# Infusion Pump User Manual

### **Notice**

- On not use the pump in the presence of mixture of flammable anesthesia gas with air, oxygen or nitrous oxide.
- © Please read and understand the user manual before using the pump.
- Please check the parameter setting before starting work.
- © The product performance has nothing to do with gravity.
- When there is air bubble in the tubing between the pump and patient, the air bubble must be cleared away manually.
- Occlusion alarm threshold is influenced by ambient temperature and material of IV set, occlusion alarm may not be accurate when the IV set is of poor quality.
- ©Don not push hard on the contact terminal of the pressure sensor, the pressure sensor may be damaged.
- ©When there are other infusion systems or accessories connected with the IV set of the pump, make sure no air bubble enter, and one-way valve must be equipped with.
- The IV tubing will be clamped automatically by the anti-flow clamp to prevent free flow when the door of the infusion pump is open in single fault state.
- ⊚In actual use, the IV set must be of qualified brand or calibrated, incorrect parameter setting or incorrect choice of IV set may cause flow rate, infusion time and residual volume inaccurate.
- ©The target volume should be close to the actual volume in the container (Usually 15ml less than the actual volume). Otherwise, please use the drip detector to avoid the air bubble alarming when there's no fluid in the tubing.
- ©The last setting of IV tubing type, KVO rate, Purge rate, pressure and IV set brand will be saved as default.
- This product is prohibited for blood infusion.
- ©In actual use, the IV tubing must be loaded in the pump according to correct order and direction, and straightened. Otherwise no medication or overdose flowing may occur, with a result of injury to the patient.
- ⊚When the door or other parts become deformed or damaged, they should be timely replaced with new parts, if not, pump will not work properly, and cause injury to the patient.
- © Check the IV tubing type choice before pressing start key to work.

- ©The battery discharge time are more than 4 hours, but the battery may not work for 4 hours as it will be influenced by run time, operation environment or undercharge.
- © Environmental Protection: when the service life of the equipment and accessories (including battery) expire, please dispose them properly to prevent environmental pollution.
- ©The pump should be fixed with the clamp supplied by the manufacturer or fixed by your own way. In order to avoid injury to the patient due to pump dropping, the pump can not be placed on the flat surface without fence.
- © The pump should be operated only by professional doctor or nurses, incorrect operations may cause injury to the patient.
- © The pump must be well grounded.
- Of the pump fails in actual use, immediately turn the pump off and stop working, timely contact the manufacturer or dealer! In single fault state, the product may infuse no more than 1ml at maximum.

### Attention: marks and their meanings

~	AC	==	DC	<b>*</b>	BF Type equipment
X	Suspend Alarm	巛	Mute	Ŵ	Attention
OFF	Turn Off	ON	Turn On		

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# Chapter 1 Safety Guide

The electrical safety classification of this instrument is Class I, electric shock protection type is BF, it is a internal power supply, continuous operation device. BF type devices are devices with a specific degree of protection against electric shock. B type protection indicates that the patient connection should meet the requirements of permit of leakage current and dielectric strength as IEC60601-1 specified.

# 1.1 Safety Instructions

In order to avoid any possible injury, please abide by the following safety instructions when operating this instrument.

**Warning:** Avoid this pump working in the presence of flammable gases or anesthetic agent, may cause danger of explosion.

Warning: Do not throw the battery into fire, may cause danger of explosion.

**Warning:** SpO2 is used to measure the function, please try to avoid intravenous fluids on the same side body, may lead to blood backflow or SpO2 measurement results inaccurate.

Caution: This instrument must be serviced by authorized qualified engineer.

**Caution**: This instrument is designed for continuous operation, IP rating is IPX1, anti-drip device, avoid being splashed by water.

**Caution**: Keep instrument clean, avoid shaking.

**Caution**: Avoid high-temperature sterilization or electron beaming, γ radiation sterilization.

**Caution**: Avoid this pump working in the environment with high-frequency interference devices, make sure it is not interfered by the strong electromagnetic interference, such as

radio transmitter, mobile phone.

**Caution**: Make sure this instrument is in good condition before use. Routine inspection should be performed every one month or shorter than that. If there's obvious damage on the instrument, please replace broken parts before use.

**Caution**: The following safety inspections must be performed by well-trained persons who have related knowledge and practical experience usually once every two years or according to the regulations specified by public institutions.

Inspect if there's mechanical or functional damage on the instrument.

Inspect if the safety labels are legible.

Verify the instrument functions are still the same as the user manual describes.

**Caution**: Expired products should be disposed according to discarding standard of electronic products or returned to the manufacturer for the purpose of recycle.

**Caution**: Expired battery should be properly disposed according to related standard.

**Caution**: Keep away from the patient when replacing battery (around 1.5 meters away from the patient).

# **Chapter 2 Brief Introduction**

# 2.1 Overview & Working Principles

This pump is a drip type infusion pump, a high-precision intelligent pump which is capable of accurately controlling the delivery rate of disposable IV set and monitoring the infusion course, by means of sensors and microprocessor accurately controlling precise stepper motor, driving transmission mechanism to drive peristaltic fingers regularly squeezing the IV tubing against the backplate.

Standard disposable sterile IV sets of qualified brand (hereinafter to be referred as IV set) is suitable for this pump, the calibration function makes IV sets of any brand is suitable for this

pump. This pump has various sound and light alarm function, so that the user can make timely response to the pump to ensure the infusion is safe. It is specially suitable for clinical treatment which require continuously and precisely controlling infusion at a constant rate, meanwhile, monitoring the infusion course. It is widely used in internal medicine, surgical, paediatrician, obstetrics, ICU, CCU wards, operating rooms and other clinical infusion treatment (but does not apply to blood infusion).

### 2.2 Features:

- ♦ 4.3" LED screen with 272×480 display, more clear.
- ♦ With heating function, suitable for infusing in winter.
- ♦ Optional function: NIBP and SpO2.
- ♦ Simple and convenient in operating, intuitive presence of working status.
- ♦ A variety of visible and audible alarm, make infusion more safety.
- Drug library with 210 kinds of medicine.
- ♦ Storage 1500 history events.
- Multi-language support.

# 2.3 Specifications:

- → Adjustable Drop Rate Range: 1~400 drops/min (step: 1 drop/min).
- ♦ Adjustable Volume Rate Range: 1~1200 ml/h (step: 0.1 ml/h)
- Flow Precision: within ±3% (using the IV set appointed by the manufacturer or calibrated high quality IV set) Mechanical precision: within ±2%.
- ♦ Purge Rate: 800 ml/h
- ♦ KVO Rate: 1 ml/h (less than 100 ml/h); 2 ml/h (100~300 ml/h);
  3 ml/h (greater than 300 ml/h);
- $\diamond$  Infusion Volume Range: 1 ml $\sim$  9999.9 ml (step: 0.1 ml)

♦ Maximum Accumulated Volume: 9999.9 ml (step: 0.1 ml)

♦ Time Range: 1 min ~ 9999 min (step: 1 min)

♦ Occlusion Alarm Threshold:

High:  $800 \text{ mmHg} \pm 200 \text{ mmHg} (106\text{kPa}\pm26.7\text{kPa})$ 

Medium:  $500 \text{ mmHg} \pm 100 \text{ mmHg} (66.7\text{kPa}\pm13.3\text{kPa})$ 

Low:  $300 \text{ mmHg} \pm 100 \text{ mmHg} (40.7\text{kPa}\pm 13.3\text{kPa})$ 

Alarm: Infusion Complete, Empty, Faulty Signal, Misoperation, Occlusion, Door Open, Air Bubble, Low Battery, Setting Error, AC power off, Idle.

♦ Air Bubble Detector:

method: ultrasonic wave, sensitivity: ≥25µL.

♦ Power Supply:

AC 85~265V, 50/60Hz;

Internal Battery: 11.1V rechargeable li-ion battery. Capacity: ≥2000mAh; the pump can work more than 4 hours at the flow rate of 25 ml/h after charging for 8 hours (Medium rate specified by GB 9706.27-2005).

♦ Power: ≤40VA

♦ Size: 188 mm(L)×198 mm(W)×228 mm(H)

♦ Weight: 2.2kg

♦ Environment Requirements:

Conditions	Transport	Storage	Operation
Ambient	-30℃ ~+55℃	-30℃ ~	+5℃ ~
Temperature		+55℃	+40℃
Relative	20% ~ 95%	20% ~	20%~90%
Humidity	(non-condensing)	95%	
Atmosphere	70kPa∼106kPa	70kPa $\sim$	86kPa $\sim$
Pressure		106kPa	106kPa

### ♦ IV Set:

Disposable IV set of any brand is suitable for this pump, IV set of new brand should be calibrated to ensure the infusion accuracy.

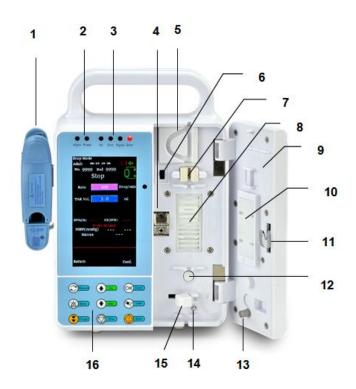
Note: 1)The IV set should be suitable for being sterilized by ethylene oxide, and conform to  $\langle GB 8368-2005 \rangle$  disposable IV set, gravity type  $\rangle$ ; the IV tubing should be made of good elastic PVC materials, the wall thickness of the tubing should be  $0.4\sim0.6$ mm; the IV tubing

made of latex or silicone materials is not suitable for this pump, it may cause abnormal flow rate, incontrollable infusion, tubing breakage, and other possible dangers.

- 2) The maximum actual flow rate is influenced by IV set elasticity, quality, parameters and run time, so it may not reach 1200 ml/h, but at least 600 ml/h.
- 3) The flow rate accuracy varies with the manufacturer of IV set, operation ambient temperature, run time, concentration of medication and other factors, so the IV set should be calibrated before use.

# **Chapter 3 Structure and Components**

# 3.1 Appearance



3-0

1—Drip Detector 2—Display 3—Alarm Light

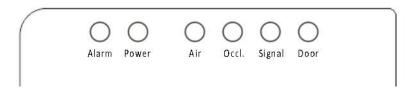
4—Door Lock Base 5—Heater 6—Heater Switch

7—Air Bubble Detector 8—Peristaltic Fingers 9—Door 10—Backplate 11—Door Lock Hook 12—Pressure Sensor

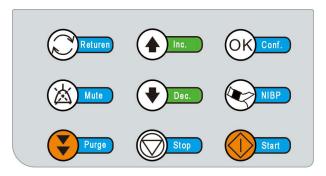
8

13—Anti Flow Clamp Reseting Pin 14—Anti-flow Clamp Reseting Axle 15—Anti-flow Clamp 16—Keyboard

# 3.2 Alarm Light and Keyboard



Alarm Light 3-1



Keyboard 3-2

# 3.3 Keys Instruction

**Return Key** ——Press this key to back up one level to the previous menu.

**Mute Key** — Press this key to clear the alarm arising in pump working, then switch the pump to parameter setting interface. Otherwise, alarm will reoccur in 2 minutes if there is no action.

**Purge Key** — In non-working status, press this key, *F-F* will blink on the display, the pump begins purging if pressing the key again within 3 seconds and holding it, purging stops after the key is released, and the pump returns to the parameter setting status; the pump exits from purging if not pressing the key again within 3 seconds, *F-F* disappears.

**Increase Key** — When the cursor stays at the parameter option, press this key to adjust, press and hold it to make the value increase rapidly.

**Decrease Key** — When the cursor stays at the parameter option, press this key to adjust, press and hold it to make the value decrease rapidly.

In infusing status, press this key, *F-F* will blink on the display, the pump begins *Purge Infusing* if pressing the key again within 3 seconds and holding it. The pump returns to normal infusing status after the key is released.

**Stop Key** — **In infusing status**, press this key to stop working, the pump returns to parameter setting status.

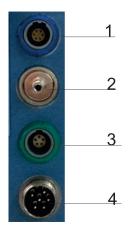
Confirm Key —— Special design to avoid misoperation: when adjusting *IV Set* tubing type and *Accuracy* Calibration, you must press *Confirm* key after parameter option is selected. Otherwise, *Increase* and *Decrease* key are not workable

Press this key to clear the alarm arising in pump working, the pump returns to parameter setting interface.

NIBP Key ——Start Key —— Press this key to begin measurement SpO2 for patient.

Start Key —— Press this key to begin infusing.

### 3.4 Back Interface



Back interface 3-3

1-SpO2

2-NIBP

- 3- Drip Detector
- 4-Communication (obligate)

# **Chapter 4 Installation and Operation**

### 4.1 Installation

Fix the infusion pump to the IV pole at a proper height by clamp. The pump should be equipped with stable IV pole. The pump must be fixed to the IV pole, putting it on the table or patient bed is prohibited. Make sure it is firmly fixed before actual use.

# 4.2 Starting

AC power light will be on after AC is connected, press the switch at the rear of the pump to **on** position, parameter setting interface appears on the display.

**Note:** if AC is not connected, the pump is powered by internal battery when turning the pump on.

# 4.3 Load, Purge, Replace IV Tubing

- 1) Hang the infusion bottle (bag) on the IV pole, the infusion bottle (bag) should be around 20cm to 80cm higher than the heart of the patient, then connect the IV set to the infusion bottle (bag).
  - 2) Close the flow regulator, extrude fluid in the drip chamber until 1/2 left.
  - 3) Open the flow regulator, expel the air from the IV tubing, then close the flow regulator.
  - 4) Pull the door lever up, open the door, load the IV tubing from top to bottom through air

bubble detector, peristaltic fingers, anti-flow clamp slot (*move the anti-flow clamp to the left*), finally the tubing comes out from the groove of the pump outer shell.

- 5) Pull the door lever up, then make the hook capture the Door Lock Base, press down the door lever, the door is well locked if it is aligned with outer shell in the same vertical plane, then open the flow regulator.
- 6) Purge: press this key, *F-F* will blink on the display, the pump begins purging if pressing the key again within 3 seconds and holding it, release it until the air is expelled from the tubing and fluid drips out from the needle, stab the needle into vein (artery) of the patient, then infusing begins.
- 7) The continuous use time of IV tubing: according to the instruction of IV set manufacturer, another section of IV tubing which is not squeezed should be moved to the peristaltic fingers after  $4\sim5$  hours continuous use (*please stop infusing when doing this*). After being squeezed for some time, the IV tubing may cause inaccurate flow rate, or the IV tubing may be broken, result in fluid leakage, air bubble and other dangers (such as medicine pollution). Therefore, please replace the IV set with new one after 12 hours continuous use.
- 8) Replace the IV tubing: after infusion completes, or press **Stop** key, then close the flow regulator to avoid free flow. Unload the IV set, then replace it with new one following step  $1)\sim6$ )

### Note:

- (1) Prevent overflow: to prevent overflow, keep the mouth of infusion bottle vertically upwards when stabing IV set into the bottle or pulling out from it.
- ② Prevent free flow: after purging the tubing, to prevent free flow of fluid, make sure the flow regulator closed until the door is locked. Open the flow regulator after the door is locked, no fluid will drips out from the needle or the orifice of the drop chamber, otherwise, stop working and check it.
- ③ When occlusion occurs, do not use purge function of the pump, please purge manually.

Make sure the drip chamber is located between the infusion bottle (bag) and the pump, the flow regulator is located between the pump and the patient, please open the regulator before starting the pump.

Do not place the squeezed section of IV tubing in the air bubble detector, it will cause false occlusion alarm.

In the interior of the pump, straighten the IV tubing in the direction of the arrow. The drip chamber should be vertical to avoid air entering into the tubing.

# 4.4 Install Drip Detector

- 1) In rate mode, the drip detector must be installed. It should be located between the orifice and the fluid level of drop chamber, that is, the bottom of the detector should be higher than the fluid level, the top of the detector should be lower than the orifice. Keep the detector vertical, make sure the fluid drips through the detecting area of infrared.
  - 2) The way to make sure the drip detector is properly installed:

Imitate fluid dripping by sweeping your finger through the detecting area of infrared, the drip indicator light will blink once while each sweeping, otherwise, it means that the drip detector goes wrong.

When the pump is working, the drip indicator light will blink once while each dripping, no blink or more than once mean the drip detector is incorrectly installed or goes wrong.

### Note:

- ① In non-rate mode, the drip detector is not required, but the IV set must be calibrated, and set the accuracy and target volume. Otherwise, the ambient temperature must be ≥18°C, and the requirement of infusion accuracy is not within 10%.
- ② Keep the detecting area of infrared away from direct light, direct sunlight shining on the drip detector is prohibited.

③ Keep the drip detector vertical downwards, no signals or abnormal signals will be

detected if the detector is inclined, and cause sound and light alarms.

4 Make sure the detecting area is not blocked by fluid in the drip chamber or drops on

the wall of the drip chamber. Please timely clean the detector if there is fluid and foreign

matter on it.

4.5 Infusion Mode

1) Turn the pump on, last infusion mode and flow rate are displayed as default.

2) Flow Rate blinks, then press **Select** key to move the cursor to Mode option.

3) Press *Increase* or *Decrease* key to select mode when the cursor stays at *Mode* option,

press **Select** key to move the cursor to parameters option under this mode.

(1) R Mode: rate mode

The rate unit in this mode is drop/min, press **Start** key to begin infusing after flow rate is

set and drip detector is install correctly. When infusion volume set to "----" mean not limit

infusion volume.

**Note:** make sure the drip detector work well under *R mode*.

2 V Mode: volume mode

The rate unit in this mode is ml/h, press **Start** key to begin infusing after infusion volume

is set. When accumulated volume amounts infusion volume of set, the pump will auto enter

KVO mode and issue alarm.

(3) **T Mode**: time mode

The user free set infusion time, infusion volume, system is automatically to calculate the

infusion rate, speed rate range is 1-1200 ml/h, when infusion volume of set is overlarge and

leads to speed rate overstep this range, the system will automatically change the infusion

time, to ensure the speed rate within this range.

Press Start key to begin infusing after the infusion mode and parameters are set.

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Press **Stop** key if you want to return to the setting interface.

**Note:** when change the time, if appearance the time cannot increase or decrease, this belongs normal, not equipment appear problem, it is in order to ensure that the speed of the user settings within the valid range.

### 4.6 Infusion Parameters Setting

Under the infusion interface, press the Increase or Decrease to move the cursor to the needed options (the background color of selected option for the pink, not the selected option for the blue), press the Confirmation key from the selected state into a state can be setup, can change the parameter values according to **Inc.** or **Dec.** key, now the "**Return**" of the screen at the lower left corner is change into "**Step**", and followed shows step value, press the Return key can changes step values (step can be set for x1, x10, x100, x1000, x10000). Respectively shows the parameters of the current parameter values increase or decrease for its minimum increment of 1 time, 10 times, 100 times, 1000 times, 10000 times. (Each parameters level step please refer to the specifications of 2.3)

# 4.7 Drug Library

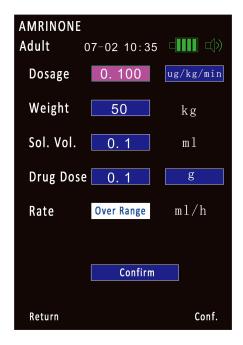
The equipment built in Cardiovascular, Respiratory System, Antibiotic, Antiviral, Digestive System, Nervous System, Painkillers, Urinary System, Hematologic System, Endocrine System, Anesthetic, muscle relaxant, Antispasmolytic etc. 13 categories of more than 210 kinds of drugs for the user to choose, if the user failed to found needed drugs in 210 drugs within this equipment, the user can select defined.

### 1) Drug Selection

Turn the pump on, press **Inc.** or **Dec.** move the cursor to "Drug Library", press **Conf.** key to enter selection interface of drug species, according to clinical need to select drug

species, press **Conf.** key enter drug selection interface chooses drug, then press **Conf.** key enter drug library parameter setting interface.

### 2) Drug Parameter Setting



Drug parameter setting 4-1

Dosage: The dose of drug use

Weight: Patient's weight

Sol. Volume: Infusion volume of infusion bag or bottle

Drug Dose: The used drugs dose

**Note:** The values of these parameters must be input according to the actual situation, and selection the correct dose and drug units, and then by the system be automatic conversion to infusion rate.

Dose optional unit: ug/kg/min, ug/kg/h, mg/min, mg/h, mg/kg/min, mg/kg/h, g/h, g/kg/min, g/kg/h, IU/h, U/min, U/h, ml/h, ng/kg/min, ug/h.

Drug optional unit: g, mg, ug, ng, ml, U, IU.

Drug quantity unit and dose unit must be the same type unit, otherwise the rate cannot be calculated, rate of position will display "Unit Error", if the rate of calculation exceed the rate range (1-1200 - ml/h), the rate of position display "Over Range". At this time the cursor cannot move to confirm option, only when the rate of calculation does not exceed rate

range can select confirm option, and then press **Conf.** key, the interface to jump to infusion interface of volume model or infusion rate equal to setting parameters rate of calculation. The drug name be showed on the left upper corner of screen, press the **Start** key begin infusion.

After drug library parameter set, only can temporarily keep, it will automatic recovery default values after the reboot.

# 4.8 History

This pump can store 1500 events, the content of the records according to the time arrayal, convenient for users to view.

```
History
Adult
           07-02 10:35
Start Time
              2014-07-02 11:58:20
End Time
              2014-07-02 12:08:20
NIBP (mmHg)
                      0/0
SP02 (%)
                        0
HR (BPM)
                        0
Mode
                   Volume Mode
Rate (m1/h)
                       Drop/min
                     110.0
TAT Vol. (m1)
Drug
                 0.000 \text{ g/kg/h}
Dosage
                    Occlusion
Status
                      0.0
Bolus (m1)
 Return
                              Conf.
```

Record Content 4-2

#### Note:

- ① Only the function of SpO2 and NIBP be used in the infusing process can display the record of SpO2 and NIBP. (When using the function of SpO2 and NIBP alone, there will be no record)
  - ② For the record of drug name and dose only after select drugs and work.

3 State records the status when infusion stopped, including: stopped manually, alarm and infusion completed etc.

# 4.9 NIBP & SpO2(Optional)

SpO2 and NIBP functions including: NIBP saturation (SPO2) and non-invasive measurement of SpO2 (NIBP). This function is suitable for adult, children and neonatal baby. It is under in time mode, volume mode, rate mode or calibrated interface can be used. In the using process could not return to the superior menu, otherwise the pump will automatically stop the SpO2 and NIBP measurement.

# 4.10 SpO2(Optional)

### 1) What is SpO2

SpO2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO2 oxygen saturation of 97%. The SpO2 numeric on the monitor will read 97%. The SpO2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

- 2) How the SpO2 / PLETH Parameter Works
- ① Arterial oxygen saturation is measured by a method called pulse oximetry. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.

The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW.

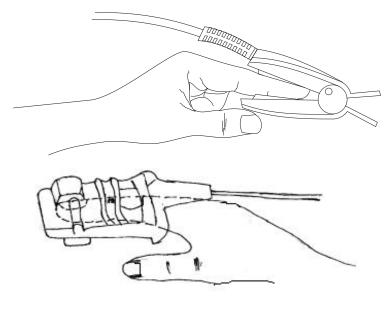
- ② The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.
  - ③ The SpO2 value and the PLETH waveform can be displayed on the main screen.
- 4 SpO2 in this manual means physiological function NIBP saturation measured through non-invasive method.
  - 3) Operating Method for SpO2
- ① Turn the pump on, enter the random mode, time mode, volume mode, rate mode or calibration mode.
  - ② Attach the sensor to the appropriate site of the patient finger.
  - ③ Plug the connector of the sensor extension cable into the SpO2 socket on the pump.

### Note:

- ① If COHb exists, MHB or dyeing dilution chemicals, there will be windage for SpO2 value.
- ② If measures part and probe cannot be positioned accurately, it may cause in inaccurate reading of SpO2, even pulse wave cannot be searched for monitoring NIBP. At the time, repositioning is required.
- ③ Excessive moving of the measured part may cause in inaccurate measurement. At the time, the patient should have been calmed or place onto a new position to reduce influences to measurement by excessive moving.
- 4 During the course of long term and continuous monitoring, peripheral circulation status and skin status should be checked once every 2 hours. If bad changes found,

measuring position should be changed timely.

During the course of long term and continuous monitoring, it is required to regularly check the position of probe to prevent moving of the probe from influencing the accuracy of measurement.



4) Limitations for Measurement

In operation, the following factors may affect the accuracy of NIBP:

① High-frequency electrical interference, including interference created by the host system, or interference from external sources, such as electrosurgical apparatus connected with the host system.

4-3

- ② Do not use oximeters and oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
  - ③ Intravascular dye injections
  - Over frequency movements
  - (5) Sensor is not positioned in a right place
  - 6 Sensor temperature (maintain between 28°C and 42°C for best operation)
  - 7 Sensor is positioned on the arms with NIBP cuff, arterial duct or internal duct.

- 8 Concentrations of Non-functional hemoglobin, such as COHb and MetHb
- - 10 Venous pulsations
- ① It is recommended to use SpO2 sensors described in chapter Accessories and Ordering Information.

# 4.11 NIBP(Optional)

NIBP is measured with oscillometry. It can be used on Adult, Pediatric and Neonate baby.

**Basic Parameter:** 

Overvoltage protection:

Adult 280 mmHg±10 mmHg

Children 237 mmHg±3 mmHg

Newborn 147 mmHg±3 mmHg

Timeout value: Adult blood pressure exceed 200mmHg: 120s,

Adult blood pressure below 200mmHg: 90s;

Neonate: 90s.

	mmHg	SYS	DIA	Mean
M	Adult	40~270	10~215	20-235
Measurement Range	Pediatric	40~200	10~150	20~165
	Neonatal	40~135	10~100	20~110

There are three modes of measurement available: manual, automatic and continuous.

Each mode displays the diastolic, systolic and mean SpO2.

- In the MANUAL mode, only one measurement is conducted for each time.
- In the AUTO mode, the measurement is cycled; you can set the interval time to 1/2/3/4/5/10/15/30/60/90/120/180/

240/480 minutes.

■ In the continuous mode, the monitor measures the SpO2 as many times as possible in five minutes.

#### Note:

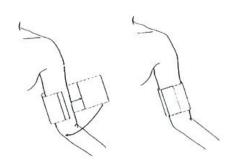
- 1 You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.
- ② For a thrombasthemia patient, it is important to determine whether measurement of the SpO2 shall be done automatically. The determination should be based on the clinical evaluation.
- ③ Ensure that the correct setting is selected when performing measurements on children. It may be dangerous for the children to use an over pressure level.

# 4.12 Operate Method of NIBP

### 1) NIBP Measurement

Make sure that the air conduit connecting the SpO2 cuff and the monitor is neither blocked nor tangled.

- 1) Plug the cuff tube in the NIBP socket interface and switch on the system.
- ② Apply the NIBP cuff to the patient's arm or leg following the instructions below (Figure 11 3).4-4
  - ③ Press NIBP key begin measurement.



Applying Cuff 4-4

#### Note:

- 1) Ensure that the cuff is completely deflated.
- ② Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.
- ③ The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.
- 4 Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:
- If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.
- If it is placed lower than the heart level, deduct 0.75 mmHg (0.10 kPa) for each inch of difference.

Size of reusable cuff for neonate/children/adult

Patient Type Limb perimeter		Cuff width	Hose
Child	(18-26) cm	10.6cm	1.5m-3m

Adult 1	(27-35) cm	14cm	1.5m-3m
Adult 2	(33-47) cm	17cm	1.5m-3m
Leg	(46-66) cm	21cm	1.5m-3m

### 2) Measurement Limitations

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

In operation, below factors may be effect the accuracy of SpO2:

- ① Patient Movement: Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.
- ② Cardiac Arrhythmia's: Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.
- 3 Heart-lung machine: Measurements will not be possible if the patient is connected to a heart-lung machine.
- ④ Pressure Changes: Measurements will be unreliable and may not be possible if the patient's SpO2 is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.
- ⑤ Severe Shock: If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

6 Heart Rate Extremes: Measurements cannot be made at a heart rate of less than 40 bpm and greater than 240 bpm.

# 4.13 Setting

Setting: Language, basic parameter, calibration, NIBP&SPO2

### 1) Setting Language

Press SET key, move the cursor to language setting, press Conj. Key to set language, choose the needed language then press Conj. System will be restart and change to the needed language.

### 2) Setting basic parameter

Users can set Alarm, Warning Volume, Date, Time, Dept., Bed, Heat Temperature, IV set, Occlusion level and Accuracy in basic parameter interface.

Temperature Ranges from 25-50  $^{\circ}$ C, Occlusion Level of High, Middle and Low. Accuracy range from  $\pm$  35%. The machine will choose the corresponding infusion specification according to the IV set.

Setting Date and Time: Move the cursor to date setting, press Conj. Key to set the date and time. Users can set time and time format (yy-mm-dd, mm-dd-yy, dd-mm-yy). Then press Conj. Key to save the modification and return; If you press the Return Key directly, the screen return, but the date setting would not be saved.

### 3) Calibration

Function of Calibration is to calibrate the accuracy of IV set, we need beaker, balance (measure the actual infusion volume) to calibrate. In calibration mode, the constant rate is 100ml/h and unchangeable, infusion volume range is 10ml-550ml. Only the infusion finished, will the calibration setting appears, the cursor stays on calibration setting.

#### Calibration method:

① set the infusion volume, put the needle into beaker, press Start key to infusion. When the infusion finished, cancel the infusion complete alarm, then calibration setting appears.

② Use the balance to weigh the infused volume, input the data, then press Conj. Key to finish the setting, and press return key, it will calculate the infusion accuracy automatically, save the setting and exit the calibration interface, calibration complete.

### 4) Setting NIBP&SPO2

Users can set the Alarm High limits and Low limits of NIBP&SPO2 (optional parameter), Patient type and Working Mode.

Alarm high and low limits: spo2, pulse rate, SBP, DBP. Alarm limits.

Patient type: Adult, Pediatric and Neonate.

Working mode: Auto, Manual mode for 1 mins, Auto 2 mins, Auto 3 mins, Auto 4 mins, Auto 5 mins, Auto 10mins, Auto 15mins, Auto 30mins, Auto 60, Auto 90mins, constant 5mins.

Manual mode: users start to measure SpO2 by themselves.

Auto mode: the machine starts to measure SpO2 at intervals automatically, users can define the time to rework.

Constant mode: machine starts to measure the SpO2 constantly, and will stop until the times up.

### 4.14 Other functions

### 1) Purge

Method: *F-F* will blink on the display screen, the pump begins purging if pressing the key again within 3 seconds and holding it.

The function of Purge is difference in working and non-working status

In working status—it is mainly applied to increase infusion volume temporary, upon the purge finished, the purge volume will be added in total infused volume.

In non-working mode—it is mainly applied to expel the air bubble from the IV tubing and lavage.

### 2) KVO

When infusion completed alarm occurs, KVO function begins to work. It aims to keep

vein open, prevent blood backflow or blood coagulation. For KVO rate, please refer to 2.3.

### 3) Heating function

Heating function is suitable for the following situations: ambient temperature is below 15°C or there is requirement for the fluid medication temperature. The Heating controlling system is optional, it can be set to control the drug's temperature in IV tubing safety.

Turn the pump on, open the door, slide the heating switch to *On* position, *Heating* function begins to work.

Set heating temperature: choose main interface—set—set basic parameter—heat—temperature.

**Note:** the adjustable maximum temperature is  $50^{\circ}$ C, but the actual temperature may not reach the target value because of the factors such as ambient temperature, flow rate and etc.

IV set tubing should be installed at the following groove to heat the temperature. (see as picture 4-5)



Picture 4-5

# **Chapter 5 Alarms**

This device has infusion alarm and NIBP&SPO2 alarm (if it has NIBP&SPO2 function).

### 5.1 Infusion alarm

Infusion complete alarm, Air Bubble alarm, Occlusion alarm, Door open alarm, Empty alarm, Faulty signal alarm, Low battery alarm, AC power off alarm.

1) Infusion complete alarm

When the target volume completed, sound and light alarms occur, the pump switchs to KVO mode, *KVO* would be displayed on the screen.

### 2) Air Bubble alarm

When the air and bubble enter into the tube and go through the bubble detector, the pump stops to infuse, bubble alarm light on and audible alarm occurs, wrong hint displays on the screen. The pump begins to re-infuse until the air bubble is eliminated.

**Note**: The pump will not detect the air bubble when it stops infusing, you can eliminate the air bubble by pressing purge button, but be sure the IV set is not connected to human body.

### 3) Occlusion alarm

In working mode, when the needle or IV set are occluded, occlusion alarm light on, visible and audible alarm occurs, the pump stops working, solve the fault or press Mute button to clear the alarm. The threshold and trigger time of occlusion alarm depend on occlusion pressure, flow rate, the hardness of the IV tubing and the blocked section of the IV tubing. For pressure levels of occlusion alarm, please refer to *Chapter 2.3 Specifications*. When the pump runs at medium rate (25ml/h) and lowest rate (1ml/h), the trigger time is shown as the Chart 1. Select a proper pressure level according to the actual situation after clearing the occlusion fault. The maximum infusing pressure of the pump is 150kPa.

Flow Rate	1 ml/h		25 ml/h	
Pressure Level	low	high	low	high
Trigger Time	1 h	2 h	5 min	5 min

Chart 1

### 4) Door Open Alarm

In working mode, pump stops infusing when the door is open. Alarm light and Door light on and with audible alarm. In non-working mode, only the door light on when door is open, it will not have audible alarm. Infusion pump cannot to infuse if the door is open.

### 5) Empty Alarm

In rate mode, the pump stops working when the infusion bottle becomes empty, occlusion occurs or the drip detector detects no signals. *Empty* is displayed, sound and light alarms occur. Press *Mute* key to clear the alarms, press *Confirm* to return to main

menu. Continue to work after replacing with new medication or clearing the fault.

Note: Empty alarm will only be occurred in Rate mode.

6) Faulty Signal Alarm

In rate mode, the pump stops working when the drip detector fails or the detecting area is blocked, sound and light alarms occur, alarm light and signal light on. Clear the alarms,

restart the pump and the pump continues to work.

7) Low Battery Alarm

When the battery is low, the battery icon will blink intermittently in red, and the pump gives intermittent sound alarm. Press *Mute* key to clear the alarm, the pump usually can work for 30 minutes at the rate of 25ml/h. The pump will stop working at least 3 minutes before the battery is exhausted. The pump must be connected with AC power to continue to

work.

**Note**: After connected to AC power, the **Power** light on and the battery starts charging.

8) AC power off alarm

The **Power** light will be off and pump will give sound alert when AC is not connected.

The battery icon displays the current power value.

5.2 SPO2 & NIBP alarm

1) SPO2 alarm

Spo2 sensor off alarm: no finger to detect by sensor.

Searching alarm: Module are searching for sensor signal

Ultra limit alarm: When the measured spo2 or pulse rate are higher than the high limit value or lower than the low limit value, the color of measured words would be changed from red words in black background to black words in red background, accompany with audible

alarm and sparking alarm icon.

2) NIBP alarm

Loose cuff alarm: cuff is loose or connected to the machine:

Air leak alarm: valve or air load is leaking;

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Weak signal alarm: patient's pulse rate is weak or cuff is too loose;

Fault air pressure: air pump cannot be opened;

Exceed the limit alarm: patient's SpO2 value exceeds the measure range.

Over exercise alarm: there is too much interference or motion artifact when measuring the signal;

Over pressure protection alarm: pressure of cuff exceeds the normal reach:

Time out alarm: measuring time exceeds the regular time.

### 5.3 Alarm cancellation

When the infusion alarms occurs, press *Mute* button to clear the voice temporary, press *Stop* button to cancel the alarm directly. Alarm would be revived automatically after cancel the alarm for 90 seconds.

When the nibp&spo2 alarm occur, it cannot be cleared by manual operation, press *Mute* button to clear the alarm temporary or the alarm will be relieved after 45 seconds automatically.

**Note**: when occlusion alarm occurs, the device would start infuse again if the alarm is relieved before press *Stop* button to cancel the alarm.

# **Chapter 6: Maintenance**

© The instrument must only be maintained by well trained professionals.

© Do not use benzene, acetophenone or other organic solvents as cleaning agent; wipe the exterior of the pump with a soft cloth sparingly dampened with cleaner, then remove the cleaner with a soft cloth sparingly dampened with water, finally dry the exterior with a soft cloth and place the pump on a dry shelf.

Off the **Power** light is not lit after connecting the pump to external power supply, please contact the manufacturer or dealer for professional repair. Unauthorized repair may cause more damage or danger.

- ©Considering the service life of the components and safety of medical instruments, it is recommended that the service life of the pump do not exceed 7 years. The instrument may become unreliable after 7 years use, which will cause danger.
- ©Unplug the pump before replacing the fuse, the fuse is of fast blow type, specification: F1AL/250V ("F" indicate fast, "L" indicate low breaking capacity).
- Maintenance of Rechargeable Battery:

When the pump is idle, please turn it off, so as to extend the service life and protect the internal battery, avoiding damage to the battery due to excessive discharge.

The inspection of charge/discharge should be performed once a month, so that the battery can power the pump when AC power fails.

Please charge the battery every three months if the pump is in long term idle status, so as to avoid the battery losing capacity due to self discharge.

- ⊚When recovering the pump from long term idle status, please reset the system time, and
  perform the inspection of charge/discharge. The internal battery provides 500
  charge/discharge cycles, contact the manufacturer or dealer if the battery capacity
  obviously decreases or fails to be charged & discharged. Unapproved battery and
  unauthorized repair is prohibited.
- The used disposable IV set should be disposed according to the operating standard of medical wastes.
- Our company can provides upon request the circuit diagram, components list and other materials specified by the standard (GB9706.1-2007 6.8.3C).
- ©The memory chip of this pump can store the data for more than 20 years.
- © Periodical inspection and maintenance should be performed at least once a year.
- This pump from the data of purchasing, our company provides free of replacement within one month and five years warranty if any damage occurred. If product is damaged within one year warranty, it should be send back to our company for maintenance, all the maintenance charge and freight are on our company charge (except the internal battery and if it is damaged artificially).
- ODo not pinch the rubber tube of NIBP cuff
- ODo not allow water or cleaning fluid invade into the coupling socket which is at the rear

end of the infusion pump to prevent damage to the instrument

- When cleaning the device, do not clean the internal of coupling socket, clean the peripheral of it
- © Disposable NIBP cuff must be recycled or disposed appropriately, for environment protection.
- ©Do not sterilize the spo2 sensor by high pressure way, do not immerse the sensor into any fluid.
- ODo not use the sensor if it has symptom of damage or metamorphic.
- © Free maintenance is not suitable for the following situation:
  - 1. Damage caused by fault installation, usage, maintenance and storage of customers;
  - 2. Expire the warranty period;
  - 3. Inconsistence or altered warranty certificate or effective certificate
  - 4. The device is dismantled without the permission of our company;
  - 5. Damage caused by exogenous action;
  - 6. Damage caused in transport and loading for repairing;
- 7. Damage caused by force majeur, such as earthquake, flood, fire, lightning or other uncontrolled natural calamities;
  - 8. Damage caused by other exogenous reasons.

### Note:

- ① If the product has performance problems and hasnot any appearance damage within one month of purchasing date, it can be replaced by an new product in the same model after the confirmation of our technical persons;
- ② Any maintanence caused by fault usage or if the product expires warrenty, all the spare parts cost are on customers' charge.
- 3 The standard maintanence period of internal battery is months according to relevant state regulations, if it expires the warranty period, the replacement cost is on customers' charge.
- 4 Power cable, pachage and appendix( User Manual, Warrenty card, Qualification) are not included in warrenty.

- ⑤ In case of product damage, please package the product appropriately when returning it back to our company.
  - 6 This warrenty is only suitable in China( not including HongKong, Macau and Taiwan)

# **Chapter 7: Trouble Shooting**

Fault	Cause	Solution	
	IV set is incorrectly loaded.	Reload IV set according to	
		the manual.	
Flow rate inaccurate	Drip detector is not installed	Reinstall Drip detector	
Flow rate illaccurate	or incorrectly installed	according to the manual	
	IV set is not calibrated.	Calibrate IV set according to	
	TV Set is flot calibrated.	the manual.	
In switch off status,	IV set is incorrectly loaded.	Readjust IV set.	
drops falls from IV	Or IV set is unqualified.	rreadjust iv set.	
tube	Parts damaged, deformed,	Readjust or replace parts	
	or screw loose.	(Performed by professionals)	

	Battery has been damaged	Charge the battery	
Battery cannot be charg	Built-in battery is not inserted	Insert the built-in battery	
	Low battery	Charging or replace the battery	
Switch on, display is black	System error	<ol> <li>Switch off, restart the pump.</li> <li>contact manufacturer or dealer for repair</li> </ol>	
Abnormal NIBP data	Cuff is leaking	Change the NIBP cuff	
Abiloillai NIBF data	NIBP module is damaged	Change the NIBP module	

	NIBP module is not powered at 12V	Provide the voltage at 12V
	Sensor has been taken off	Connect the sensor to patient's finger
	Sensor is damaged	Change the sensor
SPO2 cannot be	The spo2 socket is not	Connect the cable and
detected	connected properly	socket properly
	Spo2 signal cable is loosening	Re-connect the signal cable
	Spo2 module is damaged	Change the module

# **Appendix A Packing List**

# A.1 Main Unit and Accessories

⊚Main Unit	1	© Heater	1
©Power Cord	1	⊚NIBP cuff(optional)	1
©User Manual	1	⊚Spo2 sensor(optional)	1
	1		