UR-9000

Modular Diagnostic System

Operation Manual

SHENZHEN URAY MEDICAL TECHNOLOGY CO., LTD

Copyright and Declaration

Congratulations to be our honorable guest, welcome to use Uray-9000 system, which will bring you brand-new experience and convenience.

All contents in this manual were strictly compiled according to the related laws and regulations, as well as the specific condition of UR-9000 Modular Diagnostic System, covering all the updated information before printing. Uray is fully responsible for the revision and explanation of the manual, and reserves the right to renovate the relevant contents without separate notice.

Product Information

Product ： Modular Diagnostic System.

Specification：UR-9000 specification see table 4-1.

Working Mode: Condenser (Intermittent) 2 minutes on/18 minutes off,
NIBP (Continuous).

Add: 3rd Floor Low Cost Health Solution Center, Qinglin West Road, Longgang District, Shenzhen, China
Tel: +86 755 26619838
Fax: +86 755 26612495
Zip code: 518172

Revision Information

Revision	Date	Comment

Limitation of Liability

UR-9000 Modular Diagnostic System Operation Manual defines the rights and obligations between the URAY and the customers about the responsibility for quality warranty and after-sale service, also the related agreements on commencement and termination.

URAY warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one year from the later of the date of original purchase or installation.

Uray's duty is only for maintenance under the followings, not including the economic loss or additional fee caused by stopping use instrument. For example:

- Freight(including custom fee)
- Economic and time loss caused by incapable using instrument
- Lodgement, repast or other on the way fee.
- The loss caused by inconvenient.
- Other charge.

Uray is not responsible for the following situations that cause direct,indirect or final damage. Uray is not responsible for the security of system,reliability and running condition after the following situations happen.At the same time, And at the same time, we consider that the quality guarantee responsibility, right and duty about sale-after service, assumpsit of engender and stopping, all of that promissory free service right will be seen as permanence abandon unconditionally.

- Using abnormally,without maintenance cause instrument damaged.

- Using accessory which are not provided or allowed by Uray.
- Instrument damage caused by miss operation and carelessness which not according to Manual.
- Replace fitting not allowed by Uray or maintain, mend or modify instrument not via by Uray
- Discreteness is tear open and installation, pull and extend, debugging afresh.
- If any problem happened to the module of system, contact Uray Customer Service for technical supports and solutions;

Warranty

The use life of main machine is 5 years.Good maintenance will continue for the life of the product. The warranty of the whole machine is one year. The warranty of the whole machine is one year. the main accessories standard warranty period is 1year. Warranty period goes into effect from the date of installation. During the warranty period, free after service for product. But pls notice that, The situation of product maintenance caused by following situations,Uray will carry out fee service,you need to pay maintenance costs, accessories cost and related supporting cost.

- Artificial damage
- Misuse
- Beyond the scope of the product provisions of the grid voltage
- Irresistible natural disasters
- Replace or use components, accessories, consumables without approving by Uray or maintain by the serviceman who is not authorized by Uray.
- Non fault caused by other products
- Fault caused by not the product itself
- Consumable loss within the warranty scope (such as condenser lamp)

After the warranty period, Uray can continue to provide fee-based services, including old-for-new service.

Support

We arouse you give us a call if you meet any problems. Our company's service department opened user technique, service hotline to provide technical support and difficulty solution for user.

Please reserve relative sample and inform agent or contact Uray service department immediately if there is any fault occurred. Uray will send professional engineer or local service representative to provide timely and fully servicing if the fault cannot solve by telephone guidance.

SHENZHEN URAY MEDICAL TECHNOLOGY CO., LTD

Add: 3rd Floor Low Cost Health Solution Center, Qinglin West Road, Longgang District, Shenzhen, China

Zip code: 518172 Tel: +86-755-26619838 Fax: +86-755- 26612495

Customer service Tel: +86-4008006298 Web: www.uray.com.cn

EC REP Renault-Petersen Limited

Add 1: COUCHING HOUSE COUCHING STREET WATLINGTON OXFORDSHIRE OX49 5PX

Tel: +44 1491 613311, Fax: +44 1491 613187, Zip Code: OX49 5PX

Add 2: 5 BANKSIDE, HANBOROUGH BUSINESS PARK, WITNEY OX29 8LJ UK

Tel: +44 1993 882779, Fax: +44 11993 880110, Zip Code: OX29 8LJ UK

Guidance

This manual applies to use for Clinical medical professional.
General information for the operation of diagnostic system is contained in this manual. It covers the best guidance for a new user to master the characteristics of this system as well as for daily inquiry. Do peruse before first operation.

Illustration

All illustrations are provided in this manual for reference only. The picture and data may be not consisting with the fact.

⚠ Notice

1. Please keep manual near the product, in order to reach convenient and timely.
2. Please keep this manual complete

Content

Chapter 1 Introduction

1.1 Intended use

Modular diagnostic system is mainly used to monitor patients' vital signs (Non-invasive blood pressure) and diagnose outpatient for the bottoms of eyes, ear in medical institute.

1.2 Use scope

Modular diagnostic system is only adapting to adult, children.

Note 1: noninvasive blood pressure (NIBP) is not including neonatal measurement.

Note 2: Adult is refers to the age is above 12 years old. Children is refered to the age of 29 days to 12 years old children. Neonate is refered to after 37 to 44 weeks of pregnancy born less than 28 days baby.

1.3 Use situation

The intended use of system is for non high sensitive care, non-intensive care area, but not limited to the hospital, community hospital, and medical center. This system cannot be used at home.

Warning

1. The system should be operated by professional clinicians. Any unauthorized or untrained personnel should not carry out any operation.
2. Blood pressure measurement in this system is not suitable for neonates, but others can use for neonates.

Chapter 2 Safety

2.1 Safety information

2.1.1 Notice explanation

⚠ Notice

Explanation: Emphasize the important notice, provide instruction and explanation for product.

2.1.2 Warning explanation

⚠ Warning

Explanation: Prompting potential dangerous or unsafe operation or unsafe operation, If not avoided, it could result in death or serious personal injury or property loss.

2.2 Warning

⚠ Warning

1. Before using, the user must check the equipment, cable and accessories, to ensure work safely.
2. This device can only be connected to the protective ground supply socket, if the power socket is not connected to the grounding wire, please do not use the socket.
3. Non-invasive blood pressure is belong to the continuous operation instrument; direct ophthalmoscope, medical magnifier are belong to short-term load continuous operation instrument. Not placed in flammable or explosive environment.
4. Cannot open the equipment shell, otherwise could result in electric shock.
5. This instrument cannot be used with the defibrillation device (except NIBP module).

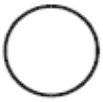
6. Please to adjust the alarm volume and alarm limit accord the patient's surrounding environment.
7. The blood pressure, blood physiological waveforms and alarm information are only for doctors' reference, cannot be used as bases for clinical treatments.
8. Please be careful of power line and various accessories cable, avoid entanglement
9. Disposable consumables must comply with local regulations or waste treatment system of hospital.
10. Direct ophthalmoscope, medical magnifier should be put in the corresponding slot; otherwise it could affect the lamp's life.
11. Direct ophthalmoscope, medical magnifier are belong to the Short-time loading continuous operation instrument. Long time work will cause lamp burning, suggest intermittent working in 1 to 2min.
12. Ensure the patients' safety, please use the specified accessories.
13. When the system and accessories are over use period, which should dispose in accordance with the local laws and regulations or the hospital system.
14. Please check if the power voltage and frequency meet the requirement of manual.
15. The system should be installed by professional personnel.
16. Please check the system carefully after installation, in order to prevent the device from falling, collision, concussion or other mechanical force.
17. Do not use this product with high frequency electric knife.

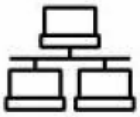
2.3 Notice

⚠ **Notice**

1、 Please install the device in the easy operation and maintenance position.
2、 Place the manual near the system.
3、 The program design of device is in accordance with the IEC 60601-1-4 standards.
4、 This manual is including all the type, if you use some parts, please refer to the relevant sections.
5、 When using with other devices, the installation must be confirmed by professional to ensure it compliance to safety requirements.

2.4 Definition of Symbols

NO.	Symbols	Definition
1		Warning, Caution or Notice, refer to instructions for use.
2		Operating instructions(see operation manual for details)
3		Power on
4		Power off
5		Alternating Current
6		Protective ground terminal
7		Danger! High voltage
8		Ⅱ classification instrument
9		Indicates that the instrument is IEC 60601-1 Type BF applied part.
10		Indicates protection against the effects of the discharge of a cardiac defibrillator. Patient connections are BF applied part and protected against defibrillation.
11		Indicates protection against the effects of the discharge of a cardiac defibrillator. Patient connections are Type CF, isolated for direct cardiac application, and protected against defibrillation.
12		**Manufacturer**

NO.	Symbols	Definition
13		Disposal (EU Countries) Indicates this monitor is subject to the Waste Electrical and Electronic Equipment Directive in the European Union.
14		Environmental protection use period- 20 years
15		Temperature limitation
16		Atmospheric pressure limitation
17		Humidity limitation
18		Network interface
19		USB interface
20		Serial Number
21		Authorised representative in the European Community
22		Force the user consult operating instructions

Chapter 3 Installation

3.1 Warning

Warning

1. The installation and adjustment of system should be operated by the engineers from Uray or authorized by Uray.
2. Before drilling on the wall, please refer to the wire layout, otherwise it can cause short circuit and fire.
3. Before drilling on the wall, please follow the manual and random file.
4. This device software copyright belongs to Uray, without permission, any organization or individual cannot tamper and copy it.
5. All the simulations and digital device must pass the IEC standard certification. If you have any questions, please contact our company.

3.2 Unpacking

Please check the packaging box carefully. If you find any damage, please contact the transport company immediately. According to packing list, check if any of devices and accessories are missed, and check if there is any mechanical damage.
Any question, please immediately contact Uray or distributor.

Warning

1. Carefully to take all of devices and accessories out of packing box, keep the package well for later transportation or preservation.
2. The disposal of packaging must comply with local laws and regulations of hospital.
3. Device may be infected in the process of transportation. Check if the packaging is damaged before use, especially the disposable accessory, if find any damage, please do not use.

3.3 Installation

3.3.1 Work environment

The operation of device must comply with the environmental specification of the manual. Keep the device work environment from noise, vibration, dust, corrosive, inflammable and explosive.

The ambient requirement of normal working:

1. Temperature:5 ℃～40 ℃
2. Humidity : 10%～95% (No condensation)
3. Pressure: 86kPa～106kPa
4. Power: 100-240V～，50/60 Hz

⚠ **Notice**

1. Ensure the system in the specified work environment, otherwise the system will be damaged.
2. Before installation, please check the power.
3. The ground terminal on the left side of system panel is recommended to directly connect to ground. User should have the responsibility to ensure the reliability of grounding line. For consideration this, the system is equipped with a removable three-wire power cables, which will link the system to ground after inserted into the appropriate three-wire outlet. If no three-wire outlet, please discuss the problem with the electrician for solution. Prohibit the use of the “two-wire to three-wire” adapter.

3.3.2 Installation step

Detailed installation steps see in the instruction “Mounting Modular Diagnostic System on the Wall” (a separate manual).

⚠ **Notice**

1. Check the system every month, if found loose, please stop using.

3.3.3 Installation confirmation

Check if the system is fixed after installation. Beware of falling risk.

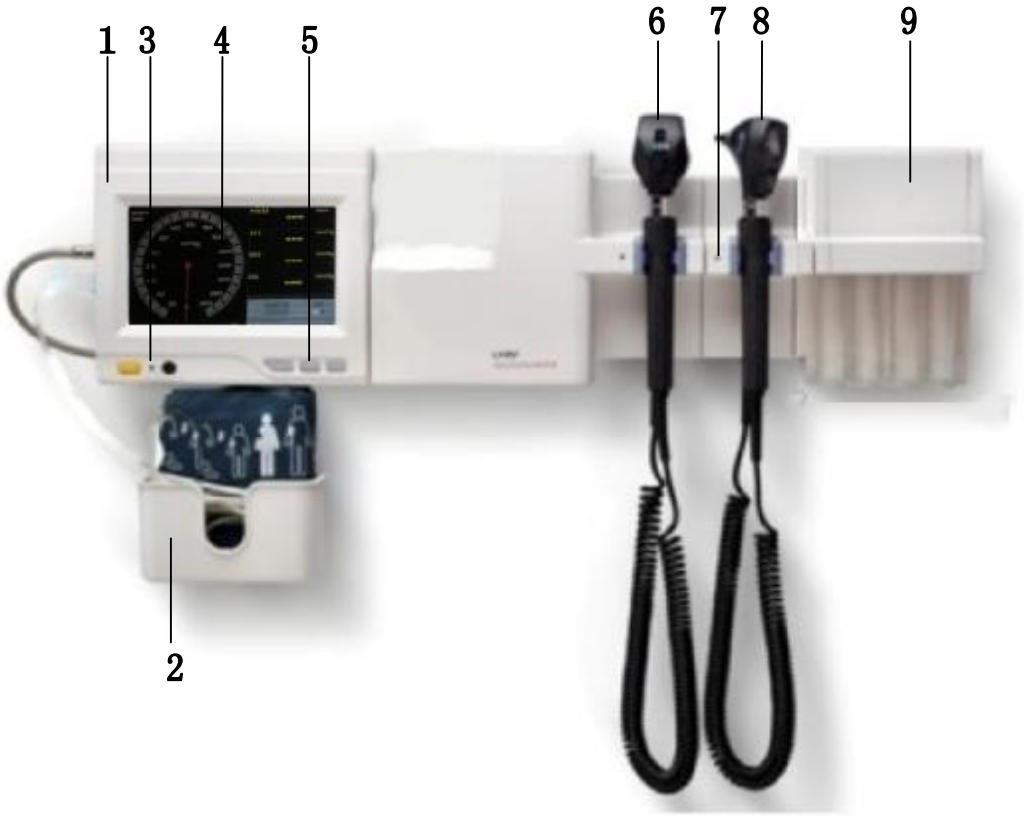
Chapter 4 Operation

4.1 Component and structure

UR-9000 Modular diagnostic system is composed of mainframe, vital signs components (non-invasive blood pressure), direct ophthalmoscope module, medical magnifier module (otoscope) and accessories. (blood pressure cuff).

4.1.1 Structure

4.1.1.1 Front view



Front view

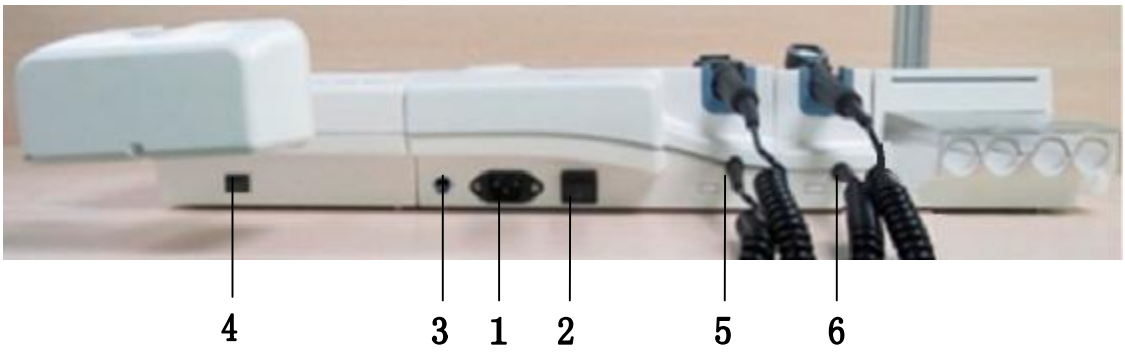
1. Vital signs components: monitor blood pressure and other vital signs parameters.
2. Box: store cuff, remote controller and others;
3. Receptor: the signal receptor of remote controller;

   Indicator of vital signs components:

   - Green: the power supply of vital signs components is normal.
   - Blue: vital signs components are power on.

4. Screen: display monitoring results and other information;
5. Menu: directly achieve the relative function when triggered;
6. Ophthalmoscope: a device containing illumination and viewing optics intended to examine the media (cornea, aqueous, lens, and vitreous), the retina, blood vessels, optic nerve and other structures of the eye;
7. LED indicator: indicate the power of relative hand-hold device;
8. Otoscope: a handheld device that provides illumination of the ear canal for observation by using a light source and an optical magnifying system;
9. Accessory box: store the otoscope earmuff.

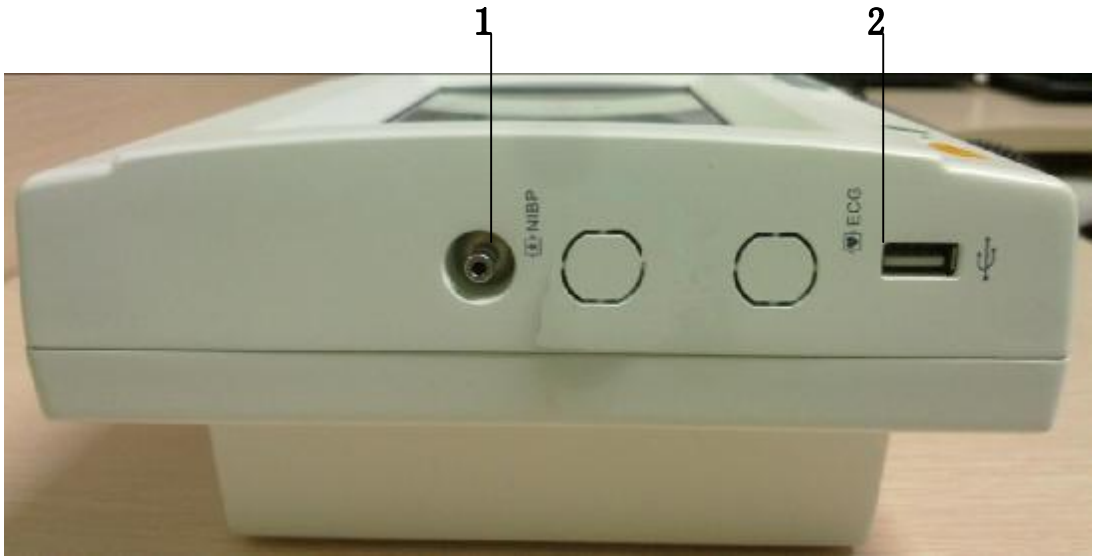
4.1.1.1 Bottom view



Bottom view

1. Power outlet: access for external power supply;
2. ON/OFF: control all the power of the system;
3. ground pole: connect to ground wire;
4. Network port: RJ45, for communication with device taking TCP/IP as the standard protocol;
5. Hand-hold device connector: connect to hand-hold device and mainframe.(Ophthalmoscope connector)
6. Hand-hold device connector: connect to hand-hold device and mainframe.(Otoscope: connector)

4.1.1.2 Left view



Left view

1. NIBP Interface
2. USB Interface

4.2 Preparation

4.2.1 Accessory connection

Finish the “Mounting Modular Diagnostic System on the Wall”, we need to connect accessory and system.

1. Noninvasive blood pressure cuff: connect to the NIBP joint.

4.2.2 Power on

1. The system can ready to power on after installation.
2. Before power on, check if the cables and accessories are connected properly.
3. Ensure the power line is inserted into socket. If you use other external power supply equipment, make sure the power line is safe.
4. Open the power switch, switch indicator is green.
5. Turn on the total power switch, system will enter self-checking and welcome interface, after that System enter the standard display modes, waiting for your operation.

⚠ **Notice**

1. If system display wrong, such as screen flicker, displaying unclear or other abnormal, please stop using immediately, and contact with the serviceman or Uray.
2. This system can connect with GB 4824 public electric network.

4.2.3 Start operation

1. Check cable and sensor are correct.
2. Check the system settings are correct.
3. To parameters measurement, please see the relevant section.

4.3 Power off

Please see the following steps to turn off system:

1. Make sure close the patient's testing and inspection.
2. Disconnect the system sensor connected with the patients.
3. Make sure keep or clean up the measuring data of patients.
4. Turn off the power.

4.4 Shortcut instruction

The front panel of system is only 3 buttons, the function as followings:

1. NIBP/Up: press this button to start the automatic mode of non-invasive blood pressure measurement. Press again, to stop the blood pressure measurement; With Menu/Enter to use, NIBP/Up as the cursor to move.
2. Menu/Enter: press this button to start the menu interface.
3. Manual/Down: press this button to start stethoscope model of non-invasive blood pressure measurement. Press again, to stop the blood pressure measurement; With Menu/Enter to use, Manual/Down as the cursor to move.

4.5 Standard display mode

Standard display mode

1. System information display area: displays the system date & time, test object, network information and so on.
2. Non-invasive blood pressure area: displays the result of Non-invasive blood pressure, including systolic pressure, mean pressure, diastolic pressure.
3. Setting menu display area: displays the test mode and more setting functions.

4.6 Setting

Please reference to the system setting section.

Including:

1. Adjust volume
2. Set date and time

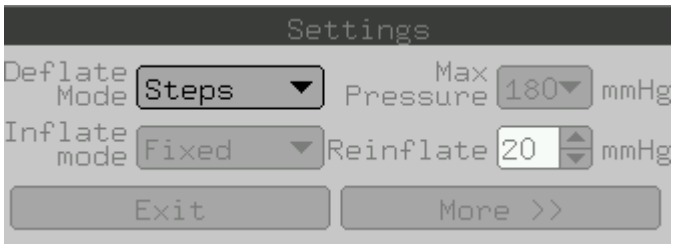
⚠ **Notice**

1. If the system is power off more than 30s, the system will automatically recover settings after restart.

4.7 Setting menu

In standard display mode, user can press the “menu” button of control or “Menu/Enter”

button to enter the “setting” as the picture below.



Setting

Press the “up” , “down” button of controller or “NIBP/Up”, “Manual/Down” button of panel and enter to corresponding menu. Press "Menu/Enter" button, which can set the mode of Non-invasive blood pressure.

- Auto mode: the system is automatically inflate and test the non-invasive blood pressure, and displayed on the screen.
- Auscultation mode: the system according to precharge for aerating, doctors diagnose patient’s blood pressure value by the "K-auscultatory method"
- Precharge: when the system reaches the set value, it will stop aerating. They are available in auscultation mode.
- General: on auscultation mode, the system will stop aerating when it reaches set value.
- Self-adaption: on auscultation mode, the system will test the pressure of Non-invasive blood for patient, according to the testing value to make the precharge value
- Inflatable: set each inflatable value, in auscultation mode, if the doctor did not hear clearly, and inflated again.
- Exit: the cursor to "exit the menu" and press "Menu/Enter" to exit the setting menu mode.
- More >>: enter the setting menu, more item settings.

Notice: if there is ">>" mark on the button, it means when you enter it, you will reach the submenu.

4.8 System menu

In general menu, press “More >>”to enter “System” interface, please see below:

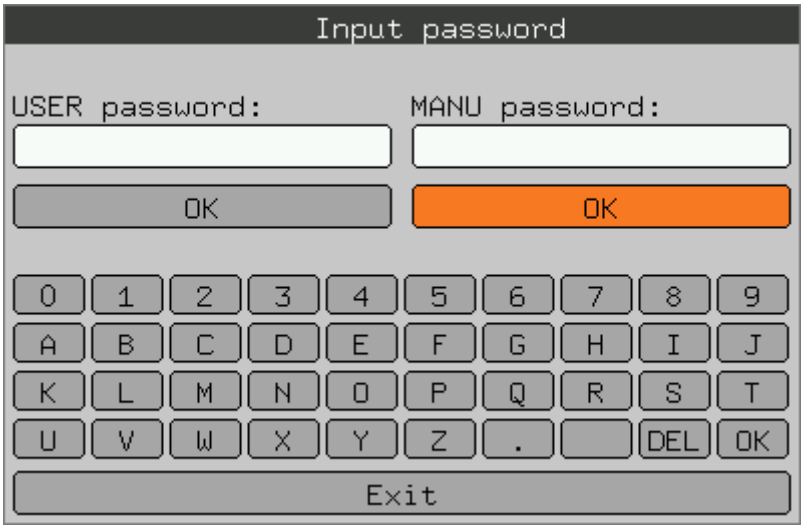
- “Maintenance >>”: for system maintenance operation.
- “System setting >>”: set the beat volume, alarm, brightness, language and system

time and date.

- “NIBP list >>”: view the history test data.
- “NIBP >>”: for NIBP set operation.
- “Calendar >>”: show the time and date.
- “Color Blindness Test >>”: for color blindness test operation.
- “Visual Acuity Test >>”: for visual acuity test operation.

4.9 Maintenance menu

In system menu, press the “maintenance >>” to enter the “Input password” interface, please see below picture.



Input password

<Maintenance>: user will have two blanks to input the password, one is for user maintenance, and another is manufactory maintenance.

<User maintenance>: The password of user maintenance is "A". After enter the password, user can enter the <User maintenance>menu.

User maintenance

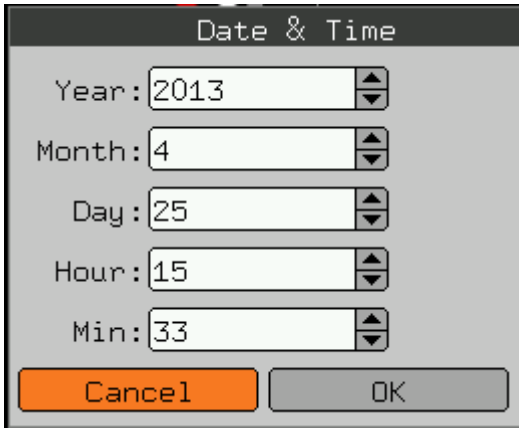
<Manufactory maintenance >: only for the service engineer.

4.10 System setting menu

In system menu, press the “system setting>>”to enter “system setting menu” interface, please see below picture.

System setting

<System setting>: user can set the mainframe IP and connect to the computer; adjust the pulse beat sound (4 grades: closed, low, middle, high); set the system time; set the display brightness.
<Time setting>: set system time and date.



Date & time

4.11 Test data list menu

In system menu, press the “Test data list>>” to enter the “NIBP list” interface, please see below picture.

When you need to search the history data, you can enter the “Test data list”. You can check the patient’s test result of systolic pressure, diastolic pressure, mean pressure and pulse rate.

NIBP list

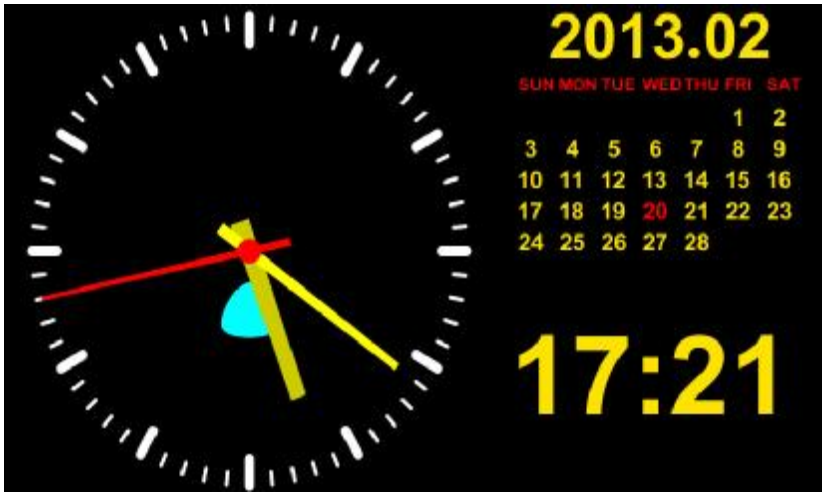
NO.	DATE/TIME	SYS	MAP	DIA	PUL
1	Apr.25,2013 15:58:45	119 mmHg	92 mmHg	78 mmHg	80 bpm
2	Apr.25,2013 15:58:03	119 mmHg	92 mmHg	78 mmHg	79 bpm
3	Apr.25,2013 15:57:27	118 mmHg	92 mmHg	79 mmHg	80 bpm
4	Apr.25,2013 15:56:51	117 mmHg	92 mmHg	80 mmHg	79 bpm
5	Apr.25,2013 15:56:05	117 mmHg	92 mmHg	79 mmHg	79 bpm
6	Apr.25,2013 15:55:21	118 mmHg	92 mmHg	79 mmHg	79 bpm
7	Apr.25,2013 15:54:44	118 mmHg	92 mmHg	79 mmHg	80 bpm
8	Apr.25,2013 15:53:59	118 mmHg	92 mmHg	79 mmHg	80 bpm
9	Apr.25,2013 15:53:22	118 mmHg	92 mmHg	80 mmHg	80 bpm
10	Apr.25,2013 15:52:44	119 mmHg	93 mmHg	79 mmHg	80 bpm
11	Apr.25,2013 15:51:37	118 mmHg	92 mmHg	79 mmHg	80 bpm
12	Apr.25,2013 15:51:01	118 mmHg	92 mmHg	79 mmHg	79 bpm
13	Apr.25,2013 15:50:17	118 mmHg	92 mmHg	79 mmHg	80 bpm
14	Apr.25,2013 15:49:09	119 mmHg	92 mmHg	79 mmHg	80 bpm
15	Apr.25,2013 15:48:32	118 mmHg	92 mmHg	79 mmHg	79 bpm
16	Apr.25,2013 15:47:53	118 mmHg	92 mmHg	79 mmHg	80 bpm
17	Apr.25,2013 15:47:17	118 mmHg	92 mmHg	79 mmHg	80 bpm
18	Apr.25,2013 15:46:35	118 mmHg	92 mmHg	79 mmHg	79 bpm
19	Apr.25,2013 15:45:47	117 mmHg	92 mmHg	80 mmHg	80 bpm
20	Apr.25,2013 15:45:00	117 mmHg	92 mmHg	80 mmHg	80 bpm

Page up | Page down | Exit

4.12 Calendar menu

In system menu, press the “Calendar >>” to enter the “Calendar” interface, please see below picture.

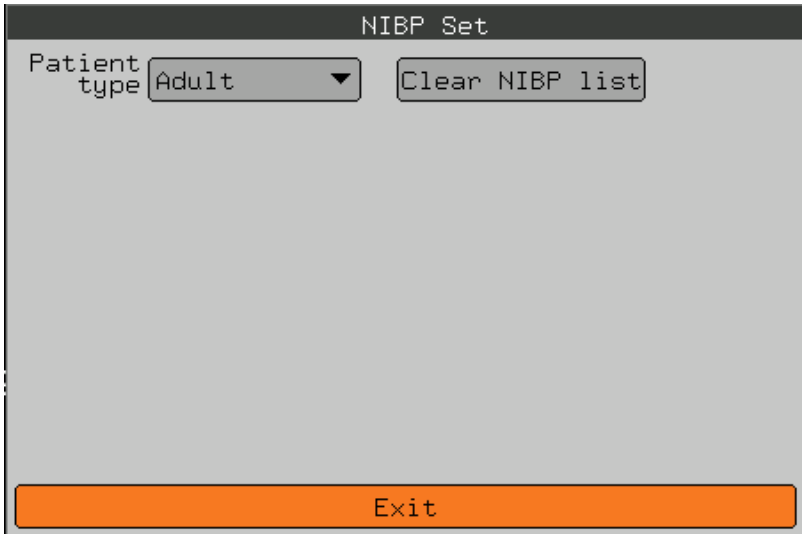
When the user is not operating system within the specified time, the screen displays as following picture.



Calendar

4.13 Pressure menu

In system menu, press the “Pressure >>” to enter the “NIBP set” interface, please see below picture.
Pressure menu can alternate the mode between adult and children. Please pay attention to the “clear NIBP list” if you press this button, all test data will be cleared.



NIBP setting

Chapter 5 NIBP

5.1 General information

NIBP measurement principle is oscillation method. Auscultation mode is that doctor measure NIBP (Manual) by "K-auscultation".

According to the design, surgical operation and defibrillator discharge period can use NIBP to measure. The display of defibrillation may be affected, after defibrillation about 5 seconds, will display normal.

5.2 Measurement principle

Oscillation method is firstly automatically inflate cuff with air pump, then slowly deflate cuff, and calculate the blood pressure by microcomputer inside with the record of all changes in the process of inflation and deflation.

Notice:

The measure result between oscillometric method and traditional NIBP (use mercurial hemadynamometer or other hemadynamometer) are the same.

average deviation: ±5mmHg; standard deviation :≤8 mmHg

5.3 Measurement limitation

For the following case, the NIBP result would cause the inaccuracy.

- Excessive movement, such as trembling and spasm
- The patient's heart rate is totally irregular, especially auricular fibrillation. The result will be inaccurate or there is no result.
- Blood pressure changed fast.
- When the patient is in massive bleeding, low blood volume, shock status, which can lead the blood pressure rapid change and hypothermia, the result would be unreliable. Because the decrease of peripheral blood will lead to the decrease of pulse.
- Pulse is too weak.
- Have used the diuretics or vasodilators.
- Obese patients.
- Environmental doesn't meet the requirement of device, such as extreme temperature, humidity and altitude.

⚠ **Notice**

1、 Do not measure the NIBP for skin injury patients.

2、 The thrombotic disease patient must according to the clinical situation to decide if measured, because the hematoma risk occurred in the bundling sleeve body.

3、 Do not WEAR the cuff in venous transfusion or intubation limbs, because during cuff inflation, may lead to injury for skin tissue.

⚠ **Warning**

1. Continual NIBP measurements can cause injury to the patient being monitored. Weigh the advantages of frequent measurement against the risk of injury.
2. Continual cuff pressure can cause injury to the patient, please make sure the connection tubing is not kinked, compressed or restricted.
3. In some cases, rapid, prolonged cycling of an NIBP cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Apply the cuff according to the directions and check the cuff site and cuffed extremity regularly when blood pressure is measured at frequent intervals or over extended periods of time.
4. Check the patient's limb to assure that circulation is not constricted, i.e. no discoloration or ischemia of the extremities. Check the limb at regular intervals based on the circumstances of the specific situation.
5. Never place the cuff in which circulation is compromised or has the potential to be compromised. Never measure NIBP on patients with sickle-cell disease or any condition where skin damage has occurred or is expected.
6. Never use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place.
7. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
8. Select an appropriate cuff and ensure that the correct patient type is selected before monitoring.
9. Wrong cuff sizes can overload inflation pressure on pediatric or neonatal patients.
10. Use clinical judgment before using NIBP monitoring on patients with serious blood clot disease due to the risk of hematoma in the limb with the cuff.
11. Use clinical judgment before using NIBP monitoring on pregnant or pre-eclamptic patients.
12. If the cuff is too small or too tight, the result will be higher than the normal value, and vice versa. Select a proper cuff for different patients and correctly place the cuff to collect reliable results.
13. Do not re-use disposable NIBP cuffs.
14. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Inspect the application site regularly to ensure

skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site or stop the blood pressure measurements immediately. Check more frequently when making automatic or stat measurements.

5.3.1 Auto measurement

Auto measurement: The system is inflate automatically and measure the blood pressure, then display the results (tie the NIBP cuff). Press the "NIBP/Up" button, the system can carry out measure automatically, and show the result.
Auscultation measurement: Press the "Manual/Down" button, doctor diagnoses the result through the auscultation measurement.

5.3.2 Blow-off

The NIBP measurement of system is rapid deflation method.
In automatic mode or auscultation mode, press "NIBP/Up" button to stop measuring, and the cuff gas released.

5.4 Measurement mode

5.4.1 General Information

Measurement mode: Auto measure mode and Auscultation measure mode.

5.4.2 Auto measurement

Manual measure: NIBP is measure automatically and show the results immediately.

5.4.3 Auscultation measurement

Auscultation measurement: press the "Manual/Down"button to start measurement, the cuff is inflate automatically and reach certain pressure, and then deflate slowly. Press again the "Manual/Down" to stop measure.

⚠ **Notice**

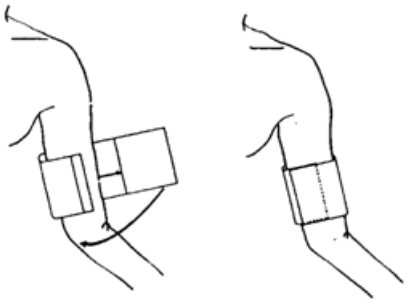
1. In NIBP measurement, if time is too long, the sleeve and body may cause

purpura, ischemia and nerve injury. For patient measurement, the doctor should check the skin color and sensitivity frequently. Once any abnormal, stop measuring immediately.

2. The gasbag in the long-term inflation with risk as above.

5.5 Measurement Step

1. Turn on the main power switch, system will enter self-checking and welcome interface, after that system enter the standard display mode, waiting for your operation.
2. Check the cuff whether connect to NIBP connector.
3. Check the patient's type, measure mode, measure parameter.
4. Make sure the patient is in the suitable condition, seat comfortably, legs uncrossed, feet flat on the floor, back and arm supported.
5. When the patient calm down after one minute, the operate the following steps. Before the first measurement, the patient should be relax for 5 minutes. And keep silent during any measurement.
6. Before using, the cuff should be deflated completely.
7. Firstly, the user need to choose the right size cuff, everyone should be chosen the cuff under the testing. And the width of the cuff should be 40% of the whole arm circumference of the adult patient (the neonate is 50%) or 2/3 of up part of arm length. The inflation part of cuff should be long enough to cover the 50%-80% of the arm. When patient is wearing the cuff, make sure flat cuff covers the upper arm surface, and the tension between cuff and upper arm is neither too tight nor too loose. Make sure the middle of cuff is at the level of the right atrium of the heart.



Wearing cuff

8. Start\Stop measurement
   - Start: press the "NIBP/Up" or "Manual/Down" to start NIBP measurement,

press again to stop measuring.

- Stop: press again “NIBP/Up”or“Manual/Down” to stop NIBP measurement.

⚠ **Notice**

1. The selection of the cuff should be depended on the ages of people.
2. The effect will be the best, when the φ signs on the cuff place on the brachial artery.
3. The tension will be good, if the people can insert one finger into the cuff.
4. The bottom of the cuff should be 2 cm higher than elbow joint.
5. Before the measuring and during the measuring, please do not let the patients talk and move, please do not hit the cuff.
6. The period of the measuring should not be too short(It must be more than 2 minutes), if the period is too short, the cuff will press the arm, the volume of the blood wound decrease, the result of blood pressure measurement would be low.
7. If an unexpected reading is obtained, please repeat the measurement or use other medical device to take measure.

5.6 Adjust the measurement result

The measure body and heart should be the same level. Otherwise, user should adjust the measurement results according to the following method.

1. 0.75mmHg（0.1kPa）; If the cuff is higher than heart level, the measure results should add 0.75mmHg (0.1kPa) each cm.
2. 0.75mmHg（0.1kPa）。If the cuff is lower than heart level, the measure results should reduce 0.75mmHg (0.1kPa) each cm.

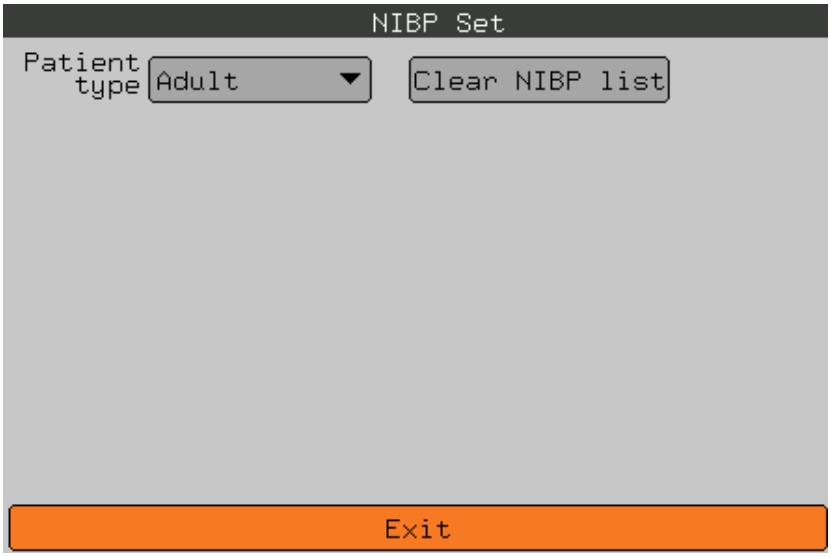
5.7 NIBP display

NIBP display

NIBP results display area: display the NIBP numerical results. There are systolic pressure, mean pressure, mean pressure, and diastolic pressure.

5.8 Setting

User can use the button or controller to set the NIBP. The operation is the same with the 4.13 section。



NIBP setting

- Object: adult and children
- Clear data list: clear all the history data of NIBP and plus.

5.9 NIBP pressure calibration

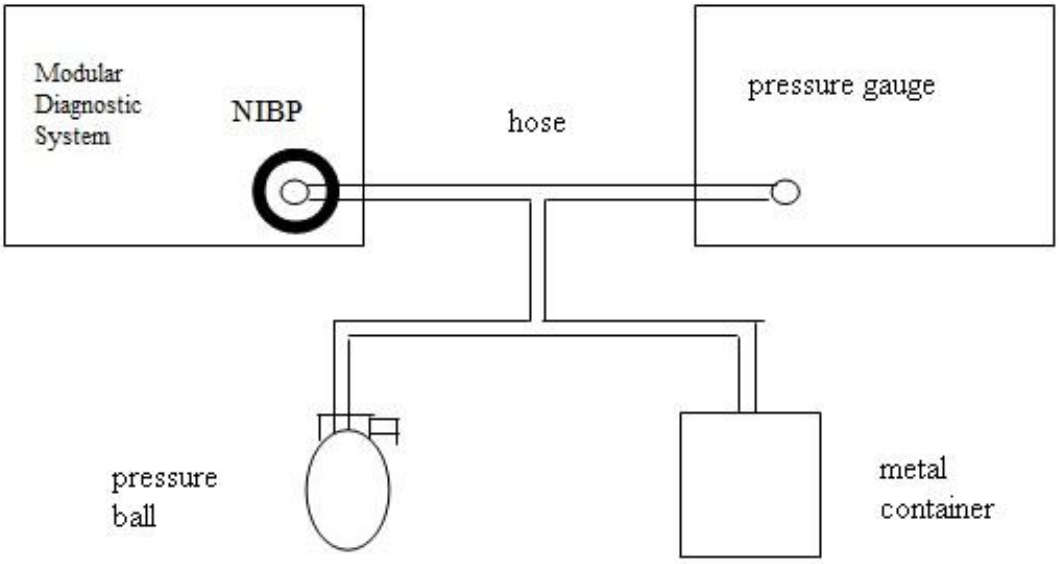
NIBP pressure should calibrate once a year, or when you think the reading is not accurate.

Before calibration, need to prepare the following tools:

- T type connector
- Gas tube
- Pressure ball
- Metal vessel 500±25mL
- Standard pressure meter: is calibrated, accuracy is higher than 1mmHg.

Calibration steps as followings:

1. Connect with the system, pressure gauge, pressure ball and metal container as shown below.



Pressure calibration connection

2. Before inflation, pressure gauge reading should be zero. If reading is not zero, please disconnect the gas path. When it become zero, and connected again.
3. Enter the system menu, select “pressure gauge mode". Switch to the pressure gauge measurement interface.
4. Check the reading of pressure gauge and system, the difference between the two should be within 3mmHg.
5. Use pressure ball inflating the metal container, so that the internal pressure reaches to 50 mmHg, then repeat step 4.
6. Use pressure ball inflating the metal container, so that the internal pressure to 200 mmHg, then repeat step 4.
7. If the reading of pressure gauge and system are more than 3 mmHg, please contact customer service.

5.10 NIBP calibration

The user cannot calibrate NIBP, when need calibrate please contact customer service. Cuff pressure sensor should be calibrated by qualified serviceman at least once a year.

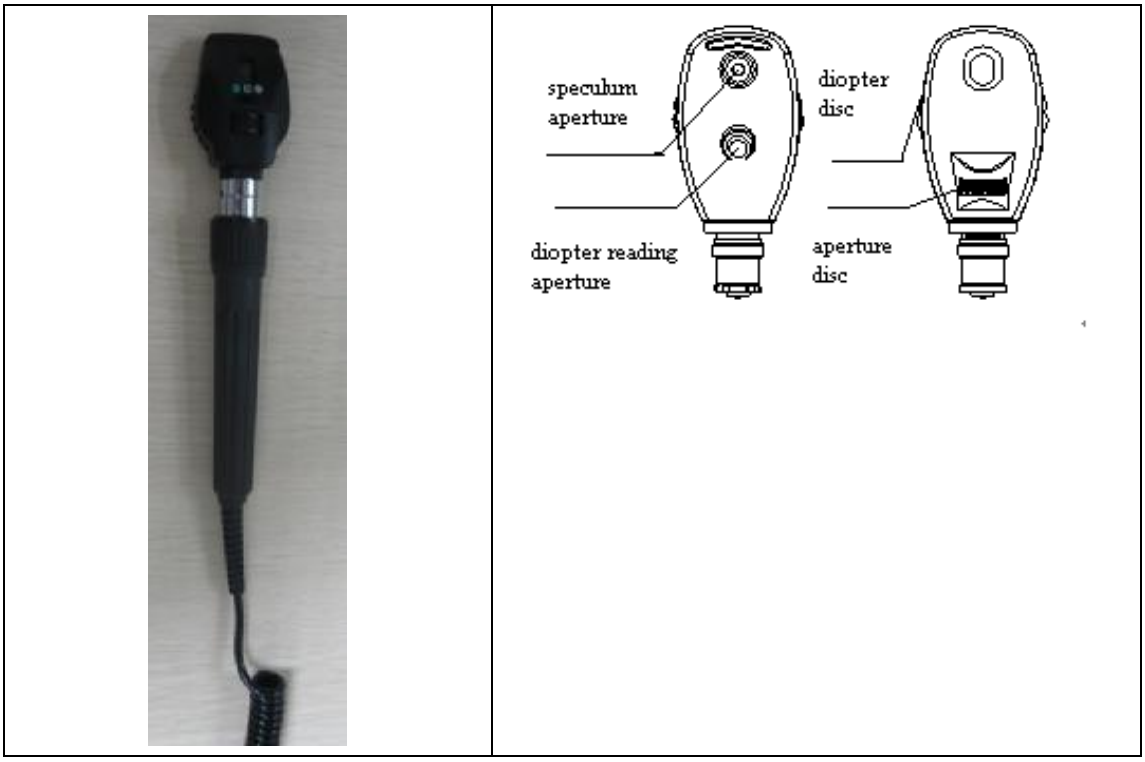
Chapter 6 Direct Ophthalmoscope

6.1 General Information

Direct ophthalmoscope is used for checking the fundus oculi pathology, abnormal dioptricmedia and the retinal location.

Fundus oculi examination plays important roles in the vitreous, retina, choroid and diseases of peripheral nerve. Many systemic diseases often occur in fundus oculi lesions, and even become the main reason for patients to see a doctor, so the eye is "the window", fundus oculi examination can provide important diagnostic information.

6.2 Appearance



Direct ophthalmoscope appearance

6.3 Operation limitation

⚠ **Notice**

1. Use direct ophthalmoscope in clean environment. When no use for long time, conserve it in packing box for dust prevention
2. Make sure no fluid penetrates into the interior of the ophthalmoscope.
3. Please do not touch the surface of the lens with hand or hard object.
4. Direct ophthalmoscope use DC low voltage, not observed electromagnetic interference with other devices. If find interference in using, the user can open or close this part to prove the interference. If it is related to this part, can be eliminated or improved interference by adjusting the space and position of the device.

6.4 Specification

6.4.1 Design feature

- Elegant in design, convenience in operation;
- The design of observation and lighting system are reasonable, even small pupil can observe the Modular fundus image clearly.

6.4.2 Optical requirement

The optical requirements of direct ophthalmoscope should be accord with the requirements of table 7-1, table 7-2

Optical Requirements

Name	Requirements
The compensating lens of dioptre includes: Unit: D	-25、-20、-15、-10、-9、-8、-7、-6、-5、-4、-3、-2、-1、0、+1、+2、+3、+4、+5、+6、+7、+8、+9、+10、+12、+15、+20、+40
Viewing angle ω	≥3°
The maximum aperture illumination angle Θ	≥9°
Observation diameter	≥3mm

Optical tolerance requirements

Name	Combined power	Tolerance
The tolerance of combined power	0.00D≤combined power≤ |3.00|D	±0.37D
	|3.00|D< combined power ≤|10.00|D	±0.5D
	|10.00|D< combined power ≤|15.00|D	±0.75D
	|15.00|D< combined power ≤|20.00|D	±1.0D
	|20.00|D< combined power ≤|25.00|D	±1.25D
	|25.00|D< combined power ≤|40.00|D	±1.75D
Compensating lens center	0.00D≤combined power≤ |10.00|D	1.0mm
	combined power >|10.00|D	0.5mm

6.4.3 Aperture

Lighting system of direct ophthalmoscope is at least 6 apertures, including large aperture, small aperture, tiny aperture, fixation aperture, stenopeic disk and cobalt blue tablets.

6.5 Operation method

The doctor holds the ophthalmoscope in 150 mm from the patients' eye.

6.6 Operation Step

1. Take away ophthalmoscope from system panel, system circuit is automatically conducted at the same time。
2. Indicator and ophthalmoscope lamp will light up at the same time.
3. Put the ophthalmoscope back after use, system circuit will cut off automatically at the same time.

6.7 Checking Method

1. The doctor's eye must be close to patient's eye, examine the right eye of patient with his right eye, hold the ophthalmoscope with right hand, sit or stand by the

right side of patient. The examination of left eye is reverse.

2. The doctor opens the patient's eyelid, and put the ophthalmoscope in 20cm from the patient's eye with +10D to check whether the refractive media is transparent. Begin to examine parts of retina after refractive media examination. Turn the diopter disc to correct refractive errors. If patient is an emmetropia or with a corrective glasses, the lens of clear viewing of the retina is the diopter of patients.
3. Ask patient to maintain their gaze fixed forward, then examine the optic and the superior temporal, inferior temporal, superior nose, inferior nose 4 quadrants in order, at last ask patient to focus his view on the temporal side and examine the macular.

6.8 Daily Maintenance

6.8.1 Change Lamp

Lamp changing should be operated by the professional operator. Power off, and remove the Ophthalmoscope head, after lamp is cool, turn handle counterclockwise to open it; Take away lamp from inside base of ophthalmoscope head with a small driver, then replace with new lamp and insert new lamp to the bottom, taking care not to touch glass; Turn handle clockwise to assemble the ophthalmoscope.

⚠ **Notice**

1. Cut off the power when changing lamp.
2. Wear protective goggles when operation
3. Discarded lamp should be carefully.

⚠ **Warning**

1. Use the indicated lamp. When changing lamp, allow lamp to cool before handling, be care for high temperature of lighted lamp.
2. If the lamp is damaged, please contact customer service for changing the indicated lamp.
3. Direct ophthalmoscope, Medical magnifier, condenser are belong to the Short-time loading continuous operation instrument. Long time work will cause lamp burning, suggest intermittent working in 1 to 2min.

6.9 Cleaning

1. Clean the surface of the handle with clean cloth with solution mixed 50％ alcohol and 50% distilled water. Do NOT use detergent with corrosion and grinding effect.
2. The lens cleaning: use lens cleaning paper or cotton to clean lens with solution mixed 50％ alcohol and 50% ether. If lens is a little dusty, use ear syringe or bush to clean it up

Chapter 7 Medical Magnifier

7.1 General Information

Medical magnifier (trade name: otoscope) is used for ENT examination.

Medical magnifier appearance

7.2 Operation limitation

⚠ **Notice**

1. Use medical magnifier should be put the dirt proof sleeve, otherwise it cannot reach the effect.
2. Medical magnifier and dirt proof sleeve need clean and disinfect regularly.
3. Don’t touch the lens surface.
4. Don’t pull the connecting wire and power line.
5. If the system is abnormal, cut off the power immediately.
6. When the system is not used a long time, the power should be cut off.
7. Please use the indicated lamp.
8. Otoscope is not observed electromagnetic interference with other devices. If find interference in using, the user can open or close this part to prove the interference. If it is related to this part, can be eliminated or improved interference by adjusting the space and position of the device.

7.3 Specification

1. With fiber-optical illumination system, illuminate the object uniformly and non-reflectively, as well as no shading;
2. Magnification is 2X±0.5X;
3. Specula diameter is 2.7 mm and 4.2 mm; Tolerance is ±0.15mm;
4. With inflating aperture for pneumatic test;
5. Elegant in design, convenience in operation;

7.4 Operation

The operation steps are step is as followings.

1. Take away otoscope from system panel, system circuit is automatically conducted at the same time, indicator and otoscope lamp will light.
2. Wear the dirt proof sleeve, then user can check the body for patient.
3. Take down the dirt proof sleeve and put the otoscope back after use.

7.5 Checking Method

1. Push the flanged end of the desired speculum onto the chrome socket and twist counterclockwise to engage. Reverse procedure to remove and discard after each use. The selection of speculum is according to the patient: adult is suit for the 4.2mm, children for 2.7mm.
2. The doctor put the speculum part into the ear canal, and observes through speculum aperture.
3. If do the eardrum test, inflate air from the inflating aperture.

7.6 Daily maintenance

7.6.1 Change lamp

Change lamp should be operated by the professional operator. Power off, and remove the otoscope head, after lamp is cool, turn the handle counterclockwise to open it; Take away lamp from inside base of otoscope head with a small driver, then replace with new lamp and insert new lamp to the bottom, notice that pls don’t touch glass; Turn handle clockwise to assemble the otoscope.

Notice

1. Cut off the power when changing lamp.
2. Wear protective goggles when operation
3. Be careful to discard lamp.

Warning

1. Use the indicated lamp. When changing lamp, allow lamp to cool before handling, be care of high temperature of lighted lamp.
2. If the lamp is damaged, please contact customer service for changing the indicated lamp.
3. Direct ophthalmoscope, Medical magnifier, condenser are belong to the Short-time loading continuous operation instrument. Long time work will cause lamp burning, suggest intermittent working in 1 to 2min.

7.7 Cleaning

1. Clean the surface of the handle with clean cloth with solution mixed 50％ alcohol and 50% distilled water. Do NOT use detergent with corrosion and grinding effect.
2. The lens cleaning: use lens cleaning paper or cotton with solution that 50％ alcohol mixed with 50% ether. If lens is a little dusty, use ear syringe or bush to clean it up.

7.8 Auralspeculum

The auralspeculum can only be used one time.

Chapter 8 Remote Controller

8.1 General information

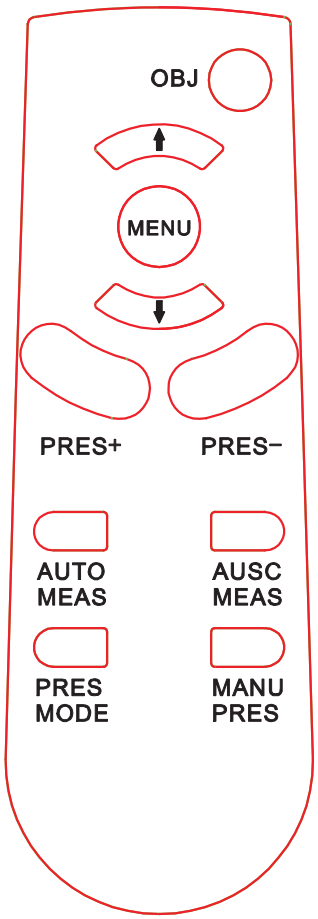
As the accessory of the system, remote controller can operate in 3 meters. It is convenient for doctor to operate the system.

The remote control is transfer to the system for the operation through the infrared signal.

8.2 Operation

1. The remote controller need insert two 7# battery before using, according to the positive and negative pole.
2. Remote controller should point "remote control receiver" when using.

8.3 Shortcut instruction



Remote controller

- Auto measure: button to start NIBP automatic mode, the same function as the “NIBP/Up” button on the front panel.
- Auscultation measure: button to start NIBP auscultation mode, the same function as the “Manual/Down” button on the front panel.
- Pressure mode :(only for auscultation mode) general node in the process of compression is not predict the measured pressure value; Self-adaption model in the process of compression is predict the measured pressure value.
- Objective: button to switch between adult and children.
- Pressure+, Pressure-: (only for auscultation mode) plus or minus ±20mmHg in pressure presetting.
- Manual pressure: (only for auscultation mode) button to inflate, the inflatable value can be set. Select auscultation mode, press “menu” button, then push <↑> or <↓> button for manual pressure mode.
- UP/DOWN and menu: to enter the menu mode, “UP/DOWN” button the same function as the front panel.

Chapter 9 Accessory

9.1 General information

Accessory is the important part of product. Please use indicative accessories.

9.2 Limitation of operation

Warning

Use indicative accessories, other accessories may be unable to meet product specifications, technical parameters and index.

1. Disposable accessories should be used once; reuse may cause performance degradation or cross contamination.
2. If find accessory package damaged, please do not use it.

9.3 NIBP Cuff

NO.	Name	Specification	Supplier	Specification of supplier
1	Blood pressure cuff	baby 10-19CM	Shenzhen Changke Connect Electron Co., Ltd	CK-XT-78243-008
		children 18-26CM		CK-XT-78243-007
		adult 25-35CM		CK-XT-78243-005
		older adult 33-47CM		CK-XT-78243-003
		thigh 46-66CM		CK-XT-78243-001
2	Specula	children 2.7mm	Shenzhen Speed Step Technology Companies	/
		adult 4.2mm		/

Chapter 10 Cleaning, Disinfection and Maintenance

10.1 General Information

⚠ **Notice**

1、 Only use listed chemicals and methods in this chapter to clean, maintain and disinfect for system. Uray is not providing any warranty if user misuse the chemicals or methods.

2、 Uray has no responsibility for effectiveness of listed chemicals and methods. About the methods of infection controlling, please consult the hospital infection prevention department or epidemiological specialist.

Routine care and regular maintenance are essential to keep the best status and precision, to minimize system problems, as well as to prolong the life span. Procedures and instructions for preventive maintenance are discussed in this chapter. More information is available at Uray Customer Service.

Please keep system and accessories from dust. To prevent damage, be sure to observe the following provisions:

- Please according to the manufacturer's instructions before dilute the cleaning agent and disinfectant, or dilute chemical concentration as low as possible.
- Never immerse system in fluid.
- Never dump liquid in the system or accessories.
- Avoid using abrasive materials (e.g., steel wool or silver polishing agent), and strong volatile organic solvents (e.g. acetone, ethyl ether, chloroform, etc)

10.2 Limitation of operation

⚠ **Warning**

1. Power off before clean the system.
2. If liquid is dumped in the system or accessories, please contact the serviceman or customer service immediately.

⚠ **Notice**

1. Clean or disinfect reusable accessories, see the chapter of manual

10.3 Cleaning

10.3.1 Cleaning agent

The instrument should be cleaned regularly, improve the clean frequency in the pollution area or sand area. Please consult or learn the hospital regulations before cleaning.

The followings are cleaning agent:

- Diluted soap water
- diluted ammonia
- Sodium hypochlorite(Bleaching powder)
- Hydrogen Peroxide（3%）
- Alcohol（75%）
- Isopropanol

10.3.2Cleaning step

See the following steps:

1. Power off before clean the system.
2. Take the instrument form the wall according to the direction.
3. Gently clean instrument surface with soft cotton.
4. Use dry cloth to clean redundant cleaning agent when necessary.
5. The instrument should be placed in dry and airy room.

10.4 Disinfection

Disinfection may damage the instrument. Follow hospital maintenance plan to disinfect system. Clean the system before disinfection.

The recommended disinfectants are 75% alcohol, 70% isopropyl alcohol, 2% glutaraldehyde.

10.5 Clean and disinfection of accessory

10.5.1 Cuff

Please regularly clean the system

1. Take the cuff form connector, the gasbag is taken from the cuff。
2. Clean the gasbag and tube with cotton cloth.
3. Immerse cuff surface in neutral soap water.
4. The cuff can use when the surface and gasbag are dry

⚠ **Notice**

1. Too much cleanliness could damage the gasbag.
2. The surface and gasbag could not be dry for high temperature.
3. Disposable cuff can be only used for one patient.
4. Don’t immerse the cuff and connector into water.

10.6 Maintenance

Follow the limitation of operation and cleaning section are a part of equipment maintenance. If equipment does not work in long time, or in wet weather conditions, please power on 3 hours every 3 months, in order to avoid moisture effects on equipment.

Chapter 11 Maintenance

11.1 General information

Please take good maintenance for your system, it will keep your device work in right way and increase its lifetime.

11.2 Limitation of maintenance

Warning

1. The hospital should establish the maintenance plan for system, otherwise it may cause the unexpected consequences, and endanger personal safety.
2. Maintenance should be operated by professional, nonprofessional operation may cause the system damage.
3. If the system is damaged, please contact the serviceman or customer service immediately.

11.3 Checkout

The system should be checked over over one year, ensure the normal running.
Checkout should include the following contents.

- Operation environment should meet the operation manual.
- The input range of power supply should meet the operation manual.
- Power line is no tear, good insulation.
- Use the indicative accessories.
- Test function is working correctly (including vital signs components, direct ophthalmoscope module, medical magnifier).
- Ground impedance and leakage current should meet the requirements.

Notice

1. If find any damage, please stop using, and contact the serviceman or customer service immediately.

11.4 Maintenance plan

The following maintenance should be operated by professional serviceman. Please clean the system before maintenance.

Maintenance items	Frequency
In accordance with the IEC 60601-1 (GB 9706.1) to carry out safety inspection.	At least once a year.
Check the following unlisted measurement items.	At least once a year, or when the measurement is inaccurate.
NIBP leak detection	At least once a year(see the chapter of NIBP)
NIBP pressure calibration	At least once a year(see the chapter of NIBP)
NIBP calibration	At least once a year(see the chapter of NIBP)
Change halogen lamp	At least once a year(see the chapter of direct ophthalmoscope)

11.5 Maintenance interface

Select 【System】à 【More】à 【Maintenance】
Please see the chapter of maintenance.

11.6 Version

Select 【System】à 【More】à 【Maintenance】to check the version number.

⚠ **Notice**

1. The version information is very important for serviceman and custom service, please confirm this step.

11.7 Customer service

In order to provide convenient customer service, please pay attention to the following information.

1. Telephone(see the manual)
2. Product name and specification
3. Product version
4. Information description
5. If you have the product photo or others, please send email to us.

Chapter 12 Technical Parameter

12.1 Classification

12.1.1 CE Classification

According to the classification of CE, this system is classified to IIa.

12.2 IEC 60601-1 Classification

According to IEC 60601-1 are classified as followings.

Classification table

Part name	Type of protection against electric shock	Grade of protection against electric shock	Operation mode	Grade of blastprotection	Liquid inlet protection
Mainframe	Ⅰ classification instrument	Not applicable	Continuous operation instrument	Not applicable(flammable gas etc)	General device (no prevention liquid function)
NIBP	Not applicable	BF			
Direct ophthalmoscope	Not applicable	BF	Short-term load continuous operation instrument		
Medical magnifier	Not applicable	BF	Short-term load continuous operation instrument		

12.3 Power specification

Input voltage	100-240V～
Input current	≤3A
Frequency	50/60Hz
Fuse	5S 1.5A 250V (slow blow fuse)

12.4 Environmental specification

Item	Normal work	Storage and transportation(In shade)
Temperature	5℃～40℃	-20℃～+70℃
Humidity	10%～95% (No condensation)	10%～95% (No condensation)
Pressure	80 kPa～106 kPa	50 kPa～106 kPa

12.5 Hardware specification

12.5.1 Physical specification

Part	Specifiation
Outside packing	Dimension: 750mm×320mm×400mm (length*width*height)
	Gross weight: 9.4kg； net weight:: 6.8kg

12.5.2 Display

Type	Color TFT
Dimension	**7** inch
Resolution ratio	800 × 480 pixel

12.5.3 Indicator

A.C. source indicator	one(green)
Vital signs components indicator	one(green and blue)

12.5.4 Interface

Power	one A.C source interface
Network with cable	one RJ45 interface (reserved)
USB interface	one USB1.1 interface
Protective earthing terminal	one

12.6 Measurement specification

12.6.1 NIBP

Measurement standard	IEC 80601-2-30		
Measurement method	Oscillography		
Measurement mode	Auto mode, auscultation mode:		
Measurement range （mmHg）		Adult	Children
	Systolic pressure	40~270	40~200
	Mean pressure	20~230	20~160
	Diastolic pressure	10~210	10~150
Measurement accuracy	Average deviation MD±0.7 kPa（5 mmHg） Standard deviation S≤1.1 kPa （8 mmHg）		
Resolution ratio	0.1 kPa（1 mmHg）		
Initial inflation pressure	Adult mode: 180mmHg±5mmHg Children mode: 140 mmHg±5mmHg		
Overvoltage protection	Adult mode: 297 mmHg±3mmHg Children mode: 237 mmHg±3mmHg		
Range of cuff pressure	330mmHg		

12.6.2 Pulse Rate

Parameter	Specification
Measurement range	25 bpm～250 bpm
Measurement accuracy	±1 bpm or±1 % choose the bigger
Resolution ratio	1 bpm

12.6.3 Direct Ophthalmoscope

Parameter	Specification
Illuminance	The illumination of 20mm distance to Ophthalmoscope is no less than 150lx
Spot	From the projection aperture 250mm distance, illuminate the object uniformly and non-reflectively, as well as no shading.
Vision Angle	≥3°
Illumination vision angle	≥9°
Minimum observation diameter	≥3mm
Color rendering index	≥85%
Diopter（unit：D）	-25、-20、-15、-10、-9、-8、-7、-6、-5、-4、-3、-2、-1、0、+1、+2、+3、+4、+5、+6、+7、+8、+9、+10、+12、+15、+20、+40
Aperture	large Aperture, small aperture, tiny aperture, fixation aperture, stenopeic disk and cobalt blue tablets
Stretching distance of spring line	≥3m

12.6.4 Medical Magnifier (Otoscope)

Parameter	Specification
Illuminance	In 20mm distance, illumination is no less than 500lx;
Magnification	2X±0.5X
Color rendering index	≥85 %
Specula diameter	Specula diameter is 2.7 mm and 4.2 mm; Tolerance is ±0.15mm;
Inflating aperture	Yes
Stretching distance of spring line	≥3m

Chapter 13 Terminology and Symbolic Interpretation

13.1 Symbol

Symbolic	English
&	And
°	degree(s)
>	greater than
<	less than
-	Minus
%	Percent
+	Plus
=	equal to
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
X	Multiply
©	Copyright

13.2 Unit

Abbreviation	English
A	ampere
bpm	beat per minute
℃	centigrade
cm	centimeter
℉	fahrenheit
g	gram
h	hour
Hz	hertz
kg	kilogram
kPa	kilopascal

L	liter
m	meter
mL	milliliter
min	minute
mmHg	millimeters of mercury
s	second
V	volt
VA	volt. ampere
W	watt

13.3 Terminology

Abbreviation	English
AC	alternating current
ANSI	American National Standard Institute
Adu	adult
CO	Carbon monoxide
CO_2	Carbon dioxide
COHb	Carboxy hemoglobin
DC	Direct current
Temp	Temperature
USB	Universal serial bus
Pediatric	Pediatric
PLETH	Plethysmogram
EtO	Ethylene oxide

Chapter 14 Troubleshooting

14.1 General information

This Chapter gives instructions for identifying, troubleshooting, and correction of problems. If malfunction are not solved according to guidance or more information is needed, please contact Uray Customer Service.

14.2 Troubleshooting guidance

The Troubleshooting Guidance is designed to assist the operator in identifying, classifying and resolving problems. Instructions are also given for obtaining technical assistance immediately from Uray Customer Service. The first step in the process is to understand normal System operation and preventive maintenance. Experience of the engineer is essential to identify, classify and resolve problems.

Common troubleshooting may be divided into three steps in order:

1. Problem Identification
2. Problem Classification
3. Problem Solution

14.2.1 Problem identification

The operator is not only to identifying,hat is wrong but also what is right. The investigation should identify the problem area and eliminate areas that are right. Once done, the trouble shooting process moves quickly to next step.

14.2.2 Problem classification

System problems are generally divided into three categories:

1. Hardware related
2. Software related
3. Subject or operation related

Hardware and software problems can only be corrected by Uray authorized engineer. User can correct subject or operation related problems with assistance from

Uray engineers.

14.2.3 Problem solution

Maintenance engineer should take appropriate action to resolve the problem. If the operator can resolve the problem, with or without technical support from Uray or local distributors, the delay time can be reduced.

14.2.4 Technical support

When failure or error happened, contact Uray Customer Service or local branch office for technical support by telephone, tax, e-mail etc in the preface of manual. Before the technical support, prepare for the following information for Customer Support Specialists,

1. The system model
2. Serial number and version number
3. Description of the problem and surroundings, including status and operation
4. Data and report of the problem

Common problems and disposals are given in this Chapter. The operator can identify the cause according to the warning information and operate according to Troubleshooting Guide.

14.3 Troubleshooting

14.3.1 Vital Signs components troubleshooting

14.3.1.1 No power

Cause:

1. Check if the 240V/110V AC power input is ok.
2. Check if the fuse is broken.
3. Check if the power supply and power socket is connected well.

Solution:

1. Make sure the power input it ok.
2. Change another fuse which has the same specification.
3. Connect the power supply to the power socket again to make sure the

connection is well.

14.3.1.2 No display

Make sure the power switch is on at first. Then you can turn off the power and remove the power input. In this time, you can use the multimeter to test the power socket is good or not, the power wire is good or not, the power wire and power socket are connected well or not。

14.3.1.3 No NIBP result

Check the cuff is bound in right position or not, the cuff leak or not, the air port and NIBP socket are connected well or not.

14.3.2 Direct ophthalmoscope troubleshooting

Phenomenon: ophthalmoscope is not working.
Solution:

1. Check the LED light corresponding with ophthalmoscope is on or not, if the LED is good, then the user can check the head of ophthalmoscope is rotated well or not;
2. Check the lamp and filament of the ophthalmoscope are broken or not;
3. Check the spring line contact well or not.

14.3.3 Medical magnifier troubleshooting

Phenomenon: medical magnifier is not working.
Solution:

1. Check the LED light corresponding with medical magnifier is on or not, if the LED is good, then the user can check the head of magnifier is rotated well or not;
2. Check if the lamp and filament of the medical magnifier are broken or not;
3. Check the spring line contact well or not.

Chapter 15 Replacement Parts List

NO.	Name	Specification	Supplier	Specification of supplier
1	Blood pressure cuff	baby 10-19CM	Shenzhen Changke Connect Electron Co., Ltd	CK-XT-78243-008
		children 18-26CM		CK-XT-78243-007
		adult 25-35CM		CK-XT-78243-005
		older adult 33-47CM		CK-XT-78243-003
		thigh 46-66CM		CK-XT-78243-001
2	Specula	children 2.7mm	Shenzhen Speed Step Technology Companies	
		adult 4.2mm		

Chapter 16 Electromagnetic Compatibility

This appendix lists the tests and compliance levels that make the UR-9000 Modular Diagnostic System suitable for use in the specified electromagnetic environment according to IEC 60601-1-2: 2007.

16.1 Instructions for Use

Medical electrical equipment can either generate or receive electromagnetic interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC60601-1-2: 2007, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN IEC60601-1-2: 2007. Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to using the product. Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of medical equipment. See your service provider for assistance with the minimum recommended separation distance between RF communications equipment and the product. The cables and other accessories for which compliance is claimed are listed in this manual.

Warning

Use of accessories other than those specified may result in increased emissions and/or decreased immunity of the UR-9000 Modular Diagnostic System.

The UR-9000 Modular Diagnostic System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it is used.

16.2 Guidance and Manufacturer's EMC Declaration

The UR-9000 Modular Diagnostic System is intended for use in the electromagnetic environment specified in the following tables. The customer or the user of the UR-9000 Modular Diagnostic System should assure that they are used in such an environment.

Table 1 Electromagnetic Emissions for all Equipment and Systems

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The UR-9000 Modular Diagnostic System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

RF emissions CISPR 11	Class A	The UR-9000 Modular Diagnostic System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 Electromagnetic Immunity for all Equipment and Systems

Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT 1 (> 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 UR-9000 Modular Diagnostic System requires continued operation during power mains interruptions, it is recommended that power the UR-9000 Modular Diagnostic System from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.

1. UT is the AC mains voltage prior to application of the test level.

Table 3 Electromagnetic Immunity for Equipment and Systems not Life-Supporting

Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80MHz to 2.5GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the UR-9000 Modular Diagnostic System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] Should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UR-9000 Modular Diagnostic System is used exceeds the applicable RF compliance level above, the UR-9000 Modular Diagnostic System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the UR-9000 Modular Diagnostic System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4 Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the UR-9000 Modular Diagnostic System			
The UR-9000 Modular Diagnostic System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the UR-9000 Modular Diagnostic System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the UR-9000 Modular Diagnostic System 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		
	150kHz to 80MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80MHz to 800MHz** $d=\left[\frac{3.5}{E1}\right]\sqrt{P}$	**800MHz to 2.5GHz** $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
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.			