RespiraSense™ Instructions for Use

Instructions for Use

English

The *Instructions for Use* are intended to provide the necessary information for the correct operation of the RespiraSense™ Device.

General knowledge of respiratory rate, patient vital monitoring and qualifications in healthcare are prerequisites for correct use of the RespiraSense™ Device by an operator.

The primary function of the RespiraSense Device is Respiratory Rate monitoring. Associated applications for monitoring Dysfunctional Breathing are included within this Instructions for Use.

The *RespiraSense™, herein called the 'RS Device', Instructions for Use* are intended to provide the necessary information for the correct operation of the Medical Device.

General knowledge of respiratory rate and patient vital monitoring, qualifications in healthcare, and the training in the use of this Medical Device are prerequisites for correct use by an operator. Do not operate the RS Device without fully reading and understanding these instructions. Do not operate the RS Device without receiving training in its use from an authorised trainer. The RS Device must only be installed and put into service in accordance with the information provided in this documentation and referenced documentation.

Notice

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

This Medical Device is available for sale within the European Union, USA, Canada, and Australia.

For more information contact the legal manufacturer:

Legal Manufacturer
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℞ Only CE 1639

Terminology

Table 1 provides a definition of the key terms used in this manual.

Table 1: Definitions of Key Terms

Term	Definition
IFU	Instructions for Use
Barcode	Rectangular optical machine-readable code for identification
bpm	Breaths per minute
dB	Decibel
ECG	Electrocardiogram
EMC	Electro Magnetic Compatibility
FPC	Flexible Printed Circuit
FFC	Flexible Flat Cable
IP	Ingress Protection (ingress of dust and vertical dripping water)
IT	Information Technology
LED	Light Emitting Diode
Lobe	The electronic component of the RS Device
MAC	Medicare Administrative Contractor
MRN	Medical Record Number
PR	Pulse Rate
QR code	Square matrix type barcode for product identification
RespiraSense™	Trade name of the medical systems manufactured by PMD Solutions and intended for use as a medical device
RR	Respiratory Rate
RS	RespiraSense
Sensor	The sensing component that is affixed on the patient body
RS Device	The combination of Lobe and Sensor
RS App	RespiraSense™ Application which has Accessory connectivity features along with RR measurement
RS System	The complete combination of Lobe and Sensor in addition to an associated mobile application
Trend line	Trend of respiratory rate values over time

Indications for Use

The RespiraSense Monitor's Sensors are indicated for continuous, non-invasive, and real-time monitoring of respiratory rate (cRR™). RespiraSense is indicated for patients 18 years and older in hospitals, hospital-type facilities and mobile. RespiraSense is not intended to be an apnoea monitor.

Additional Information on RespiraSense

- The RS Device is intended to act as a short-term continuous monitoring device. It assesses respiratory performance over time by continuously recording, storing, and periodically transmitting respiratory rate data.
- The RS Device does not perform a diagnostic function, as the data that it collects simply displays the patient's respiratory rate (plus pulse rate and SPO2 if a Pulse Oximeter accessory is used in conjunction with the RS Device). Clinicians use this data to help make or rule out possible diagnoses.
- In default configuration, the RS Device can emit an audible alert if the measured respiratory rate exceeds predetermined thresholds. The user can override the default settings to suppress Speakers and visible alerts.
- The respiratory rate information that the RS Device obtains must be evaluated by clinicians on a case-by-case basis.
- The RS Device may record abnormal data. Any abnormal data must be evaluated by a clinician. Clinicians should assess additional physiological parameters or run additional tests before making a diagnosis and prescribing treatment.

Contraindications

- Do not use the RS Device during defibrillation.
- Do not use the RS Device during MRI, X-Ray or other medical imaging procedures.
- Always remove lobe and sensor before bathing
- Do not use the RS Device in a 100% oxygen rich environment.
- If electrosurgery is being undertaken around the vicinity of the device, the RespiraSense should be removed.

Warnings

Do not modify the RS Device without the authorisation of the manufacturer. Modification of the device can lead to serious personal injury and/or failure to monitor patient.
The RS Device measurement results should be scrutinised in light of the condition of the specific patient. Any results that are inconsistent with the clinical status of the patient should be rechecked and/or supplemented with additional physiological data. Failure to adequately assess the patient can lead to unnoticed adverse events.
The RS Device should be considered as an early warning device. Failure to adequately assess the patient can lead to unnoticed adverse events.
The RS Device is not to be used on infants or neonates or under 18 years old. Use of the RS Device on infants or neonates can result in misdiagnosis, failure to monitor patient and tearing of skin.
Do not interface RS Device with any equipment, accessory or device not described in these Instructions for Use. Interface with non-authorised equipment can lead to breakage of Device, battery explosion and failure to monitor patient. Check with the authorised distributor if in doubt of any component.
Do not use RS Device on patients who are acutely ill or clinically unstable in the home healthcare environment. Use in this way will lead to failure to monitor the patient. Check with issuing organization if in doubt.
Do not use the RS Device adjacent to or stacked with other equipment as this may impede the correct operation of the Device. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
Use of portable accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in incorrect operation.
Do not use portable Radio Frequency communications equipment (including peripherals such as antenna and external antennas) within 30 cm (12 inches) to any part of the RS Device. Otherwise, degradation of the performance of this equipment could result.
Do not use any part of the RS Device during magnetic resonance imaging (MRI) scanning, or other medical imaging procedures. Induced current could potentially cause burns, tearing of skin and damage to equipment. The RS Device can affect the imaging procedure, and the MRI can affect the accuracy of the RS Device measurements.

Cautions

CAUTION	Do not use damaged Sensors.
CAUTION	Do not immerse the Sensor in water, solvents, or cleaning solutions (the Sensors and connectors are not waterproof).
CAUTION	Do not sterilise Sensors by irradiation, steam, autoclave, or ethylene oxide (unless otherwise indicated on the Sensor directions for use).
CAUTION	Do not attempt to reprocess, recondition, or recycle Sensors as these processes could damage the electrical components, and lead to patient harm.
CAUTION	Single patient use. Do not apply the same sensor to more than one patient
CAUTION	The RS system has been tested to be safe and effective for simultaneous use of a defined number of Lobes, pair accessories, and Air Gateways. Use of additional Lobes and/or Gateways may result in unsafe system performance.

Additional Cautions

The RS Device is to be operated and prescribed by qualified personnel only. This manual and all precautionary information and specifications should be read before use.
The RS Device mobile medical software application does not record or centralise any clinical information for the purpose of retaining patient records. Historical information is stored on the Lobe for the purpose of reference; however, it is deleted when the Lobe is placed on the charging unit.
Caution “Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.”
Only use the RS Device in accordance with the instructions in this manual.
During application, operators must ensure that the RS Device alert limits are set in accordance with the clinical guidelines of the hospital.
The alert signal of the RS Device reaches a nominal sound pressure level of 64 dB maximum at one meter in front of the monitor.
In cases of high or low respiratory rate readings, the clinical status of the patient should be assessed by a healthcare professional and/or supplemented with additional physiological data.
Do not place the RS Device in any position that could cause it to fall on the patient.
Always remove the Lobe and Sensor from the patient and completely disconnect the RS Device from the patient before bathing the patient.
Do not place the RS Device or any associated IT equipment where the controls or settings can be changed by the patient unless required
Do not place the RS Device on high powered electrical equipment as it could prevent the device from working correctly.
Changes or modifications not expressly approved by the party responsible for compliance could void the operator's authority to use the equipment.

Respiratory Rate is empirically calculated according to the displacement measurements the Sensor detects in the chest and abdomen during breathing and other non-breathing movements (coughing, sneezing, talking, motion). The accuracy of the RS Device is reduced during periods of excessive or continuous motion by the patient.
Instruct patients to avoid sources of electromagnetic interference, such as electric blankets and heating pads while wearing the RespiraSense to ensure the most accurate measurements. Equipment such as electric blankets and heating pads are included as sources of interference.
Inaccurate respiratory rate measurements can be caused by: – Motion artefact due to excessive or continuous movement – Electromagnetic radiation interference – Apnoea events – Misplacement – Use of device beyond working life
Setting the alert limits to extreme values may render the alert functionality useless.
In cases where the Alert LED and/or Speaker have been disabled, system feedback will be reduced. Examine Patient Information to determine expected system feedback.
The System is not to be interfaced with any Network or IT equipment not specified in these Instructions for Use.
In environments with many Bluetooth devices, updates to the Respiratory Rate Application may be delayed.

Notes

The mode of operation of the RS Device system is continuous.
Ensure product is stored according to the labelling guidelines, do not store in damp or wet conditions, near plumbing of any kind (e.g., radiator, sink, shower) or anything that could potentially cause liquid damage to the product.

Guide to Packaging and Labelling Symbols

The following table defines the symbols that are found on the packaging and labelling of the Device.

Symbol	Caution Symbol Description
	NAME AND ADDRESS OF LEGAL MANUFACTURER
	DATE OF MANUFACTURE
	LOT OR BATCH NUMBER
	DO NOT USE IF PACKAGE IS DAMAGED
	KEEP DRY

	UPPER AND LOWER TEMPERATURE LIMITS
	HUMIDITY LIMITATION
	SINGLE USE
	USE BY
	DECLARATION OF CONFORMITY (MDD 93/42/EEC) ANNEX II
	DECLARATION OF CONFORMITY (FCC)
	TYPE BF APPLIED PART IEC 60601-1
IPXX	Ingress Protection against the ingress of dust and vertical dripping water ingress. (IP 54)
	Identifies electrical equipment designed primarily for indoor use
	Non-ionizing electromagnetic radiation
SN	Serial number
	Electronic instructions for use available on the software application
	Consult Instructions for Use
	Direct Current (DC) Input/output
	Caution
	*WEEE Symbol*
	Latex free
	Magnetic Resonance unsafe

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SECTION 1 - OVERVIEW

About This Manual

This manual describes how to set up and use the RS Device system with its associated equipment. Important safety information relating to the use of the system appears before this overview. Other important safety information is located throughout the manual where appropriate.

WARNING	**Read the entire safety information section before you operate the RS Device Failure to follow instructions may result in serious injury and/or failure to monitor breathing. If in doubt, contact the issuing organisation or authorised dealer.**
WARNING	**Refer to Section 12 for details on how to access IFU on the website.**

Notification of Warnings, Cautions, and Notes

Please read and follow any warnings, cautions, and notes that appear in this manual.

The following table provides descriptions of these.

WARNING	**Provided when actions can result in a serious outcome such as injury or death to the patient or operator. The text in the warning is in bold. Harm associated with warning is also presented.**
CAUTION	Provided when special care needs to be exercised by the patient or operator to avoid patient injury or damage to the product.
Note	Provided when additional general information is required.

Respiratory Rate Monitor Overview and Terminology

Product Overview

RS Device Description

The RS Device consists of the RespiraSense™ Lobe (hereafter the Lobe), the reusable component that houses the RS Device's electronics, and a single patient use adhesive RespiraSense™ Sensor (hereafter the Sensor). The Lobe and Sensor connect via a secured FPC and are mechanically fastened together using a plastic Cradle. The Lobe and Sensor are placed ideally on the left-hand side of a patient's torso, however, can also be placed on the right hand side depending on the patient's condition. The RS Device is intended to be used with a supported mobile medical application to monitor a patient's RR status.

The Lobe is rechargeable. It is designed to be charged using the supplied Charging Station. Charging must be done outside of the immediate patient environment.

The separate RS Device components are shown in Figure 1 and Figure 2. A detailed description of the components and the interactions between components will be presented later in this IFU. The components are as follows:

- **The Sensor**: An adhesive, single-patient, sensor array.
- **The Lobe**: A reusable electronics module, housing data processing, Bluetooth communication module, LEDs and sounder.

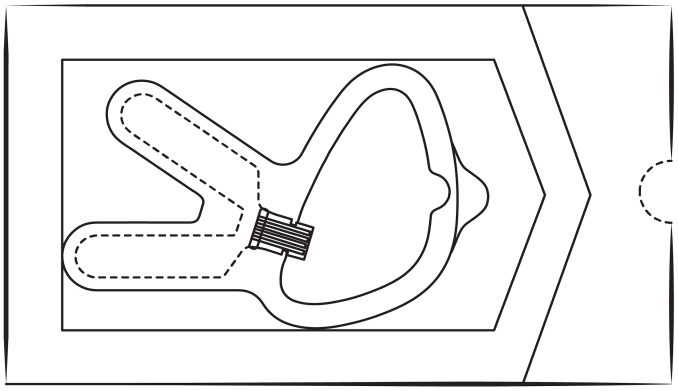


Figure 1 Sensor in Packaging

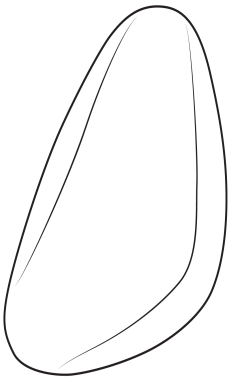


Figure 2 Lobe

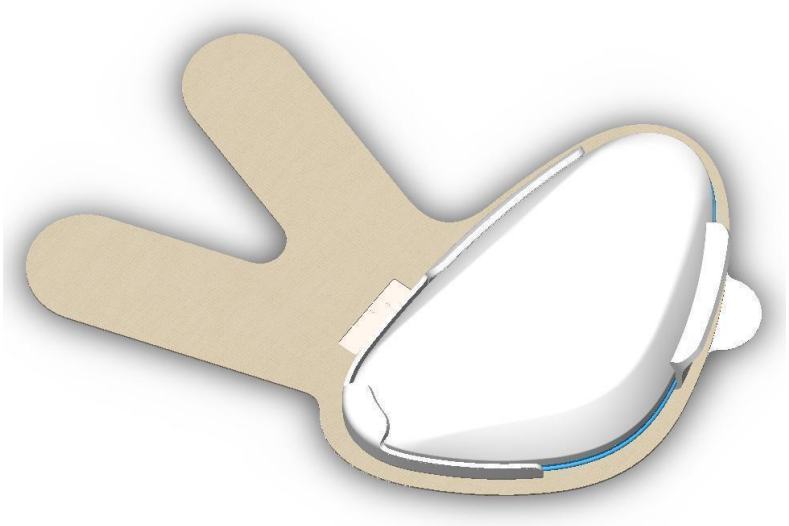


Figure 3 RS Device with Sensor and Lobe together

The RespiraSense is used with the following associated IT equipment:

A **portable hand-held device**, currently an iPad, onto which the Associated Mobile Medical Application is installed and operated. The Mobile Medical Application is shown in Table 2

Name of Application	**Clinical Indication**
RespiraSense RS App	Continuous and motion tolerant monitoring of respiratory rate

Table 2 List of Associated Mobile Medical Applications

Product Description

The RS Device is a non-invasive, wireless, Respiratory Rate (RR) monitor that is worn on the body of the patient. It is internally powered and enables continuous RR monitoring from a single application. It is designed to enhance the ability of medical staff to reliably measure respiratory rate.

The Lobe can emit an audible alert if a physiological alert condition is met. This occurs if the measured respiratory rate exceeds either lower or upper threshold limits. These limits are defined by the operator during the setup of the RS Device and can be redefined by the user by connecting to a RS Device in use.

The RespiraSense™ Respiratory Rate Monitor is comprised of the RS Device and the RS App. The RS Device is assembled then placed on the left-hand side of the patient's torso. The RS App is used to communicate with the Lobe and Sensor during patient registration and while in use. This is supplied on a portable hand-held device that allows easy data retrieval and display.

The RS App is compatible with mobile computers that comply with EN IEC 60950-1 and have the appropriate software and hardware specifications. The current mobile computer that the RS app runs on is an iPad and is provided with the RS App pre-installed. Updates to the RS App will be available from the Apple store and the RS App version will be automatically updated if the device is not in use on a patient at the time the update becomes available. Otherwise, the RS App will auto-update after closing the RS App. The updated version will be installed when the RS App is restarted.

Position of Users

During normal use, the RS Device is attached using a medical grade adhesive patch to the Patient.

The Operator, a trained medical professional, registers a RS Device to a patient using the RS App and subsequently monitors them using the app. The Operator interacts with the RS Device during registration and attachment to the patient, and during removal and disposal.

Features and Benefits

The following are the key features and benefits of the RR Monitor:

- Clinically proven technology
- Motion tolerant monitoring
- Continuous respiratory rate monitoring

Principles of Operation

The Device provides a continuous, non-invasive method of monitoring a patient's respiratory rate.

Respiratory Rate

Respiratory Rate (RR) is the number of breaths taken within a set amount of time, typically 60 seconds. This is also known as respiration rate, respiration frequency, ventilation rate, ventilation frequency, pulmonary ventilation rate or breathing frequency. Respiratory rate is a vital sign and can help in the assessment of the health status of a patient. Respiratory rates can change with fever, illness, or other medical conditions.

For ventilation to occur, some sort of mechanical displacement of the thoracic and/or abdominal region must take place.

The respiratory rate is the effect of the intercostal muscles across the ribcage contracting. This causes the sternum to lift and expand outwards across the ribs. These mechanical actions create a vacuum in the thoracic region of the body, which is compensated by air flowing from the environment into the lungs via the facial cavities – the nose and the mouth.

Ventilation also occurs mechanically when the abdomen displaces and creates a vacuum and/or drop of the diaphragm. The diaphragm is a band of muscle under the lungs that separates the thoracic regions from the abdominal region. The displacement of the abdomen has the same result as the displacement of the ribcage: air flows into the lungs through the nose and mouth.

If any problems are indicated by circulatory condition or skin integrity, remove the Sensor from the patient.

CAUTION	Do not use damaged Sensors.
CAUTION	Do not immerse the Sensor in water, solvents, or cleaning solutions (the Sensors and connectors are not waterproof).
CAUTION	Do not sterilise Sensors by irradiation, steam, autoclave, or ethylene oxide (unless otherwise indicated on the Sensor directions for use).
CAUTION	Do not attempt to reprocess, recondition, or recycle Sensors as these processes could damage the electrical components, and lead to patient harm.
CAUTION	Single patient use. Do not use the sensor on more than one patient after application

Monitoring during Motion

The RS Device measures respiratory rate during motion. However, the method of monitoring also detects non-breathing motions that can occur during talking, walking, limb movement or other similar actions. Note there is a decrease in accuracy during patient movement. In cases of extreme or prolonged motion the RS Monitor will refrain from providing a RR data point if the result is determined to be of insufficient certainty.

Declaration of Essential Performance

- The RS Device does not contain Essential Performance functions.

Specific details on the accuracy limits and alert generation criteria can be found in *Section 7 – Product Specification and Compliance.*

Intended Users

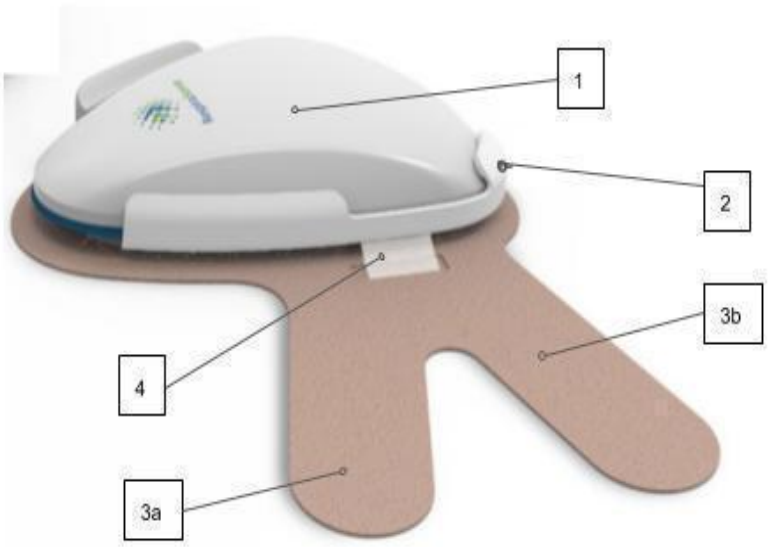
The RS Device is intended to be used by trained medical personnel only.

SECTION 2 - SYSTEM DESCRIPTION

In this section a description of the main features of the RespiraSense™ Device and associated mobile medical application is available. Detailed instructions on the use of the RS App are found in *Section 3– Patient Monitoring*.

1. RespiraSense Lobe and Sensor

Figure 4 shows the Lobe and Sensor assembly and operational features.



Reference	Name	Description
1	Lobe	Connects to the Sensor during use. Communicates with a supported mobile medical application when information is requested. Contains Speaker and LED function.
2	Cradle	Secures the Lobe to the sensor during operation and acts as the Lobe-Sensor interface
3	Sensor	Connects to the Lobe and adheres to the patient during use. 3a: Sensor upper leg, 3b: Sensor lower leg.
4	FFC Sensor Tail	The conduit which enables the electrical connection between the sensor and the Lobe.

Figure 4 RespiraSense Lobe and Sensor Assembly and Underside

2. RespiraSense Device Charging Station

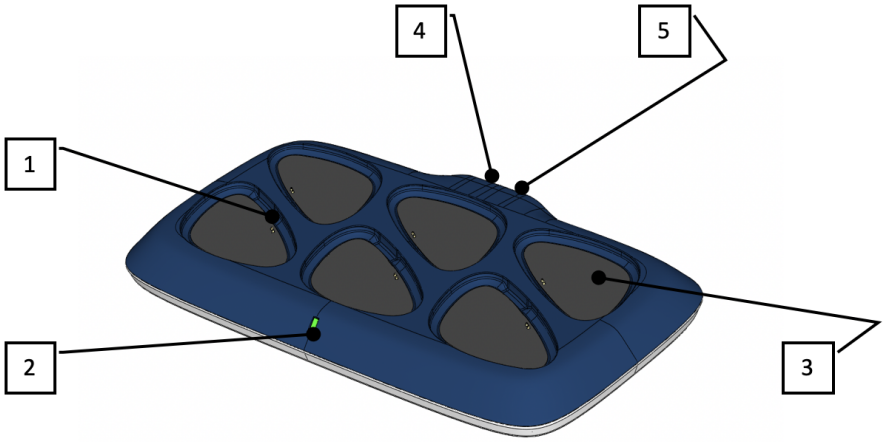


Figure 5: Multi Charger Dock

Table 3 Feature of the Multi Charger Dock

Reference	Name	Description
1	Lobe charging slot	The resting place of the Lobe during charging and storage
2	Power indicator	Green LED to indicate power is supplied to the Charger
3	Micro suction Pad	A non-adhesive based material used to secure the Lobe in the charging Slot
4	Power Plug	The port for the power adapter
5	Auxiliary USB Charger	A USB charging port for associated equipment

3. RS App

RS App is the RespiraSense RS Application that allows a user to register RS device with a patient and monitor RR data. The iPad Auto-lock setting shall be pre-configured to 'Never' to enable the RS App to always display patient data and alerts. To do this, go to your iPad Settings > Display & Brightness > Auto-**Lock**. Set Auto-**Lock** to "**Never**". The iPad can be manually locked by hitting the side switch button on the device; therefore, care is to be taken not to do this while the iPad is in use in a patient. Sound is always to be left on the iPad. The screen can be re-activated by pressing the Home button.

Figure 6: iPad Controls

Figure 7 shows the RS App Dashboard. This is the default screen displayed when the application is first started.

Accessing the Dashboard displays a list of all nearby RS Devices which are monitoring patients. A summary of up to four RS Devices are shown, with more available using a scroll interface when required. The device list can then be scrolled by holding a finger on the screen and dragging it up and down the screen. An overview of the Dashboard is shown in Figure 7 below. Details of the Patient Information Panel are presented later. The Dashboard also allows access to patient registration interfaces and the help and settings options.

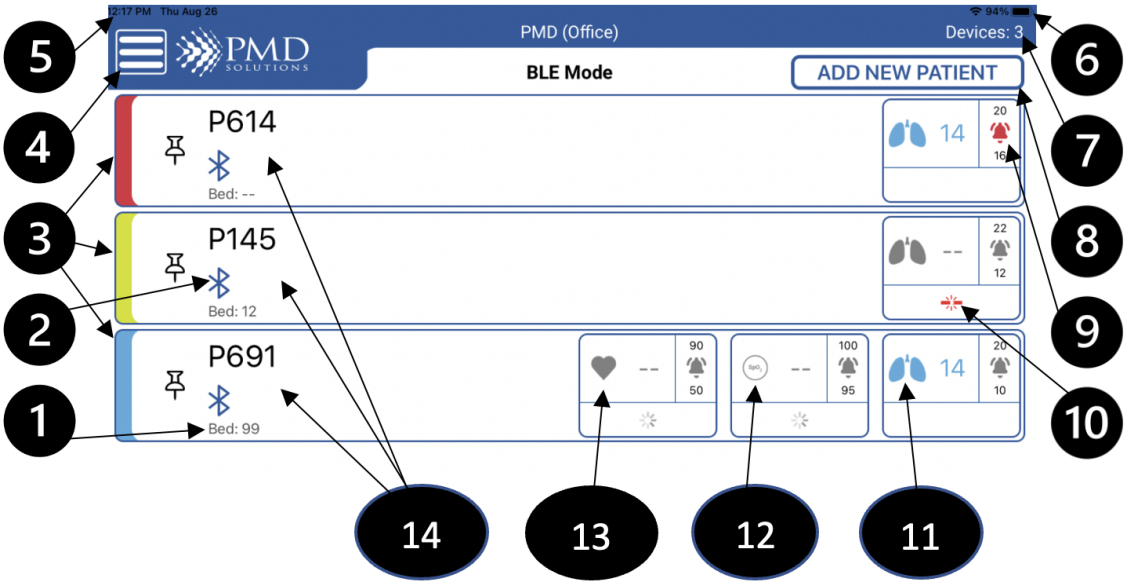


Figure 7: RS Application Dashboard

Reference	Function	Description
1	Bed number	Patient's bed number (8 characters).
2	Bluetooth Icon	Indicates Bluetooth connection.
3	Patient Summary Situation	Colour coded to patient's condition. Blue: Patient is stable. Yellow: Non-Critical Issue. Check patient. Red: Critical Issue with the patient, respiratory rate is outside of limits.
4	Side Menu	Allows the operator to navigate the app and change settings. This menu brings the user to dashboard, routers, help and settings.
5	Time & Date	Displays current time and date.
6	Power Level & Connection Symbol	Displays the current power level of the hand-held device. The charging symbol indicates when the device is charging. Connection symbol indicates that the device is connected to Wi-Fi.
7	Device count	Indicates number of devices detected

8	Add New Patient	Register a new patient with a new lobe.
9	Alert	Displays when the respiratory range is outside of the thresholds.
10	Sensor Disconnected	Sensor is not connected to the lobe
11	BPM	Breathes Per Minute
12	SpO_2	Upper Threshold always set to 100. Lower Threshold set to 95.
13	Pulse Rate	Measured in Beats Per Minute.
14	Patient Information Panel	Displays summary information for each lobe which is broadcasting information nearby. Detailed in next section. Up to 6 Lobes are displayed. In the event that there is more than 6 Lobes in the vicinity, a scroll interface will be available.

Table 4 Features of the Respiratory Rate Mobile Application

Dashboard – Patient Information Panel

Each Lobe detected by the Dashboard will display its information on a Patient Information Panel, as shown in Figure 8.

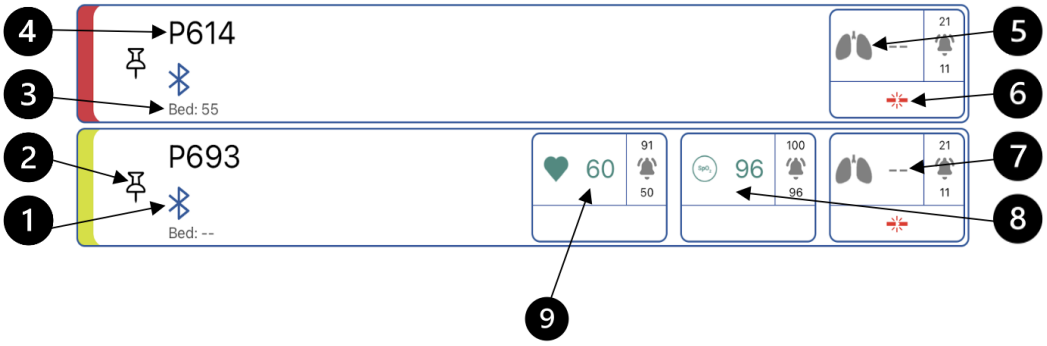


Figure 8: Patient Information Panel

Reference	Function	Description
1	Bluetooth Icon	Indicates Bluetooth connection.

2	Priority Patient Toggle	Allows user to toggle Lobe as Priority. Priority patients are shown at the top of the list. Shown in Figure 7 in deactivated state. It will show black in the active state.
3	Bed Number	Bed number (8 characters).
4	Patient ID	Displays Patient identifier
5	Respiratory Rate Icon	Shows what is being measured – respiratory rate.
6	Sensor Disconnected	Displayed on Dashboard when the sensor signal is not detected by the Lobe. FPC disconnected
7	Latest Respiratory Rate (RR)	Shows average RR of patient over the latest averaging window.
8	SpO_2	Upper Threshold always set to 100. Lowest Threshold set to 95. Will be visible on the RS app dashboard in the event a Nonin pulse oximeter is added using the "add accessory feature"
9	Pulse Rate	Measured in Beats Per Minute. Will be visible on the RS app dashboard in the event a Nonin pulse oximeter is added using the "add accessory feature"

Table 5 Features of the Patient Information Panel

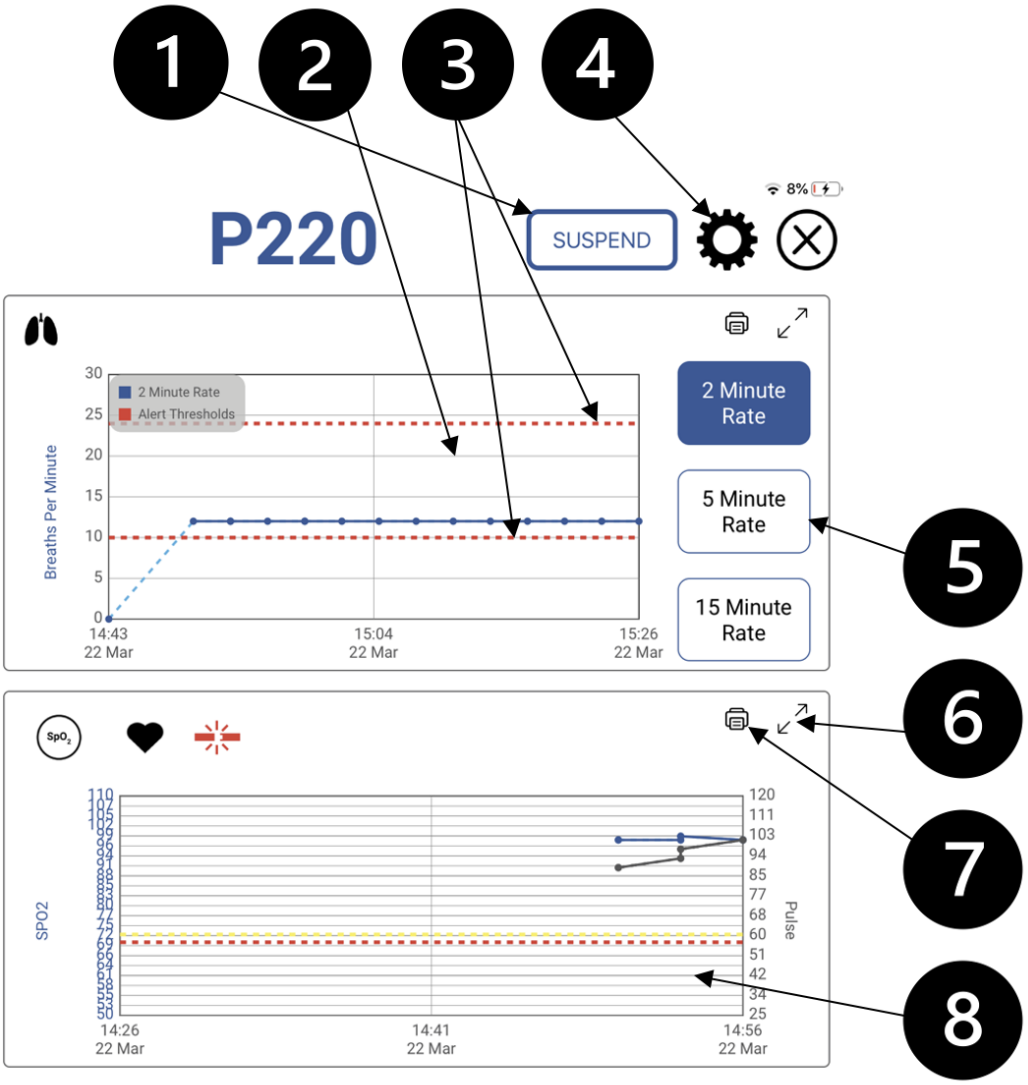
In Bluetooth mode, in the event of a RS Device leaving scan range, the Patient Information Panel will fade to grey to indicate that the application is no longer receiving data from that patient. After 15 minutes the patient will not be visible on the dashboard.

Any RS Device which is currently displaying an alert status will be placed at the top of the dashboard.

Respiratory Rate Measurement - Function Screen

Successfully requesting patient data from the Lobe results in the display of the RR Measurement Function screen as shown in Figure 9. This screen displays patient and device status information and allows the user to browse the patient's RR trend graph and alter Lobe settings as required.

Figure 9: Respiratory Rate Measurement Functions Screen



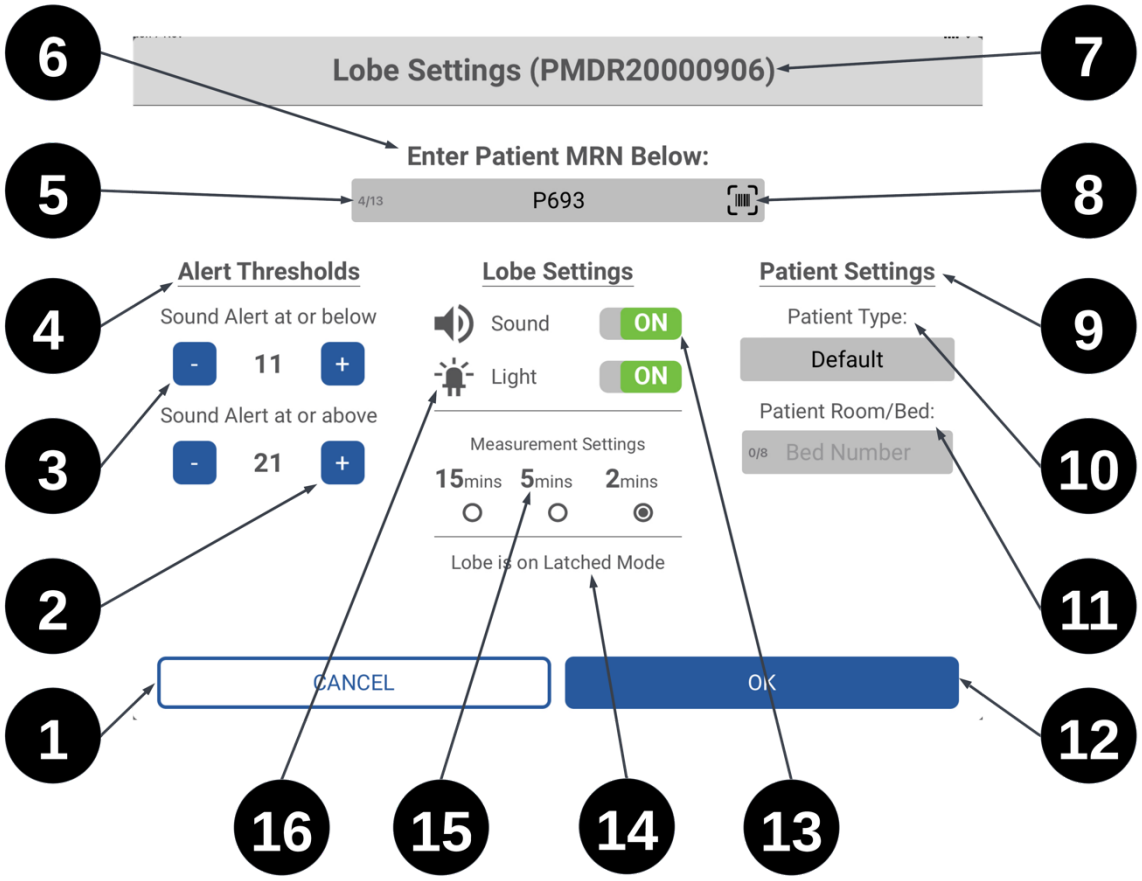
Reference	Function	Description
1	Suspend Button	Allows the operator to suspend measurement for 3 minutes before it disappears from the dashboard and app.
2	RR Measurement Trend Graph	Indicates the RR over the selected measurement time frame. A dashed blue line may be present if graph data is missing. This line is interpolated and should not be used to assess the patient.
3	Alert Limit Lines	Lines on the RR trend graph showing the currently selected alert thresholds.

4	Lobe Settings	Can be selected to bring the user to Lobe Settings Interface. The user can alter Sounder and LED settings
5	Measurement Time Frame Between Selection Buttons	Allows selection of time frame over (2, 5 and 15 minutes) to view the RR trend graph.
6	Enlarge Graph	Enlarges the graph for more detail.
7	Print Option	Allows user to print graphs of both SpO_2 and RR.
8	SpO_2 Measurement	Measurement of Pulse Rate from SpO_2 and heart rate from ECG graph- using accessory. – this is available in the event an approved Nonin pulse oximeter is added using the "add accessory feature"

Selecting the "Alert Thresholds" option on the RR Measurement Function Screen displays the Threshold Alteration Interface, shown in Figure 9. This interface allows the user to change respiratory rate alert thresholds. Details on how to use this menu is provided in *Section 3 – Patient Monitoring.*

Selecting the "Lobe Settings" option on the Measurement Function Screen displays the Indicatory Alteration Interface, shown below. This interface allows the user to change LED and Sounder settings on the Lobe. Details on how to use this menu is provided in *Section 3– Patient Monitoring.*

Figure 10: Threshold Alteration and Indicator Alteration Interface

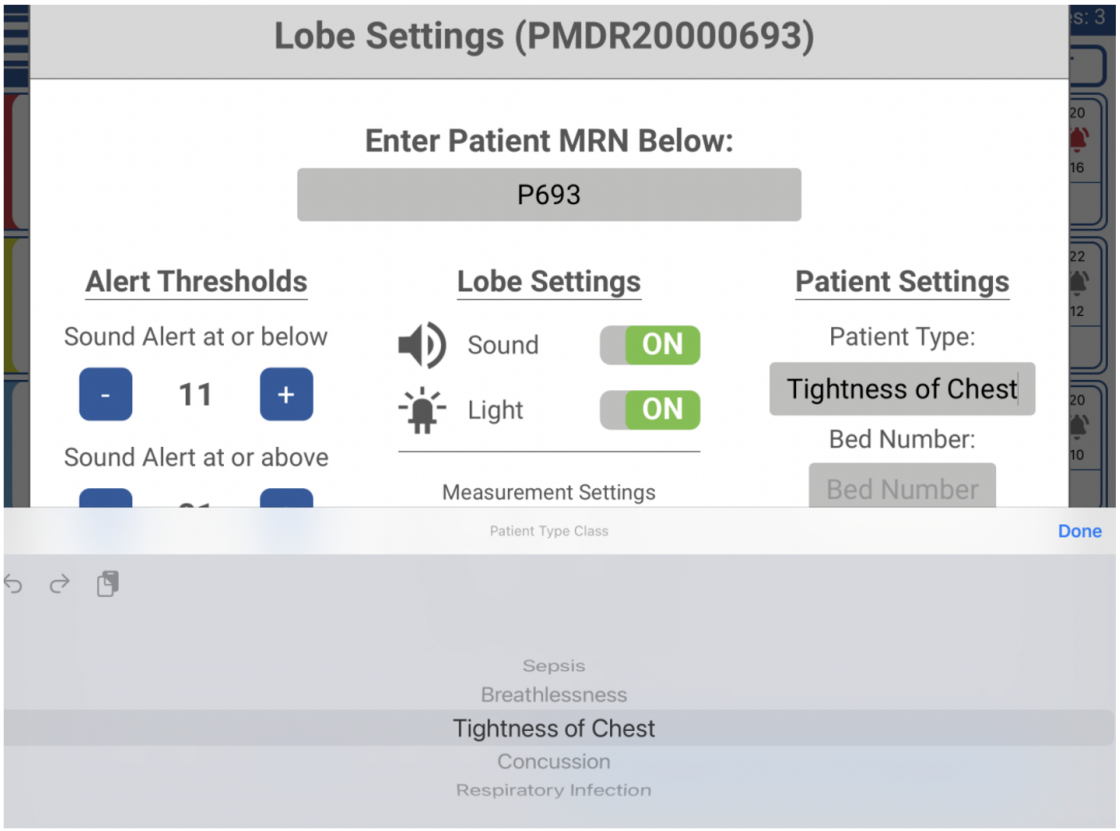


Reference	Function	Description
1	Cancel Button	Returns the user to the previous screen without changing thresholds.
2	Increase Threshold Level Button	Allows user to increase the threshold by 1bpm.
3	Decrease Threshold Level Button	Allows user to decrease the threshold by 1bpm.
4	Threshold Settings	Displays current upper bound on alert thresholds.
5	Character limit label	Displays number of characters used and total limit.
6	Lobe Name	Allows user to change the name of the lobe.

7	Lobe ID	Displays Lobe ID.
8	Barcode Scanner	Allows users to scan a patient's barcode to fill out Lobe Name automatically.
9	Patient Settings	Patients related settings.
10	Patient Type	Indicates patient type.
11	Bed Number	Bed number of patient (8 characters). Blank if unset.
12	OK Button	Prompts user to save new thresholds.
13	Sounder Settings	Displays sounder setting. Displays an X through the symbol and turns red when the sounder is set to off.
14	Latched/Unlatched	Indicate if lobe is in latched or unlatched mode.
15	Measurement Settings	Allows user to specify averaging window length.
16	LED Setting	Displays LED setting. Displays and X through the symbol when LED is set to off and also turns red.

Table 7 Features of the Threshold Alteration and Indicator Alteration Interface

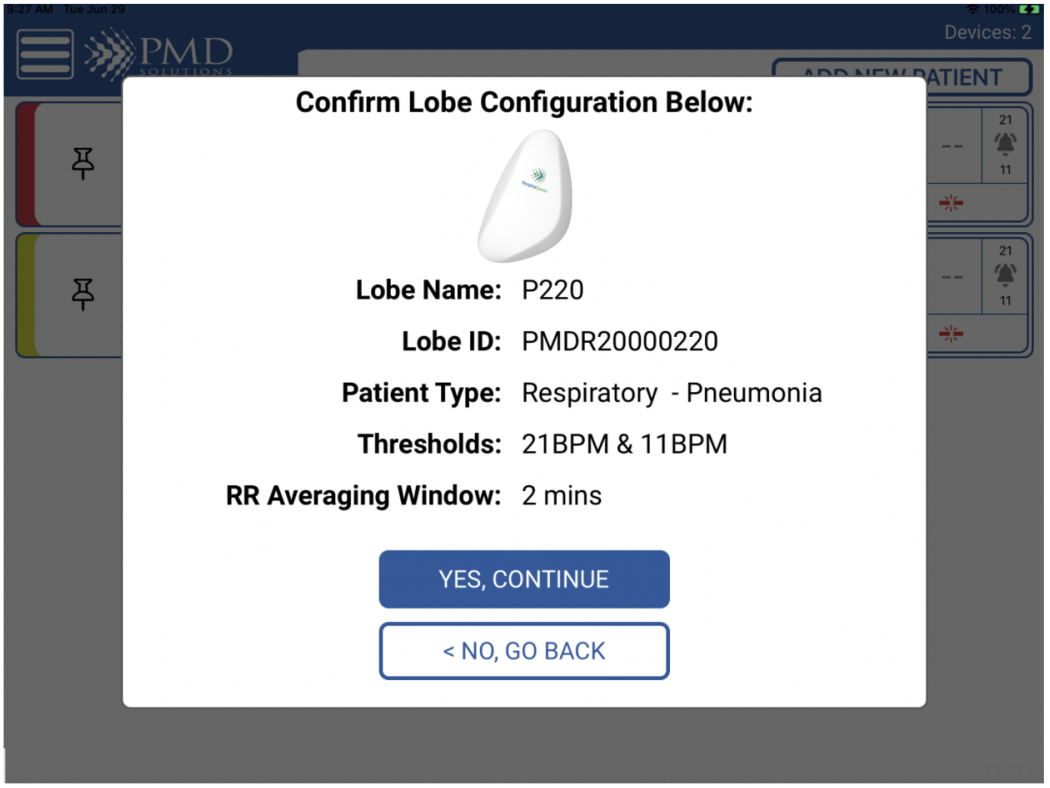
Figure 11: Patient Type Classes



Settings Change Acknowledgment Screen

Figure 12 shows the Settings Acknowledgment Screen. These screens are displayed when a user has altered settings on the device. It provides a summary of changes made to the device settings.

Figure 12: Settings Acknowledgment Screens



Addition of an Accessory

Adding an accessory i.e. the Nonin Pulse Oximeter to measure Sp02 can be monitored on the RS app in addition to the respiratory rate with RS.

If the RespiraSense device is already registered the user can add an approved accessory to the lobe through the RS app on the respiratory rate monitoring screen through settings and then add accessory. The user has the option of manually adding the Accessory MAC number or scan the QR code of the device.

Figure 13 Adding Accessory menu

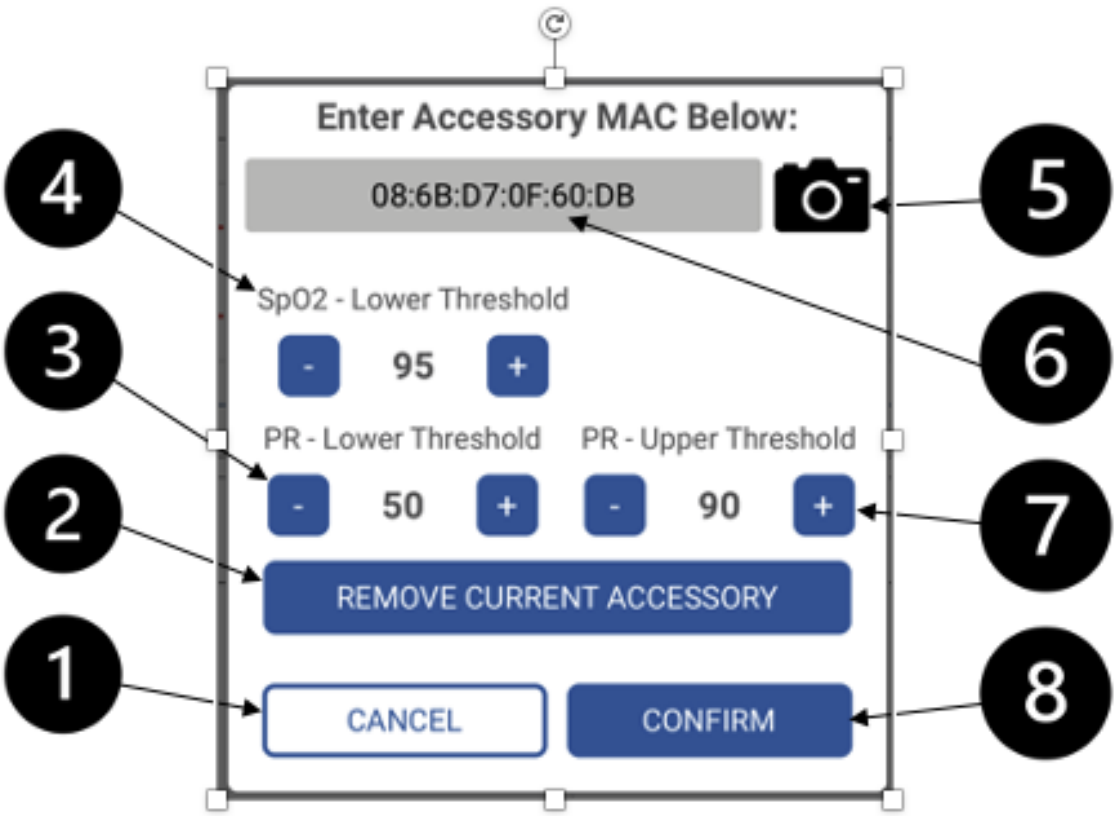


Table 8 Features of Adding an Accessory

Reference	Function	Description
1	Cancel Button	Takes user back to Lobe Settings when adding a patient or back to the Respiratory Rate Measurement Function Screen if accessory is being added to existing patient.
2	Remove Current Accessory	Removes the current accessory that is a paired with the lobe.
3	PR- Lower Threshold	Pulse Rate Lower Threshold.
4	SpO_2 – Lower Threshold	Upper Threshold always set to 100.
5	Camera Icon	Allows user to scan the QR MAC number of the accessory device.
6	Add Accessory	Manually enter input the accessory MAC number.
7	PR – Upper Threshold	Pulse Rate Upper Threshold.
8	Confirm Button	Confirms the added accessory to be measured.

Alert Function

When the RR of a patient wearing a RS Device equals or exceeds an alert limit threshold or when the Lobe is receiving no signal from the Sensor over a prolonged period, an alert state is entered. An alert scenario on the Lobe exhibits as follows:

1. A flashing Red LED.
2. An audible alert sounding three times on a 5 second cycle.

To silence the alert, the user selects the patient from the dashboard. In the case where no Sensor signal is being received, a flashing White LED will then display to show the user that the Sensor has become detached. This status will eventually result in an alert status. Figure 14 shows the popup screen when the user is prompted to pause the Alert function. See *Section 3– Patient Monitoring* for more information.

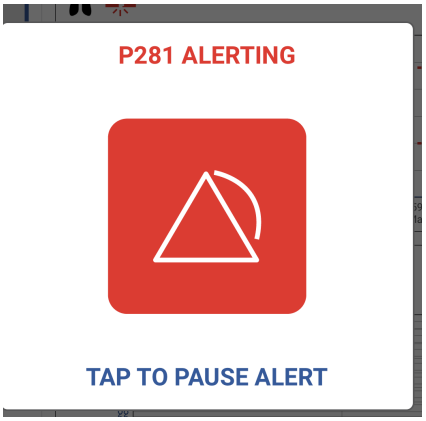


Figure 14: Alert Pause Prompt

Lobe - Low Battery Warning

Figure 15 shows the low battery warning. This warning is displayed on connection when the Lobe or accessory battery is nearing depletion on the dashboard.

Figure 15: Low Battery Warning

Note	This warning is displayed on the dashboard screen when the battery indicator shows Low Battery. The operator should replace the patient worn Lobe with another fully charged Lobe and follow the appropriate setup and operation procedures.

Checking Battery Levels

Always ensure that the Lobe and the hand-held device are sufficiently charged before and during operation. The battery level of the hand-held device is displayed on the Dashboard screen. The battery level of the Lobe is displayed on the Measurement Function Screen.

Note	When the Lobe battery indicator shows Low Battery, the LED flashes Amber every 20 seconds, and a low battery warning is displayed on the Measurement Function Screen when the Lobe is connected to.

Connection Selection Section

Selecting “Add New Patient” from the RS App Dashboard presents the user with the option of choosing from Bluetooth devices nearby and those using the Air Dashboard. Figure 17 shows this screen. All available nearby devices will be displayed as they are discovered. The user can then select the correct device from the list, by referencing the serial number on the back of the Lobe.

Figure 16: Back of Lobe with Serial ID

Table 9 Features of the Back of Lobe

Reference	Name	Description
1	Sensor ID	References the identification of the lobe
2	Back of lobe	RespiraSense

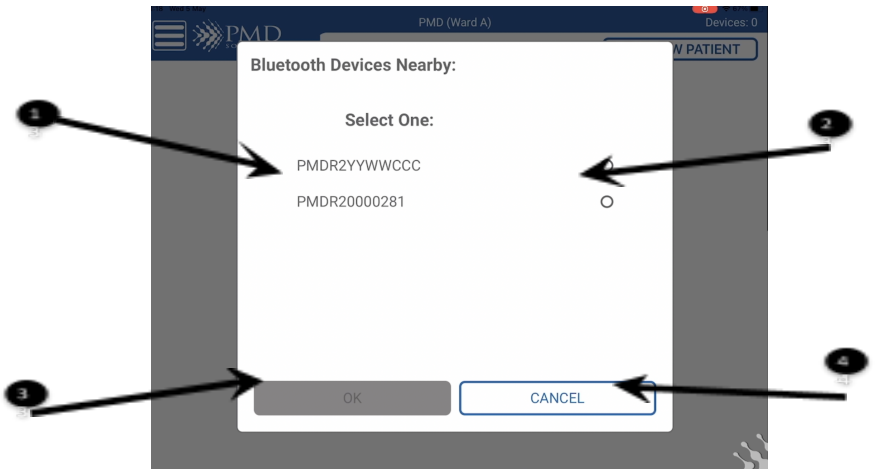


Figure 17: Connection Selection Screen

Table 10 Features of the Connection Selection Screen

Reference	Name	Description
1	List of Devices	Name of devices on the network
2	Selection Button	Allows user to connect to that device before confirming by selecting 'OK'.
3	Confirmation Buttons	Allows user to proceed with registration.
4	Cancel Button	Allows user to cancel current process.

Rename Confirmation Screen

Before completion of the renaming process, a confirmation screen is displayed. This is studied by the practitioner to ensure the device is being correctly configured when attaching to the patient. Figure 18 illustrates this screen.

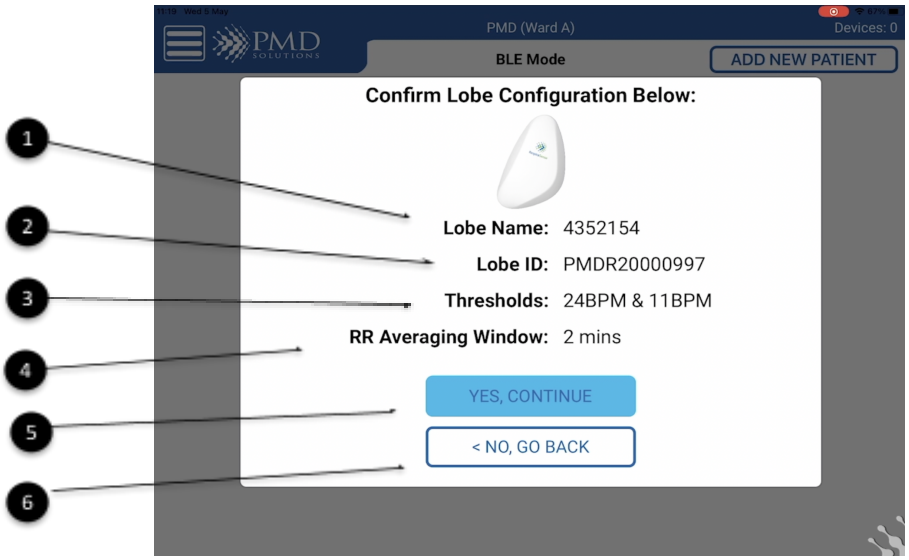


Figure 18: Rename Confirmation Screen

Table 11 Features of the Rename Confirmation Screen

Reference	Function	Description
1	Lobe Name	Displays the MRN of the patient.
2	Lobe ID	Displays the unique identifier of the Lobe which is to be registered.
3	Threshold Limits	Displays the currently configured upper limit and lower threshold limits for patient RR. Exceeding these limits will trigger an alert.
4	RR Averaging Window	Displays the currently configured RR Averaging Window.
5	Confirmation Buttons	Allows user to proceed with registration.
6	Cancel Button	Allows user to cancel the current process.

Side Menu

The side menu allows the operator to navigate the app and change settings. This menu brings the user to dashboard, routers, help and settings.

Figure 19: Side Menu Bar

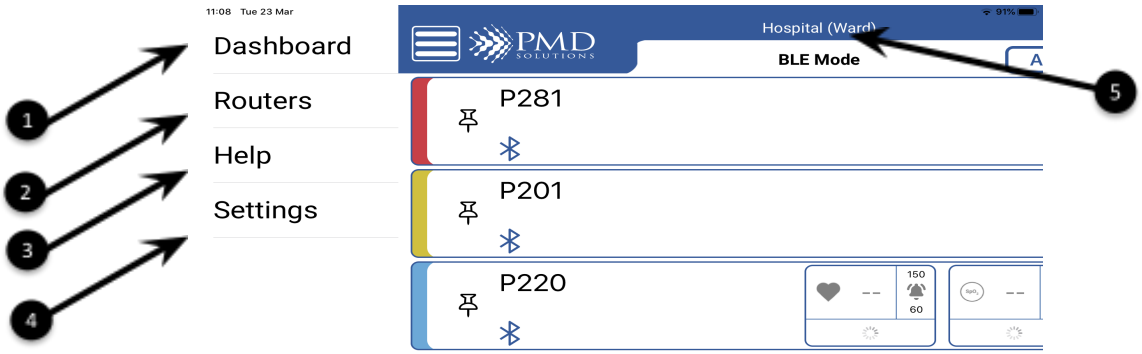


Table 12 Features of the side menu

Reference	Function	Description
1	Dashboard	Selecting this displays the lobe dashboard
2	Routers	Allows user to manage routers connected
3	Help	Allows user to choose options on how to set up devices and the instructions for use
4	Settings	Restricted access to set default monitoring, change password, system check and change administrator settings. This section is password protected.
5	Hospital Name and Ward Name	Displays hospital and ward name. This can be changed in default settings.

RS App Icons

Table 13 lists the icons used in the RS App.

Table 13: RS App Icons

Icon	Name	Description
	Help Icon	Brings user to RS App Help Menu which includes the IFU.
	Back Icon	Returns user to previous screen.
	Settings Icon	Brings user to RS App Settings Menu.
	Bluetooth Icon	Brings user to Bluetooth Selection Screen.
	Manual Input Icon	Displays onscreen keyboard for manual entry of details.
	System Sound Icon	Status display for state of System Sounder (may display with X through icon if sounder function is suppressed)
	LED Icon	Status display for state of LED Indicators (may display with X through icon if LED function is suppressed).
	Plus Icon	Increment counter upwards by one unit.
	Minus Icon	Increment counter downwards by one unit.
	Camera Button	Brings user to Camera Scan Function.
	Priority Pin Button	Allows user to toggle Lobe into and out of Priority status. Can be used to filter patients using the Priority Filter Button. Alternate: Shown as filled black when patient is included on the Priority List.
	Device Error	Displayed on the Dashboard when a device error is detected.
	Alert	Displayed when the respiratory rate is outside of the alert thresholds.
	Device Battery Low	Displayed on Dashboard when the Lobe battery is low.
	Sensor disconnected	Displayed on Dashboard when the Sensor signal is not detected by the Lobe.

 Lobe Settings Alert	Displayed on the Dashboard when any Lobe settings have been changed from default.
 Alert Paused Icon	Displayed on Measurement Screen when alert has been paused.
 Respiratory Measurement	Respiratory rate measurement - sensor connected to RS App and patient registered
 Pulse rate	Pulse rate value - SPO2 accessory connected to RS App
 SPO2 measurement	Blood oxygen saturation measurements - SPO2 accessory connected to RS App
 Print Function	Allows user to print RR and Sp02 graphs remotely via WiFi network.

BLE and Air Mode / Router Menu

The Router menu displays all Cassia routers registered with the RS App on a specific iPad, and also informs the user of their connectivity status.

The RS Application offers two modes: BLE and AIR. BLE mode is where the RespiraSense Lobe is in the vicinity of the iPad with RS App installed and in this case the lobe is connected directly to the RS App through a Bluetooth connection. However, if clinical staff require access to patient data while they are not in the vicinity of the device and the patient, the mobile app offers AIR mode. In AIR mode, the mobile app connects to PMD cloud services through the router over an internet connection and subscribes to data streams registered with PMD cloud services, so the mobile app is able to retrieve the Lobe's data over the air. The AIR mode of the mobile app is a combination of the BLE and AIR mode, so the priority is always the BLE data stream. If this is absent, the AIR stream kicks in for an individual device. Switching to Air mode from BLE is performed in the Settings and requires authorisation with an administration password.

- **BLE Dashboard** – When BLE dashboard is on, it picks up and lists all available RespiraSense devices in the vicinity of the iPad to enable selection of a lobe for patient registration on the Dashboard. The Bluetooth dashboard will always be green/ON if Bluetooth is switched on in the iPad settings.

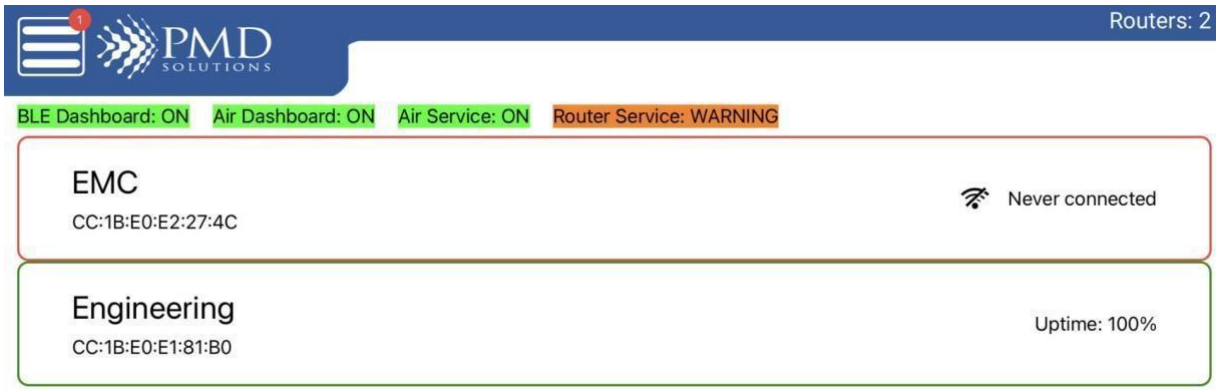
- **Air Dashboard –**The Air dashboard requires the RS App to be connected to an access controller that is managed by PMD and hosted on Amazon AWS. It performs the same function as the BLE Dashboard but uses an internet connection through an authorised Router rather than Bluetooth connection. It will be green/ON when Air Mode is authorised and is receiving information.

- **Air Service –** If the Air Service is red/OFF, the RS App cannot receive the information relayed from the cloud and is only available through local BLE range i.e., the data is available but is not being received.

- **Router Service** – If the router service is red/OFF, there is no connection from the routers to the access controller routers authorised to the RS App. An orange Router Service Warning indicates that at least one of the routers authorised to the RS application is not online.

Figure 20: Router Menu

Green colour outline indicates a solid connection. Red indicates no connection.



Help Menu

The Help menu displays a document containing these Instructions for Use and the *PDS-801-008: RespiraSense Quick Reference Guide*.

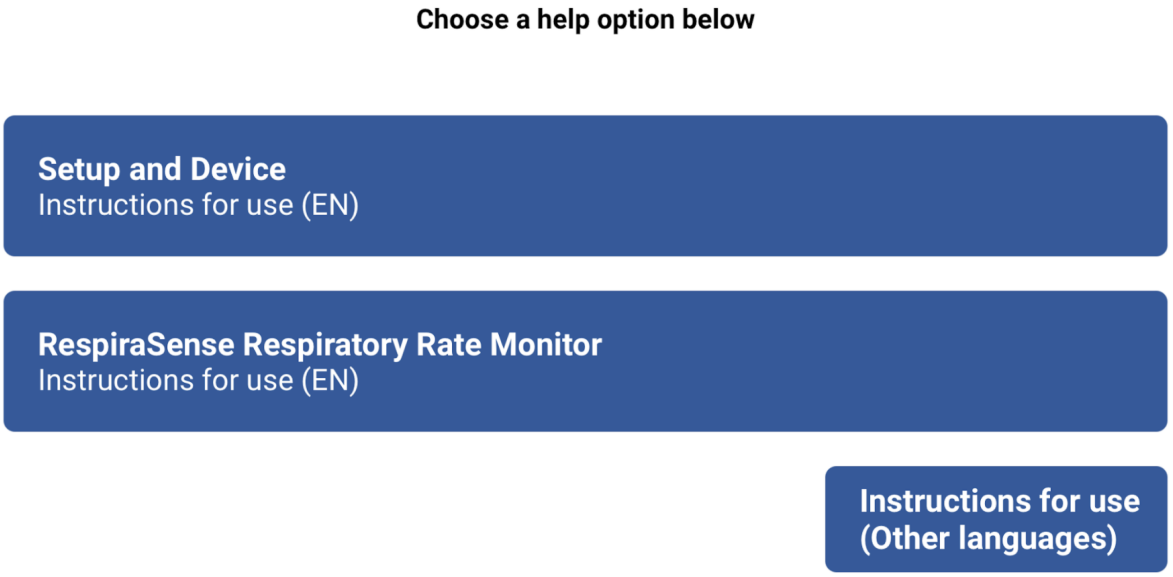


Figure 21: RS Application Help Menu

Input Characters

The RS App will only scan or accept keyboard input from characters in the ASCII set. Non-ASCII characters will be rejected and a warning displayed. The ASCII set consists of the following characters:

ASCII set details		
Capital Letters	A – Z	
Lower Case Letters	a – z	
Numeral	0 -9	
Special Characters	SPACE	:
	!	;
	"	<
	#	=
	$	>
	%	?
	&	[
	'	\
	(	]
	)	^
	*	_
	+	{
	,	|
	-	}
	.	~
	/	

SECTION 3– PATIENT MONITORING

Introduction

This section details the step-by-step instructions for using the RR Monitor in the everyday clinical setting.

Patient Monitoring is comprised of the following tasks:

1. Registering the Lobe
2. Assembling the Lobe and Sensor
3. Attaching the RS Device to the Patient
4. Multiple Patient Monitoring through Dashboard
5. Priority Patients
6. Obtaining Detailed RR Measurements
7. Dealing with Alert
8. Altering Respiratory Rate Thresholds during Monitoring
9. Altering Alert, LED and Sounder Settings
10. Removal and Disposal
11. Using the RS Device in the Home Healthcare Setting

For details on Maintenance, Configuration and other advanced use see *Section 5 – Configuration and Advanced Features* and *Section 9 - Service and Maintenance*.

CAUTION	Before Operation of the RR Monitor the operator must: ● Know how the RR Monitor derives its readings. See *Section 1 - Overview* for more information. ● Be familiar with the controls and operation of the RS Device. ● Understand the alerts and status indicators of the RS Device. See *Section 4 - Alerts and Indicators* for more information.
CAUTION	In cases where the Alert LED and/or Sounder have been disabled, system feedback will be reduced. Examine Measurement Function Screen for the Lobe to determine expected system feedback.
CAUTION	In scenarios where the Alert (flashing Red) LED has been activated, the Alert LED supresses all other LED status indicators.

Note	The brightness of the tablet screen can be adjusted using the built-in brightness setting on the hand-held device.

Preparation for Monitoring

Before the RR Monitor can be used in a clinical setting, it needs to be unpacked, inspected, correctly set up, and fully charged.

CAUTION	Carefully read all instructions prior to use. Observe all warnings and cautions noted in these procedures and throughout this manual.
CAUTION	Before use, ensure the Lobe is cleaned in accordance with hospital, administration, and/or local government policies or laws.
CAUTION	During any step of setup warning or error messages may be displayed. Read all messages carefully and act when prompted.

Step 1: Registration of a Lobe

In this Step, a fully charged Lobe is registered to a specific patient. This uniquely pairs the Lobe and patient and allows retrieval of patient data at later steps.

1. Retrieve fully charged Lobe from Charging Station. A fully charged Lobe displays a solid Green LED when in the Charging Station.
2. Wipe down Lobe in accordance with hospital, administration, and/or local government laws.
3. Launch the RS App and select **Add New Patient** on the Dashboard.
4. A Lobe can be renamed when registering the lobe; once the lobe is selected the patient MRN can be entered. *See Figure7.* A patient can be registered to a different lobe for example if one lobe's battery dies once the patient MRN name is identical the patient's information will be transferred to the new lobe and be seen on the RS app.
   For more than one patient with the same name on a ward use MRN & initials for one patient and MRN plus room number for the other patient
   Verify that alert limits, Lobe identifier, averaging window and patient ID are correct on confirmation screen.

CAUTION	Verify that the upper and lower respiratory rate thresholds are in accordance with current hospital, administrative, and/or local government law limits.

5. Select **Yes** if details are correct – this will complete the renaming process.
6. Select **No** if incorrect – this will cancel the renaming process.
7. Confirm renam is successful. On successful rename the following occurs:
   - Confirmation successful.
   - Lobe beeps twice.
   - Lobe LED is set to Flashing White.
8. The RS device can now be assembled and applied to the patient in accordance with *PDS-801-008: RespiraSense Quick Reference Guide*

Summary of the registration process.

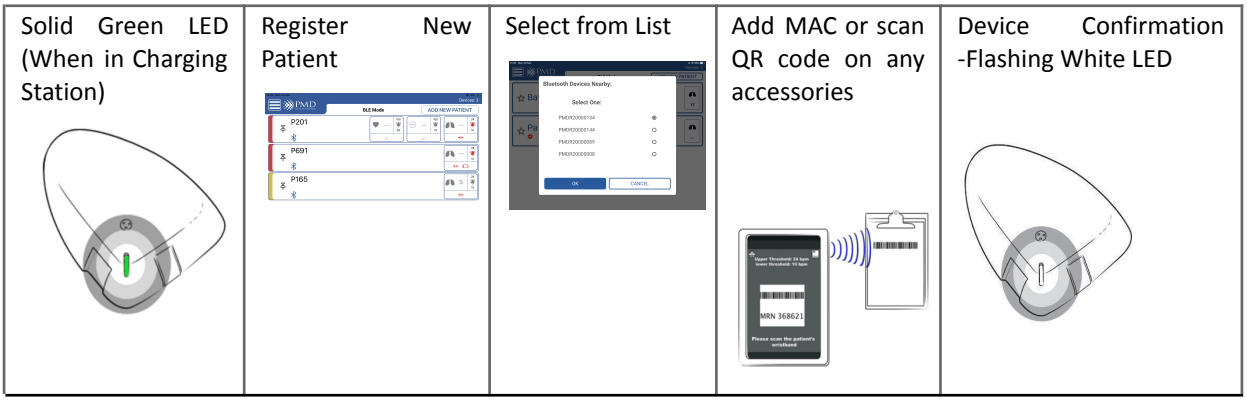


Figure 22: Summary of Registration Process

Step 2: Assembling the Lobe and Sensor

In this step, the procedure for unpacking the Sensor and attaching it to the Lobe is presented. It is important to assemble the Lobe and Sensor correctly to ensure the system accurately and safely records patient metrics.

CAUTION	Take care not to trap fingers or skin in the cradle during closing.

1. Inspect new, sealed Sensor for defect or soiling.
2. Inspect Sensor packaging to ensure use by date has not been exceeded.
3. Retrieve fully charged Lobe from the charging station.
4. Inspect Lobe for signs for soiling or mechanical damage.
5. Remove Sensor from packaging.
6. Attach sensor cradle to patient skin and when secure insert the Lobe into the sensor cradle. Tagaderm™ can be used to reinforce the sensor especially for community where the sensor has to last a few days between nurse visits
7. Confirm Assembly was successful. When successfully completed:
    - You should hear and feel a 'Click' when inserting the lobe
    - The Lobe is securely held in the cradle

Step 3: Attaching the RS Device to the Patient

In this step the correct procedure for attaching the RS Device to the patient is presented. Instruct the patient to either stand or sit straight up or lie down on their back before placement. The placement procedure is different depending on the body position of the patient when the RS Device is attached. Once attached the RS Device can be repositioned to facilitate removal and reapplication between washing, showering and tests.

WARNING	**Do not use RS Device on any patient who is allergic to medical grade adhesive. Use on such patients can lead to an allergic reaction. Check with the patient before use.**
CAUTION	RespiraSense shall not be used on neonates or infants and patients <18yrs
CAUTION	For a patient that has clammy or sweaty skin, use a barrier cream/spray/wipe/lollipop such as Cavilon and leave for 4 to 5 seconds, before applying the sensor to the patient.

1. Inspect area where RS Device sensor will be attached to ensure the skin is:
    - Clean
    - Hairless
    - Intact with no signs of compromise, cuts or thin or delicate areas
    - Dry
2. If required, clean skin using normal hospital procedure.
3. If required, trim or remove hair in accordance with hospital policy.
4. Assemble the RS Device as presented in Step 1.
5. Completely remove skin liner backing from Sensor to expose adhesive.
6. Locate the bottom rib on the patient's left-hand side. To locate the bottom rib, place finger at the sternum and run your finger along the bottom of the rib cage.
7. The sensor Finger location is along this bottom rib, midway between the sternum and the outer edge of the ribcage.
8. Place the index finger along the bottom rib at this starting location.
9. Placement of the upper leg of Sensor:

- Patient standing or sitting up: Place the upper leg of the Sensor directly below the index finger in line with the rib. Press to adhere.
- Patient lying down: Place the top leg of the Sensor on the bottom rib of patient

10. Place the bottom leg of the Sensor onto the abdomen. Press to adhere.
11. Secure remainder of RS Device assembly in place to ensure good overall adhesion.
12. Record attachment date and time in patient records. RS Device can be worn for a maximum of 96 hours.
13. If the RS device sensor is removed during use it can be reapplied if still viable and if not it should be replaced with a new sensor.
14. Insert the lobe back into the sensor.
15. Confirm attachment was successful:
    - RS Device firmly attached to the patient.
    - Patient Standing/Sitting up: Upper leg of Sensor is 1 finger width below lowest rib.
    - Patient lying down: Upper leg of Sensor on lowest rib.
    - Inspect patient periodically to ensure RS Device has not caused allergic reaction, irritation or has become uncomfortable to wear. Figure 23 summarises this process.

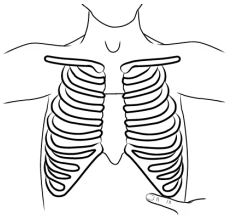
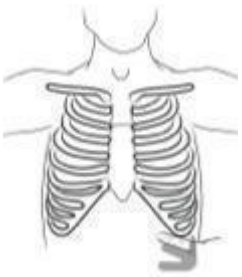
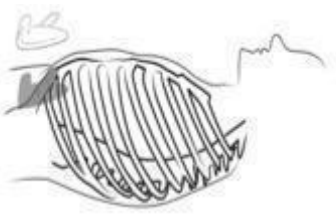
Patient standing up	Patient standing up	Patient lying down
		
Find bottom rib using index four finger	Place Sensor upper Finger below finger and in-line with rib	Place the top leg of the Sensor on the bottom rib of patient

Figure 23 ***Summary of Attachment Procedure to Patient***

Step 4: Multiple Patient Monitoring through Dashboard

In this Step, the procedure for using the Dashboard to monitor patients is discussed. The Dashboard is used to provide summary information on all patients in range of the hand-held device. The list is shown in alphabetical order except for RS Devices in an alert state or with status information, which will be shown at the top of the list. RS Devices which are given priority status will display above those without priority status.

To view multiple patients:

1. Launch RS App. A list of all nearby monitored patients will be displayed. As new devices are discovered they will be added to the list.
2. To view detailed information on a patient, tap on the patient's ID.
3. If there are more than four patient IDs available, the patient list must be scrolled through to view all patients.

Step 5: Priority Patients

In this Step, the procedure for adding, removing, and filtering Priority Patients is discussed. The Priority Patients option allows the user to filter the list of available RS Devices so that priority patients are shown at the top of the list.

To toggle Priority status:

1. Scroll dashboard to find required patient ID.
2. Add patient to the priority list by pressing the Priority Pin Button. The button will change to a black icon.
3. Remove patient from the priority list by pressing the Priority Pin Button. The button will change to a white icon.

Step 6: Obtaining Detailed Respiratory Rate Measurements

In this Step, the procedure to retrieve RR details from a RS Device in operation is discussed. The RS Device is interrogated by requesting data from the Lobe using its unique identifier – typically the patient MRN.

To obtain the respiratory rate measurements of the patient:

1. Open RS App
2. Select and tap the patient on Dashboard to show trend charts
3. The options of 2, 5, or 15-minute intervals are available to select
4. For viewing more data than the intervals in no 3, zoom in/out can be used and swipe left and right to view all available data.

CAUTION	The hand-held device does not record or centralise any clinical information for the purpose of retaining patient records. Historical information is stored on the Lobe for the purpose of reference. Data is deleted once the Lobe is placed on charger base.
Note	This is an average rate that is measured over 2-, 5- or 15-minute intervals. The interval size can be selected by the user.

Step 7: Dealing with Alert Events

This Step outlines the procedure for dealing with alert events on the RR Monitor. The alert cannot be permanently disabled. Interacting with the device pauses the alert until the next RR calculation occurs (up to 50 seconds). If the alert condition is met at this point, the alert will reactivate. The Alert Status LED and Sounder may be disabled in lobe settings. In this event the user will receive limited or no indication of the alert event from the Lobe.

The Lobe can emit an alert tone and LED signal in response to the following events:

1. Patient's RR has equalled or exceeded the upper or lower threshold limits.
2. Lobe is no longer receiving signal from the Sensor.

If the user is currently in the dashboard view, the alert status will also display on the indicator panel. If the user is currently viewing a patient's detailed results when the Lobe begins an alert cycle, the alert status will display on the screen.

WARNING	**Measurement results should be scrutinised in light of the condition of the specific patient. Any results that are inconsistent with the clinical status of the patient should be rechecked and/or supplemented with additional physiological data. Failure to adequately assess patient can lead to unnoticed adverse events.**

WARNING	**In cases where the Alert LED and/or Sounder have been disabled on the lobe, the alert system may be rendered useless. This can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter LED and Sounder settings under medical supervision.**
CAUTION	In cases of high or low respiratory rate readings the clinical status of the patient should be assessed by a healthcare professional and/or supplemented with additional physiological data.

In cases where the RR limits on the RS Device are determined to be inappropriate for a patient, the limits can be changed. To change the default threshold settings to be used on all subsequent new patients, see *Section 5 – Configuration and Advanced Features - Set Default Thresholds*.

To deal with alert scenario:

1. Manually check the patient in accordance with normal hospital procedures to ensure there is no acute need by the patient. If the patient does not require immediate attention, proceed to pause alert.
2. To pause the alert, interact with RS Device on patient in accordance with this section.
3. A confirmation window will appear prompting the user to pause the alert.
4. In scenarios where no signal is being received from the Sensor a “Check Device Hardware” test will subsequently be displayed and a flashing White LED will display on the Lobe. See *Section 6 - Troubleshooting*.

CAUTION	The above sequence pauses the alert, but it does not terminate it. If the respiratory rate threshold limits are exceeded at a later time, the Lobe can emit an alert again.

Step 8: Alter Respiratory Rate Thresholds during Monitoring

In this Step, the procedure for altering the RR Alert thresholds on a device that is currently monitoring a patient is presented.

WARNING	**Alert thresholds should be scrutinised in light of the condition of the specific patient and hospital procedures. Incorrect thresholds can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter threshold settings under medical supervision.**
WARNING	**In cases where the thresholds are set to extremes, the alert system may be rendered useless. Incorrect thresholds can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter threshold settings under medical supervision.**
CAUTION	Verify that the upper and lower respiratory rate thresholds are in accordance with current hospital, administrative, and/or local government law limits.
Note	Any alteration to default setting will result in a status message being displayed on the dashboard for that device.

To alter thresholds:

1. Connect to Lobe using the procedure in this section.
2. Select the “Alert Thresholds” Button. The view will alter to present the Threshold Settings Interface.

3. Full 1 minute manual count is needed to manage upper and lower thresholds for RR. Alter Lower and Upper Thresholds using the Plus and Minus Buttons. Adjust the threshold up or down by 1 bpm by pressing once. Holding a button will adjust the value rapidly.
4. Alter the averaging window by selecting the appropriate window size.Verify that upper and lower RR thresholds are in line with hospital guidance.
5. Verify that new settings are correct and press the “OK” button to save the new settings to the Lobe - the Sounder will beep, and the Blue LED will flash.
6. A summary will be displayed advising the user of the changes made to the indicator settings. Press OK. The user will be returned to the Monitoring Screen.
7. To instead discard altered settings, select the “Cancel” button. All changes will be discarded. The user will be returned to the Monitoring Screen.
8. Record alteration in patient records or in accordance with current hospital procedure.
9. Confirm alteration of thresholds was successful:
    - Upper and Lower thresholds display at expected values.
    - Connection Sounder and LED indications will occur.

Step 9: Alter LED and Sounder Settings

In this Step, the procedure for altering the System indicators on a RS Device that is currently monitoring a patient is presented.

WARNING	**In cases where the LED and/or Sounder have been disabled, the alert system may be rendered useless. This can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter LED and Sounder settings under medical supervision.**

To alter LED and Sounder Settings:

1. Connect to Lobe using the procedure section.
2. Select the “Lobe Settings” Button. The view will alter to present the Settings Interface.
3. Alter LED Settings by pressing the LED Toggle Button to toggle them on or off.
4. Verify that new settings are correct and press the “OK” button to save the new settings to the Lobe - the Sounder will beep and the Blue LED will flash.
5. A summary will be displayed advising the user of the changes made to the indicator settings. Press OK. The user will be returned to the Monitoring Screen.
6. To instead discard altered settings, select the “Cancel” button. All changes will be discarded. The user will be returned to the Monitoring Screen.
7. Record alteration in patient records or in accordance with current hospital procedure.
8. Confirm alteration of settings was successful:
    - System Sounder and LED icons are in the expected state.
    - Connection Sounder and LED indications will occur.

Step 10: Removal, Disposal, and Recharging

This Step presents procedures for dealing with the RS Device once patient monitoring has ended. The RS Device must be removed when necessary and dealt with correctly after use. Remove both Lobe and Sensor from the patient. Do not leave the sensor on the patient if Lobe is not attached.

1. The Lobe and Sensor must be removed when any of the following occur:
    a. Patient is discharged
    b. A period of 96 hours has elapsed since application
    c. The patient is undergoing a procedure which may damage the RS Device
    d. The patient is entering an area where environmental conditions may damage the RS Device e.g. bathing or showering

e. The RS Device becomes wet or soiled
f. Any other situation which compromised patient safety or RS Device integrity.

2. Remove Lobe first, push Lever on sensor cradle backwards to release the lobe from the sensor
3. Gently Peel the sensor off the patient's skin. If there is any difficulty in removing the Sensor, apply water to the fabric of the sensor, or a hospital approved standard adhesive mover to the Sensor.
4. Examine the patient's skin for signs of irritation or allergy.
5. Discard the Sensor in accordance with hospital, administrative, and/or local government laws.
6. Never discard the Lobe.
7. Wipe down the Lobe in accordance with hospital, administration, and/or local government laws. Please refer to section 9 for cleaning instructions.
8. Return the Lobe to the Charging Station and ensure that the LED indicator shows a fully charged status (Green) before reuse. Returning the Lobe to the Charging Station terminates the current Lobe function and returns the Lobe to an unregistered state, with no patient data within it.
9. A dead battery will take 4 hours approx to fully recharge.

CAUTION	Dispose of Sensor in accordance with hospital administration and/or local government laws. If in doubt, contact issuing organisation.
Note	Do not clean the lobe charging unit with alcohol wipes as the black stickers on the charging pads will dissolve. This does not affect charging functionality but will look dirty. If cleaning is required use a damp, but not wet, cloth to wipe it. A mild detergent may be applied to the damp cloth.

Section 4 - Alerts and Indicators

In this section the LED States and Sounder patterns of the Lobe are described. The Alert condition is also discussed.

WARNING	**In cases where the Alert LED and/or Sounder have been disabled, the alert system may be rendered useless. This can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter LED and Sounder settings under medical supervision.**

LED Function

The Lobe is fitted with a tricolour LED that shows the status of the Lobe prior, during, and after use.

LED states can be grouped into 4 simple groups. Green LEDs indicate good working order. Amber or white LEDs indicate that the user should interact with the Lobe as a non-alert status has been detected. Red LEDs indicate alert or error status. Table 14 describes in detail the different LED states. LED states with higher Priority will suppress those with lower priority.

CAUTION	In scenarios where the Alert (flashing Red) LED has been activated, the Alert LED suppresses all other LED status indicators.

Table 14: Lobe LED States

Status Indicator	Priority	Description
Flashing Red LED – 1.4 second cycle	1	Alert signal
Solid Red LED	2	Lobe error (Hardware/Software error)
Flashing White – 2 second cycle	3	FPC not connected
Flashing Blue – 3 flashes	4	Successful wireless connection between the Lobe and the hand-held device during monitoring of RR
Solid Green	5	Fully charged (while Lobe is in Charging Station)
Solid Amber	5	Charging (while Lobe is in Charging Station)
Flashing Green – 20 second cycle	5	Lobe Monitoring and in normal use
Flashing Amber – 3 second cycle	5	Lobe has been removed from charging station and not renamed.
Flashing Amber – 20 second cycle	5	Low battery. System Monitoring and in normal use

Sounder Function

The Lobe has a sounder function, described in *Table 15: Lobe Sounder States*.

Table 15: Lobe Sounder States

Sound	Description
Single audible beep	Indicates poor signal quality for the previous selected averaging window length.
Two audible beeps	Indicates a successful connection with the hand-held device and correct working order.
Three audible beeps	Alert signal (5 second repeating cycle).

Alert Condition

The Lobe has a single audible alert condition. The physiological alert condition is a general, **medium-priority event** and requires prompt attention from a trained healthcare professional. Failure to respond to this alert signal in an appropriate manner could result in patient injury.

Alert Limits

See *Section 5 – Configuration and Advanced Features- Set Default* Thresholds for more information about changing default alert limits. See *Section 3– Patient Monitoring* for details on changing threshold limits on a device in use.

Alert Pause

If the Lobe is alerting, the alert is automatically paused when you address the alert from the RS App or if the patient comes back into threshold limits and the unlatched alerts are selected in configuration settings. The alert will reactivate at subsequent readings (up to 50 seconds) if the measured respiratory rate is still outside the threshold limits.

Alert Function

The RespiraSense can emit an alert signal when certain alert criteria are reached. When the RR of a patient wearing a RS Device equals or exceeds an alert limit threshold or when the Lobe is receiving no signal from the Sensor over a prolonged period, an alert state is entered.

An alert scenario on the Lobe exhibits as follows:

1. A flashing Red LED.
2. An audible alert sounding three times on a 5 second cycle.

To silence the alert, the user selects the patient from the dashboard. In the case where no Sensor signal is being received, a flashing White LED will then display to show the user that the Sensor has become detached. This status will eventually result in an alert status. Figure 24 shows the popup screen when the user is prompted to pause the Alert function. See *Section 3– Patient Monitoring* for more information.

Figure 24: Alert Pause Prompt

An authorised user can select the default settings that are sent to each Lobe at registration. Once RespiraSense is registered and in use, a user can connect to an individual patient to alter the upper and lower alert threshold and inhibit LED and speaker notifications. The configuration options for Default Settings are shown in Table 16.

Table 16: Configuration Options for Default Alert Settings

Setting Name	Configurable Values	Default Value on new app installation	Description
Upper Threshold	7-60 bpm in increments of 1 bpm	21 bpm	The upper threshold for alert activation. The patient's RR must equal or exceed this value for this criterion to be met.
Lower Threshold	6-59 bpm in increments of 1 bpm	11 bpm	The lower threshold for alert activation. The patient's RR must equal or drop below this value for this criterion to be met.
Averaging Window	2, 5 or 15 minutes	15 minutes	This setting allows the user to select a timeframe over which the patient's RR is calculated. This also determines how long an alert sounder will be paused for.

The configuration options for a device which is currently registered are shown in Table 17.

Table 17: Configuration Options for Registered Device

Setting Name	Configurable Values	Default Value on new registration	Description
Upper Threshold	7-60 bpm in increments of 1 bpm	As per App Defaults	The upper threshold for alert activation. The patient's RR must equal or exceed this value for this criterion to be met.

Lower Threshold	6-59 bpm in increments of 1 bpm	As per App Defaults	The lower threshold for alert activation. The patient's RR must equal or drop below this value for this criterion to be met.
Averaging Window	2, 5 or 15 minutes	As per App Defaults	This setting allows the user to select a timeframe over which the patient's RR is calculated. This also determines how long an alert sounder will be paused for.
LED	On/Off	On	This setting allows the user to toggle LED states on the Lobe
Sounder	On/Off	On	This setting allows the user to inhibit the sounder on the Lobe.
Patient Type	Select from available patient types	As per App Defaults	Choose an option from the options.
Bed Number	8 characters	As per App Defaults	This setting allows the user to describe a patient's room/bed.

Alert Notification

The Lobe has a single audible alert condition. The physiological alert condition is a general, medium-priority event and requires prompt attention from a trained healthcare professional. Failure to respond to this alert signal in an appropriate manner could result in patient injury. The RS App displays alert notifications on the Dashboard by alternating the colour of the corresponding patient panel. If the patient dashboard is red there is a critical warning relating to the respiratory rate. If the patient is yellow, it displays a non-critical event and it requires attention from a trained medical professional. When a user connects to an individual patient, they will be prompted to pause the alert. The alert pauses for a time equal to the current Averaging Window. The RS App displays an alert notification by alternating the colour of the corresponding patient panel to red. In addition, a speaker will be activated on the tablet hosting the RS App. To silence the alert for a period of 2 minutes tap the corresponding patient panel.

Distributed Alarm System

A distributed Alarm system is available and is named RespiraSense Air (Air). Air consists of several Bluetooth to Internet routers or Gateways. These are strategically placed across the intended area for monitoring. The system further includes a cloud hosted server for management for the Air Gateways and transmission of the information to the RS App on Air Mode. The RS app will continue to prioritise Lobes within Bluetooth range.

<u>Installation recommendations:</u>

- It is recommended that 1 Air Gateway is used for each $10m^2$ of floor area.
- It is recommended that 1 Air Gateway is used on either side of a reinforced area of wall, including either side of elevator shafts.
- It is recommended that a bed is no further than 12m from the nearest Air Gateway.
- It is recommended to limit the number of devices per Air system to 12 Lobes with accessories, two iPads with the RS app, and 6 Air Gateways per $10m^2$ areas.

WARNING	**The delay time from the onset of the alarm conditions from the Lobe to the point that the representation of the alarm condition leaves the signal server shall be no longer than 10 seconds in addition to the moving average setting of the Lobe.**

Equipment Required:

- Cassia E1000 or S2000 Air Gateway
- Cloud Hosted Cassia Access Controller
- Could Hosted Backend Database
- RS Application

WARNING	**PMD Solutions will provide all equipment as part of the installation and commissioning of a RespiraSense Air Distributed Alarm system. Unauthorised changes to the Information Technology configuration may result in disruption of the Air system.**
WARNING	**The RespiraSense Air Distributed Alarms system does not acknowledge alarms with the Lobe. Distributed alarm functionality cannot be relied upon.**

SECTION 5 – CONFIGURATION AND ADVANCED FEATURES

This section outlines configuration and advanced uses of the RR Monitor. These procedures will not normally be used during the everyday usage of the product but are of use in troubleshooting and maintenance by trained personnel. For Troubleshooting solutions see *Section 6 – Troubleshooting*. The majority of these items are interacted with through the Settings Menu. The Settings Menu is password protected. When the Settings Menu is first accessed, the user will be prompted to set up a new password.

Note	During normal operation, no internal adjustment or recalibration is required.

Accessing the Settings Menu

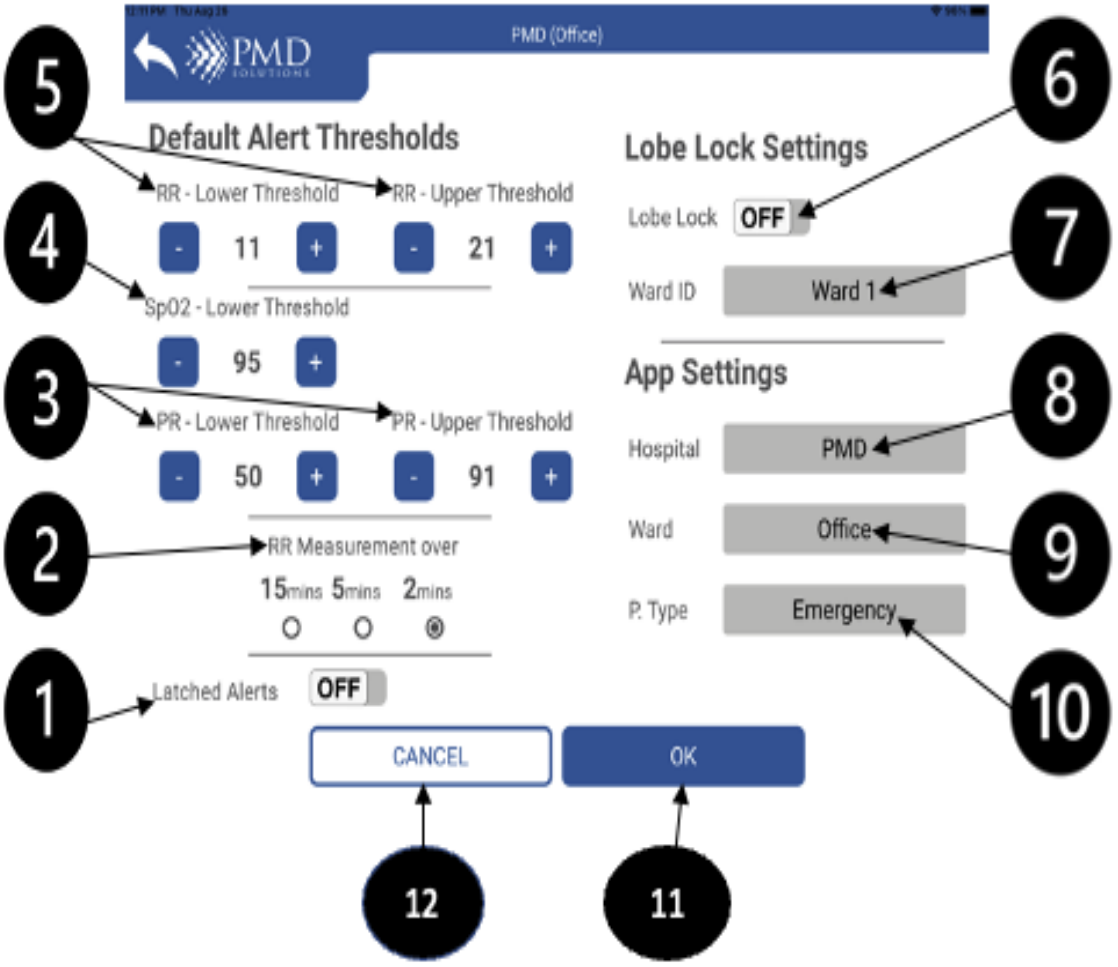
1. Select the Settings Icon from the Dashboard.
2. Enter Password.
3. Press OK.

Note	In the event that the password is lost, the application must be reinstalled to reset the password.

Set Default Thresholds

Selecting the Set Thresholds Option from the Settings Menu allows the user to alter the default thresholds used in triggering the alert on the Lobe. The default settings are the settings that will be written to a new Lobe during the renaming process. The thresholds are for an upper and lower RR, PR as well as the lower threshold for $Sp0_2$. If the thresholds are equalled or exceeded, the alert state will begin. Once set, the Save option records the thresholds. Threshold limits on a RS Device in operation can also be altered by the user, see *Section 3– Patient Monitoring* for procedure. The lobe lock setting allows a ward to be selected by default. All lobes registered to this iPad will be automatically related to this Ward. When Lobe Lock is turned on only lobes relating to this ward will be shown on the dashboard. Selection of default settings will be confirmed when 'OK' is selected.

Figure 25: Set Default Thresholds



Reference	Function	Description
1	Latched Alerts	Indicates if lobe is in Latched/Unlatched mode.
2	RR Measurement Over	Respiratory Rate over 2 minutes, 5 minutes or 15 minutes.
3	PR – Lower Threshold and PR Upper Threshold	Pulse Rate Threshold adjustment buttons.
4	SpO_2 - Lower Threshold	Upper Threshold always 100.
5	RR – Lower Threshold and Upper Threshold	Respiratory Rate Thresholds.
6	Lobe Lock	On/Off.
7	Ward ID	Ward number.
8	Hospital	Hospital's name.
9	Ward	Ward's name.
10	Patient Type	Enter what type of patient it is.
11	Ok	Ok button.
12	Cancel	Cancel Button.

WARNING	**The alert thresholds should be scrutinised in light of the condition of the specific patient and hospital procedures. Incorrect thresholds can lead to unnoticed adverse events and failure to alert user to abnormal breathing rate. Only alter threshold settings under medical supervision.**
CAUTION	Verify that the upper and lower respiratory rate, PR as well as the lower $Sp0_2$ thresholds are in accordance with current hospital, administrative, and/or local government law limits.

CAUTION	In cases of high or low respiratory rate readings, PR and Sp02 readings the clinical status of the patient should be assessed by a healthcare professional and/or supplemented with additional physiological data.
CAUTION	All new applications of the RS Device will take the default thresholds. Verify that the upper and lower RR thresholds are correct during renaming.
CAUTION	The respiratory rate, $Sp0_2$ and PR thresholds for the alert function of the Lobe have been pre-set to standard industry limits. Ensure that these limits are correct prior to application of the device.

Changing Password

Selecting the Change Password option from the Settings Menu allows the user to change the password on the Settings Menu.

Password Complexity

Any password entered into the system must meet the following criteria:

- Minimum of 8 Characters long
- Minimum of 1 Uppercase Letter
- Minimum of 1 Lower Case Letter
- Minimum of 1 Number
- Minimum of 1 Special Character

Result Screen Timeout

The iPad Auto-lock setting shall be pre-configured to 'Never' to enable the RS App to always display patient data and alerts. To do this, go to your iPad Settings > Display & Brightness > Auto-**Lock**. Set Auto-**Lock** to "**Never**". The iPad can be manually locked by hitting the side switch button on the device; therefore, care is to be taken not to do this while the iPad is in use in a patient. The screen can be re-activated by pressing the Home button.**Note**	This timeout is for the Results Screen only. All other screen timeouts are controlled by the portable hand-held device settings.

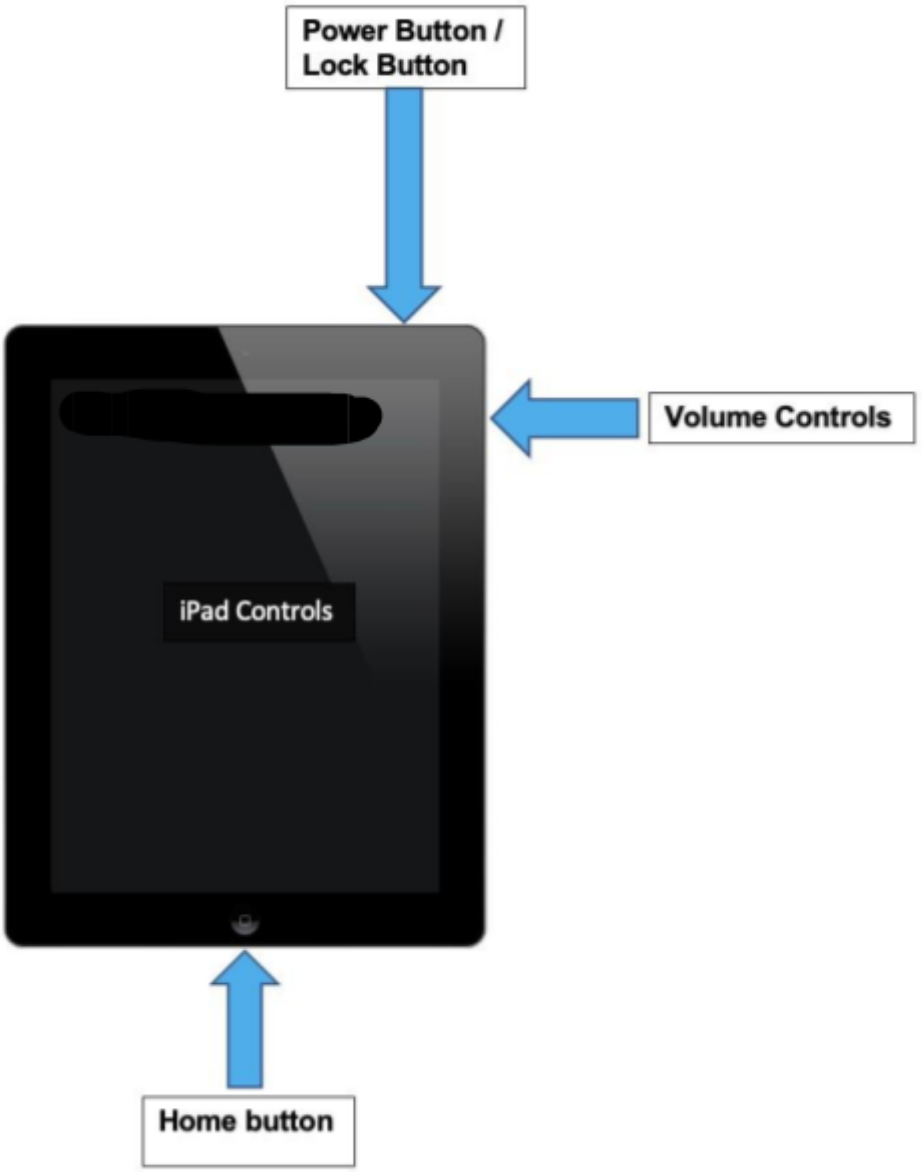


Figure 28: iPad Controls

System Check

Selecting the System Check option from the Settings Menu allows the user to perform system check procedures. Tests consist of the following:

- Accelerometer check. Move the Lobe and observe that the accelerometer reading changed.

- LED Check. Select each LED and observe Lobe to ensure correct LED displays. Combination of LEDs will produce additive colours.
- Sounder check: Select Speaker and ensure Lobe Speaker functions (to verify lobe alert sound generation).
- Firmware version.
- Bluetooth version.
- Sensor check. Insert Sensor and move legs and ensure voltages change as appropriate.

System Check is performed by the field team during the go-live event for RespiraSense usage at a clinical site and should be carried out once per year after that, or whenever a user reports a suspected functional problem.

Tablet Restrictions

iPads provided with RespiraSense™ are configured and managed by PMD on a mobile device management system. They are restricted from installing any other application on the iPad or from being able to browse the internet through the Market Distribution Blueprint.

Application Installation

Note	When deployed on an Apple device, the RS application is installed via the Apple Store. When new versions of the application become available, the user will receive an Apple notification message to Install Now or Remind Me Later.

In some instances, the RS App may require pushing from the mobile device management system. This may occur due to internet connectivity issues at the time of the update. To request this, contact PMD device solutions Ltd on customerservice@pmd-solutions.com.

Default Settings

The following table shows the default settings of the RR Monitor.

Table 18 Default Settings of the Respiratory Rate Mobile Medical Application

Option	Factory Default Setting	Configurable Indicator	Setting/Status
RR Default High Alert Limit	21 breaths per minute	7 - 60	
RR Default Low Alert Limit	11 breaths per minute	6 - 59	
RR High Alert Limit	21 breaths per minute	7-60 (in use)	
RR Low Alert Limit	11 breaths per minute	6-59 (in use)	
Averaging Window	15 minutes	2, 5 or 15 minutes	
LED Brightness	350 LUX	Non-configurable	
Status Indicator Volume	64 dB	Non-configurable	
Alert Signal Volume	64 dB	Non-configurable	
Alert Pause	Up to 50 seconds	Non-configurable	
Inactivity Time-Out (screen reverts to dashboard)	5 minutes	Non-configurable	

Tablet Restrictions	On	On, Off
System Sounder	On	On, Off - Configurable only once in use
System LED	On	On, Off - Configurable only once in use

Section 6 – Troubleshooting and App Messages

Application Messages

The following is a list of system, error, and fault messages

Message	Details
The password entered is incorrect. Please re-enter password or contact biomedical department for assistance.	Occurs when the password that has been entered at the settings password screen is incorrect. Attempt password entry again.
Passwords do not match, please re-enter passwords.	Occurs when the two passwords that have been entered when attempting to change or on first setting password are not identical. Attempt password entry again.
Password entered does not fulfil complexity criteria. Please enter the password that fulfils complexity criteria.	Occurs when the password that has been entered when attempting to change or on first setting password is not sufficiently complex to meet complexity criteria. Enter a password that fulfils all the following criteria: - Minimum of 8 Characters long - Minimum of 1 Uppercase Letter - Minimum of 1 Lower Case Letter - Minimum of 1 Number - Minimum of 1 Special Character
Connecting to selected device. Please wait.	Occurs when a device connection has been selected by the user and the connection is progressing. Wait for the device to connect.
Connection to device failed. Please attempt to connect again or contact the biomedical department for assistance.	Occurs when a requested connection has not been successful. Attempt connection again.
Registration in progress. Please wait.	Occurs when a Lobe is being registered to a patient. Wait for process to complete.
Registration has failed due to connection error. Please check the Lobe battery status and restart process.	Occurs when a Lobe fails to register to a patient. Reattempt registration procedure.
Invalid QR Code Scanned. Please ensure QR on valid Lobe is scanned.	Occurs when a QR code is scanned that does not encode the name of a Lobe. Check that the correct QR code is being scanned.
MAC address should match to this pattern: XX:XX:XX:XX:XX…….	Occurs when a QR code is scanned that is not in a supported format. Scan supported barcode format or enter details manually.
“Unsupported characters entered. Please ensure you have entered ASCII characters only. First character must be alphanumeric”	Occurs when a or more characters that are not supported. Scan supported barcode format, or enter details manually.
Settings cannot be changed due to device connection error. Please return to the dashboard and restart process.	Occurs when a connection fails during settings change. Reattempt action.
RespiraSense Respiratory Rate Monitor has encountered an error and will restart. Please check any process that was progress when the application crashed to ensure that the process completed.	Occurs when the application enters an error state that it cannot recover from. Wait for the application to automatically restart.

The Device has been worn for longer than the safe limit. Please remove Lobe and Sensor and replace.	Occurs when it is detected that the RS Device has been worn for more than 4 days. Remove Lobe and replace it with a fresh device.
The Device Battery is low. Please remove the Lobe and Sensor and replace.	Occurs when it is detected that the Lobe battery is low. Remove RS Device and replace it with a fresh device.

Troubleshooting

The following tables provide information to aid troubleshooting. The solution options should be attempted in the order provided in each solution tree.

Troubleshooting is separated into the following use cases:

1. Patient Registration
2. Assembly and Attachment
3. Reading Respiratory Rate Data from Lobe
4. Alert and Red LED Status
5. Removal, disposal and recharging

Patient Registration

Problem	Solution Tree
Tablet is unresponsive	● Restart Application. ● Power off the tablet and power back on. Restart Application. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.
Bluetooth is disabled	● Application will display a dialog prompting the user to open the settings. ● Tap the button labelled “Open Settings” ● In the settings menu scroll the left-hand menu up until you see “Bluetooth” ● Tap Bluetooth and on the right-hand side toggle Bluetooth ‘On’ and return to the application.
Unable to scan QR code using Camera	● Ensure the camera lens is not obstructed or soiled. ● Ensure there is sufficient light to scan. ● Option: Press Back Button and select Bluetooth to select the accessory from a list of available devices. ● Ensure the camera is no more than 60 cm from QR code. ● Check QR code for damage or soiling. ● Restart application and start scanning process again. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.
Lobe ID not available on list of devices using Bluetooth scanning option	● Ensure Lobe is ready to be registered, a Green LED should be flashing on a 3s cycle. ● Option: Press Cancel and select Camera to scan Lobe using camera interface. ● Reset Lobe by returning it to the Charging Station. ● Restart application and start scanning process again. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.

Default threshold limits are incorrect	● Press “No” on confirmation screen to cancel renaming. Default threshold limits are changed using a password protected setting. Return RR Monitor to authorised user to set default thresholds. Restart renaming process. ● If Yes was pressed on Confirmation screen see " Threshold Limits are incorrect " in the next subsection.
Incorrect patient MRN entered during patient registration	● Return Lobe to Charging Station to reset. ● Restart renaming procedure with correct MRN.
"Unable to Connect to Device." displayed during patient registration	● Reset Lobe by returning to the Charging Station for at least 5 seconds. Restart patient registration process. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.
Sounder does not beep at end of patient registration process	● Reset Lobe by returning to the Charging Station for at least 5 seconds. Restart patient registration process. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.
No Solid White LED at end of patient registration process Note: White LED may turn off after 2 seconds if FPC is connected at registration.	● Reset Lobe by returning to the Charging Station for at least 5 seconds. Remove Sensor from Lobe if attached. Restart patient registration process. ● Return to the issuing organisation or department. ● Seek replacement from Authorised Distributor.

Reading Respiratory Rate Data from Lobe

Problem	Solution Tree
Tablet is unresponsive	● Restart Application. ● Power off tablet and power back on. Restart Application. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Patient MRN/ID not visible on Dashboard	● Ensure Lobe has been renamed to expected ID. ● Scroll through Dashboard list to ensure patient ID is not on list (Dashboard displays maximum of 5 devices at a time and a scroll interface will be available if there are more than this). ● Check that Lobe still has battery - a Green or Amber LED should flash every 20s. Alternately, a Red LED or White LED may be active. ● If Lobe remains unresponsive, return to Charging Station.
Threshold Limits are incorrect	● Verify that other staff have not changed thresholds. ● Thresholds on in-use RS Device can be changed by selecting “Change Setting” on the Measurement Function Screen. ● Default threshold Limits are set during renaming. These limits are changed using a password protected setting. Return device to authorised user to set default thresholds.
Blue LED does not flash at end of connection process (Blue LED will NOT flash following renaming)	● Examine Patient Monitor Screen to ensure System LED is set to ON. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Latest Respiratory Rate displayed as “0”	● Ensure patient is not in need of immediate assistance. ● Ensure FPC cable is firmly connected to Lobe. ● Ensure Sensor has not detached from patient. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Historical data is not displayed	● Ensure Lobe has not been recently replaced by another staff member. If this has occurred, the previous data will have been deleted. ● Return to issuing organisation or department.
Excessive missing measurements	● Ensure placement of Sensor is in line with *PDS-801-004: RespiraSense Setup and Device Instructions for Use*. ● Enquire if patient has been excessively active. This may result in data which is not useable.
Settings saved to incorrect status	● Repeat Setting alteration process.

Alert Scenario and Red LED

Problem	Solution Tree
Tablet is unresponsive	● Restart Application. ● Power off tablet and power back on. Restart Application. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Alert does not pause when alert is addressed	● Address the alert again ● Return Lobe to Charging Station and issue new Lobe to patient. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Solid Red LED	● Hardware error: Return to issuing organisation or department.
Flashing Red LED	● Alert Scenario. Check patient. ● Check FPC cable has not become detached from unit. ● Silence alert by selecting the patient and addressing the alert. ● If alert persists without reason, return to issuing organisation or department.
Sounder does not sound when Alert event is triggered	● Examine Patient Monitor Screen to ensure Sounder is set to ON. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
LED does not exhibit when Alert event is triggered	● Examine Patient Monitor Screen to ensure LED is set to ON. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
White LED flashes when alert is paused.	● Lobe not receiving reading from Sensor. ● Check FPC is firmly seated in FPC port.

Section 7 – Product Specification

The following sections provide information about the product specifications.

Physical

The following table shows the physical specifications.

Assembly dimensions (L x W x H)	57 mm x 98 mm x 18 mm
Assembly weight	57 g
Reusable Lobe	ABS Plastic
Single patient consumable Sensor	Medical-grade silicone adhesive (3M) Spunlace Nonwoven top layer
Lobe Part Number (See Lobe Label). Only use Lobes with this Part Number with this IFU.	PDS-101-000

Environmental

The following table shows the environmental specifications.

Operating temperature	0 – 35 °C
Storage temperature	0 – 35 °C
Operating humidity	10% to 95% (non-condensing)

Battery

The following table shows the battery specifications.

Type	Lithium polymer
Capacity	660 mAh
Battery life	4+ days
Recharge time	4 hrs.

Sounder

The following table shows the sounder specifications.

Alert tone	850 Hz tone, 3 pulse, repeat time: 5 seconds
Volume	64 dB
Priority	Medium
Alert Condition Delay	Up to 52 seconds
Operator Position	Alert sounded locally on Lobe and notification transmitted to tablet if tablet is in dashboard mode.

System Limitations

The following table lists the maximum number of devices a system can have in simultaneous operation without impairing performance per iPad

Lobes	12
Accessories	12
Air Gateways	6
iPads	1
Unit Area Installation Criteria	Maximum distance from a Bed and a Air Gateway is 15 meters. In a single $15m^2$ area, the maximum number of devices is as listed above.

FCC (Federal Communications Commission) **statement**

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. WARNING: Changes or modifications not expressively approved by the party responsible for compliance could void the user's authority to operate the equipment. This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) This device may not cause interference. (2) This device must accept any interference, including interference that may cause undesired operation of the device. L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : 1) L'appareil ne doit pas produire de brouillage; 2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Compliance

The following table shows the compliance specifications.

EMC Compliance	EN 60601-1-2, Class B
Equipment classification	IEC 60601-1
Type of protection	Internally-powered (battery-powered)
Degree of protection – patient	Type BF-applied part
Mode of operation	Continuous
Ingress protection	IP54
Medical RS Device Directive 93/42/EEC: 2007	Class IIb medical Device – EU
FDA CFR 21 Part 820	Class II medical device - US

Electromagnetic Compatibility (EMC)

The RespiraSense™ is suitable for the electromagnetic environment of typical commercial or hospital settings.

During the immunity testing described below the RespiraSense Device continued to:

- Measure the Respiratory Rate within specified accuracy/error limits.
- Sounding of the Alert on respiration limit violations.

WARNINGS:

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RespiraSense System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The RespiraSense Device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the RespiraSense Device should be observed to verify normal operation. If operation is not normal, the RespiraSense Device or the other equipment should be moved.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment, if possible, to maximize distances.

Electromagnetic Emissions

Electromagnetic Emissions		
The RespiraSense™ is intended for use in the electromagnetic environment specified below. The customer or the user of the RespiraSense™ should assure that it is used in such an environment.		
Emission Tests	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The RespiraSense™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The RespiraSense™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	NA	
Voltage fluctuations / flicker emissions IEC 61000-3-3	NA	

Electromagnetic Immunity

Guidance and Manufacturers Declaration on Electromagnetic Immunity		
The RespiraSense™ is intended for use in the electromagnetic environment specified below. The customer or the user of the RespiraSense™ should assure that it is used in such an environment.		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, ± 4, ± 6 & ± 8 kV contact discharges ± 2, ± 4, ± 6, ± 8 & ± 15 kV air discharges	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient /	± 1, ± 2 kV mains power ports	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturers Declaration on Electromagnetic Immunity		
The RespiraSense™ is intended for use in the electromagnetic environment specified below. The customer or the user of the RespiraSense™ should assure that it is used in such an environment.		
burst IEC 61000-4-4	Burst Frequency:100 kHz	
Surge IEC 61000-4-5	Line to Line: ± 0.5 kV & ± 1 kV Line to Earth: ± 0.5 kV, ± 1 kV & ± 2 kV	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	0% .5 Periods 0% 1 Period 70% 25 Periods 0% 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RespiraSense™ requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the RespiraSense™ is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-48	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A/C. mains voltage prior to application of the test level.		

Guidance and Manufacturers Declaration on Electromagnetic Immunity		
Immunity Test	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	6 Vrms 150 kHz to 80 MHz 10V/m 80 MHz to 2700MHz 3V/m 2700MHz to 6000 MHz	The RespiraSense™ is suitable for the electromagnetic environment of typical hospital settings.

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

Frequency MHz	Modulation Frequency	Polarisation (V/H)	Level (V/m)	Result
385	18 Hz Pulse Modulation	V and H	27	Complied
450	50% 18 Hz Pulse Modulation	V and H	28	Complied
710	217 Hz Pulse Modulation	V and H	9	Complied
745	217 Hz Pulse Modulation	V and H	9	Complied
780	217 Hz Pulse Modulation	V and H	9	Complied
810	18 Hz Pulse Modulation	V and H	28	Complied
870	18 Hz Pulse Modulation	V and H	28	Complied
930	18 Hz Pulse Modulation	V and H	28	Complied
1720	217 Hz Pulse Modulation	V and H	28	Complied
1845	217 Hz Pulse Modulation	V and H	28	Complied
1970	217 Hz Pulse Modulation	V and H	28	Complied
2450	217 Hz Pulse Modulation	V and H	28	Complied
5240	217 Hz Pulse Modulation	V and H	9	Complied
5500	217 Hz Pulse Modulation	V and H	9	Complied
5785	217 Hz Pulse Modulation	V and H	9	Complied

Wireless

The Lobe of the RespiraSense Device contains a U-Blox NinaB11Bluetooth Module) which transmits Respiration Rate data and SPO2 and pulse rate if the Nonin accessory is paired to the lobe for data display to the RS App

Radio Technology: Bluetooth: Frequency-hopping spread spectrum Low Energy (BLE)

FCC ID: XPYNINAB1

Bluetooth Class / Power: Class 2 Bluetooth module. Software controllable power. Max power +4 dBm.

Bluetooth specification: BLE 4.2 Low Energy

RF frequencies: 40 bands (2 MHz each; centered from 2.402 to 2.480 GHz) in the range 2,400-2,483.5 GHz

Operating Range approximately 10 meters, note that the range be less depending on the presence of other wireless devices and physical obstacles.

Troubleshooting

If you experience connectivity issues between the Lobe and RS App. Try to reduce the distance between the Lobe and iPad mini (or Cassia). Try to maximize distance to other devices which may be causing interference.

See also SECTION 6 – TROUBLESHOOTING AND APP MESSAGES

Cybersecurity

The iOS on the iPad is set to automatically update

The RS application will update itself when pushed through the Managed Device System.

All updates to the RespiraSense lobe firmware will require the return of each individual RespiraSense Lobe to PMD or trained and authorized personnel must attend the site where the firmware update is required.

An admin password is setup for default settings configuration when installed.

Respiratory Rate Measurement Limits

The Respiratory Rate Measurement Limits declared for the RR Monitor are shown in *Table 19: Measurement Limits*. The statistics are based on a comparison against capnography using the Bland Altman technique and apply to the 2, 5- and 15-minute averaging timeframe.

Table 19: Measurement Limits

Measurement	No Motion	Motion
Bias (bpm)	-1.96 <= Bias < 1.96	-1.96 <= Bias < 1.96
Upper Limit of Agreement	<= 2.9	<= -2.9
Lower Limit of Agreement	>= -2.7	>= -2.7
Calculation Range	6 – 60 bpm	6 – 60 bpm
Resolution	1 bpm	1 bpm

CAUTION	Excessive movement can render the results from the device inaccurate.

Motion is defined as the following:

- Motion artifact due to walking
  - Walking of ill patients with respect to thoracic movement is defined by Hirasaki and Moore 1999, and Ceccto et al. 2009 as a superior lift of 45mm and return to normal as an inferior drop along the sagittal plane, a rotation about the lateral and medial directions about the waist along the sagittal plane of 5 degrees and tilt about the waist along midline of the transverse plane of 7 degrees at a rate of 1.4Hz or 1.4 oscillations of lift, twist, and tilt per second.
- Motion artifact due to vocalization
  - As described by Binazzi et al. 2006, vocalization patterns were introduced into simulated breathing for 30, 20, 10, 40 seconds at 3, 6, 9, 12 time minute points respectively during monitoring.
- Motion artifact due to coughing
  - As provided by the ASL 5000 simulator, a cough artefact was introduced every 30 seconds and lasted for ~1 second during each event.
- Motion artifact due to holding breath and sighing
  - As provided by the ASL 5000 simulator an apnea and sighing artifact and apnea event lasts for 10 seconds on the 3rd and 6th minute and; a sigh event at the 9th and 12th minute.

Clinical Evaluations:

- ***Comparison verses Capnography:***
  - ***Subbe et al. Bangor, Wales:*** *Continuous Monitoring of Respiratory Rate in Emergency Admissions: Evaluation of the RespiraSense™ Sensor in Acute Care Compared to the Industry Standard and Gold Standard. Sensors (Basel, Switzerland) vol. 18,8 2700. 17 Aug. 2018, doi:10.3390/s18082700*
  - ***Albon L. Portsmouth, England****: Albom L (2022) A Quality Assurance Study of Respiratory Rate Measurements on Obese Patients with a Novel Monitoring Technology. Int J Nurs Health Care Res 5: 1296. DOI: 10.29011/2688-9501.101296*
- ***Comparison verses ETCO2:***
  - ***PMD Solutions. Cork, Ireland****: Unpublished performance testing in healthy volunteers 2021 in Cork, Ireland.*

RespiraSense was evaluated across three evaluations where by Bangor and Portsmouth were clinical, Cork was bench testing with healthy volunteers. Healthy volunteers was required to demonstrate the safety and efficacy of RespiraSense in the extreme ranges of respiratory rates.

Table 20: Clinical Evaluation Summary of Results

Measurement	Capnography	ETCO2
Subject Size	N=520	N=247
Bland Altman Limits of Agreement	-2.9305 / +2.6693	-2.36623 / + 2.544371
Deming Regression	0.9188658	1
Mean Age	62	46
Age Range	22-87	18-75
Gender Population	65% Male	54% Male
Mean Body Mass Index	50.8	28
Range Body Mass Index	20 - 66.8	19.4 - 40

Sensor Specification

The RS Device Sensor is a multilayer composite of medical grade adhesives and materials enclosing the sensing element. Table 21 shows the Sensor's specifications.

Table 21: Sensor Specification

Sensor Function	Specification
Shelf life	3 years from the date of manufacturer
Duration of Use	4-days
Biocompatibility	The adhesive based components are tested to Cytotoxicity (ISO 10993-5) and Irritation and Sensitization (ISO 10993-10). Whereas the plastic-based components are tested to 10993-5
Frequency of Use	Single Patient Use > 4 days
Sterilisation	Non-Sterilised

The following table shows the Sensor patient profile specifications.

Sensor	*Application site*	*Sex*	*Weight*	*Duration of use*	*Sterile*	*Colour*
Sensor	Lat*	M/F	10-150 Kg	96 hours	No	Tan

* Lateral position adhered to bottom fixed rib with overlap of abdominal region.

The Sensor is an Applied Part under IEC 60601-1 2006 A1:2012.

Sensor Revision (See individual Sensor Label): PDS-503-001.

Use only Sensors with this part number with this IFU.

Alert Generation Criteria

An alert condition is generated when any of the following conditions are met:

- The average respiratory rate calculated over the selected timeframe equals or goes above the current upper RR threshold.
- The average respiratory rate calculated over the selected timeframe equals or goes below the current lower RR threshold.
- A zero signal has been detected in at least half of the data bins in the selected averaging timeframe.

Alerts

The following table shows the alerts specifications.

Table 22: Alert Specification

Alert Function	Specification
Audible and visual alert when respiratory rate goes outside of operator-specified limits	Lower threshold: 6 - 59 breaths per minute Upper threshold: 7 - 60 breaths per minute
Alert tone	850 Hz tone, 3 pulse, repeat time: 5 seconds
Volume	64 dB
Priority	Medium
Alert Condition Delay	Up to 52 seconds
Operator Position	Alert sounded locally on Lobe. Secondary indication is transmitted to tablet if tablet is in dashboard mode.

Display/Indicators

The following table shows the display/indicators specifications.

Table 23: Display and Indication Specification

Function	Specification
Data display	Alert status, battery low, unit charging, unit charged, Bluetooth communication active
Indicator Type	Tricolour LED

SECTION 8 - SERVICE AND MAINTENANCE

Introduction

This section provides information about how to clean the RS Device and obtain service. No part of the RS Device should be cleaned or serviced while attached to the patient.

Cleaning and Disinfection

It is recommended thorough cleaning and disinfection of the Lobe in the following events:

- If any part of it becomes soiled.
- After removal from a patient.
- Before application to a new patient.
- Before and after the charging cycle, even if it is to be placed on the same patient after charging. This requirement mandates that the maximum time between cleaning will be 4 days when the Lobe is in use.
- If the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device, so that a visibly soiled device is not used again. Removal of residual soil ensures the effectiveness of sterilization and disinfection processes and reduces the risk of infection to patients.

To clean the Lobe:

1. Remove the Sensor and Lobe from the patient.
2. Disconnect the Sensor from the Lobe.
3. Thoroughly wipe the entire Lobe with a CaviWipe™ (validated in cleaning study) , 70 % isopropyl alcohol pad, or with hospital equivalent.
4. Allow to air-dry thoroughly before reuse.

To disinfect the Lobe:

1. Follow the cleaning instructions to remove any soiling from the lobe as described above 2. Thoroughly wipe the entire Lobe with a CaviWipe™ (validated in disinfection study) , 70 % isopropyl alcohol pad, or with hospital equivalent.

3. Rinse the device with a pre-saturated water towel
4. Dry components with a lint-free towel 5. Allow to air-dry thoroughly before reuse.

In cases where the Sensor has also been soiled, discard Sensor and apply new Sensor as per Instructions for Use.

CAUTION	Do not autoclave, pressure sterilise, or gas sterilise the RS Device.

CAUTION	Do not soak or immerse any part of the RS Device in any liquid.
CAUTION	Use cleaning solutions sparingly. Excessive solution can flow into the RS Device and cause damage to internal components.
CAUTION	Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, or rough-surface materials, or bring them into contact with anything that could scratch the panel.
CAUTION	Do not use petroleum-based or acetone solutions or other harsh solvents to clean the RS Device. These substances affect the RS Device's materials and device failure can result.
CAUTION	Do not clean the charging unit with any solvent, use a damp cloth with mild detergent applied if cleaning is required

Disposal

Used Sensors should be disposed of according to hospital procedure for medical waste. Sensors are for single patient use only.

Functional Verification

Functional verification is recommended to be carried out Annually (12 months) using the supported mobile medical application.

Functional verification is also recommended in the event the device has been mis-used in terms of water ingress, soiling, corrosion observed via visual inspection, or extreme mechanical force being applied to the device.

Service and Repair

The following subsection provides information about the service and repair of the RS Device.

Repair Policy

PMD Solutions or an authorised service department must perform warranty repair and service. Do not use malfunctioning equipment. Do not attempt to repair the RS Device if it is not functioning correctly.

Please clean contaminated/dirty equipment before returning it. See *Section 6 - Service and Maintenance* for information about cleaning procedures. Ensure the RS Device is fully dry before packing it.

Note	Follow the return procedure to return the RS Device for service. See *Return* Procedure in *Section 6 - Service and Maintenance* for more information.

WARNING	**Do not remove the cover of the RS Device or associated IT equipment. Only trained operators may perform the maintenance procedures described in this manual. Refer servicing to qualified service personnel who are trained in the repair of this device. Exposure of electrical contacts can lead to burns, explosion of battery and breakage of device.**

Expected Service Life

The expected service life of the Lobe and any associated IT equipment is five (5) years from date of manufacture. Lobes that have reached the end of service life should be returned to the manufacturer.

Shelf Life (Sensor)

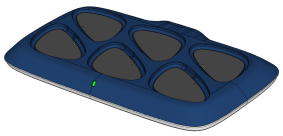
The shelf life of the Sensor is three (3) years from date of manufacture.

SECTION 9 – ASSOCIATED IT EQUIPMENT

The following section provides information about the associated IT equipment of the RR Monitor.

Note	The mobile medical software application is installed onto the hand-held device by the manufacturer.

Table 24 List of Associated IT Equipment

<table>
<tr>
<td>iPad Mini 4 or 7th Gen or above
PDS-701-000
  </td>
<td>Approved Mobile device for RS Device Mobile Medical Application</td>
</tr>
<tr>
<td>Multi Charging Dock
PDS-102-000
  </td>
<td>Charging Dock for RS Devices
<table>
<tr><td>Power Supply</td><td>25 W 5 VDC / 5 A</td></tr>
<tr><td>Output</td><td>0.5A / 5V x 6 ports
4A / 5V x 1 port (USB)</td></tr>
<tr><td>WEEE</td><td>  </td></tr>
<tr><td>CE</td><td>Power Supply and charging station are CE marked</td></tr>
<tr><td>Power source</td><td>Mains-Powered
90-264VAC~50/60Hz 1A MAX</td></tr>
</table>

The charger is to be used outside of the patient environment.
The charger is to be commissioned by IT professionals.
The charger should be operated by trained personnel.

</td>
</tr>
<tr>
<td>Air Repeater Module
PDS-901-000
  </td>
<td>WiFi to Bluetooth repeater for enabling RS Device Air Dashboard over Air Mode and to enable Distributed Alarms</td>
</tr>
</table>

	Nonin model 3150 BLE wrist-worn pulse oximeter

Section 10 – Warranty and Agreements

PMD Solutions Limited Warranty

PMD Solutions' products are warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from PMD to the original purchaser.

Excluded from this warranty are expendable supply items including, but not limited to, Sensors, adapters, and plugs. This warranty does not apply to any product which PMD Solutions determines has been modified or damaged by the purchaser.

Except for the express warranties stated above, PMD Solutions disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of PMD Solutions for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of PMD Solutions' products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the purchaser.

Sales and End-User Licence Agreement

THIS DOCUMENT IS A LEGAL AGREEMENT BETWEEN YOU, ("PURCHASER") AND PMD SOLUTIONS FOR THE PURCHASE OF THIS PRODUCT ("PRODUCT") AND A LICENCE 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 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 PACKAGING, WITH YOUR SALES RECEIPT TO PMD SOLUTIONS FOR A FULL REFUND.

Warranty

PMD Solutions warrants to the initial purchaser for a period of one (1) year from the date of purchase that: (i) each new product and the software media as delivered are free from defects in workmanship or materials, and (ii) the product and software will perform substantially as labelled in these *Instructions for Use*. PMD Solutions' sole obligation under this warranty is to repair or replace any product or software that is covered under warranty.

To request a replacement under warranty, the purchaser must contact PMD Solutions for a return of goods authorisation. If PMD Solutions determines that a product must be replaced or repaired under warranty, it will be replaced or repaired, and the cost of shipment will be covered. All other shipping costs shall be the responsibility of the purchaser.

Exclusions

The warranty does not extend to, and PMD Solutions is not responsible for, repair, replacement, or maintenance needed because of: a) modification of the product or software without PMD Solutions' written authorisation; b) supplies, Devices or electrical work external to the product or not manufactured by PMD Solutions; c) disassembly or reassembly of the product by anyone other than an authorised PMD Solutions agent; d) use of the product with Sensors or accessories other than those manufactured and distributed by PMD Solutions; e) use of the product and software in ways or in environments for which they are not labelled; and f) neglect, misuse, incorrect operation, accident, fire, water, vandalism, weather, war, or any

act of God. This warranty does not extend to any product that has been reprocessed, reconditioned, or recycled.

This warranty also does not apply to any products provided to the purchaser for testing or demonstration purposes, any temporary products modules, or any products for which the seller does not otherwise receive a usage or purchase fee: all such products are provided as is without warranty.

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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.

SECTION 11 – REQUESTING IFU

If for any reason a paper/hard copy of this IFU is required, one can be requested by emailing customerservice@pmd-solutions.com. A hard copy of the IFU will be provided within 7 calendar days and free of charge, a soft copy will be provided within 24 hours.

In addition, the RespiraSense Medical Application on the tablet will have a copy of the full IFU in the Help section.

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