Respiree

Respiree Cardio-respiratory Monitor

Operator's Manual

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RS001.2 US Ver 3 07/12/2024

WARNING: Do not operate Respiree Cardio-respiratory Monitor without completely reading and understanding the instructions

WARNING: Failure to follow all of the directions in this manual could lead to inaccurate measurements.

CAUTION: General knowledge of respiratory rate monitoring is a prerequisite for proper use

For Sales in the USA

These operating instructions provide the necessary information for proper operation of the Respiree Cardio-respiratory Monitor System. There may be information provided in this manual that is not relevant for your system. General knowledge of respiratory rate monitoring and an understanding of the features and functions of the Respiree Cardio-respiratory Monitor are prerequisites for its proper use.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) for non-invasive patient monitoring and may not be used for any processes, procedures, experiments or any other use for which the device is not intended or

cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labelling.

For professional use. See directions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

MEDICAL ELECTRICAL EQUIPMENT
WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
AAMI/IEC ES 60601-1:2005 + AMD 1:2012, IEC 60601-1-2: 2020, FCC 47 CFR Part 15 and Part 18 and ANSI IEEE C63.27-2017

Operator's Manual

Respiree

Table of Contents

About this Manual

Always use Respiree Cardio-respiratory Monitor precisely in accordance with the directions in this manual including site selection and sensor placement.

Read and follow any warnings, cautions and notes presented throughout this manual. The following section explains warnings, cautions and notes.

Documentation Features

WARNING: A WARNING is given when actions may result in a serious outcome to the patient or user (for example, injury, serious adverse effect or death).

CONTRAINDICATION: A CONTRAINDICATION is given when the medical device should not be used in the situations as described.

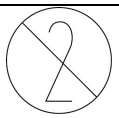
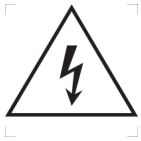
CAUTION: A CAUTION is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this instrument, or damage to the property.

Note: A Note is given when additional general information is applicable.

List of Symbols

The following symbols may appear on the product or product labelling:

Symbol	Description	Symbol	Description
	Warning/ Caution		Not for continuous monitoring (No alarm)
	Follow instructions for use		Consult instruction for use
	Model Number		Serial Number
	Manufacturer		Manufacture Date: YYYY-MM-DD
	Storage temperature range		Storage humidity limitation
	Fragile handle with care		Do not use if package is damaged
	Separate collection for electrical and electronic equipment (WEEE)		Biohazardous Waste
	Non-sterile		Single use (disposable) only

			
	Polypropylene		Recyclable
	Not made with natural rubber		Keep dry
	Federal Communications Commission (FCC) Licensing		Non-ionizing electromagnetic radiation
	Warning electricity		Electrostatic
	Type BF applied part	**Rx ONLY**	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Magnetic Resonance (MR) Unsafe		

Product Description and Indications

Product Description

The Respiree Cardio-respiratory Monitor is intended as a noninvasive device that measures and displays Respiratory Rate (RR).

The Respiree Cardio-respiratory Monitor System is available in the following models:

Product Models	Features
RS001.2.D (Cardio-respiratory Monitor)	Intended to measure and display Respiratory Rate (RR) and used with RS001.2.DS for display. Bluetooth LE radio is intended to transfer of parameter data to the Respiree Gateway.
RS001.2.G (Gateway)	Intended to sync data from RS001.2.D via Bluetooth and upload the data to cloud server via Wi-Fi or LTE.
RS001.2.DS (Dashboard)	Intended to use data from RS001.2.D to display Respiratory Rate (RR).

Indications for Use

The Respiree Cardio-respiratory Monitor is a respiratory monitor intended for hospitals and hospital-type facilities in non-ICU settings and home settings. The Respiree respiratory monitor is indicated for the non-invasive spot checking of respiration rate (RR) for adult patients.

Safety Information, Warnings and Cautions

Safety Warning and Cautions

WARNING: Handle the Respiree Cardio- respiratory Monitor and the Gateway with care. The devices can be damaged if dropped, punctured, or crushed. If you suspect damage to the devices, discontinue use to prevent injury. Do not use the devices when the casing or screen is cracked.

WARNING: Stop using the power adapter cable or the gateway if any of the following conditions exist:

- **power adapter plug or prong is damaged**
- **charging cable becomes frayed or damaged**
- **power adapter is exposed to excessive moisture, or spilled liquid**
- **power adapter enclosure is damaged**
- **USB port on the gateway is damaged or bent**

WARNING:

Use only Respiree approved patches and accessories with Respiree Cardio- respiratory Monitor. Any other 3rd party accessories may lead to degradation of signals.

Respiree patch accessory to be used within 1 year from exposure to air.

WARNING:
Reposition Respiree Cardio-respiratory Monitor when in respiratory rate on chest once at least once every 24 hours to allow patient's skin to breath.

Reposition device and adhesive patch if patient shows signs of dermal irritation.

WARNING:
Check the sensor site every hour to ensure adequate circulation, skin integrity, and sensor alignment. Skin damage, pressure necrosis or inaccurate readings may result.

Do not use the Respiree patch on open-wounds, injured, sensitive, fragile, dry or thin skin. If the patient has a history of known skin allergies, consult a doctor before using the patch.

Do not reapply adhesive patch on the same anatomical location when patient shows signs of dermal irritation.

Do not use contaminated patch.

CAUTION: The Respiree patch is a single-use and strictly one-time use patch only. Dispose of the patch after a maximum recommended time of 24 hours of use.

WARNING: Do not expose Respiree Cardio-respiratory Monitor and the Gateway to moisture (such as rain or washing under tap or shower) to ensure performance and device safety. The devices are not waterproof and should not be immersed in fluids

WARNING: Do not place Respiree Cardio-respiratory Monitor or accessories in any position that might cause it to fall on the patient.

CAUTION: Do not attempt to stack Respiree devices with other devices or use in adjacent to other devices.

WARNING: Do not open Respiree Cardio-respiratory Monitor or Gateway.

WARNING: Do not leave the Respiree Cardio-respiratory Monitor and gateway unattended around children. Small items such as the sensor may become choking hazards.

WARNING:
Store Respiree Cardio-respiratory Monitor and Gateway in a secure location according to the storage conditions when not in use. See Specifications for details.

Store the devices and accessories properly when not in use to prevent damage.

WARNING: Verify if the correct Cardio- respiratory Monitor and Gateway assigned on the Dashboard is used on patient.

WARNING: The Respiree Cardio-respiratory Monitor is fixed at chest mode only.

Site of Operation

WARNING:
Do not use Respiree Cardio-respiratory Monitor and Gateway during magnetic resonance imaging (MRI) or in an MRI environment.

Do not use Respiree Cardio-respiratory Monitor and Gateway near devices that are sensitive to magnets.

Respiree Cardio-respiratory Monitor and Gateway can be affected by strong electromagnetic interferences during operation. When not in use, switch off the device or shift device to another location in case of strong interference.

WARNING: Do not use Respiree Cardio-respiratory Monitor and Gateway in the presence of flammable anesthetics or other flammable substances, oxygen-enriched environments or nitrous oxide to avoid the risk of explosion.

WARNING: Do not use Respiree Cardio-respiratory Monitor during electrosurgery.

CAUTION:
When using Respiree Cardio-respiratory Monitor with the Gateway, keep both devices within the recommended range of each other (see Specifications for details): moving outside of this range may cause a loss in connection.

The Respiree Cardio-respiratory Monitor should be within specified meter range when syncing to the Respiree Gateway in RF interference environment. See Specifications for details.

When using the Respiree Cardio-respiratory Monitor with the Gateway, relocate the devices away from sources that may interfere with the wireless connection. The presence of other devices that may create radio frequency interference (RFI) may result in loss of Quality of Service (see Specifications for details) of the Bluetooth connection. Devices that may cause RFI include but are not limited to the following: electrocautery equipment, diathermy equipment, 5G cellular, other cellular telephones, wireless PC and tablets, wireless power transfer (WPT), pagers, RFID devices, MRI and electromagnetic security systems.

CAUTION:
There is a possibility that radio signals from high-frequency transmitters, e.g. mobile phones or similar mobile radio equipment, wireless power transfer, airport security systems, or metal detection devices (which themselves conform to the EMC regulations), may influence the proper functioning of the device if such equipment is operated in close proximity and with relatively high transmitting power. The device meets EMC requirements and is designed in such a way, that under normal conditions, there is no risk of malfunction caused by electromagnetic interference. However, in the case of signals from high frequency transmitters, the risk of electromagnetic incompatibility when operated in close proximity to electronic apparatus cannot be totally ruled out. In unusual circumstances, unintended functions of the device could be initiated, possibly giving rise to undesirable risks for the patient or user or ineffective treatment parameters.

Defibrillator Precautions

WARNING: Do not use Respiree Cardio-respiratory Monitor during defibrillation.

Charging

WARNING:
Charge the Respiree Cardio- respiratory Monitor when the battery icon display shows low.

Respiree Cardio-respiratory Monitor should be charged using the Gateway provided.

The Respiree Cardio-respiratory Monitor uses a rechargeable battery. Limit the charging time to maximum of 2 hours.

Contraindication

CONTRAINDICATION: The Respiree Cardio-respiratory Monitor excluded the following subjects in the respiration rate clinical study:

- **Compromised circulation, injury and physical malformation of fingers, toes, hands, ears or forehead/ skull or other sensor sites which would limit the ability to test sites needed for the study. Tattoo in the optical path which would limit the ability to test sites needed for the study.**
- **Severe contact allergies to standard adhesives, latex and other materials found in pulse oximetry sensors, ECG electrodes, or other medical sensors.**

Performance

WARNING: Optical, pleth based measurements (e.g. RR) can be affected by the following:

- **Improper placement or alignment of Respiree Cardio-respiratory Monitor**
- **Intravascular dyes such as indocyanine green or methylene blue**
- **Externally applied coloring and texture such as nail polish, acrylic nails, glitter, tattoo etc.**

WARNING: Inaccurate respiration rate (RR) readings may be caused by:

- **Improper Respiree Cardio-respiratory Monitor placement or alignment on the chest**
- **Excessive motion**

WARNING: The Respiree Cardio-respiratory Monitor is not an apnea monitor and should not be used for arrhythmia analysis.

WARNING: The Respiree Cardio-respiratory Monitor is non-diagnostic and non-confirmatory for any disease. The Respiree Cardio-respiratory Monitor should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: Do not self-diagnose or self-medicate on the basis of the measurements. Always consult your doctor if you are not feeling well.

WARNING: Do not use Respiree Cardio-respiratory Monitor for continuous monitoring. It is intended for spot-check use only. No alarms are provided to support continuous monitoring.

WARNING: Properly apply and avoid using Respiree Cardio-respiratory Monitor under high ambient light sources, fluorescent lights, infrared heating lamps and direct sunlight to minimize interference that may result in no or inaccurate readings.

Note: The Respiree Cardio-respiratory Monitor may be difficult to view when exposed to direct sunlight or bright lights.

WARNING:
Do not use Respiree Cardio-respiratory Monitor if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate readings.

Do not use Respiree Cardio-respiratory Monitor if the internal parts have been exposed to liquids. Damage to the internal parts may result in no or inaccurate readings.

WARNING: Corrosion, discoloration, pitting or cracked seals may cause unacceptable deterioration of the devices. Always perform visual inspection of the devices before use.

CAUTION: This device has not been evaluated for use in aircrafts.

Note: Do not assess the accuracy of the Respiree Cardio-respiratory Monitor using a functional tester.

Maintenance

WARNING:
No modification of this equipment is allowed. Do not modify equipment without authorization of manufacturer.

WARNING:
Do not repair, open or modify Respiree Cardio-respiratory Monitor or the Gateway. Damage to internal parts can result in no or inaccurate readings.

WARNING: Do not attempt to remanufacture, recondition or recycle Respiree Cardio-respiratory Monitor or the Gateway as these processes may damage the internal parts. Damage to internal parts can result in no or inaccurate readings.

WARNING: Respiree Cardio-respiratory Monitor and the Gateway is without any user-serviceable part inside and only qualified service personnel can perform maintenance service.

WARNING: Do not perform servicing or maintenance while the devices are in use.

Cleaning, Disinfecting Warnings and Cautions

WARNING: Thoroughly clean and low level disinfect the Respiree Cardio-respiratory Monitor before applying it to on a new patient.

CAUTION:
*Do not clean Respiree Cardio-respiratory Monitor with any chemical other than those specified in **Cleaning and Disinfecting**. These substances may affect the device's materials and damage internal parts.*

*Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in **Cleaning and Disinfecting** of this manual. Permanent damage to Respiree Cardio-respiratory Monitor may occur if other unspecified solutions are used.*

CAUTION:
Do not submerge Respiree Cardio-respiratory Monitor in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.

Never submerge Respiree Cardio-respiratory Monitor in water or any other liquid solution. This may cause permanent damage to the sensor.

WARNING: Wipe the lens of Respiree Cardio- respiratory Monitor if there are dirt and debris.

WARNING: Do not continue using the Cardio- respiratory Monitor if it exceeds the reuse life. Using such device may result in reduced effectiveness, malfunction or increased risk of infection from damaged device materials. See Specifications for details.

Compliance, Warnings and Cautions

WARNING: All Healthcare Professionals have to undergo training by Respiree prior to using the devices.

WARNING: For RS001.2.D and RS001.2.DS, device must be operated by trained personnel under the supervision of a physician.

WARNING: Any changes or modifications not expressly approved by Respiree shall void the warranty for this equipment and could void the user's authority to operate the equipment.

Note: When using the device with wireless features, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

Note: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

Note: The device complies with Part 15, Part 18, Part 22, Part 24, Part 27 of FCC 47 CFR rules.

Medical Device Disposal

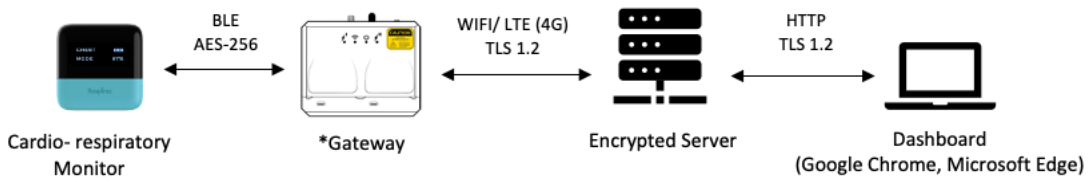
CAUTION: Comply with local laws in the disposal of the Respiree Cardio-respiratory Monitor, Respiree Gateway and Respiree patch.

Cybersecurity

While Respiree has taken appropriate security measures to protect our system from cyberattacks, it is important that the user takes steps to prevent and maintain cybersecurity. The guidelines in this section must be followed.

Respiree devices are connected to networks. No protected health information (PHI) is stored within the Cardio- respiratory monitor and the gateway devices, nor transmitted by the devices. Communications between the devices and the Respiree software platform are encrypted to industry-standards.

Description of all interfaces and communication protocols on the devices:



*Note: GPS port on the gateway is disabled and not available.

The Respiree gateway provided, shall only be used with Respiree's products and services. It cannot be used for, nor should it be used, for any other purpose, such as personal internet use.

A combination of username and password are used to control access to the Respiree Dashboard. It is the responsibility of the user to apply appropriate password policies e.g. password complexity, changing of password regularly.

Password Policies and Auto-logout

It is recommended that the user

- use a minimum password length of 8 characters
- include lower and uppercase alphabetic characters, numbers and symbols
- change password every 3 months

User will be automatically logged out from the Respiree Dashboard if the application is inactive for 30 days.

Periodical Software Updates and Patches

The Respiree Dashboard via the web interface will always have access to the most up to date version.

Lost or stolen Device

Please notify Respiree via email at helpdesk@respiree.com with the ID of the Cardio- respiratory Monitor and gateway in case of lost or stolen.

Service Unavailability

In the event of cloud/ service unavailability, user can revert to manual monitoring of respiration rate.

General Guidelines for Security

- User should always keep security software up to date on their computer.
- It is recommended to set device passcode for any computer used with the Respiree Dashboard.
- User should never disclose your username and password. No Respiree personnel will ever ask for these details.
- User should never write the username and password down.
- User should never provide an unauthorized user access to the Respiree Dashboard.
- User should never leave the Respiree Dashboard logged in and unattended. Use should always log out when the Respiree software is not in use or unattended.
- User should install or enable firewall for their network.
- Healthcare Professional should never disclose protected health information within a support message to Respiree. This includes details like patient's name or date of birth.

Cybersecurity Events

The Respiree Cardio- respiratory Monitor System logs all events including security events and store the log files in the Database. These files are analyzed by Respiree personnel during system forensics. They are not meant to be analyzed by the user.

Cybersecurity Reporting

Respiree continually monitors for vulnerabilities affecting Respiree Cardio- respiratory Monitor System and take necessary actions to mitigate the threats. In the event of a cybersecurity threat,

or abnormal activities, Respiree will inform the healthcare organization of such events via an email, follow by a phone call.

If the user suspects or detects cybersecurity threat, immediately contact Respiree via email at helpdesk@respiree.com.

Technology Overview

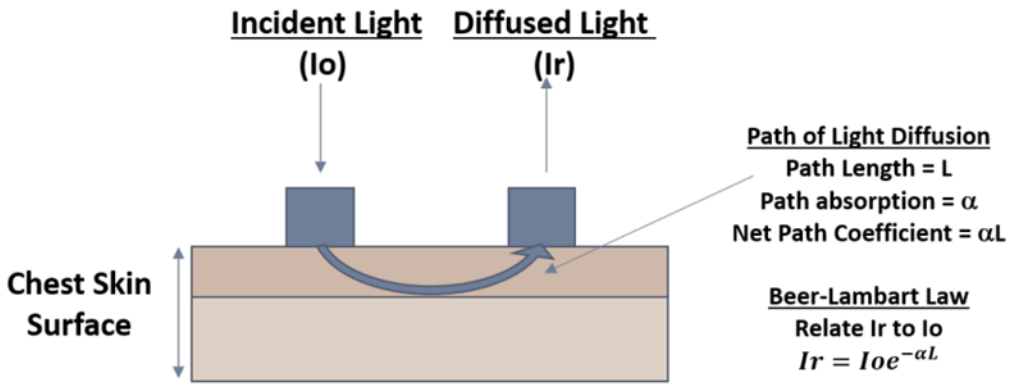
The following chapter describes the general principles of operation, parameters and measurements used by the Respiree products.

The Respiree Cardio-respiratory Monitor uses an all optical approach for direct measurement of respiratory rate from the chest.

To measure respiratory rate (RR), the Respiree Cardio-respiratory Monitor uses a disposable patch that allows the sensor to connect to the chest for measurement of chest-thorax movements.

To measure respiratory rate on the chest, the Respiree Cardio-respiratory Monitor makes use of the direct-contract optical diffuse reflectance principle of operation as shown in the figure below. The light absorption changes due to stretching of the skin is measured from a photo-sensor. Adaptive filters to remove noise and motion as well as to calculate respiratory rate accurately are utilized.

This figure is for conceptual purposes only.



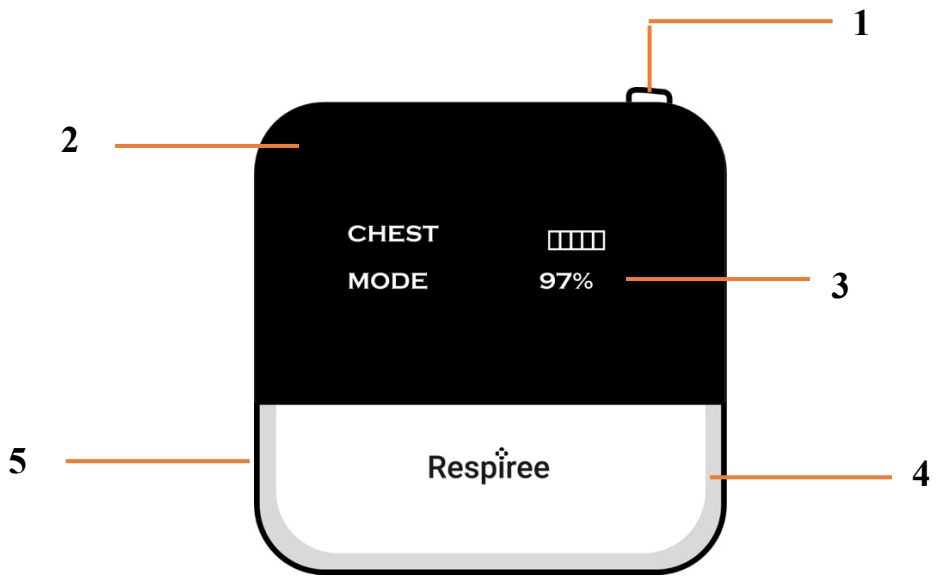
General Description for Respiratory Rate (RR)

Respiration rate can be determined by the direct absorption change due to skin stretching. The method measures the respirations per minute (RPM).

Operation

Note: RS001.2.D and RS001.2.DS to be used by a physician or healthcare professional under the supervision of a physician.

RS001.2.D Cardio-respiratory Monitor Features



ID	Description	Function
1	On-Off Button	Press and hold once to turn on/ off device.
2	Display Screen	Display of battery life and mode
3	Battery Status	Indicates the remaining relative life of the battery.
4	Recharging Port	Interface to plug in micro-USB cable for recharging of battery
5	Mode Switch	Fixed and kept at chest mode. Note: When user toggles the switch, the mode will remain at chest mode.

Note: RS001.2.D is to be used in conjunction with RS001.2.DS.

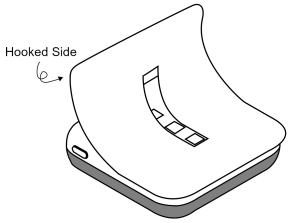
Using Respiree Cardio-respiratory Monitor

RESPIRATORY RATE (RR) Measurement (RR Mode)

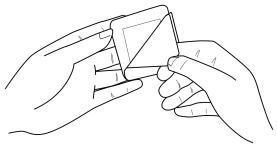
Note: Before use, ensure Cardio- respiratory Monitor is in good condition.

To take readings for Respiratory Rate, follow the instructions below:

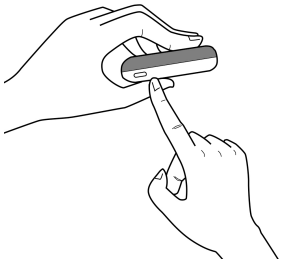
1.



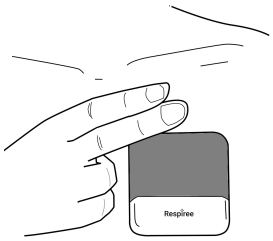
2.



3.



4.

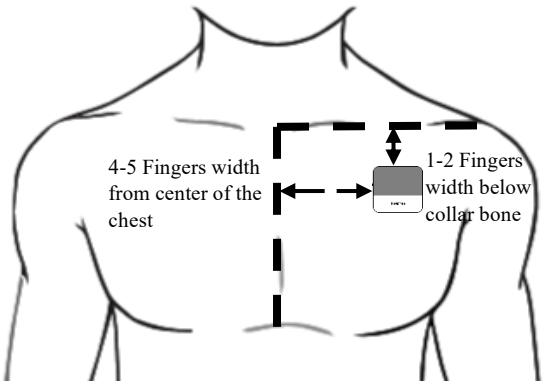


1. Take the Cardio-respiratory Monitor and a piece of RS001.2.P patch. Ensure the "sensing-side" of the monitor is along the same direction as the "longest-side" of the patch window. Place the hook side of the patch with the fastener side of the monitor.

2. Remove the non-adhesive part of the patch.

3. Turn on the device by pushing the "on-off button" on the side of the Cardio- respiratory Monitor The display will turn on with the initialization of "RR" as mode.

4. Place the Cardio-respiratory Monitor 1-2 fingers below the collarbone and 4-5 fingers from the center of the chest.



5. Wait for at least 2 minute and respiratory rate (RR) will be displayed on the dashboard screen. RR is refreshed at every processed data.

WARNING: Do not remove the Cardio- respiratory Monitor for 2 minutes when the device is on the patient.

Note: If readings are ok, display will show the respiratory rate data. If readings are perturbed by bad skin contact or too much motion, display will show "—" . See ***Troubleshooting***.

Note: Once reading is complete and spot measurement is taken, remove the Cardio-respiratory Monitor, remove the patch, throw away the patch and turn-off the monitor. Proceed to clean down the Cardio- respiratory Monitor.

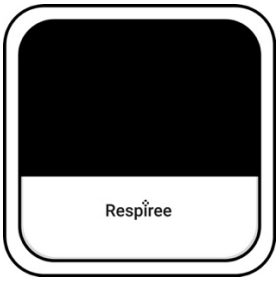
Note: If any errors occur during synchronization process, user can restart the Cardio-respiratory monitor and Gateway to restart the synchronization process again.

Protecting Cardio- respiratory Monitor from water ingression

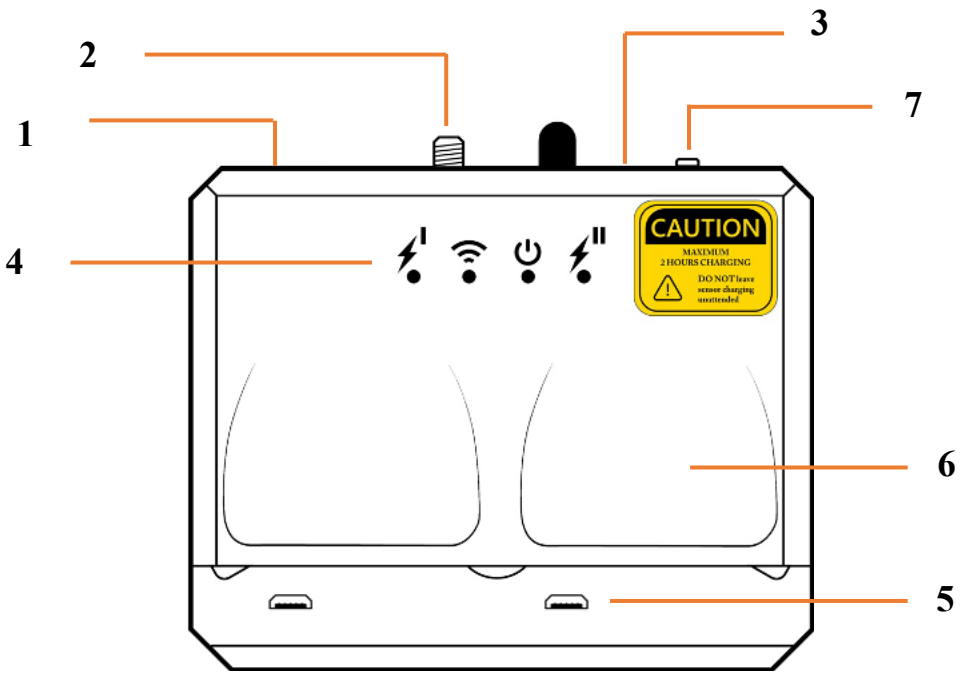
The Cardio- respiratory Monitor is IP22 rated and is not waterproof. To protect the cardio-respiratory monitor against water ingress, place the IP22 sleeve provided, on the monitor.

1. 

2. 

3. 

RS001.2.G Gateway Features



ID	Description	Function
1	Power Input	Interface to plug in power adaptor cable
2	Antenna Port	Interface to screw external antenna for LTE network connection
3	SIM Card Slot	Nano SIM card slot for LTE network connection
4	LED Status Indicator	Indicates the status during power on, network connection and charging
5	Charging Port	Interface to plug in cardio- respiratory monitor for charging
6	Docking Station	Store the cardio- respiratory monitor when not in use
7	Reset Button	Press and hold to reset the gateway when needed

The RS001.2.G Respiree Gateway can be interpreted as a router that relays information from the cardio-respiratory Monitor to the cloud server or hospital facility server. To operate the gateway, please refer to the Operating Instructions for RS001.2 System Use – Clinician User Manual

RS001.2.DS Cardio-respiratory Software Dashboard Features

The RS001.2.DS software dashboard can be accessed by using Google Chrome and Microsoft Edge. The default username and password are provided by Respiree Administrator. The RS001.2.DS is a cloud-based clinical monitoring dashboard system that provides centralized management, visibility, and control. The dashboard enables healthcare professionals/clinicians to access spot data for patients and view historical spot trends, increasing overall hospital performance and performance satisfaction.

To operate the Dashboard, please refer to the Operating Instructions for RS001.2 System Use – Clinician User Manual.

WARNING: User should ensure equipment used to access Dashboard maintains up-to-date security patch at all times. Username and password to be kept under strict lock by the dedicated healthcare professional in charge of the Dashboard. User should change their password at least once in every 3 months.

WARNING: User should lock the computer or smart device or logout of the application when not in use to prevent unauthorized use.

Note: Before use, please consult the Respiree technical assistant for RS001.2.DS setup.

Cleaning, Disinfecting, Charging and Service

Cleaning and Disinfecting Cardio- respiratory Monitor

WARNING: Before cleaning, read *Cleaning and Disinfecting Warnings and Cautions* in this manual.

WARNING: Before cleaning, make sure the device is off and is not applied to chest.

CAUTION: Thoroughly clean and low level disinfect the Cardio-respiratory Monitor before applying it to on a new patient.

Note: Before cleaning, make sure the micro-USB charging port is closed with the port cap.

To clean and low-level disinfect the Cardio-respiratory Monitor, follow the instructions below:

- After each use inspect the Cardio-respiratory Monitor for any signs of cracks, corrosion, discoloration, crevices, pitting or any other fault from sight.
- Damp a soft cloth with a commercial solution of 70% isopropyl alcohol in water.
    - Lightly wipe the surfaces of the device.
- Damp a moist cloth or cotton ball with a commercial solution of 70% isopropyl alcohol in water
    - Clean the display
    - Clean the photo-sensor parts gentle
    - Avoid touching the cloth to the Velcro part

- Pay particular attention to cracks, crevices and hard to reach areas of the device
- Allow the Cardio-respiratory monitor to dry thoroughly before using again

The surfaces of the Cardio-respiratory Monitor have been treated to be chemically resistant to following solution:

- 70% Isopropyl Alcohol

Charging

WARNING: Do not overcharge the Cardio-respiratory Monitor. Maximum charge advisable is 2 hours.

Follow the procedures below to charge the Cardio- respiratory Monitor:

1. Remove the USB charging port plastic cap on the Cardio- respiratory Monitor.
2. Dock the Cardio-respiratory Monitor onto the gateway micro- USB port.
3. Connect the gateway power adapter to the wall outlet and power on.
4. The battery status and/or the battery percentage will be updated progressively on the LCD display during charging.
5. Once fully charged (1 hour 45 mins), remove the Cardio-respiratory Monitor from the charging dock of the gateway.
6. Close the micro- USB charger port with the plastic cap.

Service

If the device does not appear to be operating correctly, see ***Troubleshooting*** in this manual.

WARNING: Do not attempt to repair the Cardio-respiratory Monitor and Gateway as this may cause damage to the device and prevent it from operating properly.

Disposal

WARNING: Device to be cleaned and recycled as per local electronics regulation.

WARNING: Patch is to be disposed as per normal hospital regulations.

Troubleshooting

Error/ Error Message	Possible Causes	Recommend Solutions
Dashboard displays "MOTION"	Significant amount of motion is being detected	Check patient and request to keep stationary
Dashboard displays "Moderate" or "Poor" under Signal Quality	Amount of motion is being detected	Check patient and request to keep stationary
Dashboard displays "BAD"	Exposed to bright lights or sunlight Bad skin contact	Relocate device so that it is not directly under bright light Check if the sensor is in contact with the skin
Dashboard displays "—"	Out of range	Reset the Cardio-respiratory Monitor using reset pin provided. Reset the gateway by plugging out and plugging in the power supply cable
Cardio- respiratory Monitor / gateway icon turns red	Cardio- respiratory Monitor / gateway is offline	Check that the Cardio- respiratory Monitor and gateway is turned on If above solution does not work: Reset the Cardio-respiratory Monitor using reset pin provided Reset the gateway by plugging out and plugging in the power supply cable

Cardio- respiratory Monitor / gateway icon turns amber/ yellow	Cardio- respiratory Monitor / gateway is unregistering	Check if Gateway is connected to Wi-Fi/ LTE. The Wi-Fi LED is light up when connected
Device does not turn on	Cardio- respiratory Monitor has low battery Faulty device	Charge Cardio- respiratory Monitor Contact Respiree Technical Services

Product Support

For additional help, contact Respiree Technical Services at helpdesk@respiree.com. Local contact information can be found at http://www.respiree.com

Limited Warranty

Respiree warrants to the original end-user purchaser the Respiree Cardio-respiratory Monitor and any software media contained in the general packaging against defects in material and workmanship when used in accordance with Respiree's user manuals, technical specifications, and other Respiree published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Respiree's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Respiree and obtain a returned goods authorization number so that Respiree can track the Product. If Respiree determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

The above warranty is in addition to any statutory rights provided to Purchaser under applicable laws and regulations of the region in which the product was sold to the extent that those rights cannot be disclaimed and are superseded by the above described warranty to the extent permitted under applicable laws and regulations of the region in which the product was sold.

All Respiree patch products sold separately by Respiree have a maximum 12 months shelf life once the product is opened. This has been tested under accelerated aging conditions.

Exclusions

The warranty does not cover the use or any defect in Respiree patch products. The warranty does not apply to any non-Respiree branded product or any software even if packaged with the Product or any Product that was (a) not new or in its original packaging when supplied to Purchaser; (b) modified without Respiree's written permission; (c) supplies, devices or systems external to the Product; (d) disassembled, reassembled or repaired by anyone other than a person authorized by Respiree; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Respiree to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labelling; (g) reprocessed, reconditioned or recycled and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or any other external cause.

No warranty applied to any Product provide to Purchaser for which Respiree, or its authorized distributor, is not paid, and these Products are provide AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and Software media, and Respiree does not make any other promises, conditions or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. In so far as the above warranties cannot be disclaimed, Respiree limits the duration and remedies of the warranties to the duration and to the remedies set forth above and as permitted by law. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product.

Additionally, Respiree will not be liable for any incidental, indirect, special or consequential loss, damage or expense arising from the use or loss of any Products or Software. In no event shall Respiree's liability arising from any Product or Software (under contract, warranty, tort, strict liability or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales and End-user License Agreement

This document is a legal agreement between you ("purchaser") and Respiree Pte Ltd ("Respiree") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Respiree for a full refund.

Restrictions

1. Copyright restrictions: The Software and the accompany written materials are copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged or included with other software or the written materials is expressly forbidden. Purchaser may be held legally responsible for any copyright infringement that is caused or incurred by Purchaser's failure to abide by the terms of the Agreement. Nothing in this License provides any rights beyond those provided by 17 U.S.C 117.
2. Use Restrictions: Purchaser may physically transfer the Product from one location to another provided that the Software is not copied. Purchaser may not electronically transfer the Software from the Product to any other instrument. Purchaser may not disclose, publish, translate, release, distribute copies of, modify, adapt, translate, reverse engineer, decompile, disassemble or create derivates works based on the Software or the written materials or the hardware.
3. Transfer Restrictions: In no event may Purchaser transfer, assign, rent, lease, sell or otherwise dispose of the Product of the Software on a temporary basis. Purchaser shall not assign or transfer this License, in whole or in part, by operation of law or otherwise without Respiree's prior written consent, except that the Software and all of Purchaser's rights hereunder shall transfer automatically to any party that legally acquires title to the Product with which this Software is included. Any attempt to assign any rights, duties or obligations arising hereunder other than as set forth in this paragraph shall be void.

Display Ranges

Parameter	Display Ranges
RR (Respiration Rate)	5 rpm to 50 rpm

Performance Specifications

Respiration Rate Accuracy			
Condition	Range	Population	ARMS*
No Motion	5 rpm to 50 rpm	Adults	<3 rpm

* ARMS accuracy is a statistical calculation of the difference between the device measurements and the reference measurements. Approximately at least two-thirds of the device measurements fell within +/- ARMS of the reference measurements in a controlled study.

RR Performance Specifications

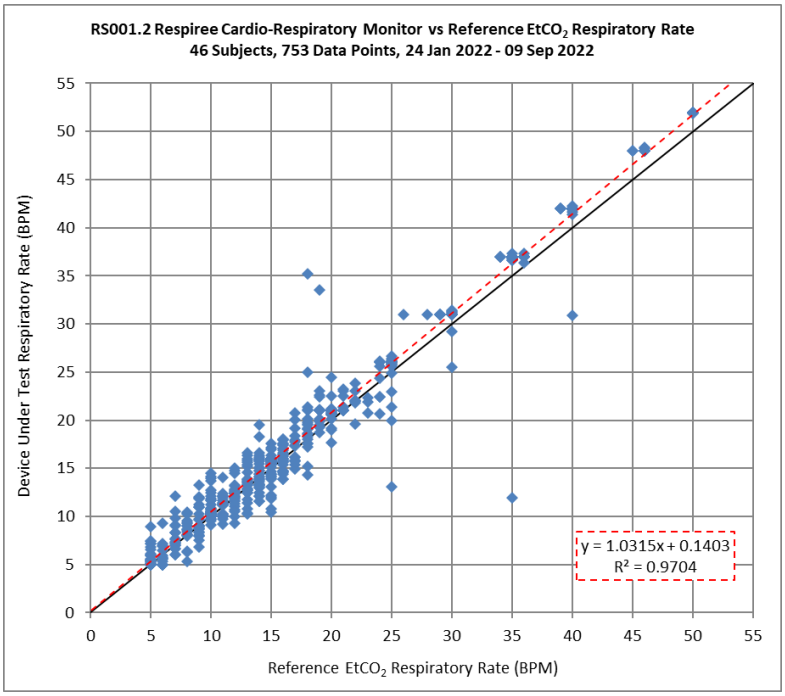


Figure 1. Regression plot of the RR measurement with respect to the Reference EtCO2 RR

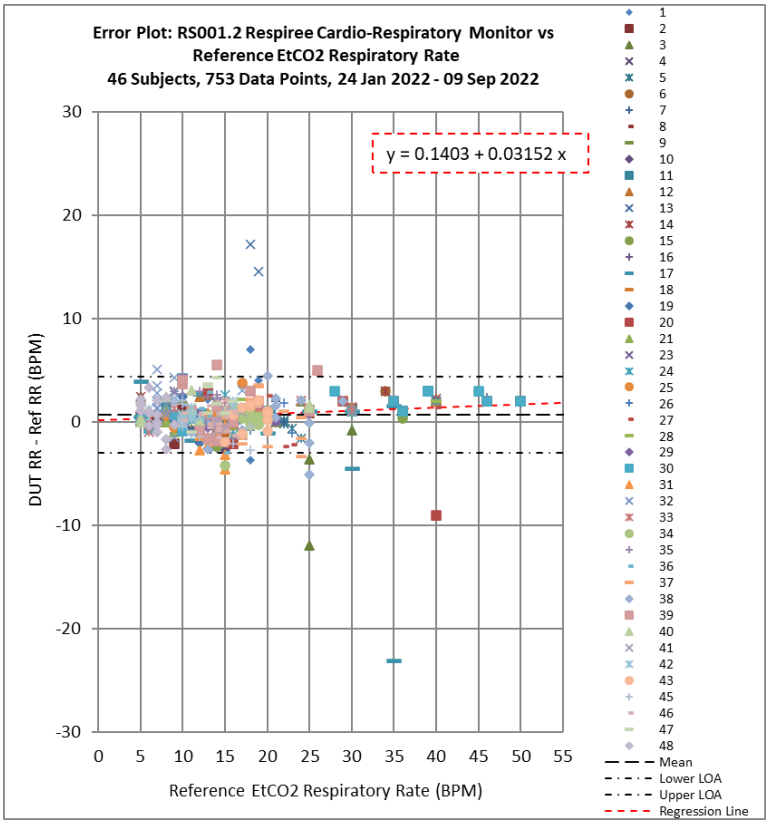


Figure 2. Bland-Altman plot of the Respiratory Rate measurement with respect to the Reference EtCO2 RR

Service Life

- Expected Service Life of the Cardio- respiratory Monitor is ~ 2.7 years.

Battery Life

- Continuous use-case battery life of 24-48 hours. Operates with a rechargeable battery. Not to be replaced.
- Typical Service Life: ~ 500 cycles degradation to 80% capacity

Operating Conditions

- Atmospheric pressure: 700hPa – 1060hPa
- The recommended operating conditions are as follows:
  - Operating temperature: 15 – 38 degrees

Note: The surface temperature of the contact area of the monitor sensor may exceed 41 degrees Celsius but below 43 degrees Celsius.

- Relative humidity: 15% - 95% (no condensing)

Transportation and Storage Conditions

- The recommended transportation conditions are as follows:
  - Storage temperature: 5 to 50 degrees
  - Relative humidity: 15% - 95% (no condensing)

Reuse Life

- The Cardio- respiratory Monitor is tested up to 1000 reprocessing time.

Physical Characteristics

- Cardio- respiratory Monitor
  - Dimensions: 44 mm x 44 mm x 13 mm
  - Weight: 22 grams
- Gateway
  - Dimensions: 105 mm x 90 mm x 40 mm
  - Weight: 130 grams

Compliance

- ANSI/ AAMI/ IEC 60601-1-2: 2014 + AMD1: 2020
- AAMI/IEC 60601-1:2005 + AMD 1:2012 + AMD 2:2020
- IEC 60601-1-6:2010, AMD1:2013, AMD2: 2020 with IEC 62366-1:2020
- IEC 60601-1-11: 2015 +AMD1: 2020
- ANSI/ AAMI/ ISO 10993-1: 2018
- ANSI IEEE C63.27 – 2021
- IEC 60601-4-5: 2021
- FCC 47 CFR Part 15
- FCC 47 CFR Part 18
- FCC 47 CFR Part 22
- FCC 47 CFR Part 27
- FCC ID: 2A3T2RS001-2

- FCC ID: 2A3T2RS001-2-G contains
  - FCC ID: 2AC7Z- ESP32S2WROVER
  - FCC ID: XMR201910BG95M3
- The radiated output power of this device meets the limits of FCC radio frequency exposure limits.
- For a Class B digital device or peripheral, the instructions furnished to the user shall include the following or similar statement, placed in a prominent location in the text of the manual: NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  - Consult the dealer or an experienced radio/TV technician for help.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. In order to avoid the possibility of exceeding the FCC radio frequency exposure limits, human proximity to the antenna shall not be less than 20cm (8 inches) during normal operation.

NOTE: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the (ITU) Radio Regulations.

EMC Essential Performance

Essential performance of the Cardio- respiratory Monitor is defined as respiration rate accuracy or an indication of abnormal operation. Accuracies may be affected as a result of exposure to electromagnetic disturbances that are outside of the environments listed in the *Indications For Use*. If issues are experienced, move the devices away from the source of electromagnetic disturbances.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Cardio- respiratory Monitor		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11 (EN55011:2016)	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11 (EN55011:2016)	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	
Gateway		
RF emissions CISPR 11 (EN55011:2016)	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11 (EN55011:2016)	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low- voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 6100-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Cardio- respiratory Monitor			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2: 2008	+/- 8 kV contact +/-15 kV air discharge	+/- 8 kV contact +/-15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3: 2010	10V/m at 80 – 2700 MHz and 9 – 28 V/m at 385 – 5785 MHz, pulse mode and other modulation	10V/m at 80 – 2700 MHz and 9 – 28 V/m at 385 – 5785 MHz, pulse mode and other modulation	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** $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 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 transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Power frequency (50 – 60 Hz) magnetic field IEC 61000-4-8: 2009	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Field Immunity IEC 61000-4-39: 2014	8 A/m at 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	8 A/m at 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME Equipment. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than [V1] V/m.			

Gateway			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2: 2008	+/- 8 kV contact +/-15 kV air discharge	+/- 8 kV contact +/-15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electricity Fast Transient/ Burst IEC 61000-4-4: 2012	+/- 2kV for power supply lines	+/- 2kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5: 2014 + 2017	+/- 0.5kV to +/- 1.0kV line to line	+/- 0.5kV to +/- 1.0kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11: 2004 + 2017	100% dip, 0.5 cycle 100% dip, 1 cycle 30% dip, 25 cycles 100% interruption, 250 cycles	100% dip, 0.5 cycle 100% dip, 1 cycle 30% dip, 25 cycles 100% interruption, 250 cycles	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 a battery.
Power frequency (50 – 60 Hz) Magnetic Field IEC 61000-4-8: 2009	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Conducted RF IEC 61000-4-6: 2013	3V, 80% AM 1kHz 0.15MHz – 80 MHz 6V, 80% AM 1kHz ISM bands & radio amateur bands	3V, 80% AM 1kHz 0.15MHz – 80 MHz 6V, 80% AM 1kHz ISM bands & radio amateur bands	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** $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 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 transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3: 2010	3V/m at 80 – 2700 MHz and 9 – 28 V/m at 385 – 5785 MHz, pulse mode and other modulation	3V/m at 80 – 2700 MHz and 9 – 28 V/m at 385 – 5785 MHz, pulse mode and other modulation	

Proximity Magnetic Field Immunity IEC 61000-4-39: 2014	8 A/m at 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	8 A/m at 30 KHz 65 A/m at 134.2 KHz 7.5 A/m at 13.56 MHz	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 ME Equipment is used exceeds the applicable RF compliance level above, the ME Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ME Equipment. [b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than [V1] V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the Device.

The device is intended for use in an electromagnetic environment where radiated RF disturbances are under control. User can help prevent electromagnetic interference by keeping the device at a minimum distance from portable and mobile RF communications equipment (transmitters). Below table details the maximum output power of transmitter:

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**	
	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.20	2.30
10	3.80	7.30
100	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Electromagnetic Immunity

Cardio- respiratory Monitor		
Immunity Test	**Compliance**	
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2.0kV, +/- 4.0kV, +/- 8.0kV, +/-15 kV air Polarity: Positive/Negative	
Radiated Emissions (Electric Field) Group 1 Class B EN 55011	30 – 230 MHz	40 dBmV/m @ 3m
		30 dBmV/m @ 10m
	230 – 1000 MHz	47 dBmV/m @ 3m
		37 dBmV/m @ 10m
	Operating Mode: Wireless (Bluetooth is on and monitoring)	
	40.3200 MHz	30 dBmV/m
	57.7260 MHz	30 dBmV/m
	60.2080 MHz	30 dBmV/m
	66.6420 MHz	30 dBmV/m
	71.6060 MHz	30 dBmV/m
	198.5140 MHz	30 dBmV/m
	Operating Mode: Charging via USB Adapter	
	47.4720 MHz	30 dBmV/m
	57.9880 MHz	30 dBmV/m
	139.2730 MHz	30 dBmV/m
	149.8540 MHz	30 dBmV/m
	208.3770 MHz	30 dBmV/m
	210.8260 MHz	30 dBmV/m

Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m	
Proximity Magnetic Field Immunity IEC 61000-4-39	30 kHz	8 A/m, CW
	134.2 kHz	65 A/m, PM 2.1 kHz
	13.56 MHz	7.5 A/m, PM 50 kHz
Radiated RF IEC 61000-4-3	385 MHz	27 V/m
	450 MHz	28 V/m
	710, 745, 780 MHz	9 V/m
	810, 870, 930 MHz	28 V/m
	1720, 1845, 1970 MHz	28 V/m
	2450 MHz	28 V/m
	5240, 5500, 5785 MHz	9 V/m

Gateway		
Immunity Test	**Compliance**	
Electrostatic Discharge (ESD) IEC 61000-4-2	+/- 8 kV contact +/- 2.0kV, +/- 4.0kV, +/- 8.0kV, +/-15 kV air Polarity: Positive/Negative	
Radiated Emissions (Electric Field) Group 1 Class B EN 55011	30 – 230 MHz	40 dBmV/m @ 3m
		30 dBmV/m @ 10m
	230 – 1000 MHz	47 dBmV/m @ 3m
		37 dBmV/m @ 10m
	Operating Mode: Wireless (WIFI is on and monitoring)	
	35.2620 MHz	40 dBmV/m
	199.9750 MHz	40 dBmV/m

	320.0060 MHz	47 dBmV/m
	360.0130 MHz	47 dBmV/m
	400.0030 MHz	47 dBmV/m
	440.0370 MHz	47 dBmV/m
	Operating Mode: Wireless (LTE is on and monitoring)	
	33.7170 MHz	40 dBmV/m
	168.9470 MHz	40 dBmV/m
	196.6180 MHz	40 dBmV/m
	320.000 MHz	47 dBmV/m
	479.6000 MHz	47 dBmV/m
	639.9950 MHz	47 dBmV/m

Bluetooth Wireless Technology Information

Product Parameters

- BT Version: Bluetooth Specification V5.2 BLE
- Send and receive no bytes limit.
- Working frequency: 2.4 GHz ISM band
- Modulation method: GFSK(Gaussian Frequency Shift Keying)
- RF Power: -96 dBm (Bluetooth Low Energy at 1 Mbps), -100 dBm (802.15.4)
- Security: Authentication and encryption
- Service: Central & Peripheral UUID FFE0,FFE1
- Power: +3.3VDC
- Power Transmit: Active mode 5.2 – 8.8 mA
- Power Receive: Active mode 4.5 – 7.9 mA
- Working temperature: –65 ~ +150 Centigrade

Gateway Parameters

- BT Version: Bluetooth Specification V4.2 BR/ EDR
- Emission frequency: 2.4 GHz

- Transmitting power: +12 dBm
- Modulation method: GFSK (Gaussian Frequency Shift Keying)
- NZIF receiver with -94 dBm BLE sensitivity
- Power: AC/ DC 12W

Wireless Risk

- BLE from both Respiree Cardio-respiratory Monitor and the Respiree Gateway are encrypted. Only Respiree devices can communicate with one another.
- Data in cardio- respiratory monitor and gateway do not consist of any patient identifiers

Quality of Service (QoS)

The device uses Bluetooth Low-power technology or wireless communications, which permits reliable communications in electrically noisy environments, and transmits physiology data upon connection with the gateway. Below is a list of compliance measures for QoS. If connection is lost, the gateway LED will indicate connection is lost. Data latency is less than 10 milliseconds.

QoS	Compliance
Operating Range	Optimal: 10 meter radius (line of sight) without RF interference In RF interference environment: 2 meter (line of sight)
Data Rate	1 Mbps
Data Format	Sends data packets every 1 second. Includes a counter that detects if packets are missing.
Accessibility	Respiree Gateway only
Signal Priorities	If connection is lost, application will indicate that the connection is lost. Application will also indicate percentage of packets received.
Encryption	256 Bit AES

WIFI Technology Information

Gateway Parameters

- Emission frequency: 2.4 GHz

- 802.11 b/g/n, 802.11 n (2.4 GHz), up to 150 Mbps
- Support WPA/ WPA2/ WPA2 – Enterprise, WPS
- TX/ RX A-MPDU, RX A-MSDU
- Modulation Method: DSSS (Direct Sequence Spread Spectrum), OFDM (Orthogonal Frequency Division Multiplexing) and OFDM with enhancements for Multi- Input Multiple Output (MIMO)
- RF power: -20 dBm

Terminal Antenna

- Integrated PCB Trace Antenna
- Frequency range: 2.4 GHz to 2.5 GHz
- Polarization: Linear
- Impedance: 50 Ω
- Gain: 2 dB (typical)

LTE Technology Information

Gateway Parameters

- Quectel BG95-M3 LPWA module
- GSM/ Edge: 850/ 900/ 1800/ 1900 MHz

Terminal Antenna

- Frequency range: 698 – 960/ 1710 – 2700 MHz
- Bandwidth: 262/ 990MHz
- Gain: 3/ 5 dBi
- Maximum Input Power: 50W
- GSM/ Edge: 850/ 900/ 1800/ 1900 MHz

Electrical Specification

Gateway Parameters

- AC Adapter rating input: 100 – 240 V ~, 50/ 60 Hz or 50 – 60 Hz or 50 Hz or 60 Hz, 500 mA
- Output: 9V, 2A

List of Accessories

1. Gateway
2. Power adapter
3. Antenna
4. Disposable Patches
5. IP22 Sleeve
6. Reset Pin

Respiree

Respiree

www.respiree.com