promedic

by COMEN

Model: **NC3**

VITAL SIGNS MONITOR

EN Instruction Manual

www.promedic-health.com

Statement

Shenzhen Comen Medical Instruments Co., Ltd (“ Comen” or “Comen Company”) possesses the copyright of the non-published Instruction Manual, and has the right to handle it as confidential data.This Instruction Manual is only used as the reference data for the operation, maintenance and servicing of Comen products.

The others have no right to disclose the content of this Instruction Manual to any third person.

This manual contains the proprietary information which is protected by copyright law. With copyright reserved, any person shall not photocopy or duplicate any part of this manual or translate it into any other language without the prior written permission of Comen Company.

Comen Company shall not assume responsibility for the incidental or consequential damages resulting from the errors in this manual or from the provision, actual performance and use of this manual. Comen Company shall not provide the proprietary right vested by patent law to any third party. Comen Company shall not assume legal responsibility for the legal consequences resulting from violating the patent law and the rights of any third party.

The content in this manual may be subject to change without further notice.

Guarantee

Under the following conditions, Comen Company shall be responsible for the safety, reliability and performance of the product:

- The product shall be used according to the Instruction Manual.

The installation, maintenance and upgrading of the product shall be conducted by the personnel recognized or authorized by Comen Company.

- The storage environment, working environment and electrical environment of the product comply with the product specifications.
- The serial number tag or manufacturing mark of the product shall be clear and identifiable. It is verified through the appraisal of Comen Company that this product is manufactured by Comen Company.
- The damages are caused by non-human factors (e.g. accidental fall and deliberate destruction).

The products that are under the warranty service regulations of Comen Company shall enjoy free service. As for the products that are beyond the warranty service regulations, Comen Company shall charge for the service. If the products are transported to Comen Company for maintenance, the user shall bear the freight (including the customs expenses).

Return of products

If the products need to be returned to Comen Company, please follow the following steps:

Acquisition of the right to return the goods: Contact the after-sales department of Comen Company, tell it the number of the instrument made by Comen; this number was printed on the equipment nameplate; if this instrument number is not legible, the goods returned shall not be accepted. Please specify the instrument number and production date, and briefly describe the reason for returning the goods.

After-sales Service Unit

Name: After-sales Service Department of Shenzhen Comen Medical Instrument Co., Ltd

Address: South of Floor 7, Block 5 & Floor 1 and Floor 6, Block4, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, Guangdong, P.R. China

Tel.: 0755－26431236

Fax: 0755－26431232

Customer Service Hotline: 4007009488

Postal Code: 518052

Content

Chapter 1 Safety

1.1 Safety Information

⚠Warning

- **To warn you of the conditions where serious consequence, disadvantageous matters or danger may occur. Failure to comply with the warning will result in severe personal injury or death of the user or the patient.**

⚠Caution

- **To indicate potential danger or unsafe operation. If not avoided, it may lead to mild personal injury, product malfunction, damages or property loss. It may also give rise to more severe harm.**

⚠Attention

- **It emphasizes primary warnings or provides descriptions or explanations so that this product can be used in a better way.**

⚠Warning

- **This monitor is used for monitoring the clinical patients, so only the doctors and nurses who are qualified through training can use this monitor.**

- **Do not posit the equipment to make it difficult to operate the power plug which uses to isolate the equipment circuits electrically from the supply mains.**
- **There is no alarm system for the monitor, only provides fault code for reference. And also it is not suitable for continuous monitoring, please pay close attention to patient's condition avoid any delay of the illness.**
- **Before use, the user shall check whether this instrument and its accessories can work normally and safely.**
- **Please assure the continuous power supply when monitor patient, the data will be lost when unexpectedly lose power.**
- **This instrument can only be connected to a power socket with protective grounding. If the power socket is not connected to grounding conductor, do not use this socket, but use the rechargeable batteries for power supply.**
- **Do not open the shell of this instrument to avoid the possible electric shock hazard. The maintenance and upgrading of this monitor must be conducted by the service personnel trained and authorized by Comen Company.**
- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.**
- **Do not use this instrument at the place where there are flammable articles such as anesthetic to prevent explosion or fire from happening.**
- **Please carefully install the power lines and the cables for various accessories to avoid the patient from being constricted or suffocated or the cables from getting entangled and keep the patient free from electrical interference.**
- **Do not use mobile phone near the monitor, because the mobile phone will generate a very strong radiation field and disturb the functions of the monitor.**
- **Before reusing these cables, check whether the function is normal.**
- **The equipment connected with the monitor shall form an equipotential body (the protective grounding wire is effectively connected).**

- **When the monitor is shared with the electrosurgery unit, the user (doctor or nurse) shall ensure the patients safety.**
- **The electromagnetic field will affect the performance of this instrument, so the use of the other equipment near this instrument must meet corresponding EMC requirements. For example: Mobile phone, X-ray or MRI equipment may be an interference source, because they will transmit high-strength electromagnetic radiation.**
- **This is not a treatment device.**
- **The duration of temperature monitoring should be less than 5 minutes.**
- **Continuous and prolonged period of monitoring may increase the risk of undesirable changes in the skin characteristics, such as extremely sensitive, reddenning, blistering, or even pressure necrosis etc.**

⚠Caution

- **To avoid damage to this instrument and guarantee patient safety, please use the accessories designated in this instruction manual.**
- **Please properly install or move this instrument and prevent the instrument from being damaged due to fall, collision, strong vibration or other external mechanical forces.**
- **Before the instrument is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the instruction manual of this instrument.**
- **When this instrument and its accessories are about to exceed the service life, they must be disposed of according to local relevant laws and regulations or the rules and regulations of the hospital.**
- **Disposal accessories only can be used for one time in case of performance reduction or cross infection.**
- **Please take out the battery of the monitor and keep properly if long**

time no use.

⚠Attention

- **Please install the equipment in a place that is convenient for observation, operation and maintenance.**
- **This instruction manual introduces the product according to the most complete configurations. The product you have purchased may not possess some configurations or functions.**
- **Please place this instruction manual near the instrument for easy and timely reference.**
- **This instrument cannot be used at home.**
- **The use of this monitor is restricted to one patient at a time**
- **The service life of the monitor is 5 years**

1.2 Contraindications

Don't monitor noninvasive blood pressure(NIBP) on patients with sickle cell disease.

1.3 Equipment Symbols

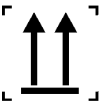
(1) Instrument Symbols

	Caution		Adult
	Neonate		Child
	The application part of Type BF		Date of manufacture

	Input/output		Serial number
	Non-invasive blood pressure		Equipotential
	Battery charging indicator lamp		On/Off key
	Reset key		AC power(AC)
	Refer to instruction manual/ booklet NOTE On ME EQUIPMENT		Conformité Européenne Complies with medical device directive 93/42/EEC
	European community representative		Manufacturer
IPX1	Protection against vertically falling water drops		

Note: Please see the content of "1.3.2 Key Function and Basic Operation" for the key symbols and their functions of the monitor.

(2) Packaging Symbols

	Up		Limit of stacking layers
	Fragile		Keep dry

Chapter 2 General

2.1 Product Introduction

2.1.1 Composition

The monitor is mainly comprised of host machine, noninvasive blood pressure cuff, blood oxygen sensor and infrared ear thermometer.

2.1.2 Intended Application

The Monitor is applicable to the monitoring and measuring of patient physiological sign parameters such as noninvasive blood pressure(NIBP), pulse oxygen saturation(SpO2), body temperature(Temp), pulse frequency / pulse(PR), the monitor message can be displayed, review and storage except printed.

It can be used in medical ward, surgical ward,clinic and emergency triage department.

The expected operator position is about one meter around the monitor in normal use.

2.2 Overview of the Monitor

The screen of this instrument adopts the 6-inch LED broken code screen, and simultaneously supports key operation mode. Next, we will introduce the basic functions of the monitor, shown as Figure 2-1:

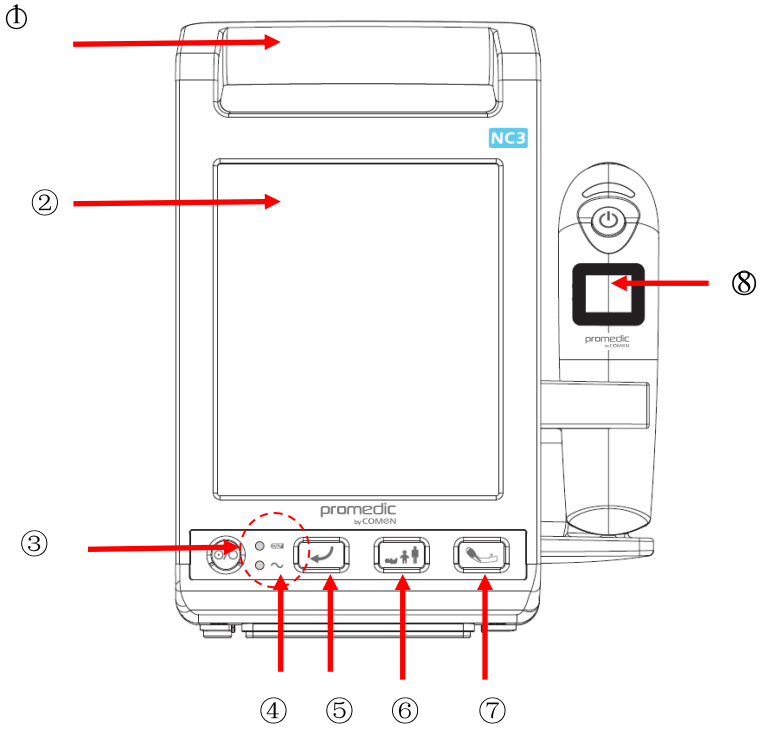


Figure 2-1 Monitor

①	Portable handle
②	Display screen
③	On/off key(build-in backlight)
④	Indicator lamp(from top to bottom: Battery indicator lamp, AC power indicator lamp) **Battery indicator**

	➢ ON: Monitor is equipped with battery and has connected with AC power source ➢ OFF: Monitor is not equipped with battery ➢ Flashing: The battery is discharging, red light flashes with the low power supply **AC power indicator lamp** ➢ ON: Monitor is connected with AC power source ➢ OFF:Monitor is not connected with AC power source
⑤	Reset key, see the contents of "key functions" for more details
⑥	Switch key for patient style
⑦	Start/stop key for NIBP measuring
⑧	Infrared ear thermometer

2.2.1 Key Functions

The operations on this monitor can be finished by keys and knobs, shown as the following table:

Key symbol	Description
	**(Reset key)** ➢ Press this key, parameters are displayed and defect code will be cleared in measurement mode ➢ Press this key more than 2 seconds in measurement mode, you will enter parameter setting mode ➢ Press this key in 10s after boot self-checking (when you hear "du") to enter maintenance mode
	**(Patient type key)** ➢ Press this key, you can switch patient style in measurement mode; ➢ Press this key, you can review measured data in review mode ➢ Press this key, maintenance functions can be performed in maintenance mode

	**(Start/Stop Key for NIBP Measurement)** At the non-blood pressure measurement state, press this key to aerate the cuff and then start one blood pressure measurement; at the measurement state, if you want to quit such measurement, press this key to stop measurement and then deflate.
	**(ON/OFF Key)** ➢ Press this key more than 2s to start the instrument. (Green backlight is lit) ➢ Long press this key to close down the instrument(Backlight is off) ➢ Press this key to enter standby mode if there is not any parameter measurements(Yellow backlight is lit)

2.3 External Interface of the Monitor

2.3.1 Left Panel

The following interfaces are provided on the left panel of the monitor, shown as follows:

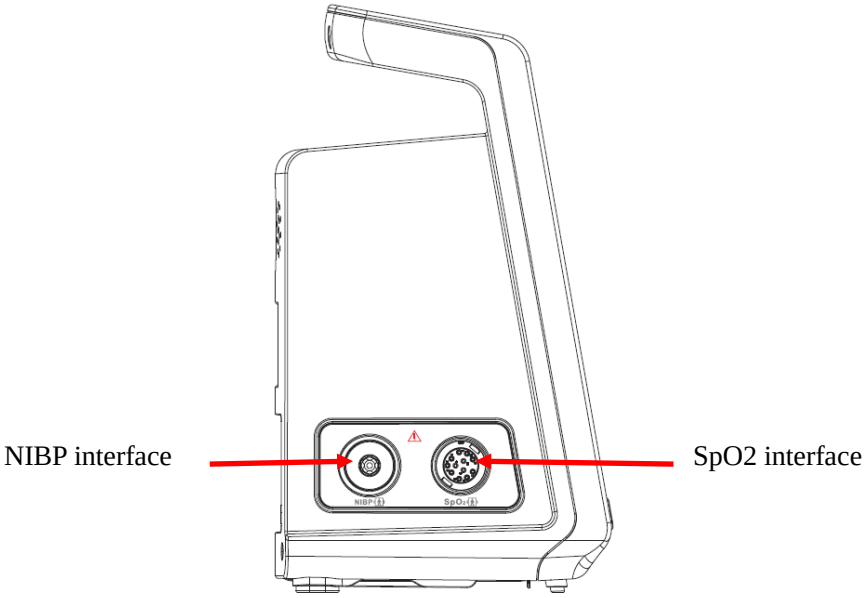


Figure 2-2 Left Panel

2.3.2 Right Panel

The following interfaces are provided on the right panel of the monitor, shown as follows:

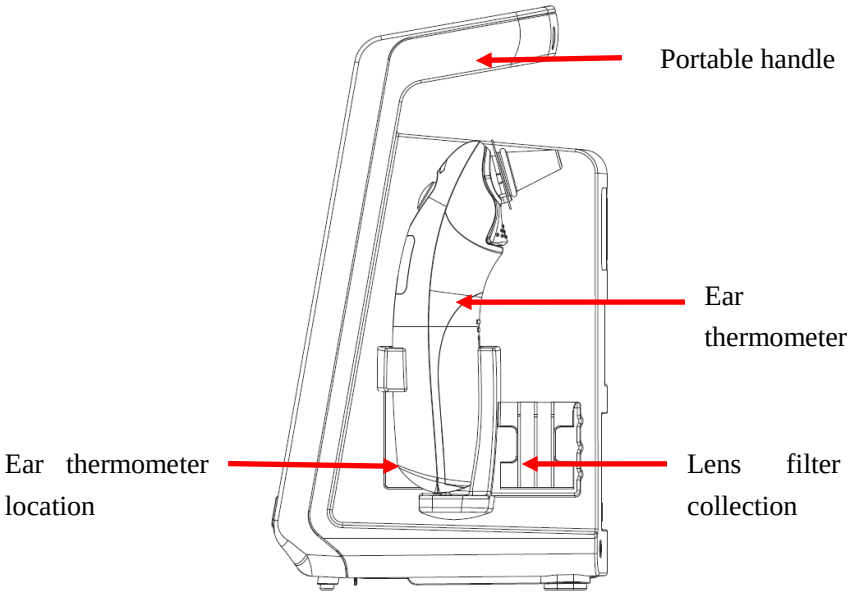


Figure 2-3 Right panel

2.3.3 Back Cover

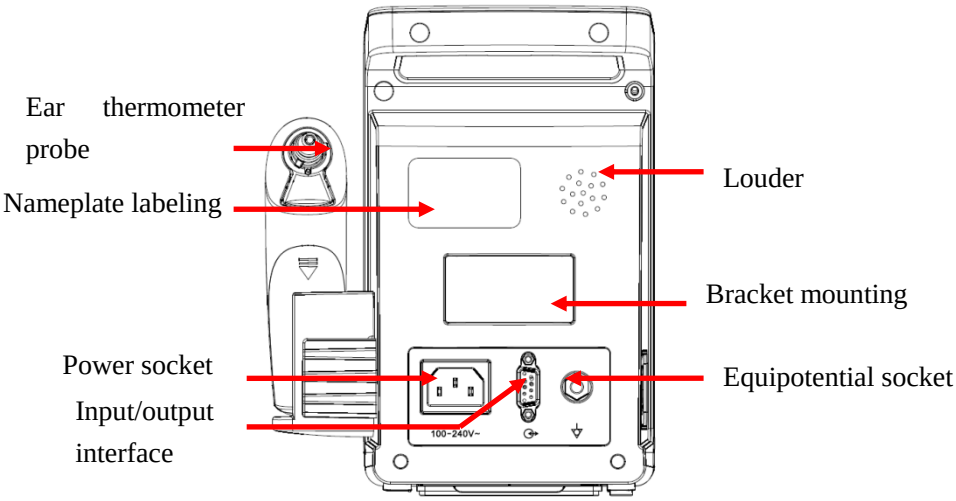


Figure 2-4 Back cover

⚠Warning

- **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).Moreover, all configurations shall abide by the content of the valid edition of IEC 60601-1-1 System Standard.Connect the additional equipment to the staffing medical system at the input/output signal port and confirm whether the system conforms to the IEC 60601-1-1 Standard.If you have any question, please contact the supplier.**
- **When the signal interfaces like patient cable interface and network interface are simultaneously connected with multiple equipments, the total leakage caused cannot exceed the tolerance.**
- **The infrared ear themometer configurated only communicates with monitors of Comen.**

2.3.4 Base Cover

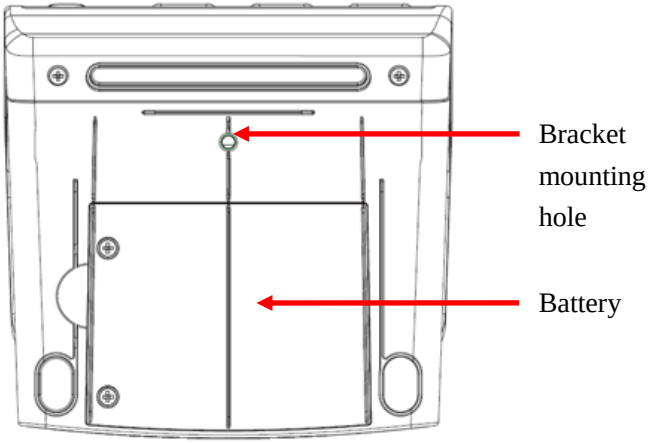


Figure 2-5 Base Cover

2.4 Screen Display

The screen of this monitor adopts LED broken code screen and simultaneously displays the patient parameters, alarm information, clock, battery and other prompt messages, etc.

The main screen is divided into four areas: 1. information prompt area or upper menu bar area ①; 2. parameter area ②; 3. lower menu bar area ③; 4. waveform area ④, which are shown as follows:

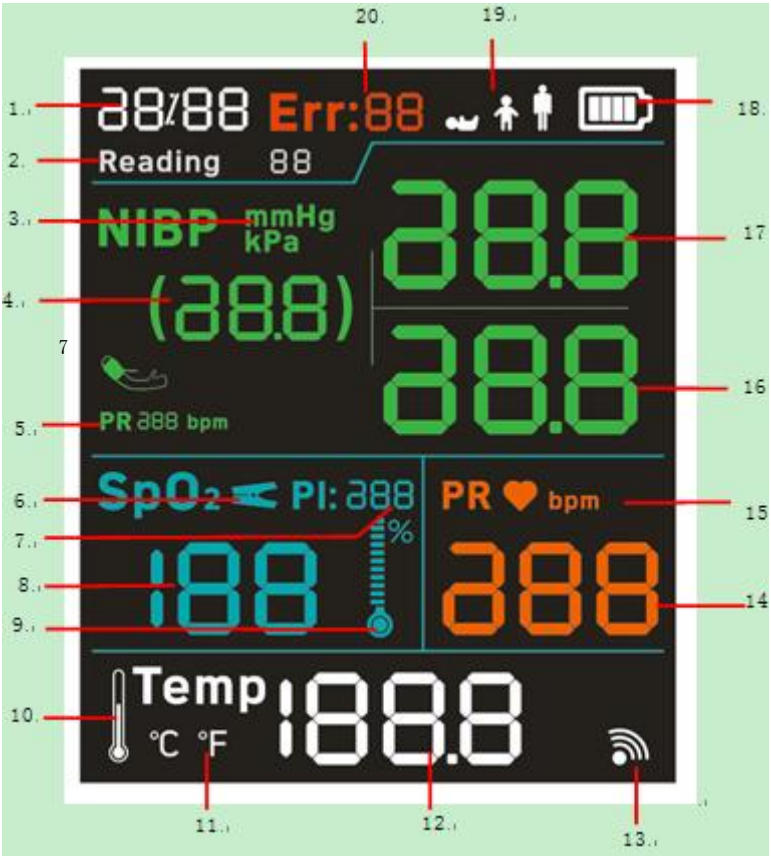


Figure 2-6 Standard Interface

1. System time

   You can set the time into Year, Month, Date, Hour, Minute, Second. The default time style is Hour: Minute, such as, 12:33.

2. Patient’s measurement data review

   50 sets data can be storage in monitor

3. NIBP symbol and unite

   mmHg or kPa can be switched.

4. Mean blood pressure(end of measurement)

   Or Cuff pressure (in measurement, leak detection or pressure calibration)

5. PR value
6. Probe checking indicator

   Comen SpO2:

   - Icon flash: Finger is poor connected or probe is disconnected

   Masimo or Nellcor SpO2

   - Icon off: Probe is off
   - Icon flash: Finger is poor connected or probe is disconnected.

7. Strength of perfusion index(only applies to Masimo SpO2)
8. SpO2 measurement value
9. Strength of pulse indicator
10. Temp measurement Logo
11. Temp unit(℉,℃)
12. Temp measurement value
13. Ear thermometer wireless connection indicator

    ON: Ear thermometer wireless connection is normal;

    OFF: Ear thermometer wireless connection is close

14. SpO2 pulse rate measurement value
15. PR measurement logo and unit
16. Diastolic blood pressure(low pressure)
17. Systolic blood pressure(high pressure)
18. Battery indicator: See the contents of “Battery” for more details
19. Patient style(neonate, child, adult)
20. Fault code: Each fault message corresponding to a fault code. See the contents of “Fault Describe table” for the details.

Chapter 3 Installation of the Monitor

⚠Warning

- **The equiment shall be installed by personnel authorized by Comen Company**
- **Do not open the shell of this instrument to avoid the possible electric shock hazard. The maintenance and upgrading of this monitor must be conducted by the service personnel trained and authorized by Comen Company**
- **The software copyright of the equipment is solely owned by us. No organizationor individual shall resort to juggling, copying, or exchanging it ot to any other infringement on it in any form or by any means without due permission**
- **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).Moreover, all configurations shall abide by the content of the valid edition of IEC 60601-1-1 System Standard.Connect the additional equipment to the staffing medical system at the input/output signal port and confirm whether the system conforms to the IEC 60601-1-1 Standard.If you have any question, please contact the supplier.**
- **If it is not evident from the equipment specifications whether particular combination is hazardous, for example, due to summation of leakage currents, consult the manufacturers or else an expert in the field, to ensure the necessary safety of all devices concerned will not be impaired by the proposed combination.**

⚠Attention

- **To ensure that the monitor works properly, please read the information in this chapter, security information and patient safety chapters before using, and install monitor as required.**

3.1 Unpacking and Examination

Carefully unload monitor and accessories from the box, and save the packaging materials for later transport or storage. Please check the accessories according to the packing list and see if there is any mechanical damage. Check all the external wires, insert any accessories needed. If there are any questions, please contact our sales department or agency immediately.

⚠Warning

- **The disposal of packaging materials shall comply with the local laws and regulations or the waste disposal rules and regulations of the hospital. The packaging materials must be placed away from the children.**
- **The monitor might be contaminated during storage and transport. Please verify whether the packages are intact before use, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

3.2 Environmental Requirements

The operating environment of the monitor must meet the requirements specified in this manual.

The environment where the monitor is used shall be reasonably free from noises, vibration, dust, corrosive, flammable, and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2inches away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference, in this case, never start the system before the condensation disappears.

⚠Warning

- **Put the monitor in the place which is easy to be observed, operated and maintained.**
- **Put the instruction near the monitor for convenient to use.**
- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**
- **Do not use this instrument at the place where there are flammable articles such as anesthetic to prevent explosion or fire from happening.**
- **The electromagnetic field will affect the performance of this instrument, so the use of the other equipment near this instrument must meet corresponding EMC requirements. For example: Mobile phone, X-ray or MRI equipment may be an interference source, because they will transmit high-strength electromagnetic radiation.**
- **Before the instrument is switched on, please confirm whether the power supply used meets the requirements for power supply voltage and frequency designated in the nameplate label or in the instruction manual of this instrument。**

3.3 Connect the AC Power Cord

Steps of connection

Confirm that the AC power supply meets the following specifications: a.c. 100～240V，50/60Hz

Use the power cord equipped with the monitor, and insert the other end of power cord into the grounded three-phase power socket.

⚠Attention

- **Plug the power cord to the dedicated hospital outlet.**
- **If a battery is provided, you must charge the battery after the transport or storage of instrument. If you do not connect the AC power and directly turn on the monitor, it will probably not work because of insufficient battery power. Connect to an AC power supply and charge the battery ,regardless of whether the monitor is turned on or not.**

Connect the equipotential grounding wire when necessary. Refer to the content of equipotential grounding in the chapter "Patient Safety".

3.4 Battery

A built-in rechargeable battery is installed in the medical monitor.,when the power suddenly turns off, the system will be automatically powered on by the battery.

Battery installation:

The battery slot locates at the bottom of the monitor, please see the contents of "Battery" chapter for more details.

Battery charge:

When connected to the AC power supply, the battery will be automatically recharged, whether the unit is in an ON or OFF position, until the battery is fully charged.

Battery indicator will be green when battery is charging; The battery icon shown on the screen indicates the current battery level:

⚠Attention

- **Monitor shall be charged timely in case of AC power is unavailable after long time storage or the battery almost run out; otherwise, the monitor might not be started again with a low power.**
- **When the monitor is connected to the AC power supply, the battery will be automatically recharged, whether the unit is in an ON or OFF position.**

3.5 Connecting Accessories

Plug the catheter of blood pressure cuff into the NIBP interface on the side of monitor, plug blood oxygen probe cable into SpO2 interface, and put a disposal earmuff on ear thermometer probe.

⚠Attention

- **See the contents of 9-11 chapters for more details.**

3.6 Power on/off

3.6.1 Check before Power on

Check the following before you start to make measurement:

- **Environment**

Check whether there is any other electrical equipment in the surrounding, such as electrtic surgical equipment, ultrasound machines and radiation machines, etc. these devices might cause interference, please turm off them if necessary.

- **Power supply**

Before the instrument is turned on, please confirm whether the power supply used meets the requirements and the connection is firm.

Shall be used with a protective earthing power socket.

- **Connecting accessories**

Make sure all the external cables, plug-ins and accessories are properly connected.

3.6.2 Power on

After finishing the installation and check, you can start the monitor and measure the parameters.

1. Plug the power cord into the AC power source. If you run the monitor on battery, ensure that the battery is sufficiently charged.

2. Press “ ” for 2s

After the system self-test has succeeded and gives a beep. the start-up screen is displayed, then monitor enters into the main screen.

The all backlight will be lit during the system self-test.(refere to figure 1-2 standard interface). If there is any one light is not lit, please restart. If the problem is not solved, please do not apply it to patient and contact with manufactors for maintenance.

⚠Attention

- **Please check whether the system self-test has succeeded when start the monitor, if not, Please contact the biomedical engineers of your hospital or maintenance engineers of the Company.**
- **You can check whether the all lights are lit in interface of setting screen brightness. Refer to figure 1-2 standard interface.**

⚠Warning

- **If you find any signs of damage to monitor functions, or an error message, do not use this monitor for patient monitoring. Please contact the biomedical engineers of your hospital or maintenance engineers of the Company.**

3.6.3 Power off

Please turn off the monitor follow the steps blow,

1. Ensure the monitoring is finish
2. Disconnect all accessories with patients
3. Long press" ", then monitor will be shutdown

⚠Caution

- **If the monitor can't be turned off or there is something special happened, you can press and hold « » more than 10s to force a shutdown. But it is not suggested as some measurement data might lose**
- **When the power is suddenly off, monitor will automatically call the latest configuration after restart.**

Chapter 4 System Settings

This monitor provides multiple working modes for user. Such as: measurement mode, parameter setting mode, review mode, maintenance mode, and standby mode. Different mode meets different requires. Here is the introduction for the mode styles and features below.

4.1 Measuring Mode

After start, system default into the measurement mode.

- Plug in the NIBP cuff, and press “  ” to start or stop NIBP measurements;
- Plug in the blood oxygen probe to measure SpO2;
- Install battery into infrared ear thermometer, temperature can be measured;
- After measuring one or multiple parameters, data will be automatically saved if there is no measurement in 2 minutes.
- Press”  ”

1. Clear the measurement data(such as NIBP.Temp, etc) and save
2. Clear the fault code

- Press and hold”  ” to enter parameter setting mode.

4.2 **Parameter Setting Mode**

a) In the measurement mode, then long press" " to enter paremeter setting mode;

b) Press" "repeatly to switch settting: the pluse sound switch setting.

c) Press " " to switch pluse sound on or off.

d) Press and hold" " to enter review mode.

4.3 **Review Mode**

In the parameter setting mode, then long press" " for 2s to enter review mode; in this mode, 50 sets measurement data can be reviewed. The data you reviewed corresponds to the data which you saved, it can be a parameter or a conbination of multiple parameters.

- Press " " to switch the stored data up one by one.
- Press" "to switch the stored data down one by one;
- Long press" " to return back to measurement mode.

⚠Attention

- **This monitor can only display the latest 50 sets of measurement data in the review mode, the rest data will be automatically cleared by the system.**

4.4 Standby Mode

4.4.1 Enter the Standby Mode

a) Press  to enter the standby mode if there is no any measurement.

b) The monitor will automatically enter the standby mode if there is no any operation in 10 minutes

c) The monitor will be shut down if there is no activity in 30 minutes.

⚠Attention

- **After enter the standby mode, the measurement data you get before will be cleared.**
- **Enter into the standby mode, screen will be off and the backlight of start/off key will turn to be yellow.**
- **Monitor will be out of the standby mode and can't enter the mode anymore when the power is too low.**

4.4.2 Out of the Standby Mode

Press any key to be out of the standby mode.

When the following happens; the monitor will withdraw the standby mode automatically;

- The monitor receives the signal that finger connects with SpO2 probe.
- The power is too low (“”shows up)
- Receive temperature data

4.5 Maintenance Mode

a) Start the monitor, press” ” to enter the maintenace mode in 10s after self-test and hearing a sound of “du”
b) Then the parameters are displayed in the corresponding area
c) Press “ ” repeat to enter switching cycle of the setting menu: NIBP unit switching, Temp unit switching, system time setting, NIBP leak detection, NIBP pressure test, brightness adjustment, the factory default configuration restoring.
d) Press and hold” ” to shut the monitor down, and the settings above will take effect when the monitor starts next time.

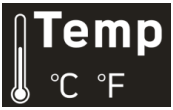
4.5.1 NIBP Unit Setting

a) Enter the maintenance mode;
b) Press” ” and switch into NIBP unit setting area;

c) Press or to switch the unit: mmHg, kPa.

4.5.2 Temp Unit Setting

a) Enter the maintenance mode;
b) Press” ” and switch into NIBP unit setting area;



c) Press or to switch the unit:℃， ℉。

4.5.3 System Time Setting

Enter the maintenance mode;

Year:

a) Press” ” and switch into ” year” setting area;

b) Press” ” then the figure will increases;

c) Press” ”, then the figure will decrease.

Month/Day

a) Press” ” and switch into ”Month” or”Day” setting area;

b) Press” ” then the figure will increases;

c) Press” ”, then the figure will decrease.

Hour/Minute

a) Press” ” and switch into ”Hour” or”Minute” setting area;

b) Press” ” then the figure will increases;

c) Press”  ”, then the figure will decrease.

When the setting is ready, press: “  ” to be out of the time setting mode.

4.5.4 NIBP Module Testing

a) Enter the maintenance mode;

b) Press  and switch the cursor into NIBP module testing area(PR parameter displaying area);

c) Press  to switch the testing items:

1) “150” stands for NIBP leak detection;
2) “250” stands for NIBP pressure testing.

d) Press  to start or stop test.

4.5.5 Brightness Adjust

a) enter the maintenance mode;

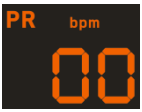
b) Press  and swith into brightness adjust area

c) Press  or  to adjust the brightness level form 01 to 05.

4.5.6 the Factory Default Configuration Restoring

d) enter the maintenance mode;

e) Press  and swith into the factory default configuration restoring interface;



f) Press  to modify the setting,  indicates current configration is not changed,  indicates restoring the factory default configration as the current configration.

The factory default configration can't be changed, but if needed, it can be restored to replace the configration made by user.

The factory default configuration items include:

- NIBP unit: mmHg
- Temp unit: ℃
- Patient type: Adult
- Pulse sound: On

Chapter 5 Battery

5.1 General

A built-in rechargeable battery is installed in the medical monitor. When connected to the AC power supply, the battery will be automatically recharged, whether the unit is in an ON or OFF position, until the battery is fully charged. In case the power fails, the system will be automatically powered on by the built-in battery thereby not interrupting the unit while working, and the indicator light for the battery will be lit after the power supply has been shut off for over 30 seconds.

The symbol "  " will be shown at the bottom right corner indicating the power condition of the battery: the green indicates the power is still full or medium level, while yellow shows a low level; and red is an extremely low level, alerting the user of the condition.

The battery icon shown on the screen indicates the current battery level:

 Indicating fully charged battery.

 Indicating the battery is charged, but not at a full level.

 Indicating that the battery in general.

 Indicating the battery is at a low level, requiring recharging the battery

 the icon flashes,indicates low battery, the battery needs to be charged immediately, or the measurement will be shutdown automatically.

The capacity of the internal battery is limited. if the power is low, icon"  " flashes, and a sound of "du" every 10s prompts user to recharge the battry, press  to turn off the sound.

When the power is too low, icon"  'flashes, a sound of "du" every 5s prompts user to recharge the battery, and it can't be turned off.

Working hours of Lithium-ion battery are not less than 12 hours with SpO2 probe connecting and NIBP measurement every 10 minutes while the environmental temperature is 25℃±5℃

⚠Attention

- **Please remove the battery and store it properly if long time no use**
- **If a built-in battery is inside the unit, the battery must be recharged after each use to ensure enough energy in the battery.**

⚠Warning

- **The battery liquid is harmful, In case the liquid contacts your skin or eye, wash it immediately with large amounts of clean water or seek medical advise.**
- **Keep the battery out of reach of children.**
- **The monitor is working, and it will be automatically turned off power when power is too low. if the energy in the battery has nearly run out, the monitor will give a high level alarm with a sound of "du" every 5s. If this case happens, the battery should be immediately connected to AC supply to be recharged. If the battery is still being used, the monitor will automatically shut off power before the battery is fully used up**

5.2 Battery Charging

When connected to the AC power supply, the battery will be automatically recharged, whether the unit is in an ON or OFF position, until the battery is fully charged. When the battery is charging, the indicator turns green, after fully charging,,icon"  ' shows up and simultaneously the indicator light turns off.

The charging time of lithium-ion battery:

- When monitor is not working, the fully charging time will not be longer than 3 hours
- When monitor is working, the fully charging time will no longer than 5.5 hours.

5.3 Installing Battery

Procedure of changing or installing the battery:

(1) Turn off the monitor, and disconnect the power cord and other connection lines.

(2) Place the monitor with the back up.

(3) Unscrew the battery cover.

(4) Take out the used battery and put the new one into the battery holder making sure the positive and negative poles match what is indicated on its shell.

(5) Replace the holder and screw it on, and turn the monitor upright.

⚠Warning

- **Use only the supplier's designated battery.**
- **Don't dismantle the battery while the monitor is turned on.**

5.4 Battery Using Guidance

Life expectancy of a battery depends on how frequent a how long it is used. For a properly maintained and stored lithium-ion battery, its life expectancy is about 3 years. For more aggressive use models, life expectancy can be less. We recommend replacing lithium-ion batteries every 3 years.

For battery life expectancy guarantee, please pay attentions to the following guidance:

- A battery performance inspection must be conducted every year; when you suspect the battery is a source of faults or before the maintenance, the inspection is also needed.
- When a battery is used or stored for every 3 month or the operating time in moticeablely shorter, the optimization shall be carried out.
- Take out the battery before transport or the monitor won't be used for 3 months.
- Before take out the battery and store, ensure there is 50% rest of the full power, and the shelf life lasts for almost 6 months. After 6 months, the battery shall be run out first.
- Ensure the environmental temperature is around 15 ℃ and there is no contact with metal objects during the storage. Or life expectancy of a battery will be noticeable shorter.

5.5 Optimization and Check of Battery Performance

(1) Optimization of battery performance

When the battery is used for the first time at least two complete cycles of optimization of the battery should be carried out. A complete optimization cycle should be: uninterrupted charging battery until the power is full, followed by use until the battery is fully discharged and monitor is automatically shut off.

This will ensure the battery is in optimization process:

(a) Disconnecting the monitor from the patient suspends all monitoring and measuring procedures.

(b) The optimized battery should be kept in the battery holder of the unit.

(c) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(d) When you disconnect the AC power supply, the monitor is powered with the battery until the battery runs out and the monitor automatically shuts off.

(e) This completes the battery optimization process.

(2) Check of Battery Performance

The service life of battery is changeable along with its storage, working environment charge cycles and service time. Even though battery is out of

service its performance will gradually deteriorate.

Procedure for checking the battery is as follows:

(a) Disconnecting the monitor from the patient suspends all monitoring and measuring procedures.

(b) When charging the battery, at least six hours of charging should be ensured until it is fully charged.

(c) Disconnect the AC power supply, power on the monitor with the battery until it is fully discharged and the monitor shuts off automatically. Record the duration.

(d) The period of battery discharge will reflect the battery performance.

(e) Once the discharge period is down to 50% of the original time, it requires changing the battery.

⚠Attention

- **In order to extend the service life of the battery it is recommended to charge it every three months after a long dormant period so as to prevent overdischarge.**
- **Battery power supply loss depends on the configuration and operation of the monitor; for example, the unit will have a big loss of battery power if it is used to measure NIBP parameter often.**

5.6 Battery Recovery

If the battery shows apparent damage or is at an energy exhaustion condition, it should be exchanged immediately, and the old battery should be recovered and

properly disposed of in accordance with relevant laws or rules and regulations for hospitals.

⚠Warning

- **Do not remove the battery or make it short-circuiting or put it into fire; otherwise, it would cause battery on fire, explosion, harmful gas leakage or other dangers.**

Chapter 6 Cleaning and Disinfection

Use only materials and methods that are approved by Comen Comany and listed in this chapter for cleaning or disinfecting the device. Comen Comany does not provide any guarantee for the damage caused by unauthorized materials or methods.

Comen Comany has no responsibility for the effectiveness of controlling infectious diseases using these chemical agents. Please contact the infectious or epidemic disease experts in your hospital for details. Also see all policies which are suitable for your hospital and locality.

6.1 General

The monitor must be kept dust-free. After monitor cleaning and disinfection, please carefully check the monitor. If you find any signs of damage or ware on the monitor, stop using the monitor. If necessary, please clean it first before returning it to Comen Comany. Please pay special attention to the following:

- Follow the manufacturer's instructions to dilute the solution, or adopt the lowest possible concentration.
- Do not let liquid enter the monitor.
- Do not pour liquid onto the monitor.
- No part of this monitor can be subjected to immersion in liquid.

■ Don’t use abrasive material (such as steel wool or silver polish etc) or bleaching powder, avoid using acetone-based cleaners such as acetone.

⚠Warning

- **Before cleaning the monitor or accessories, make sure that the equipment is switched off and disconnected fro AC power.**
- **Do not use ETO gas to disinfect the monitor or accessories.**
- **Check whether the cleaning agent is expired before using it.**
- **Use a cloth to wipe up any agent remaining on the monitor.**
- **Do not mix the cleaning agents, or dangerous gas will be produced.**
- **Do not clean or disinfect the disposable accessories. Do not reuse the disposable accessories to avoid cross infection.**
- **To protect environment, the disposable accessories must be recycled or disposed of properly.**
- **After cleaning, inspect the sensor cable for damage or aging. If any damage or aging is found, please replace the sensor cable.**

⚠Caution

- **If you accidently pour liquid onto the monitor or accessories, please contact our customer service immediately.**

⚠Attention

- **Appropriate disinfection materials for the sensor, detector, cable, probe, are introduced in the product specification offered with the appendix.**

6.2 Cleaning and Disinfection

6.2.1 Note on Cleaning and Disinfection

⚠Attention

- **The monitor and accessory surface can be cleaned with hospital-grade ethanol and dried in air or with soft, clean cloth.For protecting the environment, disposable accessories should be recycled or disposed of properly.**

⚠Caution

- **Do not autoclave the sensor.**
- **Do not soak the sensor in liquids.**
- **If the sensor or cable is damaged or has signs of deterioration, do not use again.**

6.2.2 Cleaning

The monitor must be kept dust-free. Regular cleaning of the monitor shell and screen is strongly recommended. More cleaning is needed in the environmental polluted or sandstorm areas. Before cleaning the monitor or the sensor, please consult with customer service or understand the hospital equipment cleaning regulation.

(a) Cleaning agents are listed below:

- Diluted Sodium Hypochlorite(Bleaching agent)

- Diluted Soapy Water
- Hydrogen Peroxide 3%
- Isopropanol 70%

(b) Before cleaning the monitor:

a) Make sure that the equipment is switched off and disconnected from the power line.

b) Use soft cotton ball to adsorb a small amount of cleaning agents and clean the screen.

c) Use soft cloth to adsorb a small amount of cleaning agents and clean the monitor shell.

d) If necessary, use a soft dry cloth to wipe away the excess cleaning agents.

e) Dry the monitor in air.

6.2.3 Disinfection

To avoid damage to the monitor, disinfection is recommended only when stipulated is necessary in the Hospital Maintenance Schedule. Monitor facilities should be washed first.

Disinfection material recommended: Glutaraldehyde 70%; Isopropanol 70%; Glutaraldehyde 2%.

⚠Caution

- **Do not use ETO gas to disinfect the monitor.**
- **Use a moistened cloth to wipe up any agent remaining on the monitor.**

6.3 Cleaning the Accessories

6.3.1 Cleaning and Disinfecting the SpO2 Sensor

The disposable SpO2 sensor can only be used once. The reusable sensor should be cleaned after use. The recommended cleaning agent is Isopropanol 70%. Cleaning steps are as follows:

1 Remove the sensor form the patient.

2 Clean the sensor by wiping with cotton or soft cloth moistened with Isopropanol 70%.

3 Allow the sensor to dry thoroughly prior to placement on a patient.

Disinfection:

1 If low-level disinfection is required, use 1:10 bleach/water solution.

2 Saturate the cotton or soft cloth with the cleaning solution and wipe all surfaces of the sensor and cable.

3 Saturate another cotton or soft cloth with distilled water and wipe all surfaces of the sensor and cable.

4 Dry the sensor and cable with a clean soft cloth.

⚠Warning

- **Do not use undiluted bleach or any cleaning agent other than those recommended here because permanent damage to the sensor may occur.**
- **Do not immerse the sensor or connector in any liquid solution.**

- **Do not sterillize by irradiation, steam autoclave or ethylene oxide.**

6.3.2 Cleaning and Disinfecting the Cuff

Take out the rubber bag before cleaning the cuff.

The cuff can be hand washed or machine washed in warm water or with mild detergent. Hand wash can extend the service life of the cuff. Air dries the cuff after cleaning.

The cuff may be disinfected with a cloth moistened with 70% ethanol or 70% isopropanol. Prolonged use of disinfectant may cause discoloration of the cuff.

⚠Warning

- **Don't compress the rubber pipe on a cuff.**
- **During monitor cleaning, users need only sweep the outer surface of the connector instead of its inner surface.**
- **In case a recyclable cuff is disconnected with the monitor or being cleaned, users should locate the cover cap above the rubber pipe so as to prevent any liquids from entering the rubber pipe and being absorbed into the module.**
- **Do not dry clean the cuff.**

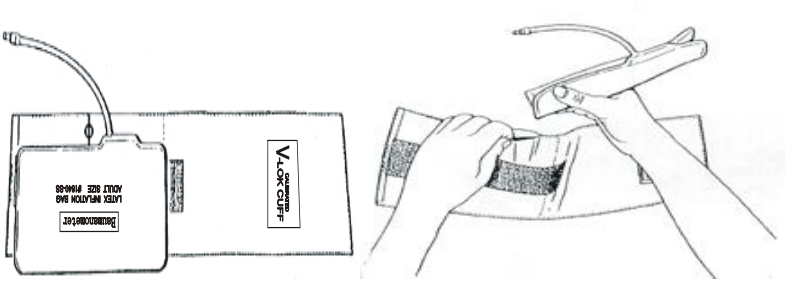
After cleaning, put the rubber bag into the cuff as following steps:

1 Place the rubber bag on the top of the cuff.

2 Roll the rubber bag lengthwise and insert it into the large opening, see the figures below.

3 Hold the hose and the cuff and shake the complete cuff until the rubber is in position.

4 Thread the hose from inside the cuff and out through the small hole under the internal flap.



6.3.3 Cleaning the Infrared Ear Thermometer

Please refer to the instruction of infrared ear thermometer.

Chapter 7 Maintenance

7.1 Maintenance and Check

The overall check of the monitor, including a safety check, should be performed only by qualified personnel before first use, every 6 to 12 month, and each time after repair.

Before using the monitor, do the following:

(a) Check the work environment and if the power supply meets the requirements.

(b) Check if there is any mechanical damage.

(c) Check if the cables are worn and ensure insulation is in a good condition.

(d) Check all the functions of the monitor to make sure that the monitor is in a good condition.

(e) Check if the accessories used are specified by the manufacturer.

(f) Check the battery.

(g) If the monitor is equipped with a recorder, please check if the recorder is normal and recording paper meets the specified requirement.

(h) Check if the wiring resistance and leakage current meet the requirements.

If you find any damage on the monitor, stop using the monitor on patient, and

contact the biomedical engineer of the hospital or our Customer Service immediately.

All the safety and maintenance checks that need to start the monitor should be performed by a qualified customer service technician. Non-professional operation can cause the monitor damage or cause a security risk, and human health may be endangered.

The circuit diagrams of the monitor can be provided by the manufacture, Comen Comany as per customers demand. Qualified technicians can use it to help the user repair some apparatus that Comen Comany classifies as “can be maintained by the user” .

⚠Warning

- **If the hospital or agency that is responsible for using the monitor does not follow a satisfactory maintenance schedule, the monitor may become damaged, and human health may be endangered.**

7.2 Maintenance Schedule

The following safety and maintenance check can be conducted by professional persons from Comen Comany. You can contact with our customer service technicians if you need the following maintenance check. Before the inspection or maintenance, the facilities should be cleaned and disinfected.

Check and maintenance	Frequency
According to IEC 60601-1 Medical electrical equipment Part 1 General requirement	Check can be conducted at least every 2 years. Or after monitor falling,, power

for safety	replacement, or when needed by customers
NIBP air leakage check	Check can be conducted at least every 1 years or when needed by customers.
NIBP adjusting	Check can be conducted at least every 1 years or when needed by customers.
NIBP pressure calibration	Check can be conducted at least every 1 years or when needed by customers.
Battery	See the section on battery for reference

7.3 NIBP Air Leakage Check

The NIBP leakage test checks the intefrity of the system and of the valve. It is required at least once a year or when you doubt the measured NIBP. If the test is passed, the “P” will be shown in mean pressure area; if not, there will be a corresponding error prompt in the NIBP information area.

Tools required:

- An adult cuff
- An air tube
- A corrected sized cylinder

Follow this procedure to perform the leakage test:

1. Press”  ” set the patient type to a dult”  ”;
2. Connect the cuff to the NIBP connector on the monitor

3. Wrap the cuff around the cylinder as shown below

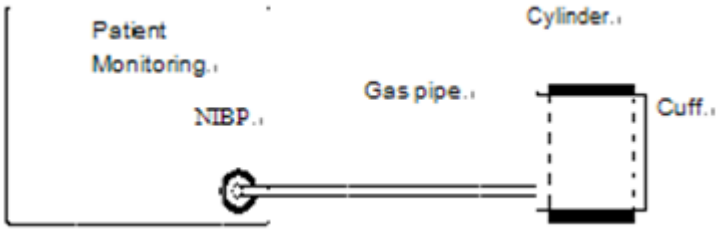


Figure 7-4 NIBP Air Leakage Checking Connection Schematic

4. Enter the maintenance mode according the steps of "maintenance mode", press" " and switch into detection interface of NIBP module, PR parameter area prompts "150".

5. Press" ", start leakage test. The real-time pressure is shown in mean pressure area.
   Press " " to stop the test if necessary.
6. After test is completed, the monitor will automatically deflate.
7. If P is shown in fault code area that means the test is OK, if F is shown, it indicates that the NIBP airway may have leakages. Check the tubing and connections for leakages, and perform a leakage test again.

⚠Warning

- **This leak detection is different from those described in the standard EN 1060-1,which is for users to simply test air leakage in NIBP inflation. If the system displays the NIBP leaks at the end of testing, please contact the Comen comany maintenance engineers.**

7.4 NIBP Pressure Calibration

The NIBP pressure calibration is required at least once a year or when you doubt the measured NIBP.

Tools required:

- T-piece connector
- Approprating tubing
- Ballon pump
- Metal Vessel(500±5%ml)
- Reference manometer(calibrated with higher than 0.75mmHg)

Following this procedure to perform the test:

1. Connect the equipment as shown:

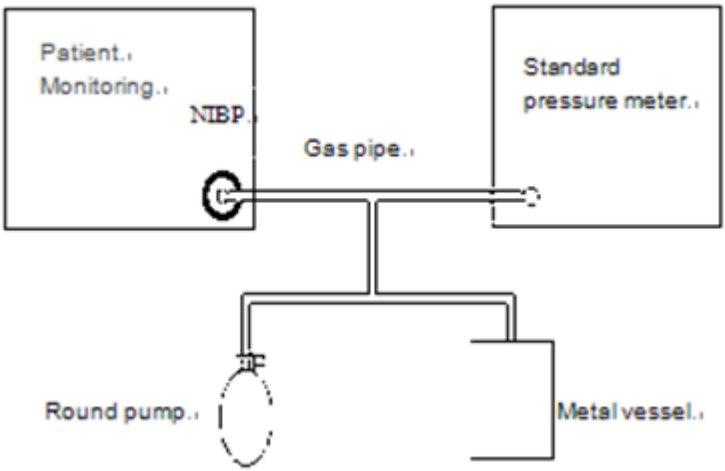


Figure 7-5 NIBP Calibration Connection Schematic

2. Before inflation, the reading of the manometer should be 0. If not, disconnect the airway and reconnect it until the readings is 0.

3. Enter “miantenance mode”, press”  ” and switch to detection interface of NIBP module, “250” is shown in RP parameter area.

4. Press”  ”, start test. The real-time pressure is shown in mean pressure area.

   Press “  ” to stop the test if necessary.

5. Raise the pressure in the metal vessel to 50mmHg with the ballon pump then stop and hold for 10s to make the value stable
6. Compare the manometer values with the displayed values. The difference between the manometer and displayed values should be no greater than 3mmHg
7. Raise the pressure in the metal vessel to 200mmHg with the ballon pump then stop and hold for 10s to make the value stable. Repeat step 6.

If the difference between the manometer and displayed values is greater than 3 mmHg, contact your service personnel.

7.5 Calibrating NIBP

NIBP overvoltage protection is not user-calibrated. Cuff-pressure transducer must be verified and calibrated once a year by a qualified service professional. Contact your service personnel when it is necessary.

Chapter 8 Patient safety

8.1 Safety Instruction

The design of the Vital Signs Monitor requires the international safety standard of medical electrical accessory.

8.2 Environment

The following guidance should be observed in the interest of absolute safety of electrical installations.

Vibration, dust, corrosives or explosive gas, extreme temperature and humidity should be avoided in the environment where the monitor is used.

Ventilation inside the instrument case where the monitor is installed should be guaranteed in such a manner that enough space is reserved in both the front to facilitate operations and the rear， so that, when the case door is open, facilitate maintenance. A void space of at least 2 inches or 5 centimeters should be cleared around the instrument for air ventilation.

The monitoring system should be in the ambient temperature -20～+60℃（keeping）0～40℃(runing) to satisfy the keeping and running requirements, An ambient environment out of this range may impair the instruments accuracy

and cause damages to its components and circuits.

8.3 Power Requirement

Refer to the section “Product Specifications”.

8.4 Grounding Protection

To protect the patients and operation staff, the shell of the monitor must be grounded. So the monitor is equipped by a removable triaxial cable. When the cable plugs in a matching plug connector, the grounding wire of the power line ground the monitor. In case a three-plug connector is not available, the electrical operating staff should be consulted.

⚠Warning

- **Replacement of the three-plug connector with a two-plug connector is strictly prohibited.**

The grounding leads should be connected with the equipotential grounding terminal of the instrument. The instrument users do not know whether a given combination of instruments may invite dangers, e.g. due to accumulations of leaked currents, should consult relevant manufactures or experts in this field so as to guarantee that the required safety of the combined instruments are not compromised when the given combination is in use.

8.5 Equipotential Grounding

The primary protection of the instrument is embodied in the building protective grounding (protective ground) system by means of power plugs grounding. The monitor should be separately connected with the equipotential grounding system for examinations of hearts or skulls. One end of the equipotential grounding leads (potential equalizing leads) should be connected onto the equipotential grounding terminals on the rear panel of the instrument and the other should be connected onto one connector of the equipotential system. The equipotential grounding system should be in place for safety functions of the protective grounding leads in case of any damage to the protective grounding system. Cardiac or brain examinations should be conducted only in the rooms equipped with protective grounding systems. A check of the instruments should be conducted to guarantee the instruments are in good repair before each examination. The cables connecting with patients and instruments should be guaranteed not having been subjected to electrolytic pollution.

⚠Waring

- **Battery power should be used to power the monitor against unstable protective grounding (protective earthing) system.**

8.6 Condensation

The working instruments should be guaranteed not to form any condensation. Transferring of the instrument from one room to another may cause condensation on the instrument. This is attributed to its exposure to humid air

at different temperatures. Unnecessary problems can be avoided by placing the instrument in a dry place before putting it into use.

Note: Condensation is defined as coagulation of gases or liquids when cooled, e.g. water vapor when cooled is transformed into water and water when cooled into ice. The lower the temperature is, the faster condensation is formed.

⚠Warning

- **Use in the presence of combustible anesthetics is prohibited to avoid any risk of explosions.**

8.7 Description of Symbols on Instrument

Please refer to Section 1-1.3: Instrument and Symbols.

Chapter 9 SpO_2 Monitoring

9.1 Definition of SpO_2 Monitoring

SpO_2 plethysmography parameters measure blood-oxygen saturation, that is, the percentage of the total oxyhemoglobin. When 97% of the total number of hemoglobin molecules combines with oxygen in the arterial blood's red blood cells, this blood will have 97% SpO_2 oxygen saturation, and at the same time the monitor reads 97% SpO_2 value. This value shows the percentage of oxygen-carrying hemoglobin molecules, constituting oxyhemoglobin. Furthermore parameters of the SpO_2 can also provide pulse rate signal and plethysmography wave.

9.1.1 Principle of Measuring SpO_2 Plethysmography Parameter

Pulse oximetry is a measurement of oxygen saturation. It is a continuous, non-invasive way of determining the hemoglobin oxygenation saturation. It is involved in measuring how much light emitting from the sensor side passes through the patient's tissue (such as a finger or ear) and then reaches the other side of the receiver.

The sensor is usually able to gauge the 660nm wavelength of red LED, and 940nm of infrared LED While LED's maximum available output power is

4mW.

Though the amount of light passing through depends on many factors, most of them are constant. However, one of the factors is that blood flow in the arteries changes with time, since it is pulsatile. It is possible to obtain arterial blood oxygen saturation by measuring the amount of light absorbed during the pulse. And surveying pulse itself can supply a “plethysmography” waveform and pulse rate signal.

The main screen can display “SpO2” value and “plethysmography” waveform.

The wavelength rang of different sensors and the information of LED’s maximum available output power are very important to clinician.

For example: Photodynamic therapy

- the wavelength gauged by sensor of Comen SpO2 module: red llight: 660nm, infrared light: 905nm;
- the wavelength gauged by sensor of Masimo SpO2 module: red llight: 660nm, infrared light: 940nm;
- the wavelength gauged by sensor of Nellcor SpO2 module: red llight: 660nm, infrared light: 890nm.

⚠Warning

- **If there is carbonyl hemoglobin, methemoglobin, or dye dilution chemical present, the SpO2 value will deviate.**
- **Though the monitor can automic inditify blood oxygen probes, the measured parameters will be abnormal if use the wrong probes, as the inside hardwares have been fixed when released.**
- **When a trend toward patient deoxygenation is indicated, blood**

samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.

9.1.2 Attentions on Monitoring of SpO_2/ Pulse

⚠Warning

- **First check whether the sensor cable is normal before the monitor is started. When you unplug the cable of the SpO2 sensor from the jack, the screen will display fault code.**
- **If the sensor or its packaging has signs of damage, do not use it and return to the factory.**
- **Do not twist the cable of electrical surgical equipment with the sensor's.**
- **Do not put a sensor on limbs with an arterial catheter or intravenous tube.**
- **Continuous and prolonged period of monitoring may increase the risk of undesirable changes in the skin characteristics, such as extremely sensitive, reddenning, blistering, or even pressure necrosis etc, especially of the newborns, or patients with perfusion disorders and varying or immature forms of skin. Particular attention to checking placement of the sensor according to the changes in the quality of skin, correct optical alignment and attachment methods. Also check, periodically, the location where the sensor is attached and make a change of the position if there is a decline of skin quality. More frequent examination may be required due to different status of indidivual patients.**

⚠Attention

- **Make sure that the nails cover the light inside the probe. Its lines**

should be placed on the back of hands.

- **SpO2 value is always displayed in a fixed place.**
- **Blood oxygen simulator can only verify the function of the oxygen sensor, but can't validate the precision.**
- **Do not place the probe and cuff on the same limb, it may occlude the blood flow and affect readings of oxygen saturation during blood pressure measurement.**
- **There is no alarm reminding when the measurement data is abnormal, please pay close attention to the patient's condition.**

9.2 Identifying SpO2 Modules

To identify which SpO2 module is incorporated into your detection integration, see the sign located at the side of monitor:

- Comen SpO2 module: no sign
- Masimo SpO2 module: MASIMO SET®
- Nellcor SpO2 module: Nellcor

The three kinds of SpO2 probe interfaces are incompatible.

9.3 Steps of Monitoring

⚠Warning

- **Select the appropriate placement according to the instrument and its supporting oxygen probe, which is fundamentally vital to a neonate.**

(1) SpO_2 plethysmography measurements:

- Turn on the monitor;
- Select an appropriate SpO2 probe according to the module, patient type and patient's weight.
- Clean the measurement site, like colored nail poish.
- Attach the sensor to the appropriate location of the patient's finger;
- According to the type of SpO2 probe, choose a extension cord and connect it.
- Insert the connector of the sensor cable into the hole marked SpO_2 on its module.
- The monior automatically recognizes the probe, and display the SpO2 data and PR.

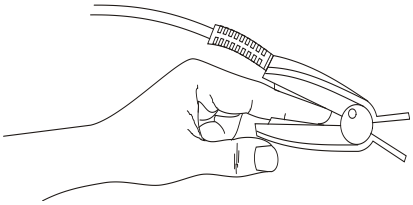


Figure 9-1 Installation of the sensor

(2) Neonatal SpO_2 plethysmography measurements:

The process of the neonatal SpO_2 plethysmography measurement is basically the same as with adult's. Following is an introduction to the neonatal oxygen probe and methods for its placement.

(a) Neonatal blood-oxygen probe

Neonatal oxygen probe consists of the Y-shaped blood-oxygen probe and neonatal oxygen probe sheath. Insert the LED side of the Y-shaped probe in the upper groove of the sheath, and respectively

the PD side of the probe within the lower (See Figure 9-2), then the neonatal blood-oxygen probe is shown in Figure 9-3。

Y-type blood oxygen probe　　Blood oxygen probe sheath for newborns

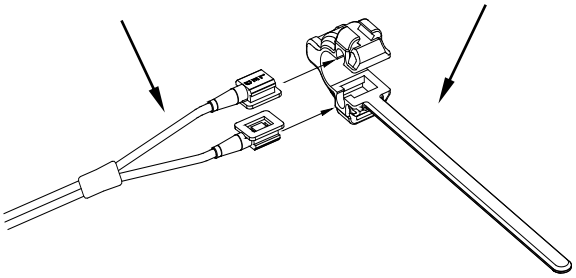


Figure 9-2 Infant blood oxygen probe (1)

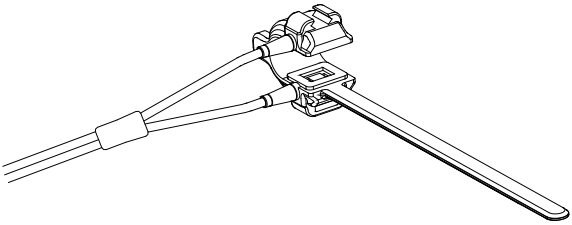


Figure 9-3 Infant blood oxygen probe (2)

(b)Placement of the neonatal blood-oxygen probe

Clamp the probe to the newborn's hand or foot (as shown in Figure 9-4). Hold the sensor, pull the band and lay its ‘V’ shaped brim into the corresponding side of the ‘V’ shaped tank of the sheath, stretch the string to an appropriate length (20mm or so) and lay the other side’s ‘V’ shaped edge of the rope into its corresponding the ‘V’ shaped groove , and then release the rope, with its both sides of the ‘V’ shape embedded in respective ‘V’ shaped groove, thread the first

latch and lock it, shown in Figure 9-4 . If the band is too long, thread the second latch. The necessity of locating the sensor in such a way has a purpose that the optical components will be in the correct and opposite position. Moreover, do not pull the band too tight, to prevent wrong measurements and seriously blockage of the blood circulation.

Figure 9-4 Installation of the infant blood oxygen probe

⚠Attention

- **When the accurate positioning between the test site and the probe fails, it may result in wrong readings of blood-oxygen saturation, and even stop monitoring because of the failure of the search for the pulse wave. In this case you should re-position the two.**
- **Excessive movement of measured sites may affect the accuracy of the measurement, therefore, you should calm the patient or replace sites in order to reduce the impact of excessive movement.**

⚠Warning

- **In a long and continuous monitoring process, check the condition of the peripheral circulation and skin under measuring every 2 hours or so, and if negative conditions happen, timely change the site under measurement.**
- **In a long and continuous monitoring process, it is advisable to check periodically the positioning of the probe to avoid inaccurate**

measurement due to changing in the positioning from moving or other factors.

9.4 Limits in Measurement

During operation, the following factors can affect the accuracy of blood-oxygen saturation measurement :

- High-frequency radio interference, for instance, interference self-generated from the host system or from electrical scientific instruments connected to the system.
- During magnetic resonance imaging scanning (MRI), do not use the photoelectric oximeter and oxygen sensor, since induced currents may cause burning.
- Intravenous dye.
- Patient's excessive movement.
- External radiation.
- Improper installation of sensor or improper contact position with the object .
- Sensor's temperature (optimal temperature should be among 28 ℃ - 42 ℃) .
- The sensor is placed on the limbs with a blood pressure cuff, arterial catheter, or the pipeline of body cavity.
- The concentrations of non-functional hemoglobin such as

carboxyhemoglobin (COHb) and methemoglobin (MetHb) etc.

- Extremely low degree of blood-oxygen saturation.
- The measured area has poor circulation.
- Syndromes such as shock, a Extreme low degree of blood-oxygen saturation, .anemia or low temperature etc and application of vasoconstrictor drugs can reduce blood flow to the level of not being able to be measured.
- Measurement also depends on both the oxyhemoglobin and reduced hemoglobin's absorption of specific wavelengths of light. If any other factors absorb the same wavelength, they will generate false measurement, lower SpO_2 values. These factors are as follows: carbonization of hemoglobin, methemoglobin, methylene blue , indigo rouge.It is recommended to use only the SpO_2 probe described in the accessories.

9.5 Setting pulse Sound

User can switch pulse sound ON or OFF, setting steps are as blow:

1. Press and hold " ↵ " in measurement mode to enter parameter setting mode.
2. Press " ↵ " to switch into pulse sound setting interface
3. Press the key, switch ON or OFF.
   - When " 

" is shown, that means OFF.
   - When " 

" is shown, that is means ON.

     Long press" ↵ " and back to recall mode, setup is complete. Or

long press “ ” to turn off the machine, setting will take effect when start again.

⚠Attention

- **if the switch turns on, the monitor issues a sound of “du” every time pluse beats when measuring.**

9.6 Display

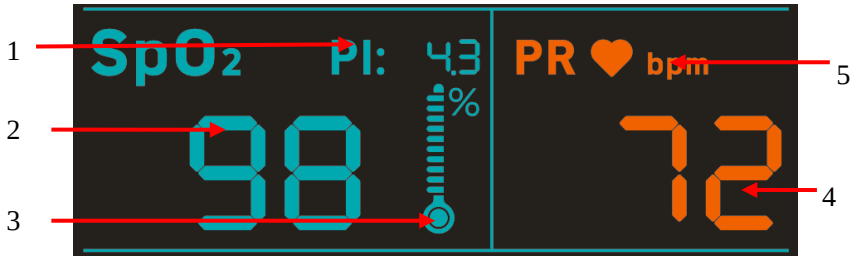


Figure 9-5 SpO2 display

1. PI (Perfusion index): Use for Masimo SpO2 module and Comen simulation SpO2 module. Perfusion index is the percentage of the pulsating quantity to the pulsating quantity caused by artery blood flow change in blood oxygen signal. Perfusion index is a reaction of blood oxygen signal intensity, part indicates the signal quality. It is the best while the index is more than 1; it can be received when index is 0.3-1 and it is weak when less than 0.3, the probe shall be adjusted if it happens. Please verify the saturation condition in other ways if it doesn’t improve.
2. SpO2 (Arterial oxygen saturation): The percentage of oxyhemoglobin to total hemoglobin.
3. Perfusion figure: Proportional to the strength of the pulse.
4. PR (Pulse rate): PR value is reflected arterial pulse caused by the mechanical activity of heart; it can be achieved through SpO2 and NIBP measurement. And when SpO2 and NIBP are measured at the same time,

PR value accesses to SpO2 value preferentially.

5. PR symbol: Indicates the heart beats.

9.7 Masimo Information

- Masimo Patent

  It contains one or more of the following U.S. patents: RE38,492, RE38,476, 6,850, 787, 6,826,419, 6,816,741, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,830, 6,067, 462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international patents or a item or a number of patents referred to in the www.masimo.com/patents. Including functions from products of Satshare ® and the U.S. Patent 6,770,028. Other patents are under application.

- Other Information

Chapter 10 NIBP Monitoring

10.1 General

Use oscillation method for Non-invasive blood pressure (NIBP) measurement.

Available for adults, children and newborns.

In order to know oscillametric method better, the following is the comparison with auscultation method:

- Auscultation method: Systolic blood pressure and diastolic blood pressure can be obtained by stethoscope, if the arterial pressure curve is normal, the mean blood pressure can be calculated.
- Oscillametric method: the vibration of the cuff reflects the blood pressure, and the maximum amplitude of the cuff corresponds to the mean blood pressure, then systolic and diastolic blood pressure can be calculated.

When measuring in children and newborns, you must ensure that the correct mode is selected (see menu settings of patient information). Wrong patient mode could jeopardize patient safety, because high blood pressure of adults does not apply to children and newborns.

The blood pressure obtained by this monitor is equivalent to auscultation method and invasive method, the deviation meets the requirement of 80601-2-30.

Clinical significance must be determined by doctor.

10.2 NIBP Monitoring

10.2.1 NIBP Measurement

⚠Warning

- **Inflation exerts pressure on measurement site during NIBP measuring, therefore, doctor should determine whether the patient is suitable to do NIBP measurement based on patient's clinical condition**
- **Before starting the measurements, make sure the selected criteria applies to your patients (adults, children, newborn).**
- **Do not install the cuff on a limb with an intravenous infusion tube or a catheter. During cuff inflation, if infusion is lowed down or clogged, the area around the tube may be damaged.**
- **Ensure that inflatable tubes that attached blood pressure cuff and monitor are smooth and with no tangles.**
- **No-invasive blood pressure measurement cannot be run in patients suffering from sickle-cell disease or skin damage or any time there may be anticipated damage.**
- **For a patients suffering from serious disturbance of blood coagulation mechanism, the decision to operate automatic blood pressure measurement must be made according to the clinical evaluation, because the friction area between body and sleeves has the risk of hematoma.**

a) Power on the monitor;

b) Verify the patient type, change it if necessary;

c) Plug the air tube into the NIBP interface on the monitor;

d) Select a correct size cuff and apply it as follows:

- Verify that the cuff is completely deflated;
- Select an appropriate cuff by referring to the limb circumference marked on the cuff; make sure that the φ mark is placed right onto the appropriate artery. Be sure that the cuff is not too tightly wrapped around the limb, otherwise it may cause discoloration or even ischemia to the far end of the limb.

e) Connect the cuff to the air tube and make sure that the bladder inside the cover is not folded and twisted.

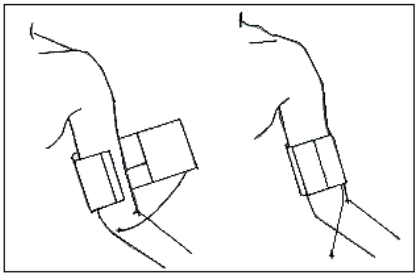


Figure 10-1 Cuff usage（Adult）

Figure 10-2 （Neonate）

⚠Attention

- **The width of the cuff should be 40％ (or 50% for neonates) of the circumference of the limb, or 2/3 of the length of the upper arm. The length of the inflated part of the cuff should be long enough to wrap 50～80% of the limb; a size unsuitable cuff will produce a wrong reading. If the size of the cuff has a problem, use a larger cuff in order to reduce errors.**

Adult/neonate/child can use the cuffs repeatedly:

patient type	Limb Circumference	Cuff width	Inflatable pipe length
infant	10～19 cm	8 cm	2 m
child	18～26 cm	10.6 cm	
adult 1	25～35 cm	14 cm	
adult2	33～47 cm	17 cm	
leg	46～66 cm	21 cm	

Neonatal/infant/adult disposable cuffs：

Size	Limb Circumference	Cuff width	Inflatable pipe length
1	3.1～5.7 cm	2.5 cm	2 m
2	4.3～8.0 cm	3.2 cm	
3	5.8～10.9 cm	4.3 cm	
4	7.1～13.1 cm	5.1 cm	

- Check if the edges of the cuff locates inside the range marked by < - >. If not, replace the cuff with a more suitable one.
- Connect the cuff and inflatable tube. Body parts used for pressure-measuring should be in the same horizontal location with patient's heart. If unable to do so, it is necessary to use the following

correction method to modify the measurement results：

a) If cuff is above the heart level location, 0.75mmHg (0.10kPa) should be added to the displayed value for per centimeter gap.

b) If cuff is below the heart level location, the displayed value should minus 0.75mmHg (0.10kPa) for per centimeter gap.

In order to obtain accurate blood pressure measurement for the hypertension patient, the patient position should be as follows:

a) Comfortably seated

b) Legs uncrossed

c) Feet flat on the floor

d) Back and arm supported

e) Middle of the CUFF at the level of the right atrium of the heart

10.2.2 Starting /Stopping Measurements

You can start or stop measurement by pressing "  " hard key on the monitor's front panel.

The default inflation pressure of this monitor is:

- Adult: 160mmHg
- Child: 120mmHg
- Neonate: 100mmHg

⚠Attention

- **During the measurement, patient shall be relax and not talk to others**
- **If you doubt the NIBP readings, determines the patient's vital**

signs by alternative means and then verify that the monitor is working correctly.

- **Press to stop the measurement.**

⚠Warning

- **If liquid splashes on the devices or accessories, especially when the liquid is likely to enter into channels or monitor, please contact the hospital's maintenance department.**

10.2.3 Measurement Restrictions

According to the patient's condition, oscillatory measurement has some restrictions. Such measurements are looking for regular impulse waves produced by arterial pressure. In the case the patients' condition makes this kind of detection difficult, measurement values become unreliable and load time increases. Users should be aware that the following conditions will interfere with the measurement method, so that pressure is not reliable or load time increases. In this case, the patient's condition will make measurement impossible.

(1) Patient Mobility

If patient is moving, shaking or in spasms, measurement will be unreliable even impossible, as these may interfere with the detection of the arterial pressure pulse and load time will be extended.

(2) Arrhythmia

If patient has shown arrhythmia caused by irregular heart beats, measurements are unreliable or even impossible and load time will be extended.

(3) Heart-Lung Machine

If patient is connected to an artificial heart-lung machine, measure cannot be conducted.

(4) Pressure Change

If within a certain time, arterial pulse pressure is being analyzed to get the measurements, when blood pressure in patients is rapidly changing, measurement will be unreliable or even impossible.

(5) Severe Shock

If a patient is in serious shock or hypothermia, the pressure will be unreliable. Causes that reduce blood flowing to periphery would cause a decline in arterial pulse.

(6) Limit Heart Rate

Blood pressure measurement cannot be performed when heart rate is lower than 40bpm (beats per minute) or higher than 240bpm (beats per minute).

(7) Obese Patients

A thick layer of fat around a limb damps oscillations from the artery, thus preventing them from reaching the cuff. The accuracy is lower than the normal one.

10.3 **NIBP Display**

NIBP measurement results are displayed in the parameter area; the following figure is for reference only; the graphic displayed on your monitor might be somewhat different:

Figure 10-2 NIBP Measurement

1	Pressure unit: mmHg or kPa	2	Mean blood pressure
3	PR value	4	Diastolic blood pressure
5	Systolic blood pressure		

Chapter 11 TEMP Monitoring

11.1 Temperature Monitoring

The temperature measurement is obtained by infrared ear thermometer. See the contents of “infrared ear thermometer instruction” for more details.

11.2 Infrared Ear Themometer

11.2.1 Front View

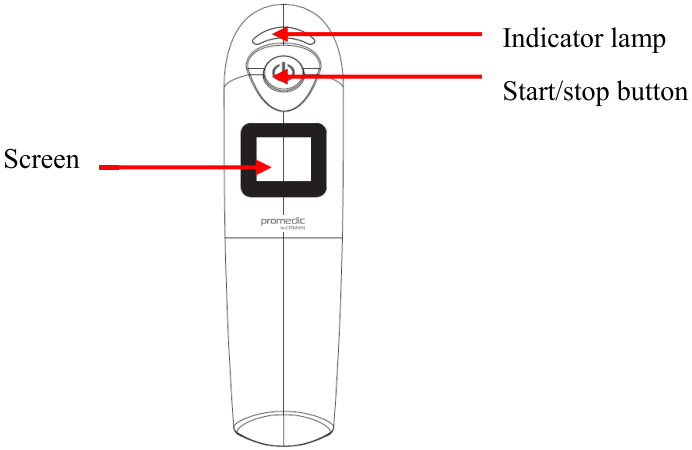


Figure 11-1 the positive of ear themometer

11.2.2 Side View

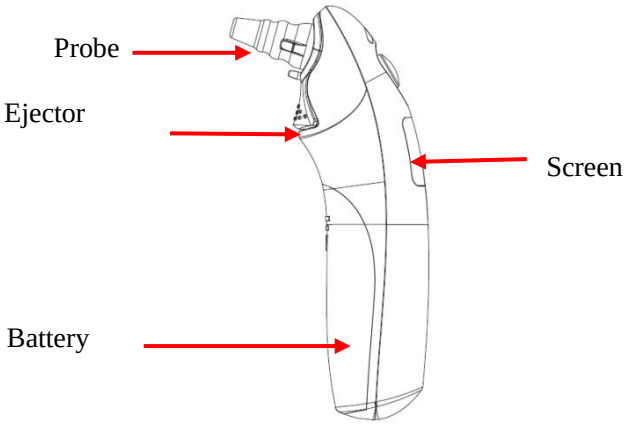


Figure 11-2 Side view

11.2.3 Temp Measurement

(a) Ensure battery is in the ear thermometer

(b) Install a new protective cover on the probe, and make it tighten

(c) Put the ear thermometer in the correct position, and press the measurement key, wait for several seconds, then issues a sound of “DI”

(d) Take out the thermometer, and then the temperature is shown on screen.

(e) Press the eject key of the protective cover, remove it and put the thermometer back.

11.2.4 Wireless Transmission Function

When the host with the ear thermometer supporting the use of common, the temperature value can be sent and displayed on the host through wireless transmission function (figure 9-3)

Figure 11-3 temperature display

(1) Wireless connection: when the ear thermometer is off, press and hold the "eject key", simultaneously press" switch key" and start the device. When the screen shows "SE" (alternate display ℃ and ℉ for twice), then loose the "eject key", and start the host which is with wireless function.

(2) Wireless connection/transmission status:

When wireless connection is successful, the screen prompts icon" "

When wireless connection is fail, there is no icon" " on screen;

When transmission is successful, icon" " doesn't flash;

(3) Trouble shooting tips:

Phenomenon	Possible Cause	Servicing Method
Er0	Wireless module doesn't work	Contact service personnel
Wireless transmission failure	Ear thermometer is far away from the receiving device	Keep ear thermometer is less than 10M away from the receiving device without any blocking
	Ear thermometer connects without any device, or receiving device is off or on standby	Match again and ensure the receiving device is on.
	Wireless transmission function is beyond fix	Contact service personnel

⚠ Warning

- **Ear thermometer must be verified and calibrated at least once every two year(or depending on hospital discipline time), contact your service personnel when a calibration is necessary.**
- **Use specified probe and protective cover, if not, it might cause damage or the measured value is not accuracy.**
- **The protective ctantou over is single-use. Repeated use might cause cross infection.**
- **Disposable protective cover must be used when measuring, if not, it might cause cross infection or inaccuracy value**
- **Befor use, check whether the cover is intact, if not, please don't use it.**
- **Handle the ear thermometer with care, the probe shall be put back into the casing when not in use.**
- **Discarding the disposable cover in accordance with the requirements of local regulations pr hospital discipline.**

⚠ Attention

- **Disposable temperature probe can only be used once.**
- **During the monitoring process, the temperature measuring instrument will automatically check itself once per hour. Self-checking will last 2 seconds, and will not affect the normal working of the temperature monitor.**

11.3 **TEMP Display**

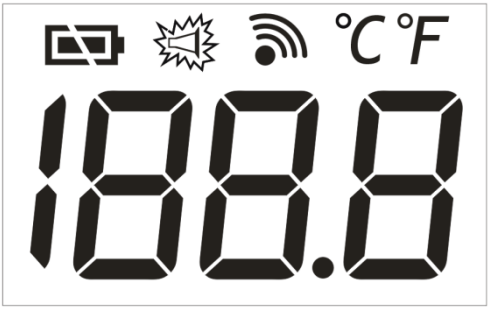


Figure 11-4 Display

Appendix I Accessory

The manufacturer recommends the following accessories for this monitor.

⚠ Warning

- **Please use accessory designated by the manufacturer. Using otheraccessories o may cause damage to this monitor.**
- **Disposable accessories only can be used once; reusing may result in performance deterioration or cross infection.**
- **Check the accessories and their packages for any signs of damage. Do not use them if any damage is detected.**
- **Disposable accessories shall be handled in accordance with the relevant rules of hospital after using.**
- **Connecting and using the accessories shall be avoided contact with each other or other metal device.**

No.	PN	Model	Type	Description
1. Comen SpO_2 sensor				
1	040-000243-00	SLZ068	/	Cable extender
2	040-000646-00	A1418-SA203MV	Reusable	Adult
3	040-000334-00	A1418-SW203MU	Reusable	Neonatal
2.Nellcor SpO_2 sensor				
4	009-000466-00	DOC-10	/	Cable extender
5	040-000087-00	OXI-A/N	Reusable	Adult/Neonatal
6	040-000086-00	OXI-P/I	Reusable	Pediatric/Neonatal
7	040-000223-00	MAX-N	Disposable	Neonatal
8	040-000004-00	MAX-P	Disposable	Pediatric
9	040-000010-00	DS-100A ＞40KG	Reusable	Adult
3.Masimo SpO2 sensor				
10	040-000204-00	MDR14DB15/M-LNC-10	/	Cable extender
11	040-000361-00	M-LNCS YI	Reusable	Neonatal
12	040-000373-00	M-LINCS DCIP	Reusable	Pediatric

13	040-000203-00	M-LNCS DCI	Reusable	Adult
14	040-000232-00	M-LNCS Neo	Disposable	Adult/Neonatal
15	040-000200-00	M-LNCS Neo-3	Disposable	Adult/Neonatal
16	040-000198-00	M-LNCS Inf-3	Disposable	Neonatal
17	040-000201-00	M-LNCS Pdtx-3	Disposable	Pediatric
18	040-000202-00	M-LNCS Adtx-3	Disposable	Adult
4.NIBP cuff				
19	040-000592-00	U1880S	Reusable	Adult; 25-35cm
20	040-000593-00	U1881S	Reusable	Pediatric; 18-26cm
21	040-000594-00	U1882S	Reusable	Infant; 10-19cm
22	040-000595-00	U1883S	Reusable	Neonatal; 6-11cm
23	040-000743-00	U1681S	Disposable	Neonatal; 3-6CM
24	040-000744-00	U1682S	Disposable	Neonatal; 4-8CM
25	040-000745-00	U1683S	Disposable	Neonatal; 6-11CM
26	040-000746-00	U1684S	Disposable	Neonatal; 7-13CM
27	040-000747-00	U1685S	Disposable	Neonatal; 8-15CM
28	040-000323-00	CM1601	Disposable	Neonatal; 3.0-5.5CM
29	040-000324-00	CM1602	Disposable	Neonatal; 4.0-7.6CM
30	040-000325-00	CM1603	Disposable	Neonatal; 5.6-10.6CM
31	040-000326-00	CM1604	Disposable	Neonatal; 7.0-12.8CM
32	040-000141-00	CM1200	Reusable	Neonatal; 6-11CM
33	040-000120-00	CM1201	Reusable	Infant; 10-19CM
34	040-000140-00	CM1202	Reusable	Pediatric; 18-26CM
35	040-000005-00	M1574A	Reusable	Adult，27-35CM
36	040-000091-00	CM1205	Reusable	Adult thigh, 46-66CM
37	040-000092-00	CM1204	Reusable	Adult thigh,33-47CM
38	040-000142-00	CM1203	Reusable	Adult; 25-35CM
5.Ear thermometer				
39	Lens filter	PC3920	Disposable	Adult/Pediatric/Neonatal

Appendix II Product Specification

I. Monitor Type

(1) Product Classification

Name	type
Classification by protection against electric shock	Class I with internal power
Degree of protection against electic shock	BF appied parts：NIBP, TEMP, SpO2,
Safety standard	MDD 93/42/EEC, EN ISO13485:2012 +AC 2012, EN ISO14971: 2012, EN 60601-1: 2006/ AC:2013, EN 60601-1-2: 2007/AC:2010, EN60601-1-6:2010, EN 980:2008, EN 1041: 2008, EN ISO10993-1:2009, EN ISO10993-5:2009, EN ISO 10993-10:2010, EN 1060-1:1995+A2:2009, EN 1060-3:1997+A2:2009, EN 1060-4:2004, EN ISO 80601-2-30：2009+A1：2013, EN ISO 80601-2-61：2011, EN 62366:2008 EN62304:2006
The degree of ingress protection（The host）	IPX1
The degree of ingress protection（infrared ear thermometer）	IPX0
The degree of safety in the condition of flammable anesthetic gas mixed with the mixture like air, the oxygen or nitrous oxide mixture (It's NA)	The device can not be used in the case of flammable anesthetic gas mixed with air and the mixture of oxygen or nitrous oxide.
Disinfection methods	Please refer to Chapter 6 for detailed information.
Operation Mode	Run the device continuously

(2) Environmental Demands

Name	Specifications	
Work environment	Range of temperature	0℃～40℃(without ear thermometer) 15 ℃ ～ 36 ℃ (with ear thermometer)
	Range of Rh	93%/non-condensing(without thermometer) ≤ 93%/ non-condensing(with thermometer)
	Range of atmospheric pressure	700hPa～1060hPa
Demands on the power supply voltage	Power voltage	100V-240V～
	Power frequency	50Hz/60Hz
	input current	0.3-0.15A
Fuse	PTC fuse/UF300 3A DIP	
transportation	Prevent severe shock, vibration and splash from rain and snow in the process of transportation	
storage	Monitors packed should be stored around -20 ℃ to 60 ℃, ≤93% in the relative humidity, non-corrosive gases and ventilated room.	

(3) Battery

Name	Specifications
Battery specifications(host)	2600mAh 11.1V lithium ion battery
Duration of charging	When monitor is not work, the fully charging time will no longer than 3 hours When monitor is work, the fully charging time will no longer than 5.5 hours.
Endurance time	It can last at least 12 hours in the fully charged condition when it is on standby. Moreover it can run five minutes after the first alarm triggered due to low battery power.
Battery Specifications(ear thermometer))	d.c 3v(2 batteries)

II. Hardware Specification

(1) Display

Name	Specifications
Broken code display	100mm*120mm

(2) Host LED

Name	Specifications
Start/stop indicator	1(Yellow/Green)
AC power indicator	1(Green)
Battery indicator	1(Green)

(3) Interface

Name	Number
Power	1
RS-232	1
Equipotential socket	1

(4) Signal Output

Name	Number
Acoustic Output	
Louder speaker	Supporting self-test sound and pulse sound

III. Monitor Specification

(1) Size and Weight

Name	Specifications
Size and Weight	Size:130mm(in length)*125mm(in width)*299mm(in height)
	Weight of the device:1.25Kg, weight of battery:0.25Kg

(2) NIBP Specifications

Name	Specifications		
Way of measurement	Self-oscillation method		
Parameter display	Systolic pressure, diastolic blood, mean pressure and pulse		
range and accuracy of measurement	Range of measurement for adult	systolic pressure	5.3-36kPa （40-270mmHg）
		diastolic pressure	1.3-28.7kPa （10-215mmHg）
		mean pressure	2.7-31.3kPa （20-235mmHg）
	Range of measurement for child	systolic pressure	5.3-26.7kPa （40-200mmHg）
		diastolic pressure	1.3-20kPa （10-150mmHg）
		mean pressure	2.7-22kPa （20-165mmHg）

	Range of measurement for neonate	systolic pressure	5.3-18kPa （40-135mmHg）
		diastolic pressure	1.3-13.3kPa （10-100mmHg）
		mean pressure	2.7-14.7kPa （20-110mmHg）
	Accuracy of Measurement	±5mmHg, when the non-invasive blood pressure is beyond the range, the monitor still displays properly, but does not consider accuracy.	
Resolution	1mmHg(0.1kPa)		
The measurement rang and accuracy of static pressure	0 mmHg（0 kPa）～300 mmHg（40.0 kPa），±3 mmHg（±0.4 kPa）		

(3) SpO_2 Specifications

Name	Specifications			
Resolution of display	1%			
Accuracy Detection		Measurement range	Accuracy(70%～100%)	Accuracy(0%～69%)
	Comen	0%～100%	±2%(measured without motion in adult/child mode) ±3%(measured without motion in adult/child mode)	Not specified
	Masimo	1%～100%	±2%(measured without motion in adult/child mode) ± 3 %(measured with motion in adult/child mode or measured in neonate mode))	
	Nellcor	0%～100%	±2%(measured without motion in adult/child mode) ±3%(measured without motion in neonate mode)	

Perfusion Index(PI)	There is indicator function in Masimo mode, the measurement range is 0.01%~20%, accuracy is not specified. In the scope of 0.05%~9.99%, the resolution is 0.01%, 0.1% in the scope of 10%~20%.

(4) Pulse Rate Speculations

Name	Specifications			
Range and accuracy		Measurement range	Resolution	Error
	Comen module	25bmp~250bpm	1bmp	±1bmp
	Masimo Module	25bpm ～ 240bpm	1bpm	±3bpm(without motion) ±5bpm(with motion)
	Nellcor Module	20bpm ～ 300bpm	1bpm	±3bpm(20bpm～250bpm) Not specified(251bpm～300bpm)
	NIBP Module	40bpm ～ 240bpm	1bpm	±3bpm or ± 3%(MAX)

(5) TEMP Specifications

Name	Specifications	
Range and accuracy	Range	34℃～42.2℃（93.2℉～107.6℉）
	Error	36℃～42℃: the error is ±0.2℃（±0.4℉） 20℃~34℃: ±0.3℃（±0.5℉）
Resolution	0.1°C	

Appendix III Fault Code Information

When failures happen, fault codes will be shown in the correspondng area, and the related parameters will flash on the screen.

In the measurement mode, press “ ” and cleared the one-time fault code, and it will be no longer prompted . But other codes, will be continuous displayed on the screen.

1. Fault Code Table

Code	Fault Description	Cause	One-Time Fault Code(YES, NO)	Solution
01	The communication of SpO2 module is stopped	There is a problem with SpO2 module or communication	NO	Stop measuring function of SpO2 module, and contact with service personnel of Comen or biomedical engineer.
02	Unrecognized probe	The probe can’t be recognized by SpO2 module	NO	Check the connection between probe and host, if the alarm still can’t be canceled, contact with service personnel of Comen or biomedical engineer.
03	Weak signal	The signal is too weak	NO	Check patient’s vital signs, and change the measurement site.
04	Too much light	SpO2 probe is	NO	Check and

Code	Fault Description	Cause	One-Time Fault Code(YES, NO)	Solution
		too loose		connect the SpO2 probe again, ensure the stable
05	SpO2 board fault	There is a problem with the module	NO	Do not use it and contact the service personnel.
06	PI too low	The SpO2 signal is too weak.	NO	Check the patient's condition and change the application site.
07	Probe fault	There is a problem with the probe	NO	Do not use the probe and contact with service personnel
08	Interference	The signal has been interfered by motion or noise around	NO	Check for any possible sources of signal noise from the area around the sensor and check the patient for great motion
10	Loose cuff	The NIBP cuff is not properly connected	YES	Check and connect the cuff again.
11	Air leak	The NIBP cuff is not properly connected or there is a leak in the airway	YES	Check the connection or use a new cuff, if the problem persists, contact with the service personnel.
12	Air pressure Err	The pressure is not stable, such as hose entenglement	YES	Check the connection or use a new cuff, if the problem persists, contact with the service personnel.
13	NIBP weak signal	The cuff is loose or the	YES	Check the patient type setting and

Code	Fault Description	Cause	One-Time Fault Code(YES, NO)	Solution
		signal is weak		the connection or replace a cuff. If the error persists, contact the service personnel
14	NIBP overrange	The measured value is not within the specified range	YES	Contact the service personnel
15	NIBP excessive motion	Arm motion	YES	Check the patient's condition and reduce the motion
16	NIBP overvoltage pretective	the airway may be occluded	YES	Check the airway and the patient's condition, if the error persists, contact the service personnel
17	NIBP air leak	There is a leak in airway	NO	Check and replace the parts that cause the leak. If the error persists, contact with the service personnel
18	NIBP system error	There is a problem with the sysem of pressure pump	NO	Do not use the NIBP module and contact with the service personnel
19	NIBP timeout	The measurement time exceeds 120s in adult/child mode or 90s in neonate mode	YES	Check the patient type setting and connection. If needed, replace a cuff, if the error persists, contact with the service personnel
20	NIBP sigal saturated	Excess motion	YES	Reduce the motion and

Code	Fault Description	Cause	One-Time Fault Code(YES, NO)	Solution
				measure again
21	NIBP self-test error	There is a problem with the sensor or other hardware	NO	Do not use the NIBP module and contact with the service personnel
22	NIBP communication error	There is a problem with the NIBP module or host	NO	Restart the monitor, if the error persists, contact with the service personnel
23	NIBP cuff type wrong	The cuff doesn't match the patient type	NO	Replace a cuff and measure
30	Ear themometer communication error	The battery is too low or there is a problem with the communication module	NO	Replace a battery, and restart the monitor,if the error persists, contact with the service personnel
46	Battery too low	The power is too low	NO	Connect the monitor to an AC power source and allow the batteries to charge.
47	12V too high	There is a problem with the system power supply	NO	Restart the monitor, if the error persists, contact with the service personnel
48	12V too low			
49	5V too high			
50	5V too low			

Appendix IV EMC

The monitor meets the requirements of IEC60601-1-2

⚠Attention

- **The monitor meets the EMC requirements of YY0505-2012**
- **The user needs to install and use according to electromagnetism compatibility information which attached with it**
- **Portable and mobile RF communication device may affect the monitor. And in case of the interference, keep the monitor away from phones and ovens, etc.**
- **Guidance and manufacturer's declaration stated in the appendix**

Guidance and declaration – electromagnetic Emissions The NC3 monitor is suitable for use in the electromagnetic environment specified below. The customer or the user should assure it to be used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment – guidance**
Radio frequency(RF) emissions CISPR 11	Croup 1	The device 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 emission CISPR 11	Class A	The model is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take
Harmonic emission IEC 61000-3-2	Inapplicability	
Voltage fluctuations/flicker IEC61000-3-3	Inapplicability	

		mitigation measures, such as re-orienting or relocating the model or shielding the location.

⚠ Warning

- **The model should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the model shoule be observed to verify normal operation in the configuration in which it will be used**
- **Class A equipment is intended for use in an industrial environment. the monitor may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conducted as well as radiated disturbances**
- **The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the model as replacement parts for internal components, may result in increased emissions or decreased immunity of the model.**
- **The use of the accessory, transducer or cable with model, other than those specified may result in increased emissions or decreased immunity of the model.**

Guidance and declaration – electromagnetic immunity

The NC3 monitor is suitable for use in the electromagnetic environment specified below. The customer or the user should assure the model to be used in such an environment.

Emission tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
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 ±1 kV for input/output 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	±1kV differential mode ±2kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NC3 monitor requires continued operation during power mains interruptions, it is recommended that NC3 monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m/50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital

			environment.
Note: UT is the AC mains voltage prior to application of the test level			

Guidance and declaration – electromagnetic immunity The NC3 monitor is suitable for use in the electromagnetic environment specified below. The customers or the users of the monitor should assure it to be used in such an 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	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the model, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 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 is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note1: the higher frequency range applies from 80MHz to 800MHz

Note2：These guidance may not be suitable to all situations as 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 model is used exceeds the applicable RF compliance level observed, additional measured may be necessary, such as reorienting or relocation the model.

b. Over the frequency ranges 150KHz to 80 MHz, field strengths should be less than 3V/m

Recommended separation distances between portable and mobile RF communications equipment and the monitor

Recommended separation distances between Portable and mobile RF communications equipment and the monitor

The NC3 monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user 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 ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz～ 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 meters (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.

Appendix V Toxic and Harmful Substance

Parts		Pb	Hg	Cd	Cr（VI）	PBB	PBDE
Housing	Front cover	○	○	○	○	○	○
	Back cover	○	○	○	○	○	○
	Button	○	○	○	○	○	○
	Optic	○	○	○	○	○	○
	Label	○	○	○	○	○	○
Display	Display	×	×	×	×	×	×
Host	Hardware	○	○	○	○	○	○
	Internal cable	○	○	○	○	○	○
	PCBA	×	○	○	○	○	○
Package	Material	×	×	○	○	×	×
General	Cable	○	○	○	×	○	○
	Power cable	○	○	○	○	○	○
Battery	Li-ion battery	×	×	×	×	×	×
Accessory	SpO_2 accessory	×	○	○	○	○	○
	NIBPaccessory	×	○	○	○	○	○
	Ear thermometer accessory	×	○	○	○	○	○
Remark	○：the content of toxic and harmful substances in the all homogeneous materials of the parts is below the standard of SJ/T11363-2006 requirement ×：the content of toxic a harmful substances in at least one homogeneous materials of the parts is beyond the standard of SJ/T11363-2006 requirement.						

promedic
by COMEN

Üretici: Shenzhen Comen Medical Instruments Co., Ltd.
Floor 7, Block 5, 4th Industrial Area of Nanyou, Nanshan District, Shenzhen, China
Tel: +86-755-26408879 I Fax: +86-755-26401232 I www.szcomen.com

EC REP **Lotus Global Co. Ltd.**
1 Four Seasons Terrace West Drayton, Middlesex London, UB7 9GG United Kingdom

İthalatçı/Distributor: Trimpeks İth. İhr. Tur. ve Tic. A.Ş.
Sultan Selim Mah.Yunus Emre Cd.No:1/11 Kağıthane 34415 İSTANBUL, TÜRKİYE
Tel +90 212 319 50 00 I Fax +90 212 319 50 50 I www.trimpeks.com

Read the instructions carefully before using this device.

CE 0120

Promedic_IB_NC3_verA_01
Revision Date: 09/01/2018

www.promedic-health.com