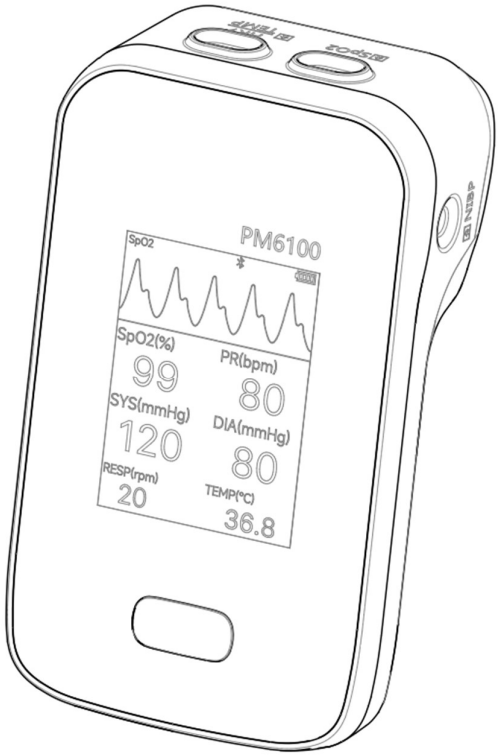
BERRY

Patient Monitor

Operation Manual

PM6100/PM6100A/PM6100B/PM6100C



Shanghai Berry Electronic Tech Co., Ltd.

Release date: 02/15/2023 Version: 1.3

Version Information

Version	Date	Content
V1.0	2016/06/27	Create this document.
V1.1	2017/10/12	Refined details.
V1.2	2021/12/12	Refined details.
V1.3	2023/02/15	Upgrade product.

Preface

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Observance of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety.

Berry doesn't make a guarantee in any forms for this manual including (but not limited to) the guarantee of its implied marketability and suitability which is put forward for certain purpose. Berry isn't responsible for the mistakes in this manual and the accidental or indirect damage caused by using this manual.

Statement & Services

Berry will be responsible for safety, reliability and performance of the device only under these circumstances:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Berry or manufacturer authorized personnel; and
- The electrical installation of the relevant room complies with the applicable national and local requirements; and
- This product is operated under strict observance of this manual.

If each hospital or organization which is responsible for using this device cannot make a satisfied repair plan, it may result in the abnormal equipment failure and threaten human health.

Berry will be responsible for technical support and any services of setting up, using and maintaining, so for lay operator

If need technical support in setting up, using, or maintaining the monitor, please contact Berry. Any unexpected operation or events, Any changes in the performance, please contact Berry for technical support and solutions.

Guarantee

■ Berry provides after-sales service in time for PM6100 which conforms to the warranty regulations.

The warranty period of the main machine is 1 year and the accessories are 6 months since the sales date.

■ Berry’s obligation under this assurance doesn’t include freight, other cost. Berry has no responsibility for direct, indirect or ultimate damage and delay under these circumstances: improper use, replace accessories not permitted by Berry or repaired by people Berry doesn’ t authorize.

■ This assurance is not applicable to these situations: non-normal use, without maintenance or broken device, Berry’ s label and mark is changed or torn off.

Safety, Reliability and Operation

Berry will be not responsible for safety, reliability and running state of PM6100 series Patient Monitor under these circumstances:

■ **Components are disassembled, stretched and reset.**

■ **PM6100 series Patient Monitor isn’t operated according to the operation manual.**

For home healthcare environment , the patient will be an intended operator, if not, the operator must be around the patient during the measurements. all measures include Heart Rate, SpO2, Pulse Rate, Body temperature, respiration rate and NIBP can be safely performed by operator.

The operator can do some simple inspection and maintenance (refer Chapter 6 Maintenance and Cleaning), and any other complex inspection, calibration, maintenance and components replacement shall be preformed by Berry or a service personal authorized by Berry, if you need related services please contact with Berry’s customer service team.

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Chapter 1 Safety Information

This chapter introduces the safety information of PM6100 series Patient Monitor (hereinafter called as Patient Monitor). Users should pay attention to and obey these notes.

The following symbol warning and caution remind users to pay attention to the potential danger while using and they should be used with the words.

WARNING:

It prompts the information about what may inflict severe hurt on human even threat to life.

CAUTION:

It prompts the information about what may inflict slight hurt on human or damage the products.

NOTE:

It emphasizes important attentions, provides illustration or explanation.

1.1 WARNING

- **Before using Patient Monitor, please read this manual carefully and the person who uses Patient Monitor must receive adequate training.**
- **Users should check Patient Monitor and its accessories if they can operate safely and normally before using.**
- **Do not use patient monitor with high frequency surgical equipment.**
- **Never open the enclosure to avoid getting an electric shock. Any repairment and upgrade should be carried out by Berry or service personal trained and authorized by manufacturer.**
- **Patient Monitor is common Non-sealing device, users should make sure the**

surface is dry and clean and prevent liquid to get in.

- **Users should place Patient Monitor properly. Avoid damage caused by falling equipment from high fall.**
- **If patient is an intended operator who uses Patient Monitor in the home healthcare environment, you must read the operation manual carefully and understand deeply or consult with the doctor and manufacturer before using. If you have any discomfort in use, please stop using immediately and go to the hospital.**
- **Do not modify Patient Monitor without authorization of the manufacturer.**
- **Don't dismantle and replace the battery without authorization. When the battery is low or it has not been used for a long time, please charge the battery in time but protecting against overcharging.**
- **Patient Monitor is without alarm function. Continuous monitoring for a long time is not suitable.**
- **Make sure not to use Patient Monitor during MRI (magnetic resonance imaging) scanning or CT (Computed Tomography) environment because induced current could potentially cause burns.**
- **Please use the accessories matching with Patient Monitor or use the accessories which the manufacturer has approved of. The operator is responsible for checking the compatibility of Patient Monitor and the accessories before use. And incompatible components can result in degrading performance. If there are signs of damage, please stop using.**
- **EXPLOSION HAZARD: Do not use Patient Monitor in the presence of flammable anesthetics, explosive substances, vapors or liquids.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Patient Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **If Patient Monitor uses unspecified and without EMC test system configuration, it can enhance electromagnetic radiation or reduce anti-electromagnetic interference performance. Please use the specified configuration.**
- **For disposal of Patient Monitor and accessories, follow local regulations or your hospital's policy regarding disposal of such Patient Monitor and**

accessories. You may contact manufacturer or local authorities to determine the proper method of disposal of potentially bio-hazardous parts and ACCESSORIES. Do not dispose randomly.

- **If the accessories are intended for single-use, please scrap according to relevant regulations after use. It is forbidden to reuse.**
- **Connect cables and hoses carefully to avoid the patient being twined or strangulated.**
- **Mental retarded persons must be used under the guardianship of normal adults to avoid strangulation due to cables and hoses.**
- **Please place the monitor away from baby or child.**
- **The lint, dust and light (including sunlight) can affect measurement accuracy and service life of the product. Don't place or use Patient Monitor in these environments.**
- **High ambient light, heat from a fireplace or radiant heater or lasers may result in inaccurate measurements.**
- **Moisture from a nebuliser or steam kettle may result in inaccurate measurements**
- **Keep the monitor away from heater, external electrical influences.**
- **Do not charge the monitor when the Mains electricity is unstable.**
- **Portable and mobile radio frequency communication equipment can affect the normal use of the monitor, keep them away if necessary.**
- **Keep the monitor away from magnetic fields, electromagnetic Fields.**
- **Do not use monitor during pressure variation environment.**
- **The degraded sensors and electrodes, or loosened electrodes, these can degrade the product performance. It is recommended to replace sensors and electrodes regularly.**
- **Please place Patient Monitor in places where children and pets do not reach to avoid damaging the product.**
- **If the Patient Monitor and accessories haven't used for a long time, cleaning and disinfection should be carried out according to the method specified in the instruction before use.**
- **Cross infection may happen when the monitor is used between different patients. Users should prevent and control it. Patient Monitor and**

accessories should be cleaned or disinfected before it is used between different patients.

- **The Patient Monitor can only monitor one patient at a time.**

Chapter 2 Summary

2.1 Product Description

PM6100 series patient monitor is a kind of patient monitor which is non-invasive, colorized, easy to be carried and it takes the rechargeable battery to power supply. It has the characteristic of small size, light weight, easy to use and so on. It is widely used in outpatient service, ward, rehabilitation institution and home nursing etc.

PM6100 series patient monitor can monitor physiological signals including HR (Heart Rate), NIBP (non-invasive blood pressure), SpO_2, PR (pulse rate), TEMP (body temperature) and RESP (Respiration rate).

The monitor use the HR&TEMP lead cable, NIBP cuff and extension catheter, SpO_2 sensor to monitor patient's physiological signals. The numerical results and waveform will be calculated and displayed on the TFT-LCD screen after further processing.

Operate and control the monitor by pressing button on the front-panel, and numerical value and waveform will be displayed on the TFT-LCD screen during the measurements. You can transfer the results calculated to the intelligent terminal such as phones, PC and tablets via the Bluetooth inside.

PM6100 series patient monitor has four different models and the corresponding functions are different. You can find the differences in detail refer to the Model differences table 2-1 below.

Function / Type	SpO_2	HR	NIBP	Temp	Communication
PM6100	●	●	●	●	●
PM6100A	●	—	●	—	●
PM6100B	●	—	●	—	—
PM6100C	●	●	●	●	—
"●": with this configuration "—": without this configuration					

Table 2-1 Model differences table

2.2 Function and Features

- Compact size, lightweight, easy to use and carry.
- Numerical results and waveform are shown on the TFT-LCD in real time.
- Include HR, NIBP, SpO_2, PR, TEMP and RESP measurement.
- Low power consumption.
- Lithium battery is built in.
- Communication with other intelligent terminals via Bluetooth.
- Automatically power off to save power.

2.3 Product Appearance

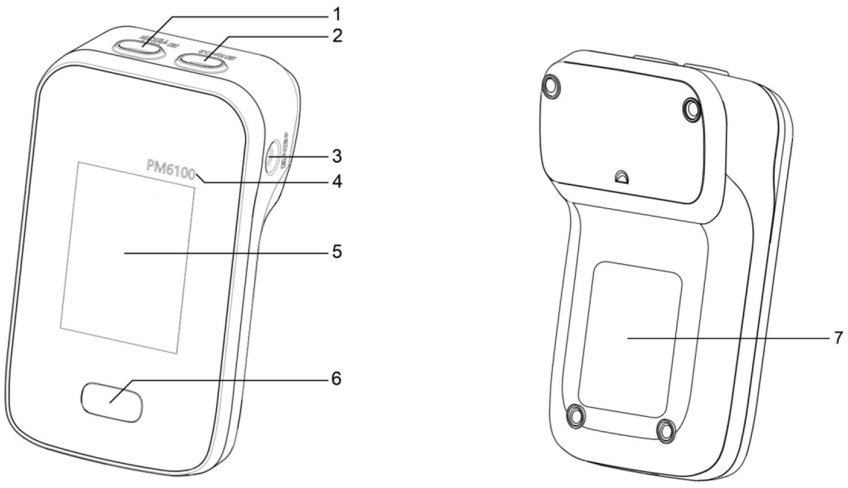

Figure2-1 Product Appearance

Number	Name	Purpose
1	HR&TEMP	Connecting HR&TEMP lead cable, charging
2	SpO_2	Connecting SpO_2 sensor
3	NIBP	Connecting NIBP cuff

4	Type Specification	PM6100/PM6100A/PM6100B/PM6100C
5	TFT screen	Displaying data like results of monitoring, waveform in real time
6	Button	Power on/off , Performing different functions
7	Nameplate	Pasting the nameplate

Table 2-2 Explanation of the product appearance

2.4 Components

PM6100 series Patient Monitor consists of the host, HR&TEMP lead cable, NIBP cuff, SpO_2 sensor, charging line.

2.5 Intended Use

PM6100 series patient monitor intended to be used to obtain measurements of vital physiological signals including HR (heart rate), NIBP (non-invasive blood pressure), SpO_2 (oxyhemoglobin saturation), PR (pulse rate), TEMP (body temperature) and RESP (Respiration rate) in routine check-up and in self-monitoring. It is not intended for continuous monitoring. And it is not intended for anesthesia, ICU and emergency care.

2.6 Applicable People and Scope

PM6100 series Patient Monitor is applicable for outpatient department, sickroom, recovery and health care organizations, community medical treatments and home nursing etc. And PM6100 series Patient Monitor is only applicable to adults, not applied to pediatric and neonatal patients, not applied to pregnant or pre-eclamptic patient.

2.7 Contraindications

- The presence of an ongoing need for measurement of pH, PaCO2, total hemoglobin, and abnormal hemoglobins may be a relative contraindication to SpO2 measurement.
- Patients with a side affected by stroke, mastectomy or renal fistula should avoid having blood pressure readings taken on this side.

Chapter 3 Preparation and Power On

3.1 Unpacking and Checking

Take Patient Monitor and accessories out of the package carefully. Then check them on the basis of packing list.

NOTE：

- **Check the product if mechanical damage exists.**
- **Check if all the lead cable and accessories are well.**

3.2 Connecting Accessories

Connect the following accessories (HR&TEMP cable, NIBP cuff, SpO_2 sensor) to the monitor according to figure2-1 and table2-1.

Figure 3-1 HR&TEMP cable

Figure 3-2 SpO_2 sensor

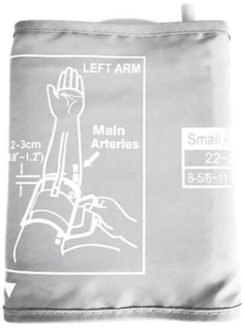

Figure 3-3 NIBP Cuff

NOTE：

- **The applied parts of Patient Monitor are TEMP cable, NIBP cuff and SpO2 sensor refer the Figure 3-5 below.**

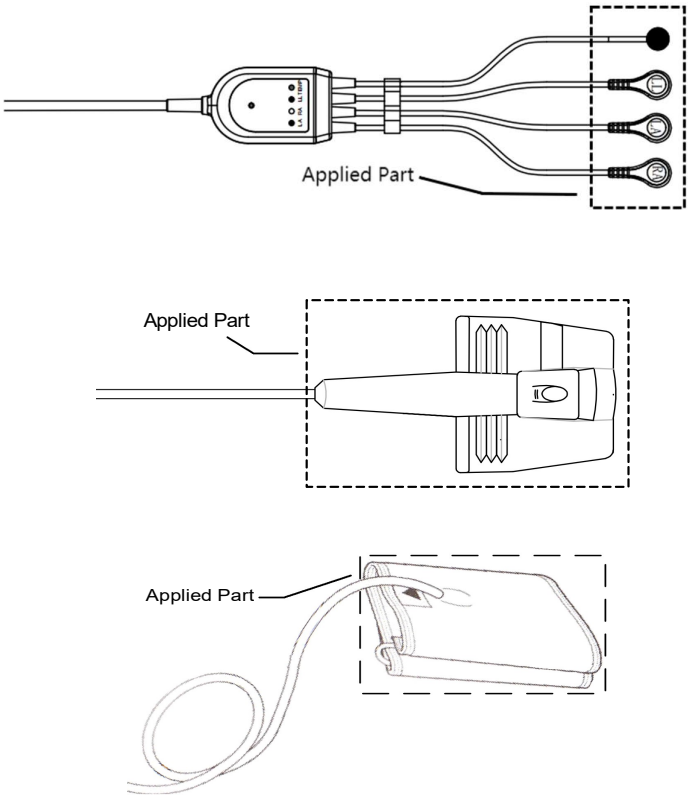

Figure 3-5 Applied Parts

WARNING:

- **All accessories above are specified by the manufacturer for this monitor, Do not use on the other monitors.**
- **Carefully route cable to reduce the possibility of patient entanglement or strangulation.**

3.3 Power On

Press the button (refer to figure2-1) after properly connecting accessories, then Patient Monitor will be power on and screen will be lit up.

Chapter 4 Operation and Display

The design concept of PM6100 series patient monitor is convenient to operate. All measurements can be performed by one button on the panel.

4.1 Display

The screen will display the numerical results and waveform like figure 4-1 below when the accessories are connected to patient monitor and human body correctly.

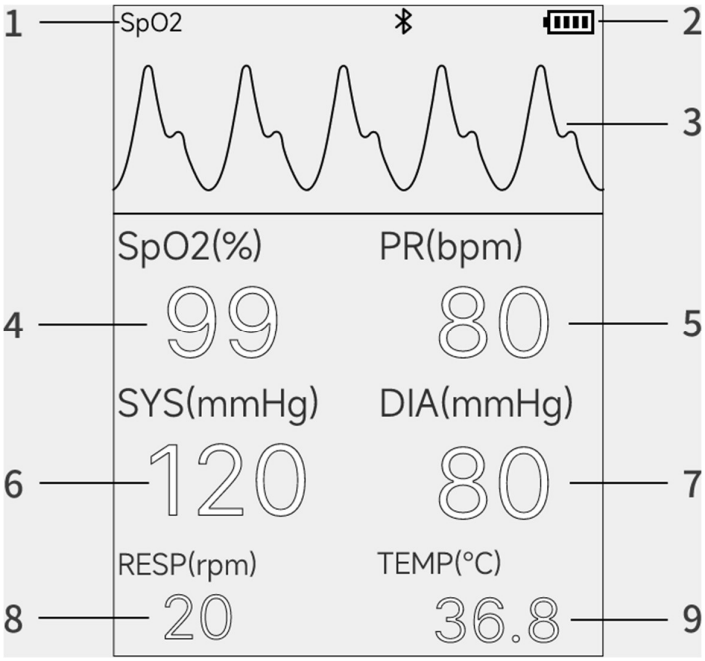

Figure 4-1 Main Screen

Number	Implication	Purpose
1	Waveform Title	Instruction of the waveform name displayed below
2	Battery indicator	Instruction of state of battery level
3	Waveform display area	Display area of the SpO2 pulse waveform
4	SpO2	Arterial oxygen saturation in the blood
5	HR/PR	Heart Rate or Pulse Rate

6	SYS	Systolic blood pressure (High pressure)
7	DIA	Diastolic blood pressure (Low pressure)
8	RESP	Respiration Rate
9	TEMP	Body Temperature

Table 4-1

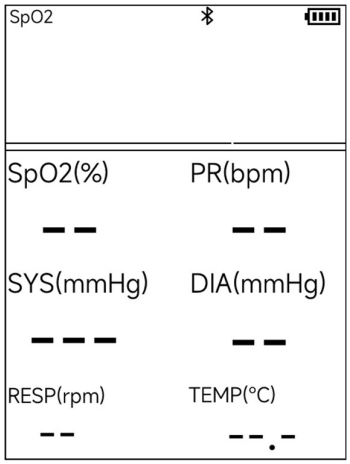

Figure 4-2 Invalid Value

When the received signal is inadequacy, "- -", "▬" will be displayed on the screen (As shown in **Figure 4-2**).

The Battery indicator provides a means to the operator to determine the state of the battery inside, different indicators symbol means different state of the battery:

"🔋" indicates the percentage of the remaining energy about 100%;

"🔋" indicates the percentage of the remaining energy about 75%;

"🔋" indicates the percentage of the remaining energy about 50%;

"🔋" indicates the percentage of the remaining energy about 25%;

"🔋" indicates the percentage of the remaining energy about 5%, the power is low, please recharge the battery, and if not the device will be power off in 5 minutes.

NOTE:

- **When you switch on the device or place the sensor, numerical value may be the data of transient process because it takes a period of time to receive stable data, trend chart may be mutated or transitive. The data cannot be used as diagnosis during transition process.**

4.2 Operation

Patient Monitor only has one button, you can realize different operation by click and long press. Click the button to switch on the device when it's off.

Click the button to start NIBP measurements when it's off. Click the button while measuring will cancel the NIBP measurement.

When finish all your measurements, you can power off the monitor by long press.

4.3 Charging

The power supply of Patient Monitor depends on the built-in lithium battery. The battery will be charged automatically when Patient Monitor is connected to USB equipment, no matter Patient Monitor is powered on or not.

CAUTION:

- **Patient Monitor takes the built-in rechargeable lithium battery. Low battery level can result in running abnormally. Never use Patient Monitor while charging in order to prevent electric shock.**

WARNING：

- **The product can't be used while the internal lithium battery is charging.**
- **When the battery is nearly exhausted, the device can last for 5 minutes.**
- **Selection and replacement of the Battery are only provided by the manufacturer.**
- **The battery charger shall meet the requirements of IEC60601-1, Class II.**
- **The output voltage of the charger should be 5V, and current should be 1A.**
- **Charge the battery if not be used for a long time.**

4.4 Bluetooth

PM6100 provides wireless connectivity with Bluetooth LE 5.0 compliance.
Measurement results from patient monitor can be transferred out via Bluetooth.

Chapter 5 Measurement parameters description

5.1 HR

5.1.1 Measuring Principle

The HR (Heart Rate) signal is the body surface performance of epicardium electrical activity when the heart beats regularly. The human body Heart Rate will be achieved on the display or record though collecting body electrical signals by the HR&TEMP lead cable. This monitor uses 3-lead cable. Place the 3-lead cable on the body properly, then heart rate will be calculated and displayed.

5.1.2 Measurement Procedure

◆ **Skin Cleaning**

Human's skin is a poor conductor, so satisfied HR measurement will be gotten only when skin and electrode are in good contact. Use soap and water to clean the skin first, then dry the skin to remove the cutin and grease. Barbering should be made at the skin which the electrodes connect with if necessary.

◆ **Electrodes Preparation**

Put the button or pinch-cock of the lead cable on the electrodes. If the electrode contains conductive gel, peel off the gummed paper and stick the electrode on human body. If the electrode doesn't contain conductive gel, you should apply conductive gel on patient before placing electrode.

◆ **Electrodes Placement**

Positions of three lead cable electrode placement refers to figure 5-1 below.

American Standard		**European Standard**		**Placement position**
Label	Color	Label	Color	
RA	White	R	Red	Under right collar bone, close to right shoulder
LA	Black	L	Yellow	Under left collar bone, close to left shoulder
LL	Red	F	Green	At the left hypogastrium

Table 5-1

The electrodes can be placed at back or side of the chest and they should be away from the place where lays chirurgic fulgurize equipment to reduce interfere in thoracotomy.

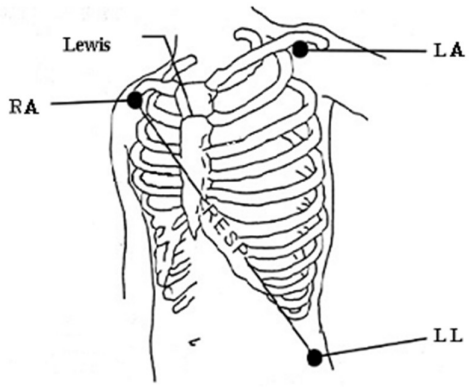

Figure 5-1 Positions of three lead cables electrode placement

CAUTION：

- **Placement position of electrodes should be less interferential.**
- **Not grounded devices and electrosurgery unit near the patient will disturb the performance.**
- **Never put the electrodes close to the ground plate of electrosurgery unit, otherwise the HR signal will be disturbed extensively. Several electrodes should be equidistant from the axis of electric cautery and ground plate.**
- **Electrodes should be stuck firmly to make sure that skin has reliable contact with the conductive part.**

5.2 SpO_2

5.2.1 Measuring Principle

SpO_2 and PLETH function can monitor physiological parameters including blood oxygen saturation (SpO_2), pulse rate (PR), plethysmography (PLETH).

SPO2 measurement is a continuous, non-invasive method of measuring Hemoglobin oxygen saturation. It depends on the principle of spectrophotometer which states that Hemoglobin and oxygen and hemoglobin receive different light with different wavelength. It measures how much lights radiated from the light source in the sensor

penetrate patient's tissue (such as fingers and toes) to the receiver. The amount of the penetrating lights depends on several factors and most of them are constant. But the arterial blood changes with time regularly because it's pulsant. The monitor achieves PR, PLETH, and SpO_2 at the same time by measuring the received lights during the pulsing. Then numerical results and PLETH waveform will be displayed on the TFT-LCD screen.

The range of the peak wavelengths: 666nm/905nm. The maximum optical output power of the light emitted: < 1mW.

NOTE:

- **The range of the peak wavelengths is specially useful for clinicians performing photodynamic therapy.**
- **Perform SpO2 measurement in the environment as Appendix I Environment Requirements, keep the finger in the SpO2 sensor stationary.**

5.2.2 Measurement Procedure

Figure5-2 shows how to put your finger in the sensor.

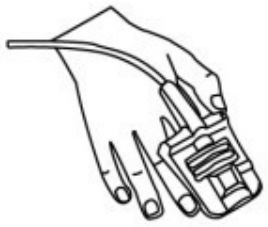

Figure5-2

NOTE：

- **The average of SpO2 and Pulse Rate calculation time is less then 10s, and the waveform of the plethysmography is filtered.**
- **Data(SPO2 and Pulse Rate) update period is less than 10 seconds.**
- **No measurement values displayed ("--" displayed)when signal inadequacy.**
- **Place the SpO2 sensor cable at the backside of the patient hand as Figure 5-2. Make sure the fingernail is just opposite to the light emitted from the sensor.**
- **The highest temperature of sensor contacts with patient's skin don't be allowed more than 41℃.**
- **A functional tester can't be used to evaluate the accuracy.**

WARNING:

- **SpO2 measurement have no alarm system, continuous monitoring for a long time is not suitable.**

5.2.3 Measuring Limit

If the result of measure is not accurate enough, you should check the patient's vital signs with other ways and check the device.

Inaccurate results may be caused by following reasons:

- **Improper SpO_2 sensor was used.**
- **The electrosurgery unit used together with Patient Monitor leads to high frequency electrical interference.**
- **Function of hemoglobin is disordered severely.**
- **There exist diluent chemicals like carboxyhemoglobin, ferrihemoglobin or dye.**
- **Intravascular stain such as indocyanine green and methylene blue.**
- **Exposed to lights excessively like surgical lamp, bilirubin lights, fluorescent lamp, infrared lamp or direct sunlight.**
- **Patient moves frequently.**
- **Vein vibrates rhythmically.**
- **SpO_2 value is too low.**
- **Sensor isn't placed well or at the correct place.**
- **Sensor, NIBP cuff, arterial duct are connected to the same limb.**

Each of the following circumstances may result in the lost of pulse signal:

- **Sensor is too tight**
- **Exposed to lights excessively like surgical lamp, bilirubin lights, fluorescent lamp, infrared lamp or the sunshine.**
- **SpO_2 sensor and NIBP cuff are connected to the same limb.**
- **Patient suffers from hypopiesia, badly vasoconstriction, anemia or low temperature.**
- **Arterial occlusion exists near the sensor.**
- **Cardiac arrest or shock appears.**

NOTE：

- **The SpO2 basic functions of this monitor has been verified via SpO_2 simulator (Type of SpO_2 simulator: FLUKE Prosim 8 Software Version V2.05). This verification can be performed by service personal or the manufacturer.**
- **When the pulse oximeter probe faults(probe cable open or short circuit), the result value will be "- -" and the wave will be "" for indication.**

WARNING：

- **Check if the SpO_2 sensor and lead cable are in good condition before monitoring. Do not use it if you find anything damaged.**
- **The SPO2 function is intended for patient assessment. It must be used in conjunction with clinical signs and symptoms. It is not intended for treatment.**
- **Lead cable of electrosurgery unit and SpO_2 sensor can't be twined together.**
- **Take down the SpO_2 sensor from patient in time after measuring.**
- **Don't put the SpO_2 sensor on the limb which is connected with arterial catheter and intravenous catheter.**
- **If the pulse cannot be searched or the value isn't reasonable, you should check the patient first. If the patient is well, check the SpO_2 sensor's placement and its connection to Patient Monitor. When you confirm the above mentioned have no problem, you can find a qualified engineer to check if the device and SpO_2 sensor works normally.**
- **Constant and long time monitoring may increase unpredictable change on the skin. Such as allergy, red and swollen, blister, pressure necrosis etc. Some patients need examination more frequently such as people with perfusion disturbance or sensitive skin. During constant and long time monitoring, you should check the placement of the sensor per 2-3 hours and move the SpO_2 sensor appropriately when the skin changes.**
- **Make sure no dirt and scar exists at the measuring position, or the low SpO_2 signal will result in the inaccurate results.**
- **Make sure to verify to the compatibility of the monitor and spo2 sensor, only the sensor specified by manufacturer is applicable to this monitor.**

- **Misapplication of a PULSE OXIMETER PROBE with excessive pressure for prolonged periods can induce pressure injury**
- **Don't perform SpO_2 sensor and NIBP measure on the same arm simultaneously. Obstruction of blood flow during NIBP measure may adversely affect the reading of the SpO_2 value.**
- **The SpO_2 simulator is calibrated to display functional oxygen saturation.**
- **The material in contact with the patient has been passed test for biocompatibility.**

CAUTION:

- **SpO_2 sensor is precise and fragile, stress and crash should be avoided. It should be rolled up loosely while not using. Don't pull it forcibly to avoid damage of SpO_2 sensor and the lead cable.**

5.3 NIBP

5.3.1 Measuring principle

Patient Monitor uses the method of oscillographic vibration to measure noninvasive blood pressure, Oscillography inspects the change of blood pressure in artery and the pressure in the cuff. The change of pressure in the NIBP cuff will be inspected while the cuff is deflated.

5.3.2 Measurement Procedure

Standard size of cuff: 22~30cm

◆ **Cuff Selection**

Recognize limbs circumference of patient. Then choose the appropriate cuff.

◆ **Cuff Placement**

1. Make the patient comfortably seated and legs uncrossed, feet flat on the floor, back and arm supported.

2. Make the cuff surround limb comfortably, middle of the cuff at the level of the right atrium of the heart.

3. Symbol of the brachial artery should be above the brachial artery just right.

4. The cuff should be above the elbow 2-3cm (0.8-1.2 inches).

5. The inflatable tube can't be kinked or winded, keep the cuff and the heart on the same level to achieve accurate measured value.

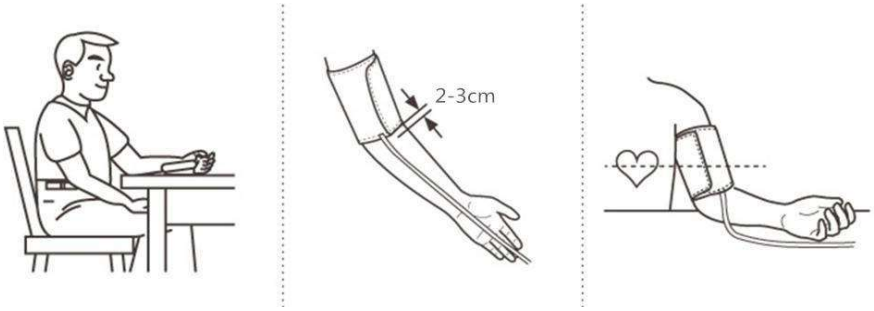

Figure 5.3.2-1

◆ **NIBP Measure**

Click the button to choose the NIBP function, NIBP will be measured after you long press the button. The measurement will be canceled if you long press again during the process of measurement.

◆ **Manometer test mode**

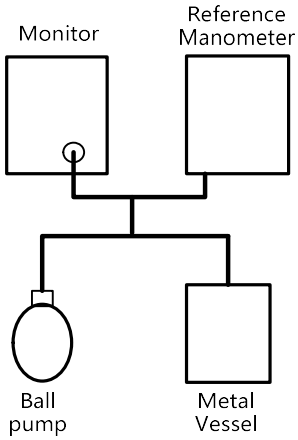

Figure 5.3.2-2

For Manometer test mode, this test mode was designed to test the static pressure range and verify the calibration of the NIBP function. This test mode is restricted to service personal and Berry's custom service team. Follow the procedure below to perform the calibration.

1. Connect the monitor to a metal vessel with a capacity of 500 ml ±5%.

2. Connect a calibrated reference manometer and a ball pump.

3. Close the valves inside, then inflate the metal vessel using the ball pump until the reference manometer reads 0, then 50 and finally 200mmHg, or other values.

4. The difference between the indicated pressure of the reference manometer and the reading from the monitor will not exceed 3mmHg. If these values are not met, try to contact our customer service.

NOTE:

- **If you are in doubt about the accuracy of any reading(s), please take a 3-5 minutes break, then perform a NIBP measurement again, if the readings are still dubious, please check the patient's vital signs by an alternative method before checking the function of the monitor or contact with the manufacturer.**
- **The range of cuff pressure is from 0mmHg to 280mmHg.**
- **If the internal battery is failure or depletion, the monitor will shutdown for protection and cancel the NIBP results indication.**
- **Values of BLOOD PRESSURE outside the range in "Parameter Specifications" will display "E0" for indication.**

5.3.3 Measuring Limit

NOTE:

- **Width of the cuff should be 40% of limbs circumference or 2/3 of the upper arm's length. The inflatable part's length of the cuff should encircle 50-80% of the limbs. Cuff which is inappropriate in size will result in wrong readings. Bigger cuff in size can be used to reduce errors.**
- **Limb used to measure pressures should be laid at the same level with patient's heart. If this cannot be realized, following correction methods should be taken to correct the results:**

  If the cuff's position is higher than heart's, you should plus 0.9mmHg (0.10KPa)/cm to the displayed value.

  If the cuff's position is lower than heart's, you should minus 0.9mmHg (0.10KPa)/cm from the displayed value.

- **If you doubt the accuracy of reading, inspect patient's vital sign with other ways before checking Patient Monitor.**

  1. Before performing a NIBP measurement, please check the monitor and cuff hygienic conditions, make sure the monitor and cuff are free of dust and dirt or any other hygienic issues, if not, please clean and disinfect first.

  2. Measure your blood pressure according to temperature, humidity and altitude ranges specified in the operation manual.

  3. Not too frequent measurements in a short time. (recommended to measure intervals at least 5 minutes apart)

  4. Make sure the cuff placement right according to "Cuff Placement" above.

  5. Keep quiet and relax, any movement during measurement may lead to inaccurate reading.

- **Be aware that the following conditions to perform a NIBP measurement. if not, could interfere with the measurement, make the measurement unreliable, prolong the measurement, or even make a measurement impossible:**

  Movement. the patient is moving, shivering, or having convulsions.

  Cardiac Arrhythmia. the patient's cardiac arrhythmia has caused an irregular heartbeat.

  Pressures Changes. The patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

  Severe Shock. If the patient is in severe shock or hypothermia, reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

  Heart Rate Extremes. The monitor is unable to perform pressure measurements at a heart rate of less than 40 bpm and greater than 240 bpm.

WARNING:

- **NIBP function can be only applied to adult, not applied to pediatric and neonatal patients, not applied to pregnant or pre-eclamptic patient.**
- **The NIBP measurement of the device may have an effect on blood**

circulation. Continuous cuff pressure due to connection tubing kinking may cause harmful injury to the patient.

- **Too frequent measurements can cause injury to the patient due to blood flow interference.**
- **Don’t use it to patient who suffers from sickle cell disease and has skin been damaged or expected to be damaged. If NIBP should be measured depends on the clinical evaluation, because danger of haematoma may happens at the place where cuff rubs.**
- **Do not apply the CUFF over a wound, as this can cause further injury.**
- **Don’t put the cuff on the arm on the side of a mastectomy to measure. It can lead to inaccurate measurements.**
- **Do not perform SpO2 and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the reading of the SpO2 value.**
- **Try to stay relaxed and don't talk during the measurement. It is recommended to measure intervals at least 5 minutes apart.**
- **Don’t put the cuff on the limb which is in venous transfusion or inserted catheter. If the infusion is slow down or blocked during inflation, it may result in tissue’s damage near the catheter.**
- **Don’t put the cuff on the limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, because temporary interference to blood flow and could result in injury to the patient.**
- **Check the operation of the automated sphygmomanometer does not result in prolonged impairment of patient blood circulation.**
- **Any reading can be affected by the measurement site, the position of the patient, exercise, or the patient’s physiologic condition.**
- **The unmatched size of cuff, the cuff is too tight or too loose, they can affect the reading.**
- **If you do not measure your blood pressure according to temperature, humidity and altitude ranges specified in the operation manual, it can lead to inaccurate reading.**
- **Compression or restriction of the connection tubing could result in prolonged measurement and inaccurate reading.**
- **NIBP measurements performed in long intervals may incur ischemia and**

neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, change the position of the cuff on the patient or stop the blood pressure measurements immediately.

5.4 TEMP

5.4.1 Measuring Principle

Patient Monitor uses thermistor temperature sensor to measure body temperature. The resistance value of thermistor encapsulated in the temperature sensor will change with body temperature. Temperature value will be calculated by the resistance value Patient Monitor measures. Then the value will be displayed on TFT-LCD screen.

Mode of operation of the clinical thermometer: direct mode.

5.4.2 Measurement Procedure

1. Insert the plug of HR & Temp lead cable (including TEMP) into the socket in Patient Monitor first.

2. Put the TEMP sensor on the suitable position of patient's body skin surface.

3. Then switch on Patient Monitor.

4. Keep waiting until the measured data stop changing frequently. Then you can read stable temperature of patient from the TFT-LCD screen.

NOTE：

- **Because thermistor in the temperature sensor is wrapped by the insulating course, Change of the resistance with temperature will be slow down. You should wait at least five minutes after the sensor being laid on body surface to achieve accurate results. It is recommended to measure intervals at least 3 minutes apart.**
- **Normal body temperature differs by body parts, time and age.The normal output range of axillary temperature is from 35.2℃. to 36.9℃.**
- **The calibration of the TEMP function is required every two years. If you need to calibrate the TEMP function, please contact our Customer Service.**
- **The measurement range of TEMP is from 25℃ to 45℃, if the results exceed temperature range in Appendix Ⅰ: Technical Specifications, the device will display "- - . -" for indication.**

- **The transient response period for a continuous TEMP measurement is less than 50s.**

WARNING：

- **You should check if the temperature sensor and cables are normal before measuring. Don't use it if you find anything damaged.**
- **The sensor should be removed from the patient in time after measuring.**
- **Connect lead cables carefully to avoid the patient being winded or suffocated. Lead cables of electrosurgery unit and TEMP sensor can't be winded together**
- **If you find the numerical value isn't reasonable, you should check the patient first. If the patient is in good condition, check if the sensor is clung to the skin and lead cables connected to Patient Monitor is correct. When you confirm the above mentioned have no problem, you can find a qualified engineer to check if the device and sensor works normally.**
- **Cross infection may happen when Patient Monitor is used between different patients. Users should prevent and control it. TEMP sensor should be cleaned or disinfected before it is used between different patients.**
- **The operation environment temperature shall meet the requirements in "Appendix Ⅰ: Technical Specifications" Environment Requirements, if not the results of TEMP measurement will be inaccuracy.**

CAUTION：

- **Pick and place the TEMP sensor and lead cable carefully. Take good care of it by rolling up it loosely while not using. Don't pull it forcibly to avoid the sensor and lead cable being damaged.**

Chapter 6 Maintenance and Cleaning

6.1 Maintenance Inspection

WARNING:

- **Do not maintain monitor or accessories while in use with patient.**
- **Replace any component in the monitor could result in an unacceptable risk.**

You should check up the following items before you use Patient Monitor:

CAUTION:

- **If there exists any mechanical damage.**
- **Check all the exposed lead cable, the inserted part and accessories.**
- **Check all the functions of Patient Monitor which may be used to monitor patient and make sure Patient Monitor is in good working condition.**

An intended operator could be a patient , a clinician, a doctor or a nurse. A qualified service personal is who has adequate training, knowledge, and practical experience to perform maintenance and calibration tests, inspect the compatibility of accessories and the monitor and inspect the essential performance and basic safety of the monitor. If you need these services, you can consult Berry's Customer Service Team for help.

Daily Checks

The following checks should be performed before any measurements:

- Check the monitor and all accessories are in good conditions, have no mechanical and functional damage
- Make sure the monitor and all accessories are free of dust and dirt.
- Check the battery level, if power low, please charge the battery.

Periodic safety checks

The following safety checks should be performed every 24 months:

- Inspect the equipment for mechanical and functional damage by service personal or the operator.
- Inspect the safety relevant labels for legibility by service personal or the operator.

- Verify the device functions properly as described in this manual by a service personal.
- Verify the device essential performance and basic safety by Berry's Customer Service Team. .
- If the device is not functioning properly or fails any of the above tests, do not attempt to repair the device. Please return the device to the manufacturer for any required repairs.

Calibration and Replacement

The calibration of the monitor should be performed every 24 months. If you need these services, you can consult Berry's Customer Service Team for help.

Any Replacement can only be preformed by Berry, contact us if you need.

If any signs can indicate that function of Patient Monitor has been damaged, it can't be used for patient and contact with biomedicine engineer in hospital or maintenance engineer of our company.

Also Our company will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to service personnel to repair those parts of the monitor that are designated by the manufacturer as repairable by service personnel. Service personnel must inspect Patient Monitor comprehensively including safety inspection every 6-12 months or after maintenance.

Troubleshooting Table

Trouble	Possible Reason	Solution
Bluetooth can not be searched.	1. Bluetooth function of intelligent terminal and Patient Monitor isn't turned on. 2. The intelligent terminal and Patient Monitor doesn't support Bluetooth. 3. The distance between intelligent terminal and Patient Monitor is too far to connect Bluetooth.	1. Turn on the Bluetooth function of intelligent terminal and Patient Monitor. 2. Make sure all the devices supports Bluetooth. 3. Keep the specified distance between intelligent terminal and Patient Monitor.
The screen is suddenly off.	1. The device will power off automatically if you haven't used it	1. You can restart the device.

	for a long time. 2. Quantity of electricity is exhausted.	2. Charge the battery.
Numerical value of NIBP is not accurate or no data.	1. Blood catheter is blocked. 2. NIBP cuff leaks. 3. The position of NIBP cuff is wrong.	1&2. Change NIBP cuff. 2. Place NIBP cuff according to the instruction of Operation Manual.
Unstable numerical value of SpO_2 and HR appears during the measure.	Your body doesn't keep still and relax.	Keep still and relax.
Numerical value of SpO_2, HR，NIBP can't be displayed on the screen	1. TEMP lead cable and SpO_2 sensor isn't inserted to the device properly. 2. The finger isn't placed deep enough in the sensor. 3. Placement position of electrodes or NIBP cuff is not appropriate.	1. Pull out the lead cable and insert it to the device correctly. 2. Place your finger till the end of sensor. 3. Stick the electrodes or NIBP cuff at the right place in accordance with Operation Manual.
Numerical value of TEMP is not accurate.	Test time is too short.	Read numerical value after 5 minute measuring.

6.2 Cleaning and Disinfection

Keep the monitor, cables and accessories free of dust and dirt. After cleaning and disinfecting, check the equipment carefully.

WARNING:

- **Never immerse or soak Patient Monitor and reusable accessories.**
- **We recommend that Patient Monitor and reusable accessories should be disinfected only when necessary as determined by your local policy, to avoid long term damage to the product.**
- **Never use cleaning agents/disinfectants other than the recommended.**

- **Never permit high-pressure and high-temperature disinfection of Patient Monitor and reusable accessories.**
- **Please shut off the power before cleaning and disinfection.**
- **Do not do cleaning or disinfection the monitor or accessories while in use with patient.**

◆ Cleaning

1. Clean Patient Monitor and reusable accessories with cotton or soft cloth moistened with water.
2. After cleaning, wipe off the water with a soft cloth.
3. Allow Patient Monitor and reusable accessories to air dry.

◆ Disinfection

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde 2% solution disinfectants.

1. Clean Patient Monitor and reusable accessories as instructed above.
2. Disinfect Patient Monitor and reusable accessories with cotton or soft cloth moistened with one of the recommended disinfectants.
3. After disinfection, be sure to wipe off the disinfectant left on Patient Monitor and reusable accessories with a soft cloth moistened with water.
4. Allow Patient Monitor and reusable accessories to air dry.

Appendix Ⅰ: Technical Specifications

Basic Specification

Size: 140mm (Length)×82mm (Width)×46mm (Depth).

Weight: 256±10g (not including accessories).

Screen: 2.8 inches colorized TFT-LCD screen.

Environment Requirements

◆ **Temperature:**

Operation: +5℃～+40℃.

Transport and storage: -10℃～+50℃.

NOTE:

- **When the environment temperature is 20℃, the time required for Patient Monitor to warm from the minimum storage temperature between uses until it is ready for intended use is 5 to 10 minutes.**
- **When the environment temperature is 20℃, the time required for Patient Monitor to cool from the maximum storage temperature between uses until it is ready for intended use is 5 to 10 minutes.**

◆ **Relative Humidity:**

Operation: 15% - 85% (no condensation).

Transport and storage: 10% - 90% (no condensation).

◆ **Atmosphere Pressure:**

Operation: 800hPa – 1050hPa.

Transport and storage: 700hPa – 1060hPa.

Parameter Specifications

◆ **HR**

Measurement range: 25～250bpm.

Accuracy: ±2bpm or 2%, whichever is greater.

◆ **RESP**

Measurement range: 5～100brpm.

Accuracy: ±2brpm.

◆ **TEMP**

Measurement range: 25～45℃.

Measurement accuracy: ±0.2℃.

◆ **SpO_2**

Measurement range: 35~100%.

Accuracy: ±2% (80%~100%), ±3% (70%~79%), ±3% (35% ~ 69%)

- **The method of confirming the blood oxygen measurement accuracy is to compare the SPO2 measurement value with the value of blood gas analyzer.**
- **The accuracy of 35% ~ 69% has passed proving and comparison with SpO2 simulator** (FLUKE Prosim 8, Software Version V2.05) .

◆ **PR**

Measurement range: 25~250bpm.

Accuracy: ±2bpm or 2%, whichever is greater.

- Pulse Rate accuracy has passed proving and comparison with SpO_2 simulator (FLUKE Prosim 8, Software Version V2.05) .

◆ **NIBP**

Measurement range of Systolic blood pressure: 60～230mmHg.

Measurement range of Diastolic blood pressure: 40～130mmHg.

Static pressure accuracy: ±3 mmHg or 2 %, whichever is greater.

The numerical step of blood pressure readings are 1mmHg.

Battery

Built-in battery (can't be disassembled): 3.7V, 1800mAh lithium battery.

Continuous operating time: 10 hours.

Cyclic charge and discharge: 500 times.

Bluetooth

PM6100 series Patient Monitor is with the Bluetooth communication function. It can send data to intelligent terminal and computer (Related software has been installed.) with communication function.

Packing List

Name	Model/Type	Manufacturer	Quantity
Patient Monitor	PM6100(A/B/C)	Shanghai Berry Electronic Tech Co., Ltd	1PCS
HR&TEMP cable	BME03T	Shanghai Berry Electronic Tech Co., Ltd	1PCS
SpO_2 Sensor	BST09001S	Shanghai Berry Electronic Tech Co., Ltd	1PCS
Blood Pressure Cuff	MH002RC12HP1	Minhua Medical Apparatus Supplies Co., Ltd.	1PCS
Charging Line			1PCS
The operation manual	PM6100-SMS-01	Shanghai Berry Electronic Tech Co., Ltd	1PCS

Expected service life

Patient Monitor: 3 years

Accessories: 2 years (except the disposable accessories)

AppendixⅡ: Symbol Meaning

Symbol	Meaning
	Refer to instruction manual/booklet.
	Type **BF** applied part.
	The product does not contain alarm function.
	When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling.
	European Union for approval.
	Do not re-use.
	Service life.
	Manufacture.
	Date of manufacture.
	Serial Number.
	Batch Code.

REF	Catalogue Number.
EC REP	Authorized representative in the European Community/European Union.
IPX1	The product is protected against harmful effects of vertically falling drops per IEC 60529.

FCC Warning

This device complies with part 15 of the FCC Rules.Operation is subject to the following two conditions:(1) This device may not cause harmful interference,and (2) this device must accept any interference received ,including interference that may cause undesired operation .

NOTE 1:This equipment has been tested and found to comply with the limits for a Class B digital device ,pursuant to part 15 of the FCC Rules.These limits are designed to provide reasonable protection against harmful interference in a residential installatiol.This equipment generates,uses and can radiate radio frequency energy and ,if not installed and used in accordance with the instructions,may cause harmful interference to radio communications.However,there is no guarantee that interference will not occur in a particular installation.If this equipment does cause harmful interference

to radio or television reception ,which can be determined by turning the equipment off and on,the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

NOTE 2:Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

FCC ID: 2BD8CPM6100

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EC REP **Prolinx GmbH**

Brehmstr. 56, 40239, Duesseldorf

Germany

Appendix Ⅲ EMC Declaration

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

Guidance and manufacturer's declaration - electromagnetic emission
The Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Patient Monitor should assure that it is used in

such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Patient 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 CISPR11	Class B	The Patient Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration-electromagnetic immunity			
The Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Patient Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
ELECTROSTATIC DISCHARGE [a)] IEC 61000-4-2	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15 KV air	±8 KV contact ±2 KV, ±4 KV, ±8 KV, ±15 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%.
RATED power frequency magnetic fields [b) c)]	30A/m [d)] 50 Hz	30A/m [d)]	Mains power quality should be that of a typical commercial or hospital

IEC 61000-4-8	or 60 Hz		environment.

[a] Discharges shall be applied with no connection to an artificial hand and no connection to PATIENT simulation. PATIENT simulation may be connected after the test as needed in order to verify BASIC SAFETY and ESSENTIAL PERFORMANCE.

[b] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

[c] During the test, the ME EQUIPMENT or ME SYSTEMS may be powered at any NOMINAL input voltage, but with the same frequency as the test signal (see Table 1).

[d] This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEMS and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEMS will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance.

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

Guidance and manufacturer's declaration - electromagnetic immunity		
The Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Patient Monitor should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted disturbances included by RF fields [a] IEC 61000-4-6	3 V [b] 0.15 MHz - 80 MHz 6 V [b] in ISM and amateur radio bands between 0.15 MHz - 80 MHz 80% AM at 1 kHz	3 V [b] 6 V [b]
Radiated RF EM	10 V/m [b]	10 V/m [a]

fields [b] IEC 61000-4-3	80 MHz – 2.7 GHz [c] 80% AM at 1 kHz [d]	

[a] The following apply:

- All PATIENT-COUPLED cables shall be tested, either individually or bundled

- PATIENT-COUPLED cables shall be tested, using a current clamp unless a current clamp is not suitable. In cases were a current clamp is not suitable, an EM clamp shall be used.

- No intentional decoupling device shall be used between the injection point and the PATIENT COUPLING POINT in any case.

- Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

- Tubes that are intentionally filled with conductive liquids and intended to be connected to a PATIENT shall be considered to be PATIENT-COUPLED cables.

- If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

- The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

[b] r.m.s., before modulation is applied

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency	Band [a]	Service [a]	Modulation [b]	Maximum	Distance	IMMUNITY TEST

(MHz)	(MHz)			power (W)	(m)	LEVEL (V/m)
385	380—390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430—470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704—787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800—960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700—1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400—2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28

5240 5500 5785	5100—5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a)] For some services, only the uplink frequencies are included.

[b)] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c)] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.