SH330
Respiratory Tract Humidifier for Medical Use

0perating Manual

Revision D

Content

Revision	Description of Operating Manual Change	Date Issued
A	First release operating manual	2007.6
B	Add 7 Servicing steps Add 9 Environmental Protection Add Appendix A	2011.12
C	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

Cautions

Consult accompanying documents.

. **SH330** Respiratory Humidifier 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 instrument 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 the manufacturer accredited personnel.

. Clinic safety has been carefully considered during design. But the operator shall not neglect the observation of instrument status and the patient's nursing.

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

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

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

. **SH330** Humidifier storage environment: temperature（0℃～40℃）, RH（≤93%）, atmospheric pressure（50kPa~106kPa）. No corrosion. Any excess may damage this system.

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

. Users with only 2-phase power system shall be attention don't mix the earth and neutral wires. **SH330** humidifier is an instrument of Class I with Type BF applied part. So it is also necessary to ensure the earth of machine's rear wires in good condition!

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

.Ensure the power supply comply with the requirement on the nameplate, otherwise it will damage the equipment.

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 Number

Follow operating instruction

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 have "attention" "note" "warning" appeared in this manual:

"**Attention**": To prevent errors in operation.

"**Note**": Indicate various functions and point out advanced features.

"**Warning**": Refer to possibilities of danger or equipment damages.

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

Attention: Only trained personnel can operate this humidifier according to this manual.
Attention: 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 with 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.

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 the heater control knob 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.

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 Shock:	Type BF
Type of Protection Against Electric Shock：	Class I
Water-proof protection:	Drip-proof IPX1
Protection Against Inflammable Anesthetic Gases:	No Category AP/APG
Operation Mode：	Continuous Operation
Pollution degree:	2
Overvoltage category:	II
Altitude:	≤2000m

1.4 Structures

SH330 Respiratory Humidifier is a hanging basic type and composed of mainframe 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 as the following:

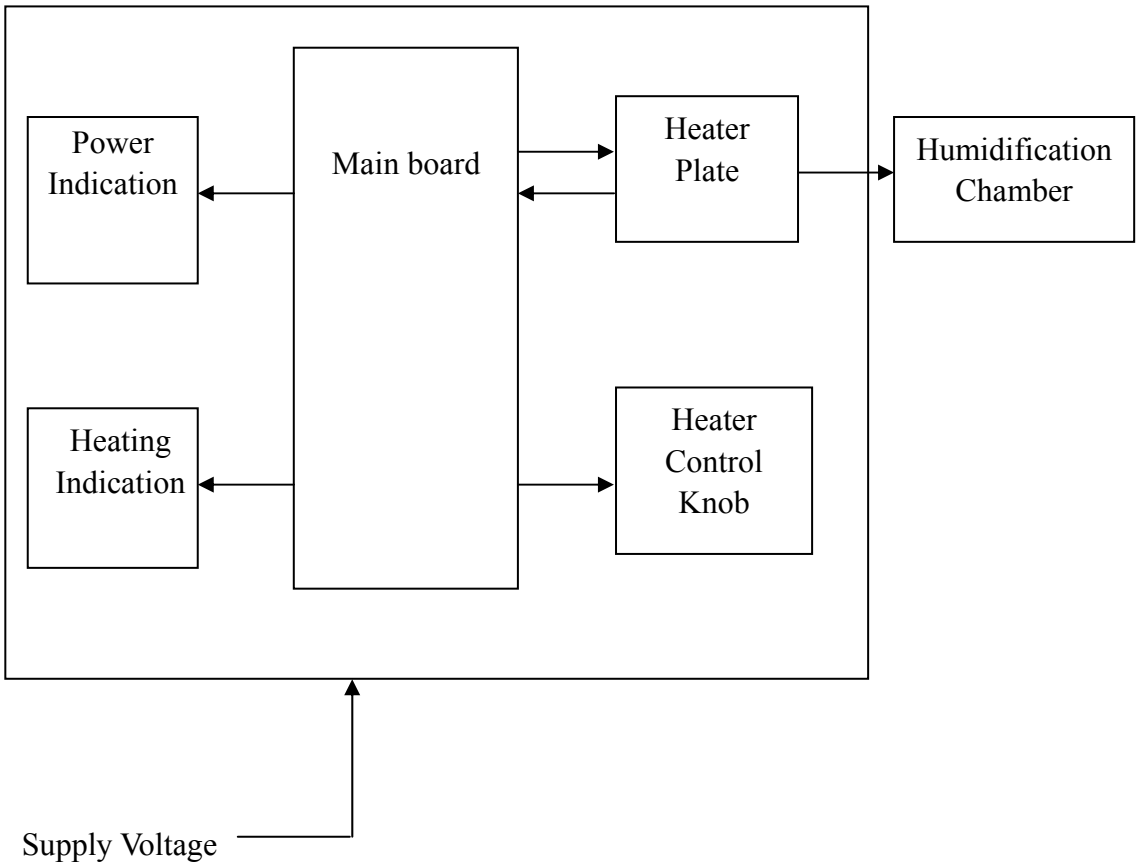


Fig. 2-1 SH330 Respiratory Humidifier

3 Technical Characteristics

3.1 Working Conditions

Temperature	18℃~26℃
Relative Humidity	⩽80%
Atmospheric Pressure	86kPa~106kPa
Operating gas inlet temperature	18℃~26℃

Attention: The operating temperature over the recommended one may affect the performance.

3.2 Temperature Control Range

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

Table 3-1

The position 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℃
a.5	step 5	60±3℃
a.6	step 6	63±3℃
a.7	step 7	66±3℃
a.8	step 8	69±3℃
a.9	step 9	72±3℃

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:

Φ22mm×60cm+Φ22mm×60cm silica gel tubes, with a water trap between them.

（3）Type of humidification chamber: SH330

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℃～27℃
5 step	5L/min~30L/min	27℃～30℃
9 step	5L/min~30L/min	30℃～34℃

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)
1step	5L/min~40L/min	＞10mg/L
9step	5L/min~20L/min	＞33mg/L

Warning: 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
2	~ 230V	1A

Rated frequency 50/60Hz
Power consumption ＜120VA+10%
Heater plate capacity 85W
Heater plate thermal cutout 110±5℃

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 ≤10 mL/min

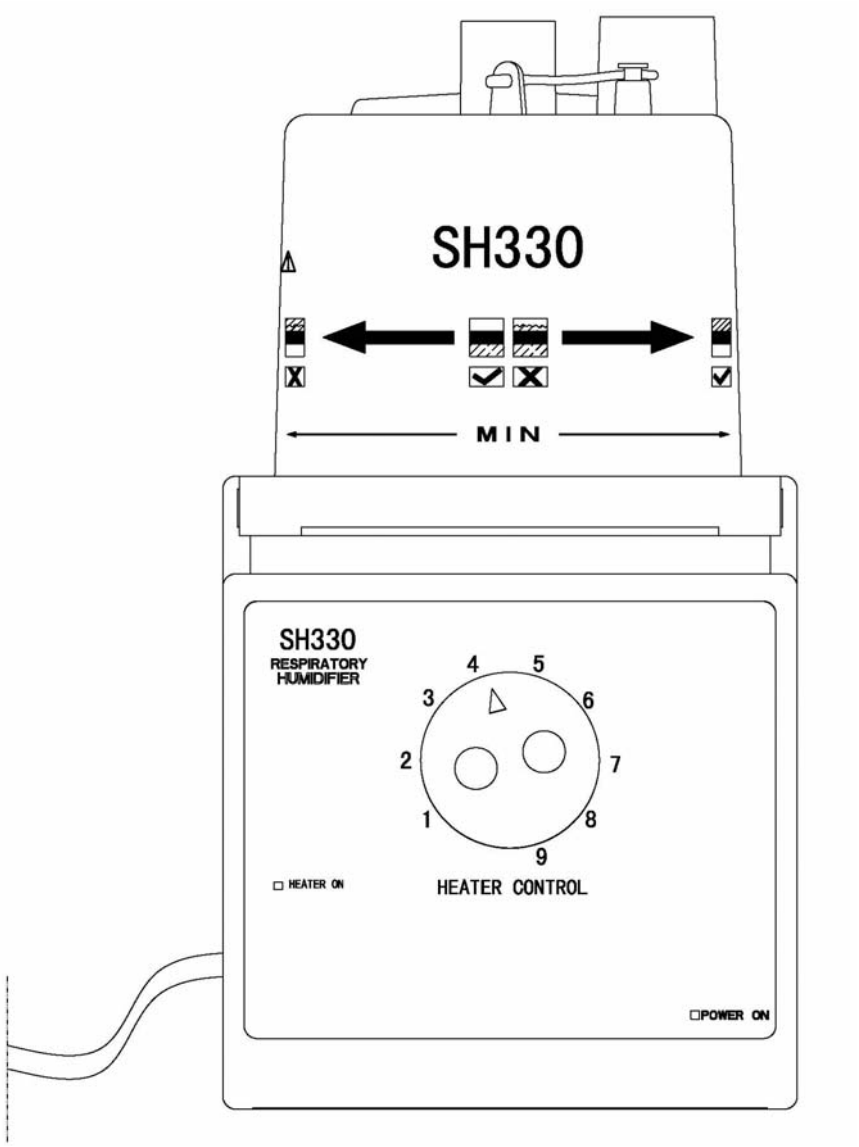
3.6 warm-up time

The time required (warm-up time) for the measured gas temperature to reach the set temperature from a starting temperature of (23±2) °C shall be less than 30min.

4 Weight & Dimensions

Dimensions 135mm(W)×170mm(H)×156mm (D) (without chamber fitted)
Weight 1.2kg (max) (without chamber fitted)
2.0 kg (max) (with chamber fitted & filled with water)

Fig. 4-1 Front View of Humidifier



5 Equipment Installation & Adjustment

Before starting the system, please obey the following rules to ensure the safety of patient, operator and equipment.

Attention：The working environment of SH330 Respiratory Humidifier shall comply with the following:

Temperature 18℃~26℃
Relative Humidity ≤80%
Atmospheric Pressure 86kPa~106kPa

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

Warning：The storage environment of SH330 Respiratory Humidifier: Temperature（0℃~40℃），RH（≤93%），atmospheric pressure（50kPa~106kPa）, no corrosion, any excess may damage the system.

Attention：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's working properly and safely before using.

5.1 Installation site

It is forbidden to use the **SH330** Respiratory Humidifier in flammable and/or explosive environment. **SH330** Respiratory Humidifier must be operated by the 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.

Warning：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.

Warning: We should place the device away from the position where it is difficult to disconnecting the device from supply mains.

5.2 Power supply requirement

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

Warning：Ensure the power supply comply with the requirement on the nameplate, otherwise it will damage the equipment.

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

5.3 Switch system

Connect the power supply and switch on then the power indicator light on.

Front panel is shown in figure 5-1.

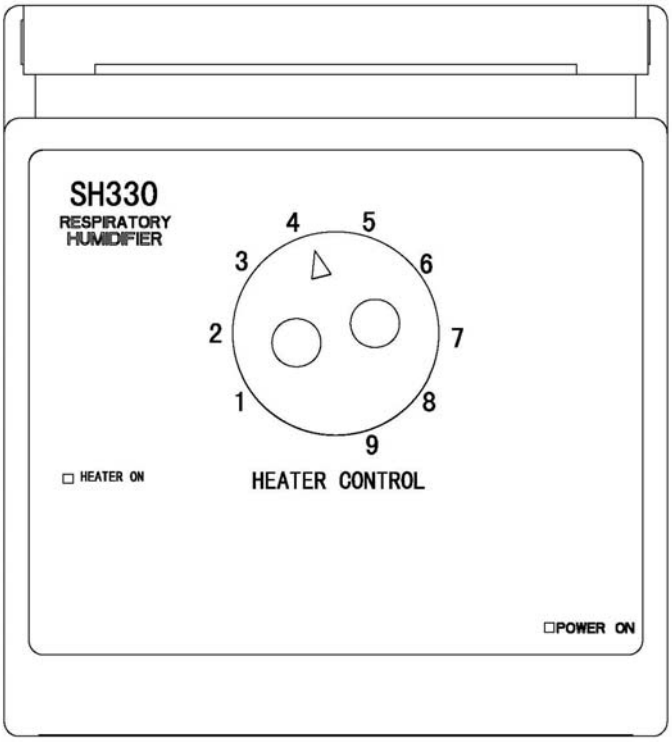


Fig.5-1

Power Switch(at the side panel) ON/OFF Switch	“	” means power on; “○” 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）Fix **SH330** Respiratory Humidifier on the respiratory bracket and make sure the height of **SH330** Respiratory Humidifier shall be lower than that of the patient.

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

（3）Pour in the water between the 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.

Warning：Only use the accompanying chamber for such humidifier.

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

Warning：Don't fill the water exceeding 37℃ into the humidification chamber.

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

（5）Insert the airway adapter into the inlet 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.

Warning: 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)

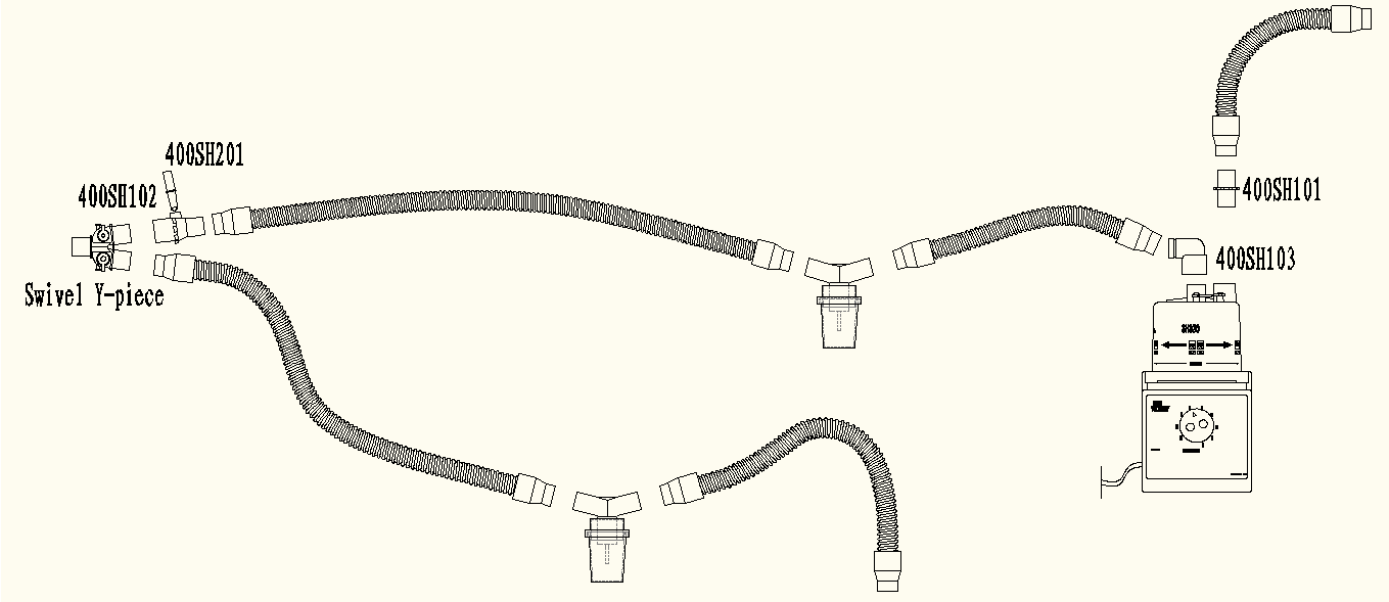


Fig. 6-1 the typical system (two tubes with water traps)

Components in this system:

Humidification chamber: SH330

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

Adapters: 400SH101, 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 connected power supply.
（3）Check good earth.
（4）Check right ventilation circuit.
（5）Start the ventilator and gas supply to set up the normal application airflow.

Warning：Ensure the airflow flowing before this machine connected with patient.

（6）Turn on the power switch on the right side of **SH330** humidifier then the **“POWER ON”** indicator light on.
（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 tube.

Warning：Don't touch heater plate—the surface temperature may reach 85℃。

Warning：Periodically inspect the temperature of patient inputting airflow by the indication of thermometer.

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

Warning：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.

（12）Return the switch and pointer to the opening status after working finished then put the power off. Disconnect various connections carefully then make cleaning and disinfection of the whole equipment and accessories then use it directly next time.

Attention：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±5℃ 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.

Warning: When the unconventionality appears（including out of control or broken）the overheating protection will just be opened. If it occurred to your machine please contact with the local supplier or our customer service department directly.

7 Service

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

Warning: 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.

Attention: **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. Users who really want circuit diagram and description of the circuit functions could contact our company.**

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 one screw fixed in PCB.
(2) Pull out all the connectors connected to the PCB.
(3) Remove the PCB carefully.

7.2 Replace the Fuses

Warning: **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.

Table 7-1 power and types of the replacing fuses

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

7.3 Replace the PCB

Table 7-2 part number of PCB

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

(1) Open the shell.
(2) Disconnect all cables 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

7.4.1 Reset the thermal cutout

Attention: 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.

7.4.2 Replace the heater plate

Table 7-3 Part number of heater plate

Model	Supply voltage	Heater plate part number
SH330	110VAC	099 018 122
	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.

Attention: **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.

Attention: **the mains cable can not be disconnected by users, it just be replaced by professional serviceman.**

7.6 Assemble and disassemble the subassembly of humidification chamber

1. Disassemble the humidification chamber

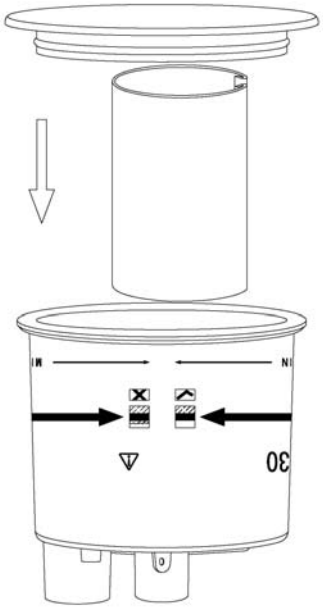
（1）Turn off the **SH330** Humidifier and unplug the inlet/outlet tubes connected with the humidification chamber.

（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） 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.

（2） Put inner-tube correctly after cleaning and drying. Press the humidification cup to make the chamber base to the right position. (The method is shown in Fig 7-1)



The installation diagram of the inner-tube

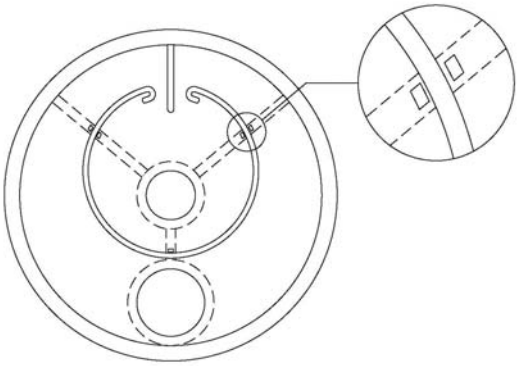


Fig 7-1

3. Replace the “O” circle of chamber base

（1） When replacing the “O” circle please take out the “O” circle from the chamber base trough .

（2） Put the new “O” circle into the chamber base trough and 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.

8 Cleaning, Disinfection& Maintenance

8.1 Cleaning of Shell

1、Cut off system power supply.
2、Add domestic cleanser into water. Dip cotton cloth into water. Clean the shell with the cloth.
3、Dry the shell with dry cloth.
Attention：Don't use organic benzene, anther, benzene, trichloroethylene etc to clean the shell.

8.2 Cleaning of power cable

1、Cut off system power supply.
2、Add domestic cleanser into water. Dip cotton cloth、soft brush into water. 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. 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℃，15min), disinfecting with high-pressure and high-temperature.
4、After the temperature drops, dry the chamber with dry cloth.
Attention：It is wrong to disinfect all the accessories of humidification chamber when they are bounded together.
Note: All the parts of chamber can be disinfected for 100 times.
Attention：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 make a risk control of environmental damages.

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

10.1 Transportation

Packed products are allowed for the transportation by highway, airway and railway.

Prevent from impulsion, acute shake and moisture during transportation.

10.2 Storage

This product shall be stored in the environment of temperature 0℃~40℃, RH≤93%, atmospheric pressure 50kPa~106kPa, no corrosive materials and good ventilation.

Attention: When the 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.

Table A-1

NO.	Part number	name	NO.	Part number	name
1	001 005 003	Chamber guard	13	006 002 204/ 006 002 504	Sticker
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 waterproof cap	18	003 001 413	Screw
7	099 019 001	Power switch assembly	19	099 024 202/ 099 024 207	PCB assembly
8	003 002 412	Screw	20	003 001 210	Screw
9	001 010 001	Mains cord presser	21	099 021 002	Front case assembly
10	003 005 605	Nut	22	003 008 510	Heater plate spring
11	002 004 001	Inner bracket	23	090 018 122/ 099 018 132	Heater plate assembly
12	003 002 616	Screw			

We will provide the circuit diagram and other data about servicing according to the user’s requirements.

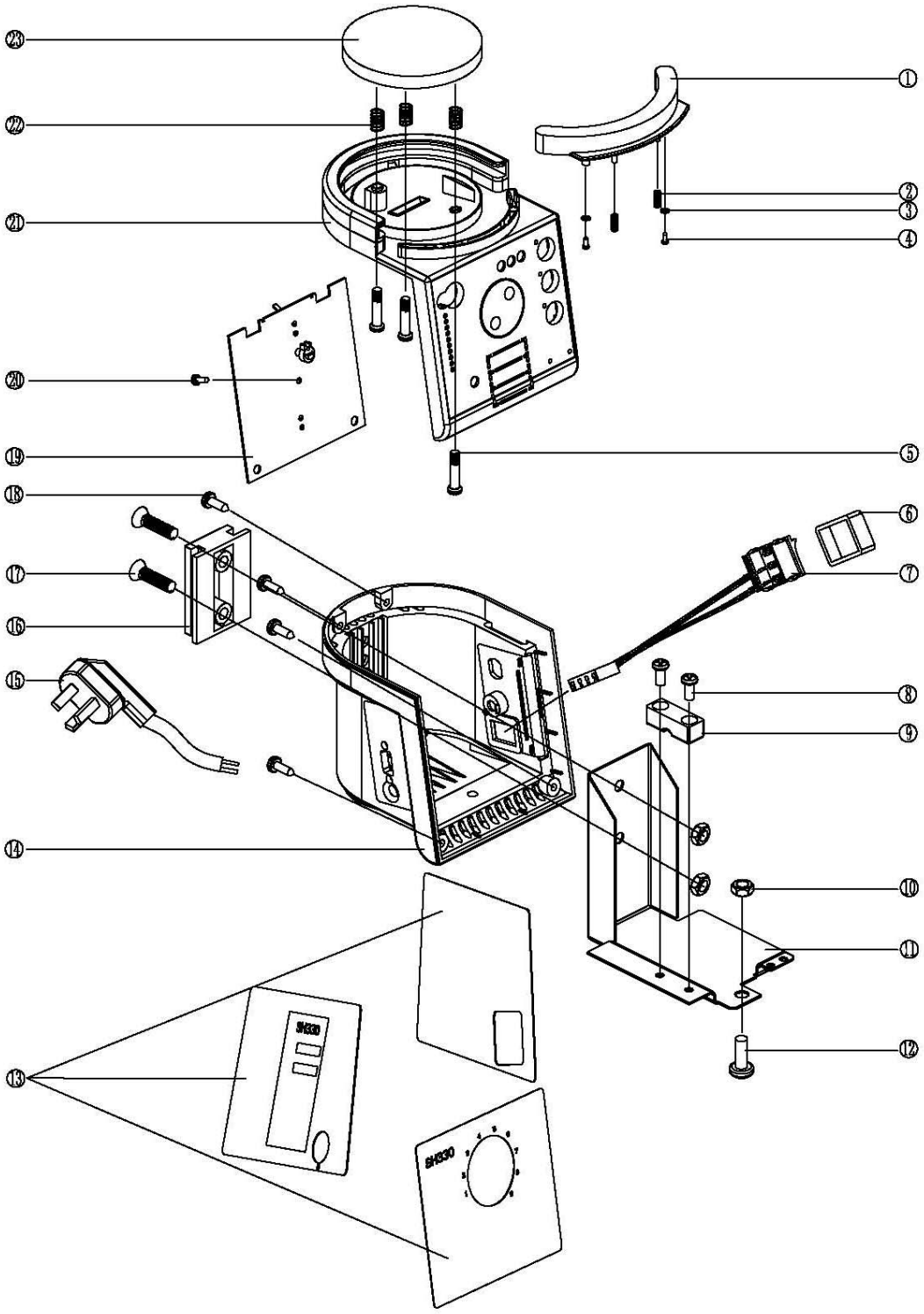


Fig. A-1 The humidifier's exploded view

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

Table A-2

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 /004 004 009	Heater wire	11	003 002 406	Screw
5	004 005 001	Insulator	12	003 007 411	Washer
6	002 006 001	Heater wire presser	13	099 017 003	Protective earth cord
7	003 002 408	Screw	14	004 022 002	Temperature probe of HP

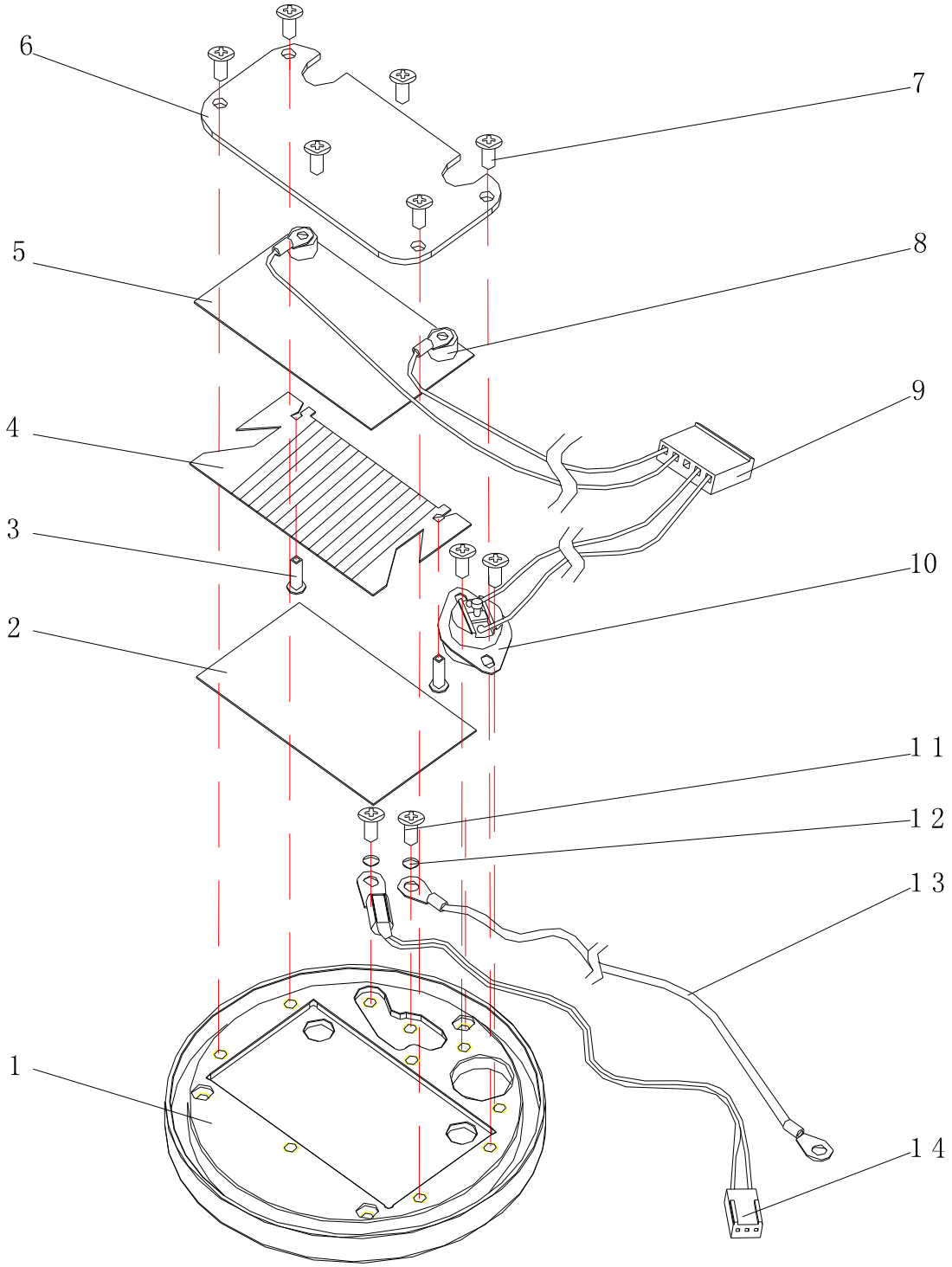


Fig.A-2 The heater plate's exploded view

Appendix B

EMC Information

<u>Warning</u>: The use of accessories other than those specified by JIKE 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.		
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 domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

B.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Emissions test	**IEC 60601-1 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70 % U_T (30 % dip in U_T) for 25 cycle 40 % U_T (60 % dip in U_T) for 5 cycles ＜5%U_T (＞95 % dip in U_T) for 0,5 cycles ＜5% U_T (＞95 % dip in U_T) for 5 sec	70 % U_T (30 % dip in U_T) for 25 cycle 40 % U_T (60 % dip in U_T) for 5 cycles ＜5%U_T (＞95 % dip in U_T) for 0,5 cycles ＜5% U_T (＞95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SH330 requires continued operation during power mains interruptions, it is recommended that the SH330 be powered from an uninterruptible power 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.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

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.

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. **Recommended separation distance** d = $\left[\frac{3.5}{V1}\right]\sqrt{P}$ d = $\left[\frac{3.5}{E1}\right]\sqrt{P}$ 80 MHz to 800 MHz d = $\left[\frac{7}{E1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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** $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	**800 MHz to 2,5 GHz** $d = \left[\frac{7}{E1}\right]\sqrt{P}$
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	121.67	121.67	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.