dynarex®
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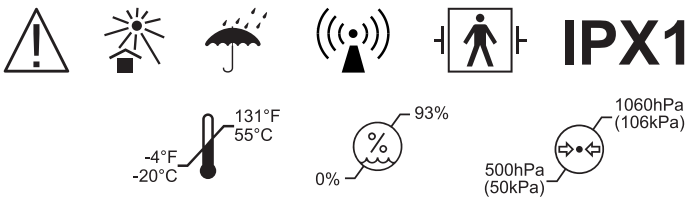
Items 10840 & 10841

Vital Signs Monitor

with SpO_2, Blood Pressure and Temperature Modules User's Manual



℞ Only **CAUTION:** Federal (USA) law prohibits this device to sale by or on the order of a physician.

Not made with natural rubber latex.

Model No. VS1

Manufactured for: Dynarex Corporation • 11 Dynarex Drive • Middletown, NY 10941 • USA • www.dynarex.com
Made in China

ABOUT THIS MANUAL

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance, correct operation, and ensuring patient/operator safety. The manual is geared toward clinical professionals who are expected to have a working knowledge of medical procedures, practices, and terminology as required for monitoring patients. This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact the manufacturer. This manual should be kept close to the device for quick and easy reference..

All illustrations in this manual serve as examples only. They may not reflect the setup or data displayed on your product.

Conventions

- 【】is used to enclose screen texts.
- → is used to indicate operational procedures.

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CHAPTER 1 – GENERAL INTRODUCTION

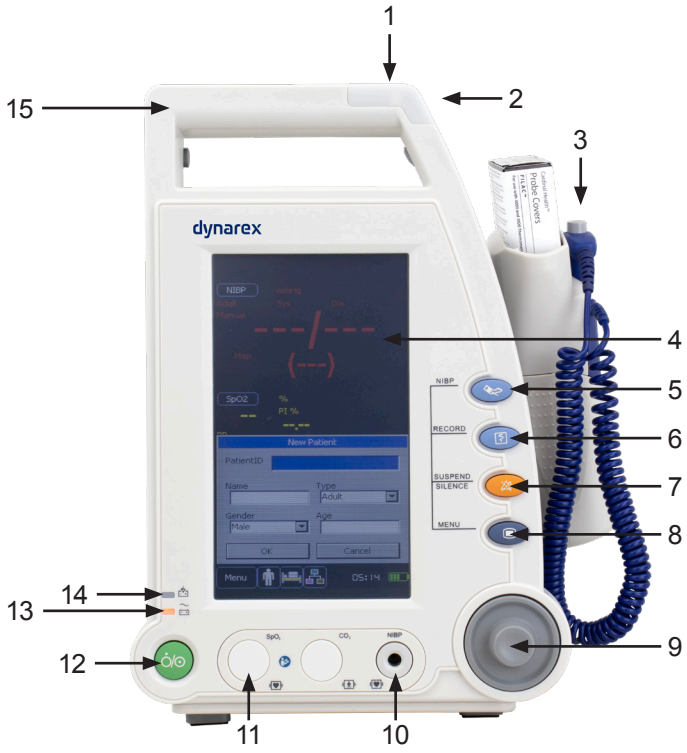
1. INTENDED USE

The vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing, and alarming of multiple physiological parameters of patients, including Pulse Oxygen Saturation (SpO_2), Pulse Rate (PR), Non-Invasive Blood Pressure (NIBP), and Temperature (Temp).

The vital signs monitor is used to monitor vital signals for patients and is suitable for use in hospital environments including outpatient departments and NICU. It is not intended for helicopter transport, ambulances or home use. It's applicable for adult, pediatric and neonatal patients.

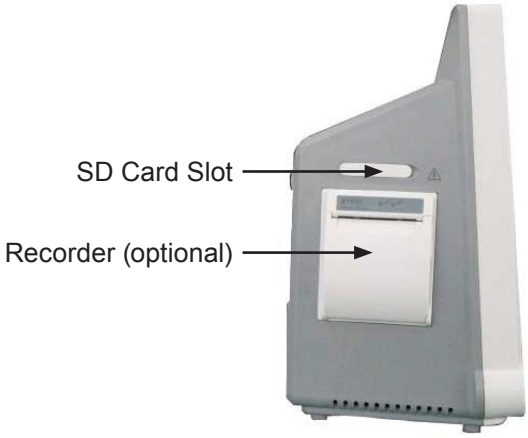
2. MAIN UNIT

FRONT VIEW



REAR VIEW

SIDE VIEW



BOTTOM VIEW

Battery Removal: To remove the battery, simply push the two tabs forward and remove the cover. Push the locking clip and the battery will lift slightly and can be removed by pulling the tab.

Replace Battery: Insert the battery into the compartment and snap into place. Snap bottom cover back into place.

FRONT VIEW

1. Physiological alarm: When a physiological alarm occurs, this lamp will light up as follows:

   High-level alarm: The lamp quickly flashes red.

   Medium-level alarm: The lamp slowly flashes yellow.

   Low-level alarm: The lamp lights yellow without flashing.

2. Technical alarm: When a technical alarm occurs, this lamp will light up as follows:

   Medium-level alarm: The lamp slowly flashes blue.

   Low-level alarm: The lamp lights blue without flashing.

3. Temperature Probe

4. Display Screen

5.  NIBP Button: To start or stop NIBP measurement.

6.  RECORD Button: To start or stop recording.

7.  SUSPEND/SILENCE Button: Press to pause or re-active alarms. Press and hold to silence alarms or device sounds.

8.  MENU Button: Press to change the screen. Press to return to the main screen when a menu is opened.

9. CONTROL KNOB: Turn left or right to move the cursor. Press down on desired operation to input data or change settings.

10. NIBP Connector

11. SpO_2 Connector for 10480 and 10481

12. On/Off Button: Press to turn on after the AC power is connected or the battery is installed. Press and hold to turn off the monitor.

13. Power Indicating Light

    Green: monitor is connected to the AC outlet.

    Orange: monitor is powered by battery only.

14. Battery Charging Indicating Light

    Light up: When the battery is being charged.

    Off: When the battery is fully charged or no battery in monitor.

15. Handle.

REAR VIEW

1. Temperature Connector

2. AC Power Cord Port

3. Serial Port (used for software upgrades)

4. Wired Network Connector Port: Standard RJ45 socket, used for connection with compatible central monitoring system.

5. USB Port: Connect to USB device, such as keyboard, mouse and barcode scanner.

6. Nurse Call Connector: Used for connection with compatible hospital nurse call system.

7. Cooling Fan and Sound Output

CAUTIONS

- All the simulation and digital equipment connected with this monitor must be the products certified by the designated IEC standards (e.g. IEC 60950 Data Processing Equipment Standard and IEC 60601-1 Medical Equipment Standard). All configurations shall abide by the content of the valid edition of IEC 60601-1 System Standard. Connect the additional equipment to the staffing medical system at the input/output signal ports and confirm whether the system conforms to the IEC 60601-1 Standard. If you have any questions, please contact the manufacturer.
- When the signal interfaces are simultaneously connected with multiple equipment, the total leakage caused cannot exceed the tolerance.
- If using a central monitoring system, you must ensure compatibility with this unit.

3. WORKING MODES

- **CLINIC MODE** – used for the monitoring of several patients. Each patient has his/her own ID number and the monitoring results are saved according to their ID numbers. When a patient with the same ID number appears again, the monitor will automatically locate the previous monitoring data and will add current data to the previous one. Remote monitoring (connection to the central unit network) is available with this mode.
- **MONITOR MODE** – used to monitor the same patient for an extended period of time. In this mode, the small-sized monitor is used to monitor the patient's SpO_2 and NIBP. Remote monitoring (connection to the central unit network) is available with this mode.

	MONITOR MODE	CLINIC MODE
ALARM PAUSE	✓	✘
TECHNICAL ALARM	✓	✓
PHYSIOLOGICAL ALARM	✓	✘
RECORDING REVIEW	✓	✓
ALARM REVIEW	✓	✓
PARAMETER STORAGE	✓	✓
ALARM MESSENGER STORAGE	✓	✘
NURSE CALL	✓	✘
COMMUNICATION WITH CENTRAL NETWORK	✓	✓
MULTI PATIENT MONITORING	✘	✓

CHAPTER 2 – SAFETY

1. WARNINGS & CAUTIONS

WARNINGS

- Unauthorized modification of this monitor is strictly prohibited. Please contact a licensed service professional or the manufacturer.
- This monitor is to be used by trained clinical professionals. Any persons not trained to operate this device must not perform any operations.
- The monitor can only be used on one patient at a time.
- Before each use, ensure that all cables and accessories are in the correct operating condition.
- This monitor should only be connected to a grounded, protective socket. If the socket is not grounded, use the internal battery to provide power to the device.
- Do not come into contact with the patient during defibrillation.
- Unauthorized opening of the monitor may cause an electrical shock hazard. All servicing and upgrades must be performed by a Dynarex authorized service professional.
- Take precautions for patient safety when using this device with Electrosurgical Units (ESU).
- Do not use this monitor on a patient during defibrillation. This could cause serious injury or even death.
- If the monitor and/or its accessories come into contact with any type of liquid, especially within the housing of the monitor, stop using the unit and contact a Dynarex authorized service professional. Please ensure the monitor and its accessories are completely dry.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring. Auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm condition.
- The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.
- To avoid inadvertent disconnection, route all cables in a way to prevent a tripping hazard. To avoid the risk of entanglement or strangulation by the patient or personnel, wrap and secure all excess cables away from patient or personnel.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude. Please store in a dry, controlled environment.
- The monitor is only to be operated by a trained professional and by the order of a physician.

- The monitor may not function properly due to the strong magnetic and radio frequency fields generated by the MR scanner.
- Ensure the monitor is working properly under specified conditions. Otherwise, the technical specifications mentioned within this manual will not be met, possibly leading to damage to the equipment and other unexpected results.
- Leave enough space around all sides of the monitor to guarantee normal ventilation to avoid overheating.
- If the monitor is mechanically damaged or not working properly, do not use it for any monitoring procedure on a patient. Contact your licensed service personnel or the manufacturer.
- Use only batteries specified in this manual and recommended by the manufacturer.
- Keep out of reach of children.

CAUTIONS

- Use only authorized parts and accessories specified in this manual to ensure patient safety.
- The service life of this monitor is 5 years. This monitor and all the accessories must be disposed of in compliance with the regulations for such devices. Any concerns with the disposal of this monitor, please contact the manufacturer or your local government agency.
- Magnetic and electrical fields are capable of interfering with the performance of the monitor. Please make sure that all external devices operated in the vicinity of the device comply with the monitor and relevant EMC requirements. Mobile phones, X-ray equipment or MRI devices are possible sources of interference.
- Before plugging in the monitor, check that the voltage and frequency ratings of the power cord are the same as those indicated on the monitor's label or stated in this manual.
- Always handle with care when installing or transporting the monitor to avoid damage caused by dropping, unwanted impacts, strong vibrations or other mechanical forces.
- When THERMAL CUT-OUT operates, the monitor will function continually without any SAFETY HAZARD by using its rechargeable battery. However, the battery will no longer be charging. While the battery is low, the device will give both visible and audible warnings at 5 minutes intervals.
- Remove the battery before shipping or if the device will not be used for an extended period.

NOTES

- Position the monitor in a location where the main screen and access to the operating controls are easily accessible.
- Keep this manual with or near the monitor for quick, easy reference.
- The software was developed in compliance with IEC 62304.
- This manual describes all the features and options available. However, this monitor may not have all those listed.
- Should the monitor temporarily lose patient data, continuous patient observation should be followed, or alternative monitoring devices should be used until the device function is restored.
- When the AC power is interrupted, the monitor will automatically switch to battery operation.
- During the loss of power or when the monitor is powered off, the settings prior to the power loss will be restored. After restarting the monitor, select continuing the current patient. The previous settings will be maintained. If a new patient is selected, the factory default settings will be loaded.

2. DECLARATION – ELECTROMAGNETIC EMISSIONS

The Vital Signs Patient Monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Vital Signs Patient Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Vital Signs Patient Monitor according to the maximum output power of the communications equipment. Please contact Dynarex at QA.Support@Dynarex.com for more information and manufacturer technical specifications.

Special considerations should be given to the proximity of the Vital Signs Patient Monitor and patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electrical interference or death. Contact Dynarex at QA.Support@Dynarex.com for manufacturer electromagnetic interference technical specifications.

Interference to electronic equipment may occur in the vicinity of devices marked with this symbol:

3. EQUIPMENT SYMBOLS

SYMBOL	SYMBOL NOTES
	Type CF applied part; defibrillation protected. The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Type BF applied part; defibrillation protected. The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Refer to instruction manual.
	Non-ionizing radiation
	Dangerous voltage
	Equipotential grounding
100V-240V~	Alternating current input range: 100V-240V
	USB socket
	Network connector
	Nurse call connector
	Manufacture date
	Manufacturer
SN	Serial number
	Temperature Limitation
	Humidity Limitation
	Pressure Limitation

IPX1	Degree of protection against liquid entry
Hospital Only	Symbol marked on a tag attached to the supply cord of the monitor to warn that the supply cord should be connected to the sockets which are Hospital Only to achieve grounding reliability.
SpO_2	Short for “Pulse Oxygen Saturation”
NIBP	Short for “Non-Invasive Blood Pressure”
Temp	Short for “Temperature”
	Symbol for the disposal of electrical and electronics devices according to Directive 2002/96/EC.

4. PACKAGING SYMBOLS

SYMBOL	SYMBOL NOTES
	Fragile: Shows handle with care during transportation.
	Upward: Shows the upright position during the transportation of the package.
	Wetness: Shows not to get the package wet.
	Temperature: Keep away from heat and sunlight.
	Stacking Limit. Maximum stacking layers, N represents the number of layers limit. (N is 6).

CHAPTER 3 – OPERATIONS

1. UNPACKING AND INSPECTING

1. Before unpacking the monitor, inspect the packaging carefully for signs of damage. If any damage is detected, contact the carrier or the sales representative immediately.
2. If there is no damage to the package, carefully remove the monitor and the accessories.
3. Keep all the packaging materials for future use to transport or store the monitor safely.
4. Inspect the packaging to make sure all the accessories are present as listed on the packing list.
5. Inspect the monitor and accessories for any physical or mechanical damage. If there is evidence of damage, please contact your sales representative.

2. GETTING STARTED

2.1 INSPECTING THE DEVICE

Before the monitor is used on a patient, please follow the checkpoints on the device including all connected modules:

- Inspect for any mechanical damage.
- Inspect for any incorrect connection for all the external cables and accessories.
- Plug the power cord into the AC power source.
- If using battery power only, ensure that the battery has enough power for monitoring.
- When using the battery for the first time, it must charge following the instructions advised in the Battery chapter.

2.2 STARTING THE DEVICE

Press the power button and the technical alarm lamp will light up blue followed by the physiology alarm lamp in yellow and red. After a quick “beep”, the system enters the main screen displaying NIBP, SpO_2, Pleth and Temp.

2.3 STARTING MONITORING

1. Choose which parameter will be measured and monitored.
2. Check all the parameter settings.
3. Start monitoring the patient as described in related chapters for each parameter.

2.4 SHUTTING OFF THE DEVICE

Once the patient’s vital signs have been measured and stored properly, remove all the cables and sensors from the device. Press and hold the power button and the device will shut down.

CAUTION

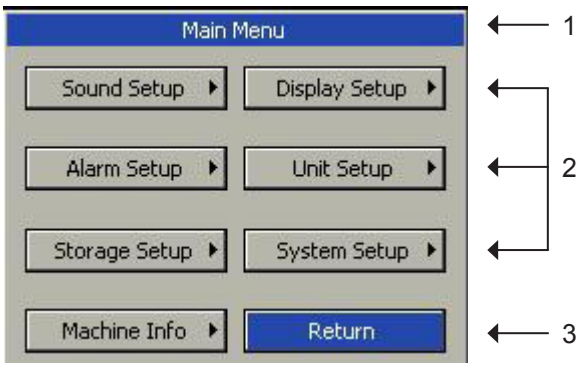
- If the monitor won’t shut down normally, press and hold the power button for more than 5 seconds. This could result in the loss of some stored data.

3. OPERATION MODES

1. Select or in the Icons area after starting the monitor to enter **【 Mode Select 】**.
2. Select **【 Clinic Mode 】** or **【 Monitor Mode 】** then press the Control Knob on the selected mode.
3. If the patient you are going to monitor is displayed, press the Control Knob to **【 Continue 】**.
4. If the patient is new, select **【 New Patient 】** then press the Control Knob.
5. Input the new patient’s information in **【 New Patient 】** using the Control Knob as your cursor.

4. USING MENU

Turn the Control Knob left or right to select the **【 Menu 】** and to open the following Main Menu. You can finish most operations and settings through **【 Menu 】**. The Main Menu under Monitor Mode is different from that under Clinic Mode. The following figure shows the Main Menu under Monitor Mode.



1. Main Menu Title.
2. Menu Selections: Press ► to enter the sub-menu.
3. Exit to Main Screen: Press **【 Return 】**.

5. GENERAL SETUP

5.1 CHANGING THE LANGUAGE

1. Select【 **Menu** 】→【 **System Setup** 】
2. Select【 **Language** 】→ choose a desired language. The unit is preloaded with English, Spanish, French and Italian, etc.
3. Select【 **Return** 】→ exit the current menu.

5.2 SETTING THE SCREEN SAVER

Under the Clinic Mode:

1. Select【 **Menu** 】→【 **Display Setup** 】.
2. Select【 **Screen Save Time** 】→ choose a desired setup.

5.3 SETTING THE DATE AND TIME

1. Select【 **Menu** 】→【 **System Setup** 】→ 【 **Date Time Setup** 】.
2. Set【 **Year** 】【 **Month** 】【 **Day** 】【 **Hour** 】 【 **Min** 】【 **Sec** 】to the desired value.
3. Select【 **Return** 】select【 **Yes** 】to finish setting up.

5.4 ADJUSTING THE VOLUME

Under the Monitor Mode:

ALARM VOLUME

1. Select【 **Menu** 】→【 **Sound Setup** 】.
2. Select【 **Alarm Volume** 】→ choose the desired volume.

BEEP VOLUME

1. Select【 **Menu** 】→【 **Sound Setup** 】.
2. Select【 **Beep Volume** 】→ choose a desired value.

6. DEFAULT SETUPS

CAUTION

- During power failures, the system will restore the setup automatically after restarting the device.

Changes can be made during set-up operations, but the changes are not always appropriate or correct. Therefore, you may restore some of the factory default during use to ensure that various set-up of the device is applicable to the monitored patient.

1. Select【 **Menu** 】→【 **System Setup** 】.
2. Select【 **Default Config** 】.
3. Select【 **Yes** 】to load the user config and alarm limit shown in the Remind menu.
4. Select【 **No** 】to exit the Remind menu.

7. NURSE CALL

The nurse call function will send a signal to the nurse when the alarm sounds. The nurse call output connector must be connected to the hospital's nurse call system by a nurse-call cable for the function to be operational.

The nurse call function is valid when the following conditions apply:

- The nurse call function is open.
- An alarm condition occurs.
- The monitor is not in the situation that alarm functions are paused or the system is silenced.

WARNINGS

- You must ensure the nurse call system is compatible with this unit.
- The nurse call function should not be used as the primary patient alarm source. It is highly recommended to combine auditory and visual alarm signals as well. The professional medical staff and nurses should be aware of the primary information, symptoms and physiological conditions of each patient.

7.1 TURNING THE NURSE CALL ON/OFF

1. Select【 **Menu** 】→【 **System Setup** 】→ 【 **Machine Mainte** 】→ enter the password.
2. Select【 **Factory Mainte** 】→ enter the password.
3. Select【 **Nurse Call** 】, select【 **On** 】.

7.2 SETTING NURSE CALL TYPE

1. 【 **Select Menu** 】→【 **System Setup** 】→ 【 **Machine Mainte** 】→ enter the password.
2. Select 【 **Nurse Call** 】to enter the nurse call menu.
3. Set 【 **Nurse Call Type** 】to 【 **Normally Open** 】or 【 **Normally Closed** 】.

7.3 SETTING CALL TIME

1. Select 【 **Menu** 】→【 **System Setup** 】→ 【 **Machine Mainte** 】→ enter the password.
2. Select 【 **Nurse Call Setup** 】to enter nurse call setup menu.
3. Select 【 **Call Time** 】to 【 **1 Sec** 】or 【 **Continuous** 】.

7.4 TRIGGERING NURSE CALL

1. Select 【 **Menu** 】→【 **System Setup** 】to enter system setup menu.
2. Select 【 **Nurse Call Setup** 】to enter nurse call setup menu.
3. Set 【 **PhyAlarm Trigger** 】and 【 **TecAlarm Trigger** 】to 【 **Off** 】【 **Low** 】【 **Med** 】【 **High** 】.

8. ID NAME

ID name will be set up under the Clinic Mode.

1. 【 **Menu** 】→【 **System Setup** 】→【 **ID Name** 】 to enter ID Name menu.
2. Define the ID Name rule according to your usage.

9. PATIENT ID

You can use a barcode scanner to input the Patient ID, please follow these steps before inputting the patient ID:

1. Open the barcode scanner switch in the factory configuration.
2. Connect the barcode scanner to the monitor and this icon will appear at the bottom of the display screen indicating the barcode scanner is supported by the device. If the barcode scanner is not supported, this icon will display indicating the barcode scanner is not compatible.

CAUTION:

- Other USB devices, including USB keyboards, may interfere with the operation of a barcode scanner. It is recommended to use the barcode scanner provided or a compatible barcode scanner designated by the manufacturer.
- Please check whether the switch of the barcode scanner is on before starting.
- The barcode scanner will only operate in the patient ID input interface. The monitor will not process any inputs when using the scanner in other input interfaces.

10. VIEWING THE MACHINE INFO

1. Select 【 **Menu** 】→【 **Machine Info** 】monitor and software data.

CHAPTER 4 – USER INTERFACE

1. DISPLAY STYLE

Display style for the user interface can be changed for the following:

- Display Screen brightness
- Wave and parameter screen color
- Sweep mode of wave

1.1 ADJUSTING THE SCREEN BRIGHTNESS

1. Select【 **Menu** 】→【 **Display Setup** 】.
2. Select【 **Back Light** 】→ select the desired value.

1.2 SELECT THE COLOR

1. Select【 **Menu** 】→【 **Display Setup** 】.
2. Select【 **Color Setup** 】→ choose a desired color for each parameter and waveform.
3. Select【 **Default Setup** 】→ to change back to the factory default colors.

1.3 SCREEN SWITCH

The screen layout can be changed as follows:

1. Select【 **Menu** 】→【 **Display Setup** 】.
2. Select【 **Screen Switch** 】→ choose a desired screen to display:【 **NIBP Review** 】【 **Trend Screen** 】【 **Alarm Screen** 】.

1.4 STANDBY MODE

The device has a standby function under the clinic mode. Please set as follows:

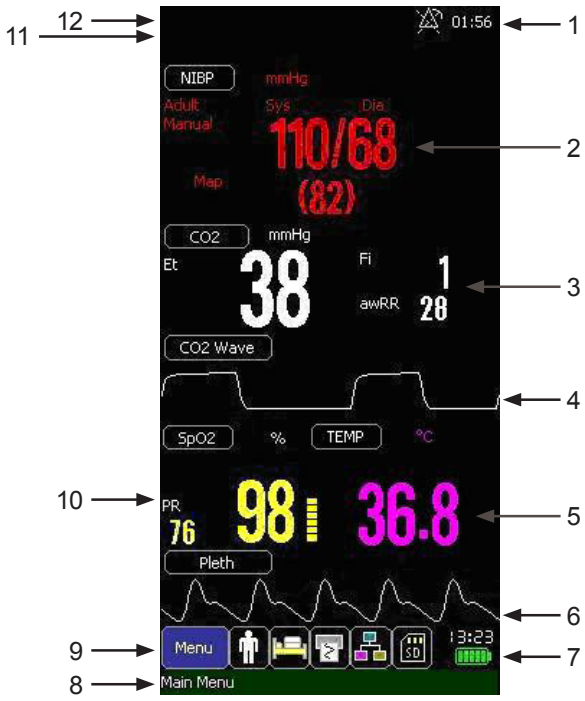
1. Select【 **Menu** 】→【 **Display Setup** 】→【 **Screen Save Time** 】.
2. Set the desired screen save time. If there is no activity after the set screen time setting, the device will enter standby mode.
3. To exit out of standby, press any button (including the touch screen).

2. SCREEN LAYOUT

The monitor has been configured with a color TFT LCD to display parameters and waves of patient SpO_2, and NIBP.

2.1 STANDARD SCREEN

Parameters displayed under the screen are SpO_2, SpO_2, and TEMP. Waves displayed under the screen are for SpO_2.



1. Alarm Pausing/Silence Area (displays alarm pausing icon and time/silence icon)
2. NIBP Parameters

   The parameters can be changed as required. Use the Control Knob to highlight the “NIBP” cell to enter the【 **NIBP Setup** 】menu.
3. Temperature Parameter

   The parameters can be changed as required. Use the Control Knob to highlight the “TEMP” cell to enter the menu.
4. SpO_2 Parameter Wave

   The parameters can be changed as required. Use the Control Knob to highlight the “SpO_2” cell to enter the【 **Pleth Setup** 】menu.
5. Time and Battery Status (displays system time and battery status).
6. Prompt Messages Area (displays the menu which the cursor is on or prompt messages).
7. Icons

   【 **Menu** 】【 **Patient Information** 】【 **Recorder Setup** 】【 **Network Setup** 】【 **SD Card** 】

8. SpO_2 Parameter

   The parameters can be changed as required. Use the Control Knob to highlight the "SpO_2" cell to enter the **【 SpO_2 Setup 】** menu.

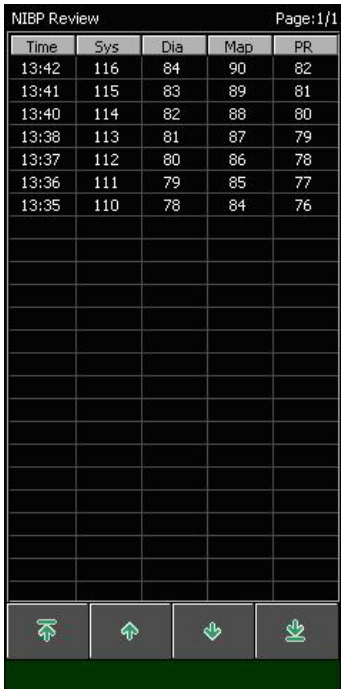
9. Physiological Alarm

   The physiological alarm message is displayed here. When multiple alarms of different levels occur, the device will give visual and audible alarm indications according to the alarm level.

10. Technical Alarm

    Technical alarm messages are displayed here. When multiple alarms of different levels occur, the device will give visual and audible alarm indications according to the alarm level.

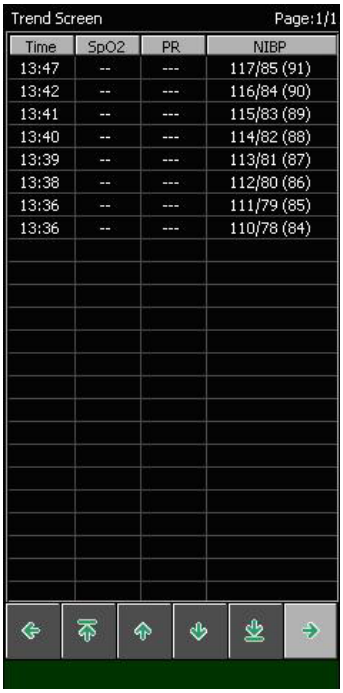
2.2 NIBP REVIEW



To review the NIBP measurements, select the "MENU" button on the right side of the device.

2.3 CLINIC REVIEW AND TREND SCREEN

Under the Monitor Mode, the following screen is called the "Trend Screen". Under the Clinic Mode, the screen is called "Clinic Review". The screens will show all measurements for each parameter.



To review the CLINIC/TREND measurements, select the "MENU" button on the right side of the device.

STORAGE SETUP

1. Select **【 Menu 】** → Select **【 Storage Setup 】**.
2. Select **【 Trend StorInter 】** to the desired value between **【 1 Min 】** and **【 10 Min 】**.

2.4 REVIEWING MENU

Access the review menu by the following two methods:

- Select **【 Menu 】** → **【 History Review 】**.
- Select **【 Menu 】** → **【 Data Manage 】** → **【 Data Manage 】**.

HISTORY REVIEW

1. Select **【 History Review 】** to enter **【 History Review 】**.
2. Turn the Control Knob to select a patient from the list, then select **【 LookUp 】** to view patient's **【 Detail Record 】**.
3. Select **【 Record 】** or press the button on the front panel of the device to print out the current page.

DATA MANAGEMENT

View one patient's ID record:

1. Use a barcode scanner to input the patient's ID number in **【 LookUp ID Record 】** or input the ID number manually.

2. Select the button【 **LookUp ID Record** 】on the right to view patient's【 **Detail Record** 】.

Record Viewing History:

1. Set【 **LookUp** 】and choose the desired time.
2. Select【 **LookUp** 】to enter【 **History Review** 】.

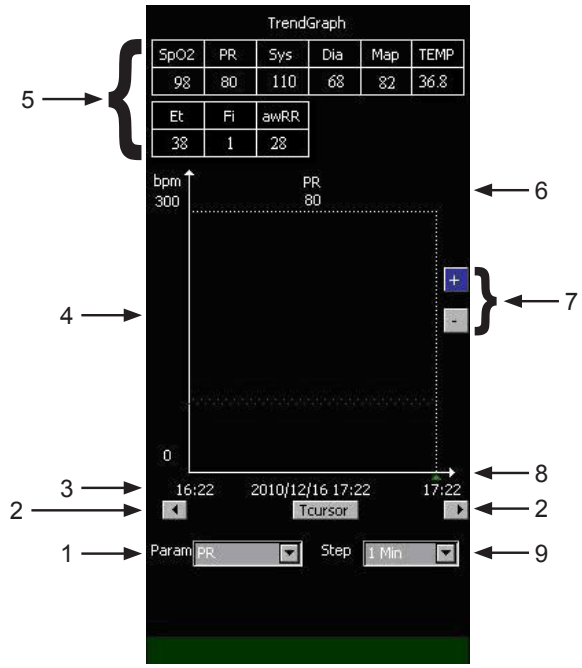
CAUTION

Successful scanning results using a barcode scanner will fill in the Lookup ID Record automatically. The ID will be replaced instead of accumulating when repeat scanning occurs.

2.5 ALARM SCREEN

To review the ALARM measurements, select the "MENU" button on the right side of the device.

2.6 TREND GRAPH



To review the TREND GRAPH, select the "MENU" button on the right side of the device.

1. Select Parameters
   - Turn the Control Knob to select【 **Param** 】.
   - Press the Control Knob to select the desired graph【 **NIBP** 】【 **SpO_2** 】【 **PR** 】【 **TEMP** 】.
2. Turning Pages

   You can turn pages through the page up and page down buttons to browse more Trend Graph information. The left button is the page-up button, while the right one is the page-down button. As shown in the above figure.
3. Time Scale

   The scale is to display time. You can browse the selected parameter's trend graph during the time between the left time and the right time on the time scale. The date and time displayed under the time scale are the date and time the cursor now indicates.
4. Scale

   To scale the value of parameters.
5. Parameter Displaying Area

   Displays values of all the monitored parameters at the time where the cursor is indicated.

6. The Selected Parameter

   Displays the name of the selected parameter and its value at the time where the cursor was.

7. Setting Interval

   Interval is the time between the left time and the right time on the time scale. It can be 1, 2, 3, 4 or 5 hours. Turn the Control Knob to select **【 Setting interval 】**. The sign of "+" is to add the time value while "–" is to decrease it. Each time you press the two buttons, the time will add 1 hour or decrease by 1 hour.

8. Cursor

   Indicates the selected parameters trend graph. Turn the Control Knob to select the **【 Tcursor 】** button. The color of the button and cursor will turn green. Turn Control Knob to move the cursor to the desired location.

9. Setting Step

   Step is the duration of time the cursor moves along the time scale. Turn the Control Knob to select **【 Step 】** then select the desired time: **【 1 Min 】**, **【 5 Min 】** or **【 10 Min 】**.

3. PATIENT INFORMATION

Select the "Patient Information" icon to enter the **【 Patient Info 】** menu.

Fields to be completed are: Patient ID, Name, Type, Gender and Age

3.1 MONITORING THE SAME PATIENT

When the patient to be monitored is the one displayed in the **【 Patient Info 】** menu, select **【 Return 】**. The monitor will continue to monitor the same patient and add current data to the history.

3.2 ADMITTING A NEW PATIENT

When the patient to be monitored is new, select **【 New Patient 】**. Input the new patient's ID, Name, Type, Gender and Age. Select **【 OK 】** to save the information.

3.3 PATIENT ID

CLINIC MODE:

Under the **【 Patient Info 】** menu, select **【 New Patient 】**, **【 Patient ID 】** will be created according to **【 ID Name 】** automatically. You can also input **【 Patient ID 】** through a barcode scanner or manually. Through **【 Patient Info 】** menu, you can change the patient info. After amending the patient information, select **【 Return 】** to save the data.

MONITOR MODE:

Under the **【 Patient Info 】** menu, select **【 New Patient 】**, to input **【 Patient ID 】** through a barcode scanner or manually. Through the **【 Patient Info 】** menu, you can change the patient info. After amending the patient info, select **【 Return 】** to save the data.

CAUTION:

- Once a field is successfully scanned, the cursor must be moved to the next dialog box otherwise the new scan will override the previous data.
- The history data will be deleted while admitting a new patient under Monitor Mode.

4. MACHINE MAINTENANCE

Select **【 Menu 】** → **【 System Setup 】** → **【 Machine Mainte 】** → enter the passwords.

1. NIBP Test

   Select **【 NIBP Test 】**

2. NIBP PR

   Select **【 On 】** or **【 Off 】**

3. Touch Screen Adjustment

   Select **【 Touch Adjust 】** to adjust the touch screen.

4. Nurse Call

   Select **【 Nurse Call 】** for Nurse Call set up.

5. Desat Limit

   Set up the SpO_2 desat value.

6. Alarm Suspend Time

   Set the value of Alarm Suspend Time.

7. Factory Maintenance

   Used for factory maintenance.

CHAPTER 5 – ALARM

An alarm refers to a prompt that is given by the monitor for medical personnel through visual, audio and other means when a vital sign appears abnormal or a technical problem occurs.

NOTES

- The monitor generates all audio and visual alarms through speakers, alarm lamps and screens. When the monitor powers on, the alarm lamp will be lit once and the speaker will beep once, which indicates the alarm system of the monitor is working properly.
- When the operator notices that the alarm system is not functioning in sync with the light indicators and alarm sound, verification of the alarm system function is needed. Remove and re-insert the probe to verify the technical alarm and change the alarm limit to exceed the physiological measure value to verify the physiological alarm.
- After the supply mains have been interrupted, the alarm system will run as before after the monitor has been restarted.

WARNINGS

- Do not set the alarm limits to extreme values that can render the alarm system useless.
- Alarm volume is preset by factory default. The operator may select different presets according to the patient's needs. The alarm preset will recover to the defaulted one as soon as a new patient is connected.
- If different alarm presets are used for the same or similar equipment in any single area, a potential hazard may exist.

1. ALARM CATEGORY

The monitor is equipped with three unique alarms/ status messages and is classified as the following categories:

Physiological alarms, Technical alarms and Prompt Messages.

1. Physiological Alarms:

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

2. Technical Alarms:

   Technical alarms are triggered by the monitor malfunction due to improper operation or system problems. The problems may result in abnormal systems operation or irresponsible monitoring parameters. Technical alarm messages are displayed in the technical alarm area.

3. Prompt Message:

   Prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the monitor will show some messages to indicate the system status.

2. ALARM LEVEL

According to the severity of the alarm, the monitor's physiological alarms are classified into three categories: High-Level alarms, Medium-Level alarms and Low-Level alarms.

- High-Level Alarm: Indicates that the patient is in a life-threatening situation and emergency treatment is necessary. This is the highest-level alarm.
- Medium-Level Alarm: Indicates that the patient's vital signs appear abnormal and immediate treatment is required.
- Low-Level Alarm: Indicates that the patient's vital signs appear abnormal and immediate treatment may be required.

The levels of some physiological alarms are factory pre-defined and can't be changed by the users. However, some levels of physiological alarms can be changed by users.

The device technical alarms are classified into two categories: Medium-Level and Low-Level. The levels of technical alarms are factory pre-defined and can't be changed by the users.

3. ALARM INDICATORS

When an alarm occurs, the device will signal by the following methods:

- Alarm Tone: A speaker in the monitor will give an alarm sound in a different tone.
- Alarm Lamp: The alarm lamp on the monitor flashes in a different color and speed for different types of alarms.
- Alarm Message: Alarm messages are displayed on the screen.
- Flashing Numeric: The number of parameters for the alarm will flash.

CAUTION: The presentation of each alarm prompted is related to the alarm level.

3.1 ALARM TONE

The different levels of alarms are indicated by the system in the following audio signals:

ALARM LEVEL	AUDIBLE PROMPT
High	"DO-DO-DO------DO-DO, DO-DO-DO------DO-DO"
Medium	"DO-DO-DO"
Low	"DO-"

3.2 ALARM LAMP

When a physiological alarm occurs, levels are indicated in the following visual signals:

ALARM LEVEL	VISUAL PROMPT
High	Alarm lamp flashes in red with 2 Hz.
Medium	Alarm lamp flashes in yellow with 0.5 Hz.
Low	Alarm lamp lights on in yellow without flashing.

When a technical alarm occurs, the levels are indicated in the following visual signals:

ALARM LEVEL	VISUAL PROMPT
Medium	Alarm lamp flashes in blue with 0.5 Hz.
Low	Alarm lamp lights on in cyan without flashing.

CAUTION: When multiple alarms of different levels occur at the same time, the monitor will select the alarm of the highest level and give visual and audio alarm indications.

3.3 ALARM MESSAGE

PHYSIOLOGICAL ALARM

Physiological alarm messages are displayed in the physiological alarm area. The system uses different symbols and background colors for the alarm messages to match the alarm level as follows:

ALARM LEVEL	SYMBOL	BACKGROUND COLOR
High	***	red
Medium	**	yellow
Low	*	yellow

CAUTION: The monitor will not give a physiological alarm under clinic mode.

TECHNICAL ALARM

Technical alarm messages are displayed in the technical alarm area. The system uses different symbols and background colors for the alarm messages to match the alarm level as follows:

ALARM LEVEL	SYMBOL	BACKGROUND COLOR
Medium	**	yellow
Low	*	cyan

PROMPT MESSAGES

Prompt messages are displayed in the technical alarm area. Prompt messages have no color, visual and audio alarm indicators.

4. ALARM VOLUME SETTING

The alarm volume can only be set only in the monitor mode:

1. Select【**Menu**】→【**Sound Setup**】.
2. Select【**Alarm Volume**】→ select the desired level (Min. Volume = 0, Max. Volume = 5).

Maintenance Mode requires a password, which will be supplied by the factory.

5. PARAMETER ALARM

Set【 **Alarm Setup** 】only under Monitor Mode.

5.1 TURN ON/OFF THE ALARM

1. Select【 **Menu** 】→【 **Alarm Setup** 】.
2. Set【 **Class** 】to any option but【 **Off** 】to turn on the alarm, while set【 **Class** 】to【 **Off** 】to turn off the alarm.

5.2 SETTING ALARM LEVEL

1. Select【 **Menu** 】→【 **Alarm Setup** 】.
2. Set【 **Class** 】to【 **Medium** 】or【 **High** 】.

5.3 SETTING ALARM LIMIT

1. Select【 **Menu** 】→【 **Alarm Setup** 】.
2. Set【 **High Lim** 】and【 **Low Lim** 】to a desired value.

6. PAUSING ALARMS

Press the button on the front panel of the monitor, to silence/suspend all alarms on the device:

- Visual and audible alarms will be silenced or suspended.
- Parameters of physiological alarm will stop flashing.
- Physiological alarm message will no longer be displayed.
- Remaining time and will be shown in the physiological alarm area.
- Technical alarm message will still be shown in the technical alarm area.

Once the paused alarm time has reached its limit, the monitor alarm system will start again. Press the to silence the alarm until the condition has been resolved. Once the alarm conditions are met, the device will return to normal status.

SETTING ALARM PAUSE TIME

Set the silence time only under Monitor Mode.

1. Select【 **Menu** 】→【 **System Setup** 】→【 **Machine Mainte** 】→ enter the password.
2. Set【 **Alarm suspend Time** 】to desired limit【 **1 Min** 】【 **2 Min** 】【 **3 Min** 】.

7. SILENCE

Press and hold the suspend/silence button for 1 second to set all the monitor sounds to silence. The icon will be displayed in the upper right corner of the screen. When in silence mode, the alarm indicators are valid except audible alarm. Press the button again to exit the silence mode. A new alarm will cancel the silence automatically.

8. ALARM WHEN POWER IS LOST

After a loss of power, the alarm settings prior to the power loss will be restored. Once the monitor has been restarted, you can continue with the current patient and all settings will be maintained. If a new patient is selected, the factory default settings will be loaded.

CHAPTER 6 – SPO_2

1. INTRODUCTION

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, usually shortened as SpO_2) adopts the principles of light spectra and volume tracing. The LED emits light with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and total hemoglobin.

$$SpO_2\ \% = \frac{\text{Oxygenated hemoglobin}}{\text{Oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

Wavelengths of the light emitted by the pulse oximeter probe are nominally 660nm for red LED and 940nm for infrared LED.

2. SAFETY INFORMATION

WARNINGS

- Use only the SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.
- When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.
- Do not use the monitor and the SpO_2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
- Prolonged, continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Check the SpO_2 sensor and its package for any sign of damage before use. Do not use the sensor or extension cable on a patient if any damage is detected.
- Before use, the operator must ensure the compatibility of the monitor, SpO_2 sensor and extension cables. Failure to do so may lead to the patient getting burned.
- Do not get the sensor wet or soak in water.
- Follow all Local, State and Federal Regulations for the disposal of this product or similar products.

CAUTIONS

- Function testers cannot be used to evaluate the accuracy of the SpO_2 Probe.
- FLUK prosim8 SpO_2 simulation (software version: V2.06.04) was used to verify SpO_2 function of the monitor.

NOTE: To validate the PR accuracy, PULSE OXIMETER was referenced to compute the PR accuracy.

3. MONITORING PROCEDURE

1. Depending on the patient category, weight and application site, select the appropriate SpO_2 sensor as needed.
2. Clean the application site thoroughly and remove any nail polish.
3. Apply the sensor to the patient.
4. Select the extension cable according to the SpO_2 connector.
5. Plug the SpO_2 sensor into the extension cable.

4. SPO_2 DISPLAY

4.1 SPO_2 FOR 10840

WAVEFORM DISPLAY

PARAMETER DISPLAY

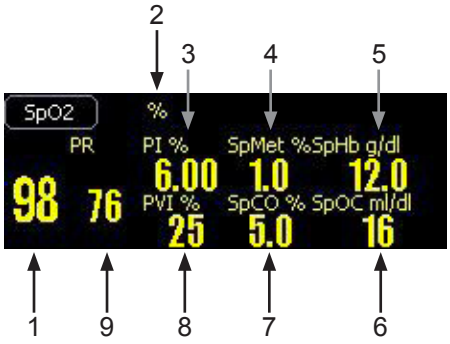
1. Pleth Waveform
2. "%" indicates SpO_2
3. SpO_2 value
4. Pleth Bar
5. Pulse Rate
6. SpO_2 Signal Intensity

SIGNAL INTENSITY INDICATOR	DESCRIPTION
"Weak Signal"	The signal strength is too weak to measure.
"*"	The signal strength is low.
"**"	The signal strength is good.
"***"	The signal strength is best.

WARNING: When a "Weak Signal" warning occurs, the professional staff should check the patient's condition manually and move the probe to another appropriate location for a measurement.

4.2 PROPRIETARY SPO_2 FOR 10841

The Proprietary module is intended to monitor the SpO_2, PR, PI, SpMet, SpHb, PVI, SpCO and SpOC of patients. The following figure shows the SpO_2 display screen, the display on your monitor may look slightly different.



1. SpO_2 value.
2. SpO_2 unit.
3. PI (Perfusion Index) value and unit.
4. SpMet (Methemoglobin Saturation) value and unit.
5. SpHb (Total Hemoglobin) value and unit.
6. SpOC (Oxygen Content) value and unit.
7. SpCO (Carboxyhemoglobin Saturation) value and unit.
8. PVI (Pleth Variability Index) value and unit.
9. PR value.

PARAMETER DESCRIPTIONS

- Perfusion Index (PI) is a value that indicates arterial pulse signal strength as the percentage of pulsatile signal to non-pulsatile signal. The perfusion index allows clinicians to place sensors on optimal sites.
- Methemoglobin Saturation (SpMet) is a value that represents the percentage of methemoglobin saturation within the blood.
- Total Hemoglobin (SpHb) is a measurement of the total hemoglobin concentration in arterial blood.
- Oxygen Content (SpOC) is a measurement of the total oxygen content present in the blood.
- Carboxyhemoglobin Saturation (SpCO) is a value that represents the percentage of carboxyhemoglobin saturation within the blood.
- Pleth Variability Index (PVI) is a measurement of peripheral perfusion changes secondary to respiration, or the PI amplitude modulation over respiration, and can be closely related to intrathoracic pressure changes.

5. SETTING SPO_2

5.1 OPENING THE SPO_2 MENU

Select "SpO_2" to enter **【 SpO_2 Setup 】** menu.

1. Set **【 Beep Volume 】** select **【 Off 】** or **【 1-5 】**.
2. Set **【 Scan Speed 】** select desired mm/s speed.
3. Set **【 SpO_2 Average Time 】** select desired seconds.
4. Set **【 Sensitivity Mode 】** find details following.
5. Set **【 FastSatMode 】** find details following.
6. Set **【 SmartToneMode 】** find details following.
7. Set **【 WaveformMode 】** select desired setting.
8. Set **【 AlarmDelay 】** select desired seconds.

Pleth Scan Speed

1. Select "Pleth" to enter **【 Pleth Setup 】**.
2. Set **【 Scan Speed 】** select desired setting.
3. Set **【 Wave Color 】** select desired color.

5.2 SETTING AVERAGE TIME

The SpO_2 reading shown on the monitor is the average of data collected within a specific time. The shorter the average time, the quicker the device responds to the patient's oxygen saturation level. Contrarily, the longer the average time is, the slower the monitor responds to the patient's oxygen saturation level. When a critical patient is monitored, selecting a shorter average time will help to determine the patient's current condition. The parameters should be determined by licensed professional staff.

5.3 SETTING DESAT LIMIT

Desat Limit means that when the measuring value is lower than the limit, the highest alarm will sound.

Set the Desat Limit as follows:
Select【 **Menu** 】→【 **System Setup** 】→【 **Machine Mainte** 】→ enter the password.

5.4 PROPRIETARY SPO_2 MODULE SETUP FOR 10841

SETTING SENSITIVITY MODE

Select【 **Sensitivity Mode** 】in the SpO_2 setup menu with the options of【 **Max** 】【 **Normal** 】or【 **APOD** 】.

1. 【 **Max** 】

   This mode should be used for the sickest patients, where obtaining a reading is most difficult. The mode is recommended during procedures and when clinician and patient contact is continuous.

2. 【 **Normal** 】

   This mode provides the best combination of sensitivity and probe-off detection performance. The mode is recommended for most patients.

3. 【 **APOD** 】

   This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. The mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.).

SETTING FAST SAT MODE

The Fast Sat mode is clinically applicable during procedures when detecting rapid changes in oxygen saturation is paramount such as induction, intubation and sleep studies. Select【 **Fast Sat Mode** 】in the SpO_2 parameter setting menu. Select【 **On** 】or【 **Off** 】.

SETTING SMART TONE MODE

Smart Tone Mode is a feature that affects pulse beep and can be selected in the SpO_2 parameter setting menu. When you set it to【 **On** 】, it will allow the audible pulse beep to beep when the pleth shows signs of motion. The pulse beep is suppressed during signs of motion when Smart Tone is set to【 **Off** 】.

SETTING WAVEFORM MODE

Select【 **Waveform Mode** 】in the SpO_2 parameter setting menu and select【 **Resp. Out** 】or【 **Resp. In** 】. Resp. out is short for Respiration Signal Filtered Out, and Resp. in is short for Respiration Signal Included.

SETTING ALARM DELAY

Select【 **Alarm Delay** 】, set desired delay time for the alarms.

SETTING SPHB MODE

While monitoring Hemoglobin levels, there are two blood sample sources from which Hemoglobin readings can be obtained, Arterial and Venous. Select【 **SpHb Mode** 】→【 **Arterial** 】or【 **Venous** 】.

SETTING SPHB AVERAGE TIME

You can change the averaging time mode for SpHb by selecting【 **SpHb Average Time** 】in the SpO_2 parameter setting menu. Select【 **Short** 】【 **Medium** 】【 **Long** 】.

SETTING SPHB PRECISION

The SpHb precision can be displayed on the screen, select【 **SpHb Precision** 】in the SpO_2 parameter setting menu, and select the proper time as required.

SETTING SPHB UNIT

Select【 **SpHbUnit** 】in the SpO_2 parameter setting menu. The options are【 **g/dL** 】and【 **mmol/L** 】.

6. PROPRIETARY INFORMATION FOR 10841

PROPRIETARY PATENTS

This device is covered under one or more of the following U.S.A. patents: 5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975 and other applicable patents listed at: www.Proprietary.com/patents.htm

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Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

CHAPTER 7 – NIBP

1. INTRODUCTION

The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. The method of oscillometric indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring the change of the pressure within the cuff along with the volume of the arteries and calculates the average pressure. The NIBP measurement is suitable for use in the presence of electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

Qualified Physicians can only determine the clinical significance of the NIBP measurement.

2. SAFETY INFORMATION

WARNINGS

- Incorrect settings could put the patient's safety at risk. Higher adult settings are not suitable for pediatric and neonatal patients.
- Do not measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred.
- The effectiveness of NIBP in pregnant women, including those with pre-eclampsia, has not been determined.
- Use clinical judgment to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the extremity fitted with the cuff.
- Use clinical judgment to decide whether to perform Auto BP measurement on patients with thrombasthenia.
- Do not use the NIBP cuff on an extremity with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
- If you doubt the NIBP measurements, check the patient's vital signs by other methods and then check the monitor.
- Continuous cuff pressure due to tube kinking may affect blood flow and could result in injury to the patient.
- Do not use the cuff over a wound.
- The pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same extremity.

3. MEASUREMENT LIMITATIONS

Correct NIBP measurements are nearly impossible with heart rate extremes of less than 40 bpm, greater than 240 bpm, or if a patient is on a heart-lung machine. The measurement may be inaccurate or impossible under the following conditions:

- Excessive and continuous patient movement such as shivering or convulsions
- Regular arterial pressure pulse is hard to detect
- Cardiac arrhythmias
- Rapid blood pressure changes
- Severe shock or hypothermia that reduces blood flow to the extremities
- Placement on swollen extremities

4. MEASUREMENT MODE

There are three modes of measuring NIBP:

- Manual: Measurement on demand.
- Auto: Continually repeated measurements in interval.
- STAT: Rapid series of measurements over a five-minute period. The device returns to the previous mode. Only used on supervised patients.

5. MONITORING PROCEDURE

5.1 PREPARING TO MEASURE NIBP

1. Select to enter【**Patient Info**】and enter the patient's information.

   NOTE: To obtain accurate routine blood pressure measurements in patients with hypertension:

   Keep the patient in a suitable position which includes:

   a. Comfortable seating

   b. Legs uncrossed and feet flat on the floor

   c. Back and arm supported

   d. Middle of the cuff placed at the same level as the right atrium of the heart

   e. Patient needs to be relaxed and not talk during the measurement procedure

   f. Normal operating position is on the right side of the monitor

2. Select the appropriate cuff according to patient category:

   - Measure the circumference of the patient extremity.
   - Select the appropriate cuff (The applicable limb circumference for the cuff is marked on the cuff). The width of the cuff should be about 40% of the limb circumference (50% for neonate) or ⅔ of the upper arm's length. The inflatable part of the cuff should be long enough to encircle 50%-80% of the limb.

   NOTE: Accurate blood pressure measurement depends on the suitability of the cuff.

3. Confirm the cuff has been entirely deflated.
4. Plug the air pipe plug of the cuff into the connector (NIBP) on the monitor. (Attention: nip the part of the air pipe plug of the cuff close to the socket with your fingers before pulling it out).
5. Tie the cuff to the upper arm or thigh of the patient. Ensure the mark "Φ" on the cuff lies above artery while the air pipe is under the cuff, ensuring the air pipe outside the cuff does not knot and the white line on the cuff is within the range "⟺", otherwise the cuff should be replaced.

   The monitor is applicable for standard neonatal cuffs, pediatric cufs and adult cuffs. (Including arm cuff and thigh cuff).

NOTES

- While measuring blood pressure, the patient should remain relaxed and silent.
- Cuff placement on the extremity shall be on the same level as the patient's heart to avoid a reading error resulting from the hydrostatics effect of the blood flow between the heart and cuff. If the cuff position is higher than heart level, the BP reading will be lower. The measured result will add 0.75mmHg (0.1kPa) for each centimeter higher. If the cuff position is lower than heart level, the BP reading will be higher, so the measured result will be lower by 0.75mmHg (0.1kPa) per centimeter.
- Environmental and operational factors can affect the performance of the NIBP module and its BP reading.
  1) Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.
  2) Wrong cuff size or a folded/twisted bladder, can cause inaccurate measurements.
  3) Do not wrap the cuff too tightly around the extremity.

5.2 STARTING/STOPPING MEASURING

Press  on the front panel of the device to start measuring NIBP. Press  again to stop measuring NIBP.

5.3 AUTO MEASUREMENT

1. Select "NIBP" to enter【 **NIBP Setup** 】.
2. Set【 **Interval** 】to the desired limit.
3. Start the auto measurement manually for the first time, and then enter the Auto mode. The monitor will start the measurement continually in set intervals after the first measurement.

   Press the button  during the auto measurement and the measuring will be paused.

   Press the button  again to start the auto measurement.

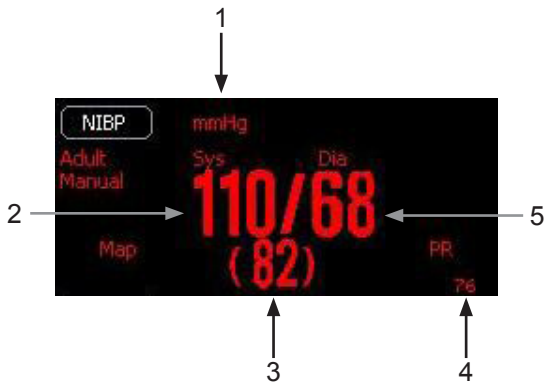
WARNING: Prolonged NIBP measuring in the Auto mode can lead to ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurements immediately.

5.4 STAT MEASUREMENT

1. Select "NIBP" to enter【 **NIBP Setup** 】.
2. Select【 **STAT** 】to start the STAT Measurement.

6. NIBP DISPLAY

There is no waveform displayed for NIBP measurements. NIBP readings are displayed in the parameter area. The following figure shows the NIBP display screen, the display on your device may look slightly different:



1. Pressure unit
2. Systolic blood pressure
3. Mean arterial blood pressure
4. Pulse Rate (obtained from NIBP)
5. Diastolic blood pressure

7. SETTING NIBP

Select ”NIBP” to enter **【 NIBP Setup 】** menu.

7.1 SETTING UNIT

【 NIBP Setup 】 set **【 Unit 】** to **【 mmHg 】** or 【 kPa 】.

7.2 SETTING INITIAL PRESS

【 NIBP Setup 】 set **【 Init Press 】** to the desired value.

8. SETTING VENIPUNCTURE PRESS

NIBP cuff can be used to cause sub-diastolic pressure and block the venous blood vessel to assist venous puncture.

1. Select “NIBP” to enter **【 NIBP Setup 】**.
2. Set **【 Veni. Press 】** to the desired value.
3. Select **【 Venipuncture 】**.
4. Puncture vein and draw a blood sample.
5. Select **【 Venipuncture 】** again to deflate the cuff. The cuff deflates automatically after a set time if you do not deflate it.

9. NIBP RESETTING

Select **【 Reset 】**. in **【 NIBP Setup 】**. to restore the inflation value of the blood pressure pump to the initial value. In case the blood pressure pump doesn’t work as normal, without any prompt, the blood pressure pump can be checked by resetting the values. The blood pressure pump, in abnormal conditions due to unexpected reasons, will automatically restore.

10. AIR LEAKAGE TESTING

Air leakage testing will test the airflow system for any leaks. If no error displays on the NIBP parameter screen, this indicates that the airway is in good working condition and no leaks were detected. If the airway leaks, a prompt message appears on the NIBP display screen.

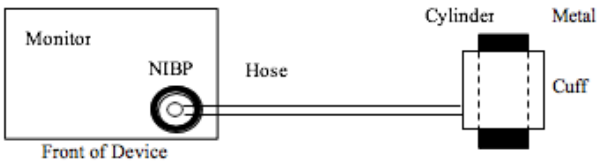
NIBP Air Leakage Testing should be done every 2 years or when inconsistent readings continue to happen.

Before testing, have the following components available:

- One Adult Cuff.
- One Inflating Hose.
- One Cylinder Metal Vessel.

AIR LEAKAGE TEST PROCEDURE

1. Enter【 **Patient Info** 】set【 **Type** 】【 **Adult** 】.
2. Connect the cuff securely with the socket for the NIBP air hole.
3. Connect the cuff to a suitable Cylinder Metal Vessel, shown as follows:

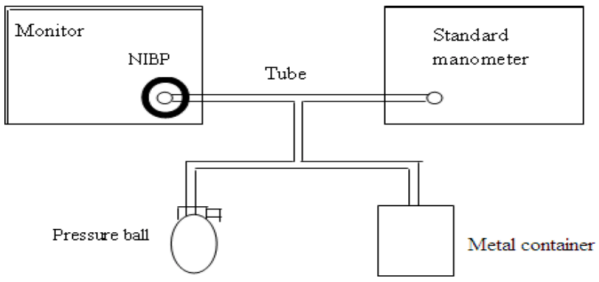


4. Enter【 **NIBP Setup** 】select【 **Leakage** 】.
5. After 20 seconds or so, the system will automatically open the deflating valve which marks the completion of the air leakage test.
6. If no error information displays on NIBP parameter screen, the airway is in good working condition and no leaks exist. If the prompt 【 **Air Leak** 】displays, it indicates that the airway may have leaks. In this case, the user should check for a loose connection. After confirming secure connections, the user should perform the air leakage test again. If the failure prompt still appears, please contact a licensed repair technician or the manufacturer.

11. NIBP CALIBRATION

The maintenance and calibration of the NIBP measurement is necessary once a year. If needed, please contact a professional service technician. Calibration tools: 3-way connector, pipe, roundness pump, metal container (500±25 ml), standard manometer (Calibration already, precision over 1mmHg)

1. Connect monitor, manometer, roundness pump and metal container as follows:

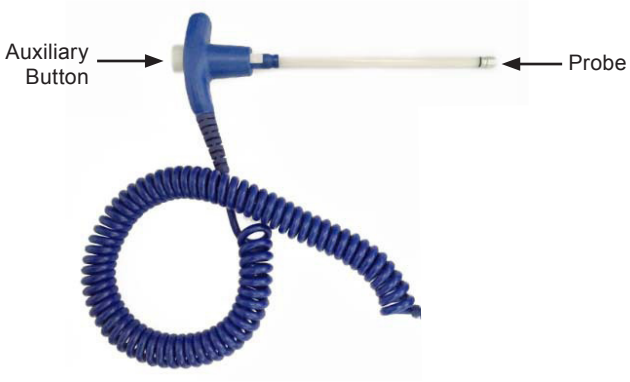


2. Reading of the manometer should be 0 before deflating, if not, cut the connection until it returns to zero.
3. Select【 **Menu** 】→【 **System Setup** 】→ 【 **Maintenance** 】→ enter password.
4. 【 **NIBP Test** 】→【 **Calibration** 】.
5. Turn up the pump's output pressure to 150mmHg. The pressure shown on the monitor and consulting manometer should not be over 3mmHg. Set【 **Calibration** 】for 150mmHg, select【 **OK** 】.

CHAPTER 8 – TEMPERATURE

1. PRINCIPLE OF TEMPERATURE MEASUREMENT

The Temperature Probe uses a pre-heating mode to get the necessary temperature compensation in real-time to make the probe's temperature approach the human body temperature rapidly. The accurate temperature will be converted into electrical signals that will be sent to the main system.



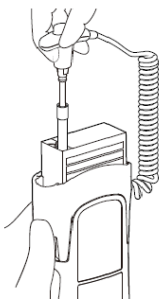
2. TEMPERATURE MEASURING

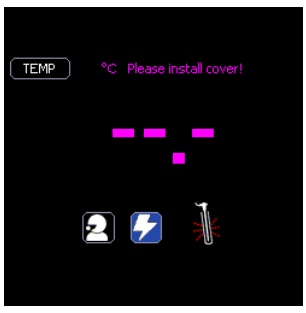
1. Select the appropriate measurement sites: Oral or Axillary.
2. Three modes of measurement: Fast, Cold, Monitor
   - Oral measurement: Fast mode and Cold mode.
   - Axillary measurement: Fast mode, Monitor mode and Cold mode.

NOTES

- Fast mode is suitable for patients with body temperatures ranging between 36°C to 38°C.
- Cold Mode is suitable for patients with a low body temperature of 33°C.
- Monitor mode will continually measure and monitor the patient's temperature.

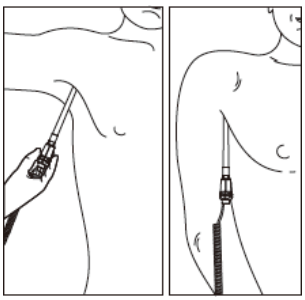
3. When the Temperature Probe is removed from the housing unit, the interface will start flashing and prompts: "Please install cover!".

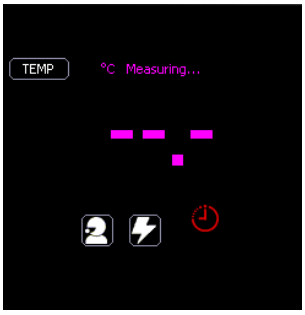




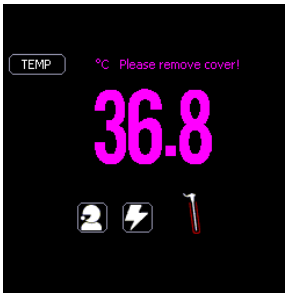
4. Once the disposable probe cover is securely in place and the probe is placed in the appropriate area on the patient, the screen will display "Measuring".

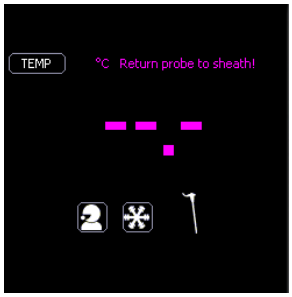
   Under normal circumstances, the oral temperature will take approximately 8 seconds to register, and the axillary temperature needs about 16 seconds. If the patient is measured in Monitor mode, the measurement interface remains in this state, and the real-time measurement data will be displayed all the time.





5. After the measurement is completed, the screen flashes and prompts the operator to "Please remove cover!" and "Return probe to sheath!". Discard the disposable probe cover and replace the probe.

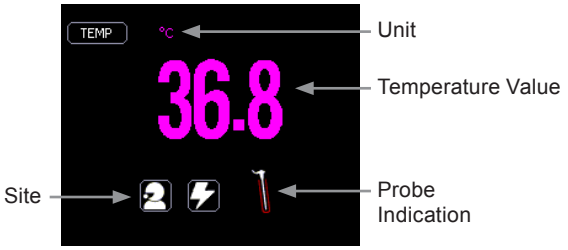




CAUTION

The system will automatically switch to temperature mode when there is unstable probe contact during oral and axillary temperature measurements. The unstable contact of the probe with the patient measurement site will not allow for fast temperature. When the temperature is close to the patient's temperature, the system will lock the measurement data and display the measurement results on the screen. Measurement modes and sites can only be changed when the temperature probe is in the holder.

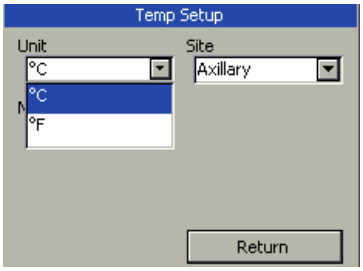
3. TEMPERATURE DISPLAY



4. SETTING TEMPERATURE

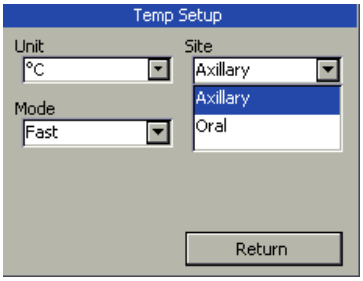
4.1 SETTING UNIT

1. Select “TEMP” to enter the temperature setup menu.
2. Set【 **Unit** 】to【 **°C** 】or【 **°F** 】.



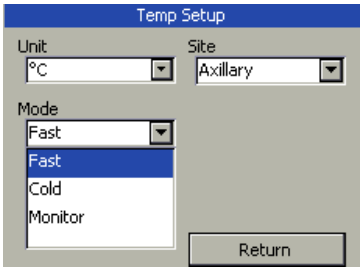
4.2 SETTING MEASURING SITES

1. Select “TEMP” to enter the temperature set-up menu.
2. Set【 **Site** 】to【 **Oral** 】or【 **Axillary** 】.



4.3 SETTING MEASURING MODES

1. Select “TEMP” to enter the temperature setup menu.
2. Set【 **Mode** 】to【 **Fast** 】or【 **Cold** 】or【 **Monitor** 】.



4.4 SETTING ALARM

Select【 **Menu** 】→【 **Alarm Setup** 】Set the desired alarm level and alarm limit.

5. TEMPERATURE ALARM

- If the measured value is lower than 30.0°C, an alarm indicating that the temperature is lower than the low limit will occur, and the LCD will display “Lo”.
- If the measured value is higher than 43.0°C, the alarm indicating that the temperature is higher than the high limit will occur and, the LCD will display “Hi”.
- When the measuring result is higher or lower than the alarm setup range, the alarm will occur too.

6. WARNINGS

- Measurements without the probe cover may result in inaccurate readings.
- At least once a year, calibration should be performed according to hospital regulations.
- If the temperature exceeds the measurement range, an alarm will appear on the screen. Check whether the temperature probe is placed on the patient’s appropriate site.

CHAPTER 9 – RECORDING

1. RECORDER

This monitor uses a thermal recorder that supports various record types. It can output the patient's information, measurement data, review data and two waveforms.

2. RECORDING TYPE

Several recording mode types are as follows:

1. Real-time recording of manual startup
2. Circular recording of an automatic startup with the given time interval
3. Alarm record triggered by out-of-limit parameter and so on
4. Recording started by manual operation and related to a special function

3. STARTING/STOPPING RECORDING

Recordings can be started and stopped as follows:

- Press [ ] on the front panel of the monitor to start real-time recording.
- Press [ ] again to stop recording.

4. SETTING RECORDER

Select to enter **【 Recorder Setup 】**.

4.1 SETTING CYCLE RECORD

1. Enter **【 Recorder Setup 】**.
2. Set **【 Cycle Record 】** to the desired value.

4.2 SETTING CYCLE RECORD TIME

Certain time intervals can be set for the recorder to automatically start recording in line with the given time interval.

1. Enter **【 Recorder Setup 】**.
2. Set **【 Cycle Record Time 】** to the desired value.

4.3 SETTING ALARM RECORD

1. Enter **【 Recorder Setup 】**.
2. Set **【 Alarm Record 】** to **【 On 】** or **【 Off 】**.

4.4 SETTING ALARM RECORD TIME

1. Enter **【 Recorder Setup 】**.
2. Set **【 Alarm Record Time 】** select the desired value.

CAUTION

When the log has reached its capacity, the contents already recorded will be overwritten by the new contents.

4.5 SETTING GRIDDING

1. Enter **【 Recorder Setup 】**.
2. Set **【 Open Grid 】** to **【 On 】** or **【 Off 】**.

4.6 SETTING RECORDER SPEED

1. Enter **【 Recorder Setup 】**.
2. Set **【 Recorder Speed 】** to the desired value.

5. INSTALLING RECORDING PAPER

1. Press both sides of the recorder door with one hand and pull outwards to open the recorder door.
2. Put the recording paper into the recorder with the thermal side up (smooth side).
3. Close the door of the recorder and pull some recording paper outside of the paper-out port.

CAUTIONS

- Must use thermo-sensitive record paper; otherwise, it will lead to recording failure, a bad-quality record or damage to the thermo-sensitive printing head.
- Do not pull out the recording paper during recorder printing; otherwise, the recording meter may be damaged.
- Unless for paper replacement or fault remedy, do not keep the recorder door open.

6. CLEARING PAPER JAM

1. Open the recorder door.
2. Pull out the recording paper and cut off the wrinkled paper.
3. Load the recording paper once again and close the recorder door.

CHAPTER 9 – RECORDING *(Continued)*

7. CLEANING RECORDER

Over time, paper scraps will accumulate on the printer head and affect the quality of the printing and the mechanical parts such as the printer head and roll shaft.

The recorder can be cleaned by the following methods:

1. Before cleaning, wear anti-static wrist straps to help avoid any damage to the recording meter resulting from static.
2. Open the recorder door and remove the recording paper.
3. Use a soft, clean cloth with a small amount of rubbing alcohol to gently clean the surface of thermo-sensitive parts of the printing head.
4. Let the rubbing alcohol completely dry and re-load the recording paper once and close the door.

CAUTIONS

- Do not use any hard material to clean the thermo-sensitive parts of the recorder.
- When cleaning, do not press hard on the printing head.

CHAPTER 10 – BATTERY

1. INTRODUCTION

The monitor has a rechargeable battery which will automatically take over during power failures without interruption. The battery will need no special maintenance during normal conditions. If the monitor is connected to the AC power source, the battery will continue to keep its charge.

Battery message indications displayed on the main screen:

-  The icon indicates that the battery is fully charged.
-  The icon indicates that the battery is more than halfway charged.
-  The icon indicates that the battery is halfway charged.
-  The icon indicates that the battery is less than halfway charged.
-  The icon indicates that the battery is very low.
-  The icon indicates that the battery needs to be charged immediately.

2. INSTALLING A BATTERY

The battery compartment is located on the bottom panel of the monitor. Please refer to the following steps when installing or charging the batteries.

1. Turn off the power and disconnect the power cord and other connected wires.
2. Open the battery door by pressing the locking tabs.
3. Press the battery locking tab and remove the battery.
4. Insert the new battery and snap it into place with the locking tab.
5. Replace the battery door and make sure it locks into place.

3. OPTIMIZING BATTERY PERFORMANCE

A battery needs at least two optimizing cycles for the first time it is used. A battery cycle is defined as one complete, uninterrupted “charge” of the battery, which is followed by a complete, uninterrupted “discharge” of the battery. A battery should be conditioned regularly to maintain its useful life cycle. Condition a battery once when it is used or stored for two months, or when its run time becomes noticeably shorter.

To optimize the battery’s life cycle:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimization into the battery compartment on the monitor.
3. Place the monitor on the charging stand and plug in the AC power cord. Allow the battery to be charged uninterrupted for at least 6 hours.
4. Remove the AC power cord and allow the monitor to run off the battery power until it shuts off.
5. Repeat step 3 and allow the battery to be charged again, uninterruptedly for at least 6 hours.
6. The optimization of the battery is over.

4. CHECKING BATTERY PERFORMANCE

The performance of a battery may deteriorate over time. To check the performance, follow these procedures:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor on the charging stand and plug in the AC power cords. Allow the battery to be charged uninterruptedly for at least 6 hours.
3. Disconnect the AC power cords and allow the monitor to run on battery power until it shuts off.
4. The operating time of a battery reflects its performance directly.

CAUTION

- The operating time of a battery depends on the configurations and operations of the monitor. NIBP measurement, SpO_2 measurement and the use of a recorder will deplete the battery faster.

5. DISPOSAL OF BATTERIES

Damaged or depleted batteries should be properly discarded following Local, State and Federal Regulations.

CAUTION

The life of this battery depends on the service time and frequency. Generally, this battery can be charged up to 300 times depending on the usage and settings.

WARNING

Do not disassemble the battery, dispose of them in fire or cause them to short circuit. They may ignite, explode, or leak, causing personal injury.

CHAPTER 11 – MAINTENANCE & CLEANING

1. INTRODUCTION

To avoid damage to the monitor and the accessories, keep them free of dust and dirt.

1. Dilute the cleaning liquid to the lowest concentration level.
2. Do not immerse the equipment or accessories in liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the housing.
5. Never use abrasive materials (such as steel wool or silver polish), or erosive cleaners (such as acetone or acetone-based cleaners).

WARNING

Always power down the system and disconnect all power cables from the outlets before cleaning.

CAUTION

If liquid spills on the monitor or accessories, contact a licensed professional technician or the manufacturer.

2. CLEANING OF MONITOR

1. Common detergents and non-corrosive disinfectants used in hospitals can be used to clean the monitor. Many cleaning detergents should be diluted prior to use and be used according to the detergent manufacturer's instructions.
2. Avoid the use of alcohols, amino or acetonyl detergents.
3. The enclosure and screen of the device shall be free of dust and can be wiped with a lint-free soft cloth or sponge soaked in detergent. While cleaning the side and back panels, be especially careful to keep liquid away from the cables and outlets.
4. Do not use abrasive material including wire brush or metal brightener during the cleaning process.
5. If a cable or plug accidentally gets wet, rinse it with distilled water or deionized water and dry it in an environment of temperature 40°C to 80°C for at least one hour.

3. CLEANING AND STERILIZING OF ACCESSORIES

3.1 CLEANING A SPO_2 SENSOR

A disinfection solution with isopropyl alcohol 70%, and 10% decolourant is recommended to be used for sterilization at a lower standard. Don't use undiluted decolourant (5%~5.25% sodium hypochlorite) or other non-recommended disinfectors to avoid damage to the sensor.

ATTENTION

- Do not sterilize the sensor by ray, steam or epoxy ethane.
- Do not submerge the sensor in liquid.

3.2 CLEANING THE NIBP CUFF

1. Clean the cuff regularly.
2. Remove the cuff from the connector and take the airbag out of the sheath.
3. Use a damp, soft cloth with mild detergent to wipe the airbag and tubing.
4. Clean the cuff sheath with mild detergent.
5. Air dry all the components at room temperature and enclose airbag with cuff sheath before using.

ATTENTION:

- Excessive or frequent cleaning may damage the airbag. Only clean when necessary.
- Do not dry the airbag and sheath in high temperatures.
- Disposal cuffs are only to be used for one patient.
- When cleaning, keep water and cleaning solutions away from cuff connectors.

3.3 CLEANING THE TEMPERATURE PROBE

A disinfection solution with isopropyl alcohol 70% is recommended to be used for sterilization at a lower standard. Don't use undiluted decolourant (5%~5.25% sodium hypochlorite) or other non-recommended disinfectors to avoid damage to the sensor.

1. Use a clean, soft cloth with water or alcohol solution to wipe the lens gently. Do not submerge the probe in the water or other liquids.
2. Dry the lens at room temperature for 30 min before using. Avoid solarizing directly while the temperature is beyond 10ºC-40ºC.

ATTENTION

- Do not sterilize the sensor by ray, steam or epoxy ethane.
- Do not submerge the sensor in liquid.
- Excessive or frequent cleaning may damage the airbag. Only clean when necessary.

CHAPTER 12 – ACCESSORIES

WARNINGS

- Only use recommended accessories. Using other accessories may cause damage to the monitor.
- Disposable accessories are designed for single patient use only. Reusing accessories may cause a risk of cross-contamination and may affect measurement accuracy.
- Check the accessories and their packaging for any sign of damage. Do not use them if any damage is detected.

1. SPO_2

SPO_2 FOR 10840

TYPE	PN	PATIENT CATEGORY
Reusable	15-100-0013	Adult finger
	15-100-0014	Pediatric finger
	15-100-0015	Neonatal foot/hand

SPO_2 EXTENSION CABLE FOR 10840

ACCESSORIES	PN
Extension cable	15-031-0016

PROPRIETARY SPO_2 EXTENSION CABLE FOR 10841

ACCESSORIES	MODEL/PN
Extension cable	2525

PROPRIETARY SPO_2 SENSOR FOR 10841

TYPE	MODEL/PN	PATIENT CATEGORY
Reusable	DCI / 2501	Adult finger
	DCIP / 2502	Pediatric finger
Disposable	Neo / 2514	Infant foot/hand

2. NIBP

DISPOSABLE CUFFS

MODEL	PATIENT CATEGORY	LIMB CIRCUMFERENCE (CM)
15-100-0104	Neonatal	3-5.5
15-100-0105		4-8
15-100-0106		6-11
15-100-0107		7-13

REUSABLE CUFFS

PN	PATIENT CATEGORY	LIMB CIRCUMFERENCE (CM)
15-100-0118	Adult	25-35
15-100-0142	Adult thigh	44-53
15-100-0120	Large adult	33-47
15-100-0121	Pediatric	18-26
15-100-0122	Infant	6-11

3. TEMPERATURE PROBE

ACCESSORIES	MODEL
Fast temp electronic thermometer	F3000-2
Fast temp probe cover	F3000-3

4. BARCODE SCANNER

ACCESSORIES	MODEL
Barcode scanner	FG2100

APPENDIX A – PRODUCT SPECIFICATIONS

1. SAFETY SPECIFICATIONS

1.1 CLASSIFICATION

Classification of Protection against electric shock	Class I
Degree of protection against electric shock	SpO_2, NIBP, Temp: CF
Degree of protection against hazards of explosion	Not suitable
Degree of protection against ingress of liquid	IPX1
Mode of operation	Continuous

NOTE

Class I: Internally and externally powered equipment

CF: Applied part

BF: Applied part

Not Suitable: Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide

1.2 ENVIRONMENTAL SPECIFICATIONS

Temperature	Operating	5ºC ~ 40ºC
	Transportation and Storage	-20ºC ~ +55ºC
Humidity	Operating	15% ~ 85% (noncondensing)
	Transportation and Storage	10% ~ 93% (noncondensing)
Atmospheric Pressure	Operating	700 ~ 1060 hPa
	Transportation and Storage	500 ~ 1060 hPa

1.3 POWER SPECIFICATIONS

Input voltage	AC (100-240) V,(50/60) Hz
Input power	70VA
Fuse	T1.6AL/250V, 2-Φ5×20mm

1.4 PHYSICAL SPECIFICATIONS

PART	WEIGHT (KG)	SIZE (W × H × D) (MM)
Mainframe	About 2.5 (Including a lithium battery)	<160 × 130 × 260
Temperature module	About 0.16 (Including the connecting wire)	153 × 40.5 × 60

2. HARDWARE SPECIFICATIONS

2.1 DISPLAY

Type	Color TFT LCD
Size (diagonal)	7”
Resolution	234×480 pixels
Anti-glare screen	✓
LCD switch	✓
TEMPERATURE MODULE	
Type	Black and White LCD
Size	1.2"

2.2 RECORDER

Type	Thermal dot array
Paper width	50 mm
Recording width	40 mm
Recording speed	25 mm/s
Recording waveform	double tracks

2.3 BATTERY

Type	Rechargeable Lithium Ion Battery
Model	LB-08
Size	105 mm × 78 mm × 20 mm
Weight	<360 g
Quantity	1
Rated voltage	11.1 VDC
Capability	4000 mAh
Operating time	8 hours – Using a new and fully charged battery at 25ºC ambient temperature, connecting SpO_2 sensor and NIBP work on AUTO mode for 15 minutes interval.
Charge time	6h to 100% (Standby)
Turn off delay	5-15 min after the low battery alarm first occurs.
Indicator of battery capability	✓

2.4 AUDIO INDICATOR

Speaker	Gives audible alarm, QRS tone; Supports Pitch Tone and multi-level volume; Alarm tones meet the requirement of IEC 60601-1-8.
Alarm pressure	45 dB to 85 dB. Testing place is 1 meter from the tone.

2.5 INPUT DEVICE

Function button	5, NIBP, record, suspend/silence, screen switch and power switch
Knob	With
Barcode scanner	Optional
TEMPERATURE MODULE	
Button	1, START

2.6 MAINFRAME LED

Physiological alarm indicating lamp	1 (Yellow/Red)
Technical alarm indicating lamp	1(Cyan/ Yellow)
Power indicating lamp	1(Green/Orange) Green: When powered with AC, it lights green while turn on and off the monitor. Orange: When powered with battery, it lights orange only while turn on the monitor.
Battery charging indicating lamp	1 (Orange)

2.7 CONNECTORS

Center computer connector	RJ-45, 10M/100M, TCP/IP
Serial port	RS232 serial port
Nurse call	Nurse call connector
Equipotential grounding point	1
USB connector	Barcode scanner or other USB devices supported by monitor
SD card connector	reserved connector
Wireless network	reserved connector
Temperature module connector	Temperature probe connector

2.8 SIGNAL OUTPUT

NURSE CALL OUTPUT	
Drive mode	Relay
Electric specification	≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolated voltage	1500VAC
Signal type	N.C., N.O.

2.9 DATA STORAGE

CLINIC MODE	
Patient quantity	1000
Recording number	16000
Single patient clinic Record number	(1-16000)

MONITOR MODE	
Patient quantity	1
Trend data	3 kinds of resolution: 1Min, 5Min, 10Min. 1Min: can store 96 hours 5 Min: can store 480 hours 10 Min: can store 960 hours
Alarm events	1000
NIBP measurement record	5000

3. MEASUREMENT SPECIFICATIONS

3.1 SPO_2

DIGITAL SPO_2 MODULE FOR 10840

Measurement technic	Digital SpO_2
Monitoring parameters	SpO_2 and PR
SpO_2 measurement range	(0~100) %
Resolution	1%
Accuracy	±2% (70~100) % SpO_2 (0~69) % unspecified
PR measurement range	(25~255) bpm
Resolution	1 bpm
Accuracy	±1% or ± 1 bpm, whichever is the greater
Resisting low perfusion ability	With powerful ability of resisting low perfusion, PR amplitude can reach to 0.2% with value of SpO_2 displaying
SpO_2 alarm range	(0~100) %, high/low limit can be adjusted continuously
PR alarm range	(0~300) bpm, high/low limit can be adjusted continuously
Recovery time after defibrillation	≤10 s.
Update time	1s

PROPRIETARY SPO_2 MODULE FOR 10841

Measurement range	0%~100%
Resolution	1%
Accuracy	70%~100%: ±2% (Adult/Pediatric, non-motion conditions) 70%~100%: ±3% (Neonate, non-motion conditions) 70% to 100%: ±3% (motion conditions) 0%~69%, undefined
Recovery time after defibrillation	2s-4s, 4s-6s, 8s, 10s, 12s, 14s, 16s
Average time	≤10 s.
SpO_2 alarm range	(0~100)%, high/low limit can be adjusted continuously
Update time	1s
PR	
Measurement range	25 bpm~240 bpm
Accuracy	±3 bpm (non-motion conditions) ±5 bpm (motion conditions)
Resolution	1 bpm
SPCO	
Measurement range	0% to 100%
Accuracy	0% to 40%: ±3% (non-motion conditions) >40%, unspecified
SPMET	
Measurement range	0% to 100%
Accuracy	0% to 15%: ±1% (non-motion conditions) >15%, unspecified
PI	
Measurement range	0.05% to 20%
SPHB	
Measurement range	0 g/dl to 25 g/dl
Accuracy	8 g/dl to 17 g/dl: ±1 g/dl (non-motion conditions) <8 g/dl or >17 g/dl, unspecified
SPOC	
Measurement range	0 ml/dl to 35 ml/dl

NOTE: The Proprietary sensors have been validated for motion accuracy in human blood studies on healthy adult 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, which encompasses 68% of the population.

3.2 NIBP

Measurement way	Automatic oscillometry		
Measurement range	Adult	Sys	(30~270) mmHg
		Dia	(10~220) mmHg
		Map	(20~235) mmHg
	Pediatric	Sys	(30~235) mmHg
		Dia	(10~220) mmHg
		Map	(20~225) mmHg
	Neonatal	Sys	(30~135) mmHg
		Dia	(10~110) mmHg
		Map	(20~125) mmHg
Cuff pressure range	(0~300) mmHg		
Resolution	1 mmHg		
Pressure accuracy	Static: ±3 mmHg Clinic: Average error: ±5 mmHg, standard deviation: ≤8 mmHg		
Unit	mmHg, kPa		
PR range	(40~240) bpm		
Recovery time after defibrillation	≤10 s.		
PR Resolution	1bpm		
Cuff auto deflation	The cuff will deflate automatically when power is off or time of measurement is beyond 120 seconds (90 seconds for neonate) or the cuff pressure is beyond the overpressure protection set by software and hardware.		
Measurement time	Normally, it is 20s to 45s (depending on HR and moving interference typically)		
Overpressure protection	Adult	(297±3) mmHg	
	Pediatric	(252±3) mmHg	
	Neonatal	(147±3) mmHg	
Alarm range	Sys	(0~300) mmHg, high/low limit can be adjusted continuously	
	Dia	(0~300) mmHg, high/low limit can be adjusted continuously	
	Map	(0~300) mmHg, high/low limit can be adjusted continuously	

3.3 TEMPERATURE

Sensor type	Thermosensitive sensor
Measurement range	30.0ºC~43.0ºC (86ºF~109.4ºF)
Measurement part	Oral, Axillary
Measurement modes	Fast modes, Monitor modes and Cold modes
Unit	ºC, ºF
Resolution	0.1ºC/ºF
Accuracy	Oral Fast mode: ±0.2ºC Axillary Fast mode: ±0.1ºC Monitor mode, Cold mode: ±0.1ºC (the accuracy must be tested in constant temperature water tank)
Update time	Every 1s
Preheat time	About 800 ms
Self-checking	Every 3s
Alarm range	30.0~43.0ºC, up-low range can be adjustable
Alarm indication	Sound and light alarm, three alarm level, alarm message display with flashing words.
Recovery time after defibrillation	≤10 s.
Transient response time in Monitor mode	<30s
minimum measuring time in monitor mode	100s

APPENDIX B – FACTORY DEFAULTS

1. PATIENT MESSAGES

PATIENT MESSAGES	FACTORY DEFAULTS
Type	Adult

2. ALARM

ALARM SETUP	FACTORY DEFAULTS
ALM Volume	2
Alarm paused time	2 min

3. INTERFACE SETUP

INTERFACE SETUP	FACTORY DEFAULTS
Brightness	3

4. SPO_2

4.1 GENERAL SETUPS

SPO_2 SETUP	ADULT	PEDIATRIC	NEONATAL
Alarm switch	On		
Alarm Level	Medium		
Alarm Print	Off		
Average Time	8s		
High alarm limit of SpO_2	100%	100%	95%
Low alarm limit of SpO_2	90%	90%	85%
Desat Limit	85%		
PLETH			
Wave Speed	25mm/s		
Color	Yellow		

4.2 SPECIAL SETUPS (PROPRIETARY) FOR 10841

SPO_2 SETUP	FACTORY DEFAULTS
Sensitivity Mode	Normal
Fast Sat Mode	off
Smart Tone Mode	off
Waveform Mode	Resp. out
Alarm Delay	off
SpHb Mode	Arterial
SpHb Average Time	Long
SpHb Precision	0.1
SpHb Unit	g/dL

5. NIBP

NIBP SETUP	ADULT	PEDIATRIC	NEONATAL
Alarm switch	On		
Alarm Level	Medium		
Alarm Print	Off		
High alarm limit of Sys	160 mmHg	120 mmHg	90 mmHg
Low alarm limit of Sys	90 mmHg	70 mmHg	40 mmHg
High alarm limit of Map	110 mmHg	90 mmHg	70 mmHg
Low alarm limit of Map	60 mmHg	50 mmHg	25 mmHg
High alarm limit of Dia	90 mmHg	70 mmHg	60 mmHg
Low alarm limit of Dia	50 mmHg	40 mmHg	20 mmHg
Measure Mode	Manual		
Unit	mmHg		
Interval	15 min		
Color	red		
Venipuncture Press	60 mmHg	40 mmHg	30 mmHg
Inflation	170 mmHg	130 mmHg	100 mmHg

6. TEMPERATURE

TEMPERATURE SETUP	FACTORY DEFAULTS
Alarm switch	On
Alarm Level	Medium
Unit	ºC
High alarm limit of temperature	39ºC
Low alarm limit of temperature	36ºC

APPENDIX C – ALARM MESSAGES

1. PHYSIOLOGICAL ALARM MESSAGES

The third column in the following tables show the factory default “Alarm level.”
Levels with a “*” can be changed by the user.

SPO_2

ALARM MESSAGES	CAUSE	LEVEL
SpO_2 High	SpO_2 measuring value is above the high alarm limit	Medium *
SpO_2 Low	SpO_2 measuring value is below the low alarm limit	Medium *
SpO_2 Desat	SpO_2 measuring value is too low.	HIGH
PR High	PR measuring value is above the high alarm limit	Medium *
PR Low	PR measuring value is below the low alarm limit	Medium *
SpO_2 No Pulse	SpO_2 signal is predominantly invalid and therefore, cannot be analyzed	HIGH

NIBP

ALARM MESSAGES	CAUSE	LEVEL
NIBP Sys High	NIBP Sys measuring value is above high alarm limit	Medium *
NIBP Sys Low	NIBP Sys measuring value is below low alarm limit	
NIBP Dia High	NIBP Dia measuring value is above high alarm limit	
NIBP Dia Low	NIBP Dia measuring value is below low alarm limit	
NIBP Map High	NIBP Map measuring value is above high alarm limit	
NIBP Map Low	NIBP Map measuring value is below low alarm limit	

TEMPERATURE

ALARM MESSAGES	CAUSE	LEVEL
Temperature High	Temperature measuring value is above high alarm limit	Medium *
Temperature Low	Temperature measuring value is below low alarm limit.	Medium *

2. TECHNICAL ALARM MESSAGES

SYSTEM

ALARM MESSAGES	CAUSE	LEVEL
Battery Failure	Battery failure or no battery.	Low
Battery Low	Voltage of battery is too low.	Medium
SD Write Protected	SD memory card is write-protecting.	Low
SD Unknown part	The inserted SD card is unrecognized.	Low
SD Write Error	SD card is miswriting.	Medium
SD No Space	SD card has no space.	Medium
Flash No Space	Interior flash has no space.	Medium
Recorder Error	No paper in the recorder when recording or the recorder door is open, or recorder is absent.	Low

SPO_2 FOR 10840

ALARM MESSAGES	CAUSE	LEVEL
SpO_2 Sensor off	SpO_2 sensor may be disconnected from the patient or the monitor	Medium
SpO_2 sensor error	SpO_2 sensor failure	Low
SpO_2 signal weak	SpO_2 signal is weak.	Low

PROPRIETARY SPO_2 FOR 10841

ALARM MESSAGES	CAUSE	LEVEL
SpO_2 No cable	No cable connected	Low
SpO_2 Replace cable	Cable life expired; Cable is defective	
SpO_2 Incompatible cable	Cable is incompatible	
SpO_2 Unrecognized cable	Cable is unrecognized	
SpO_2 No sensor	No sensor connected	
SpO_2 Replace sensor	Sensor life expired; Sensor is defective	
SpO_2 Invalid sensor	Sensor is incompatible; Sensor is unrecognized	
SpO_2 No tape	No tape	
SpO_2 Replace tape	Tape life expired; Tape is defective	
SpO_2 Invalid tape	Tape is incompatible; Tape is unrecognized	
SpO_2 Sensor Calibrating	Sensor is calibrating	
SpO_2 Sensor off	Sensor may be disconnected from patient	
SpO_2 Pulse search	Searching pulse	
SpO_2 Interference	Interference detected	
SpO_2 Low perfusion	Low perfusion index	
SpO_2 Demo Mode	The monitor is at demo mode	
SpO_2 Check sensor	Check sensor is connecting	
SpO_2 Low SIQ	SpO_2 Signal IQ is low	
SpO_2 Low PR SIQ	PR Signal IQ is low	
SpO_2 Low PI SIQ	PI confidence is low	
SpO_2 Low SpCO SIQ	SpCO Signal IQ is low	
SpO_2 Low SpMet SIQ	SpMet Signal IQ is low	Low
SpO_2 Low SpHb SIQ	SpHb Signal IQ is low	
SpO_2 Low SpOC SIQ	SpOC Signal IQ is low	
SpO_2 Low PVI SIQ	PVI Signal IQ is low	
SpO_2 Board Failure	SpO_2 board is failure	
SpO_2 Failure	SpO_2 module is failure	
SpO_2 Communication Error	SpO_2 communication is error	
SpO_2 Enter Programming Mode	SpO_2 is entering programming mode	
SpO_2 Weak signal	SpO_2 signal is weak	
SpO_2 PR Over 239bpm	SpO_2 PR is over 239bpm	

NIBP

ALARM MESSAGES	CAUSE	LEVEL
Self-test Failed	Transducer or other hardware failure.	Low
Loose Cuff	1. Cuff is completely unwrapped. 2. The cuff is not connected. 3. Adult cuff used in neonate mode.	
Air Leak	Air leak in pneumatics, hose, or cuff.	
Air Pressure Error	Unable to maintain stable cuff pressure, e.g. kinked hose	
Weak Signal	Very weak patient signal due to a loosely wrapped cuff. The pulse of patient is too weak	
Range Exceeded	Measurement range exceeds module specification	
Excessive Motion	1. Too many retries due to interference of motion artifact. 2. Signal is too noisy during measurement, e.g. patient has severe tremor. 3. Irregular pulse rate, e.g. arrhythmia	
Overpressure Sensed	Cuff pressure exceeds the specified high safety limit. Could be due to rapid squeezing or bumping of cuff.	
Signal Saturated	Large motion artifact that saturates the BP amplifier's amplitude handing capability.	
Pneumatic Leak	Module reports Air Leakage failure while in the Pneumatic Test mode.	
System Failure	Module occurs abnormal processor event.	
Time Out	Measurement took more than 120 seconds in adult, 90 seconds in neonate mode.	
Cuff Type Err	Neonate cuff is used in adult mode.	

TEMPERATURE MEASUREMENT

ALARM MESSAGES	CAUSE	LEVEL
Fast temp module error	Temperature module breakdown	Middle
Temperature sensor disconnection	The temperature sensor is not installed.	Middle
Temperature over range Up	The ambient temperature is higher than 43ºC.	Low
Temperature over range Down	The ambient temperature is lower than 30ºC.	Low

APPENDIX C – ALARM MESSAGES *(Continued)*

3. PROMPT MESSAGES

SYSTEM

ALARM MESSAGES	CAUSE	LEVEL
Recording	Recorder is in printing operation.	No level

SPO_2

ALARM MESSAGES	CAUSE	LEVEL
Search pulse	SpO_2 module is searching for pulse.	No level
Motion interference	Patient movement is too much.	No level

NIBP

ALARM MESSAGES	CAUSE	LEVEL
Software Overpress	NIBP is testing Software Over-Pressure.	No level
Hardware Overpress	NIBP is testing Hardware Over-Pressure.	
Manometer	NIBP is testing Manometer.	
Air Leakage Testing	NIBP is testing Air Leakage.	
Venipuncture	NIBP is in venipuncture.	

APPENDIX D – GUIDANCE AND MANUFACTURER'S DECLARATION OF EMC

Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.		
EMISSION TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
RF emissions CISPR 11	Group 1	The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

APPENDIX D – GUIDANCE AND MANUFACTURER'S DECLARATION OF EMC *(Continued)*

Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

APPENDIX D – GUIDANCE AND MANUFACTURER'S DECLARATION OF EMC *(Continued)*

Guidance and manufacturer's declaration – electromagnetic immunity –for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**. $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

APPENDIX D – GUIDANCE AND MANUFACTURER'S DECLARATION OF EMC *(Continued)*

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the V6 monitor			
The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHZ to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHZ to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Warning

• This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

• Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

Caution

• This unit has been thoroughly tested and inspected to assure proper performance and operation!

• This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used

LIMITED WARRANTY

Your Dynarex Product is warrantied to be free of defects in materials and workmanship for two (2) years on the unit, and six (6) months on the connected accessories included with the unit from the original date of purchase. This item was built to exacting standards and carefully inspected prior to shipment. This Limited Lifetime Warranty is an expression of our confidence in the materials and workmanship of our products and our assurance to the consumer of years of dependable service.

The Warranty shall not apply under the following conditions:

- Problems arising from normal wear
- Problems arising from failure to adhere to the product instructions
- Problems arising from misuse, negligence, accident or improper operation, maintenance or storage
- Problems arising from modifications or unauthorized repairs, parts or attachments
- Products where the serial number has been removed or defaced
- Problems with non-durable components, such as rubber accessories, casters, and grips, which are subject to normal wear and need periodic replacement

Dynarex shall not be liable for any consequential or incidental damages whatsoever. Dynarex shall repair or replace defective products at its option. The foregoing warranty is exclusive and in lieu of other express warranties, if any, including the implied warranties of merchantability and fitness of a particular purpose. The remedy for any violation of the implied warranty shall be limited to repair or replacement of the defective product pursuant to the terms contained herein.

If you have a question about your Dynarex device or this warranty, please contact an authorized Dynarex dealer.

SYMBOL GLOSSARY
For an explanation of symbols used in Dynarex packaging, visit **dynarex.com/symbols.php**

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