Operator's Manual

RS001 Cardio-respiratory Monitor

These operating instructions provide the necessary information for proper operation of the RS001.2.S, RS001.2.C, RS001.2.A, RS001.2.DS and RS001.2.D models of the RS001 Respiree Cardio-respiratory Monitor. For Models RS001.2.S, RS001.2.C, RS001.2.A, these operating instructions shall be accompanied by brief training by a qualified healthcare worker.

There may be information provided in this manual that is not relevant for your system. Do not operate RS001 Respiree Cardio-respiratory Monitor without completely reading and understanding these instructions. If in doubt about the operating instructions, contact your physician for more information.

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.

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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: 2014, FCC 47 CFR Part 15 and Applicable Standards (ISO 80601-2-61:2017)

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About this Manual

Do not operate the RS001 Respiree Cardio-respiratory Monitor without completely reading and understanding the instructions.

Always use the RS001 Respiree Cardio-respiratory Monitor precisely in accordance with the directions in this manual including site selection and sensor placement. Failure to follow all of the directions in this manual could lead to inaccurate measurements.

Read and follow any warnings, cautions and notes presented throughout this manual. The following are explanations of warnings, cautions and notes.

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).

WARNING: This is an example of a warning statement.

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 other property.

CAUTION: This is an example of a caution statement.

A note is given when additional general information is applications

Note: This is an example of a note.

Product Description and Indications

Product Description

The RS001 Respiree Cardio-respiratory Monitor is intended as a noninvasive device that measures and displays arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR). RS001 Respiree Cardio-respiratory Monitor is available in the following versions:

Product Models	Features
RS001.2.S	Intended to measure and display arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR).
RS001.2.C	Intended to measure and display arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR). Bluetooth LE radio is intended to transfer of parameter data to a compatible smart device.
RS001.2.D	Intended to measure arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR) and used with RS001.2.DS for display. Bluetooth LE radio is intended to transfer of parameter data to a compatible smart device.
RS001.2.A	Android App used for the display of result data (arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR) from RS001.2.C.
RS001.2.DS	Intended to use data from RS001.2.D and display arterial oxygen saturation (Sp02), Pulse Rate (PR) and Respiratory Rate (RR).

Intended Use

RS001 breathing frequency monitor is intended for measurement of respiratory rate, heart rate and SPO2 in a non-invasive manner. Equipment is not intended for connection to separate power supply when in use. The monitor is indicated for use as suitable for use on adult patients. The operation of the monitor has been studied on adults (age >18 years old) during rest conditions.

Indications for Use

The RS001 Respiree pulse oximeter and respiratory monitor is indicated for the noninvasive spot checking of arterial oxygen saturation (Sp02) and pulse rate (PR) for adult patients during no motion conditions and for patients who are well or poorly perfused.

The RS001 Respiree pulse oximeter and respiratory monitor is indicated for the noninvasive spot checking of respiration rate (RR) for adult patients.

RS001.2.D and RS001.2.DS is indicated for use in a clinical setting under a physician or by healthcare professionals under the supervision of a physician.

RS001.2.C, RS001.2.S and RS001.2.A is indicated for use in a home setting and may be applied by the patient. Training by a healthcare professional before use is required and will be arranged by Respiree.

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.

Safety Information, Warnings and Cautions

Safety Warnings and Cautions

- **WARNING**: Do not use RS001 Cardio-respiratory Monitor during magnetic resonance imaging (MRI) or in an MRI environment.
- **WARNING**: Do not place RS001 Cardio-respiratory Monitor or accessories in any position that might cause it to fall on the patient.
- **WARNING**: Do not use RS001 Cardio-respiratory Monitor during defibrillation.
- **WARNING**: Do not use RS001 Cardio-respiratory Monitor during electrosurgery.
- **WARNING**: Do no use RS001 Cardio-respiratory Monitor in the presence of flammable anesthetics or other flammable substances, oxygen-enriched environments or nitrous oxide to avoid the risk of explosion.
- **WARNING**: Only use the RS001 Cardio-respiratory Monitor in pulse oximetry mode to secure on the finger. Excessive pressure to a finger can cause skin damage.
- **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.

- **WARNING:** Do not leave the RS001 Cardio-respiratory Monitor unattended around children. Small items such as the sensor may become choking hazards.

- **WARNING:** Turn off RS001 Cardio-respiratory Monitor when charging as use is not intended while charging.

- **WARNING:** Avoid charging for extended periods – recommended maximum of 120 minutes.

- **WARNING**: Do not open the RS001 Cardio-respiratory Monitor.

- **WARNING**: RS001 Cardio-respiratory Monitor is without any user-serviceable part inside and only qualified service personnel can perform maintenance service.

- **WARNING**: Do not expose the RS001 Cardio-respiratory Monitor to moisture (such as rain or washing under tap or shower) to ensure performance and device safety. Device is not waterproof and should not be immersed in fluids.

- **WARNING**: RS001 Cardio-respiratory Monitor 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**: RS001 Cardio-respiratory Monitor is only to be used for charging with the provided charging cable.

- **WARNING**: Use only Respiree RS001 approved patches and accessories with RS001. Any other 3rd party accessories may lead to degradation of signals.

- **WARNING**: Reposition RS001 Cardio-respiratory Monitor when in respiratory rate on chest once at least once every 24 hours to allow patient's skin to breath.

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

- **WARNING**: Reposition device if patient shows signs of dermal irritation.

- **WARNING**: Do not use the RS001 Respiree patch on open-wounds, injured skin or sensitive and fragile skin. If the patient has a history of known skin allergies, consult a doctor before using the patch.

Performance Warnings and Cautions

- **WARNING**: RS001 Cardio-respiratory Monitor is not an apnea monitor and should not be used for arrhythmia analysis.

- **WARNING**: RS001 is non-diagnostic and non-confirmatory for any disease. RS001 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 RS001 Cardio-respiratory Monitor for continuous monitoring. It is intended for spot-check use only. No alarms are provided to support continuous monitoring.

- **WARNING:** RS001 Cardio-respiratory Monitor does not provide low SPO2 alarms.

- **WARNING**: Do not use RS001 Cardio-respiratory Monitor if it appears or is suspected to be damaged. Damage to internal parts can result in no or inaccurate readings.

- **WARNING**: Do not repair, open or modify the RS001 Cardio-respiratory Monitor. Damage to internal parts can result in no or inaccurate readings.

- **WARNING**: Do not use the RS001 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**: Optical, pleth based measurements (e.g. Sp02 and RR) can be affected by the following:
    - Improper placement or alignment of RS001
    - Intravascular dyes such as indocyanine green or methylene blue
    - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
    - Blood pressure cuff applied to the same arm as the sensor site under pulse oximetry mode
    - Placing the RS001 sensor on any extremity with an arterial catheter
    - Elevated levels of bilirubin
    - Venous congestion
    - Abnormal venous pulsations
    - Abnormal pulse rhythms due to physiological conditions or induced through external factors

    - Physiological conditions that can significantly shift the oxygen disassociation curve
    - A physiological condition that may affect vasomotor tone or changes in vasomotor tone

- **WARNING**: Inaccurate Sp02 readings may be caused by:
    - Elevated levels of COHb and/or MetHb
    - Severe anemia
    - Extremely low arterial perfusion
    - Excessive induced motion
    - Hemoglobinopathies and Hemoglobin synthesis disorders

- **WARNING**: Inaccurate respiration rate (RR) readings may be caused by:
    - Improper RS001 placement or alignment on the chest
    - Excessive motion

- **WARNING:** Properly apply and avoid using the RS001 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.

- **WARNING:** RS001 Respiree patch accessory to be used within 1 year from exposure to air.

- **CAUTION:** When using RS001 Cardio-respiratory Monitor with a smart device, 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 with the smart device.

- **CAUTION**: When using the RS001 Cardio-respiratory Monitor with a smart device, relocate the devices away from sources that may interfere with the Bluetooth 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, other cellular telephones, wireless PC and tablets, pagers, RFID devices, MRI and electromagnetic security systems.

- **CAUTION**: Do not attempt to remanufacture, recondition or recycle RS001 Cardio-respiratory Monitor as these processes may damage the internal parts. Damage to internal parts can result in no or inaccurate readings.

- **Note**: The RS001 Cardio-respiratory Monitor may be difficult to view when exposed to direct sunlight or bright lights.

- **Note**: Do not assess the accuracy of the RS001 Cardio-respiratory Monitor using a functional tester.

Cleaning, Disinfecting, Service Warnings and Cautions

- **WARNING**: RS001 Cardio-respiratory Monitor uses a rechargeable battery. Limit the charging time to maximum of 120 minutes.

- **WARNING**: Thoroughly clean and low level disinfect the RS001 Cardio-respiratory Monitor before applying it to on a new patient

- **CAUTION**: Do not clean RS001 Cardio-respiratory Monitor with any chemical other than those specified in ***Cleaning, Disinfecting and Service***. These substances may affect the device's materials and damage internal parts.

- **CAUTION**: Do not submerge RS001 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.

- **CAUTION**: Do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any cleaning solution other than those recommended in ***Cleaning, Disinfecting and Service*** of this manual. Permanent damage to RS001 Cardio-respiratory Monitor may occur if other unspecified solutions are used.

- **CAUTION**: Never submerge RS001 Cardio-respiratory Monitor in water or any other liquid solution. This may cause permanent damage to the sensor.

- **CAUTION**: The RS001 Respiree patch is a single-use and strictly one-time use patch only. Dispose off the patch after a maximum recommended time of 24 hours upon use.

Compliance Warnings and Cautions

- **WARNING**: For RS001.2.C, RS001.2.S and RS001.2.A, device must be operated by patients that have received appropriate training by registered nurses or physicians prior to usage.

- **WARNING**: For RS001.2.C, RS001.2.S and RS001.2.A, results presented are non-diagnostic and non-confirmatory for any disease. Patients that are trained users are encouraged to see their physician or registered nurses if they are unwell and not rely on their results for any form of self-diagnosis.

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

- **CAUTION**: Comply with local laws in the disposal of the RS001 Cardio-respiratory Monitor and Respiree patch.

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

- **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 the Part 18 of FCC 47 CFR rules.~~

Technology Overview

The following chapter describes the general principles of operation, parameters and measurements used by the Respiree RS001 products.

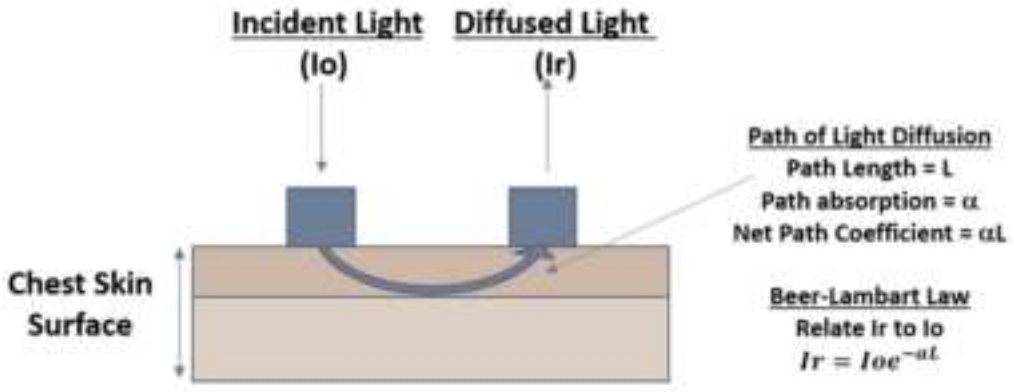
The RS001 Respiree Cardio-respiratory Monitor uses an all optical approach for direct measurement of pulse oximetry (similar as that of conventional pulse oximeters) and direct measurement of respiratory rate from the chest. The Near Infra-red sensor module is common to both measurements.

To measure pulse oximetry and that measures displays Pulse Rate (PR or HR) and Arterial Oxygen Saturation (Sp02), RS001 Cardio-respiratory Monitor uses a finger adapter and a switch on the RS001 monitor to switch to the pulse oximetry mode.

To measure respiratory rate (RR), RS001 Cardio-respiratory Monitor uses a disposable patch that allows the sensor to connect to the chest for measurement of chest-thorax movements. A switch on the RS001 monitor allows the sensor to switch the respiratory rate measurement mode.

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.



To measure pulse oximetry on the chest, the Respiree Cardio-respiratory Monitor makes us of the photo-photoplethysmography effect that measures the amount of light absorbed by the varying quantities of arterial blood changes.

General Description for Oxygen Saturation (Sp02)

Pulse oximetry is governed by the following principles:

- Oxyhemoglobin (oxygenated blood) and dexoyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry)
- The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

General Description for Pulse Rate (PR or HR)

Pulse rate (PR or HR) is measured in beats per minute (BPM) and is based on the optical detection of the peripheral flow pulse.

General Description for Respiratory Rate (RR)

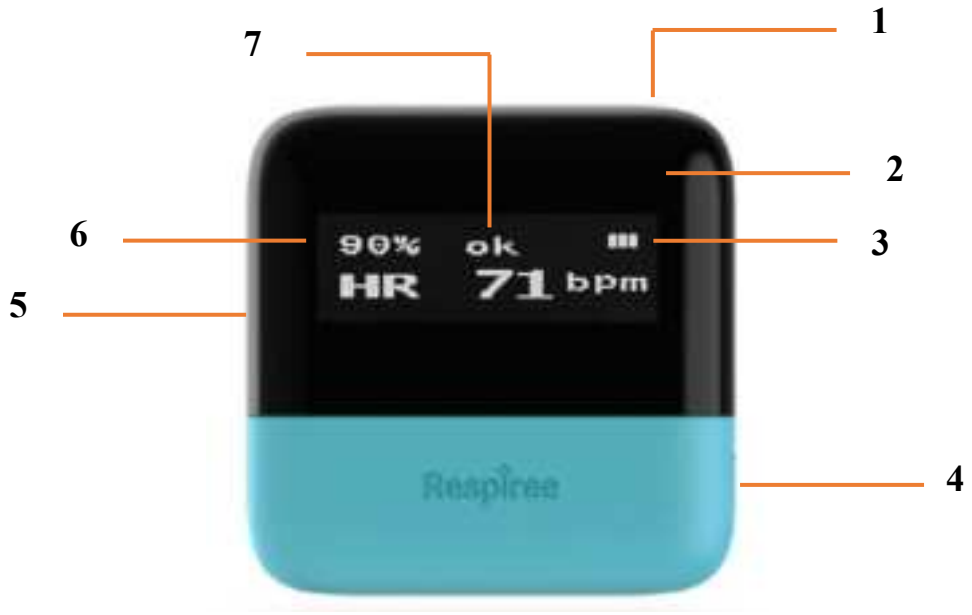
Respiration rate can be determined by the direct absorption change due to skin stretching. The method measures the respirations per minute (RPM).

Operation

Models : RS001.2.C and RS001.2.S

Note : This section refers to models RS001.2.C and RS001.2.S to be used by users in a home setting and have been appropriately trained by Respiree.

RS001.2.C and RS001.2.S Cardio-respiratory Monitor Features



ID	Description	Function
1	On-Off Button	Press once to turn on device. Press once again to turn off device.
2	Display Screen	Display for measurements and indicators.
3	Battery Status Indicator	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	Switch downwards for Pulse Oximetry Mode and switch upwards for Respiratory Rate Mode. Mode type will be displayed on screen.
6	Sp02/RR Indicator	Under Pulse Oximetry Mode, Sp02 is indicated on the top of “HR”, while PR is indicated next to bpm. Under Respiratory Rate mode, Sp02 is not indicated and “RR” is replaced with “HR”.

7	Warning Indicator	Indicates the type of error and warning flags. 4 types of warning indicators are provided. “Ok” if no error or warnings. “MOT” if excess motion. “SAT” if ambient light is too bright. “ERR” if sensor is faulty.

Using RS001.2.C and RS001.2.S Cardio-respiratory Monitor

RESPIRATORY RATE (RR) Measurement (RR Mode)

To take readings for Respiratory Rate, follow the instructions below:
Note: Before use, ensure sensor is in good condition

1. **2.** **3.** **4.**

1. Take the sensor and piece of RS001.1.P patch for use with RS001 device. Ensure the “sensing-side” of the sensor 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 RS001 device.

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 sensor. The display will turn on with the initialization of “RR” as mode.

4. Place the sensor 2 fingers from the collarbone on the left-side of the chest.

5. Wait for 1 minute and respiratory rate (RR) will be displayed on the screen. RR is refreshed every 5 seconds.

   Note: If readings are ok, display will show “ok” under Warning Indicators. If readings are perturbed by motion or ambient light, display will show “MOT” or “SAT”. If sensor is faulty, readings will display “ERR”. See ***Troubleshooting***.

Note: In cases where the user has hyperopia or presbyopia, it is recommended that the patient attempt the Bluetooth pairing process first (Page 16) before attaching the sensor to the patch. This will allow the readout to be provided immediately on the Android app upon attachment.

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

WARNING: Do not remove the sensor for 1 minute when the sensor is on the patient.

PULSE OXIMETRY (PR, Sp02) Measurement (HR Mode)

To take readings for Pulse Oximetry, follow the instructions below:
Note: Before use, ensure sensor is in good condition

1.

2.

3.

4.

1. Take the sensor and the pulse oximetry adapter for use with RS001 device. Switch the mode of operation downwards, away from the on-off button, to HR mode.

2. Ensure the sensor fits into the adapter provided and turn on the sensor. Use the holes on the adapter as guide for fitting the sensor.

3. Place the finger along the sensing side of the RS001 monitor.

4. Take the strap of the adapter and place into the slot and tighten accordingly. Ensure placement of the finger is according to the picture in 3 and 4.

5. Wait for 45 seconds and Sp02 and PR will be displayed on the screen. Sp02 and PR are refreshed every 5 seconds.

Note: If readings are ok, display will show "ok" under Warning Indicators. If readings are perturbed by motion or ambient light, display will show "MOT" or "SAT". If sensor is faulty, readings will display "ERR". See ***Troubleshooting***.

Note: Once reading is complete and spot measurement is taken, remove the sensor, remove the adapter and turn-off the sensor. Proceed to clean down the sensor and adapter.

WARNING: Do not remove the sensor for 45 seconds when the sensor is on the patient.

Connecting to a Smart Device via Bluetooth (Optional)

Bluetooth LE is an optional feature and comes only with the RS001.2.C Cardio-respiratory model version.

The RS001.2.C version provides a Bluetooth LE wireless feature to allow connection to a compatible smart device. The Bluetooth communication is only available to smart devices using the Respiree Health App. RS001.2.C version can only communicate to a single smart device at one time to minimize the risk of unauthorized access.

Note: The RS001.2.C requires the use of the Respiree Health App to communicate to a compatible smart device.

Pair RS001 Cardio-respiratory Monitor to Smart Device

1. Ensure the Bluetooth is enabled on the smart device through the device settings.
2. Ensure the Respiree Health App is installed on the smart device. This is only available on an Android version and provided by Respiree.
3. Launch the Respiree Health App once installed.
4. Turn on the RS001 Cardio-respiratory Monitor
5. Follow the Respiree Health App instructions to pair the device.
6. When the Respiree Health App identified the RS001 Cardio-respiratory Monitor, press/select it to pair.
7. Once the RS001 sensor is connected, the Respiree Health App returns to the Main screen.
8. Place the RS001 sensor on the patient's finger, confirm that readings on the RS001 sensor and the Respiree Health App are the same without a delay greater than 10 seconds.

Note: If the delay is greater than 10 seconds, move the RS001 closer to the smart device.

Verify Paired RS001 Cardio-respiratory Monitor

1. On the smart device, access the Register Device option
2. Locate Paired Device

Note: RS001.2.C will always be in Bluetooth mode

3. Compare the Paired Device information to the Bluetooth Serial Number RS XXXX.

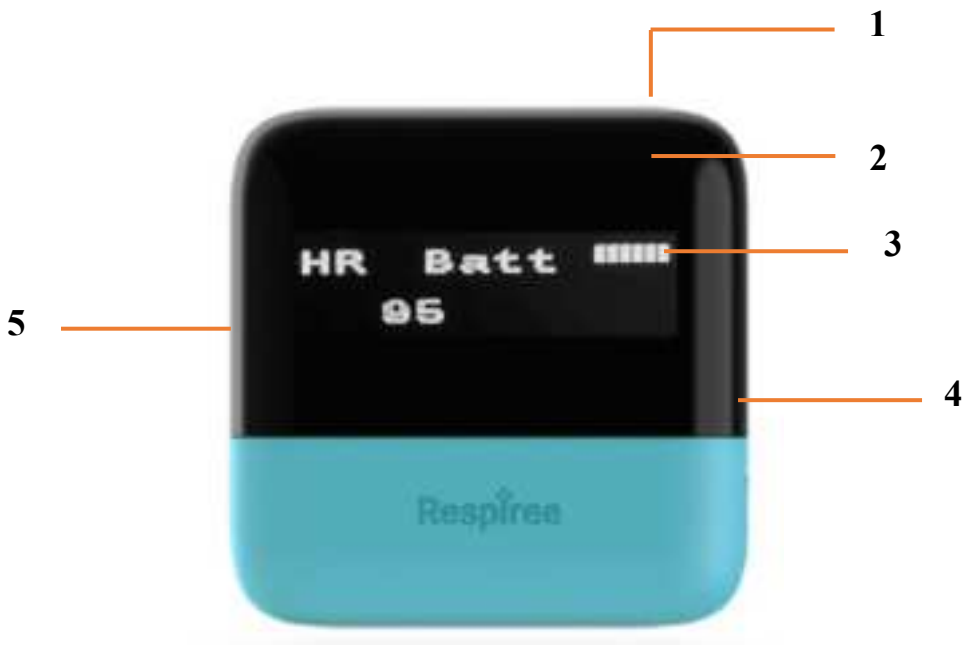
Disconnect Paired RS001 Cardio-respiratory Monitor

1. On the smart device and access the Respiree Health App
2. Press/select the Register Device option.
3. Select the device and click on Unregister device. The RS001.2.C sensor will be disconnected from the smart device. The sensor will need to be paired if it is to be used again with this smart device.

Models : RS001.2.D and RS001.2.DS

Note : This section refers to models 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 once to turn on device. Press once again to turn off device.
2	Display Screen	Display for measurements and indicators.
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	Switch downwards for Pulse Oximetry Mode and switch upwards for Respiratory Rate Mode. Mode type will be displayed on screen.

Note: RS001.2.D and RS001.2.DS are to be used under supervision of a physician. RS001.2.D is to be used in conjunction with RS001.2.DS. All other instructions and warnings are similar to RS001.2.S and RS001.2.C.

RS001.2.DS Cardio-respiratory Software Dashboard Features

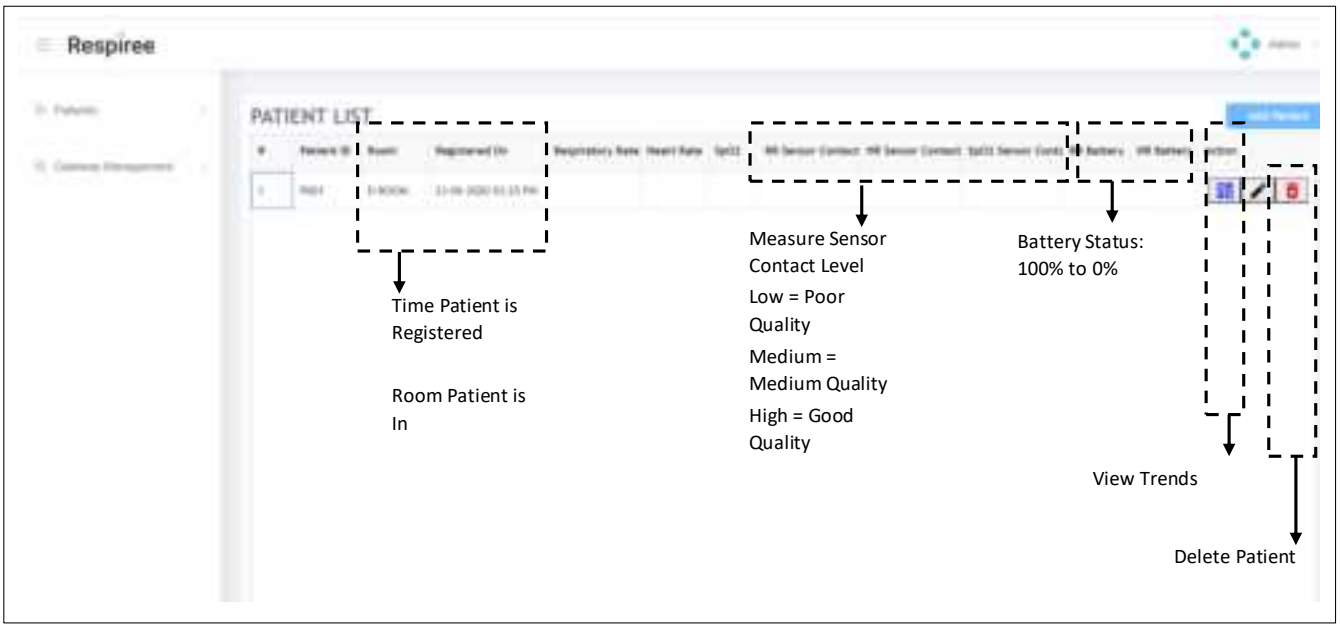
The RS001.2.DS software dashboard can be accessed by any web browser. The default username and password are “admin” and “password”.

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

RS001.2.DS main dashboard interface consists of the below:

(1) Patient ID
(2) Room Number
(3) Registration Time
(4) Respiratory Rate
(5) Heart Rate
(6) Oxygen Saturation
(7) RR Sensor Contact Quality
(8) HR Sensor Contract Quality
(9) Battery Level of RR Sensor (for sensor on chest)
(10) Battery Level of HR Sensor (for sensor on finger)

RS001.2.DS main dashboard interface appears as the follows:



RS001.2.DS dashboard permits 3 main use-cases as follows

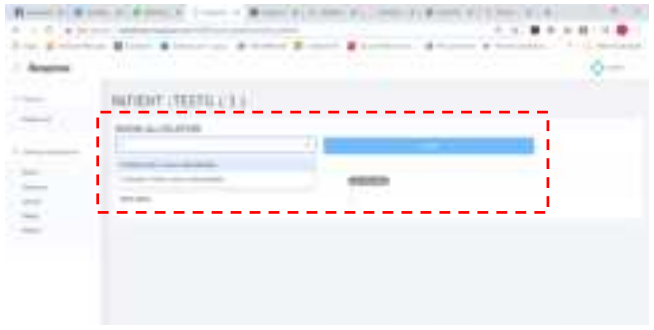
(1) Patient registration
(2) Changing sensor
(3) Patient deregistration

(1) To register patient, Click on Add Patient first. Then Enter Patient ID. Subsequently Select Room and Click Assign. Following which, Select the RS001.2.D sensor for Respiratory Rate measurement and RS001.2.D sensor for Pulse Rate measurement. See below process for patient registration.

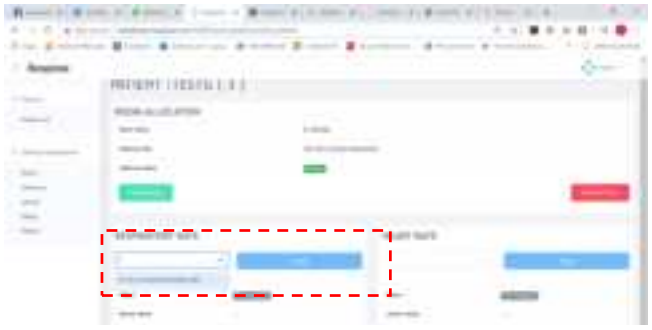
Step 1 – Click "Add Patient"

Step 2 – Enter Patient ID "XXXXY" [4 Digit + 1 Alphabet] and Click Save

Step 3 – Select Room under Room Allocation and Click Assign



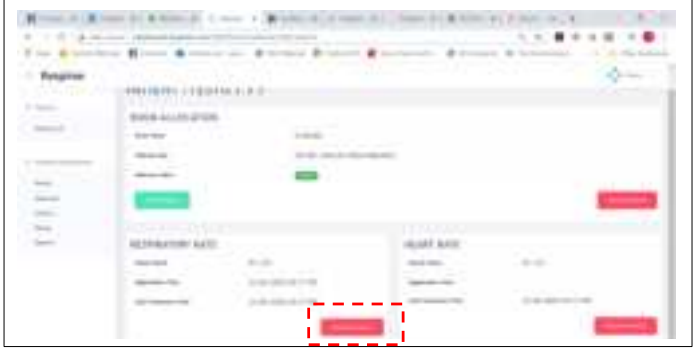
Step 3 – Select Respiratory Rate and Click Assign – Do the Same for Heart Rate



(2) To replace sensor, click on the Pencil Icon on Patient ID on main dashboard. Then Click on Remove Sensor under either the Respiratory Rate or Heart Rate. Click OK to confirm removal. Reassign a new RS001.2.D sensor. Following are processes for changing or replacing the sensor.

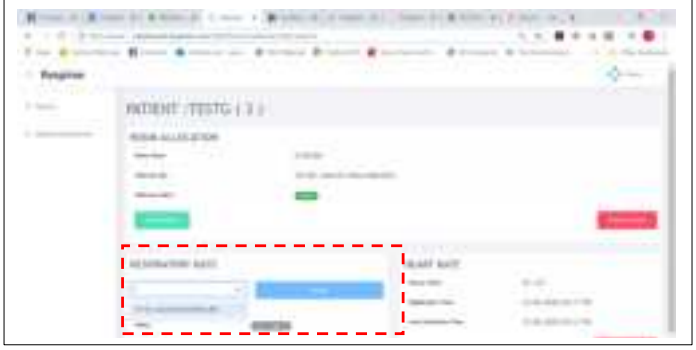
Step 1 – Click "Pencil Icon" on Patient ID

Step 2 – Click "Remove Sensor" under the Respiratory Rate



Step 3 – Click "OK" when ask if want to remove?

Step 4 – Reassign a new sensor [Turn on sensor and go to room and replace]



(3) To remove or deregister patient, simply click on the "trash" icon to delete patient on the main dashboard page.

Using RS001.2.D Cardio-respiratory Monitor

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

RESPIRATORY RATE (RR) Measurement (RR Mode)

To take readings for Respiratory Rate, follow the instructions under "**Using RS001.2.C and RS001.2.S Cardio-respiratory Monitor** " from points (1) to (4):
Note: Before use, ensure sensor is in good condition

Note: Ensure RS001.2.D is registered to the RS001.2.DS dashboard

PULSE OXIMETRY (PR, Sp02) Measurement (HR Mode)

To take readings for Pulse Oximetry, follow the instructions under "**Using RS001.2.C and RS001.2.S Cardio-respiratory Monitor** " from points (1) to (4):
Note: Before use, ensure sensor is in good condition

Note: Ensure RS001.2.D is registered to the RS001.2.DS dashboard

Cleaning, Disinfecting, Charging and Service

Cleaning and Disinfecting RS001 Cardio-respiratory Monitor

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

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

CAUTION: Thoroughly clean and low level disinfect the RS001 Cardio-respiratory Monitor before applying it to on a new patient.

CAUTION: Thoroughly clean and low level disinfect the Respiree RS001 finger adapter 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 RS001 Cardio-respiratory Monitor, follow the instructions below:

- Damp a soft cloth with a commercial solution of 70% isopropyl alcohol in water.
    - Lightly wipe the surfaces of the device.
    - Lightly wipe the surfaces of the adapter.
- 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 RS001 Cardio-respiratory monitor and adapter to dry thoroughly before using again

The surfaces of the RS001 Cardio-respiratory Monitor have been treated to be chemically resistant to following solution:

- 70% Isopropyl Alcohol

Service

WARNING: Do not attempt to repair the RS001 Cardio-respiratory Monitor as this may cause damage to the device and prevent it from operating properly.

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

Disposal

WARNING: Device to be cleaned and recycled as per local electronics regulation. Patch is to be disposed as per normal hospital regulations.

Charging

WARNING: Do not overcharge the sensor. Maximum charge advisable is 120 minutes.

WARNING: Turn off the RS001 Cardio-respiratory Monitor before charging device.

Follow the following procedures to charge the sensor:

1. Turn off the sensor before charging.
2. Remove the USB charging port plastic cap.
3. Insert provided micro USB cable into sensor.
4. Connect USB cable to a 5V 1A maximum USB charger.
5. Once fully charged (30 minutes), remove micro USB charger.
6. Close the micro USB charger port with the plastic cap.

Troubleshooting

Error on Error Message	Possible Causes	Recommend Solutions
Device displays “ERR”	Faulty device	Contact Respiree Technical Services
Device displays “MOT”	Significant amount of motion is being detected	Check patient and request to keep stationary
Device displays “SAT”	Exposed to bright lights or sunlight	Relocate device so that it is not directly under bright light
Device display does not switch to the correct mode	Mode switch is not in the correct position Faulty device	Check that the mode switch is switched upwards (towards on-off button) for RR mode and downwards for HR mode Contact Respiree Technical Services
Device does not turn on	Low Battery Faulty device	Charge monitor Contact Respiree Technical Services

Product Support

For additional help, contact Respiree Technical Services at (+65) 90617570. Local contact information can be found at http://www.respiree.com

Limited Warranty

Respiree warrants to the original end-user purchaser the Respiree RS001 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 RS001 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 RS001 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

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Specifications

Display Ranges

Parameter	Display Ranges
Sp02 (Oxygen Saturation)	0% to 100%
PR (Pulse Rate)	25 bpm to 240 bpm
RR (Respiration Rate)	4 rpm to 70 rpm

Performance Specifications

Sp02 Accuracy			
Condition	Range	Population	ARMS*
No Motion	70% to 100%	Adults	3%
Low Perfusion	70% to 100%	Adults	3%

Pulse Rate Accuracy			
Condition	Range	Population	ARMS*
No Motion	40 bpm to 200 bpm	Adults	3 bpm
Low Perfusion	40 bpm to 200 bpm	Adults	3 bpm

Respiration Rate Accuracy			
Condition	Range	Population	ARMS*
No Motion	4 rpm to 40 rpm	Adults	3 bpm
Motion	4 rpm to 40 rpm	Adults	3 bpm

* 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.

Sp02 Performance Specifications

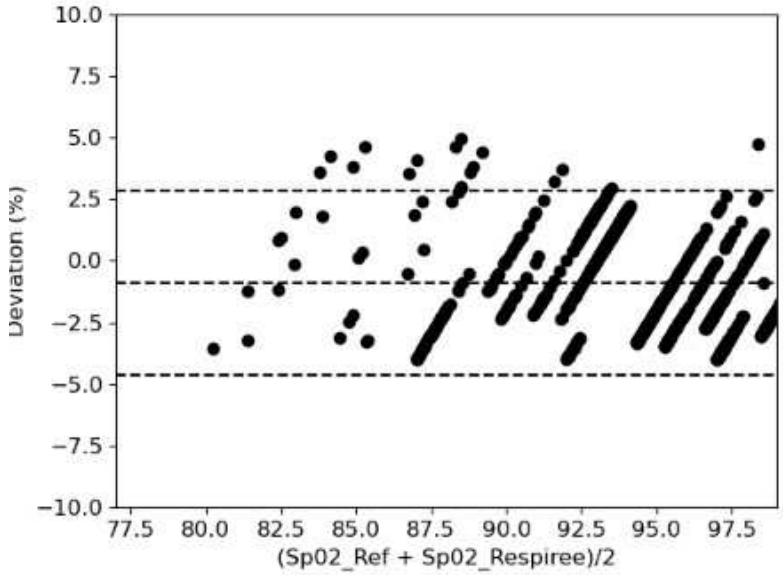


Figure 1. Bload-Altman plot of the RS001 Cardio-respiratory Monitor Pulse Oximeter (ARMS 70-100%)

RR Performance Specifications

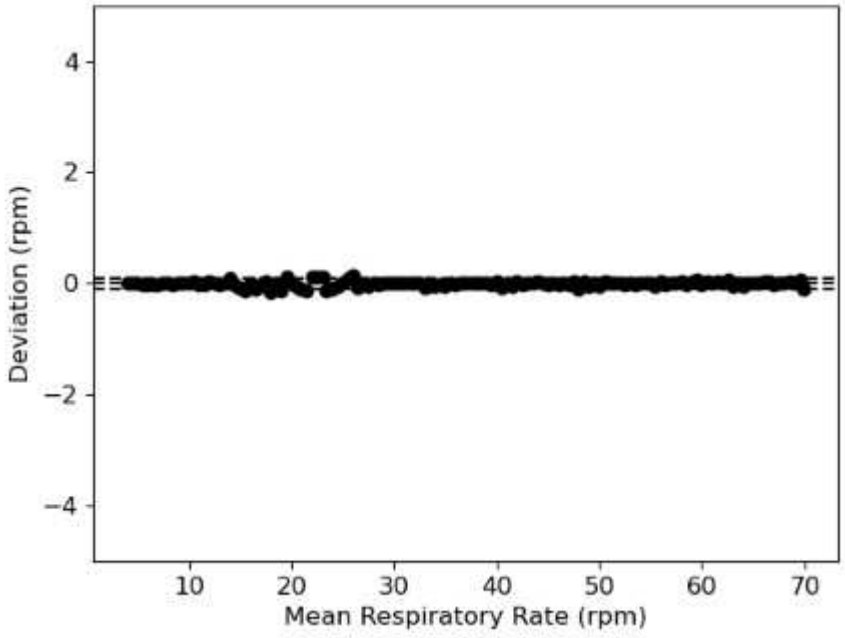


Figure 2. Bland-Altman plot of the Respiratory Rate measurement with respect to the respiration rate value on a simulator (RRef)

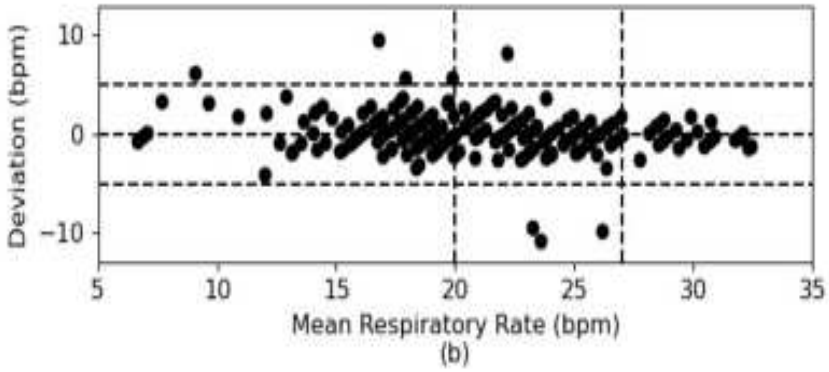


Figure 3. Bland-Altman plot of the Respiratory Rate measurement with respect to the clinician-scored respiration rate value on hospitalized subjects

Medical Conditions

Medical Conditions from clinical study of hospitalized patients

Disease Type	Number
Chronic Obstructive Pulmonary Disease	27
Asthma	37
Pneumonia	44
Type 1 and Type 2 Respiratory Failure	10
Congestive Heart Failure	7
Influenza	3
Sepsis	2
Bronchiectasis	2
Pulmonary Embolism	1
Pulmonary Odema	1
Myocardial Infarction	4
Urosepsis	1
Cellulitis	1

Battery Life

- Continuous use-case battery life of 24-48 hours. Operates with a rechargeable battery. Not to be replaced.

Environment Conditions

- The recommended storage and environment conditions are as follows:
    - Operating temperature: 15 – 35 degrees
    - Storage temperature: 15 – 40 degrees
    - Relative humidity: 15% - 95% (no condensing)

Transportation Conditions

- The recommended transportation conditions are as follows:
    - Operating temperature: 15 – 35 degrees
    - Storage temperature: 15 – 40 degrees
    - Relative humidity: 15% - 95% (no condensing)

Physical Characteristics

- Dimensions: 43 mm x 43 mm x 13 mm
- Weight: 22.1 grams

Compliance

- ISO 80601-2-61: 2017
- IEC 60601-1-2: 2014
- AAMI/IEC 60601-1:2005 + AMD 1:2012
- FCC 47 CFR Part 15
- IEC 60601-1-6:2010, AMD1:2013 with IEC 62366-1:2015 and IEC 60601-1:2005
- FCC ID: 2A3T2RS001-2
- 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.

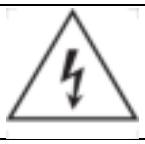
    —Increase the separation between the equipment and receiver.

    —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.

Symbols

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

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instruction for use
CE 0197	Mark of conformity to European medical device directive 93/42/EEC		Type BF applied part
	Non-sterile		Polypropylene
	Separate collection for electrical and electronic equipment (WEEE)		Recyclable
		EC REP	Authorized representative in the European community
	Federal Communications Commission (FCC) Licensing		Single use (disposable) only
	Non-ionizing electromagnetic radiation		Biohazardous Waste
	Warning electricity		Not for continuous monitoring (No alarm)

	Electrostatic		Not made with natural rubber
	Caution		Model Number
	Manufacturer		Serial Number
	Manufacture Date: YYYY-MM-DD		Fragile handle with care
	Storage temperature range		Do not use if package is damaged
	Keep dry		Storage humidity limitation

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