



GIMA

PROFESSIONAL MEDICAL PRODUCTS

NIBP SIMULATOR

User manual

ATTENTION: The operators must carefully read and completely understand the present manual before using the product.

Gima 54601



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Notice

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Manufacturer's responsibility

Our company is responsible for effects on safety, reliability and performance of the equipment:

- ◆ Assembly and maintenance are carried out by persons authorized by our company
- ◆ The NIBP simulator, hereafter known as the "simulator", is operated in accordance with the User Manual.

Convention

 **Warning:** Points some information you should know to avoid injury to user.

 **Caution:** Points some information you should know to avoid damage to the simulator.

Notice: Points some important information you should pay attention to.

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Chapter 1 Safety

1.1 Instructions for Safe Operations

To avoid possible injuries and residual risks, the following instructions for safe use should be obeyed when operating the device:

-  **Warning:** Explosive hazard: Do not use the simulator in environment with inflammable gas, such as anesthetic.
-  **Warning:** Make sure to be connected with proper external power.
-  **Warning:** Don't use two-pin plug. As there may be hazard of electrical shock when using the two-pin plug without earth wire. Be sure to use three-pin plug with effective earth wire.
-  **Warning:** The disposal of scrap instrument and its accessories and packing (including plastic bag, foam and paper box) should follow the local laws and regulations.
-  **Warning:** Do not place the equipment in a position where it is difficult to operate the power switch.
-  **Warning:** If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
-  **Caution:** Please check the packing before use to make sure the simulator and accessories are totally in accordance with the packing list, otherwise the simulator may have the possibility of working abnormally.
-  **Caution:** Please don't test the simulator with functional tester for technical information.
-  **Caution:** Do not inflict pressure greater than 450 mmHg (60 kPa) to the pressure port to avoid damage to internal components.
-  **Caution:** Operation temperature should be within +5~+40 °C. If exceeding this range, error may occur.

1.2 Notice

-  Keep the simulator away from dust, vibration, corrosive or inflammable substance. and avoid excessive temperature and humidity.
-  If the simulator gets wet or has coagulation, please stop using it.
-  When carried from cold environment to warm or humid environment, please do not use the simulator immediately.
-  DO NOT operate buttons on front panel with sharp things.
-  DO NOT have the simulator immersed in liquid. When it needs cleaning, please use soft and dry cloth soaked with soft detergent to wipe its surface.

Chapter 2 Overview

The simulator is a multipurpose tester applied to the oscillometric Non-Invasive Blood Pressure Monitor (NIBP Monitor). It can provide dynamic blood pressure simulations, static pressure calibration, automated leak testing, and pressure relief valve testing.

User can set the testing mode as not only the built-in mode but also other user-defined modes. With its internal pump, the tester can generate pressure up to 400 mmHg (53.3 kPa) for leak testing, pressure sourcing, and relief valve testing.

Chapter 3 Technical Specifications

3.1 Main Functions

- Test pressure leak on cuff, hose, and connectors
- Test the Relief valve of the NIBP monitor
- Static Pressure Test
- Pressure source output
- Dynamic BP simulations, including NIBP output of arm and wrist.
- NIBP simulations for adult, neonate, arrhythmias, and respiratory interference, etc.
- Built-in air chamber to simulate adult or neonate cuff.

3.2 Main Parameters

- Power supply: AC 100 ~ 240 V 50/60 Hz, < 60 VA
- Environment Conditions
 - Storage Environment:
 - a) Storage temperature: -20 °C~+65 °C
 - b) Relative humidity: < 90 %, non-condensing
 - Operating Environment:
 - a) Indoor use
 - b) Working temperature: +5 °C~+40 °C
 - c) Relative humidity: < 90 %, non-condensing
 - d) Height above sea level: 3000 m
 - e) Atmospheric pressure: 80 kPa~106kPa
 - f) Rated pollution degree: 2
- Pressure measurement
 - Unit: kPa, mmHg, cmH₂O, inH₂O, psi
 - Range: 0 mmHg~400 mmHg
 - Resolution: 0.1 kPa, 1 mmHg, 1 cmH₂O, 1 inH₂O, 0.1 psi
 - Accuracy: 0 ~ 300 mmHg: ±(0.5 % of reading +1) mmHg
 - 301 ~ 400 mmHg: ±2 % of reading
- Pressure output

Range of pressure output: 50 mmHg~400 mmHg

Difference between target pressure and actual pressure: ± 10 mmHg from 100-400 mmHg with a minimum volume of 300 cc

Total airtightness: Total airtightness < 2.25 mmHg/min, with shutdown state.

Internal leak rate < 2 mmHg/min, with a minimum volume of 300 cc.

■ Heart rate simulation

Heart Rate Accuracy: ± 1 bpm (except patient conditions)

Accuracy under Patient Conditions:

Weak pulse, Tachycardia, Obese, Geriatric: $\pm (1\% \text{ of reading} + 1)$ bpm

Mild exercise: $\pm (1.5\% \text{ of reading} + 1)$ bpm

Strenuous exercise: $\pm (3\% \text{ of reading} + 1)$ bpm

Chapter 4 Installation

4.1 Front Panel

The front panel of the simulator is shown as Figure 1:

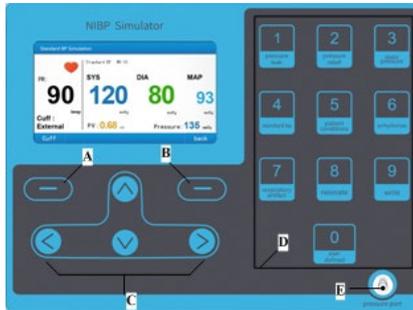


Figure 1 Front panel

Buttons and function introduction:

| Buttons on the front panel | Name | Functions |
|----------------------------|----------------|--|
| A | Enter Key | Confirm function selection and parameter setting, or perform special function indicated in the interface. |
| B | Return Key | Get back to the previous interface. |
| C | Direction keys | Four direction keys(up, down, right and left) for function selection or perform special function indicated in the interface. |
| D | Number keys | Ten keys from 0 to 9, for entering parameters or as a shortcut to perform dynamic BP simulation and pressure test. |
| E | Pressure port | Connected to the NIBP Monitor to output dynamic simulated BP or as pressure source to test relief valve and leak rate. |

User can make the simulator perform BP simulation or pressure test functions quickly by pressing corresponding number keys(0~9)

The relation between functions and number keys is shown as the following table.

| Number keys | Functions | Function Introduction |
|-------------|----------------------|---|
| 1 | Pressure Leak | Boost the pressure up to the user-defined target value(Maximum is 400 mmHg) by the air pumping system, then test the pressure leak complexion of the tested instrument after a period of time. |
| 2 | Pressure Relief | Inflate to the NIBP monitor until its relief valve opens or the pressure reaches the target value. |
| 3 | Static Pressure | As a pressure gauge to measure the static pressure produced by the external equipment connecting to pressure port, or as a pressure source to generate and measure static pressure synchronously. |
| 4 | Standard BP | Provide seven different standard arm NIBP simulations. |
| 5 | Patient Conditions | Simulate the BP output of patient conditions including healthy, geriatric, obese, tachycardia, bradycardia, as well as different levels of exercise. |
| 6 | Arrhythmias | Simulate erratic heart rhythms, including atrial fibrillation and premature ventricular contraction. |
| 7 | Respiratory Artifact | Simulate the BP variation from a heart beat to another, which influenced by the intrathoracic pressure change. |
| 8 | Neonate | Test the capability of the NIBP monitor to measure neonate. |
| 9 | Wrist | Test the NIBP monitor with wrist cuff. |
| 0 | User defined | Allow user to define the value of simulated BP. |

4.2 Connection

Power switch and power cord socket locate at the back of simulator. Connect the simulator to mains with the accompanying power cord, then turn on the power switch, the simulator will start working.

The methods of connecting the simulator and NIBP monitor are shown as Figure 2~4. User needs to prepare the accessories such as external cuff, hose, three port connector (T-type or Y-type), which our company doesn't provide.

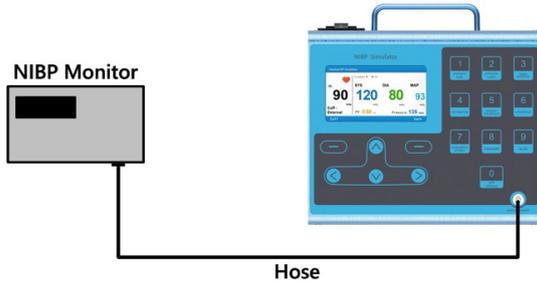


Figure 2 Connect the simulator and NIBP monitor using internal cuff

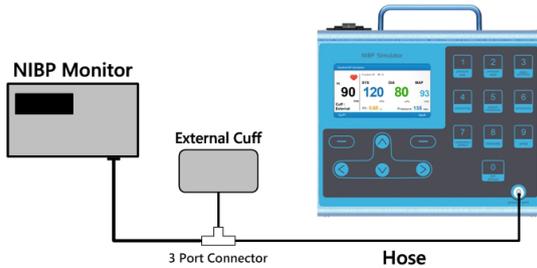


Figure 3 Connect the simulator and NIBP monitor using external cuff

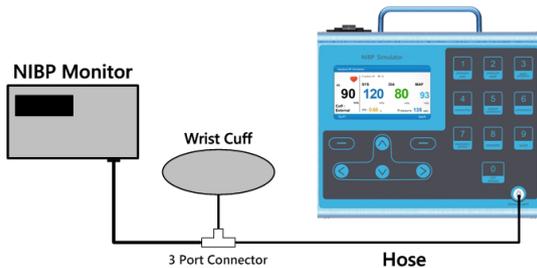


Figure 4 Connect the simulator and NIBP monitor using wrist cuff

4.3 Accessories

- 1) User Manual
- 2) Power cord
- 3) Fuse

Chapter 5 Operations

After power on the simulator, the screen will display information about the manufacturer as well as the product name and model, then system will initiate and enter the "Main Menu" shown as Figure 5.

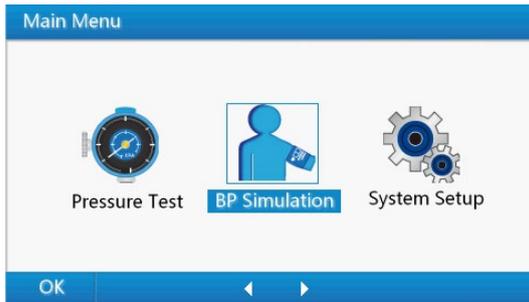


Figure 5 Main menu

5.1 System Setup

It is recommended to set the system according to requirement firstly for the first use. All settings (except zeroing pressure) will be saved automatically, and have no need to reset next time.

Use left or right key to select "System Setup" in "Main Menu", then press "Enter Key" to "System Setup Menu" shown as Figure 6. In this interface, pressing "Return Key" can get back to "Main Menu".

The system setup menu includes the following items:

- Units of pressure
- Zero Pressure
- Display Brightness
- Key Sound
- Language
- Version



Figure 6 System setup menu

■ Measurement Units Setting

BP simulation and Pressure test have different kinds of units for option.

BP simulation units: mmHg(default), kPa

Pressure test units: mmHg(default), kPa, cmH₂O, inH₂O, psi

These units have the following conversion relations:

$$1\text{mmHg} = 0.019337 \text{ psi}$$

$$1\text{mmHg} = 1.3595 \text{ cmH}_2\text{O}$$

$$1\text{mmHg} = 0.53525 \text{ inH}_2\text{O}$$

$$1\text{mmHg} = 0.13332 \text{ kPa}$$

Steps for units setting :

1. Use up or down key in "**System Setup Menu**" to select "**Units of Pressure**", then press "**Enter Key**" to the unit setting interface shown as Figure 7, the units displayed with black color are current effective units for BP simulation and pressure test.

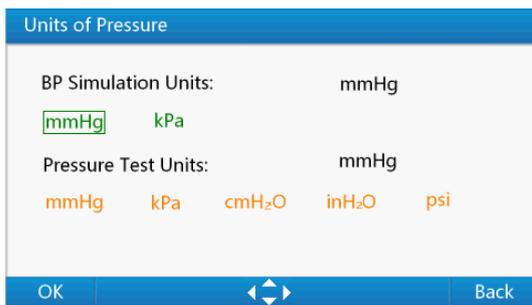


Figure 7 Unit setting interface

2. Use up or down key in the unit setting interface to select setting BP simulation units or pressure test Units, then use left or right key to select units.
3. Press "**Enter Key**" after selecting the BP simulation unit to save the setting for BP simulation, then the pane jumps to the area of pressure test units for selection, After selecting pressure test unit ,press "**Enter Key**" to save the setting for pressure test ,then the simulator will return to "**System Setup Menu**"automatically. In the unit setting interface, pressing "**Return Key**" can return to "**System Setup Menu**".

■ Zero Pressure

This function can make current pressure become zero, if the pressure of the simulator is not zero at the beginning resulted from some factors, please modify the measurement by this function.

Steps for zero pressure:

- 1) Remove the external equipments connecting to pressure port to make the pressure port contact with atmosphere.
- 2) Use up or down key in "**System Setup Menu**" to select "**Zero Pressure**", then press "**Enter Key**" to zero pressure interface shown as Figure 8.
When entering zero pressure interface, the simulator will measure current pressure once,
the measured pressure will be displayed in the interface. If it is 0, zeroing pressure is unnecessary, otherwise please zero pressure following the third step.
- 3) Operate following the prompts in the interface to remove connection to the pressure port, then press "**Enter Key**", the pressure value will become 0. After finishing, pressing "**Return Key**" can get back to "**System Setup Menu**".

Notice: The modification effect of zeroing pressure can last until next zeroing or turn off the power .

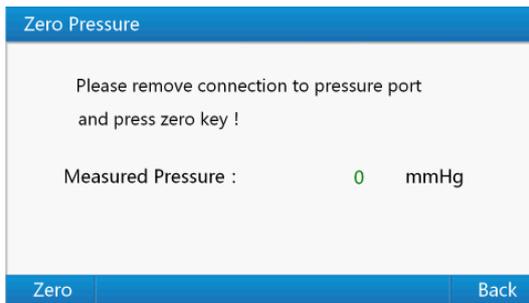


Figure 8 Zero pressure interface

■ Display Brightness Setting

Screen brightness can be adjusted by user, which is convenient for operation in different light conditions.

Steps for setting brightness:

- 1) Use up or down key in "**System Setup Menu**" to select "**Display Brightness**".
- 2) Press left or right key to change brightness, four levels for option.

■ Key Sound Setting

Key sound can be on or off.

Steps for setting key sound:

- 1) Use up or down key in "**System Setup Menu**" to select "**Key Sound**".
- 2) Press left or right key to turn on or off the key sound.

■ Language Setting

The language can be changed by user.

Steps for setting language

- 1) Use up or down key in "**System Setup Menu**" to select "**Language**".
- 2) Press left or right key to set the language .

■ Version

Use up or down key in "**System Setup Menu**" to select "**Version**",software and hardware version will be displayed in a new window.

5.2 Pressure Test

Use left or right key in "**Main Menu**" to select "**Pressure Test**", then press "**Enter Key**" to "**Pressure Test Menu**" shown as Figure 9. In this interface, pressing "**Return Key**" can get back to "**Main Menu**".

The pressure test menu includes the following items:

- Pressure Leak
- Pressure Relief
- Pressure Gauge
- Pressure Source



Figure 9 Pressure test menu

■ Pressure Leak Test

Method: Add pressure to target pressure set by user (setting range:50-400mmHg), then measure the leak complexion of the pressure system after a period of time. Internal leak rate of the simulator itself is no more than 2 mmHg/min.

Steps for pressure leak test:

- 1) Use up or down key in "**Pressure Test Menu**" to select "**Pressure Leak**", then press "**Enter Key**" to "**Pressure Leak Test**" interface shown as Figure 10,As a shortcut,you can use number key "**1**" to this interface quickly, In this interface, pressing "**Return Key**" can get back to "**Pressure Test Menu**".

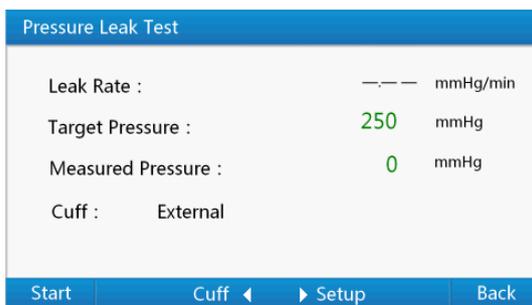


Figure 10 Pressure leak test interface

- 2) This interface displays current target pressure, you can set the target pressure by using right key to enter the setting interface shown as Figure 11. In this interface, use the number keys to input target pressure, and after entering a digit, the cursor will automatically move to next digit for input. After input the target pressure, press "**Enter Key**" to save. In this interface, pressing "**Return Key**" can get back to "**Pressure Leak Test**" interface.

Notice: Range for target pressure is 50-400mmHg, if the input target pressure exceeds this range, it will be adjusted to this range automatically.

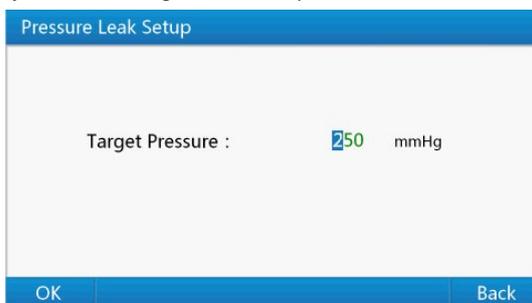


Figure 11 Target pressure setup interface

- 3) Use left key to select whether to connect the internal adult cuff. If selecting "**Internal Adult**", the system will connect the internal adult cuff. If selecting "**External**", the system will not connect the internal adult cuff.
- 4) Press "**Enter Key**" to start pumping air. After the pressure achieves the target pressure, waiting several seconds for stabilization, then the system will start testing. Real-time leak rate and pressure will be displayed in the interface. Default unit for leak rate is mmHg/min, and kPa/min, cmH₂O/min, inH₂O/min or psi/min is optional.
- 5) While testing, Pressing "**Enter Key**" can stop measuring, the interface will display the measured final leak rate.

Notice: When testing the pressure leak rate of the NIBP monitor, make sure the internal valve of the measured device is off.

■ **Pressure relief test**

Steps for pressure relief test:

- 1) Use up or down key in "Pressure Test Menu" to "Pressure Relief", then press "Enter Key" to "Pressure Relief Test" interface shown as Figure 12,As a shortcut, you can use number key "2" to this interface quickly, In this interface, Pressing "Return Key" can get back to "Pressure Test Menu".

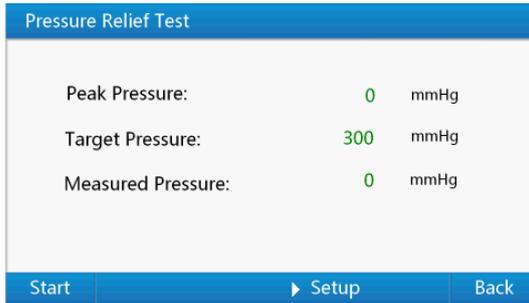


Figure 12 Pressure relief test interface

- 2) This interface displays current target pressure, you can set the target pressure by pressing right key to enter the setting interface . Setting method is similar with that in "Pressure Leak Test" .
- 3) Press "Enter Key" to start pumping air, the real-time pressure will be displayed in this interface, when the relief valve of the monitor becomes open, the simulator will stop pumping, then the measured pressure relief value will be displayed. When the pressure achieves the target pressure, but the relief valve of the monitor is still off, the denotative message "No Relief!" will appear in the interface.

Notice: When testing pressure relief, make sure the internal valve of the measured monitor is off. It is recommended to measure several times to get accurate pressure relief value.

■ Pressure gauge

When working as a pressure gauge, the simulator can measure the static pressure produced by external equipment connected to the pressure port.

Steps for pressure gauge test:

- 1) Use up or down key in "Pressure Test Menu" to select "Pressure Gauge", press " Enter Key" to "Pressure Gauge Test" interface shown as Figure 13.As a shortcut, you can use number key "3" to enter this interface quickly.The value displayed in this interface is the static pressure produced by external equipment. In this interface, Pressing "Return Key "can get back to "Pressure Test Menu",and Pressing "Enter Key" can go to "Pressure Source Test" interface.
- 2) Use left key to select whether to connect the internal adult cuff. If selecting "Internal Adult", the system will connect the internal adult cuff.If selecting "External", the system will not connect the internal adult cuff.

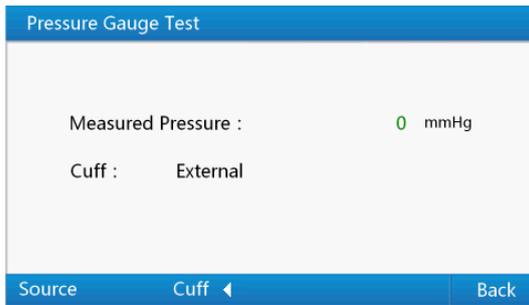


Figure 13 Pressure gauge test interface

■ Pressure Source Test

Pressure source test refers to the simulator can produce and measure pressure synchronously, which can be used for static calibration for NIBP monitor, verification for general sphygmomanometer and evaluating any instrument whose pressure measurement range is within 0~400mmHg.

Steps for pressure source test :

- 1) Use up or down key in "Pressure Test Menu" to select "Pressure Source", then press "Enter Key "to "Pressure Source Test" interface shown as Figure 14. Pressing "Return Key "in this interface can get back to "Pressure Test Menu". As a shortcut, you can use the number key "3" to "Pressure Gauge Test" interface firstly, then press "Enter Key "to the "Pressure Source Test" interface.
- 2) Current target pressure is displayed in this interface. Target pressure can be set by user. Setting method is similar with that in "Pressure Leak Test".
- 3) Use left key to select whether to connect the internal adult cuff. If selecting "Internal Adult", the system will connect the internal adult cuff. If selecting "External", the system will not connect the internal adult cuff.
- 4) Press "Enter Key "to start adding pressure. The pressure will be added until achieving the target pressure. Real-time pressure will be displayed in this interface.

Notice: Before pressure source test, it is recommended to test pressure leak firstly to make sure there is no leak.

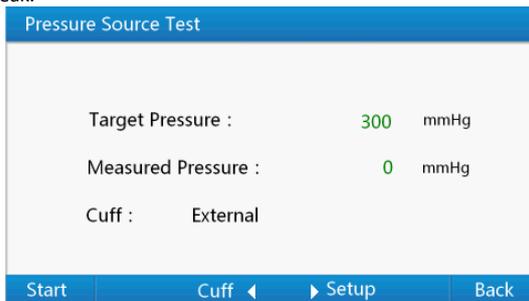


Figure 14 Pressure source test interface

5.3 BP simulation

The simulator can simulate BP output of adult, neonate, patient conditions, arrhythmia and respiratory Artifacts.

Use left or right key in "Main Menu" to select "BP Simulation", press "Enter Key" to "BP Simulation Menu "shown as Figure 15. In this menu,Pressing "Return Key "can get back to "Main Menu".

The BP simulation menu includes the following items:

- Standard BP
- Patient Conditions
- Arrhythmias
- Respiratory Artifacts
- Neonate
- Wrist
- User-Defined

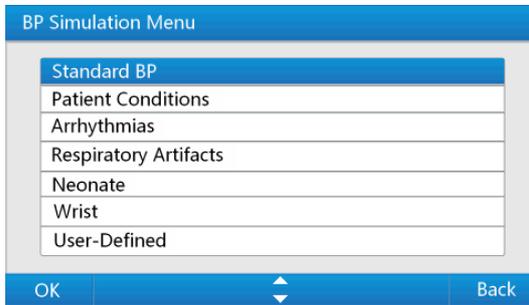


Figure 15 BP simulation menu

In BP simulation menu, use up or down key to select the BP type to be stimulated, press "Enter Key" to relevant simulation interface. As a shortcut,you can use number key to select the BP type to be stimulated quickly. In each simulation interface, press "Enter Key" to select cuff type, and up or down key to select different simulated BP values.

Notice: When performing BP simulation functions, make sure to select proper cuff type to avoid working abnormally.

Optional cuff types for different BP simulations:

- Standard BP : Internal Adult Cuff or External Cuff
- Patient Conditions BP :Internal Adult Cuff or External Cuff
- Arrhythmias BP :Internal Adult Cuff or External Cuff
- Respiratory Artifacts BP :Internal Adult Cuff or External Cuff
- Neonate BP:Internal Neonate Cuff
- Wrist BP :External Cuff
- User-Defined BP :Internal Adult Cuff ,Internal Neonate Cuff or External Cuff

When using external real cuff,measurement consistency depends on the air volume stored in the cuff, so the consistency will always be influenced by the wrapping objective and degree of tightness.

There is an air chamber for simulating real cuff inside of the simulator. Internal cuff has a fixed volume (290cc), which is equal to a real adult cuff. Using internal cuff can avoid influence of cuff wrapping, which ensures the simulation accuracy and repeatability during testing process. When using internal cuff can't meet some special requirement, please use external cuff.

■ **Standard BP Simulation**

The simulator provides several groups of standard BP output for NIBP monitor using arm cuff.

Steps for checking NIBP monitor using standard BP simulation:

- 1) Select "**Standard BP**" in "**BP Simulation Menu**" or use number key "**4**" to the standard BP simulation interface shown as Figure 16.

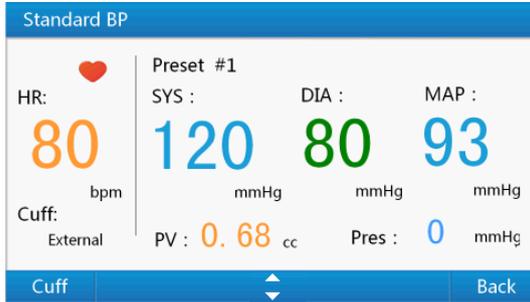


Figure 16 Standard BP simulation interface

- 2) Press "**Enter Key**" to select internal adult cuff or external cuff.
- 3) Use up or down key to select the stimulated BP value.

Seven groups of simulated standard BP are showed in the following table:

| Standard BP | BP(mmHg) SYS/DIA(MAP) | HR(bpm) | PV(cc) |
|-------------|-----------------------|---------|--------|
| 1 | 120/80 (93) | 80 | 0.68 |
| 2 | 150/100 (116) | 80 | 0.65 |
| 3 | 200/150 (166) | 80 | 0.60 |
| 4 | 255/195 (215) | 80 | 0.55 |
| 5 | 60/30 (40) | 80 | 0.75 |
| 6 | 80/50 (60) | 80 | 0.71 |
| 7 | 100/65 (76) | 80 | 0.69 |

- 4) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 5) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ **Patient Condition**

The simulator can simulate BP output under some basic patient conditions.

Steps for checking NIBP monitor using patient condition BP simulation:

- 1) Select "**Patient Condition**" in "**BP Simulation Menu**" or use number key "**5**" to the patient condition BP simulation interface shown as Figure 17.



Figure 17 Patient condition BP simulation interface

- 2) Press "**Enter Key**" to select internal adult cuff or external cuff.
- 3) Use up or down key to select the simulated BP value.

Eight groups of simulated patient condition BP are shown as the following table:

| Patient conditions | BP(mmHg) SYS/DIA(MAP) | HR(bpm) | PV(cc) |
|--------------------|-----------------------|---------|--------|
| Healthy heart | 120/80 (93) | 75 | 0.68 |
| Weak pulse | 110/80 (90) | 95 | 0.50 |
| Mild exercise | 140/90 (106) | 120 | 1.00 |
| Strenuous exercise | 140/90 (106) | 162 | 1.40 |
| Obese patients | 120/80 (93) | 90 | 0.50 |
| Geriatric patient | 150/110 (123) | 95 | 0.40 |
| Tachycardia | 120/105 (110) | 130 | 0.40 |
| Bradycardia | 120/60(80) | 45 | 1.10 |

- 4) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 5) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ Arrhythmia

BP output in Arrhythmia state may cause fault results for some NIBP monitors.

Steps for checking NIBP monitor using arrhythmia BP simulation:

- 1) Select "**Arrhythmia**" in "**BP Simulation Menu**" or use number key "**6**" to the arrhythmia BP simulation interface shown as Figure 18.



Figure 18 Arrhythmia BP simulation interface

- 2) Press "**Enter Key**" to select internal adult cuff or external cuff.
- 3) Use up or down key to select the simulated BP value.

Four groups of simulated arrhythmia BP are shown as the following table:

| ArrhythmiaTypes | BP (mmHg) SYS/DIA(MAP) | HR(bpm) | PV(cc) |
|-----------------------------|------------------------|---------|------------|
| Premature Atrial Con. #1 | 138/53 (81) | 80 | About 0.70 |
| Premature Atrial Con. #2 | 144/64 (90) | 83 | About 0.70 |
| Premature Ventricular Cont. | 118/61 (80) | 83 | About 0.70 |
| Atrial Fib and PVC | 139/72 (94) | 91 | About 0.70 |

- 4) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 5) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ Respiratory Artifact

Respiratory artifact BP simulation shows the influence of intrathoracic pressure to BP change in the heartbeat process. Intrathoracic pressure change will affect ventricular filling in diastolic period, thereby affect blood volume pumped by heart.

Steps for checking NIBP monitor using respiratory artifact BP simulation:

- 1) Select "**Respiratory Artifact**" in "**BP Simulation Menu**" or use number key "7" to the respiratory artifact BP simulation interface shown as Figure 19.

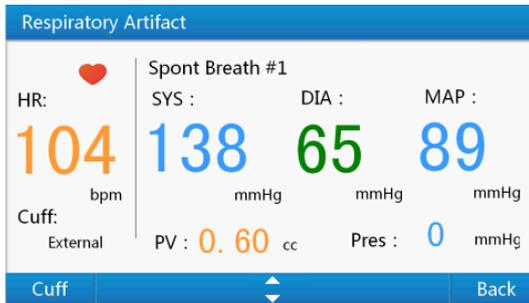


Figure 19 Respiratory artifact BP simulation interface

- 2) Press "**Enter Key**" to select internal adult cuff or external cuff.
- 3) Use up or down key to select the simulated BP value.

Four groups of simulated respiratory artifact BP are shown as the following table:

| Respiratory Artifact Types | BP (mmHg) SYS/DIA(MAP) | HR (bpm) | PV(cc) |
|----------------------------|------------------------|----------|------------|
| Spont breath #1 | 138/65(89) | 104 | About 0.60 |
| Spont breath #2 | 149/65(93) | 105 | About 0.60 |
| Spont breath #3 | 112/47(68) | 86 | About 0.60 |
| Controlled Ventilation | 132/44(73) | 98 | About 0.60 |

- 4) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 5) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ **Neonate**

Neonate BP simulation is used for checking whether the NIBP monitor has the capability of measuring neonate.

Steps for checking NIBP monitor using neonate BP simulation:

- 1) Select "**Neonate**" in "**BP Simulation Menu**" or use number key "**8**" to the neonate BP simulation interface shown as Figure 20.



Figure 20 Neonate BP simulation interface

- 2) Use up or down key to select the stimulated BP value.

Four groups of simulated neonate BP are shown as the following table:

| Neonate | BP (mmHg) SYS/DIA(MAP) | HR(bpm) | PV(cc) |
|---------|------------------------|---------|--------|
| 1 | 35/15 (22) | 120 | 0.11 |
| 2 | 60/30 (40) | 120 | 0.10 |
| 3 | 80/50 (60) | 120 | 0.10 |
| 4 | 100/70 (80) | 120 | 0.10 |

- 3) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 4) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ **Wrist**

The wrist BP simulation is used for checking NIBP monitor with wrist cuff.

Steps for checking NIBP monitor using wrist BP simulation:

- 1) Select "**Wrist**" in "**BP Simulation Menu**" or use number key "**9**" to the wrist BP simulation interface shown as Figure 21.



Figure 21 Wrist BP simulation interface

- 2) Use up or down key to select the simulated BP value.

Three groups of simulated wrist BP are shown as the following table:

| Wrist BP | BP(mmHg) SYS/DIA(MAP) | HR(bpm) | PV(cc) |
|----------|-----------------------|---------|--------|
| 1 | 120/80 (93) | 80 | 0.50 |
| 2 | 160/100 (120) | 80 | 0.50 |
| 3 | 80/55 (63) | 80 | 0.50 |

- 3) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 4) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".

■ **User defined**

The simulator supports nine simulation modes for user-defined.

Steps for checking NIBP monitor using user defined BP simulation:

- 1) Select "**User-Defined**" in "**BP Simulation Menu**" or use number key "**0**" to the user defined BP simulation interface shown as Figure 22.
- 2) Use up or down key to select the simulated BP value.

User can set each group of simulated BP value according to requirement, take the following steps:

In this interface, press right key to the edit interface shown as Figure 22. In edit interface, press left or right key to select the parameter to be edited, use number keys to input parameter and after entering a digit, the cursor will automatically move to next digit for input. After inputting the BP parameter, press "**Enter Key**" to save. In this interface, pressing "**Return Key**" can get back to the user defined BP simulation interface.

Parameters for user-defined and range:

- SYS: 20~300 mmHg
- DIA: 10~250mmHg
- PV: 0.10~2.40 cc
- HR: 30~250 bpm;pulse volume>2.00cc,maximum HR:200bpm

Notice:

When the user defined BP value exceeds the above range, it is thought as invalid, and user needs to set again.

DIA should be smaller than SYS.

PV and HR should not be set to maximum at the same time.

- 3) Press "**Enter Key**" to select internal adult cuff, internal neonate cuff or external cuff.
- 4) Press the start button of NIBP monitor to measure , then compare the simulated BP value of the simulator with the result measured by the monitor.
- 5) After finishing measurement, press "**Return Key**" to "**BP simulation Menu**".



Figure 22 User defined BP simulation interface

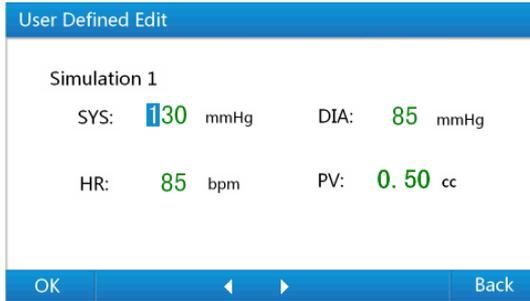


Figure 23 User-defined edit interface

Chapter 6 Cleaning, Maintenance, Transportation and Storage

6.1 Cleaning

Clean the surface of the simulator with a dry, soft cloth soaked in mild detergent periodically.

6.2 Maintenance

- 1) Non-authorized personnel are not allowed to open the enclosure of device to avoid causing damage to the internal components.
- 2) Inspect the device regularly to ensure that there is no obvious damage that could affect safety or performance.
- 3) All maintenance and upgrades must be carried out by professionals trained and authorized by the company.
- 4) Avoid liquid entering the device, which may affect its performance and safety.
- 5) Avoid violent impacts that may cause damage to the device.
- 6) The device has been calibrated before leaving factory. It should be calibrated once a year since the date of leaving factory. The calibration can be carried out by the calibration organizations commissioned by the company or you can contact the company for calibration.

6.3 Transportation and Storage

- 1) The packed simulator can be transported by ordinary conveyance or according to transport contract. The simulator can not be transported mixed with toxic, harmful, corrosive material.
- 2) The packed simulator should be stored in room with good ventilation and without corrosive gases and Temperature: $-20^{\circ}\text{C}\sim+65^{\circ}\text{C}$; Relative Humidity: $<90\%$.

Chapter 7 Questions and Solutions

| NO. | Trouble | Possible Reason | Solution |
|-----|---|--|--|
| 1 | When the simulator is set to a fixed BP value, results measured by the same monitor for several times are different, and sometimes the difference is up to 5mmHg. | <p>The simulator produces consistent and repetitive simulation signal, in ideal condition, the difference between two continuous measurements is no more than 2mmHg. So the difference here is mainly caused by the NIBP monitor.</p> <p>According to relative standards, average deviation between checking system and compare system should be less than ± 5mmHg, and standard deviation should be less than 8mmHg. So 5, 6 even 10mmHg in a test is normal, neither the monitor nor the simulator has problems. Some monitors are more repeatable than others, and repeatability is one measure of the overall quality of the monitor.</p> | Having some difference is normal and acceptable. |
| 2 | When the simulator is set to a fixed BP value, the results measured by different monitors are different, and sometimes the difference is very obvious. | Some monitors were designed to give readings close to those obtained by the auscultatory method of blood pressure determination. Other monitors have been designed to agree with Invasive Blood Pressure readings. It is well known that Invasive and Auscultatory BP readings on the same subject can be quite different. Therefore it is not surprising that automated Oscillometric NIBP monitors using Invasive readings as a reference would give different readings than a monitor based on Auscultatory readings. | Different monitors were designed to agree with different reference data, neither the monitor nor the simulator is broken, or gives fault data. |
| 3 | The simulator can not be turned on. | <ol style="list-style-type: none"> 1.The power cord is not connected to power socket tightly. 2.The fuse is broken. 3.The simulator is broken. | <ol style="list-style-type: none"> 1.Please connect the power cord to power socket tightly.. 2.Replace the broken fuse with accompanying fuse. Method: Pull out the power cord, draw out the fuse cabinet with a screwdriver, take out the fuse with a forceps, replace it, then push the fuse cabinet to original position. 3.Please contact local customer service center. |

| | | | |
|---|--|--|---|
| 4 | When checking the NIBP monitor with the simulator, the monitor inflates again and again, no readings after a long time or the measured results have big error. | <ol style="list-style-type: none"> 1.Select improper cuff. 2.There is leak in cuff, hose, or connectors. 3.The monitor selects wrong measurement mode or the monitor is broken. 4.The simulator is broken. | <ol style="list-style-type: none"> 1.Please check the consistency between selected cuff type of the simulator and the connection way of the simulator and the monitor, if not consistent, please select proper cuff following the user manual. 2.Perform leak test, if there is leak, please connect all joints well or replace the leaking cuff, hose or connectors.If there is leak still, please contact with local customer service center. 3.Select right measurement mode or repair the monitor. 4.Please contact with local customer service center. |
| 5 | After turn on the simulator, it can not enter to main menu. | Zero drift occurs in internal pressure sensor | Please contact with local customer service center, or go to agent consigned to by our company for calibration. |

Chapter 8 Replaceable accessories

- 1) Power cord: meet the standard H05VV-F.
- 2) Fuse: 1.6A, 250V, 5*20mm, glass, quick fuse.

Chapter 9 Symbol Meanings

| Symbol | Meanings |
|---|---|
|  | Caution: read instructions (warnings) carefully |
|  | WEEE disposal |
|  | Serial number |
| SYS | Systolic BP |
| DIA | Diastolic BP |
| MAP | Mean BP |
| PV | Pulse Volume |
| HR | Heart Rate |
| BP | Blood Pressure |
| NIBP | Non-Invasive Blood Pressure |
| bpm | beats per minute |
| — . — — | Waiting for measuring |
|  | Power Off |
|  | Power On |
| min | Minute |
| Exer | Exercise |
| PVC | Premature Ventricular Cont |
| Pre | Premature |
| Spont | Spontaneous |
| Pres | Pressure |
|  | Manufacturer |
|  | Date of manufacture |
|  | Follow instructions for use |
|  | Product complies with European Directive |
|  | Authorized representative in the European community |
|  | Imported by |

Chapter 10 Specification

| Requirement for power supply | |
|--------------------------------------|------------------------------|
| AC 100 ~240 V 50/60 Hz < 60 VA | |
| Fuse | |
| 1.6 A 250 V 5*20 mm glass quick fuse | |
| Dimension and Weight | |
| Dimension | 207(L) × 220(W) × 121 (H) mm |
| Weight | About 2.1 kg |



Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies