BONHAWA

Respiratory Humidifier

Instructions for Use

Models: RHF G3-1 & RHF G3-2

CE
2862

TABLE OF CONTENTS

1. Preface 5
2. Intended Use 5
3. Indication for Use 5
4. Contraindications 5
5. Clinical Benefits 5
6. Residual Risks and Undesirable Side-Effects 6
7. Product Name and Models 6
8. Symbols 7
9. Contents List 7
10. Warnings and Cautions 8
11. Disclosures 11
12. Device Overview 12
13. Setting Up 16
    13.1. Getting Started 17
    13.2. Install Heated Breathing Set 17
    13.3. Connecting Water Source 17
    13.4. Connect Patient Interface 18
    13.5. Connect Power 18
    13.6. Connect to Oxygen Supply 18
14. Therapy Configuration 19
    14.1. Unlock the Screen 19
    14.2. Set Mode 19
    14.3. Set Therapy Parameters 20
        14.3.1. Set Flow 20
        14.3.2. Set Gas Delivery Temperature 20
    14.4. Set Threshold for Oxygen Concentration Alarm 20
    14.5. Lock the Screen 20
        14.5.1. Automatic Lock 20
15. Advanced Settings 21
    15.1. Set High Leak Detection 21
    15.2. Set Brightness 21

15.3. Filter Service 21
15.4. Factory Default Settings 22
15.5. Settings Storage 22
16. Operation 23
16.1. Start Therapy 23
16.2. Oxygen Concentration 23
16.3. Stop Therapy 23
17. Alarms 24
17.1. Alarm Signal Functionality Test 26
18. Maintenance 27
18.1. Inspection and Replacement Schedule 27
18.2. Remove Breathing Accessories 27
18.3. Air Filter Replacement 28
18.4. Exterior and Touch Panel Cleaning and Disinfecting 28
18.4.1. Approved Cleaning Agents 28
18.4.2. Cleaning Instructions 29
18.4.3. Approved Disinfecting Agents 29
18.4.4. Disinfecting Instructions 29
19. Service 30
20. Waste Disposal 30
20.1. Accessories 30
20.2. The Device 30
21. Troubleshooting 30
22. Technical Specifications 31
22.1. Input Specification 31
22.2. Air Filter 31
22.3. Operating Environment 31
22.4. Alarms 33
22.5. Electromagnetic Compatibility 33
23. Incident Reporting 36
24. Warranty 36

NOTE: This product is protected by the following granted, continued, and pending patents:

US 11,135,390; US 11,318,268; US 11,468,988; US 11,954,331; US 11,642,477; US 11,702,602, US 11, 826,510; US 11,865,259; US 11,896,847; etc.

1. Preface

The Instructions for Use includes information regarding set-up, operation, and maintenance for the Bonhawa Respiratory Humidifier, models RHF G3-1 and RHF G3-2. The Bonhawa Respiratory Humidifier is for non-invasive high flow oxygen therapy with humidification, and for the purposes of this document it will be referred to as ‘device’. This device is intended to be used by a healthcare professional. Read through the Instructions for Use before using the device.

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, 10kg and above, in hospitals and long-term care facilities.

4. Contraindications

The Bonhawa Respiratory Humidifier is contraindicated for use with unresolved tension pneumothorax and facial trauma.

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 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. 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. Un-warmed 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 therapy by professionals and monitoring patients with COPD via pulse oximetry is recommended.

7. Product Name and Models

Product Name: Bonhawa Respiratory Humidifier

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

RHF G3 – 1

Third Identification Code for Product

Secondary Identification Code for Product

Product Platform Code for Bonhawa Respiratory Humidifier

8. 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

9. Contents List

Item	Quantity	Item	Quantity
Bonhawa Respiratory Humidifier	1	Power Cord	1
Quick Start Guide	1	Air Filter Pack	1

10. Warnings and Cautions

WARNINGS: Warnings 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 device is not a life-support device.
- The device uses oxygen concentration, respiratory gas flow and temperature, and provides alarms which need to be controlled and monitored to achieve its intended use. The device shall be used only by healthcare professionals.
- Closely monitor the patient's 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 device in an MRI (Magnetic Resonance Imaging) environment.
- The performance of the device may be affected if used in combination with devices other than the ones recommended by the manufacturer (e.g., nasal cannula).
- The device shall be used in a well-ventilated environment away from flammable gases including anesthetics.
- The device 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 device. Safety and effectiveness of high flow oxygen therapy may be compromised if using accessories that are not approved or recommended by Telesair.
- Stop using the device 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 device prior to cleaning.
- Power off and unplug the device immediately when liquids are spilled onto the device. Let the device dry prior to plugging power back to the device.
- The surrounding area of the device 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.
- Avoid using the device adjacent to or stacked with other equipment.
- If there is any flame in the vicinity, do not use the device.
- The device 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 device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- When the device 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 device is in operation. Monitor the breathing circuit for condensate at low flow and lower temperatures. Do not drain condensate back into the water chamber.

CAUTIONS:

- Normal operation of the device shall be verified if using the device adjacent to or stacked with other equipment is necessary.
- The device shall be used in an environment with good ventilation.
- Avoid using the device 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 device and cause the device 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 device, do not place the device upside down or on its side.
- When the device is not in use, ensure that the water chamber is empty or removed prior to transport.

- During intra-hospital transport, mount the device only on a mobile stand or trolley intended for medical equipment and capable of providing adequate stability and load support.
- Allow the water chamber to cool down for at least 10 minutes before removing it from the device.
- Device performance may be adversely affected, and device may be damaged if incorrect substances or methods for cleaning are performed.
- Do not disassemble the device. 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 of Bonhawa Respiratory Humidifier

Figure 12-2 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		

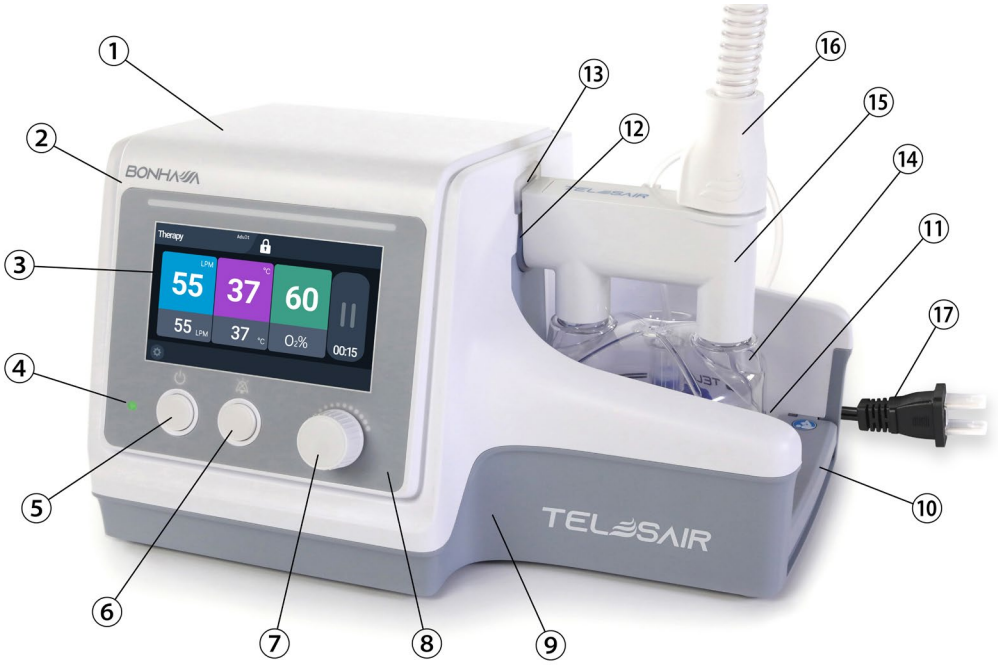


Figure 12-3 Component Diagram of Bonhawa Respiratory Humidifier, Front View

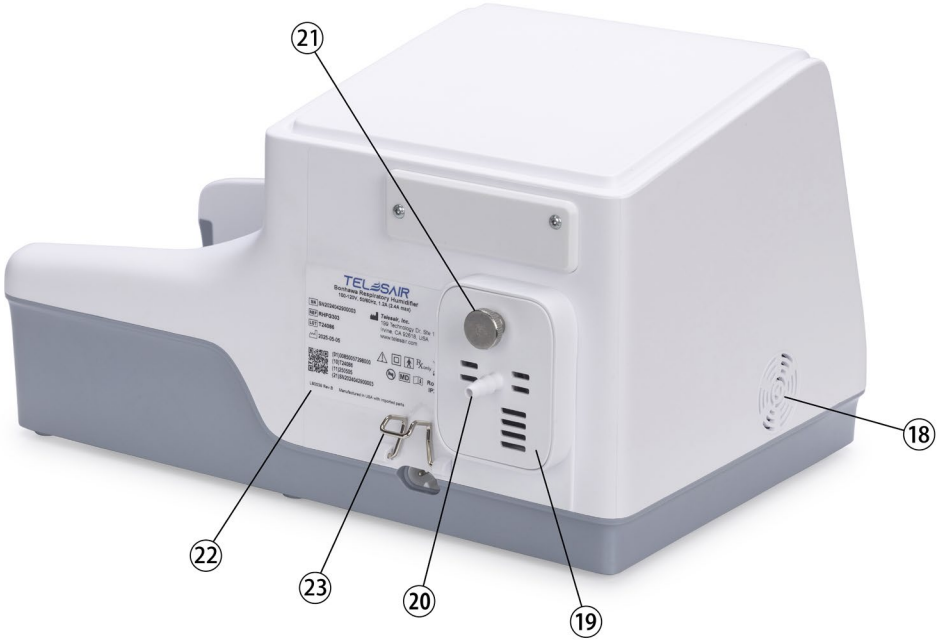


Figure 12-4 Component Diagram of Bonhawa Respiratory Humidifier, Rear View

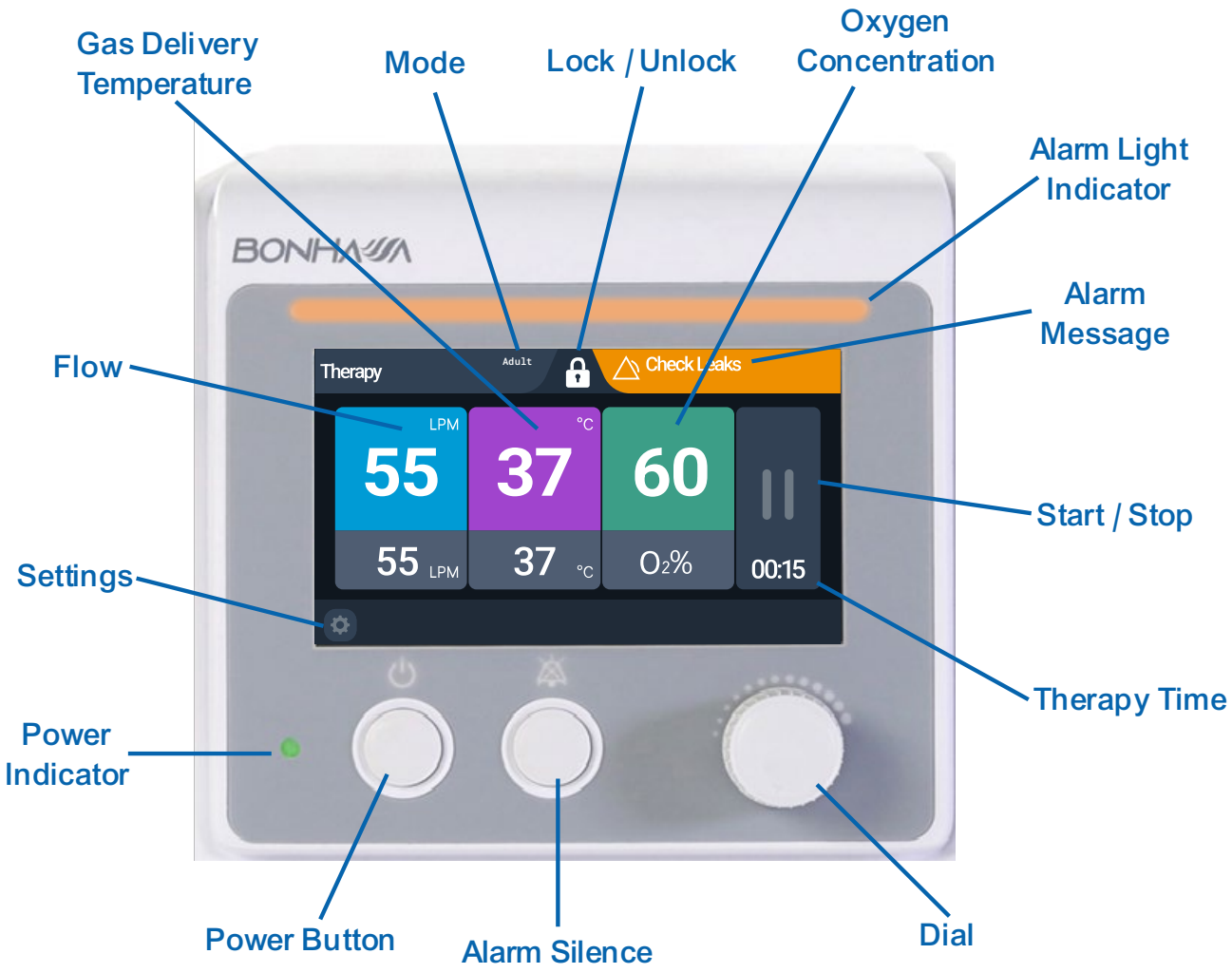


Figure 12-5 User Interface of Bonhawa Respiratory Humidifier

Table 12-2 Heated Breathing Set (HBK01) Contents

		
Water Chamber Adaptor	**Water Chamber**	**Heated Breathing Circuit**

Table 12-3 Patient Interface – Nasal Cannula

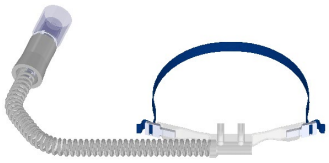
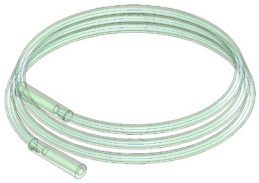
	Size	Catalog Number	Recommended Flow Rate Range
	Small	ENC03	2 – 25 L/min (Pediatric Mode) 10 – 40 L/min (Adult Mode)
	Medium	ENC02	10 – 80 L/min (Adult Mode)
	Large	ENC01	20 – 80 L/min (Adult Mode)

Figure 12-6 Bonhawa optional trolley (CTP02)

Table 12-3 Required accessories (not supplied)

			
Oxygen Flow Meter Nipple	**Oxygen Flow Meter**	**Oxygen Tubing (2m)**	**Sterile 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. The outlet of the oxygen flow meter connects to a DISS fitting that provides a barbed

connector interface that facilitates the oxygen tubing connection to the gas inlet of the device. Both the flowmeter and DISS fitting 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 must have a flush flow rate of 80 LPM or higher to support the requirement of the device.

The oxygen tubing is also a commonly used component available in hospital respiratory departments. Sterile distilled water is used to provide a water source for the device. Sterile distilled water is used and is readily available in hospitals and long-term care facilities. This sterile water is provided 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.

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. Setting Up

> **NOTE:** The operator must check if the device 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 therapy.

WARNING: The operator must ensure that all parts or “accessories” used are manufacturer approved and are compatible with the device. 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 device.

> **NOTE:** The accessories recommended or approved by Telesair can be found in Table 12-2 and Table 12-3.

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.

13.1. Getting Started

1. Obtain the heated breathing set (breathing circuit, water chamber, and water chamber adaptor) and the appropriate patient interface.
2. Place the device on a level, stable surface positioned slightly below the patient's head.
3. Verify that the air filter is properly installed.
4. Open the packaging of the heated breathing set.

13.2. Install Heated Breathing Set

1. Connect the four-pin end of the heated breathing circuit to the water chamber adaptor.
2. Remove the caps on the water chamber.
3. Attach the water chamber adaptor firmly onto the ports of the water chamber.
4. Press the finger guard of the device and slide the heated breathing set into the water chamber adaptor interface (13 in Figure 12-3) until the finger guard clicks into place.

13.3. Connecting Water Source

1. Clip the water chamber tubing into the water chamber adaptor.
2. Hang a sterile bag of distilled water about 20 cm (8") above the device.
3. Insert the bag spike into the water bag port. Water should drip into the chamber automatically.
4. Check that water flows into the water chamber.

WARNING: Adding substances other than sterile distilled water can adversely affect the normal functionality of the device.

NOTE: Make sure that both the water bag and the water chamber are not empty during operation to ensure continued humidification. Refer to Table 13-1 for 1-litre water bag emptying time under different settings.

Table 13-1 Minimum Water Usage (1-litre bag) Time Under Different Settings

Flow LPM	Temperature		
	31 °C	34 °C	37 °C
2	--	219 h	--
10	51 h	43 h	37 h
30	17 h	14 h	12 h
60	8 h	7 h	6 h
70	7 h	6 h	5 h

13.4. Connect Patient Interface

1. Connect the patient interface (e.g., nasal cannula) to the patient end of the breathing circuit.

13.5. Connect Power

1. Connect the device to a power source using the power cord provided.
2. Engage the latch to prevent the power cord from inadvertently disconnecting.
3. Press the Power Button to turn on the device. The main therapy screen will be displayed within 15 seconds and the device will enter **Standby**.

13.6. Connect to Oxygen Supply

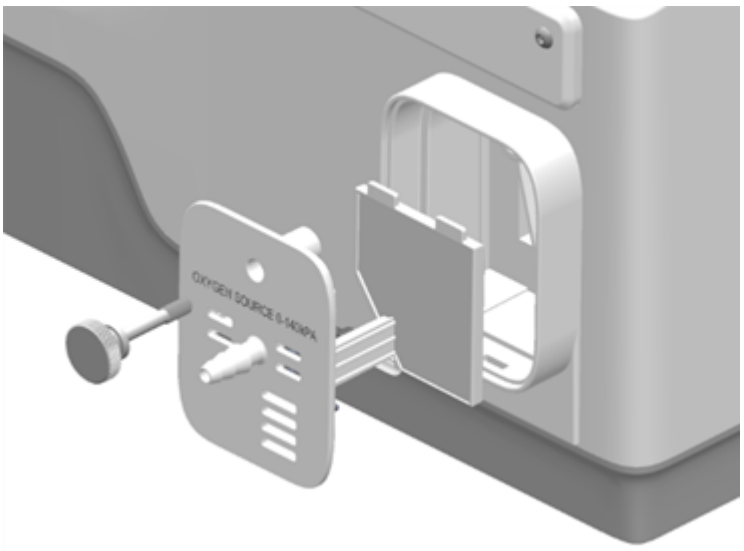


Figure 13-1 Air Filter Assembly Overview

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

WARNING: Only connect pure medical oxygen gas to the oxygen inlet port of the device. Do not connect other gases or gas mixtures.

1. Connect the oxygen tubing to the oxygen inlet port and ensure the connection is secure.
2. Verify that the **O_2%** displays 21% when no oxygen is flowing.
3. Turn on the oxygen supply and start therapy based on Section 16.1.
4. Verify that the **O_2%** increases.

14. Therapy Configuration

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

14.1. Unlock the Screen

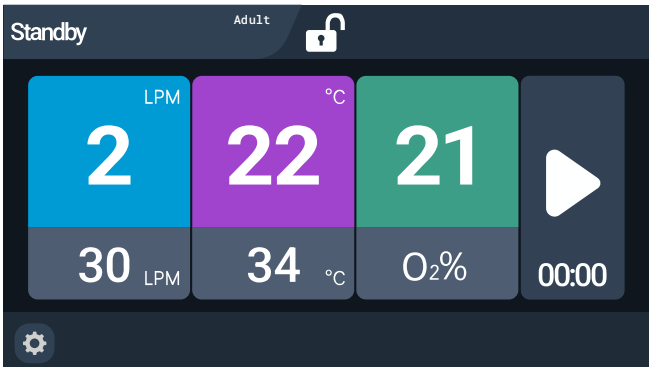
Unlock the screen to change therapy settings and start therapy.

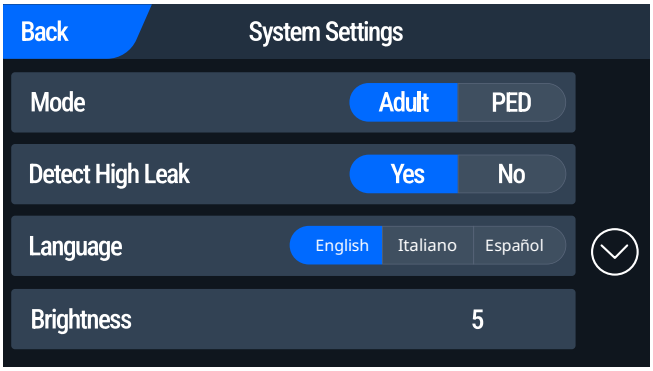
1. Press the Lock / Unlock icon to unlock the screen.

14.2. Set Mode

Based on the patient who will be receiving the treatment, the mode can be set to **Adult** or **PED**.

1. Press the Settings icon to enter the **System Settings** screen.





2. Press **Adult** or **PED** to set the mode.

14.3. Set Therapy Parameters

The upper values in the colored tiles display monitored values in real time. The lower values display the set values. A parameter is selected for adjustment when the tile changes color and the set value is highlighted.

14.3.1. Set Flow

1. Press the Flow parameter.
2. Rotate the Dial to adjust the flow setting.
3. Press the Dial or press the parameter again to confirm the setting.

14.3.2. Set Gas Delivery Temperature

1. Press the Gas Delivery Temperature parameter.
2. Rotate the Dial to select the temperature setting.
3. Press the Dial or press the parameter again to confirm the setting.

14.4. Set Threshold for Oxygen Concentration Alarm

Set the thresholds for the **Oxygen too High** and **Oxygen too Low** alarms.

WARNING*:* Setting the oxygen alarm limits at extreme thresholds will effectively disable oxygen alarm detection.

1. Press **O2%** to enter the **Oxygen Alarm Limit Setting** screen.
2. Press the **Oxygen Upper Limit** or **Oxygen Lower Limit**.
3. Rotate the Dial to adjust the limit.
4. Press the Dial or press the limit again to confirm the setting.
5. Press **Back** to exit the **Oxygen Alarm Limit Setting** screen.

14.5. Lock the Screen

Lock the screen to save the settings.

1. Press the Lock / Unlock icon to lock the screen.

14.5.1. Automatic Lock

If unlocked, the device will automatically lock the screen when **Therapy** starts or after 10 seconds of inactivity when no setting is selected.

15. Advanced Settings

15.1. Set High Leak Detection

When using a patient interface with low resistance other than the supported cannulas, the **Check Leaks** alarm may persist. To stop the undesired alarm, high leak detection can be turned OFF.

WARNING: Turning off high leak detection will not alarm when the cannula is disconnected. Only turn off high leak detection when needed.

1. Press the Settings icon to enter the **System Settings** screen.
2. Press **Yes** or **No** to detect or not **Detect high leak**.

15.2. Set Brightness

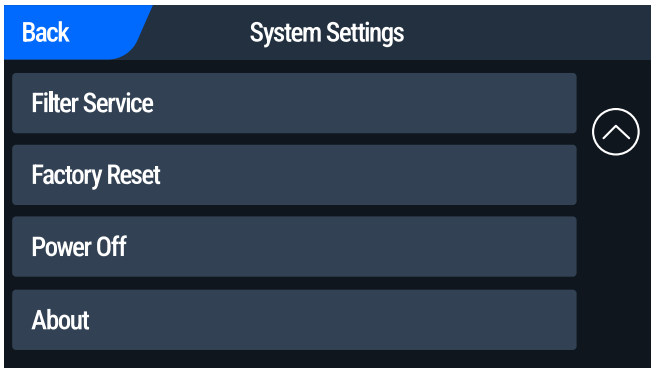
The screen brightness can be adjusted.

1. Press the Settings icon to enter the **System Settings** screen.
2. Press **Brightness.** The value will be highlighted.
3. Rotate the Dial to change to brightness level.
4. Press the Dial or press **Brightness** again to save the setting.

15.3. Filter Service

The device comes with an air filter that must be periodically replaced. To ensure the device is properly maintained, the device will assist with a built-in reminder to replace the air filter. To reset the reminder count down,

1. Press the Settings icon to enter the **System Settings** screen.
2. Press **Filter Service** on page two of the **System Setting** screen.



3. If the filter was replaced (reference section 18.3 for replacement instructions), press **Yes** to reset filter countdown.

4. If only checking the filter time remaining, press **No** to go back without resetting the filter count down.

NOTE: a reminder screen will pop-up automatically when the filter count down has reached zero.

15.4. Factory Default Settings

A factory reset restores the device settings to the factory default values listed below.

Mode	Adult
Flow	30LPM
Gas Delivery Temperature	34°C
Oxygen Lower Limit	21%
Oxygen Upper Limit	95%
Detect High Leak	Yes
Brightness	8

15.5. Settings Storage

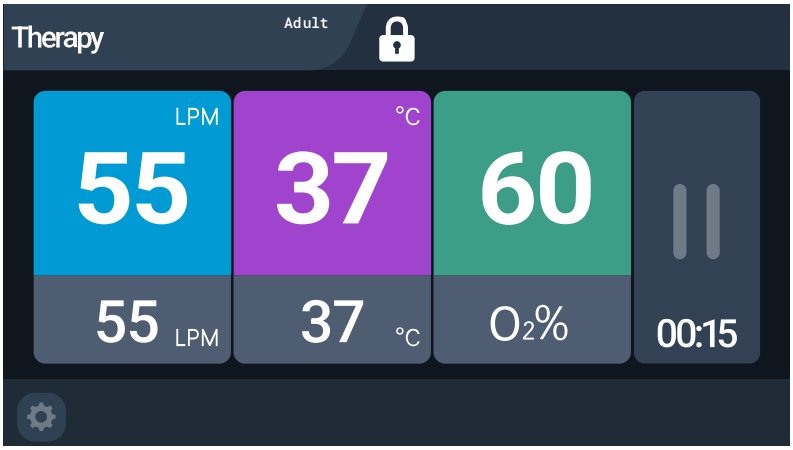
All settings are saved and are maintained across power cycles.

16. Operation

16.1. Start Therapy

NOTE: Do not titrate oxygen until the device enters **Therapy**.

1. Press the Lock / Unlock icon.
2. Press the Dial or press Start / Stop to start **Therapy**.



3. Titrate oxygen using the external flow meter to achieve the desired Oxygen Concentration.

16.2. Oxygen Concentration

The **O_2%** displayed on the screen indicates the Oxygen Concentration delivered during therapy. Regularly monitor the displayed **O_2%** and the patient's SpO_2 to ensure the prescribed oxygenation target is maintained while the device is delivering therapy.

16.3. Stop Therapy

1. Turn off oxygen flow.
2. Press the Lock / Unlock icon.
3. Press the Dial or press Start / Stop to stop **Therapy**. The device will enter **Cooling Down**.

NOTE: When the heater plate has cooled down, the device will enter **Standby**.

4. Press and hold the Power Button for 4 – 5 seconds to enter the **Power Off** screen.
5. Press **Confirm** to turn off the device.

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 and 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 nnn" "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 Water Chamber Adaptor"	The water chamber adaptor is not installed correctly or is faulty	Flow and oxygen	Connect the Water Chamber Adaptor properly or replace if alarm persists

Alarm Priority	Alarm Messages	Conditions	Impacts	Response Actions
2	“Check Circuit”	The breathing circuit is not installed correctly or is faulty	Flow and oxygen	Connect the Breathing circuit properly or replace if alarm persists
2	“Check Leaks”	The system has high flow leakage	Flow and oxygen	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	Flow and oxygen	Check for the occlusion in the circuit and interface and remove the occlusion
2	“Oxygen too Low”	The oxygen level is below the threshold	Oxygen levels	Check the external oxygen flowrate settings and the oxygen alarm settings
2	“Oxygen too High”	The oxygen level is above the threshold	Oxygen levels	Check the external oxygen flowrate settings and the oxygen alarm settings
2	“Flow Too Low”	The flow cannot reach the flow setting	Flow, oxygen and humidity levels	Restart the device
2	“Flow Too High”	The flow is more than the set value	Flow, oxygen and humidity levels	Restart the device

Alarm Priority	Alarm Messages	Conditions	Impacts	Response Actions
2	“Check Water Chamber”	The water ran out in the water chamber	Humidity level	Stop the therapy, replace the water bag and restart the therapy.
2	“Temperature Too Low”	The gas temperature cannot reach the setting value	Humidity level	Restart the device.
2	“Temperature Too High”	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 Test

The alarm signal functionality can be tested by following the steps given below.

NOTE: This test may be performed at any time when the device is turned on and not connected to a patient.

1. Install the heated breathing set.
2. Turn on the device.
3. Disconnect the breathing circuit.
4. Verify that the “Check Circuit” alarm message is displayed, the alarm light indicator is flashing, and the alarm sound is audible.

CAUTION: Do not use the device if any alarm indications are absent. Refer to the Bonhawa Respiratory Humidifier technical manual for the troubleshooting procedure. If the problem persists, please contact Telesair Customer Service.

18. Maintenance

It is important that device is cleaned between patients as well as on a weekly basis during normal use and/or for same patients to ensure the 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 maintenance. Please contact Telesair Customer Service for questions about maintenance.

18.1. Inspection and Replacement Schedule

SPU Parts/Accessories/Consumables	Inspection	Maximum use/Replace after
Heated Breathing Set (Water Chamber Adaptor) (Breathing Circuit) (Water Chamber)	Every Use	1 Week/every patient **WARNING:** All consumables are single patient use only. They must be disposed of after use and between patients.
Nasal Cannula		1 Week/every patient **WARNING:** All consumables are single patient use only. They must be disposed of after use and between patients.

Non-SPU Maintenance Items	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

18.2. Remove Breathing Accessories

Water chamber adaptor, breathing circuit, water chamber, nasal cannula

1. Turn off the device.
2. Disconnect the power cord.
3. Hold the water chamber adaptor with one hand and pull the breathing circuit upward to disconnect it.
4. Press the finger guard down and slide the water chamber and water chamber adaptor out of the device.

18.3. Air Filter Replacement

1. Ensure the device is powered off.
2. Unscrew the thumb screw.
3. Remove the gas inlet cover.
4. Replace the old air filter with a new one and close the cover.

18.4. Exterior and Touch Panel Cleaning and Disinfecting

CAUTION: To prevent possible damage to the device, use only those cleaning and disinfecting agents listed in this document.

CAUTION: To prevent possible damage to the device, 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 device.

CAUTION: Do not attempt to submerge or wash the device with excessive liquids.

CAUTION: Do not attempt to clean or disinfect the device while the heater plate is hot.

CAUTION: Allow the device 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 device.

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 device 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 Cleaning Agents

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

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

18.4.2. Cleaning Instructions

Cleaning removes contaminants and soil.

1. Wash hands and wear gloves.
2. Power off and unplug the device.
3. Apply cleaning agent to a soft, lint-free cloth or disposable wipe. The cloth or wipe should be saturated, not dripping.
4. Wipe the entire exterior surfaces and touch panel.
5. Allow the cleaning agent to remain on the surface for 90 seconds.
6. Wipe until all visible contaminants and soil are removed.
7. Rinse with a clean, water-dampened cloth for 90 seconds.
8. Allow the device to dry completely before reuse.

18.4.3. Approved Disinfecting Agents

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

Disinfectant
CLOROX Disinfecting Wipes or equivalent

18.4.4. Disinfecting Instructions

Disinfection reduces the number of microorganisms.

1. Wash hands and wear gloves.
2. Power off and unplug the device.
3. Wipe the entire exterior surfaces and touch panel with the disinfectant.
4. Allow the disinfectant to remain on the surface for the contact times specified by the disinfectant manufacturer.
5. Rinse with a clean, water-dampened cloth for 90 seconds.
6. Allow the device to dry completely before reuse.

19. Service

The device is designed to operate without scheduled preventative maintenance service. Under normal conditions, periodic service is not required. If the device has been subjected to abnormal conditions (e.g., high impact such as a hard drop), service is needed to verify performance and safety. This shall include a gas pathway leak test. Contact your local Telesair representative with questions regarding service and operation of your Bonhawa Respiratory Humidifier or email service@telesair.com.

20. Waste Disposal

20.1. Accessories

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

20.2. 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.

21. Troubleshooting

Read the following table for troubleshooting when the device 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 device at any point.

Table 21-1 Troubleshooting

Problem	Possible Cause	Trouble Shooting Actions
Screen is off	Power to the device might have been disconnected	Connect the device 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

22. Technical Specifications

22.1. 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

22.2. 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)

22.3. Operating Environment

Temperature	+18°C to +28°C
Humidity	10% 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 device 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 device	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℃	≥ 33mg/L
34℃	≥ 16mg/L
31℃	≥ 16mg/L

NOTE: The displayed temperature is referenced at the outlet of the water chamber adaptor.

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	±15% of reading or 3 LPM, whichever is greater
Pediatric Mode	2 to 25 LPM	1 LPM	

NOTE: Flow rate is expressed in BTPS condition in this document.

NOTE: The performance of humidification may decrease by the presence of large unintended leaks

22.4. 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

22.5. Electromagnetic Compatibility

The device is suitable for professional healthcare facility environment. The device 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 device is interrupted or degraded due to EM disturbances, the operator may expect that the normal operation be restored if the EM disturbances are removed.

<table>
<tr><th colspan="3">Manufacturer’s declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure 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 A</td><td rowspan="3">The device 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 device or shielding the location.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>N/A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>N/A</td></tr>
<tr><td>Electrostatic discharge (ESD) IEC 61000-4-2</td><td>±8 kV contact
±2, 4, 8 and 15 kV air</td><td>Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Electrical fast transient/burst IEC 61000-4-4</td><td>±2 kV for power supply lines</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge IEC 61000-4-5</td><td>±1 kV differential mode</td><td>Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11</td><td>0 % 0.5 Periods
0% 1 Period
70% 25 Periods
0% 5 sec</td><td>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 beyond that provided by the battery, it is recommended that the device is powered from an uninterruptible power supply.</td></tr>
</table>

Manufacturer's declaration - electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
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.		
Conducted RF IEC61000-4-6	3 V 0.15 MHz – 80 MHz 6 V rms in ISM bands	The device is suitable for the electromagnetic environment of typical hospital settings.
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.7 GHz	

The device 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

23. Incident Reporting

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

24. Warranty

The Bonhawa Respiratory Humidifier (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- 949-570-3553

Email: service@telesair.com

Web: https://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