: 2010MHz ~ 2025MHz TD-SCDMA B39: 1880MHz ~ 1920MHz EGSM900: 880MHz ~ 915MHz, 925MHz ~ 960MHz DSC1800: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz
Frequency characteristic	Bandwidth: 1.4/3/5/10/15/20 MHz
Radiated power	Class 3 (23dBm±2dB) for LTE FDD Class 3 (23dBm±2dB) for LTE TDD Class 2 (24dBm+1/-3dB) for TD-SCDMA Class 3 (24dBm+1/-3dB) for WCDMA Class 3 (24dBm+2/-1dB) for CDMA BC0 Class E2 (27dBm±3dB) for EDGE 900MHz Class E2 (26dBm±3dB) for EDGE 1800MHz Class 4 (33dBm±2dB) for EGSM900 Class 1 (30dBm±2dB) for DCS1800
Cellular mobile network (5G)	
Modulation type	3GPP Release 13, 3GPP Release 14: LTE-Cat NB1
Transmission frequency	B1: 1920MHz ~ 1980MHz, 2110MHz ~ 2170MHz B3: 1710MHz ~ 1785MHz, 1805MHz ~ 1880MHz B5: 824MHz ~ 849MHz, 869MHz ~ 894MHz B8: 880MHz ~ 915MHz, 925MHz ~ 960MHz B20: 791MHz ~ 821MHz, 832MHz ~ 862MHz
Radiated power	23 dBm ±2 dB

16. Defibrillation Electrodes Specifications

External defibrillation paddles	
Model	Physical dimension and area
CM3901	Adult electrode area: 85±8.5cm^2 Pediatric electrode area: 22±2.2cm^2 Cable length: ≥2m when stretched Cable diameter: φ6.8±1.0mm
CM-D01-001	

Internal defibrillation paddles	
Model	Physical dimension and area
CM3902	Electrode area: 40.46 cm^2 ~44.72 cm^2 Cable length: 5.3 m±0.15 m Cable diameter: φ7.0±1.0 mm
CM3903	Electrode area: 23.28cm^2~25.74cm^2 Cable length: 5.3 m±0.15 m Cable diameter: φ7.0±1.0 mm
CM-D01-008	Electrode area: 6.93cm^2 ~7.65cm^2 Cable length: 5.3 m±0.15 m Cable diameter: φ7.0±1.0mm

Defibrillation electrodes			
Meets the requirements of IEC 60601-2-4			
AC impedance	The impedance value for a pair of electrodes connected gel-to-gel in series with a 50Ω resistor, when measured with the maximum rate discharge energy of the defibrillator monitor, shall not exceed 3Ω.		
Combined offset instability and internal noise	After a 1-minute stabilization period, a pair of electrodes connected gel-to-gel shall not generate a voltage greater than 100μV p-p in the passband of 0.15 to 100Hz, for a period of 5 minutes following the stabilization period.		
Defibrillation recovery	4 seconds after the 3 electric shocks of 360J or maximum energy at a time interval of 1 minute, the absolute value of polarization potential of a pair of electrodes connected gel-to-gel in series with a 50Ω resistor shall not exceed 400mV. After 60s, it shall not exceed 300mV.		
Model	Intended patient type	Physical dimension	
		Total area	Effective area
CM3921	Pediatric	75±5cm^2	43±5cm^2
CM3922	Pediatric/Adult	148±5 cm^2	87±5cm^2
CM3922A	Pediatric/Adult	148±5cm^2	87±5cm^2
CM3925	Pediatric	88±5cm^2	63±5cm^2
CM3926	Pediatric/Adult	145±5cm^2	110±5cm^2
CM3927A	Pediatric/Adult	110±5cm^2	100±5cm^2