H60 Heated Humidifier

User Manual

CE 0123

The H60 Heated Humidifier is designed only for use with specific Luna™ E-20A and E-20C Series devices. Do not use the H60 Heated Humidifier with any other devices.

The humidifier moistens the air delivered by the Luna™ E-20A and E-20C Series devices. It is for use in the home or hospital / institutional environment.

The H60 Heated Humidifier is only used for single patient and must not be re-used on another person. This is to avoid the risk of cross-infection.

The H60 Heated Humidifier is not intended for use with a patient whose upper airway has been bypassed.

Table of Contents

1. Warning, Caution and Important Tip

WARNING!
Indicate the possibility of injury to the user or operator.

CAUTION!
Indicate the possibility of damage to the device.

IMPORTANT TIP!
Place emphasis on an operating characteristic.

Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

2. Symbols


Operating Instructions


Type BF Applied Part


Class II (Double Insulated)

AC Power

DC Power

IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)


Hot Surface

Serial Number of the Product


Manufacturer

European CE Declaration of Conformity


Water Filling Prohibited Here


Water Inlet


Directional Indicator for Removing the Water Inlet Cap


Directional Indicator for Screwing the Water Inlet Cap

3. Features

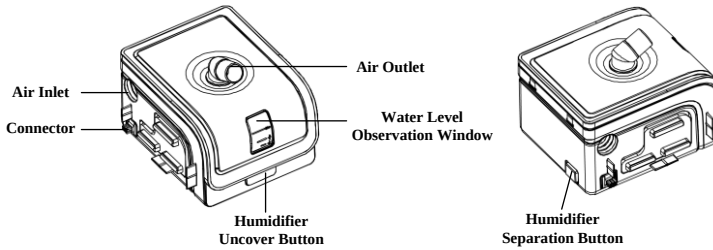

Fig. 3-1

Name	Function
Air Inlet	Connect to the outlet of the main device
Air Outlet	Deliver humidified air to the patient; connect to the air tubing
Connector	Heat the water in the water chamber and detect the temperature
Water Level Observation Window	Observe the water level in the water chamber
Humidifier Uncover Button	Press this button to open the top cover of the humidifier
Humidifier Separation Button	Press this button to separate the humidifier from the main device

4. Daily Use

IMPORTANT!

• Never operate the humidifier if any of its parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled. Do not use the humidifier if the water chamber is leaking or damaged in any way. Have any damaged parts replaced before continuing use.

• Read all instructions before using the humidifier.

• Use only with 3B / BMC devices whose instructions specify the use of this humidifier.

• Please use the mask which meets ISO17510-2:2009.

CAUTIONS!

• This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

• Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.

• When humidifier is used outside the specified ambient temperature range or

humidity range, the performance of humidifier will be compromised.
• U.S. federal law restricts this device to sale by or on the order of a physician.

WARNINGS!
• Use the humidifier only for its intended use as described in this manual.
• Use only accessories recommended by 3B / BMC.

4.1 Connecting, Separating the Humidifier and Main Device

4.1.1 Connecting the Humidifier to the Main Device

Remove the shield from the main device, following the steps below:

(1) Overturn the main device and find the buckle slot at the bottom of the main device, as shown in Fig. 4-1.
(2) Remove the shield by inserting a flat tool into the buckle slot.

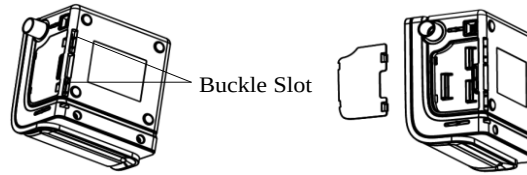

Fig. 4-1

After the shield is removed, place the humidifier and main device near each other as shown in Fig. 4-2. The air outlet of the main device should be targeted to the inlet of the humidifier. Push the two devices together until they click into place. Fig. 4-2 shows their positions before and after connection to each other.

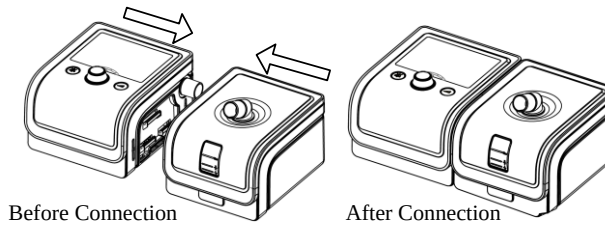

Fig. 4-2

CAUTION!
• When the main device delivers air and the humidity setting is adjusted, if the indicator lights of the humidifier do not light up, it may be that the humidifier and main device are not connected correctly.

4.1.2 Separating the Humidifier from the Main Device

Press **the Humidifier Separation Button** on the humidifier and, at the same time, pull the humidifier and main device apart in opposite horizontal directions, as shown in Fig. 4-3.

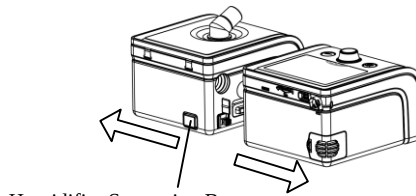

Fig. 4-3

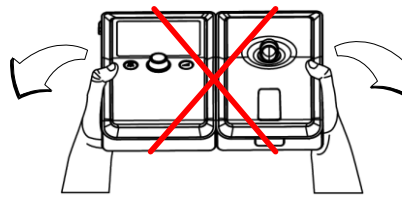

Fig. 4-4

CAUTIONS!

• Do not move the connected unit upwards or downwards while pulling the devices apart (see Fig. 4-4). It could cause damage to the devices.

• Place the shield back on the main device when the humidifier is not in use.

4.2 Filling the Water Chamber

4.2.1 Removing the Water Chamber

Press **the Humidifier Uncover Button** to open the top cover. Hold the front center of the humidifier with your thumb and index finger, and pull the chamber out of the humidifier, as shown in the figure below.

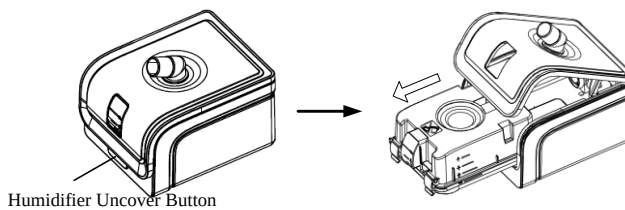

Fig. 4-5

WARNING!

• Turn the device off and allow approximately 15 minutes for the heater plate and water to cool.

4.2.2 Overturning the Water Chamber

Turn the water chamber over so that it is bottom up, as shown in the figure below.

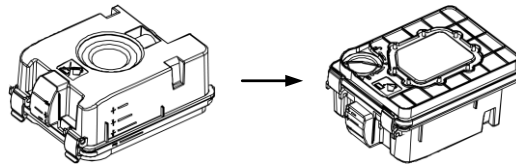

Fig. 4-6

WARNINGS!

• Never touch the heater plate unless the humidifier is unplugged and the plate has cooled down.

• Fill the water chamber only after it is turned over, otherwise the device could be damaged.

4.2.3 Removing the Water Inlet Cap

Turn the water inlet cap counterclockwise so the arrowhead on the cap points to the triangle symbol △, and then remove the cap.

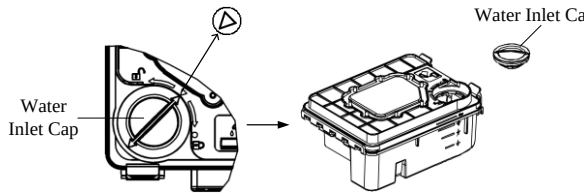

Fig. 4-7

4.2.4 Filling Water

Fill the water chamber with approximately 350 ml of water through the water inlet. Make sure that the water does not exceed the maximum water level line. Observe the water level in the water chamber through the Water Level Observation Window.

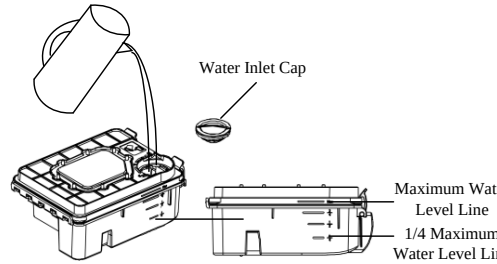

Fig. 4-8

WARNING!

• Every time before treatment, be sure to drain any residual water out of the water chamber, and ensure the maximum water level line is not submerged by water.

CAUTIONS!

• Empty the water chamber when the humidifier is not in use.

• Distilled water is recommended.

4.2.5 Returning the Water Chamber

Put the cap back on the water chamber after it is filled with water. Turn the cap clockwise until the arrowhead on the cap points to the round symbol O. Overturn the water chamber and return it to the humidifier.

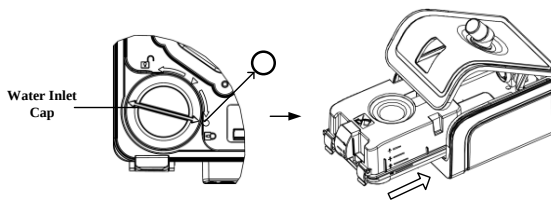

Fig. 4-9

WARNING!

• For safety purposes, the filled humidifier must be placed on a flat surface at a level lower than the patient's head when he or she lies down on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing inhibiting breathing.

CAUTIONS!

• Avoid moving or tilting the humidifier when the water chamber has water in it.

• Do not turn the humidifier on without the water chamber installed.

• Take precautions to protect furniture from water damage.

4.3 Emptying the Water Chamber

(1) Remove the water chamber according to instructions in 4.2.1.

(2) **Empty the water chamber:** Separate the main body of the water chamber from the chamber base, and pour any remaining water out of the main body of the water chamber. Undo the **Water Chamber Buckle**, and open the water chamber as shown below.

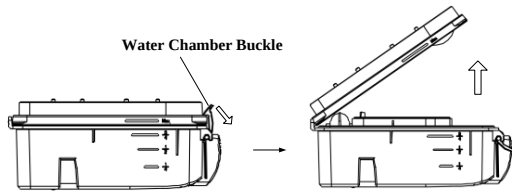

Fig. 4-10

CAUTION!

• Empty and air-dry the water chamber when the humidifier is not in use.

(3) Assemble the water chamber: Place the main body of the water chamber on a level surface, and then insert the chamber base into the main body of the water chamber and fasten the **Water Chamber Buckle**, as shown in the figure below.

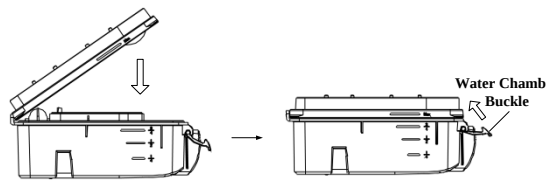

Fig. 4-11

4.4 Setting the Humidity Level

After the main device is powered on, turn **the knob** to turn on or turn off the humidifier and to adjust the humidity level according to instructions on the screen of the main device.

There are five humidity levels available, and the number of blue indicator lights that light up is directly proportional to the humidity level. If none of the indicator lights light up, it means that the humidifier is turned off.

The temperature of the water in the water chamber maintains a constant set level. Three indicator lights light up when the humidity is adjusted to Level 3, as shown in Fig. 4-12.

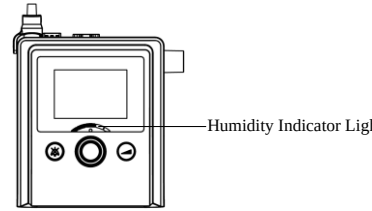

Fig. 4-12

CAUTIONS!

• Generally speaking, the humidity inside the mask is low when the water temperature is low.

• The greater the difference between the temperature inside the air tubing and room temperature is, the more easily condensation occurs inside the tubing.

• If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is proper; if there are lots of condensed water droplets inside the tubing and / or mask, it means that the humidity level is too high and should be set lower; Nasal dryness means that the humidity level is too low and should be set higher.

WARNING!

• Do not touch the heater plate of the humidifier when it is working, otherwise you may get burned. Turn off the heater plate when the humidifier is not in use.

5. Cleaning

Clean the water chamber before first use of the humidifier or at least once every week. If the humidifier has not been in use for a long time, clean the water chamber before reusing it.

WARNING!

• To avoid electrical shock, disconnect the power cord of the device before cleaning the humidifier. DO NOT immerse the humidifier in any fluids.

• The device shall not be serviced or maintained while in use with a patient.

• Sterilization of this device and its components other than recommended is not permitted.

CAUTIONS!

• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent or antimicrobials should not be used in cleaning either. These solutions may harden cleaned materials or reduce their life.

• Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176˚F). High temperatures could reduce product life.

5.1 Seperating the Humidifier Top Cover from its Main Body

Press the **Humidifier Uncover Button** to lift and open the top cover of the humidifier. Continue to lift the top cover until it seperates completely from the main body of the humidifier, as shown in the figure below.

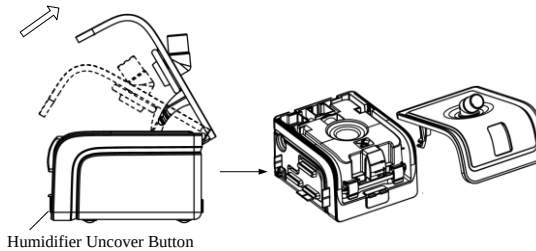

Fig. 5-1

5.2 Removing the Water Chamber

Pull the water chamber out of the main body of the humidifier horizontally, as shown in the figure below.

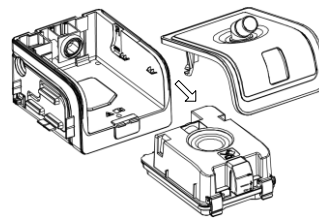

Fig. 5-2

5.3 Detaching the Air-intake Assembly

After the water chamber is removed, detach the **air-intake assembly** from the main body of the humidifier by pulling it upwards, as shown in the figure below.

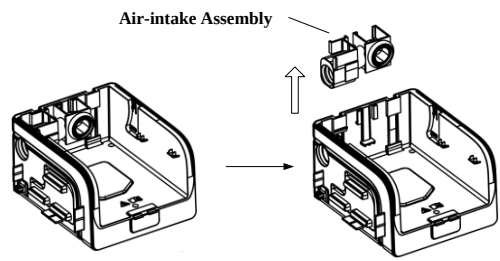

Fig. 5-3

5.4 Cleaning the Water Chamber

WARNINGS!

• Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.

• Allow the water in the chamber to cool down to room temperature before removing it from the humidifier.

CAUTIONS!

• Clean the water chamber only after the water in it cools. Make sure that no water enters the main device.

• After cleaning, rinse all parts throughly in clean water to make sure that no washing liquid is left; then wipe all parts dry with a lint-free cloth, so as to prevent calcareous accumulations.

• Inspect the water chamber for any leak or damage. Replace the water chamber if any damage is present.

(1) Opening the Water Chamber: Undo **the water chamber buckle** and then open the water chamber.

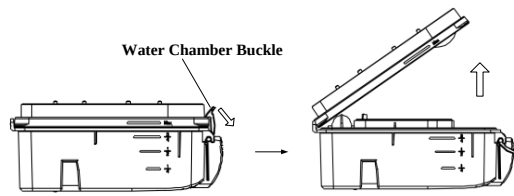

Fig. 5-4

(2) Cleaning the Water Chamber: Wash the two parts of the water chamber, as shown in Fig. 5-5. You may also clean them with a scouring pad (dip the scouring pad in washing liquid if necessary), rinse them throughly, and then wipe them dry with a soft cloth.

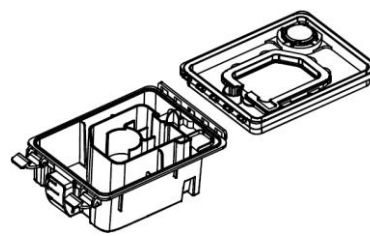

Fig. 5-5

(3) Assembling the Water Chamber: Place the two parts of the water chamber

together as shown in Fig. 5-6. Press hard until they click into place.

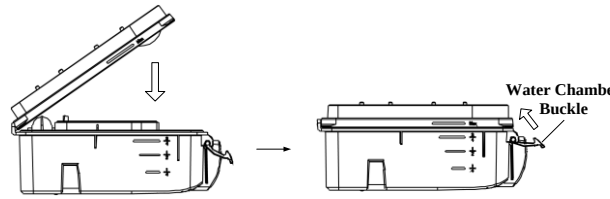

Fig. 5-6

5.5 Cleaning the Air-intake Assembly

First remove the sealing elements from the air-intake assembly, and then clean the air intake and sealing elements seperately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), and then rinsed thoroughly. Wipe the air intake with soft cloth, and allow the sealing elements to air dry.

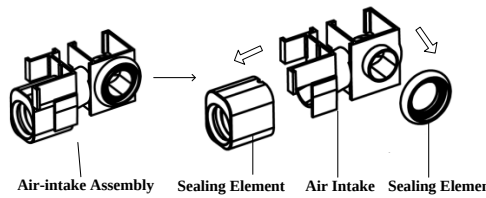

Fig. 5-7

5.6 Cleaning the Top Cover and Main Body of the Humidifier

Clean the top cover and main body of the humidifier seperately with running water, as shown in the figure below. They can also be cleaned with a scouring pad (dip the pad in mild scrubbing solutions if necessary), then rinsed thoroughly, and at last wiped with soft cloth.

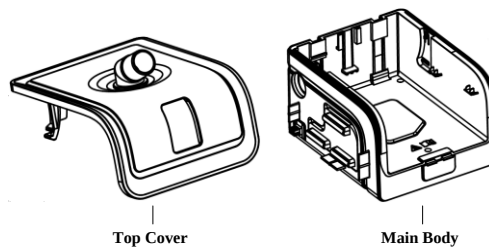

Fig. 5-8

5.7 Reassembling the Humidifier

(1) Set up the air-intake assembly: First install the sealing elements to the air intake, as shown in the figure below.

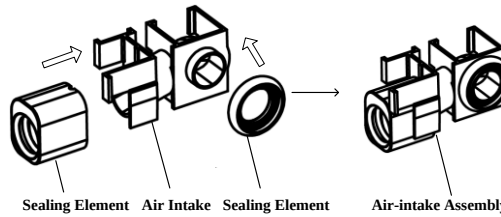

Fig. 5-9

(2) Then install the air-intake assembly back to the main body of the humidifier, as shown in the figure below.

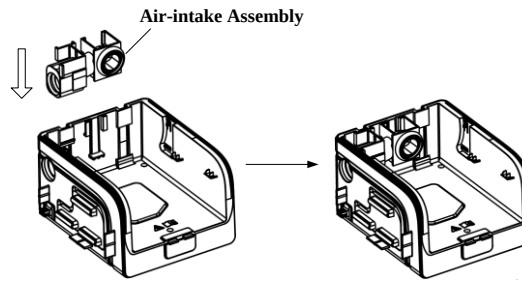

Fig. 5-10

(3) Return the water chamber to the main body of the humidifier, as shown in the figure below.

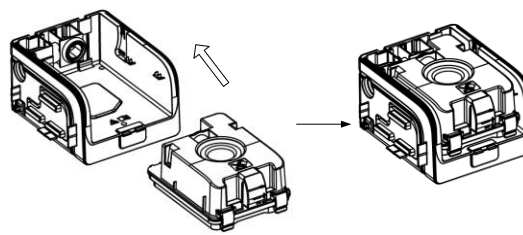

Fig. 5-11

(4) Connect the top cover and main body of the humidifier properly, as shown in the figure below.

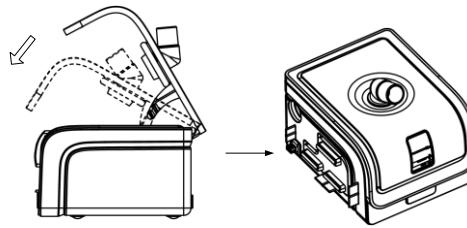

Fig. 5-12

6. Service

The humidifier does not require routine servicing.
If the humidifier malfunctions, contact your home care provider immediately. Never attempt to open the humidifier's enclosure. If necessary, contact your local authorized dealer or 3B Medical, Inc. for technical support and documents.

7. Specifications

Size

Dimensions: 120 mm × 196 mm × 134 mm
Weight: < 1 kg
Water Capacity: 350 ml at recommended water level

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	5°C to 35°C (41˚F to 95˚F)	-25°C to 70°C (-13˚F to 158˚F)
Humidity:	15% to 93% Non-condensing	up to 93% Non-condensing
Atmospheric Pressure:	760 to 1060 hPa	760 to 1060 hPa

Power Requirements (when the heated humidifier is used with the main device.)

100 ～ 240 V AC, 50 / 60 Hz, 2.0 A max.

Type of Protection Against Electric Shock

Class II Equipment

Degree of Protection Against Electric Shock

Type BF Applied Part

Degree of Protection Against Ingress of Water

IP22

Heater Settings

1 to 5 (95˚F to 167˚F / 35°C to 75°C)

Maximum Operating Pressure

30 hPa

Pressure Drop with Humidifier

< 0.4 hPa at 60 LPM flow

Humidifier Performance

Humidity Output: No less than 10 mg H_2O/L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Delivered Gas Temperature

< 43°C

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1

8. Disposal

When necessary, dispose of the device and accessories in accordance with local laws and regulations.

9. Traveling with the System

Packing the System

(1) Remove the water chamber and pour out all water.

(2) Return the empty water chamber to the humidifier.

(3) Put the humidifier in your carry-on bag.

When traveling, the optional carrying case is for carry-on luggage only. The carrying case will not protect the humidifier if it is put through checked baggage.

Security Stations

For ease at security stations, there is a note on the bottom of the humidifier stating that it is medical equipment. It may be helpful to bring this manual along with you for security personnel.

10. EMC Requirements

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The device 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</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The device is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor 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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical home or hospital
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 home or hospital
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{p}$ $d = 1.2\sqrt{p}$ 80 MHz to 800 MHz $d = 2.3\sqrt{p}$ 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 meters (m). Field strengths from fixed RF transmitter, 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: 
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 applied.
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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	150 kHz ～ 80 MHz $d = 1.2\sqrt{p}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{p}$	800 MHz ～ 2.5 GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

11. Warranty

3B Medical, Inc. warrants that this humidifier shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by 3B Medical, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, 3B Medical, Inc. will repair or replace, at its option, the defective material or part. 3B Medical, Inc. will pay customary freight charges from 3B Medical, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

To exercise your rights under this warranty, contact your local, authorized dealers or:

3B Medical, Inc.
21301 US Highway 27 N
Lake Wales, FL 33859
T: (863) 226-6285
F: (863) 226-6284

For additional information, please visit our Patient Portal at:
www.3bproducts.com
icodeconnect.com – Web-based cloud for report generation and storage
www.bmc-icode.com – Website for iCode data report retrieval

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