RespiraSense™ Instructions for Use

Instructions for Use

English

PDS-801-007

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 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 only for sale within the European Union, Canada and Australia.

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Emergo Australia
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Terminology

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

Table 1: Definitions of Key Terms

Term	Definition
Instructions for Use	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
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
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
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 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. 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 pre-determined thresholds. The user can override the default settings to suppress Sounders 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.
- The RS Device can be used in the home environment **as instructed by a clinician operator**. While in use in the homecare environment, the RS Device can be worn by a patient, including while sleeping overnight. The device can monitor the patient's respiratory rate and provide a record for subsequent review by any healthcare practitioner.

Contraindications

- It is not to be used on neonates or infants (as defined by the FDA: Paediatric subpopulations are defined in Section 520(m)(6)(E)(ii) and adopted reference in Section 515A of the FD&C Act). The device will be for use on adolescents and adults only.
- Do not use the RS Device during defibrillation.
- Do not use the RS Device during MRI, X-Ray or other medical imaging procedures.
- Do not use the RS Device in an 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. 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

The RS Device is to be operated 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.
Only use the RS Device in accordance with the instructions in this manual.
During application, operators must ensure that the RS Device alarm limits are set in accordance with the clinical guidelines of the hospital.
The alarm signal of the RS Device reaches a nominal sound pressure level of 64 dB maximum at one meter in front of 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 heavy electrical equipment or other 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 alarm limits to extreme values may render the alarm functionality useless.
In cases where the Alarm LED and/or Sounder 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 a radiator or anything that could potentially cause water 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
	Serial number
	Electronic instructions for use available on the software application
	Consult Instructions for Use

Symbol	Caution Symbol Description
	Direct Current (DC) Input/output
	Caution
	*WEEE Symbol*
	Latex free

TABLE OF CONTENTS

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 can 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 issuing organisation or authorised dealer.**
WARNING	**Refer to Section 13 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 a 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 is comprised of the RespiraSense™ Lobe (hereafter the Lobe), the reusable component that houses the RS Device's electronics, and a single 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 on the left-hand side of a patient's torso. 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, single-use sensor array.
- **The Lobe**: A reusable electronics module, housing data processing, Bluetooth communication module, LEDs and sounder.

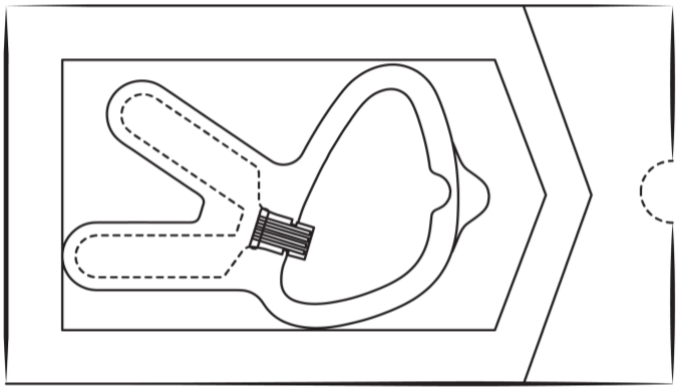


Figure 1 Sensor in Packaging

Figure 2 Lobe

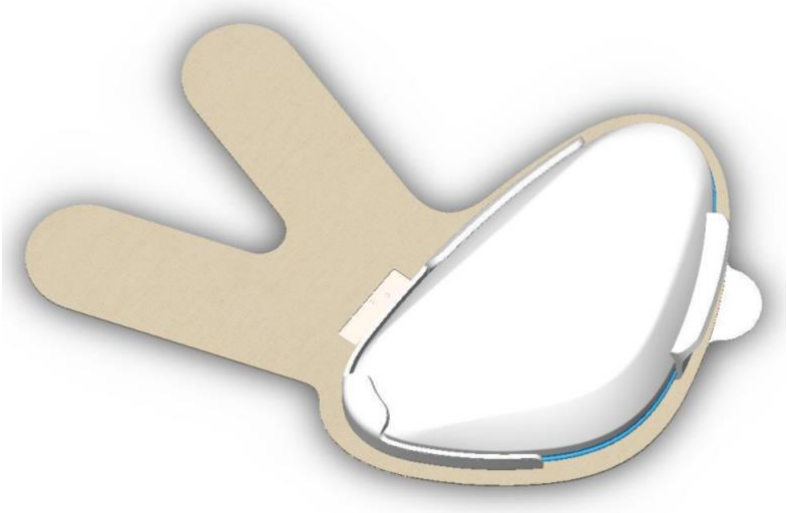


Figure 3 RS Device with Sensor and Lobe together

The RespiraSense is used with the following associated IT equipment:

A **portable hand-held device**, typically a tablet computer, onto which the Associated Mobile Medical Applications are installed and operated. The main Associated Mobile Medical Applications are show in Table 2. These Instructions for Use will concentrate on the Respiratory Rate Monitoring application. The instructions for Use for the other available applications can be found in *Section 11 – Associated Mobile Medical Applications.*

Table 2 List of Associated Mobile Medical Applications

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

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 alarm 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 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 following Essential Performance criteria have been declared for RS Device**:**

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

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

Intended Users

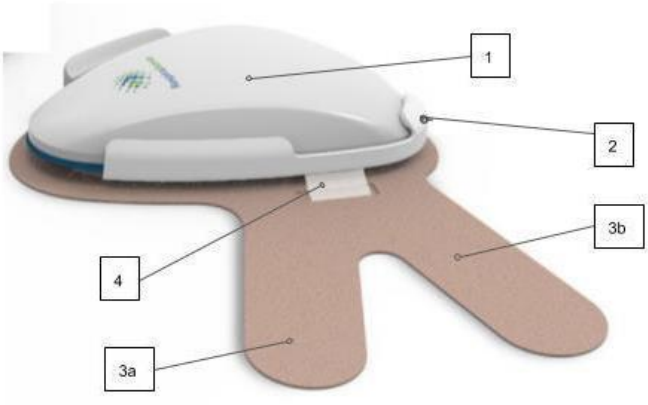
The RS Device is intended to be used by trained medical personnel only.

SECTION 2 - SYSTEM DESCRIPTION

In this section a description of the main features of the RespiraSense™ Device and associated mobile medical applications 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

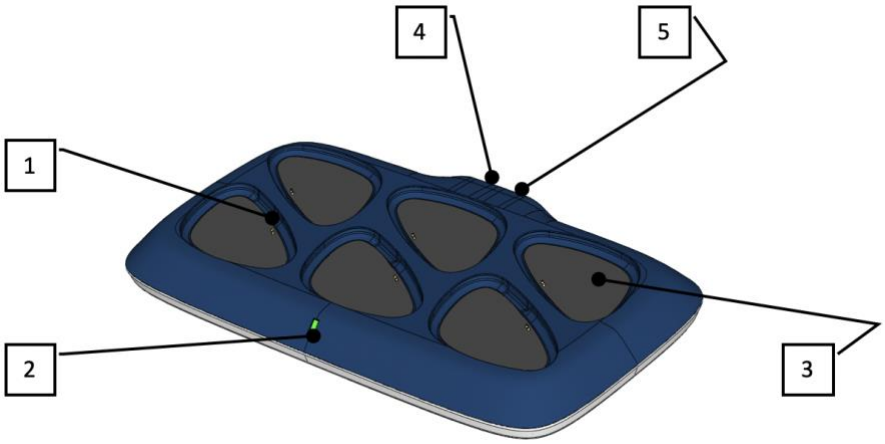


Figure 5: Multi Charger Dock

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 alarms. 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.

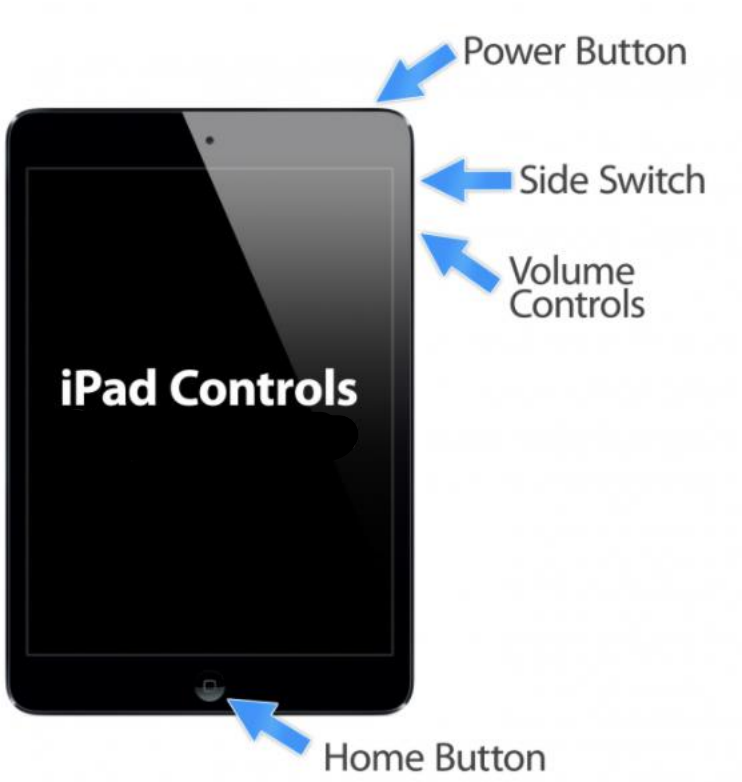


Figure 6: iPad Controls

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 6 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.

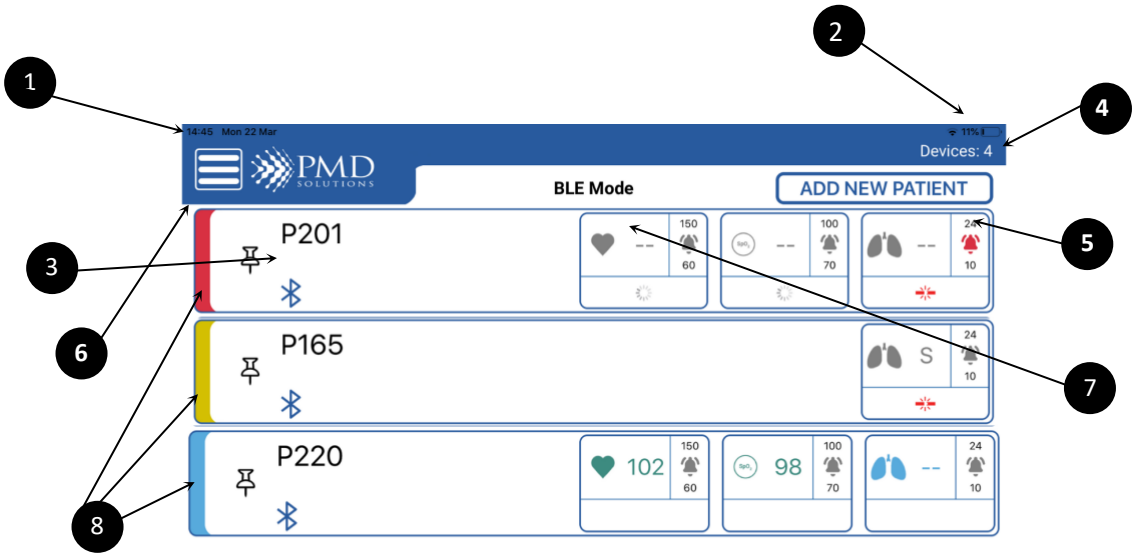


Figure 7: RS App Dashboard

Table 4 Features of the Respiratory Rate Mobile Application

Reference	Function	Description
1	Time	Displays the current time
2	Power Level	Displays the current power level of the hand-held device. The charging symbol appears when device is charging.
3	Patient Information Panel	Displays summary information for each Lobe which is broadcasting information nearby. Detailed in next section. Up to 6 Lobes are displayed. If there are more than 6 Lobes in the vicinity, a scroll interface will be available.
4	Device Count	Indicates number of devices detected.
5	Register new patient Device Count	Indicates number of devices detected. Allows the operator to associate a Lobe with the Medical Record Number (MRN) or another identifying name of a patient. See *Section 3– Patient Monitoring* for more information about preparing for monitoring.
6	Side Menu	Allows the operator to navigate the app and change settings. This menu brings the user to dashboard, routers, help and settings.
7	Network mode	Allows the operator to see whether the lobes are operating on Bluetooth and Air mode

Reference	Function	Description
8	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.

Dashboard – Patient Information Panel

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

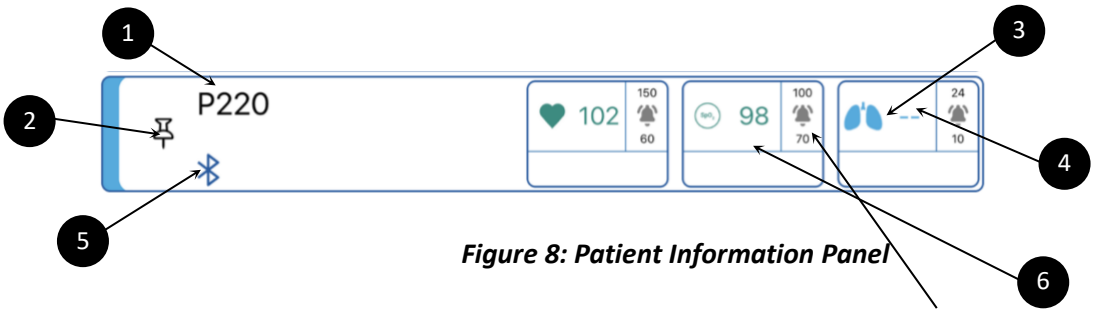


Figure 8: Patient Information Panel

Table 5 Features of the Patient Information Panel

Reference	Function	Description
1	Patient ID	Displays Patient identifier.
2	Priority Patient Toggle	Allows user to toggle Lobe as Priority. Priority patients are shown at the top of the list. Shown in Figure 6 in deactivated state.
3	Respiratory Rate Icon	Shows what is being measured- respiratory rate.
4	Latest Respiratory Rate (RR)	Shows average RR of patient over latest averaging window.
5	Status Information	Displays low priority alerts relating to Lobe: Device Error, Low Battery, Non-Default Settings and/or Sensor Disconnect.
6	Latest SpO2 Measurement	Displays SpO2 measurement of patient.
7	Alarm Thresholds	Upper and Lower Alarm Thresholds Set for patient.

In the event of an alarm scenario, the Patient Information Panel will flash Red.

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 alarm 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.

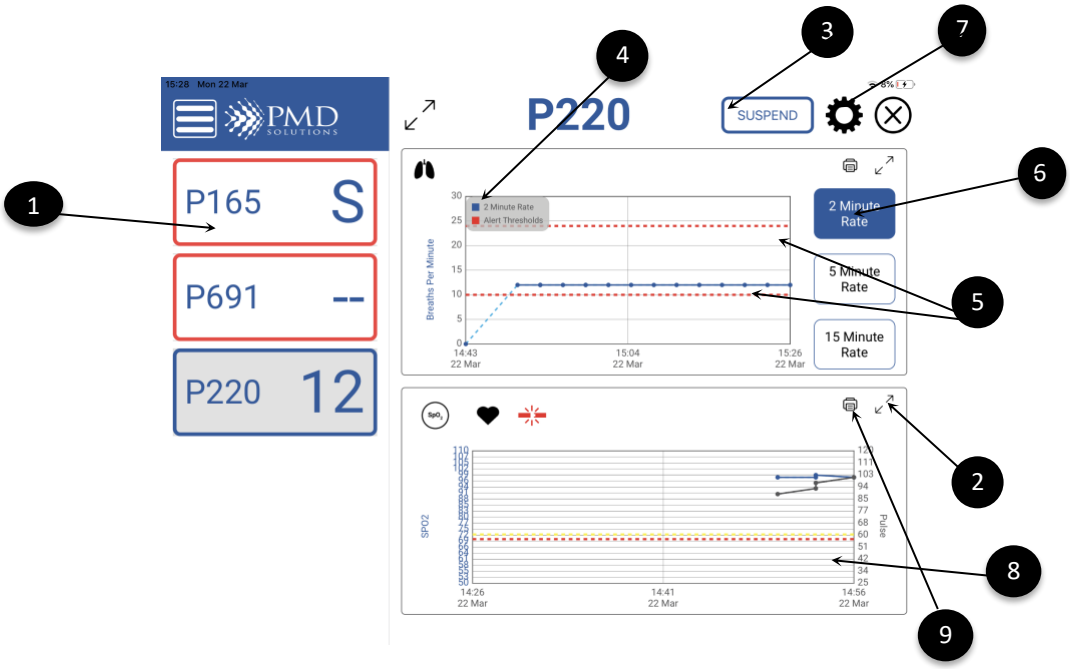


Figure 9: Respiratory Rate Measurement Function Screen

Table 6 Features of the Respiratory Rate Measurement Function Screen

Reference	Function	Description
1	Patient Identifier	Displays the MRN of the patient or the Device ID if this was scanned during maintenance.
2	Expand Graphs	Allows user to expand graph to full screen display.
3	Suspend Button	Allows operator to suspend measurement for 3 minutes before it disappears from the dashboard and app.
4	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.
5	Alarm limit lines	Lines on the RR trend graph showing the currently selected alarm thresholds.
6	Measurement Time Frame Selection Buttons	Allows selection of time frame over which to view the RR trend graph. Options are to display over the last 4, 12, 24 or All hour(s).
7	Lobe settings	Can be selected to bring user to Lobe Settings Interface. The user can alter Sounder and LED settings.

Reference	Function	Description
8	Sp02 measurement	Measurement of Pulse Rate from Sp02 and heart rate from ECG graph-using accessory
9	Print Option	Allows user to print graphs of both Sp02 and RR.

Threshold Alteration and Indicator Alteration Interface

Selecting the "Alert Thresholds" option on the RR Measurement Function Screen displays the Threshold Alteration Interface, shown in Figure 10. This interface allows the user to change respiratory rate alarm 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.*

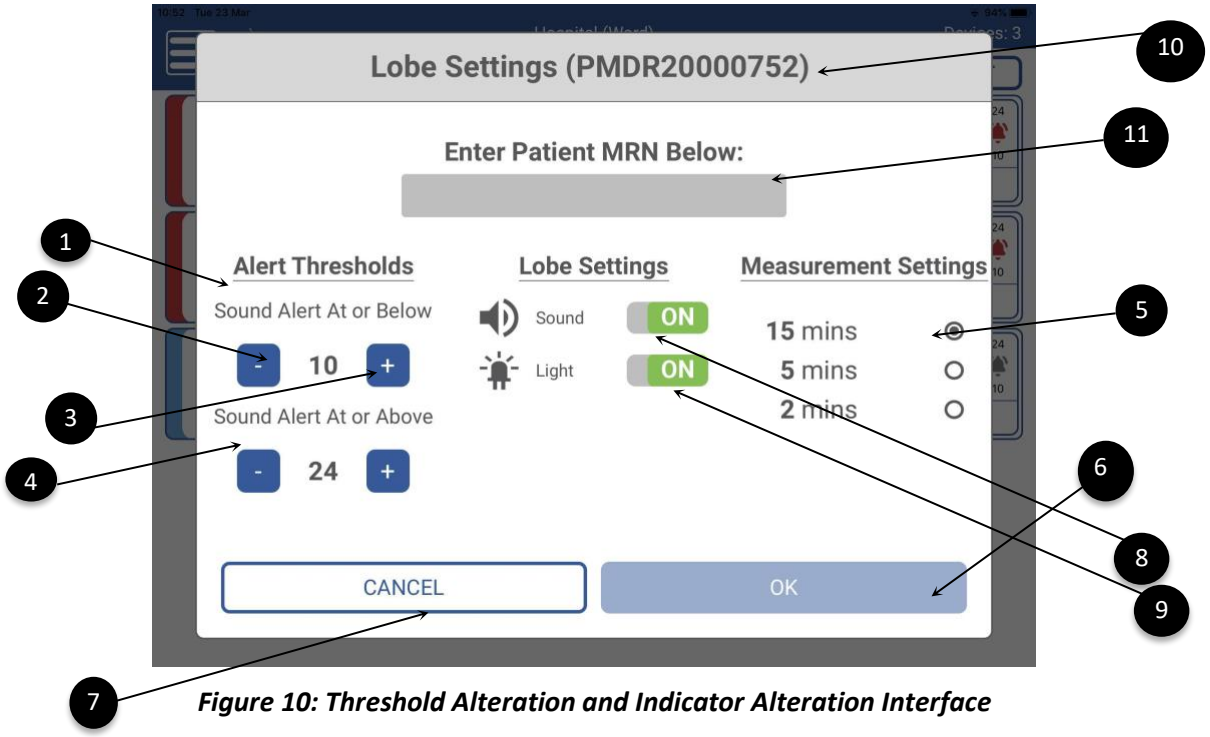


Figure 10: Threshold Alteration and Indicator Alteration Interface

Table 7 Features of the Threshold Alteration and Indicator Alteration Interface

Reference	Function	Description
1	Lower Threshold	Displays current bound on alert thresholds
2	Decrease Threshold Button	Allows user to decrease threshold by 1 breath per minute (bpm).
3	Increase Threshold Button	Allows user to increase threshold by 1 bpm.
4	Upper Threshold	Displays current upper bound on alert thresholds
5	Averaging Window	Allows user to specify averaging window length.

Reference	Function	Description
6	OK Button	Prompts user to save new thresholds
7	Cancel Button	Returns user to previous screen without changing thresholds
8	Sounder Setting	Displays sounder setting. Displays with an X through the symbol when sounder is set to off. By turning sound off, sound alarm on the lobe will be turned off not on the app.
9	LED Setting	Displays LED setting. Displays with an X through the symbol when LED is set to off.
10	Lobe Name	Allows user to change the name of the lobe
11	Lobe ID	Displays Lobe ID

Settings Change Acknowledgment Screen

Figure 11 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 11: Settings Acknowledgment Screens

Addition of an Accessory

Adding an accessory such as a Pulse Oximeter to measure Sp02 can be monitored on the RS app in addition to the respiratory rate with RS.

If the device is already registered the user can add an accessory 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 12*: Adding accessory menu*

Table 8 Features of the Adding Accessory Menu

Reference	Function	Description
1	Add Accessory	Allows user to manually input the accessory MAC number
2	Camera Icon	Allows user to scan the QR MAC number of the accessory device
3	Exit 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.
4	Confirm	Confirms the added accessory to be measured

Alarm Function

When the RR of a patient wearing a RS Device equals or exceeds an alarm limit threshold or when the Lobe is receiving no signal from the Sensor over a prolonged period, an alarm state is entered. An alarm 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 alarm, the user scans the patient's MRN barcode or 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 alarm status. Figure 13 shows the popup screen when the user is prompted to pause the Alarm function. See *Section 3– Patient Monitoring* for more information.

Figure 13: Alarm Pause Prompt

Lobe - Low Battery Warning

Figure 14 shows the low battery warning. This warning is displayed on connection when the Lobe or accessory battery is nearing depletion on the dashboard.

Figure 14: 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 16 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 15: Back of Lobe with Serial ID

Table 9 Features of the Connection Selection Screen

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

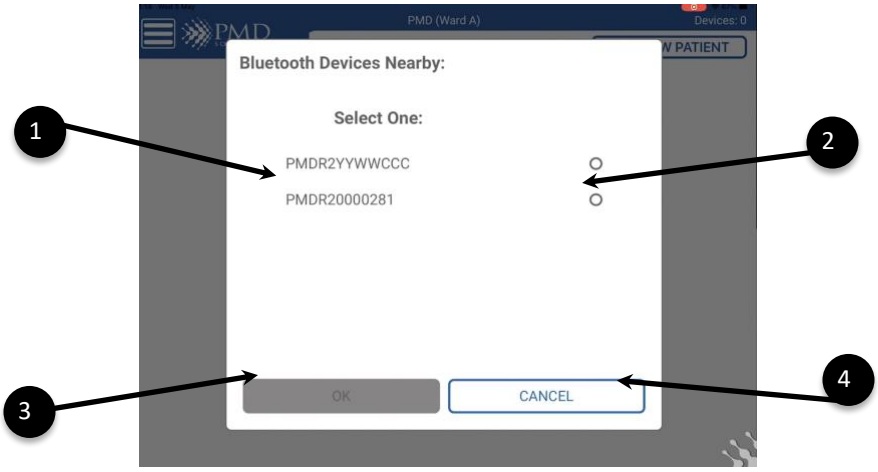


Figure 16: Connection Selection Screen

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 patient. Figure 17 illustrates this screen.

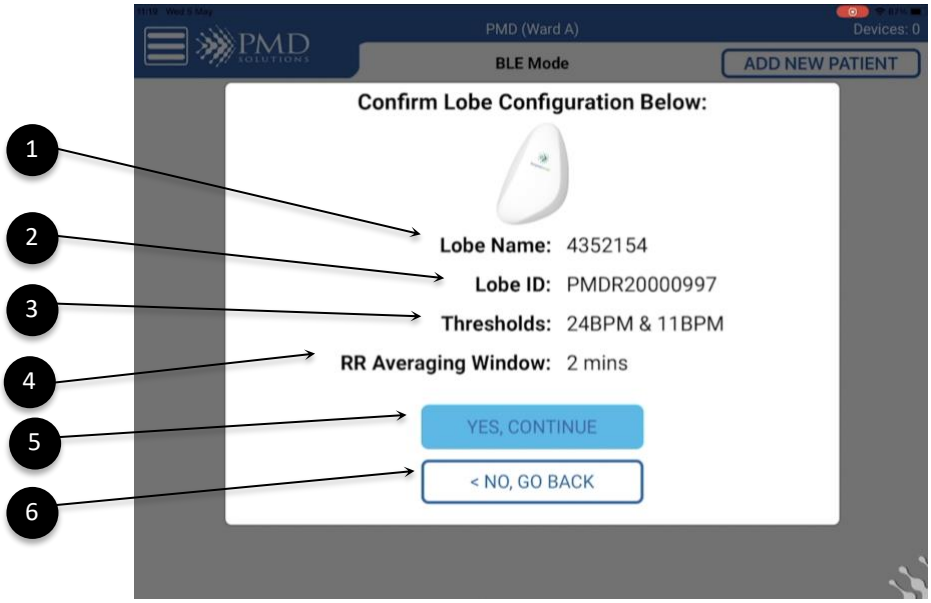


Figure 17*: Rename Confirmation Screen*

Table 11 Features of the Rename Confirmation Screen

Reference	Function	Description
1	Lobe ID	Displays ID of Lobe which is to be registered.
2	Patient MRN	Displays the MRN of the patient or the name of the RS Device if alternative to MRN was used.
3	Threshold Limits	Displays the currently configured upper limit and lower threshold limits for patient RR. Exceeding these limits will trigger an alarm.
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 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.

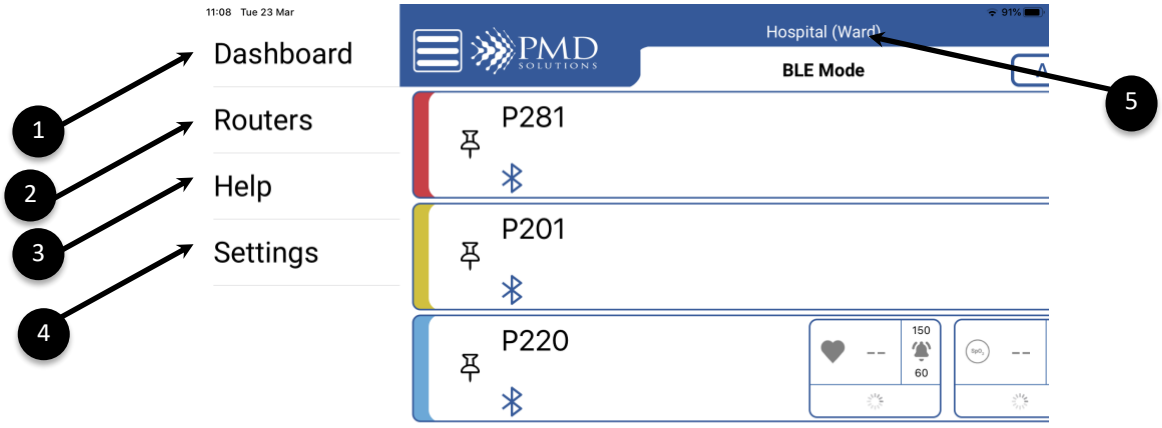


Figure 18: Side Menu Screen

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.

Icon	Name	Description
	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.
	Alarm	Displayed when the respiratory rate is outside of the alarm 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.
	Alarm Paused Icon	Displayed on Measurement Screen when alarm 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

Icon	Name	Description
	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.

Help Menu

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

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 Alarm
8. Altering Respiratory Rate Thresholds during Monitoring
9. Altering Alarm, LED and Sounder Settings
10. Removal and Disposal

- 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 alarms and status indicators of the RS Device. See *Section 4 - Alarms and Indicators* for more information.
CAUTION	In cases where the Alarm 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 Alarm (flashing Red) LED has been activated, the Alarm 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 take action 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 Figure 9.* 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.
5. Verify that alarm 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.

6. Select **Yes** if details are correct – this will complete the renaming process.
7. Select **No** if incorrect – this will cancel the renaming process.
8. Confirm rename is successful. On successful rename the following occurs:
    - Confirmation successful.
    - Lobe beeps twice.
    - Lobe LED is set to Flashing White.
9. 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.

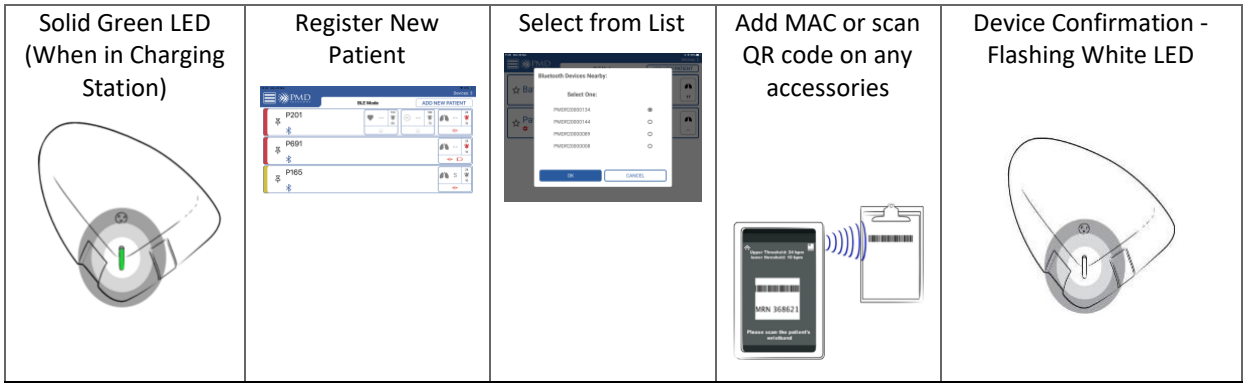


Figure 19: Summary of Registration Process

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 charging station.
4. Inspect Lobe for signs for soiling or mechanical damage.
5. Remove Sensor from packaging.
6. Insert the Lobe into the Cradle on the sensor
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 patient before use.**
CAUTION	RespiraSense shall not be used on neonates or infants
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 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 index finger in line with the rib. Press to adhere.
    - Patient lying down: Place the upper leg of the Sensor at the location of the index finger. Press to adhere.
10. Place 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 should be replaced with a new sensor.
14. Confirm attachment was successful:

- RS Device firmly attached to 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.

15. Inspect patient periodically to ensure RS Device has not caused allergic reaction, irritation or has become uncomfortable to wear.

Figure 20 summarises this process.

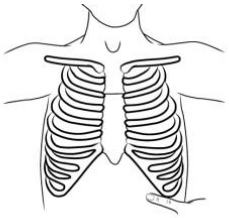
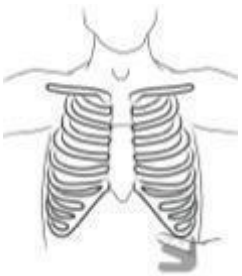
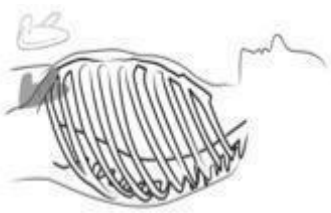
Patient standing up	Patient standing up	Patient lying down
		
Find bottom rib using index four finger	Place Sensor upper Finger below finger and in-line with rib	Find bottom rib with index finger and place Sensor upper leg on top of finger

Figure 20 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 alarm 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 priority list by pressing the Priority Pin Button. The button will change to a black icon.
3. Remove patient from 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. If requested, up to 96 hours of historical data from the patient can be displayed. To obtain the respiratory rate measurements of the patient dependant on averaging time:

1. Open RS App.
2. Scan for patient by using one of three methods:
    a) Patient ID visible on Dashboard: Tap on Patient ID.
    b) MRN Available: Select the Camera icon on the Dashboard and scan the MRN barcode of the patient using the camera interface provided.
    c) MRN Not Available: Select the Camera icon on the Dashboard and select the Manual Input Icon. Enter patient identifier using the provided onscreen keyboard.
3. Confirm successful connection:
    - Lobe LED will blink Blue 3 times (presence of alarm overrides this LED state).
    - Lobe will emit two consecutive connection beeps.
4. Manually record the respiratory rate information in the patient's Vital sign medical record or in accordance with hospital, administration, and/or local government laws.

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.

5. Select Show Graph on the results screen. Four options are displayed for viewing historical respiratory rate measurements:
    - 4 hours.
    - 12 hours.
    - 24 hours.
    - All – displays all available data points (minimum 1 hour).
6. Select the appropriate option. The relevant measurements are displayed.
7. If another patient is to be scanned, use the back button to return to the Dashboard view.

Step 7: Dealing with Alarm Events

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

The Lobe can emit an alarm 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 Sensor.

If the user is currently in the dashboard view, the alarm status will also display on the indicator panel. If the user is currently viewing a patient's detailed results when those Lobe beings an alarm cycle, the alarm 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 Alarm LED and/or Sounder have been disabled on the lobe, the alarm 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 change. 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 alarm scenario:

1. Manually check patient in accordance with normal hospital procedures to ensure there is no acute need by the patient. If patient does not require immediate attention, proceed to pause alarm.
2. To pause the alarm, interact with RS Device on patient in accordance with this section.
3. A confirmation window will appear prompting the user to pause the alarm.
4. In scenario 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 alarm, but it does not terminate it. If the respiratory rate threshold limits are exceeded at a later time, the Lobe can emit an alarm again.

Step 8: Alter Respiratory Rate Thresholds during Monitoring

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

WARNING	**Alarm 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 alarm 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 procedure in this section.
2. Select the “Alert Thresholds” Button. The view will alter to present the Threshold Settings Interface.
3. Alter Lower and Upper Thresholds using the Plus and Minus Buttons. Increment the threshold up or down by 1 bpm by pressing once. Holding a button will increment the value rapidly.
4. Alter the averaging window by selecting the appropriate window size.
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 alarm 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 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 patient. Do not leave sensor on 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. Depress the Lever on the cradle and push upwards in the space of the lobe to release the Lobe from the Sensor
3. Examine patient's skin for sign of irritation or allergy.
4. Gently Peel the sensor off patient's skin with Lobe attached. If there is any difficulty in removing the Sensor, first remove the Lobe, and then apply water to the fabric of the sensor, or a hospital approved standard adhesive mover to the Sensor.
5. Discard the Sensor in accordance with hospital, administrative, and/or local government laws.
6. Wipe down the Lobe in accordance with hospital, administration, and/or local government laws.
7. Return the Lobe to the Charging Station and ensure that the LED indicator shows a fully charged status (Green) before re-use. Returning the Lobe to the Charging Station terminates the current Lobe function and returns the Lobe to an unregistered state, with no patient data with in it.

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.

Using the RS Device in the Home Healthcare Setting

This section outlines the specific safety, setup and configuration information for the RR Monitor when used in the homecare setting.

CAUTION	At any point during the use of the RR Monitor, if in doubt of operation, cleanliness or status of the RS Device, contact issuing organisation.

Limitations of Respiratory Rate Monitoring Outside of a Clinical Environment

The RR Monitor is not precluded for use outside of a clinical environment and can also be used in the home environment as instructed or directed by the clinician operator. While in use in the homecare environment, the RS Device can be worn by a patient including while sleeping overnight. The RS Device monitors the patient's respiratory rate and provides a record for subsequent review by any healthcare practitioner.

In the home use scenario, the RS Device shall first be fitted to the patient by the operating healthcare practitioner. The operating healthcare practitioner shall then instruct the patient not to interact with the RS Device, but to wear it as instructed for the time period of clinical interest (e.g. throughout the day or just while asleep etc.). The patient shall be given a guideline leaflet (*PDS-801-003: Home Use Instructions for Use*) containing contact information and any warnings and precautions to be taken while wearing the RS Device. The operating healthcare practitioner shall remove the RS Device from the patient when the study is completed.

Setup for Home Use

The medical practitioner uses the following steps to activate and configure a device for home use.

1. Activate, assemble and apply the RS Device.
2. Follow the instructions to **turn off all Sounder and all LED** alerts.
3. Follow the instructions to set the upper and lower RR thresholds to 60 and 6 BPM respectively.
4. Brief patient on all contraindications contained in these Instructions for Use.
5. The RR Monitor is now ready for use in the home healthcare environment.

Home User Maintenance

The RS Device will be supplied by the medical practitioner cleaned, charged and ready to use.

CAUTION	If the RS Device is soiled by biological or chemical agents, immediately remove the RS Device using protective clothing, place in a secure location away from children, and contact the issuing organisation.

If dust or lint builds up in RS Device crevasses, remove the device from the patient and clean it in accordance with hospital procedures. If this does not work, contact the issuing organisation.

If the power on the RS Device depletes, contact the issuing organisation.

Environmental Considerations

WARNING	**The Lobe contains a Lithium-Ion battery which may explode if incorrectly handled or stored. Carefully read and comply with this section and *Section 7 – Product Specification* to ensure safety.**

The RS Device must be stored in an environment conforming to the limits outlined in Section 7 – Product Specification. Inspect that section for details.

The RS Device must not be used in conjunction with an electric bed heating blanket or similar device. Direct heat from radiators, hot water bottles or other personal heating devices should not be placed near the RS Device.

In environments in which a nebuliser, humidifier or similar device is used, particular care must be taken that humidity does not exceed the specified limit.

Degradation of Device

Both the Sensor and the Lobe components of the RS Device can degrade due to incorrect storage conditions, mechanical damage, or overuse.

Never use a RS Device that shows signs of wear and tear. Contact the issuing organisation.

The excessive presence of a White LED can indicate that the FPC connection has come loose. Inspect the RS Device to ascertain if this is the case.

Children and Pets

Never leave any part of the RS Device in the reach of unsupervised children or pets. Small parts constitute a choking hazard.

The RR Monitor is not a toy.

Keep all packaging materials out of reach of children and pets.

Movement

Excessive movement can render the results from the RS Device inaccurate. Sudden movement or mechanical force can cause the Lobe to become dislodged. Ensure that Lobe is secure after such movement. Special care should be taken by carers when assisting patients that they do not dislodge the RS Device.

Electromagnetic Interference

Wireless communication equipment such as wireless network devices, mobile phones and personal walkie-talkies can affect the operation of the RS Device. Such equipment should be kept at a minimum distance from any part of the RS Device. For example, a typical mobile phone with a maximum output power of 2W should be kept a minimum distance of 3.3m away from the device to ensure correct operation. See *Section 7 – Product Specification* for further information.

SECTION 4 - ALARMS AND INDICATORS

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

WARNING	**In cases where the Alarm LED and/or Sounder have been disabled, the alarm 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-alarm status has been detected. Red LEDs indicate alarm or error status. Table 14 describes in detail the different LED states. LED states with higher Priority will supress those with lower priority.

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

Table 14: Lobe LED States

Status Indicator	Priority	Description
Flashing Red LED – 1.4 second cycle	1	Alarm 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	Alarm signal (5 second repeating cycle).

Alarm Condition

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

Alarm Limits

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

Alarm Pause

If the Lobe is alarming, the alarm is automatically paused when you scan the relevant patient MRN. The alarm will reactivate at subsequent readings (up to 50 seconds) if the measured respiratory rate is still outside the threshold limits.

Note	The only way to pause the alarm is to scan the MRN of the patient. When you scan the MRN, the most recent respiratory rate measurements and a message stating that the RR Monitor alarm has been paused are displayed.

Alarm Function

The RespiraSense can emit an alarm signal when certain alarm criteria are reached. An authorized 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 alarm threshold and inhibit LED and sounder notifications.

The configuration options for Default Settings are show in Table 16.

Table 16: Configuration Options for Default Alarm Settings

Setting Name	Configurable Values	Default Value on new app installation	Description
Upper Threshold	7-60 bpm in increments of 1 bpm	20 bpm	The upper threshold for alarm 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	12 bpm	The lower threshold for alarm activation. The patient's RR must equal or drop below this value for this criterion to be met.
Threshold Time	0 – 15 minutes in increments of 1 minute 0 corresponds to no Threshold Time	0 minutes	This setting represents **the continuous amount of time** that the upper or lower threshold must be breached for an alarm condition to activate. When set to 0, any breach of a threshold will activate the alarm.
Inhibit During Movement	Off / On	Off	This setting allows the user to inhibit alarm generation when the algorithm determines that the patient is moving.
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 alarm 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 alarm 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 alarm 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 alarm sounder will be paused for.
LED	On/Off	On	This setting allows the user to toggle LED stats on the Lobe
Sounder	On/Off	On	This setting allows the user to inhibit the sounder on the Lobe.

Alarm Notification

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

The RS App displays alarm 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 alarm. The alarm pauses for a time equal to the current Averaging Window.

The Air App displays an alarm notification by alternating the colour of the corresponding patient panel to red. In addition, a sounder will be activated on the tablet hosting the Air App. To silence the alarm for a period of 2 minutes tap the corresponding patient panel.

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 alarm 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 Sp02. If the thresholds are equalled or exceeded, the alarm 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.

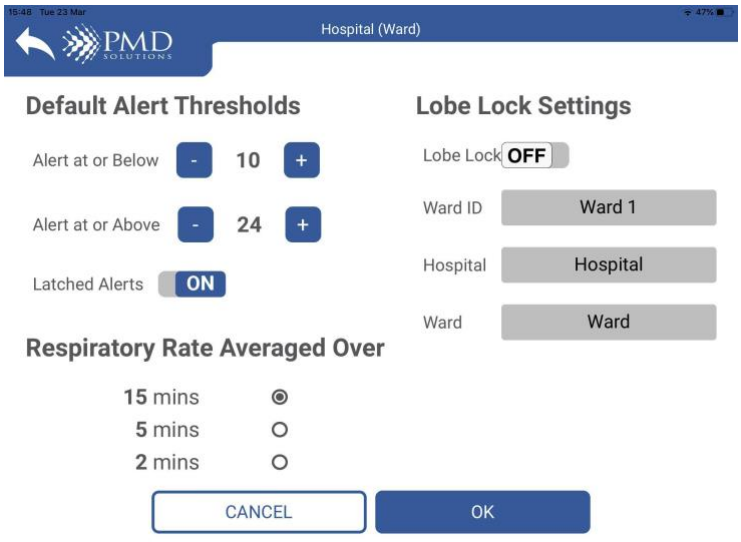


Figure 21: Set Default Thresholds

WARNING	**The alarm 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 Sp02 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, Sp02 and PR thresholds for the alarm 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

Set Result Screen Timeout

Selecting the Set Result Screen Timeout option from the Settings Menu allows the user to alter the amount of time the Measurement Function Screen is displayed. This setting should be decided on with the consultation of the end user and with consideration to patient confidentiality in the case the RS Device is left unattended with a results screen displaying.

Note	This timeout is for the Results Screen only. All other screen timeouts are controlled by the portable hand-held device settings.

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 accelerometer reading change.
- LED Check. Select each LED and observe Lobe to ensure correct LED displays. Combination of LEDs will produce additive colours.
- Sounder Check: Select Sounder and ensure Lobe Sounder functions.
- Firmware version.
- Bluetooth version.
- Sensor check. Insert Sensor and move legs and ensure voltages change as appropriate.

System Check should be carried out once per year, or whenever a user reports a suspected functional problem.

Tablet Restrictions

This menu allows the user to set the Tablet Lock option on or off. Enabling the Tablet Lock will restrict this portable hand-held device's use to the RS App only. Attempting to access other portable hand-held device features and apps will return the user to the RS App.

Note	This functionality can only be used on iOS Systems.
Note	Certain basic functionality cannot be supressed. This includes the navigation button swipe up menu and the system settings swipe down menu on iOS systems.

Installing Application from Distribution Service

Note	When deployed on an Apple device, the application will be installed and managed by the manufacturer.

In some instances, the RS App may require reinstallation or updating. To do 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 Setting/Status Indicator
RR Default High Alarm Limit	24 breaths per minute	7 - 60
RR Default Low Alarm Limit	10 breaths per minute	6 - 59
RR High Alarm Limit	24 breaths per minute	7-60 (in use)
RR Low Alarm Limit	10 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
Alarm Signal Volume	64 dB	Non-configurable
Alarm Pause	Up to 50 seconds	Non-configurable
Result Screen Time-Out	2 minutes	30, 60, 90 seconds
Tablet Restrictions	Off	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 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 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 device to connect.
Connection to device failed. Please attempt to connect again or contact 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 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 correct QR code is being scanned.
Barcode is not a supported format. Please enter MRN using keyboard entry option.	Occurs when a barcode is scanned that is not in a supported format. Scan supported barcode format or enter details manually.
Barcode encodes unsupported characters. Please enter MRN using keyboard entry option.	Occurs when a barcode is scanned one or more characters that are not supported. Scan supported barcode format, or entre details manually.
Settings cannot be changed due to device connection error. Please return to 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 application to automatically restart.

Message	Details
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 with fresh device.
The Device Battery is low. Please remove Lobe and Sensor and replace.	Occurs when it is detected that the Lobe battery is low. Remove RS Device and replace with 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. Alarm and Red LED Status
5. Removal, disposal and recharging

Patient Registration

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.
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 Lobe QR code using Camera	● Ensure 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 camera is no more than 60 cm from QR code. ● Check Lobe QR code for damage or soiling. ● Restart application and start scanning process again. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.

Problem	Solution Tree
Unable to scan Patient MRN barcode	● Ensure camera lens is not obstructed or soiled. ● Ensure there is sufficient light to scan. ● Option: Patient MRN can be inputted manually using keyboard. ● Ensure camera is no more than 60 cm from barcode. ● Check patient barcode for damage or soiling. ● Restart application and start scanning process again. ● Return to 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 issuing organisation or department. ● Seek replacement from Authorised Distributor.
Unable to enter Patient MRN using keyboard	● See "Tablet is unresponsive".
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 next sub-section.
Incorrect patient MRN scanned 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 Charging Station for at least 5 seconds. Restart patient registration process. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
No Patient MRN barcode available	● Select manual input option on the application.
Sounder does not beep at end of patient registration process	● Reset Lobe by returning to Charging Station for at least 5 seconds. Restart patient registration process. ● Return to 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 Charging Station for at least 5 seconds. Remove Sensor from Lobe if attached. Restart patient registration process. ● Return to 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 MRN is not on list (Dashboard displays maximum of 6 devices and a scroll interface will be available if there are more than 6 devices). ● Option: Scan patient MRN using camera. ● Ensure MRN has not been filtered out using the selection tool. ● 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.
No Patient MRN barcode available	● Select manual input option on the Application. ● Option: Select patient MRN directly from dashboard.
Unable to scan Patient MRN barcode	● Ensure camera lens is not obstructed. ● Option: Select patient MRN directly from dashboard. ● Ensure there is sufficient light to scan. If light levels are low, patient MRN can be manually inputted using keyboard. ● Ensure camera is no more than 60 cm from barcode. ● Check patient barcode for damage or soiling. ● Restart Application and start scanning process again. ● Return to issuing organisation or department. ● Seek replacement from Authorised Distributor.
Unable to enter Patient MRN using Keyboard	● See "Tablet is unresponsive".
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.
Sounder does not beep at end of connection process	● Examine Patient Monitor Screen to ensure System Sounder is set to ON. ● Return to issuing organisation or department.

Problem	Solution Tree
	● Seek replacement from Authorised Distributor.
"Device not found." displayed when connecting to device	● Ensure correct barcode is being scanned. ● Ensure Lobe is in range. ● Reconnect to Lobe. ● 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.
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.

Alarm 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.
Alarm does not pause when MRN scanned	● Ensure correct MRN has been scanned. ● 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.

Problem	Solution Tree
Flashing Red LED	● Alarm Scenario. Check patient. ● Check FPC cable has not become detached from unit. ● Silence alarm by scanning patient barcode. ● If alarm persists without reason, return to issuing organisation or department.
Sounder does not sound when Alarm 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 Alarm 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 alarm is paused.	● Lobe not receiving reading from Sensor. ● Check FPC is firmly seated in FPC port.

Home Use Environment

Problem	Solution Tree
Patient reports sounder is activated	● Instruct patient to place device in location where it is not causing disturbance. ● When returned, check that device is set up correctly.
Patient reports device has fallen off	● Instruct patient to place device in a secure place away from children and pets.

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.

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

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

Respiratory Rate Measurement Limits

The Respiratory Rate Measurement Limits declared for the RR Monitor are show 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	
Bias (bpm)	-1 <= Bias < 1
Upper Limit of Agreement	<= 3
Lower Limit of Agreement	>= -3
Calculation Range	6 – 60 bpm
Resolution	1 bpm

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

Non-Invasive and Continuous Respiratory Rate Monitoring Compared to Electrocardiogram and Nurse Evaluation

In 41 comparisons between a prototype version of the RespiraSense™ Respiratory Rate Monitor, electrocardiogram and nurse visual observations, the RR accuracy was as shown *in*

Table 20 Clinical Evaluation Summary of Results (Lee P, "Clinical evaluation of a novel respiratory rate monitor", *J Clin Monit Comput*. 2016 Apr;30(2):175-83).

Table 20: Clinical Evaluation Summary of Results

Measurement	ECG	Nurse Evaluations
Correlation	0.84	0.79
Mean Standard Deviation	[-0.72,-0.12]	[-2.78, -1.49]
Range of respiratory rates	8 - 24	
Mean Age	52	
Age Range	20 - 84	
Sex	55% Male (45% Female)	

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	2 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 Use
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.

Alarm Generation Criteria

An alarm 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.

Alarms

The following table shows the alarms specifications.

Table 22: Alarm Specification

Alarm Function	Specification
Audible and visual alarm when respiratory rate goes outside of operator-specified limits	Lower threshold: 6 - 59 breaths per minute Upper threshold: 7 - 60 breaths per minute
Alarm tone	850 Hz tone, 3 pulse, repeat time: 5 seconds
Volume	64 dB
Priority	Medium
Alarm Condition Delay	Up to 52 seconds
Operator Position	Alarm 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	Alarm status, battery low, unit charging, unit charged, Bluetooth communication active
Indicator Type	Tricolour LED

CE Notice

Marking by the symbol CE 0120 indicates compliance of the RS Device to the Medical RS Device Directive of the European Community. Such marking is indicative that the RespiraSense Device meets or exceeds the following technical standards:

Guidance and manufacturer's declaration – electromagnetic emissions		
The Respirasense V2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Respirasense V2 should assure that it is used in such an environment		
Emissions test	**Compliance**	
RF Emissions CISPR 11 EN 55011: 2009 + A1: 2010	Group 1	The Respirasense V2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
RF Emissions CISPR 11 EN 55011: 2009 + A1: 2010	Class B	Class B equipment is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and manufacturer's declaration – electromagnetic immunity			
The BE1551 Slot Power supply is intended for use in the electromagnetic environment specified below. The customer or the user of the Respirasense V2 should assure that it is used in such an environment			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2: 2009	±8 kV contact ±15 kV air	±2, 4, 6 & 8 kV contact ±2, 4, 8 & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 EN 61000-4-8: 2010	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: Ut is the a.c.mains voltage prior to application of the test level			

Recommended separation distances between portable and mobile RF communication equipment and the PB840 Ventilator

The Respirasense V2 is intended for use in an electromagnetic environment specified in Table 201. The customer or the user of the Respirasense V2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Respirasense V2 as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [1.17]\sqrt{P}$	80 MHz to 800 MHz $d = [1.17]\sqrt{P}$	800 MHz to 2.5GHz $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Respirasense V2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Respirasense V2 should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3 EN 61000-4-3: 2010	10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	d = [1.17]√P…80MHz to 800 MHz d = [2.33]√P…800 MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BE 1551 is used exceeds the applicable RF compliance level above, the BE 1551 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the BE 1551.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1]V/m

SECTION 9 - 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

The Lobe should be cleaned and disinfected:

- If any part of it becomes soiled.
- After removal from a patient.
- Before application to a new patient.
- Before and after 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.

To clean and disinfect the Lobe:

1. Remove the Sensor and Lobe from the patient.
2. Disconnect the Sensor from the Lobe.
3. Wipe the entire Lobe with a 70 % isopropyl alcohol pad, or with hospital equivalent.
4. 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 use only.

Functional Verification

Functional verification is carried out using one of the supported mobile medical applications.

See *PDS-801-007: RespiraSense Respiratory Rate Monitor Instructions for Use* for details on how to use the functional verification features *built into the RespiraSense Respiratory Rate Application.*

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 years from date of manufacture. Lobes that have reached the end of service life should be returned to the manufacturer.

Shelf Life (Sensor)

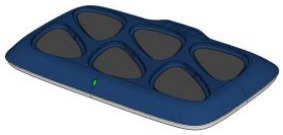
The shelf life of the Sensor is 2 years from date of manufacture.

SECTION 10 – 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 Applications</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</td>
</tr>
</table>

	Nonin model 3150 wrist-worn pulse oximeter

SECTION 11 – ASSOCIATED MOBILE MEDICAL APPLICATIONS

In this section, a description of the associated mobile applications and their instructions for use is provided. The RS Device can also be used for Dysfunctional Breathing monitoring. It is the mobile application that functions, and measurements are recorded by the RS Device.

These associated mobile medical applications are available from the manufacturer upon request as they may not be included.

Description of the RS App Air Mode

In this section, a description of the main features of RespiraSense Air is provided.

Air Dashboard

Figure 22 shows the Air Dashboard. The Air Dashboard shows the same information as the RS App Dashboard but has reduced functionality. The figure shows Patient 4 in an alarm state with the Alarm Icon visible.

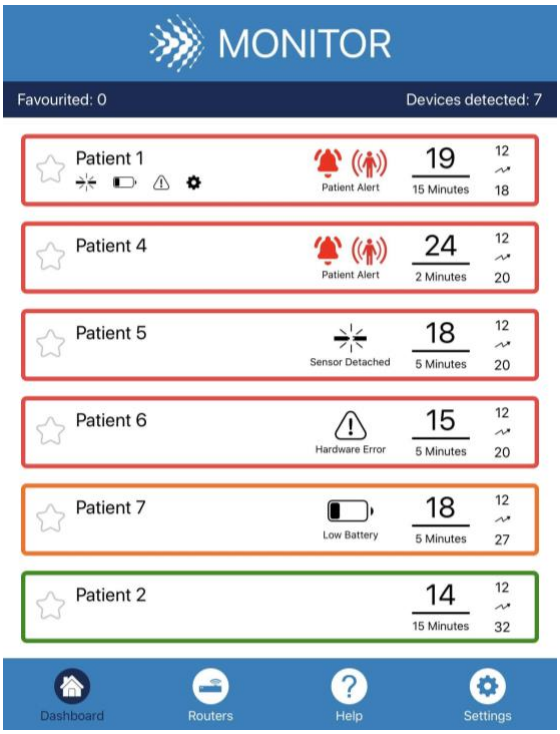


Figure 22: Air Dashboard

Figure 23 shows a warning message that the Air Dashboard may display. This message occurs when the wireless connection between the dashboard and the comments that transmit data to it are severed or experiencing difficulty.

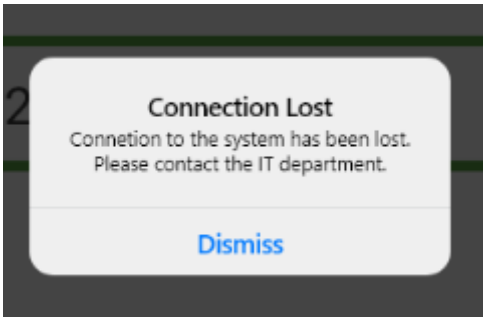


Figure 23: Air Dashboard Connection Warning

RS App Air mode Icons

Table 25: Air App Icons lists the icons used in the Air App.

Table 25: Air App Icons

Icon	Name	Description
	Router Icon	Brings user to Air App Router screen to review the status of configured routers. This icon can also have a number displayed in a badge
	Router Icon with number	If a router goes offline (e.g. a network issue, loss of power etc.) then the icon will display a badge indicator containing the number of routers that have changed state.
	Help Icon	Brings user to Air App Help Menu which includes the IFU.
	Settings Icon	Brings user to Air App Settings Menu.
	Priority Toggle 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 yellow when patient is included on the Priority List.
	Device Error	Displayed on the Dashboard when a device error is detected.
	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.
	Alarm Paused Icon	Displayed on Air Dashboard when alarm has been paused.

Air Router Screen

Figure 24 shows the Air routers screen. One or more routers are required to relay data from the Lobe to the Air Dashboard for display. Each row shows the current status of a configured router on site.

Each router item displays the location of the router (as configured during site setup), the MAC address of the router and the connection status. The uptime is the percentage of time the router has been online. In Figure 23, Site Router 1 has a connection issue and has never connected to the Air system.

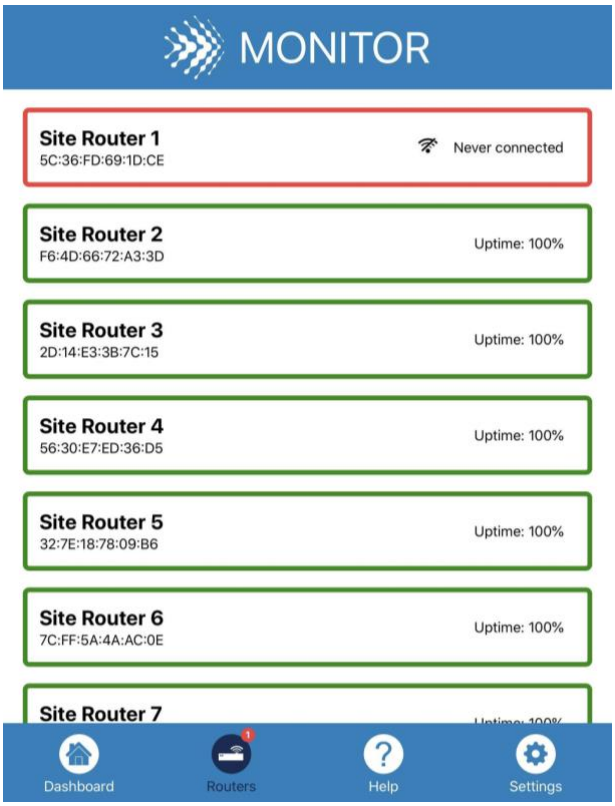


Figure 24: Routers screen

SECTION 12 – 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.

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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.

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SECTION 13 – 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

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