BONHAWA

Respiratory Humidifier

Instructions for Use (IFU)

Models: RHF G3-1 & RHF G3-2

CE
2862

Table of Contents

1. Preface

These Instructions for Use (IFU) includes the information regarding set-up, operation, and maintenance for the Bonhawa Respiratory Humidifier, model RHF G3-1 and RHF G3-2.
The Bonhawa Respiratory Humidifier is for non-invasive use (NIV) only.
This device shall be used by a healthcare professional. Read through this user's guide before using the system.

2. Intended use

The Bonhawa Respiratory Humidifier is indicated for the treatment of respiratory insufficiency for spontaneously breathing patients with warmed and humidified respiratory gases. The Bonhawa Respiratory Humidifier is intended for use by healthcare professionals in hospitals and long-term care facilities only.

3. Indication for use

The Bonhawa Respiratory Humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The Bonhawa Respiratory Humidifier is for patients, 20kg and above, in hospitals and long-term care facilities.

4. Contraindications

The Bonhawa Respiratory Humidifier should not be used to treat patients with the following pre-existing conditions:

- Tension Pneumothorax
- Facial Trauma
- Upper airway obstruction
- Central apnea
- Blocked nasal passages/choanal atresia

5. Clinical Benefits

The intended clinical benefit provided by high flow nasal cannula therapy is to treat the indicated respiratory insufficiency through higher flow rates. Higher flow rates are provided to match patient demand. The resulting clinical outcomes are:

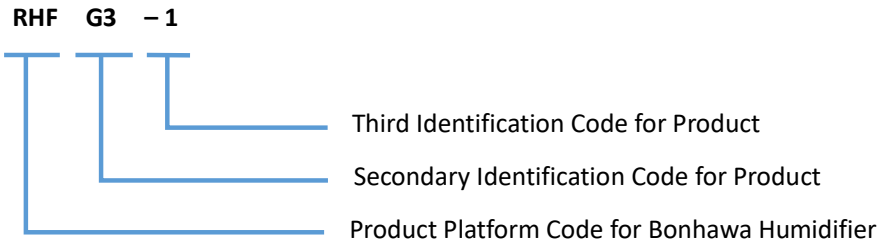
- More stable oxygen concentration delivery
- End inspiratory pressure improving distribution of gas
- Improved comfort with the delivery of warmed and humidified air promoting bronchial hygiene

- Patients benefit from the provided gas being heated and humidified in order to avoid the creation of a humidity deficit which may result in airway inflammation and desiccated secretions.
- Higher oxygen flows of oxygen have been shown to be effective in achieving higher levels of inspired oxygen to the lung. This increased flow of inspired oxygen can improve patient oxygenation status.
- Higher flows of respiratory gas reduce patient anatomical dead space. Reduced anatomical dead space enhances CO_2 removal by washing the airways with respiratory gas flow.

6. Product Name and Models

Product Name: Bonhawa Respiratory Humidifier

Product Models: RHF G3 – 1, RHF G3 – 2



7. Symbols

The following symbols may appear on the product or packaging.

	Read instructions before use		Refer to instructions (www.telesair.com)
	Warning or caution		Warning: Hot Surface
	Maximum water level	IP22	Ingress protection rating
	Date of manufacture Country of manufacture		Manufacturer
	Lot Number		Serial number
	Electronics waste to be disposed of properly	**RoHS**	Compliant with RoHS guidelines
	Type BF applied part		EU Representative

	Alarm Symbol		Alarm Paused
	Audio Paused		Power on/off
	Class II equipment		Model/ Catalog Number
	Settings Locked		Settings Unlocked
	System Settings		Non-sterile
	Do not re-use		Medical Device
	Prescription only		MRI Unsafe
	EC Certification		Package Quantity

8. Contents List

Item	Quantity	Item	Quantity
Bonhawa Respiratory Humidifier	1	Instructions For Use (IFU)	1
Quick Start Guide	1	Air Filter, pack of 3	1
Power Cord	1		

9. Residual risks and undesirable side-effects

Known side-effects of High Flow Oxygen Therapy are related to the provision of oxygen at high flow-rates. Unwarmed and dry respiratory gas may have undesirable effects on patients receiving therapy and are associated with cannula or mask discomfort, naso-oropharynx drying and irritation. Excessive provision of oxygen may have been associated with reduced respiratory drive in COPD patients. Administration of the therapy by professionals and monitoring patients with COPD via pulse oximetry is recommended.

10. Warnings and Cautions

Warnings: Warning identify conditions or practices that could result in serious adverse reactions or potential safety hazards.

Cautions: Cautions identify conditions or practices that could result in damage to the humidifier or other equipment.

Warnings:

- The humidifier is not a life-support device.
- The humidifier uses O_2 concentration, respiratory gas flow and temperature, and provides alarms which need to be controlled and monitored to achieve its intended use. The humidifier shall be used only by healthcare professionals.
- Closely monitor the patient and heart rate, respiratory rate, and SpO_2 through pulse oximetry.
- The water chamber, water chamber adaptor, nasal cannula and breathing circuit are single patient use only.
- To prevent patient, bystander, and equipment harm, do not operate or place the humidifier in an MRI (Magnetic Resonance Imaging) environment.
- The performance of the humidifier may be affected if used in combination with devices other than the ones recommended by the manufacturer (e.g., nasal cannula).
- The humidifier is not intended to treat patients whose upper airways have been bypassed.
- The humidifier shall be used in a well-ventilated environment away from flammable gases including anesthetics.
- The humidifier shall not be used in the operating room.
- Keep the power cord away from any surface with high temperature.
- To avoid strangulation, arrange the power cord and the breathing circuit such that they will not circle around the neck or head.
- Only the accessories approved or recommended by Telesair should be used with the humidifier. Safety and effectiveness may be compromised if using accessories that are not approved by Telesair.

- Stop using the humidifier and contact Telesair Customer Service if any of the following occurs: unexpected noise, damaged device housing or any change in performance for unknown reasons.
- Do not immerse the device or accessories into fluid, including power cable or power plug.
- Power off and unplug the humidifier prior to cleaning.
- Power off and unplug the humidifier immediately when liquids are spilled onto the device. Let the device dry prior to plugging power back to the humidifier.
- The surrounding area of the system shall be kept dry and clean.
- Covering breathing circuits with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.
- Do not directly touch the heater plate by hand or body within 10 minutes after the treatment.
- Avoiding using the humidifier adjacent to or stacked with other equipment.
- If there is any flame in the vicinity, do not use the humidifier.
- The humidifier shall not be used in the operating room or in the presence of flammable gases.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Bonhawa humidifier System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- System performance may be adversely affected, and device may be damaged if incorrect substances or methods for cleaning are performed.
- Water chamber, water chamber adaptor, nasal cannula and breathing circuit are single patient use only.
- The humidifier shall not be used with nitric oxide. Such use might cause the humidifier to not function correctly causing serious deterioration of health.
- When the humidifier is in operation, do not block the air intake port on the device or occlude the breathing circuit.

Place the device on a level surface, lower than the patient's head to prevent water from entering the breathing circuit or patient interface when the humidifier is in operation.

Cautions:

- Normal operation of the humidifier shall be verified if using the humidifier adjacent to or stacked with other equipment is necessary.
- The humidifier shall be used in an environment with good ventilation.
- Avoid using the humidifier near active high-frequency surgical equipment and the radio frequency shielded room for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.
- The following conditions may affect the essential humidification performance, flow delivery, or oxygen concentration accuracy of the humidifier and cause the humidifier to alarm:
  - Electromagnetic fields that exceed the level specified in IEC 60601-1-2
  - Radio frequency equipment for mobile communication
  - Radiation, e.g., CT or X-ray
  - Magnetic fields, e.g., MRI
  - Defibrillators or other shortwave therapy equipment
  - Operation of high frequency equipment, e.g., diathermy
- To prevent water inside the water chamber from getting into the humidifier, do not place the device upside down or on its side.
- Ensure that the water chamber is empty or removed prior to transporting the humidifier system.
- Allow the water chamber to cool down for at least 10 minutes before removing it from the humidifier.
- System performance may be adversely affected, and device may be damaged if incorrect substances or methods for cleaning are performed.

- Do not remove the humidifier cover. Any repair or servicing activity must be carried out by Telesair-authorized service personnel using appropriate tools.

11. Disclosures

The Bonhawa Respiratory Humidifier is not made with natural rubber latex.

The Bonhawa Respiratory Humidifier is not made using phthalates including DEHP.

12. Device Overview

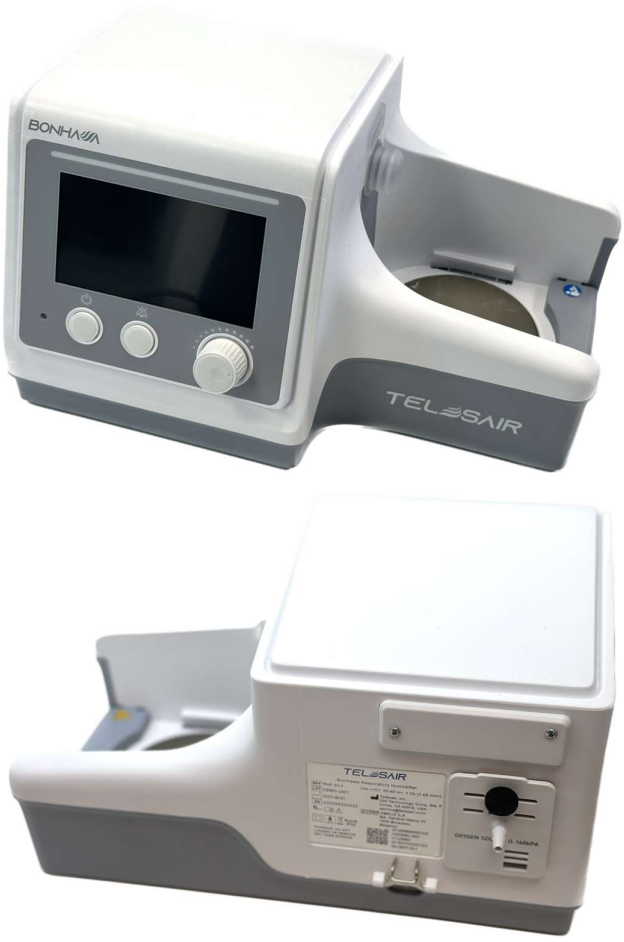


Figure 12-1 Front and Back of Bonhawa Respiratory Humidifier

Table 12-1. General assembly components

1	Top Outer Housing	13	Water Chamber Adaptor Interface
2	Alarm Light Indicator	14	Water Chamber
3	Touch Screen Display	15	Water Chamber Adaptor
4	Power Indicator	16	Heated Breathing Circuit
5	Power Button	17	Power Cable

6	Alarm Silence Button	18	Speaker
7	Dial	19	Gas Inlet Cover (Oxygen supply & Air)
8	Display Panel Cover	20	Oxygen Inlet Port
9	Bottom Outer Housing	21	Thumb Screw
10	Finger Guard	22	Label
11	Heater Plate	23	Power Cable Holder
12	Air Outlet		

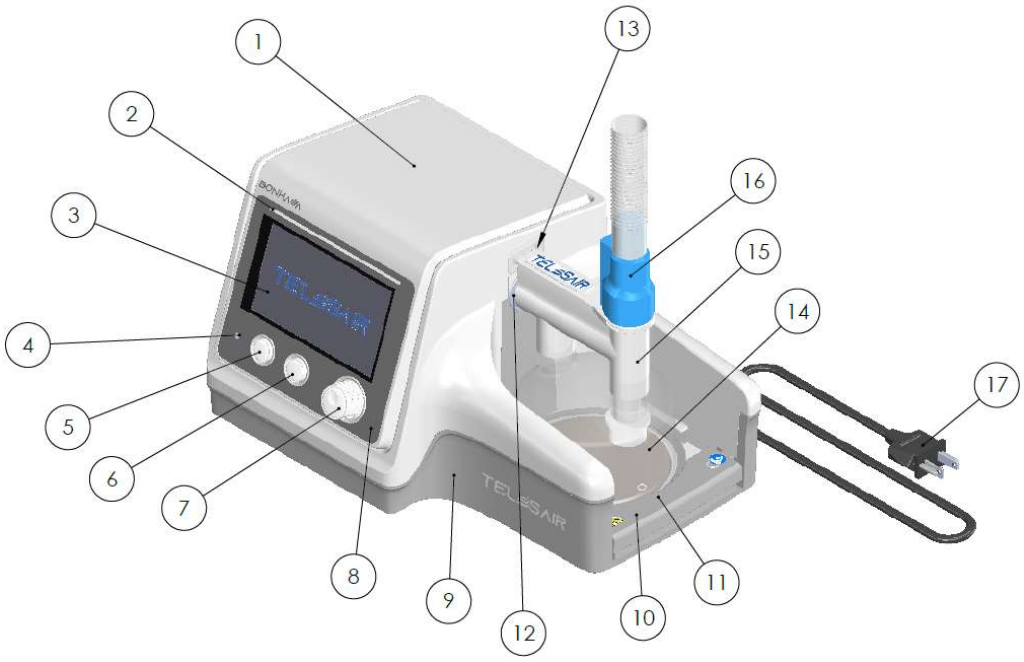


Figure 12-2 Front view of Bonhawa Respiratory Humidifier

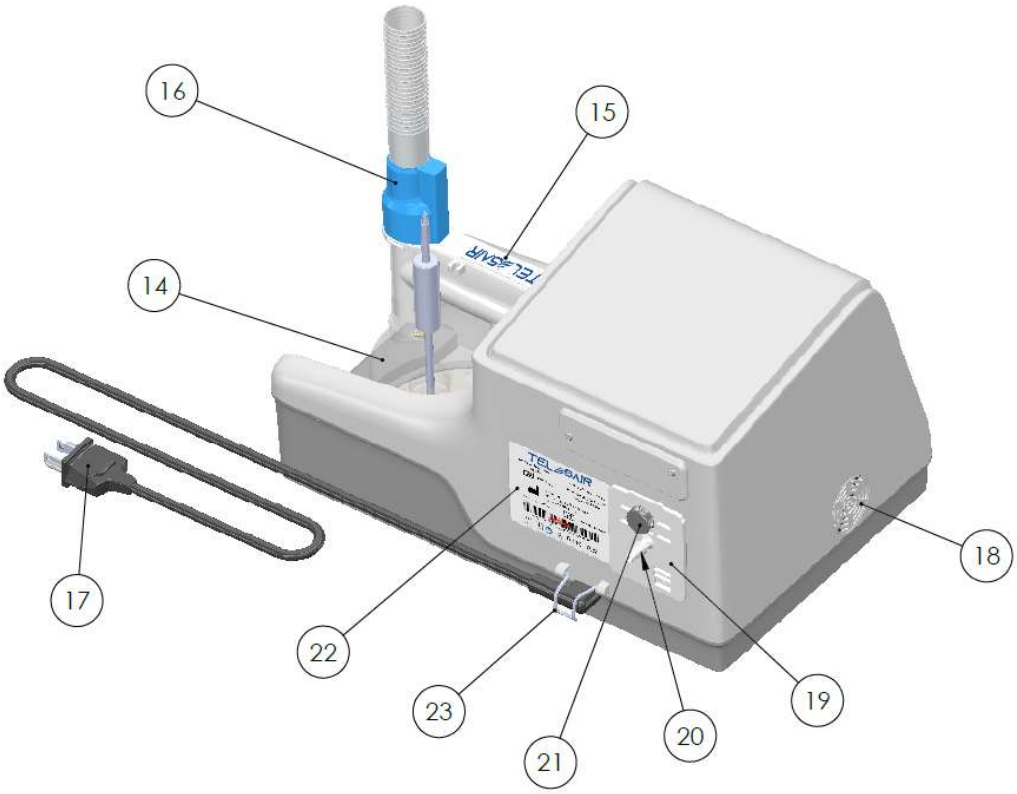


Figure 12-3 Back view of Bonhawa Respiratory Humidifier

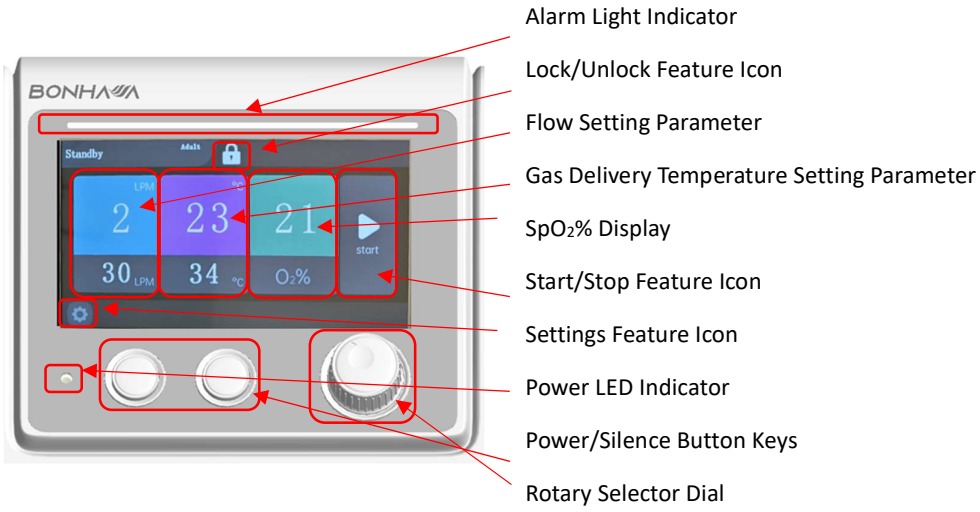
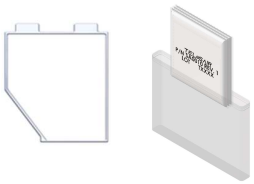


Figure 12-4 User Interface of Bonhawa Respiratory Humidifier

Table 12-2. Consumable accessories

	
Water Chamber Adaptor **Telesair Catalog Number:** **WCA01**	**Air Filter, 3 pack** **Telesair Catalog Number: AF3**

	
Water Chamber **Telesair Catalog Number:** **EWC01** **Manufacturer's Part Number:** **EM05-130D-1**	**Breathing Circuit** **Telesair Catalog Number: EBC01** **Manufacturer's Part Number:** **EM01-730**

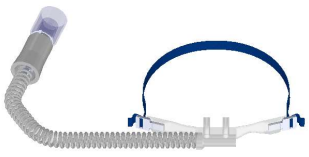
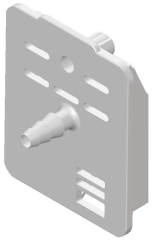
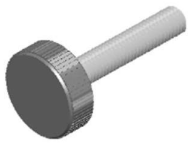
Patient Interface, Nasal Cannula	Size Description	Telesair Catalog Number	Manufacturer's Part Number	Recommended Flow Rate Range
	**Small**	**ENC03**	**EM05-503B**	**2 – 25 L/min (Pediatric Mode)** **10 – 60 L/min (Adult Mode)**
	Medium	**ENC02**	**EM05-502B**	**10 – 80 L/min (Adult Mode)**
	Large	**ENC01**	**EM05-501B**	**10 – 80 L/min (Adult Mode)**

Table 12-3. Durable accessories

110V Power Cord Telesair Catalog Number: AC1	220V Power Cord Telesair Catalog Number: AC2	O_2 Inlet Telesair Catalog Number: O2I	5mm Thumbscrew Telesair Catalog Number: TSW01

Table 12-4. Customer provided accessories not included but necessary for use

			
DISS Fitting for Oxygen Flow Meter **Recommended supplier:** **Maxtec, catalog number RP11P34** **www.maxtec.com**	**Oxygen Flow Meter** **Recommended supplier:** **Maxtec, catalog number R220P01-001** **www.maxtec.com**	**O_2 Tubing (2m)** **Recommended supplier:** **Vyaire Medical, catalog number 001350** **www.vyaire.com**	**Sterile Distilled Water**

The Oxygen Flow Meter provides a diameter indexed safety system (DISS) fitting that connects the hospital facility oxygen supply to the inlet of the Oxygen Flow Meter. An adjustment knob, a part of the Flow Meter, facilitates the flow setting of delivered oxygen to the Bonhawa Respiratory Humidifier. The outlet of the Oxygen Flow Meter connects to a DISS fitting that provides a barbed connector interface that facilitates the Oxygen (O_2) Tubing connection to the O_2 inlet of the Bonhawa Respiratory Humidifier.

The Oxygen Flow Meter (RP220P01-001) and DISS Fitting (RP11P34) are available from Maxtec with the provided catalog numbers. Both are representative of the types of respiratory delivery components that are commonly used in hospital respiratory departments and long-term care facilities. **Note:** The Oxygen Flow Meter has a flush flow rate of matching the 80 LPM requirement of the humidifier.

The Oxygen Tubing is also a commonly used component that is used in hospital respiratory departments. The image shown above is catalog number 001350 which is available from Vyaire Medical.

Sterile distilled water is used to provide a humidification water source for the Bonhawa device. Sterile distilled water is used and is readily available in hospitals and long-term care facilities. This sterile water is provided by Pharmacy or a certified 3rd party in a bag or bottle that is to be spiked to provide a water line from the bag to the inlet of the water chamber. The water chamber is provided with a spike tubing connection for completing this fluid interface. A representative image of a sterile distilled water bag is provided in the table 12-4, above.

Refer to your hospital policy or contact your local sales representative for assistance in locating these accessories if they are not readily available in your facility.

13. Assembly

1. Getting Started
    - ✓ Identify the necessary components.
    - ✓ Place the humidifier on a level and secure surface, which is slightly lower than the head of the patient.
    - ✓ Open the bag containing breathing circuit set (breathing circuit, water chamber and water chamber adaptor).
2. Water Chamber Insertion:
    - ✓ Remove the caps on the water chamber, connect the water chamber adaptor to the water chamber, push the assembly all the way down onto the ports of the water chamber. Make sure that there is a tight connection between the water chamber adaptor and the water chamber.
    - ✓ To install the water chamber onto the humidifier, firmly press down the finger guard and slide the water chamber towards the humidifier until the inlet port of water chamber adaptor is firmly connected with the humidifier and the finger guard is up and in locked position.
3. Water Source Installation
    - ✓ Place the water tubing into the clip present on the water chamber adaptor.
    - ✓ Hang a Sterile bag of distilled water about 20 cm (8”) above the humidifier, connect the water chamber tubing via spike port into the water bag.
    - ✓ Open the cap on the spike port, the water from the bag should enter the drip chamber then fill the water chamber automatically.
    - ✓ Check the water chamber and make sure it does not exceed the max water level.

MAX

Note: Make sure that both the water bag and the water chamber are not empty during operation to ensure continued humidification.

WARNING: Adding substances other than distilled water can adversely affect the normal functionality of the humidifier

4. Breathing Circuit Installation
   - ✓ To install the heated breathing circuit, push all the way down to connect one end of the breathing circuit (with the tear drop shape connector) to the vertical outlet port of the water chamber adaptor, double check if the heated breathing circuit is securely fastened onto the water chamber adaptor.
5. Patient Interface Installation
   - ✓ Connect the patient interface, such as a nasal cannula, to the other end of the breathing circuit, read the instructions for use of the interface before using it.

14. Connect to Oxygen Supply

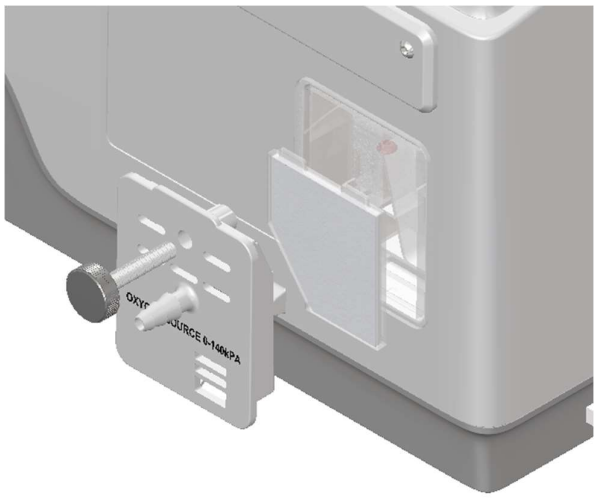


Figure 14-1 Air Filter Assembly Overview

1. Check if the Air Filter is installed properly.
2. Secure the O_2 Inlet to the device with the 5mm Thumbscrew.
3. Power ON the device.
4. Connect the O_2 tubing to the O_2 inlet port and ensure that the connection is tight and secure.
5. Verify the O_2% displays 21% on the display when there is no oxygen flowing through the device.

WARNING: Do not connect the Oxygen supply before turning on the device.

6. Turn ON oxygen supply and start therapy based on the descriptions in Section 15.2
7. Observe the O_2% display increase to the intended Oxygen concentration level.
8. Turn OFF oxygen supply when therapy is completed.
9. Power OFF the device.

15. Operation

15.1. Start Therapy

1. The operator must check if the entire humidifier system has been correctly set up for the patient who will be receiving the treatment, including therapy setting parameters and the accessories used. To help achieve better efficacy, the operator should assess the setting parameters and alarm limits periodically during the therapy.

WARNING: Operator shall make sure that all parts or "accessories" used are manufacturer approved and are compatible with the humidifier.

WARNING: Using accessories that are not approved by Telesair may compromise the safety and efficacy of the device. Use only the breathing circuits and accessories that are approved by Telesair with the Bonhawa humidifier.

Note: The accessories recommended or approved by Telesair can be found in table 12.2

WARNING: Before use, the operator must make sure that the power cord is in good condition, and a good power connection between the device and the power source is secured during operation.

2. Connect the humidifier to main power using the power cord provided. Ensure the latch is engaged to prevent the power cord disconnection inadvertently.
3. To power on the humidifier, press the Power Key present on the humidifier control panel. The therapy page will be displayed within 15s when powered on and the system enters *Standby*.

4. Do not initiate the flow of oxygen into the device until the Bonhawa Respiratory Humidifier is in Therapy Mode.
5. Press the dial once, *Therapy* starts. On the screen, the flow, temperature, and oxygen concentration are displayed.
6. Initiate oxygen flow using the external flow meter to achieve the desired O_2 concentration.

15.2. Oxygen Concentration

The O_2% displayed on the device screen is the Oxygen concentration level during therapy delivered to the patient. Regularly check the displayed O_2% and the desired SpO_2 level while the Bonhawa Respiratory Humidifier is delivering therapy.

15.3. Stop Therapy

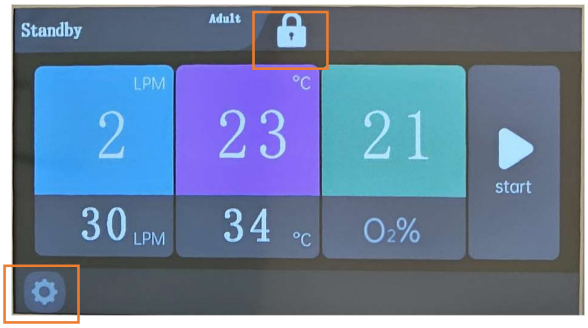
1. Turn off the flow of oxygen before switching from Therapy Mode.
2. To stop the therapy, press down the Dial key during *Therapy*, the humidifier will stop and begin to cool off.
3. When the system is cooled down, the humidifier will enter Stand-by.
4. In Stand-by, press the Power key for 3 seconds to initiate power off cycle, power off the humidifier by pressing Confirm on the touch screen.

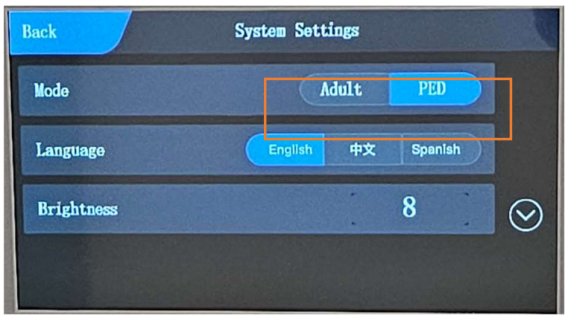
16. Setting Functions

The settings of the humidifier should only be adjusted by trained healthcare professionals.

16.1. Enter the Setting Functions

1. Press *Lock Key* icon on the touch screen to unlock it.
2. Once the screen is unlocked, therapy settings can be changed.
3. To change the therapy mode (Adult or Pediatric), press the *Gear* icon to enter *System Settings* page.





4. Once therapy settings changes are completed, press the *Lock* icon to save and apply the settings.

16.2. Set Flow

1. On the setting page, the flow setting can be entered by pressing the Flow (LPM) on the touch screen. The upper part of the icon will turn grey, and the lower values of the icon can be adjusted.
2. Rotate the Dial key to adjust the setting value to adjust the flow setting.
3. Push the Dial key or touch the Flow setting to confirm the setting value.

16.3. Set Gas Delivery Temperature

1. At the setting page, the gas delivery temperature parameter can be entered by pressing Temperature.
2. Rotate the dial to adjust the setting value to adjust the gas delivery temperature setting.
    - Adult mode: the gas delivery temperature can be set to 31℃, 34℃, or 37℃
    - Pediatric mode: the gas delivery temperature can be set to 34℃
3. Push the Dial to confirm the setting value.

16.4. Set Threshold for Oxygen Concentration Alarm

The thresholds for O_2 too High and O_2 too Low alarms can be adjusted on the *Oxygen Alarm Limit Setting* page.

1. On the setting page, press the *O_2%* on the display to enter the *Oxygen Alarm Limit Settings* page
2. Press the *Oxygen Upper Limit* setting, the setting value is highlighted
3. Use the Dial to change the limits.
4. Press the limit value to accept the change
5. Press *Back* to exit the *Oxygen Alarm Limit Setting* page

6. Press the *Lock* icon to save the settings

WARNING: Setting O_2 alarm limits at extreme thresholds will effectively disable O_2 alarm detection.

16.5. Set Therapy Mode

Based on the patient who will be receiving the treatment, the therapy mode can be set to Adult (High Flow) Mode or Pediatric Mode. The therapy can be set on the *System Settings* page.

1. Press the *Lock Key icon*
2. Press the *Gear* icon to enter *System Settings* page
3. Select *Adult* or *PED* therapy mode
4. Press *Back*
5. Press the *Unlock Key* icon to save the setting

16.6. Factory Default Settings

Therapy mode	Adult
Flowrate	30LPM
Temperature	34^{o}C
O_2 **alarm lower limit**	21%
O_2 **alarm upper limit**	95%

16.7. Settings Storage

All settings are saved and are maintained across power cycles.

17. Alarms

The device generates an alarm with both visual and audio indications to alert the user that the normal operation of the device is interrupted by conditions listed in Table 17-1. The table lists Alarm priority, Alarm Message, its description (with fault detection), impact, fault responses. The alarm priority is listed in descending priority; lower priority number is higher in alarm priority, with one being the highest priority. System error alarms are technical alarms. All other alarms are patient alarms.

Depending on the alarm condition, alarm detection may take up to 120 seconds to trigger an alarm.

A visual alarm message will be displayed on the screen and the corresponding audio alarm is a repeating 3-beep sound for every 5 seconds. By pressing down the audio pause key , the audio alarm signal can be silenced for 2 minutes.

Alarm settings are retained and restored after shutdown or power loss.

Table 17-1 List of Alarm Conditions

Alarm Priority	Alarm Messages	Conditions	Impacts	Response Actions
1	"System Error XX-XX" "Please Turn Off the device"	Internal fault is detected by the device	Normal device operation is interrupted.	Turn off the device and try to trouble shoot as per the technical manual; unplug the device if necessary
2	"Check Circuit"	The breathing circuit or water chamber adaptor is not installed correctly	O_2 and humidity levels	Connect the Breathing circuit or the Water Chamber Adaptor Properly
2	"Check Leaks"	The system has high flow leakage	O_2 and humidity levels	Check for leaks in the device/ Patient interface connection and resolve if needed.
2	"Circuit Occlusion"	The circuits or patient's user interface is occluded	O_2 and humidity levels	Check for the occlusion in the circuit and interface and remove the occlusion
2	"Oxygen too Low"	The oxygen level is below the threshold	O_2 and humidity levels	Check the external O_2 flowrate settings

				and the O_2 alarm settings
2	“Oxygen too High”	The oxygen level is above the threshold	O_2 and humidity levels	Check the external O_2 flowrate settings and the O_2 alarm settings
2	“Flow Too Low”	The flow cannot reach the flow setting	O_2 and humidity levels	Restart the device
2	“Flow Too High”	The flow is more than the set value	O_2 and Humidity Levels	Restart the device
2	“Check Water”	The water ran out in the water chamber	Humidity level	Stop the therapy, replace the water bag and restart the therapy.
2	“Low Temperature”	The gas temperature cannot reach the setting value	Humidity level	Restart the device.
2	“High Temperature”	The gas temperature exceeds the setting value	Humidity level	Restart the device.
0	No message – Audio alarm only	The power is disconnected while the device is ON	Normal device operation is interrupted. Device is powered off.	Check power and the power connection

17.1. Alarm Signal Functionality Testing Method

The Alarm Signal Functionality can be tested by following the steps given below.

Note: This test can be performed at any time when the device is turned on and off patient.

1. Once the device is installed properly and ready to be used, Turn on the device.
2. Remove the breathing circuit.
3. Verify the “Check Circuit” visual alarm signal, displayed alarm message, and alarm sound is audible.

CAUTION: Do not use the humidifier if either of the alarm indications is absent. Refer the Bonhawa Respiratory Humidifier technical manual for troubleshooting procedure. If the problem persists, please contact Telesair Customer Service associate.

18. Maintenance

It is important that humidifier is cleaned between patients as well as on a weekly basis during normal use and/or for same patients to ensure best treatment. Follow the instructions in the sections below to learn how to disassemble, clean, inspect and reassemble your device.

The manufacturer will provide the schematics, parts list, and other documents to facilitate the maintenance. Please contact Telesair Customer Service for questions about maintenance.

18.1. Inspection and Replacement Schedule

WARNING: All the consumables are single patient use only. They must be disposed after use and between patients.

Parts/ Accessories/ Consumables	Inspection	Maximum use/Replace after
Air Filter	Every week	4 weeks *WARNING:* Replace the filter immediately if it is damaged or granular dust clogging is observed
Water Chamber Adaptor	Every Use	1 Week/every patient
Breathing Circuit		1 Week/every patient
Water Chamber		1 Week/every patient
Nasal Cannula		1 Week/every patient

18.2. Disassembling and Replacement Procedure

Air Filter

- ✓ Power OFF the device.
- ✓ Disconnect oxygen tubing.
- ✓ Unplug the Power Cord.
- ✓ Unscrew the Thumb Screw.
- ✓ Remove the O_2 Inlet Cover.
- ✓ Remove the old Air Filter and place a new Air Filter and close the cover.

Water Chamber Adaptor/ Breathing Circuit/ Water Chamber/ Nasal Cannula

- ✓ Turn OFF the device.
- ✓ Disconnect the Power Cord.
- ✓ Firmly hold Water Chamber Adaptor with one hand and pull the breathing circuit in upward direction with the other hand.
- ✓ Carefully press down the Finger Guard and pull out the Water Chamber along with the Water Chamber Adaptor.
- ✓ Replace with new accessories as needed.

18.3. Exterior and Touch Panel Cleaning

- CAUTION: To prevent possible damage to the humidifier, use only those cleaning and disinfecting agents listed in this document.
- CAUTION: To prevent possible damage to the humidifier, do not drip or spray any liquids directly onto any surface including the front touch panel, keys, knobs, connection points, and ports.
- CAUTION: Never clean or disinfect the touch panel with an abrasive brush or device, as this will cause irreparable damage.
- CAUTION: Do not attempt to sterilize or autoclave the humidifier.
- CAUTION: Do not attempt to submerge or wash humidifier with excessive liquids.
- CAUTION: Do not attempt to clean or disinfect humidifier while the heater plate is hot.
- CAUTION: Allow the humidifier to dry prior to reconnecting the Power Cord
- NOTE: Use of unapproved cleaning and disinfecting agents may cause

damage to the enclosure, touchscreen, or parts of the humidifier.

- NOTE: Do not clean or disinfect the internal area of the air outlet port, as this can damage the valve located within this port.
- NOTE: Standard cleaning and disinfection process must be performed on the humidifier between patients.

The water chamber, water chamber adaptor, breathing circuit, and the patient interface are consumables, which must be changed between patients or changed every week for the same patient.

18.3.1 Approved Cleaning Agents

The following cleaning agents are acceptable for use on the front touch panel and exterior surfaces of the humidifier.

Cleaning Agent
Ruhof Endozime® Multi-Tiered Enzymatic Detergent or equivalent

18.3.2 Cleaning Instructions

1. Power off and unplug the humidifier before cleaning
2. The operator must wash his/her hands properly and avoid touching the connection port without gloves.
3. Apply cleaning agent to a soft lint-free cloth or use a disposable wipe. The cloth or wipe should be saturated, not dripping.
4. Wipe cleaning agent over the entire exterior surface and touch panel of humidifier.
5. Let the cleaning agent remain on the surface for 90 seconds.
6. Continue wiping until all visible contaminates and soiling are removed.
7. Rinse with a clean, water-dampened cloth for 90 seconds and let dry completely before reuse.

18.4. Exterior and Touch Panel Disinfecting

- CAUTION: To prevent possible damage to the humidifier, use only those cleaning and disinfecting agents listed in this document.
- CAUTION: To prevent possible damage to the humidifier, do not drip or spray any liquids directly onto any surface including the front touch panel, keys, knobs, connection points, and ports.

- CAUTION: Never clean or disinfect the touch panel with an abrasive brush or device, as this will cause irreparable damage.
- CAUTION: Do not attempt to sterilize or autoclave the humidifier.
- CAUTION: Do not attempt to submerge or wash humidifier with excessive liquids.
- CAUTION: Do not attempt to clean or disinfect humidifier while the heater plate is hot.
- CAUTION: Allow the humidifier to dry prior to reconnecting the Power Cord
- NOTE: Use of unapproved cleaning and disinfecting agents may cause damage to the enclosure, touchscreen, or parts of the humidifier.
- NOTE: Do not clean or disinfect the internal area of the air outlet port, as this can damage the valve located within this port.
- NOTE: Standard cleaning and disinfection process must be performed on the humidifier between patients.

The water chamber, water chamber adaptor, breathing circuit, and the patient interface are consumables, which must be changed between patients or changed every week for the same patient.

18.4.1 Approved Disinfecting Agents

The following disinfecting agents are acceptable for use on the front touch panel and exterior surfaces of the humidifier.

Disinfectant
CLOROX Disinfecting Wipes or equivalent

18.4.2 Disinfecting Instructions

1. Power off and unplug the humidifier before cleaning.
2. The operator must wash his/her hands properly and avoid touching the connection port without gloves.
3. Utilize disinfecting agent wipe and apply over the entire exterior surface of the humidifier for 90 seconds.
4. Let the disinfectant remain on the surface for the contact times indicated in the specifications for the disinfecting agent.
5. Rinse with a clean, water-dampened cloth for 90 seconds and let dry completely before reuse.

18.5. Service

Bonhawa Respiratory Humidifier shall be serviced at 2-year intervals as part of a preventative maintenance schedule. This shall include a gas pathway leak test of the humidifier. Refer to the Bonhawa Respiratory Humidifier technical manual.

19. Waste Disposal

19.1. Accessories

When expended, the disposable water chamber, breathing circuit and patient interface must be disposed based on the waste management regulations of local government.

19.2. The Device

Consult with the local waste management services or your distributor before recycling the device. Special handling and disposal for electrical or electronic equipment waste may be required based on local regulations.

20. Troubleshooting

Read the following table for troubleshooting when the humidifier system is not working as intended. Contact Telesair Customer Service if you are not able to solve the problem. Do not open the enclosure of the humidifier at any point.

Table 20-1 Troubleshooting

Problem	Possible Cause	Trouble Shooting Actions
Screen is off	Power to the humidifier might have been disconnected	Connect the humidifier to power source, making sure there is a good and secure connection between the two.
Condensation of water vapor inside the patient's nose, the breathing circuit, or the patient interface	The ambient temperature might be too low	Try to increase the ambient temperature
	The setting of humidity level might be too high	Change the humidity setting to a lower level

21. Technical Specifications

21.1 Input Specification

Model	RHF G3 - 1	RHF G3 - 2
Power Supply AC Voltage	100-120V	220-240V

Power Supply Frequency	50/60Hz	50/60Hz
Power Supply Current	1.2A (2.4A max)	1.0A (2.0A max)
Maximum Oxygen Gas Supply	80 L/min max	80 L/min max

21.2 Air Filter

Material:	Double Laminated Spunbond Polypropylene
Efficiency:	>99.5% at 32LPM (0.1 micron) 99.9996% Bacterial Filtration (40cm^2) 99.996% Viral Filtration (40cm^2)

21.3 Operating Environment

Temperature	+18°C to +28°C
Humidity	25% to 85%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa
Altitude	0 - 2000 m

WARNING: Do not use the humidifier at altitude higher than 2000 m (6000 ft) or outside the temperature range of +18°C to +28°C. The quality and efficacy of therapy can be adversely affected.

Environmental Conditions for transport or Storage: –10°C to +60°C, at a relative humidity between 10% to 95%, non-condensing, and atmospheric pressure of 1040hPA to 700hPA

Classification	
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
The degree of safety when used under flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide	Non-AP/APG type
Operating mode	Continuous
Physical	
Dimension (H x W x D)	319 mm X 223 mm X 185 mm
Weight	2.6 Kg

Water capacity (When filled to maximum water level)	150 ± 30 mL
Pressure drops across water chamber	<1 hPa, when flow rate is 60 LPM,
Water chamber leak	<0.025 LPM, when pressure is 60hPa
Water chamber compliance	<0.7 mL/hPa when empty <0.5 mL/hPa, when at maximum water level
Maximum working pressure of humidifier	40hPa
Sound Pressure Level does not exceed during normal operation	50 dB(A)
Temperature	
Warm-up time needed, when starting temperature is 23±2°C:	10 min to reach 31°C and 34°C 30 min to reach 37°C
Static temperature stability	±2°C
Maximum temperature of delivered gas	≤43°C
Oxygen Monitor	
Accuracy	≤±3%, between 21% and 95%
Humidification Performance	
37°C	≥33mg/L
34°C	≥16mg/L
31°C	≥16mg/L

Note: The displayed temperature is referenced at the inlet of heated breathing circuit.

Therapy Mode	Flow Setting Range	Flow Setting Resolution	Flow Delivery Accuracy
Adult Mode	10 to 80 LPM	1 LPM for flow range between 10 and 25 LPM 5 LPM for flow range between 25 and 80 LPM	±1 LPM at 2 LPM ±2 LPM between 3 LPM – 10 LPM ± 3 LPM between 11 – 20 LPM ±15% of reading between 21 LPM – 80 LPM
Pediatric Mode	2 to 25 LPM	1 LPM	

Note:

- Flow rate is expressed in BTPS condition in this document.
- The performance of humidification may decrease by the presence of large unintended leaks

Alarms:

The alarm system complies with IEC 60601-1-8, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential requirements; collateral standard - alarm systems.

Alarm sound level exceeds 45 dB(A) @ 1m.

Cables that are likely to affect the EMC compliance are listed in the following table.

Type	Maximum length
Power cord	2.0 m

Note: Use only Telesair-provided power cables

Electromagnetic compatibility

The ME EQUIPMENT or ME SYSTEM is suitable for Professional healthcare facility environment.

The humidifier is compliant to applicable electromagnetic compatibility requirement (EMC) according to IEC 60601-1-2, for light industrial and hospital environments.

When normal operation of the humidifier is interrupted or degraded due to EM disturbances, the operator may expect that the normal operation be restored if the EM disturbances are removed.

MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS:

Manufacturer's declaration - electromagnetic emissions		
The Bonhawa Respiratory Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Bonhawa Respiratory Humidifier should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The BONHAWA HUMIDIFIER 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 A	The BONHAWA HUMIDIFIER is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BONHAWA HUMIDIFIER or shielding the location.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Manufacturer's declaration - electromagnetic Immunity		
The Bonhawa Respiratory Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Bonhawa Respiratory Humidifier should assure that it is used in such an environment		
Immunity Test	**Compliance level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, 4, 8 and 15 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 IEC 61000-4-4	±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	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations	0 % 0.5 Periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BONHAWA HUMIDIFIER requires continued operation during power mains interruptions beyond that

on power supply input lines IEC 61000-4-11	0% 1 Period 70% 25 Periods 0% 5 sec	provided by the battery, it is recommended that the BONHAWA HUMIDIFIER is powered from an uninterruptible power supply.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity magnetic fields IEC 61000-4-39	(8A/m, CW, 30kHz) (65 A/m (rms), PM at 2.1 kHz PM, 50% duty cycle, 134.2kHz) (75 A/m (rms), PM at 50 kHz, 50% duty cycle, 13.56MHz)	Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances
NOTE U_T is the A.C. main voltage prior to application of the test level.		

MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are Professional Healthcare Facility Environment.

Manufacturer's declaration - Electromagnetic Immunity		
The Bonhawa Respiratory Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Bonhawa Respiratory Humidifier should assure that it is used in such an environment		
Immunity Test	**Compliance level**	**Electromagnetic Environment Guidance**

Conduced RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 V 0.15 MHz – 80 MHz 6 V rms in ISM bands 3 V/m 80 MHz to 2.7 GHz	The BONHAWA HUMIDIFIER is suitable for the electromagnetic environment of typical hospital settings.

The Bonhawa Respiratory Humidifier was also tested for radiated immunity to RF wireless communication equipment at the test levels below.

Frequency (Hz)	Modulation	Level V/m
385	Pulse, 18 Hz, 50% DC	27
450	FM, 1 kHz Sine, ±5 Hz Deviation	28
710, 745, 780	Pulse, 217 Hz, 50% DC	9
810, 870, 930	Pulse, 18 Hz, 50% DC	28
1720, 1845, 1970	Pulse, 217 Hz, 50% DC	28
2450		28
5240, 5500, 5785		9

22. Incident Reporting

If a serious incident has occurred while using the Bonhawa Respiratory Humidifier, please contact your local Telesair representative and Competent Authority.

23. Warranty

The Bonhawa (RHF G3-1 & RHF G3-2) has a useful life of 5 years. Telesair will provide a warranty on the humidifier from the date of purchase for the time period listed below, if the device is used under normal conditions.

Model Type	**Warranty Period**
RHF G3-X	**2 Years**

Telesair will be responsible for repairing or replacing the defective product or any of its components during the Warranty Period if the product fails under normal conditions. This warranty is not transferable. It is only available to the original buyer of the device.
The coverage of the limited warranty will be voided if any of the following conditions occur:

- Repairs or services performed by any unauthorized service agency or personnel
- Any damage resulted from abuse, modification, alteration, or any other improper use of the product
- If the product is sold or resold outside the region of its original purchase

- Any damage or contamination caused by cigarettes or other smoke.

Warranty claims must be made by the original buyer of the device. Contact Telesair dealer or Telesair Customer Service for more information on warranty rights.

After Sales Service: Telesair Inc.

Registrant: Telesair Inc.

Address: 199 Technology Drive, Suite 110, Irvine, CA 92618 USA

Tel: +1-626-387-7709

Email: service@telesair.com

Web: http://www.telesair.com/

EU Registered Agent: OBELIS S.A

Address: Bd. Général Wahis, 53, 1030 Brussels, Belgium

Tel: +32.2.732.59.54

Fax: +32.2.732.60.03

E-mail: mail@obelis.net

Web: www.obelis.net