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CMS-LITE Management Software Version 1.6

User Manual



About this Manual

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Statement

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

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Responsibility of the Manufacturer

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

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

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

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

Terms Used in this Manual

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

WARNING

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

CAUTION

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

NOTE

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

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1 Intended Use and Safety Guidance

1.1 Intended Use/Indications for Use

CMS-LITE Data Management Software (hereinafter referred to as CMS-LITE) is used for centralized management of patients' monitoring data. CMS-LITE allows users to access monitoring information for connected patients. It also allows users to view patient information. Besides, CMS-LITE allows users to view, review, and print trend data of multiple physiological parameters.

1.2 Safety Guidance

Federal (U.S.) Law restricts CMS-LITE to sale by or on the order of a physician.

WARNING

- 1 Incorrect system operation may lead to false display results and hence adverse effects on the medical decision making. The system is intended for use by well-trained healthcare professionals. Anyone unauthorized or untrained must not operate the system. The system is not intended for home use. Any use of the system requires full understanding and strict observation of all sections of the user manual.
- 2 Incorrect system operation may further lead to significant system failures. The system thus should be installed by a qualified service engineer. Do not switch on power until all cables have been properly connected and verified.
- 3 Do not use it in the presence of flammable anesthetic due to explosion risk.
- 4 To avoid the risk of electric shock, do not remove the unit covers.
- 5 In order to avoid the risk of receiving an electric shock, do not move the host and displays while powering on the system.
- 6 Only accessories supplied by the manufacturer should be connected to the system. Usage of incompatible accessories may lead to system failure which may result in wrongful system operation and may have adverse effect on appropriate patient monitoring.
- 7 In order to avoid impairment of data transmission, ensure that the environment in which the system is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc.
- 8 In order to avoid the risk of receiving an electric shock, additional multi-socket outlet or extension cord cannot be connected to the system.

WARNING

- **9** CMS-LITE system can only collect, supervise, record, store and display the information from a monitor but cannot replace the monitoring function of the monitor itself. Thus ensure that connected monitor work properly according to corresponding documentation in order to avoid health risks for affected patients.
- 10 The wireless monitors and CMS-LITE form a wireless local area network (WLAN), and bidirectional data transmission between them is achieved by radio. Its RF emissions may cause interference in nearby electronic equipment. So the RF device must comply with the local standards and certification requirements. Also, a loss of transmission data between them may occur due to interference caused by other RF signals.
- 11 CMS-LITE software component may only be installed on EDAN recommended devices. Usage in connection with other devices will lead to malfunctions and/or system failures which do not allow or impair patient monitoring functions significantly.
- 12 Only use operating systems that are approved by EDAN. Using operating systems that are not approved by EDAN may compromise the system performance and cause a potential hazard.
- 13 Information displayed on CMS-LITE is not intended to and should not be the sole or primary information source for making therapeutic and/or diagnostic decisions. Use other medical review methods, hospital guidelines and best clinical practices instead in order to avoid significant health risks for affected patients.
- 14 The clinical decision based on the output of CMS-LITE is determined by the clinician. To avoid risks for the health of the patient, go to the corresponding primary bedside monitor to confirm the results obtained from the CMS-LITE before giving invasive treatment to a patient and observe other medical review methods, hospital guidelines and best clinical practices.
- 15 The appliance coupler or mains plug is used as isolation means from supply mains to avoid the risk of receiving an electric shock. Position the CMS-LITE in a location where the operator can easily access the disconnection device.
- 16 To avoid abnormal system operation or failure, 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.
- 17 Incorrect system settings may lead to system failures. The system settings must be configured by the authorized hospital personnel.

WARNING

- 18 If any value displayed on the CMS-LITE screen is doubtful, first determine the vital signs of the patient by alternative means and then verify that the CMS-LITE and the connected monitoring devices are working properly in order to avoid health risks for affected patients.
- 19 To avoid the risk of receiving an electric shock, do not touch the exposed contacts of either component, especially the power component.
- 20 Ensure that the equipment is supplied with continuous electric power during operation from the mains power or UPS. Failure to do so will result in failure of monitoring during periods of power failure. However, the previous settings will be recovered when the power is restored.
- 21 Check before use that the equipment, cables and transducers are not visibly damaged since that may affect monitoring capability and patient safety. The recommended inspection interval is one week or less. If damaged, the equipment must be replaced immediately.
- 22 Do not modify the IP address of the M3, M3A, M3B and iM8 series monitors, otherwise the system will identify it as a new device, and the system administrator needs to add the device to the department device list again in order for the device to get online again.
- 23 To avoid system failure, operating other software on the screen is prohibited when running CMS-LITE in Monitoring Station.

<u>CAUTION</u>

- 1 To avoid system failure, the system should be used within a temperature range from +5 °C to +40 °C (41 °F~104 °F). Keep the environment clean. Avoid vibration. Keep it far from corrosive reagents, dust areas, high-temperature and humid environment.
- 2 To avoid the risk of receiving an electric shock, turn off the system power before connecting or disconnecting any accessory to the system.
- 3 To avoid system failure, do not operate the system if it is not running normally or requires service.
- 4 To avoid electric shock, turn off the system power and remove the power cable before maintaining the system.

- 5 Failure to implement a recommended maintenance schedule may cause undue equipment failure and possible health hazards. Preventive maintenance of the system including periodic cleaning and a visible check can be performed by the user.
- 6 The maintenance operations like software upgrade of the system can only be completed by qualified service professionals of the manufacturer.
- 7 Avoid using worn material to clean. Remove all dust from the exterior surface of the equipment with a soft brush or cloth, slightly dampened with a mild detergent solution or cool disinfector. Especially the tie-in and panel edge should be noticed. Otherwise, equipment failure could result.
- 8 To avoid system failure, avoid pouring liquids on the equipment while cleaning, and do not immerse any parts of the equipment into any liquids.

NOTE:

- 1 The typical position of the operator is in front of the system. Position the device of the system in a location where the operator can easily see the screen and access the operating controls.
- 2 The illustrations in this manual are for reference only and its actual appearance may differ.
- 3 Refer to *CMS-LITE Data Management Software Installation Guide* for detailed information of installation and uninstallation.

1.2.1 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. Manufacturer recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

- 1. Physical safeguards physical safety measures to ensure that unauthorized personnel do not have access to the system.
- 2. Operational safeguards safety measures during operation.

- 3. Administrative safeguards safety measures in management.
- 4. Technical safeguards safety measures in technical field.

- 1 The access/operation of the CMS-LITE is restricted to authorized personnel only. Assign only staff with a specific role the right to use the system.
- 2 Ensure that all device components maintaining personal information (other than removable media) are physically secure (i.e. cannot remove without tools).
- 3 Ensure that the system is connected only to the device authorized/approved by manufacturer. Users should operate all CMS-LITE deployed and supported by manufacturer within specifications authorized by manufacturer, including the software, software configuration, security configuration, etc. approved by manufacturer.
- 4 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the Factory Maintain settings.
- 5 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.
- 6 When connecting the system to a shared network, data security issues of the network topology and configuration must be considered. Since the patient sensitive data are not encrypted and might be transmitted from the system to the network, the medical institution should be responsible for the network security. Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against DoS and DDoS attacks, and keep it up to date.
- 7 DoS and DDoS protection of the router or switch must be turned on for defensing against attacks.
- 8 When the system is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the system.
- 9 For security, disable all unused USB and network ports.
- 10 When deploying the network, it is recommended to isolate the network and the Intranet system of the hospital by using VLAN so as to ensure the network security. Only trusted devices are allowed to join the VLAN network.

- 11 Make sure networking function is used in a secure network environment.
- 12 Please protect the privacy for the information and the data displayed on the screen, and for the information and the data stored in the CMS-LITE.
- 13 When building the networking environment: 1) If a wireless router is used, please turn on the MAC address filtering function of the wireless router and add the MAC address of the monitor to the rule list. The wireless router only allows devices in the rule list to access the wireless network. 2) It is suggested to build a VLAN, assign the LAN ports where the approved switch port, monitor and CMS-LITE are into the same VLAN, and isolate them from other VLANs.

NOTE:

- 1 To replace the communication encryption certificate, refer to *CMS-LITE Data Management Software Installation Guide* for details.
- 2 Log files generated by the system are used for system troubleshooting and do not contain protected medical data.

| 1 | ĺĺ | Operating instructions |
|---|----------------|--|
| 2 | elFU indicator | Consult instruction for use are supplied in electronic form instead of in paper form |
| 3 | LOT | Batch code |
| 4 | \sim | Date of manufacture |
| 5 | *** | Manufacturer |
| 6 | P/N | Part Number |

1.3 Explanation of Symbols

| 7 | | The products marked with this symbol apply to the European WEEE directive. This symbol Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment. |
|----|---------|--|
| 8 | CE | CE marking |
| 9 | Rx Only | Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician. |
| 10 | EC REP | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
| 11 | MD | Medical Device |
| 12 | UDI | Unique Device Identifier |

NOTE:

- 1 The user manual is printed in black and white.
- 2 The 1st symbol applies to paper manual. The 2nd symbol applies to electronic manual. If both paper manual and electronic manual are configured, the paper manual shall prevail.

2 Introduction

2.1 Overview

CMS-LITE connects with monitor via network, and provides data management for one monitor, including iM3 (available only when iM3 in its Monitor mode, and also, unavailable when iM3 encryption is TLS), M3, M3A, M3B, iM50, iM60, iM70, iM80, iM8, iM8A, iM8B, X8, X10, X12, elite V5, elite V6, elite V8 monitor that complies with the network protocol of the manufacturer. CMS-LITE also supports H100B and H100N data management.

CMS-LITE is only used as data management software and cannot be used for monitoring purpose. CMS-LITE can display the following physiological parameters: ECG (3-lead, 5-lead, 6-lead and 12-lead), RESP, SpO₂, PR, NIBP, TEMP (T1, T2 and TD), IBP (ART, PA, CVP, RAP, ICP, LAP, P1, P2, and PPV), CO₂, AG and Quick TEMP.

NOTE:

The above are for reference only. The parameters actually displayed are related with user settings.

2.2 Network Structure

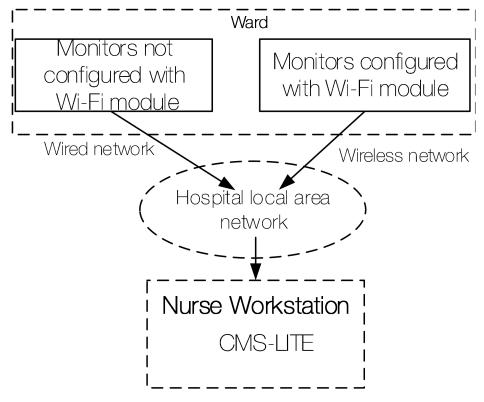
The typical system network is shown in below figure. The system supports communication with wired and wireless monitors:

Wired network

The CMS-LITE and monitors interconnect through an Ethernet network switch.

Wireless network

The CMS-LITE and monitors can interconnect through wireless network consisting of Wireless Access Points and Ethernet switches.



Typical System Network

2.3 System Functions

The CMS-LITE can realize the following system functions:

- Connecting to one bedside monitor;
- Displaying, storing, reviewing and printing the patients' monitoring data of the connected monitor.

3 Basic Operations

CAUTION

- 1 Ensure that the CMS-LITE operating environment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.
- 2 To avoid environmental pollution and misappropriation, be sure to observe the applicable waste control regulations and keep it out of reach of children when disposing of the packaging material.
- 3 To protect hospital personnel from electric shock, the CMS-LITE must have their casings properly grounded. The CMS-LITE host is provided with a 3-wire power cord. Plug it into a properly grounded 3-wire receptacle.

NOTE:

Never place the CMS-LITE within a patient environment.

3.1 Switching on the System

NOTE:

- 1 Before starting the system, please verify that the dongle has been inserted into an available USB port. Otherwise, you may fail to access the system.
- 2 If system gets stuck, the dongle will give out an alarm sound till the system resumes normal status.

Perform safety checks before starting the system. To start the CMS-LITE, follow these steps:

- 1. Connect the power cord to an uninterruptible power supply (UPS).
- 2. Press the power button on the front panel of the device. The power indicator on the front panel lights up and the device performs hardware self-test. If the device works normally, the main screen appears. If the device detects abnormity during self-test, it displays error information on the screen. In this case, you should record the error information, shut down the device and contact technical representative of EDAN. After the system self-test is completed, you will access the CMS-LITE system interface and the system will also finish the environment self-test automatically.

Network adapter should be correctly installed, or you may not access the CMS-LITE.

3.2 Main Screen

CMS-LITE can display the monitoring data using a single display. CMS-LITE system will enter the main screen after the system starts up.





3.2.1 System Information Area

The hospital information will be displayed in this area.

3.2.2 Patient Sectors

One patient is monitored by a monitor. This monitor will occupy a patient sector when it is connected to the CMS-LITE. The patient sector has the following operating states:

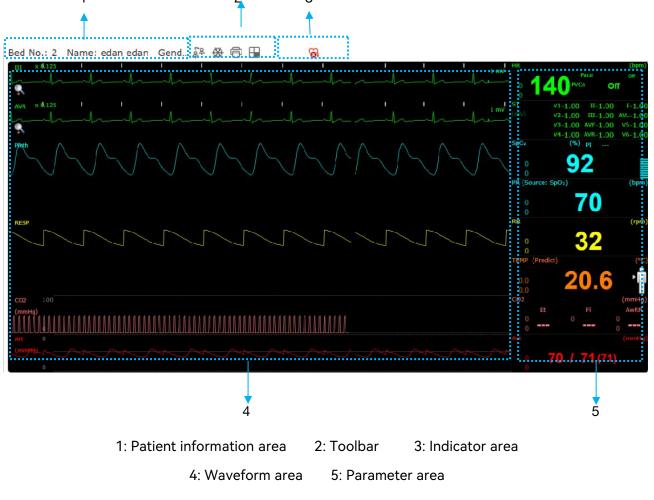
• Monitoring: indicates that the patient is being monitored and the monitor is communicating with the CMS-LITE. Patient information, waveforms, trend data

and alarm information are displayed.

- Network Disconnected: indicates no monitoring device is assigned to this patient sector or this patient sector has been set to idle status. The patient sector is available for admitting a new monitoring device. The gray font **Disconnected** with black background is displayed.
- Improper Offline: indicates that this patient sector has a patient admitted but its corresponding monitor may be turned off or disconnected from the CMS-LITE. Patient information and **Device Offline** with yellow background are displayed. The alarm sound for improper offline will be given out only once.
- Patient discharged: indicates that the patient has been discharged from the monitor or from the CMS-LITE. Bed No. with black ground is displayed.
- Standby: indicates that the monitor is in standby mode. The white font **Standby** with black background is displayed.

Patient Sector in Monitoring State

When a patient sector is in the monitoring state, it displays real-time patient data transmitted from the monitoring device (see below for network related delay), as shown be $\frac{1}{2}$ $\frac{2}{3}$



- 1 Patient information area: displays the bed No., patient name, gender and patient type.
- 2 Toolbar:

| \$ | Switch patient; |
|----|--|
| * | Freeze: Freezing or unfreezing the waveforms displayed in the window; |
| ē | Print: Real-time printing |
| | Screen selection: Select the screen style: ECG multi-lead, trend screen, OxyCRG. |

3 Indicator area: When no prompts occur, the following indicators will be displayed.

| Indicator | Description | Indicator | Description |
|-----------|-------------|-----------|-------------|
| S | Pace on | 6 | Pace off |

- 4 Waveform area: Display real-time waveforms transmitted from a monitor.
- 5 Parameter area: Display real-time parameters transmitted from a monitor.

3.2.3 Quick Control Area

The **Main Menu** key is permanently located at the bottom.

Shortcut keys

The shortcut keys in the quick control area allow you to quickly access some functions.

| Button Button Label | | Function |
|--|-----------|----------------------------------|
| History Patient Review User Maintain | | Enter Patient Review interface. |
| | | Enter the user maintenance menu. |
| £ | Admission | Admit a patient. |

| Button | Button Label | Function |
|--------|--------------|------------------------------|
| Ç | Review | Enter the review interface. |
| ¢ | System Setup | Enter the system setup menu. |

The shortcut keys displayed on the screen are configurable. To configure the desired shortcut keys, follow these steps:

- 1. Access the shortcut keys setup menu in either of the following ways:
 - Select Main Menu
 Setup > System Setup > Shortcut Setup.
 - Select System Setup
 Shortcut Setup.
- 2. Select the desired shortcut key by clicking \checkmark in **Available Shortcuts**. Drag the shortcut key to adjust the sequence. Remove the shortcut key by clicking in **Selected Shortcuts**.

Other On-Screen Keys:

| lcon | Label | Function | |
|----------|---------------------|--|--|
| Ģ | Networking State | Check the server IP address and networking status. : failed to connect to the server. | |
| — | Minimize | Minimize the window. | |
| \times | Close | Shut down the CMS-LITE. | |

Networked State

The networked state window has several panes representing the monitors that can be supported and connected to the CMS-LITE. The pane only displays the bed number.

You can access main interface by clicking on the pane

The pane has the several types of state:

• Blank: Network disconnected.

- Without background and white bed number: Improper offline.
- With green background and white bed number: Networked monitoring.

3.3 Shutting down the System

It is important to shut down the system properly. To prevent inadvertent errors,

please select **Close** on the main menu 😐 to shut down the CMS-LITE.

WARNING

- 1 Shut down the system by strictly observing the shutdown procedure to avoid serious result.
- 2 When using an UPS (optional), do not switch off the UPS by force. Otherwise it can result in a system failure and can affect the future operation of the system.

<u>CAUTION</u>

Hospitals without a stable power source should use a UPS to provide power to the CMS-LITE. The UPS must not be turned off. When there is a power failure, the system should be shut down by following the specified shutdown procedure before the UPS is exhausted. If the system has a sudden power failure, system failure may occur and consequently the system may not work correctly next time.

NOTE:

Contact the service staff if the password is lost.

4 Patient Management

The CMS-LITE provides different patient management capabilities. Consult the system administrator for more authorities.

- Admitting patients
- Viewing patient information
- Deleting history patient

4.1 Admitting a Patient

There are two methods to admit patients, admitting on CMS-LITE/monitors or scanning the patient barcode.

Click Admission in the quick control area or select Main Menu > Patient Management > Admission.

To admit patients by manually entering patient information, manually enter the patient information, select a monitoring device for the patient from **Monitoring Device** drop-down list and then click **Admission**.

To admit patients by scanning barcode/QR Code, Click **Scan Code**. Scan the barcode/QR code of the patient with the scanner.

After admitting patients, the CMS-LITE can display and store the physiological parameters, waveforms, alarm information.

NOTE:

The system only supports USB scanner. The barcode/QR code scanner needs to be procured for and set up separately.

WARNING

For those bedside monitors that have been networked with CMS-LITE for the first time, you have to complete patient admission by using the methods mentioned above, which enables the monitors to be online and managed by CMS-LITE. Otherwise, the monitors will not be online on CMS-LITE, and the monitoring data will not be saved by CMS-LITE.

4.2 Viewing the Patient Information

When the patient is admitted by the CMS-LITE, the patient information can be viewed.

The patient information include Bed No., MRN, last name, first name and so on.

On the **Patient Management** tab sheet, select **Monitoring Summary** to display the statistical results of monitoring data during the current patient monitoring period, including monitoring time, physiological alarm times, arrhythmia alarm times, waveform storage duration, trend storage duration, NIBP measurement times, TEMP measurement times and PAWP measurement times.

4.3 Deleting the History Patient

Click The and enter the required password to delete the selected history patient data.

5 Review

The user can review historical data for online patients and discharged patients in the review interface. The review interface provides several tabs to display historical data from different aspects. To access the review interface of online patients, select the **Review** shortcut key in the quick control area, select **Main Menu** > **Review** > choose the specific review item or switch Tab in single bed interface; To

access the review interface of discharged patients, select **Main Menu Patient Review** > **History Patient Review**. The review tabs for the online patients and discharged patients are the same.

5.1 History Patient Review

Select **Main Menu > Review** > **History Patient Review** to access the history patient review interface. The user can select:

History Patient Review: review the historical patient data. In the history patient review interface:

Enter the key words to display the patients that meet the search conditions. Click

 \bigcirc to update the patient list data to the latest.

Select a specific patient and click specific tab to review the data from different aspects.

Review the online patient history data of other departments if the permission is granted. Consult the system administrator for more authorities.

Click III and enter the required password to delete the selected history patient data.

 Backup Data Import: review the patient data stored in the backup file directory. In the backup data import interface:

Click Like, select the directory where the backup files are stored and click **Confirm**.

After successful import, the user can view the patient's monitoring data in the history patient review interface.

NOTE:

1 It takes time for CMS-LITE to load the backup data, wait for a while. The

specific time depends on the amount of data.

- 2 During reviewing backup data, discharging or deleting patients is unavailable.
- **Data Import**: review the patient data imported from USB flash disk. For importing the data from H100B/H100N, connect the H100B/100N to PC through data cable.

| Symbol | Description |
|-------------------|--|
| Let (blue symbol) | Review the patient's current monitoring data. |
| (white symbol) | Review the patient's historical monitoring data. |

In the data import interface:

- Click , the system will automatically identify the file directory in MCD format in the USB flash disk for loading.
- After selecting the file (multiple options), click $\stackrel{\bullet}{\rightharpoonup}$ to import.
- After successful import, the user can view the patient's monitoring data in the history patient review interface.

NOTE:

- 1 The following monitoring devices support USB flash disk importing: (Mx 1.2 version or above) iM50, iM60, iM70, iM80, elite V8, elite V6, elite V5, X series, iM3 and iM20.
- 2 When reviewing the patient trend data imported from the USB flash disk, it is recommended to set the resolution to more than 1 minute.
- 3 It is recommended to use a compatible cable for importing data from H100B/H100N to CMS-LITE.

5.2 Alarm Review

Click the **Alarm Review** tab to review the physiological alarm events within most recent 720 hours.

NOTE:

When the user views the patient alarm review information of a device, the Alarm Level, Event Type and Select Parameter will be consistent with the last settings to the patient.

5.2.1 Alarm List

The alarm events are displayed in descending chronological order. The most recent alarm event is displayed at the top. The number of asterisk symbols before an event matches different alarm levels, refer to Section *Alarm Indications*. Event lock status, trigger time, end time, and alarm level with different color background are displayed for each event.

Sequencing the Alarm List

The user can sequence all alarms in ascending or descending order by clicking on the heading of following column:

- Alarm Time: Sequencing all alarms in ascending or descending order by occurring time.
- End Time: Sequencing all alarms in ascending or descending order by ending time.
- Alarm Level: Sequencing all alarms in ascending or descending order by level.
- Lock: Sequencing all alarms by lock status.

At the same time, one of the following symbols will appear on the bottom of the heading:

- The symbol ▲ indicates ascending sequence, and
- The symbol ▼ indicates descending sequence.

Filtering Alarm Events

The user can filter alarm events by **Event Type**, **Alarm Level**, and **Select Parameter**. By clicking \checkmark next to them, the user can select event type, alarm level, and parameters. The combination of selected filter criteria is used to filter events. Events after filtering will be displayed in the event list.

Locking and Unlocking Alarm Event

Select an event from the list and mark it with a symbol $\sqrt{}$ on the alarm review interface when the user thinks that the alarm is very important. The locked alarm cannot be deleted automatically. The locked event needs to be unlocked before being deleted. The user can click the symbol $\sqrt{}$ to unlock the locked alarm.

5.2.2 Alarm Event Detail Window

Enter the alarm event detail window by selecting an event from the list.

In the alarm event detail window:

- The upper half of the window displays:
 - Alarm parameter name and values in large font;
 - All valid parameter values at alarm triggered time;
 - Alarm notes.
- The lower half of the window displays 8 seconds (default) of waveforms (sweep: 25 mm/s) before and after the alarm triggered time. According to the actual needs, click on Waveform Length and select the alarm review waveform length in the drop-down list.
- Click Select Parameter and choose the alarm parameters to be displayed in the window.
- The waveform to be displayed in the window can be selected by Select Wave. If the selected alarm parameter has no waveform, the window does not display waveform data by default.
- Click O to update the alarm list data to the latest.

Annotating Alarm

The user can enter notes for the alarm event. Up to 64 characters can be entered.

Alarm Message Annotation will be displayed in the alarm review interface, move the mouse pointer to the title Alarm Message Annotation. When notes are available, an I-beam | is displayed in the text entry field. After completing the notes, move the mouse pointer elsewhere, and the notes will be automatically saved.

5.2.3 Printing Alarm List/Events

To print alarm list or events, follow these steps:

- 1. Click the Alarm Review tab to enter the tab sheet.
- 2. Click Print.
- 3. Select the desired option from the drop-down list.
 - Print Alarm List: print the entire alarm event list.
 - **Print Alarm Information**: print the details of the selected alarm event.

In the Print Preview interface, the user can click **Export** to export the alarm event list or detailed alarm information and can also click **Print** to print the alarm event list or detailed alarm information.

5.3 Trend Review

Click the **Trend Review** tab to review the selected patient data in trend graph and trend table within most recent 720 hours. When the user views the patient wave review information of a device, the **Resolution setting**, **Review Length Setup** and **Param Select** will be consistent with the last settings to the patient.

In the trend review window:

- Select Trend Table to review the trend table only. Select Trend Graph to review the trend graph only. Select Trend Table, Trend Graph to review the trend table and trend graph simultaneously.
- For trend table, click Resolution setting and select the desired option to change the interval of the trend data. Among these options, selecting NIBP Measurement Time, TEMP Measurement Time, or Display Time Points for PAWP Measurement means to view the trend table when NIBP, TEMP, PAWP measurements were acquired. When the time interval is set to 1 s, 5 s, 30 s, 1 min, 5 min, 15 min, 30 min, 60 min, 120 min, 180 min and 240 min, the system will automatically adjust the next measurement time review data. For example, if the time interval is set to 30 min, and the start time 12:03, the next review time will be 12:30, and then at 13:00, 13:30, and so on. Beside, the trend table will display NIBP measurement data with hour and minute. NIBP Measurement Time merges the most recent valid parameter data within the same minute into the NIBP time column for the current minute. When there are multiple sets of NIBP data in the same minute, all are displayed in chronological order.
- For trend graph, select **Review Length Setup** to change the length of trend data displayed on the current screen. The y-axis scale will automatically adjust according to the value within x-axis time, in order to achieve the optimum display effect.
- Click Select Parameter to enter the Param Group Setup interface. Refer to Section *Trend Review* for the related settings.
- Select Trend Table Time Setup to set the start time of the trend table and Trend
 Graph Time Setup to set the start time of the trend graph.
- Double click the specific column in the trend table to mark the time, after which the system jumps to the waveform review window and displays the waveform data for the marked time.
- Select Print > Print Trend Table or Print Trend Graph to print the trend data in the current window. In the print preview interface, the user can click Export to export the trend data and can also click Print to print the trend data. In Printer Setup menu,

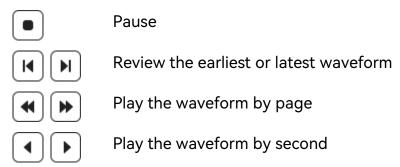
• Select \bigcirc to update the trend data to the latest.

5.4 Waveform Review

Click the **Waveform Review** tab to review the waveform data for the selected patient within most recent 720 hours. When the user reviews the waveform of the certain patient, then select **Wave** and **Sweep** will be consistent with the last settings to the patient.

Timeline and waveforms are displayed in the left part of the window. Parameter values are displayed in the right part of the window.

The user can click the button in the play control bar to review the waveform data in different forms or drag the scroll bar at the bottom to review the desired waveform.



In the waveform review window:

- Select Show Parameters/Hide Parameters to show or hide the related parameter values in the right part of the window.
- Click Select Wave to enter the Param Group Setup interface.
 - Select the parameters to be displayed. After exiting the setup interface, the waveform of the corresponding parameter will be displayed in the waveform review window.
 - Select the parameters to be displayed. Click Create Param Group, the user can create customized parameter groups based on the selected parameters. Click to set the parameter group name. Click to save settings. Click to remove the parameter group from the list.
 - Select the parameter group in **Current Param Group**. After exiting the setup interface, the waveform of the corresponding parameter will be displayed in the waveform review window.

- Click **Sweep** to select the desired waveform speed from the drop-down list.
- Select **Time Setup** to set the start time of the waveform during the monitoring time.
- Select to print the waveform displayed on the current screen. In the print preview interface, the user can click **Export** to export the waveform and can also click **Print** to print the waveform.
- Click C to update the waveform data to the latest.
- Drag the mouse on the selected waveform to measure the time length of the waveform.

5.5 ECG Review

Click the **ECG Review** tab to review the ECG full size waveforms or ECG compressed waveforms for each patient. When the user views the patient wave review information of a device, then select **Wave**, **Sweep** and **ECG Compressed Wave** will be consistent with the last settings to the patient. Meanwhile, the CMS-LITE supports to convert the raw data collected by the monitoring device to static or dynamic ECG data, and users can view the analysis reports generated by EDAN ECG workstation and ECG network.

5.5.1 ECG Full Size Waveforms

Click **ECG Review** to view the ECG full size waveform for the selected patient within most recent 720 hours. Timeline and waveforms are displayed in the left part of the window. Parameter values are displayed in the right part of the window.

In the ECG full size waveform window:

- Select ECG Compressed Waveform to switch to the ECG compressed waveform window.
- Select Show Parameters/Hide Parameters to show or hide the related parameter values in the right part of the window.
- Click **Sweep** to select the desired waveform speed from the drop-down list.
- Select Print > Waveform Print to print the waveform displayed on the current screen. In the print preview interface, the user can click Export to export the waveform and can also click Print to print the waveform.
- Click C to update the waveform data to the latest.

Drag the mouse on the selected waveform to measure the time length of the waveform.

5.5.2 ECG Compressed Waveforms

Click **ECG Compressed Waveform** to view the ECG compressed waveform for the selected patient. The start time and end time of the waveform in the current screen are displayed at the top of the window. The start time of the waveform in each line is displayed before the waveform.

In the ECG compressed waveform window:

- Select **Full Size Waveform** to switch to the full size waveform window.
- Click Select Wave to choose the required waveforms to be displayed in this window.
- Click **Sweep** to select the desired waveform speed from the drop-down list.
- Click anywhere in the compressed waveform area to amplify 5 seconds of waveform segment (sweep: 25 mm/s) before and after the selected time. All valid parameter values at the selected time are displayed as well.
- Double click the compressed waveform area to select multiple compressed waveform segments. Press the up and down keys on the keyboard to select the compressed waveform segment and display the corresponding amplified waveform.
- Select Print > Print current one segment or Print multi-segment to print the current one segment or multiple segments displayed on the current screen. Select Cancel multi-segment selection to deselect the segments. In the print preview interface, the user can click Export to export the waveform segments and can also click Print to print the waveform segments.
- Select \bigcirc to update the waveform data to the latest.

5.6 NIBP Review

Click the **NIBP Review** tab to review the NIBP measurement data of the selected patient within most recent 720 hours.

In the NIBP review window:

Select Show Parameters/Hide Parameters to show or hide 8 seconds of all related parameter values before and after the NIBP measurement time. •

- Select Print All/Print Current Page to print all pages or the current page. In the print preview interface, the user can click Export to export the NIBP measurement data and can also click Print to print the NIBP measurement data.
- Select
 O
 to update the NIBP data to the latest.

6 Calculation

CMS-LITE provides functions including drug calculation and titration table, hemodynamic calculation, oxygenation calculation, renal function calculation and ventilation calculation. Click the patient sector area and select the **Calculation** tab on the auxiliary screen to access the calculation screen.

A maximum of 720 hours of calculation results can be reviewed on CMS-LITE. The calculation time is displayed on the right part of the calculation screen. The user can select the desired calculation time to view the corresponding calculation result.

In the calculation window:

- Select Get Info to directly obtain the parameter values from the monitoring device.
- Select **Calculate** to output calculation result.
- Select **Save** to store the calculation result.
- Select **Clear All** to empty the input and calculation result.
- Select **Delete** to delete the selected calculation result.
- Select **Print** to print the selected calculation result. In the print preview interface, the user can click **Export** to export the calculation result and can also click **Print** to print the calculation result.

WARNING

- 1 The input or operation errors may result in incorrect calculation results which may put the health of the patient at risk. The correctness of the input parameters and the suitability of the calculated results should thus be carefully verified by appropriate means.
- 2 The calculations in the titration table are subject to the drug calculations, therefore, always ensure the correctness of the drug calculations and confirm the basic, step and dose type. Otherwise, incorrect calculation result may occur. These are mere mathematical tools and neither shall nor may replace adequate review by a physician in each individual case.
- 3 The calculation results are for reference only and the calculation significance must be determined by the physician. Do not rely exclusively on the system to avoid patient injuries.

6.1 Drug Calculation

 From the Drug drop-down list, you can select one to calculate its amount, liquid volume, concentration, etc.

- Drug A
- Drug B
- Drug C
- Drug D
- Drug E
- Aminophylline
- Dobutamine
- Dopamine
- Epinephrine
- ♦ Heparin
- Isuprel
- ♦ Lidocaine
- Nipride
- Nitroglycerin
- Pitocin

NOTE:

Drug A, Drug B, Drug C, Drug D and Drug E are user-defined drugs.

The calculation procedure is listed below:

- 1. Confirm whether the patient type is correct and the weight is entered.
- 2. Select a drug to be calculated from the drug list.
- 3. Input correct parameter values under the direction of a doctor.
- 4. Select **Basic**, **Dose Type** and **Step** for titration table.
- 5. Click on the **Calculation** button, the calculation result will be displayed in the drug parameter area and titration table.

6.1.1 Drug Calculation Formula

Formulas for drug calculation are:

```
Concentration = Amount / Volume
```

Inf. Rate = Dose / Concentration Duration = Amount / Dose Dose= Inf. Rate × Concentration Dose (weight based) = Inf. Rate × Concentration / Weight Drip Rate = Inf. Rate / 60 × Drop Factor Dose/min = Dose/hr/60 Dose/kg/min = Dose/min/Weight Dose/kg/hr = Dose/kg/min×60 NOTE:

Drip Rate and Drop Factor are not available in the neonate mode.

WARNING

Inappropriate formula may result in incorrect calculation results. Prior to performing drug calculation, you must confirm that the above formulas are what you need. These are mere mathematical tools and neither shall nor may replace adequate review by a physician in each individual case.

Relationship between calculation units:

```
1 g = 1000 mg
```

1 mg = 1000 mcg

1 M unit = 1000 K units

6.1.2 Titration Table

The titration table shows information on the currently used drugs. The user can view the drug dose that will be applied to the patient at different infusion rates. The titration table is located at the middle part of the drug calculation screen.

6.2 Hemodynamic Calculation

6.2.1 Input Parameters

| ltems | Unit | English Full Name/Description |
|-------|------|---------------------------------|
| PAWP | mmHg | Pulmonary artery wedge pressure |

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| ltems | Unit | English Full Name/Description |
|--------|-------|--------------------------------|
| CVP | mmHg | Central venous pressure |
| C.O. | L/min | Cardiac output |
| HR | bpm | Heart rate |
| EDV | ml | End-diastolic volume |
| AP MAP | mmHg | Mean Artery Pressure |
| PA MAP | mmHg | Pulmonary artery mean pressure |
| PAP | mmHg | Pulmonary artery pressure |
| Height | cm | 1 |
| Weight | kg | / |

6.2.2 Output Parameters

| Items | Unit | English Full Name/Description | Formula |
|-------|----------------------|-------------------------------------|---|
| CI | L/min/m ² | Cardiac index | Cl (L/min/m ²) = C.O. (L/min)/BSA (m ²) |
| BSA | m ² | Body surface area | BSA (m ²) = Weight ^{0.425} (kg) × Height ^{0.725} (cm) × 0.007184 |
| SV | ml | Stroke volume | SV (ml) = C.O. (L/min)/HR (bpm) × 1000 |
| SVI | ml/m ² | Stroke volume index | SVI (ml/m ²) = SV (ml)/BSA (m ²) |
| SVR | DS/cm⁵ | Systemic vascular resistance | SVR (DS/cm ⁵) = 80 × [AP MAP (mmHg) - CVP (mmHg)]/C.O. (L/min) |
| SVRI | DS · m²/cm⁵ | Systemic vascular resistance index | SVRI ($DS \cdot m^2/cm^5$) = SVR (DS/cm^5) × BSA (m^2) |
| PVR | DS/cm⁵ | Pulmonary vascular resistance | PVR (DS/cm ⁵) = 80 × [PA MAP (mmHg) – PAWP (mmHg)]/C.O. (L/min) |
| PVRI | DS · m²/cm⁵ | Pulmonary vascular resistance index | PVRI (DS \cdot m ² /cm ⁵) = PVR (DS/cm ⁵) × BSA (m ²) |

Calculation

| ltems | Unit | English Full Name/Description | Formula |
|-------|---------|-------------------------------------|---|
| LCW | kg∙m | Left cardiac work | LCW (kg·m) = 0.0136 × [AP MAP (mmHg) - PAWP (mmHg)] × C.O. (L/min) |
| LCWI | kg∙m/m² | Left cardiac work index | LCWI (kg \cdot m/m ²) = LCW (kg \cdot m)/BSA (m ²) |
| RCW | kg∙m | Right cardiac work | RCW (kg · m) = 0.0136 × [PA MAP (mmHg) - CVP (mmHg)] × C.O. (L/min) |
| RCWI | kg∙m/m² | Right cardiac work index | RCWI (kg \cdot m/m ²) = RCW (kg \cdot m)/BSA (m ²) |
| LVSW | g∙m | Left ventricular stroke work | LVSW (g·m) = 0.0136 × [AP MAP (mmHg) - PAWP (mmHg)] × SV (ml) |
| LVSWI | g·m/m² | Left ventricular stroke work index | LVSWI $(g \cdot m/m^2) = LVSW$ $(g \cdot m)/BSA (m^2)$ |
| RVSW | g∙m | Right ventricular stroke work | RVSW (g · m) = 0.0136 × [PA MAP (mmHg) - CVP (mmHg)] × SV (ml) |
| RVSWI | g·m/m² | Right ventricular stroke work index | RVSWI $(g \cdot m/m^2) = RVSW$ $(g \cdot m)/BSA (m^2)$ |
| EF | % | Ejection fraction | EF (%) = SV (ml)/EDV (ml) × 100 |

6.3 Renal Function Calculation

6.3.1 Input Parameters

| Items | Unit | English Full Name/Description |
|-------|-------------------------|-------------------------------|
| URK | mmol/L | Urine potassium |
| URNa | mmol/L | Urinary sodium |
| Urine | ml/24h | Urine |
| Posm | mOsm/kgH ₂ O | Plasm osmolality |
| Uosm | mOsm/kgH ₂ O | Urine osmolality |

| ltems | Unit | English Full Name/Description |
|-------|--------|-------------------------------|
| SerNa | mmol/L | Serum sodium |
| SCr | µmol/L | Serum creatinine |
| UCr | µmol/L | Urine creatinine |
| BUN | mmol/L | Blood urea nitrogen |
| UUN | mmol/L | Urine urea nitrogen |

6.3.2 Output Parameters

| ltems | Unit | English Full Name/Description | Formula |
|-------------------|----------|--|---|
| URNaEx | mmol/24h | Urine sodium excretion | URNaEx (mmol/24h) = URNa (mmol/L) × Urine (ml/24h)/1000 |
| URKEx | mmol/24h | Urine potassium excretion | URKEx (mmol/24h) = URK (mmol/L) × Urine (ml/24h)/1000 |
| Na/K | % | Sodium potassium ratio | Na/K (%) = URNa (mmol/L)/URK (mmol/L) × 100 |
| CNa | ml/24h | Clearance of sodium | CNa (ml/24h) = URNa (mmol/L) × Urine (ml/24h)/SerNa (mmol/L) |
| CCr | ml/min | Creatinine clearance rate | CCr (ml/min) = UCr (µmol/L) × Urine (ml/24h)/[SCr (µmol/L) × 24 × 60] |
| CUUN | ml/min | Urine urea nitrogen clearance rate | CUUN (ml/min) = UUN (mmol/L) × Urine (ml/24h)/[BUN (mmol/L) × 24 × 60] |
| FENa | % | Fractional excretion of sodium | FENa (%) = [URNa (mmol/L) × SCr (µmol/L)]/[Ucr (µmol/L) × SerNa (mmol/L)] × 100 |
| FEUr | % | Fractional Excretion of Urea | FEUr (%) = [SCr (μmol/L) × UUN (mmol/L)]/[UCr (μmol/L) × BUN (mmol/L)] × 100 |
| Cosm | ml/min | Osmolar clearance | $\begin{array}{llllllllllllllllllllllllllllllllllll$ |
| CH ₂ O | ml/24h | Free water clearance | $\begin{array}{llllllllllllllllllllllllllllllllllll$ |
| U/P osm | / | Urine to plasma osmolality ratio | U/P osm = Uosm (mOsm/kgH ₂ O)/Posm |

| ltems | Unit | English Full Name/Description | Formula |
|---------|------|--|---|
| | | | (mOsm/kgH ₂ O) |
| BUN/SCr | / | Blood urea nitrogen creatinine ratio | BUN/SCr = [BUN (mmol/L)/SCr (µmol/L)] × 1000 |
| U/SCr | / | Urine-serum creatinine ratio | U/SCr = UCr (µmol/L)/SCr (µmol/L) |

6.4 Oxygenation Calculation

6.4.1 Input Parameters

| ltems | Unit | English Full Name/Description |
|-------------------|-------|--|
| FiO ₂ | % | Percentage fraction of inspired oxygen |
| PaO ₂ | mmHg | Partial pressure of oxygen in the arteries |
| PaCO ₂ | mmHg | Partial pressure of carbon dioxide in the arteries |
| SaO ₂ | % | Arterial oxygen saturation |
| PvO ₂ | mmHg | Partial pressure of oxygen in venous blood |
| SvO ₂ | % | Venous oxygen saturation |
| Hb | g/L | Hemoglobin |
| RQ | 1 | Respiratory quotient |
| ATMP | mmHg | Atmospheric pressure |
| C.O. | L/min | Cardiac output |
| Height | cm | 1 |
| Weight | kg | 1 |

6.4.2 Output Parameters

| ltems | Unit | English Full Name/Description | Formula |
|-----------------|--------|----------------------------------|---|
| BSA | m² | Body surface area | BSA (m ²) = Weight ^{0.425} (kg) × Height ^{0.725} (cm) × 0.007184 |
| VO ₂ | ml/min | Oxygen consumption | VO_2 (ml/min) = Ca-vO ₂ (ml/L) × C.O. (L/min) |

| ltems | Unit | English Full Name/Description | Formula |
|-------------------------------------|----------|---|---|
| Ca-vO ₂ | ml/L | Arteriovenous oxygen content difference | $Ca-vO_2 (ml/L) = CaO_2 (ml/L) - CvO_2 (ml/L)$ |
| O ₂ ER | % | Oxygen extraction ratio | $O_2 ER$ (%) = VO_2 (ml/min)/DO ₂ (ml/min) × 100 |
| DO ₂ | ml/min | Oxygen transport | DO_2 (ml/min) = CaO_2 (ml/L) × C.O. (L/min) |
| PAO ₂ | mmHg | Partial pressure of oxygen in the alveoli | PAO ₂ (mmHg) = [ATMP (mmHg) - 47 mmHg] × FiO_2 (%)/100 - PaCO ₂ (mmHg) × [FiO_2 (%)/100 + (1 - FiO_2 (%)/100)/RQ] |
| AaDO ₂ | mmHg | Alveolar-arterial oxygen difference | $AaDO_2 (mmHg) = PAO_2 (mmHg)$ - $PaO_2 (mmHg)$ |
| CcO ₂ | ml/L | Capillary oxygen content | $CcO_2 (ml/L) = Hb (g/L) \times 1.34 + 0.031 \times PAO_2 (mmHg)$ |
| Qs/Qt | % | Venous admixture | Qs/Qt (%) = $[CcO_2 (ml/L) - CaO_2 (ml/L)]/[CcO_2 (ml/L) - CvO_2 (ml/L)] × 100$ |
| AaDO ₂ /PaO ₂ | / | AaDO ₂ /PaO ₂ | $AaDO_2/PaO_2 = [PAO_2 (mmHg) - PaO_2 (mmHg)]/PaO_2 (mmHg)$ |
| DO ₂ I | ml/min/m | Oxygen delivery index | DO_2I (ml/min/m ²) = DO_2 (ml/min)/BSA (m ²) |
| VO ₂ I | ml/min/m | Oxygen consumption index | VO_2I (ml/min/m ²) = VO_2 (ml/min)/BSA (m ²) |
| CaO ₂ | ml/L | Arterial oxygen content | CaO ₂ (ml/L) = 100 ×1.34 × Hb (g/L) × SaO ₂ (%)/100 + 0.031 × PaO ₂ (mmHg) |
| CvO ₂ | ml/L | Venous oxygen content | $CvO_2 (ml/L) = 100 \times 1.34 \times Hb$ (g/L) × SvO ₂ (%)/100 + 0.031 × $PvO_2 (mmHg)$ |

6.5 Ventilation Calculation

6.5.1 Input Parameters

| ltems | Unit | English Full Name/Description |
|------------------|------|--|
| FiO ₂ | % | Percentage fraction of inspired oxygen |

| ltems | Unit | English Full Name/Description |
|-------------------|------|--|
| RR | rpm | Respiration rate |
| PeCO ₂ | mmHg | Partial pressure of mixed expiratory CO ₂ |
| PaCO ₂ | mmHg | Partial pressure of carbon dioxide in the arteries |
| PaO ₂ | mmHg | Partial pressure of oxygen in the arteries |
| VT | ml | Tidal volume |
| RQ | / | Respiratory quotient |
| ATMP | mmHg | Atmospheric pressure |

6.5.2 Output Parameters

| ltems | Unit | English Full Name/Description | Formula |
|-------------------------------------|-------|---|---|
| PAO ₂ | mmHg | Partial pressure of oxygen in the alveoli | $PAO_{2} (mmHg) = [ATMP (mmHg) - 47 mmHg] \times FiO_{2} (%)/100 - PaCO_{2} (mmHg) \times [FiO_{2} (%)/100 + (1 - FiO_{2} (%)/100)/RQ]$ |
| AaDO ₂ | mmHg | Alveolar-arterial oxygen difference | $AaDO_2 (mmHg) = PAO_2 (mmHg) - PaO_2 (mmHg)$ |
| AaDO ₂ /PaO ₂ | / | AaDO ₂ /PaO ₂ | $AaDO_2/PaO_2 = [PAO_2 (mmHg) - PaO_2 (mmHg)]/PaO_2 (mmHg)$ |
| MV | L/min | Minute volume | MV (L/min) = VT (ml) × RR (rpm)/1000 |
| VD | ml | Volume of physiological dead space | VD (ml) = $[(PaCO_2 (mmHg) - PeCO_2 (mmHg) \times VT (ml)]/PaCO_2 (mmHg)$ |
| VD/VT | % | Physiological dead space in percent of tidal volume | VD/VT (%) = $[PaCO_2 (mmHg) - PeCO_2 (mmHg)]/PaCO_2 (mmHg) \times 100$ |
| VA | L/min | Alveolar volume | VA (L/min) = [VT(ml) - VD(ml)] × RR (rpm)/1000 |

7 System Setup

The CMS-LITE comes with factory defaults. The user can make changes to the configuration items in line with provided options and functionalities. Certain authority is required if the user wants to modify some system configurations. CMS-LITE can be configured to restrict controls and access based on user role. Consult the system administrator for more details.

Select the **System Setup** shortcut key in the quick control area to enter the system setup tab sheet. **NOTE:**

Settings in User Maintain are password protected, which is intended for use only by authorized personnel.

7.1 Hospital Information Setup

In the **System Setup** interface, the user can select **Hospital Information Setup** to set the hospital name and Logo.

7.2 Display Setup

In the **System Setup** interface, the user can select **Display Grid** to display the grid in the waveform area.

7.3 Setting Parameter Units

The user can set the unit for each parameter as required. To set the desired parameter units, follow these steps:

- 1. In the System Setup tab sheet, select Param Unit Setup.
- 2. Select a parameter and choose the desired unit from the drop-down list.

7.4 Setting Parameter Colors

The user can set the display colors of parameters as desired. Parameter-related information such as parameter values and waveforms are displayed in the same color on the screen.

To set the desired parameter colors, follow these steps:

1. In the System Setup tab sheet, select Param Color Setup.

2. Select a parameter, choose the desired color from the color box on the left side, and click **OK** to make the settings effective; or select **Restore the Default** to restore default settings.

WARNING

Certain color settings may impair readability of certain values. Ensure the color is easily recognized; otherwise it may put the health of the patient at risk.

7.5 Printing Settings

To set double-sided printing, in the **System Setup** page, select **Print Setup**, switch on the **Duplex Print**. The default setting is off.

8 User Maintain

Enter the required password to access the user maintenance menu to set the language and patient key information, etc.

8.1 Setting Language

The user can select the desired language.

To set the language, follow these steps:

- 1. In the User Maintain tab sheet, select Language Setup.
- 2. Select the desired language from the drop-down list. Setting will take effect immediately.

8.2 Monitoring Device Management

Select **Monitoring Device Management** in the **User Maintain** tab sheet to show the department device list. Clicking the heading of any column sorts the list in ascending or descending order.

In the monitoring device management window:

- Click I to set the Device Name, Device Model, and Device SN. Click I to save the settings.
- Click

 to add device to the department device list. Click Confirm after selecting the specific device and department.
- Click U to delete the device from the department device list. Click Confirm after selecting the specific device.

8.3 Patient Information Items Management

Select **User Maintain > Manage Patient Info. Items** to display the patient information items. The default patient information items include: Bed No., MRN, patient last name, patient first name, gender, patient type, blood type, pace analysis, date of birth, date of admission, height, weight, doctor name, and department.

In the patient information items management window,

1. Click I to create the customized patient information items as needed. Up to 6 new customized information items can be created. Click I to delete customized

patient information items after the confirmation.

- **Text**: enter the name and click **Confirm**.
- Numeric: enter the Name, Unit, Resolution, and Range and click Confirm.
- Option: enter the Name and click Add. Double-click the option entry box tomodify the name. Click Confirm. The user can also select an option as the default option; Click Move up or Move down to adjust the option's location; click Delete to delete the selected option.
- 2. Select the patient information item that needs to be displayed. After clicking \square , the information item will be displayed in the patient management, patient admission page and all printed patient information. Bed No., patient type, date of admission, pace analysis, department, date of birth, and MRN are always displayed and the user cannot hide them.
- 3. Click it is select the patient key information items as desired. Click **Save** and the patient key information will be marked with * in the patient information window.

8.4 Bar Code Settings

Select **Bar Code Setting** to set the start and end codes. Otherwise the barcode cannot be recognized correctly. After setting start and end codes, user may also set male code and female code to distinguish the gender of the patient.

8.5 About

By selecting **User Maintain > About**, the user can view the system information such as the Client Version Information and Server List.

9 Printing

9.1 Printing Report with a Printer

NOTE:

Ensure the printer is properly installed before use. For more details about the printer, refer to the document accompanying the printer.

CMS-LITE can be connected to a printer to output reports on A4 paper. HP LaserJet Series printers are recommended. The printer has its independent power supply. It is connected to the host via a USB interface or a network (wired or wireless).

9.2 Printing Preview/ Printing Settings

9.2.1 Printing Preview

Click on **Print** on the preview interface. If a report consists of more than one page, the user may select a certain page to preview by entering the page or turning the page. Besides, the user can adjust the zoom setting by choosing a certain option from the drop-down list of the **SIZE**.

9.2.2 Printing Settings

In the setup menu, select the **Printer Name**, **Paper Type**, **Copies** and then click **OK** to print out the report. To set double-sided printing, in the **System Setup** page, select **Print Setup**, switch on the **Duplex Print**. The default setting is off.

9.3 Export of PDF Files

CMS-LITE can export the PDF files by installing a PDF printer software. The software PDFCreator is recommended. The user can obtain the installation version of PDFCreator on the CMS-LITE installation disk or download it from the website http://www.pdfforge.org/.

To export the PDF file, choose a PDF printer (for instance, PDFCreator) from the drop-down list of the **Printer Name**, and then click **Export**.

10 Maintenance

EDAN recommends that all repairs are carried out by trained service personnel and that only authentic EDAN repair parts are used. Using non-EDAN repair parts may adversely affect the operation of the device.

If the product fails to function properly, or if assistance is needed, for service and for spare parts, contact EDAN's service center. A representative will assist in troubleshooting the problem.

If the user has any questions about maintenance, technical specifications, or malfunctions of devices, contact the local distributor.

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

WARNING

To avoid risks for the health of the patient, go to the corresponding primary bedside monitor to confirm the patient condition when there is communication failure.

<u>CAUTION</u>

- 1 The safety checks or maintenance involving any disassembly of the CMS-LITE should be performed by professional service personnel. Otherwise, undue equipment failure and possible health hazards could result. If needed, contact EDAN for information concerning the repair of the CMS-LITE.
- 2 The maintenance operations such as software upgrade resulting from OS update shall only be conducted by EDAN-qualified service professionals. Otherwise, undue equipment failure and possible health hazards could result.

10.1 Regular Inspection

Every 24 months a regular inspection (functional and safety check) according to IEC 60950 for the PC is recommended to be performed by trained service personnel to ensure its reliability, in addition to national regulations and laws (for example, accident prevention regulations).

The following items should be checked:

- If the environmental condition and power supply meet requirements.
- If the power supply cord is damaged and the insulation is not cut.

- If the device and accessories are damaged.
- If the sound system works properly.
- If each function of the system is in good condition.

If any damage or abnormality is found, do not use the system and contact customer support.

10.2 Cleaning

Regular dust cleaning is recommended by users at least every four months. If you are in an area that is heavily polluted or dusty, the equipment should be cleaned more frequently.

<u>CAUTION</u>

- 1 To avoid the risk of short circuit, shut down and disconnect CMS-LITE from the mains power before cleaning the device.
- 2 To avoid device malfunction, never immerse any part of the CMS-LITE in liquids or allow liquid to enter the interior. If liquids are spilled on the device or accessories, or they are accidentally immersed in liquid, contact service personnel immediately.
- 3 To avoid the device malfunction, check the device after cleaning. Do not use it if there is any sign of damage.

NOTE:

- 1 Defective components should only be replaced by EDAN original spare parts.
- 2 The UPS battery needs exchanging every two years.

Appendix I Specifications

A1.1 Environment Specification

| Temperature | |
|-----------------------|-----------------------------------|
| Working | +5 °C to +40 °C (+41 °F ~+104 °F) |
| Transport and Storage | -20 °C to +55 °C (-4 °F ~+131 °F) |
| Humidity | |
| Working | 15%RH ~ 95%RH (non-condensing) |
| Transport and Storage | 15%RH ~ 95%RH (non-condensing) |
| Altitude | |
| Working | 70 kPa ~ 106 kPa |
| Transport and Storage | 70 kPa ~ 106 kPa |

A1.2 Recommended Configuration

The recommended hardware configurations for the CMS-LITE are shown as below.

| Components | Requirements | |
|----------------|---|--|
| System | Meet the IEC/EN control requirements for ITE device | |
| PC workstation | CPU: Intel Core i5, 3 rd generation, Dual core 3.1 GHz or above | |
| | Memory: At least 8 G | |
| | Hard disk: At least 1 T | |
| | Display interface: 2 or above (at least one VGA interface and one HDMI interface) | |
| | LAN port: 2 or above | |
| | USB port: 2 or above | |
| | OS: Windows 10 Pro 32/64 bit | |
| Keyboard | PS/2 or USB keyboard with CE mark | |
| Mouse | PS/2 or USB mouse with CE mark | |

| Display | Specifications: | |
|----------------|-------------------------|--|
| | Dimensions (inch) | Resolution (pixel) |
| | 19 (widescreen) | 1440X900 |
| | *19 (regular-screen) | 1280X1024 |
| | 22 (widescreen) | 1920X1080 |
| | *Recommended | |
| Printer | HP LaserJet series | |
| UPS | 1000 W | |
| Network device | Structure | Ethernet 802.3 |
| specifications | Device | Network switch |
| | Transmission rate | 10 M, 100 M |
| | Transmitted information | Waveforms, parameters and alarms of all networked bedside monitors |
| | Compatible monitors | Patient monitors complying with EDAN network protocol |

CAUTION

Ensure that the computer hardware meets the requirements for software installation and operation. Also, the video adapter, the audio adapter, the network adapter and their respective drivers should be installed properly on the computer; otherwise, the software and other components may not run correctly.

NOTE:

- 1 The hardware specifications require the use of PC that complies with IEC/EN requirements for ITE equipment.
- 2 The configuration mentioned above is for reference and not permanent. EDAN preserves the right to change and upgrade system settings.
- 3 It is recommended to install the antivirus software (recommend Kaspersky software) on the computer which is used for CMS-LITE, and also keep it updated in time.

A1.3 Database Capacity

| Database capacity | 40000 patients data | |
|-------------------|---------------------|--|
|-------------------|---------------------|--|

A1.4 Review

| Short trend | Most recent 12 hours of short trends for all parameters |
|-------------------------------|---|
| Trend graph and trend table | Most recent 720 hours of trend graph and trend table for all parameters |
| Full disclosure | Most recent 720 hours of full disclosure waveforms and |
| waveforms | ECG compressed waveforms |
| Physiological alarm events | Most recent 720 hours of the events |
| NIBP review | Most recent 720 hours of NIBP measurement data |
| History patient review | At least 40000 patients data |

A1.5 Print

| Paper type | A4 | |
|------------|-------------------------------------|--|
| Printout | Patient information | Trend table/graph |
| | • Real-time monitoring data | NIBP review |
| | • Alarm list or waveform | Calculation result |
| | Waveform review | Monitoring summary |

Appendix II Abbreviation

| Abbr | English Full Name/Description |
|--------------------|-------------------------------------|
| AG | Anaesthesia gas |
| Art | Arterial |
| AwRR | Airway respiration rate |
| BP | Blood pressure |
| CMS | Central monitoring system |
| CO ₂ | Carbon dioxide |
| CVP | Central venous pressure |
| Des | Desflurane |
| Dia | Diastolic |
| ECG | Electrocardiogram |
| Enf | Enflurane |
| Et | End-tidal |
| EtCO ₂ | End-tidal carbon dioxide |
| EtN ₂ O | End-tidal nitrous oxide |
| EtO ₂ | End-tidal oxygen |
| Fi | Fraction of inspired |
| FiCO ₂ | Fraction of inspired carbon dioxide |
| FiN ₂ O | Fraction of inspired nitrous oxide |
| FiO ₂ | Fraction of inspired oxygen |
| Hal | Halothane |
| Hb | Hemoglobin |
| HR | Heart rate |
| IBP | Invasive blood pressure |

| Abbr | English Full Name/Description |
|------------------|---|
| ICP | Intracranial pressure |
| IEC | International Electrotechnical Commission |
| lso | Isoflurane |
| LAP | Left atrial pressure |
| ΜΑΡ | Mean arterial pressure |
| N ₂ O | Nitrous oxide |
| NIBP | Non-invasive blood pressure |
| O ₂ | Oxygen |
| PA | Pulmonary artery |
| PAWP | Pulmonary artery wedge pressure |
| Pleth | Plethysmogram |
| PR | Pulse rate |
| PVC | Premature ventricular complex |
| RAP | Right atrial pressure |
| Resp | Respiration |
| RR | Respiration Rate |
| Sev | Sevoflurane |
| SpO ₂ | Pulse Oxygen Saturation |
| SYS | Systolic pressure |
| ТВ | Blood Temperature |
| TD | Temperature difference |
| TEMP | Temperature |
| USB | Universal serial bus |

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