### SH330 Respiratory Tract Humidifier for Medical Use

**Operating Manual Revision F** 

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Revision	Description of Operating Manual Change	Date Issued
А	First release operating manual	2007.6
В	Add 7 Servicing steps Add 9 Environmental Protection Add Appendix A	2011.12
С	Add 3 and 7 Some requirements of 110V voltage	2012.03
D	Chapter 3 Add 3.2b), 3.3, 3.5 and 3.6 Chapter 6 Modify Fig.6-1 Chapter 7 Add 7.7 Chapter 8 Modify the cleaning and disinfection methods Appendix B Add Appendix B	2013.2
Е	Section1.1 Add contraindication and applied part Add 7.8 Troubleshooting Chapter 10 Add transportation environment	2016.8
F	Section 7.6 modify the humidification chamber	2017.4

### Cautions

# Consult accompanying documents.

. **SH330** Respiratory Tract Humidifier for Medical Use (Respiratory Humidifier for short in the following) can only be operated by appointed personnel.

. Take care of explosion-proof. Don't use **SH330** Respiratory Humidifier near flammable anesthetic.

. Read carefully of this manual and all manuals of accessories, attentions and warnings before using. Users must check the safety of this manual to ensure it is in complete and good working conditions.

. Maintenance, covering or random removal of this instrument is prohibited when it is connected with patients.

. Don't open the shell without permission. Internal problem shall be maintained by service personnel authorized by manufacturer.

. Clinic safety has been carefully considered during design, but the operator shall not neglect to observe the status of the instrument and the patient's nursing.

. Take care of the prevention of collision or acute shake.

. Setting the cable and whorl pipe carefully and avoid winding or choking the patients.

. The power cable of **SH330** Humidifier can only be connected to the standard socket in hospital.

. **SH330** Humidifier storage and transportation environment: temperature (-10  $^{\circ}C \sim 50^{\circ}C$ ), RH ( $\leq 93\%$ ), atmospheric pressure (50kPa~106kPa). No corrosion. Any excess may damage the system.

. When voltage fluctuation of mains exceeds 10%, it is suggested to use AC stabilizer.

. Users shall choose the power supply on the nameplate of humidifier.

. The power supply system shall be coincided with the local national electrical safety standards.

#### Symbols:



Type BF



Attention: Consult accompanying documents



Drip proof protection to IPX1





Caution: Hot surfaces may exceed 85℃

Electric Shock Hazard

Date of manufacture



CE marking



Name and address of the manufacturer



Do not discard WEEE collection



Serial Number

LOT Lot Number



### Attentions

Read this manual carefully before use. Follow the operation regulation strictly. Our company guarantees the quality of our products. Customers can put forth any enquiries when you met any problems in operation. We shall provide you the ardent service.

This manual provides all necessary information to meet the requirements of operating **SH330** Respiratory Humidifier.

Don't operate the machine before reading this manual!

In order to operate the equipment conveniently, there will be "attention" "note" "warning" appeared in this manual:

"<u>Attention</u>": To prevent errors in operation.

"<u>Note</u>": Indicate various functions and point out advanced features.

"<u>Warning</u>": Refers to possibilities of danger or equipment damages.

For information support or service please contact the local accredited organizations.

### **<u>Attention</u>**: Only trained personnel can operate this humidifier according to this manual.

<u>Attention</u>: Do not modify the equipment without authorization of the manufacturer.

#### Packing & Transportation:

Move the equipment out of the transport packing and check if it is damaged. If there is any problem please keep all packing materials, bill of lading and other necessary explanatory materials then contact the local dealer in time.

#### Service:

Contact the local dealer for services needed. Before asking service please finish the adjustment operation to confirm the whole machine's status. Please also provide the machine's series number and the details of your problems.

#### Maintenance:

It is suggested that the local accredited professional serviceman perform such maintenance every 12 months.

<b>Company:</b>	Wuxi Jike	Electronics	Co., Ltd.
Company.	vi uni onite	Literionies	

Address:	2 <sup>nd</sup> workshop floor & 3 <sup>rd</sup> office floor of the 4 <sup>th</sup> building,
	NO. 29 Changjiang South Road, New District, Wuxi,
	Jiangsu Province, P. R.China

PC: 214028

Tel: (86)-510-85228335

Fax: (86)-510-85223855

Website: http://www.jike-medical.com

E-mail: wuxijike@sohu.com

Address of Authorized EC Representative:

Name Wellkang Ltd

Suite B, 29 Harley Street LONDON W1G 9QR, England, United Kingdom

Fax: +44(20)76811874

#### 1 Introduction

#### 1.1 Intended Use

**SH330 Respiratory Humidifier** is designed for ventilators or other positive pressure systems to warm and humidify the airflow. The airflow is warmed and humidified by ventilating through the warm water's surface. Reducing the stimulation to the cardiopulmonary system produced by the mechanical ventilation, keeping the pulmonary alveolus moist, being beneficial to sputum aspiration, preventing the airway obstruction. The temperature is regulated by setting up temperature setting button, and it also can be monitored alone.

Good appearance and convenient installation. It's suitable for using with ventilators in all levels of hospital.

The system is intended to be used in a hospital environment by trained healthcare providers. It shall be used on children and adults. It also can be used on the patient whose upper respiratory tract is bypassed.

It is used with ventilators or other positive pressure systems to warm and humidify the airflow.

Contraindication: No

Applied part: all the breathing tubes connecting to the patient port

#### **1.2 Main Functions**

**SH330 Respiratory Humidifier** has 9 steps to control the temperature range with the function of overheating protection.

#### 1.3 Classification

Product safety:	Comply with IEC60601-1&ISO8185
Degree of Protection Against Electric Sh	lock: Type BF
Type of Protection Against Electric Shoc	ck: Class I
Degree of Protection Against Ingress of	Water: Drip-proof IPX1
Protection Against Inflammable Anesthe	tic Gases: no Category AP/APG
Operation Mode:	Continuous Operation
Pollution degree:	2
Overvoltage category:	II
Altitude:	≤2000m

#### **1.4 Structures**

**SH330 Respiratory Humidifier** is hanging basic type and composed of the main frame of humidifier, humidification chamber, adapters, breathing tubes, water traps and thermometer .

#### 1.5 Others

Refer to relevant contents in chapters 2~10 for more details.

#### 2 Working Principle

The schematic figure of the machine is shown in the following:

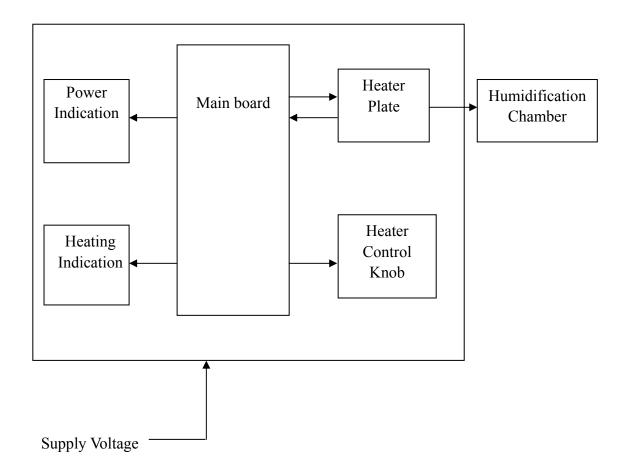


Fig. 2-1 SH330 Respiratory Humidifier

#### **3** Technical Characteristics

3.1	Working condition	
	Temperature	18°C~26°C
	Relative humidity	$\leqslant$ 80%
	Atmospheric pressure	86KPa~106KPa
	Operating gas inlet temperature	18℃~26℃

### <u>Attention:</u> The operating temperature over the recommended one may affect the performance.

#### 3.2 Range of temperature control:

a) Static Temperature Range  $1 \sim 9$  steps (The temperature of chamber water are showed in the following table 3-1)

	Tuble e	1
The position	on of temperature control knob	Chamber temperature
a.1	step 1	45±3℃
a.2	step 2	49±3℃
a.3	step 3	53±3℃
a.4	step 4	57±3°C
a.5	step 5	60±3℃
a.6	step 6	63±3°C
a.7	step 7	66±3°C
a.8	step 8	69±3℃
a.9	step 9	72±3°C

Table 3-1

b) Control Performance of Dynamic Temperature

We get data in table 3-2 under the following test conditions.

Test conditions:

- (1) The testing working Temperature: 18℃~26℃, Temperature of input gas: 18℃~26℃.
- (2) Pipeline requirements:

 $\Phi$  22mm × 60cm +  $\Phi$  22mm × 60cm silica gel tubes, with a water trap between them.

(3) Type of humidification chamber: SH360

 Table 3-2
 Control Performance of Dynamic Temperature

Temperature setting steps	The range of continuous flow	Air temperature control range of the input port of patient
1 step	5L/min~30L/min	24°C~27°C

5 step	5L/min~30L/min	27°C~30°C
9 step	5L/min~30L/min	30°C~34°C

#### 3.3 Humidification system output

### The output shall meet the requirements in table 3-3. Attention: the test condition is the same as the above one.

Table 3-3 system output

Temperature setting steps	The range of continuous flow	Output(mg/L)
1 step	5L/min~40L/min	>10mg/L
9step	5L/min~20L/min	>33mg/L

<u>Warning</u>: The performance of our humidification system will degrade and the output may exceed the requirement of table 3-3, if the flow and temperature exceed the approved ones.

#### **3.4 Electrical ratings**

NO.	Power supply	Fuse capacity
1	110V ~	2A 250VAC
2	230V ~	1A 250VAC
Rated frequency	50/60Hz	
Power input	120VA	
Heater plate capacity	85W	
Heater plate thermal cutou	at $110\pm5^{\circ}$ C	

#### 3.5 Characteristics of the chamber

Max operate pressure	≪6kPa
Pressure drop	< 0.2kPa(the flow is 60L/min)
Max volume	350mL
Adaptability	6mL/KPa~12mL/KPa
Leakage rate	$\leq 10 \text{ mL/min}$

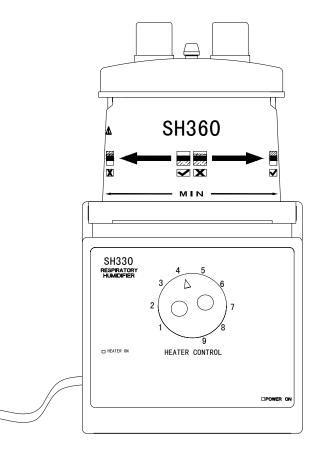
#### 3.6 warm-up time

The time required (warm-up time) for the measured gas temperature to reach the set temperature from a starting temperature of  $(23\pm2)$  °C shall be less than 30min.

#### 4. Weight & Dimensions

Dimensions135mm(W)×170mm(H)×160mm(D) (without chamber fitted)Weight1.2kg (max) (without chamber fitted)2.0kg (max) (with SH360 chamber fitted& filled with water)

#### Fig. 4-1 Front View of Humidifier



#### 5 Equipment Installation & Adjustment

Before starting the system, please keep up the following requirements to ensure the safety of patient, operator and equipment.

### <u>Attention</u>: The working environment for SH330 Respiratory Humidifier shall comply with the following:

	8
Temperature	18℃~26℃
Relative Humidity	$\leqslant$ 80%
Atmospheric pressure	86KPa~106KPa

<u>Warning</u>: The power cable of SH330 Respiratory Humidifier can only be connected to the standard socket of the hospital.

<u>Warning</u>: The storage environment of SH330 Respiratory Humidifier: Temperature (-10 °C ~50 °C), RH ( $\leq 93\%$ ), Atmospheric pressure (50KPa~106KPa), no corrosion, any excess may damage the system.

<u>Attention</u>: When the machine is operated from the storage status to the working status and if the storage condition exceeded the working requirements then it is necessary to check if it is working properly and safely before using.

#### 5.1 Installation site

It is forbidden to use the **SH330** Respiratory Humidifier in flammable or explosive environment. **SH330** Respiratory Humidifier must mate with the ventilator and be operated by well-trained medical personnel.

If the equipment is not working well please don't disassemble or assemble the system rudely. Just mark a warning on it and contact the accredited personnel for maintenance right away.

<u>Warning</u>: The functions of humidifier shall be badly affected when there is high frequency surgical apparatus, shortwave or microwave equipments operating nearby. If it occurs, we shall remove the humidifier away from these devices.

<u>Warning:</u> The performance of the humidification system may be badly affected when the system are exposed to environments of electrocautery, electrosurgery, defibrillation, X ray( $\gamma$  ray), infrared radiation, transient electromagnetic field, including MRI and radio interference. So we shall remove the humidifier away from these environments.

<u>Warning</u>: Mains plug is intended to be used as the isolation means from the supply mains, please don't position the device so that it is difficult to operate the disconnection device.

<u>Warning</u>: The operator or patient may touch the enclosure of the humidifier and chamber, their materials are ABS and PC. They are safe enough to not cause harms to operator or patient.

#### 5.2 **Power supply requirement**

SH330 Respiratory Humidifier must be connected to the power supply with a

3-line protective earth socket, and the earth must comply with the local national regulation. Please check if the voltage at site complies with the rated requirement on the humidifier nameplate or not. **SH330** Respiratory Humidifier is connected with the power supply by its power cord.

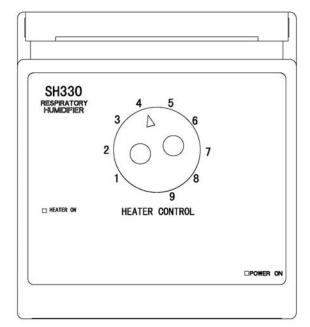
# <u>Warning</u>: Ensure the power supply comply with the requirement on the nameplate, otherwise it will damage the equipment.

<u>warning</u>: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

#### 5.3 Switch system

Connect **SH330** with the power supply, press the power switch and the power indicator light on.

Front panel is shown in figure 5-1.





Power Switch(at the side panel) ON/OFF Switch	"   " means power on; " $\bigcirc$ " means power off
Power Indicator POWER ON	Used to indicate the status of power supply for the whole machine
Heater Indicator HEATER ON	Used to indicate the heating status of heater plate
Heater Control Knob HEATER CONTROL	Revolve the knob to select temperature range

#### 6 Basic Steps

#### 6.1 Make some preparations before opening the machine

# **Warning:** Check accessories for any physical damage before use and replace if damaged.

(1) Fixed **SH330** Respiratory Humidifier on the bracket of ventilators, make sure **SH330** Respiratory Humidifier should be lower than the patient.

(2) Ensure the humidification chamber and connection tubes clean and humidification chamber's bracket correctly installed before using.

(3) Pour water into the chamber between maximum and minimum level.

(4) Lay the humidification chamber on the chamber guard, and press the chamber guard down, then slide the chamber onto the heater plate. They are locked automatically, and the chamber guard will spring up automatically.

<u>Warning</u>: Only use the assorted chamber for this humidifier (the recommended chamber is SH360).

**Warning:** Don't fill the water exceeding the maximum level otherwise the water may spill into the breathing tube and vice versa.

<u>Warning</u>: Don't fill the water exceeding  $37^{\circ}$ C into the humidification chamber.

<u>Warning</u>: Quality water required: The distilled water is available otherwise the machine shall be affected.

(5) Insert the airway adapter into the outlet of the chamber according to the arrow directions on top of the humidification chamber.

(6) Connect the airway inlet, outlet tubes and water trap of SH330 Respiratory Humidifier.

**Warning:** Range the breathing tube to make it collect water and drain out anytime.

Warning: We should not put things on the tubes.

**Warning**: We recommend our assorted chamber, breathing tubes and connectors. The performance and using may be affected when using incompatible breathing tubes and accessories.

<u>Warning</u>: The performance of related machines may be affected or it may damage the machines when using the recommended accessories on other humidifiers.

(7) Insert the thermometer into the airway thermometer adaptor of humidifier. (System connection is shown in fig. 6-1)

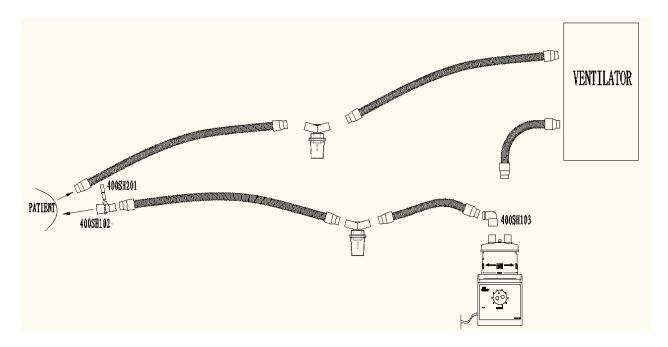


Fig. 6-1 the typical system (two tubes with water traps)

Components in this system:

Humidification chamber: SH360

Respiratory tubes: silica gel tubes, we suggest the length to be 60cm

Adapters: 400SH102, 400SH103

Thermometer: 400SH201

Other accessories: Swivel Y-piece and water trap

We should choose the components according to the practical conditions.

#### 6.2 Basic operation steps

(1) Plug power cord of SH330 humidifier into the required socket.

- (2) Check if power supply is connected.
- (3) Check good earth.
- (4) Check right ventilation circuit.
- (5) Start the ventilator and gas supply to set up a normal application airflow.

Warning: Ensure airflow flowing before connecting the machine with patient.

(6) Press down the power switch at the right side of SH330 humidifier then the "POWER ON" indicator is lit.

(7) Use thermometer to monitor the temperature of output airflow so as to set the heater control.

(8) Turn the "HEATER CONTROL" knob for steps, clockwise means temperature up and anticlockwise means temperature down. Each step adjustment takes about 20 minutes to stabilize the temperature. (9) The "**HEATER ON**" indicator light on when the machine is heating.

(10) When the water level is lower than the minimum one, we should add water into the chamber by using a syringe. Add some water into syringe, open the water feed cap, and add the water into chamber through the water feed hole by the syringe.

(11) **SH330** humidifier must be turned off when the airflow is interrupted or stopped.

Attention: Many operation factors may focus on breathing tubes.

<u>Warning</u>: Don't touch heater plate—the surface temperature may reach  $85^{\circ}C_{\circ}$ 

<u>Warning</u>: Periodically inspect the airflow temperature at patient port displayed on the thermometer .

<u>Warning</u>: Periodically inspect water level in chamber to avoid it too high or too low.

<u>Warning</u>: We should clear the condensate water in water trap in time, or the condensate water may get into the breathing tubes and block the airway.

<u>Note</u>: The temperature of the breathing tube is below  $43^{\circ}$ C.

(12) Disconnect the patient connections, then switch off the power and return the control knob to the position below step 5 after working finished to avoid operating at high steps when opening the device next time. Then disconnect the plug and various connections carefully. Clean and disinfect the whole equipment and accessories then we can use it directly next time.

<u>Attention</u>: Pour out the water in the humidification chamber then clean and dry it after use. Assembly and disassembly methods are shown in 7.6.

#### **6.3 Overheating Protection**

If the temperature of heater plate reached  $110 \pm 5$  °C the overheating protection relay will cut off the power supply of **SH330** humidifier and the power indicator is cut off also. After cooling the overheating protection relay and power supply shall be reset by hand. Refer to 7.4.1 for more details.

<u>Warning</u>: When the unconventionality appears (including out of control or damaged) the overheating protection will just appear. If it appeared when you are using, please contact with the local supplier or our customer service department directly.

#### 7 Service

<u>Attention:</u> the contents of the whole parts are shown in appendix A, the complete exploded view is shown in Fig. A-1.

<u>Warning</u>: Ensure all the screws are fixed tightly on both the inside and outside of humidifier after servicing finished and humidifier being assembled. The humidifier may be badly affected whenever anyone of the screws is loose.

Do not use excessive force when re-fastening screws, in order to avoid permanent damages such as units cracking.

<u>Attention</u>: Because the SH330 humidifier is complex, the electronic parts are especially complicated, if the PCB components are damaged, we recommend users not to maintain it. You should buy another one with the same type to replace it. Or you can send the humidifier to our service department for maintenance.

<u>Warning</u>: we will make available on request circuit diagrams, component part lists and other information that will assist SERVICE PERSONNEL to repair those parts of the device that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

<u>Attention</u>: the service personnel should be trained and written authorized by manufacturer.

<u>Warning</u>: Before service, pull out the mains plug from the main supply socket-outlet.

#### 7.1 Open the shell and remove the PCB

#### 7.1.1 Open the shell

(1) Ensure the mains plug has been disconnected from the wall socket.

(2) Put the humidifier upside down and remove the four screws out of the rear cover.

(3) Separate the front cover of the shell from the rear cover carefully (See the whole exploded view in Fig. A-1).

#### 7.1.2 Remove the PCB

(1) Remove the screw fixed in PCB.

(2) Pull out all the connectors connected to the PCB.

(3) Remove the PCB carefully.

#### 7.2 Replace the Fuses

<u>Warning</u>: Be sure to replace fuses with correct type and rating, specified in table 7-1.

(1) Open the shell (See 7.1.1).

(2) Remove the damaged fuse, replace a new one with the same type then assemble the whole shell.

	1		
Model	Supply voltage	Fuse type	Part number
	110140	F1 2A 250VAC Fast Blow	004 021 104
GU220	110VAC	F2 2A 250VAC Fast Blow	004 021 104
SH330	22014	F1 1A 250VAC Fast Blow	004 021 102
	230VAC	F2 1A 250VAC Fast Blow	004 021 102

Table 7-1 power and types of the replacing fuses

#### 7.3 Replace the PCB

Table 7-2 part number of PCB

Model	Supply voltage	PCB part number
GU220	110VAC	099 024 202
SH330	230VAC	099 024 207

(1) Open the shell.

(2) Disconnect all cables and connecting lines of signal connectors on the PCB.

(3) Unscrew the power cable, remove the wires.

(4) Unpack the replaced PCB and replace it with the type given in Table 7-2.

(5) Reconnect all the cables and connecting lines of connectors.

(6) Install the new PCB and assemble the whole shell.

#### 7.4 Service the heater plate

#### 7.4.1Reset the thermal cutout

# <u>Attention</u>: The heater plate must cool sufficiently before resetting the thermal cutout.

(1) Disconnect the power supply and open the shell.

(2) Put the humidifier upside down, and find out the reset hole. Press the reset

button by a screwdriver (See the whole exploded view in Fig. A-1, A-2).

(3) Assemble the whole shell.

#### 7.4.2Replace the heater plate

Table 7-3 Part number of heater plate

Model	Supply voltage	Heater plate part number
GUIDOO	110VAC	099 018 122
SH330	230VAC	099 018 132

(1) Open the shell and remove the PCB.

(2) Unscrew the three fix screws on the heater plate (See the whole exploded view in Figure A-1, A-2).

(3) Remove the heater plate out of front part of the shell, and be careful not to lose three springs underneath the heater plate.

- (4) Replace the heater plate. The type shall accord with Table 7-3.
- (5) Install the springs and screws, and also the new heater plate.

(6) Assemble the PCB and the shell.

# <u>Attention</u>: If the heater plate partly damaged, it is suggested to replace a complete one.

#### 7.5 Replacing the mains cable

- 1. Open the case.
- 2. Disconnect the ribbon of mains cable on the PCB, open the dark green terminal, and take down the cables (two). Open the earthing screw on the bracket, and take down the earth wire. Open the white fixing piece of mains cable by screwdriver.
- 3. Take the mains cable away from the rear of the case.
- 4. Replace the mains cable; fix it on the bracket by fixing piece. Connect two of the cable to the terminal on PCB. Also connect the earthing cable to the earthing terminal on the bracket. Fix the cable on PCB by new ribbon.

5. Close the case.

<u>Attention</u>: the mains cable can not be disconnected by users, it just be replaced by professional serviceman.

<u>Warning</u>: Replacing the mains cable by a new one which is supplied by the manufacturer.

# 7.6 Assemble and disassemble the subassembly of humidification chamber

#### 1. Disassemble the humidification chamber

(1) Turn off the **SH330** Humidifier and unplug the inlet/outlet tubes connected with the humidification chamber.

(2) Press down chamber guard. Move ahead the humidification chamber and remove it from the mainframe of **SH330** humidifier.

#### 2. Disassemble and assemble the humidification cup

(1) Disassemble the coping from humidification cup by anticlockwise rotation.

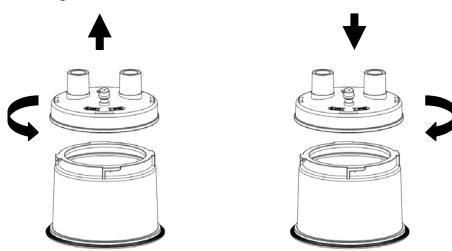
(2) apart the chamber base and humidification cup after holding them with two hands respectively. Or use the small screwdriver to prise the humidification cup out lightly along the edge of the chamber base to make

#### them apart.

(3) After cleaning and drying (if need sterilization, refer to section8.3), press the humidification cup to make the chamber base to the right position.

(4) Assemble the coping with the humidification cup by clockwise rotation.

Fig 7-1 Disassemble and assemble method



Disassemble the coping

Assemble the coping

#### 3. Replace the coping washer of humidification cup.

(1) Disassemble the coping washer from the coping trough when replace the coping washer.

(2) Put a new one into the coping trough then press the coping washer evenly with hand.

#### 4. Replace the "O" circle of chamber base

(1) Disassemble the O circle from the chamber base trough when replace the O circle.

(2) Put a new O circle into the chamber base trough then press the O circle evenly with hand.

#### 7.7 Periodic Safety Checks

The following safety checks should be performed at least every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- \* Inspect the equipment and accessories for mechanical and functional damage.
- \* Inspect the safety relevant labels for legibility.

- \* Inspect the fuse to verify compliance with rated current and breaking characteristics.
- \* Verify that the device functions properly as described in the instructions for use.
- \* Test the protection earth resistance according IEC 60601-1: Limit 0, 2 ohm.
- \* Test the earth leakage current according IEC 60601-1: Limit: NC 500 uA, SFC 1000uA.
- \* Test the patient leakage current according IEC 60601-1: Limit: 10 uA (BF).
- \* Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 60601-1: Limit: 5 mA (BF).

The leakage current should never exceed the limit. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

#### 7.8 Troubleshooting

When trouble occurs, take quick action referring to the table below. If there is any damage or the humidifier is suspected to be faulty as a result of checking, pull out plug from mains socket-outlet, attach an "unusable" or "repair request" label to the humidifier and contact manufacturer or his agent.

Symptom	Corrective Action	Section
The gas was not heated	The heater-wire under the heater	7.4
by the device when	plate breaks, replace the heater-wire	
power button pushed and	or heater plate.	
POWER ON indicator		
and HEATER ON		
indicator are all on.		
The POWER ON	Check the fuse, replace if	7.2
indicator and HEATER	necessary;	
ON indicator are not on,	Check the thermal cut-out tripped,	
also the humidifier don't	reset by hand if necessary;	
work when power button	Faulty PCB, replace.	7.3
pushed.		

#### 8 Cleaning, Disinfection & Maintenance

#### 8.1 Cleaning of Shell

1. Disconnect the power plug.

2, Add domestic cleanser into water. Dip cotton cloth into water. Twist the cloth to make it dry. Then clean the shell with the cloth.

3. Dry the shell with dry cloth.

<u>Attention</u>: Don't use organic benzene, anther, benzene, trichloroethylene etc to clean the shell.

#### 8.2 Cleaning of power cable

1, Disconnect the power plug.

2、Add domestic cleanser into water. Dip cotton cloth、 soft brush into water. Twist the cloth to make it dry. Then clean the cable with the brush and cloth.

3. Dry the cable with dry cloth.

#### 8.3 Cleaning and Disinfection of humidification chamber

1. Take the chamber apart. Add domestic cleanser into water. Dip cotton cloth into water. Twist the cloth to make it dry. Then clean the parts of chamber with the cloth.

2. Dry all the parts with dry cloth.

3. Put all the parts into high-pressure disinfecting boiler (103.4KPa,  $121^{\circ}$ , 15min), disinfecting with high-pressure and high-temperature.

4. After the temperature drops, dry the chamber with dry cloth.

<u>Attention</u>: It is wrong to disinfect all the accessories of humidification chamber when they are bounded together.

**<u>Note</u>**: All the parts of chamber can be disinfected for 100 times.

<u>Attention</u>: The tubes used with humidifier should be cleaned and disinfected by following the manufacturer's requirements.

#### 8.4 Maintenance

Inspect and maintain the equipment & accessories periodically. Ensure the heater plate and chamber base are free from surface contaminations and damages. Heater plate surface can be cleaned by the wet cloth and dried by soft cloth.

#### 9 Environmental protection

The humidifiers are used with ventilators to warm and humidify airflow. It has a certain life just like other medical equipments. If a certain part is determined to be scrapped, it is necessary to reclaim according to local regulations.

#### 9.1 Humidification chamber

As the chamber directly connecting the patient's respiratory tract, it may be infected with special viruses, the waste or trash in the chamber optional discarding may pollute the environment. The users must carry on the normal cleaning and disinfecting, give it to qualified companies to deal with according to the hospital processes.

#### 9.2 The main frame of humidifier

After normal cleaning and disinfecting, the users must refer the humidifier to qualified companies according to abandonment orders of electronic products and hospital processes.

#### **10** Transportation & Storage

Transportation and Storage environment: temperature -10 °C ~50 °C, RH  $\leq$  93%, atmospheric pressure 50kPa ~ 106kPa, no corrosive materials and good ventilation.

Prevent from impulsion, acute shake and moisture during transportation.

<u>Attention</u>: When storage conditions are not satisfied, it is necessary to keep the equipment in working environment more than 8 hours from storage status into working status.

#### Appendix A

A.1 The following tables are the parts number detailed list of replaceable parts of humidifier. The figure is the exploded views of humidifier.

		16	ible A-		
NO.	Part number	name	NO.	Part number	name
1	001 005 003	Chamber	13	006 002 204/	Sticker
		guard		006 002 504	
2	003 008 428	Guard spring	14	099 022 002	Rear case
					assembly
3	003 006 310	Washer	15	004 001 2**	Mains cord
4	003 001 208	Screw	16	001 015 001	Outer bracket
5	003 011 420	Screw	17	003 003 630	Screw
6	001 012 002	Switch	18	003 001 413	Screw
		waterproof cap			
7	099 019 001	Power switch	19	099 024 202/	PCB assembly
		assembly		099 024 207	
8	003 002 412	Screw	20	003 001 210	Screw
9	001 010 001	Mains cord	21	099 021 002	Front case
		presser			assembly
10	003 005 605	Nut	22	003 008 510	Heater plate
					spring
11	002 004 001	Inner bracket	23	090 018 122/	Heater plate
				099 018 132	assembly
12	003 002 616	Screw			

Table A-1

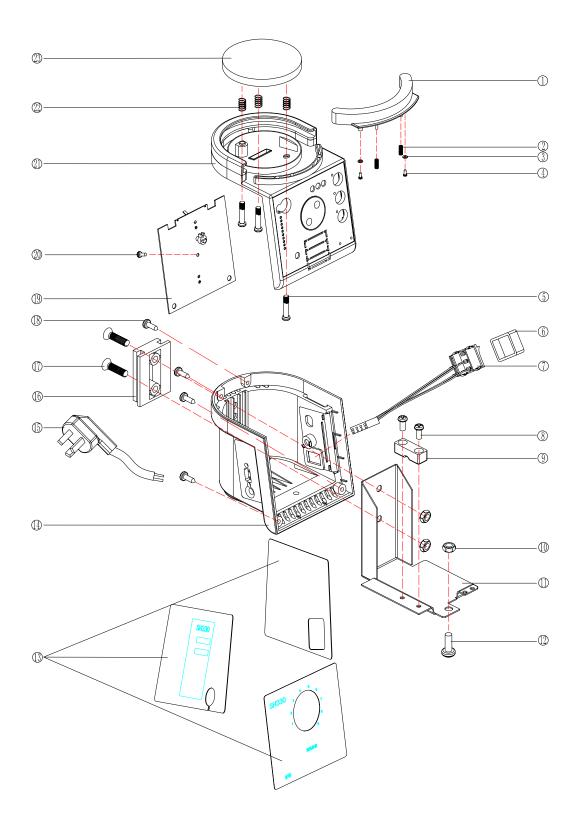


Fig. A-1 The humidifier's exploded view

A.2 The following tables are the parts number detailed list of heater plate. The figure is the exploded views of heater plate.

		140	Ne A-Z		
NO.	Part Number	Name	NO.	Part Number	Name
1	002 003 001	Heater plate	8	004 031 405	Emifil
2	004 005 002	Insulator	9	099 020 003	High temperature
					cord assembly
3	003 010 310	Tubular rivet	10	004 006 002	Thermal cutout
4	004 004 007	Heater wire	11	003 002 406	Screw
	/004 004 009				
5	004 005 001	Insulator	12	003 007 411	Washer
6	002 006 001	Heater wire	13	099 017 003	Protective earth
		presser			cord
7	003 002 408	Screw	14	004 022 002	Temperature
					probe of HP

Table A
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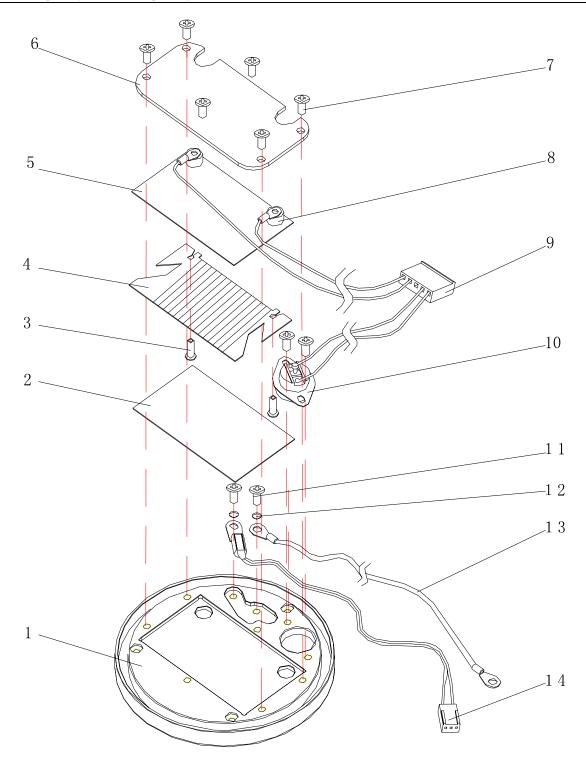


Fig.A-2 the heater plate's exploded view

#### Appendix B

#### **EMC Information**

<u>Warning</u>: The use of accessories other than those specified by the manufacturer may result in increased emissions or decreased immunity of the equipment or system.

#### **B.1** Electromagnetic Emissions

#### Guidance and manufacturer's declaration – electromagnetic emissions

The SH330 is intended for use in the electromagnetic environment specified below. The customer or the user of the SH330 should assure that it is used in such an environment.

	1	
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The SH330 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 B	The SH330 is suitable for use in all establishments, including
Harmonic emissions IEC 61000-3-2	Class A	domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Emissions test	IEC 60601-1 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)	$\pm 6 \text{ kV} \text{ contact}$	± 6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic
IEC 61000-4-2	±8 kV air	± 8 kV air	material, the relative humidity should be a least 30 %.
Electrical fast	$\pm$ 2 kV for power supply	$\pm$ 2 kV for power supply	Mains power quality should be that of a
transient/burst	lines	lines	typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
IEC 01000-4-5	$\pm 2 \text{ kV}$ common mode	$\pm 2 \text{ kV}$ common mode	
Voltage dips, short interruptions and voltage	70 % U <sub>T</sub> (30 % dip in U <sub>T</sub> ) for 25 cycle	70 % <i>U</i> <sub>T</sub> (30 % dip in <i>U</i> <sub>T</sub> ) for 25 cycle	Mains power quality should be that of a typical commercial or hospital environment
variations on power supply	40 % <i>U</i> <sub>T</sub> (60 % dip in <i>U</i> <sub>T</sub> )	40 % <i>U</i> <sub>T</sub> (60 % dip in <i>U</i> <sub>T</sub> )	If the user of the SH330 requires continued
input lines IEC 61000-4-11	for 5 cycles $<5\%U_{\rm T}(>95\%$ dip in $U_{\rm T})$ for 0,5 cycles	for 5 cycles $<5\% U_T(>95\% dip in U_T)$ for 0,5 cycles	operation during power mains interruptions it is recommended that the SH330 be powered from an uninterruptible power
	<5% <i>U</i> <sub>T</sub> (>95 % dip in <i>U</i> <sub>T</sub> ) for 5 sec	<5% U <sub>T</sub> (>95 % dip in U <sub>T</sub> ) for 5 sec	supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Mains power quality should be that of a typical commercial or hospital environment.

#### **B.2** Electromagnetic Immunity

#### Guidance and manufacturer's declaration – electromagnetic immunity

The SH330 is			<b>leclaration</b> – <b>electromagnetic immunity</b> netic environment specified below. The customer or the user
	should assure that it i	-	-
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the SH330 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	3 V	Recommended separation distance
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V/m	3 V/m	$ d = \left[ \frac{3.5}{V1} \right] \sqrt{P} $
IEC 61000-4-3	80 MHz to 2,5 GHz		
			$d = \left[\frac{3.5}{E1}\right]\sqrt{P}  80 \text{ MHz to } 800 \text{ MHz}$
			$d = \left[\frac{7}{E1}\right]\sqrt{P}  800 \text{ MHz to } 2.5 \text{ GHz}$
			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 <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> .
			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.

- <sup>a</sup> 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 SH330 is used exceeds the applicable RF compliance level above, the SH330 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SH330.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

#### Recommended separation distances between portable and mobile RF communications equipment and the SH330

The SH330 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SH330 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SH330 as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	$d = \left[\frac{7}{E1}\right]\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.