SENSIBLE MEDICAL
Seeing through walls

# ReDS™ System Healthcare Provider User Manual

ReDS™ System V2.6

**RA-14529 Rev. A**

December 2017

# About This Manual

This user manual describes how to use the ReDS™ System to monitor the fluid status of patients.

This manual describes the ReDS System V2.6. It applies to healthcare providers (HCPs) who are using the device to monitor patients. In addition, the HCP Quick Reference Guide is also provided for your convenience. Patients using the device must use the ReDS System Patient Manual for patients (Doc number RA-30129) and the Quick Reference Guide for Patients, (Doc number: RA-03518) which are provided in the ReDS System package.

This manual contains the following chapters:

- **Chapter 1, Introducing the ReDS System,** page 14, introduces the ReDS System and describes it components.
- **Chapter 2, Setting Up,** page 24, describes how to adjust the sensor vest to fit a specific patient and other general setup procedures that must be performed once before starting to use the ReDS System.
- **Chapter 3, Taking a Measurement,** page 45, describes how to measure a patient using the ReDS System.
- **Chapter 4, Multi-patient Use of the ReDS System in a clinical setting**, page 56, describes how to use the ReDS System device with multiple patients.
- **Chapter 5, The SensiCloud™ Portal,** page 60, describes how to use of the SensiCloud Portal to monitor the thoracic fluid status of multiple patients.
- **Chapter 6, Assigning ReDS System to a Patient for Home Use,** page 78, discusses the main issues that healthcare professionals should communicate to patients when prescribing the ReDS System for home use.
- **Chapter 7, Transmission to Cloud and System Configuration,** page 83, describes the Transmission to Cloud and system configuration options.
- **Chapter 8, Troubleshooting,** page 86, describes how to troubleshoot various system problems. This information is provided in order to allow you to solve simple problems. If a problem cannot be solved, please contact support.
- **Appendix A, Labeling,** page 88, shows the labels that are attached to the ReDS System components and describes the symbols that appear on them.
- **Appendix B, Handling,** page 90, describes how to install, store, clean and maintain the ReDS System.
- **Appendix C, Technical Information,** page 92, provides ReDS System technical specifications and other technical information.

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# Legal Notice



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**Configuration: U GAS0045**
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**SensiCloud™ SW Version: 1.3**


**Federal law restricts this device to sale by or on the order of a physician**

# Support and Contact Information

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The WEEE symbol indicates that this system contains electrical and electronic components which must be collected and disposed of separately.

Never dispose of electrical and electronic waste in general municipal waste. Collect and dispose of separately.

Make use of the return and collection systems and components available to you, or use your local recycling program. Contact your local authority or place of purchase to find out what options are available.

Electrical and electronic equipment contain hazardous substances which, when disposed of incorrectly, may leak into the ground. This can contribute to soil and water pollution which is hazardous to human health and endangers wildlife.

It is essential that customers look to recycle electrical and electronic waste to avoid it going to landfill sites or incineration without treatment.

# Conventions Used in This Manual

**WARNING!**

Warnings indicate conditions or practices that could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

**CAUTION:**

Caution indications relate to conditions or practices that are potentially hazardous that may result in minor or moderate injury to the user or damage to the equipment or other property. Caution indications may also be used to indicate practices that are necessary for the effective use of the device.

**NOTE:**

Notes provide additional important information.

# Important Safeguards

To ensure proper and dependable usage of the ReDS System, read all the instructions provided in this user manual before using the ReDS System.

**WARNINGS!**

1. The ReDS System should only be operated in accordance with the manufacturer's instructions, as specified in this user manual.
2. Keep this system away from heat or open flame.
3. Do not use this system in an explosive environment or in the presence of flammable anesthetics or gases.
4. Do not use this system in oxygen-rich environments.
5. Do not connect other devices to this system's USB port, except as instructed in this manual, as this may compromise electrical safety.
6. This system should not be operated if there is any visible physical damage to any of its parts (Sensor Vest, Bedside Console, Power Supply or cables), such as cracks, breaks, tears and so on.
7. No modification of this equipment is allowed.
8. The ReDS System should not be used in the vicinity of RF emitters such as magnetic resonance imaging (MRI) machines, computed tomography (CT) machines, RF diathermy devices, RFID devices and electromagnetic security systems such as metal detectors, as this may result in increased electromagnetic interference to the ReDS System.

**CAUTIONS:**

1. Do not operate the ReDS System without proper training. For additional information, contact support.
2. In case of user discomfort, abort the operation of this system by using the console or by unfastening and removing the sensor vest.
3. Federal law (USA) restricts this device to sale by or on the order of a physician.
4. Each sensor vest is only intended to be used by the patient for whom it was set up, as described in Chapter 2, Setting Up on page 24.
5. To ensure high quality measurements, use the device over plain, light clothing, such as a t-shirt or an undershirt. Metal elements under the sensors should be avoided, such as jewelry. Avoid using the device over a bra.
6. Pay attention to the sensor vest cable in order to avoid entanglement, strangulation or pulling the Bedside Console.
7. Place the Bedside Console on a flat and stable surface to prevent tipping and falling.
8. The basket on the cart is designed to carry weight of up to 3 Kg (6.5 pounds). Do not overload it, as this may make the device unstable.
9. Avoid exposing the system to liquids, as this may cause device damage.
10. This system should only be serviced by qualified personnel.
11. Remove the vest before performing defibrillation to avoid system damage or ineffective defibrillation therapy.
12. The ReDS System fluid reading is intended to be used as an adjunct parameter to standard clinical assessment methods.
13. When considering using the ReDS System, take the following patient-related considerations into account:
    - Physical deformities in the thorax area that may prevent application or correct adjustment of the sensor vest.
    - Recent surgery in the torso area.
    - Surgical wounds, healing tissue or recent skin grafts or flaps on the thorax.
    - Burns, open wounds or skin infections on the thorax.
    - Osteoporosis or osteomyelitis of the ribs.
    - Complaints of chest-wall pain.

**CAUTIONS Continued**

14. In the following cases remove the sensor vest, turn off the system, disconnect the power supply and contact support:
    - Recurring device malfunction message
    - Device is not responding
    - A measurement that does not stop automatically within four (4) minutes of starting.
15. When connecting the USB modem, to reduce risk of damage to the system, do not touch the system's USB port as identified by the following label: 
16. The use of USB accessories other than those specified may result in increased electromagnetic interference or decreased electromagnetic immunity of the ReDS System.
17. The ReDS System should not be used adjacent to, or stacked with, other electronic equipment. See Table 7 and Table 8 for minimal separation distances.
18. After completing the vest adjustment procedure, lock the vest adjustment using the provided pins and caps. Do not alter the vest adjustment as this may result in low quality measurements.
19. To ensure accurate measurements make sure to read and enter the chest size ruler value accurately.
20. The system is intended for indoor use and storage, avoid exposing to high or low temperatures, humidity and pressure conditions (*See Section C Technical Specifications*) as this may cause system malfunctions.
21. Exercise caution when locking and unlocking the vest adjustment to avoid pinching or pinpricking.
22. Do not use the vest in case the vest adjustment locking pins are exposed.
23. Persons with medical implants KEEP BACK 30 in. (76cm) from the unlocking magnet.
24. To avoid damage, keep magnetic media such as computer disks (including the ReDS System Console), credit cards and tapes away from the unlocking magnet.
25. Stop using the device if there is a reason to suspect that it has been contaminated.
26. When using the device with multiple patients make sure to use the vest with proper disposable infection control garments to protect patients. Please refer to chapter 4 for additional information.

# 1 Introducing the ReDS System

This chapter introduces the ReDS System and describes its components.

## Overview

The ReDS System is a non-invasive device consisting of a Bedside Console connected to a wearable vest that is used for the measurement of lung fluid. A measurement session lasts 90 seconds. Measurement results in impedance units (Ω Ohms) or in percent units (%), representing the volume of fluid in the lung out of the total lung volume.

The system may be used for monitoring of a single patient over a period of time. In that case, the device is set up and later assigned to that patient. The device might also be used by a health care provider to obtain readings of multiple patients.

Measurement results are optionally transmitted via a cellular or Wi-Fi data link to a secured cloud based portal, SensiCloud™, for physician review.

## Indications for use

ReDS System is intended for use by qualified health care practitioners and by patients, under the direction of a physician, in hospitals, hospital-type facilities and home environments, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

ReDS System is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Recovering from Coronary Artery Disease related event

# Patient Population

The system is suitable for:

- Patients over 21 years of age.
- Male and female patients of height between 155 cm (5' 1'') to 195 cm (6' 5'') with a body mass index of 22 to 36.
- Patients within the height range having a BMI of 36 to 38 can use the system if their chest size ruler value (as measured by the vest) is 4 or more.

# Contraindications

The ReDS System is not appropriate for patients with rib fractures, with or without flail chest.

# System Components

The ReDS System consists of the following components:

- **Bedside Console** (with optional Tabletop or Cart mounting), page 15
- **Sensor Vest,** page 18
- **SensiCloud,** page 22, is a software application intended for storage and display of fluid content measurements collected automatically from the ReDS System.

## Bedside Console

The following describes the components of the Bedside Console.


**Figure 1: Front of Bedside Console, Tabletop Mounting**

**NOTE:**

Note that the Bedside Console contains a battery that enables it to stay ON and perform other functions without being connected to a power outlet. However in order to perform measurements the Console must be connected.

The back of the console has a stand for positioning it upright on a tabletop, as shown below:


**Figure 2: Back of Bedside Console, Tabletop Mounting**

**Figure 3: Bedside Console, Cart Mounting**

## Wireless Connectivity

If the SensiCloud portal option is included with the system, a cellular USB modem is provided with the device. This modem enables the transmission of measurement results data to a secured cloud server for healthcare provider review. Cellular technologies supported are the standard technologies provided by US carriers for data communications including: GSM, GPRS, EDGE, HSPA, UMTS, LTE and CDMA. Depending on the technology available, the modem transmits in one of the following frequency bands: 700, 750, 800, 850, 900, 1700, 1800, 1900, 2100 or 3500 Mhz. The modem complies with FCC Class B limits. The provided modem is either the Sierra Wireless U308 SHOCKWAVE USB Modem FCC ID: N7NU309 or other equivalent qualified modem.

Alternatively, a Wi-Fi solution for connectivity is also available in cases of cellular coverage problems. Wi-Fi technology supported will be one or more of the 802.11 technologies IEEE 802.11b/g/n and the operating frequency band will be either 2.4Ghz or 5Ghz. The Wi-Fi adapter complies with FCC Class B limits. The Wi-Fi adapter to be provided is CISCO Linksys AE2500 Wireless-N USB Adapter or other equivalent adapter. If needed, a router may also be provided. For further information regarding Wi-Fi option please contact support.

**NOTE:**

Avoid using the device in places where the use of cellular devices is prohibited. You may use it in such places if the USB cellular modem is not connected.

## Sensor Vest

The right inside of the sensor vest has two sensors, one in the front and one in the back, for measuring lung fluid content. The measurement information is transferred to the Bedside Console via a cable from the sensor vest.

The following describes the components of the sensor vest.

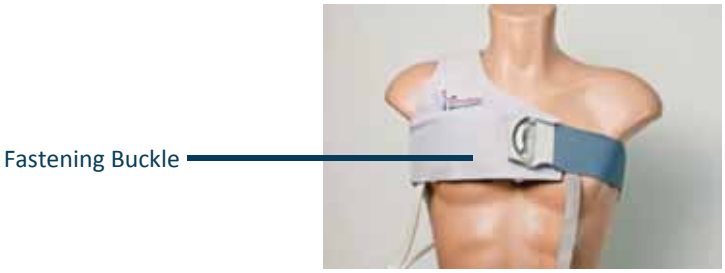



**Figure 4: Sensor Vest**

### Sensor Vest Fastening Flaps and Fastening Strap

The sensor vest has three adjustable fastening flaps (that enable the sensor vest to fit snuggly on the patient), and one fastening strap, as follows:

- **Right Fastening Flap:** This flap closes around the patient's right rib cage.
- **Left Fastening Flap:** This flap closes around the patient's left rib cage.
- **Shoulder Fastening Flap:** This flap closes around the patient's shoulder.
- **Fastening Strap:** This strap is used during the adjustment procedure for tightening the sensor vest on the patient's body.

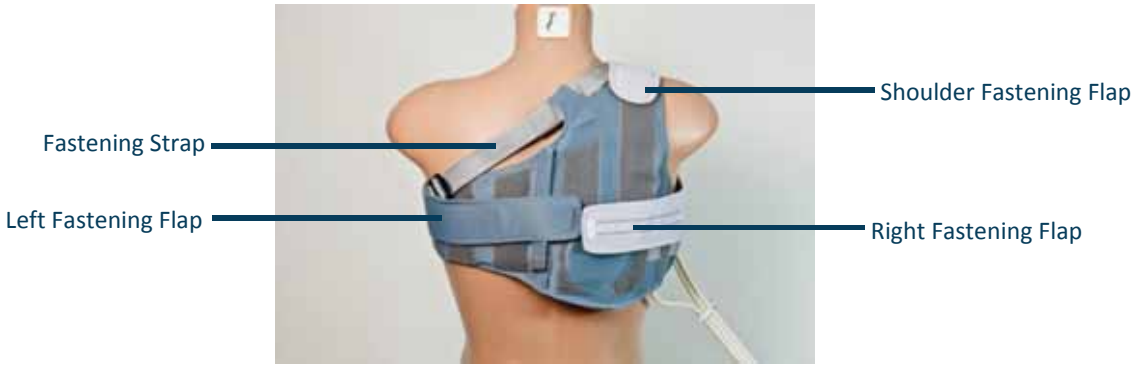



**Figure 5: Fastening Flaps and Fastening Strap**

## Back Center Strip

The Back Center Strip is used to position the sensor vest properly on the patient's body during the a0djustment process.


**Figure 6: Back Center Strip**


**Figure 7: Back Center Strip – Height Indicators**

## Two Positioning Reference Points

Two circular reference points help position the sensor vest on the patient's body. The top one is to be positioned just below the patient's suprasternal (Jugular) notch, and the bottom one rests below on the patient's breastbone (sternum).

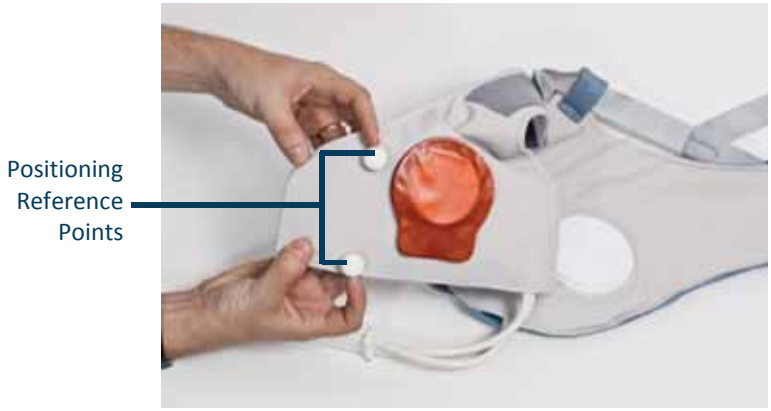



**Figure 8: Positioning Reference Points**

## Sensor Vest Inside View

The following shows the sensors embedded inside the sensor vest.

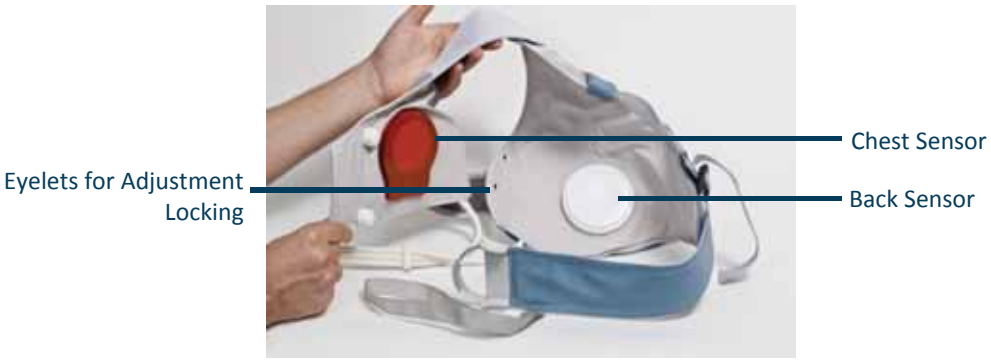



**Figure 9: Chest and Back Sensors**

- **Chest Red Sensor:** This sensor inflates during measurement for better contact with the patient's upper-right chest through the clothing.
- **Back White Sensor:** This sensor is positioned on the upper-right part of the patient's back.
- **Eyelets for Adjustment Locking:** Adjustment locking pins are inserted here (see page 37 for additional information)

## Sensor Vest – Inside Left-front View

The front bottom of the sensor vest has an insert for a card with the following information:

**Figure 10: Sensor Vest Label**

- **PSS S/N:** The serial number of the sensor vest.
- **Pt. ID:** The name or identifying ID number of the patient.

## Chest Size Ruler

The Chest Size ruler is used to measure the chest size when the sensor vest is worn by the patient.

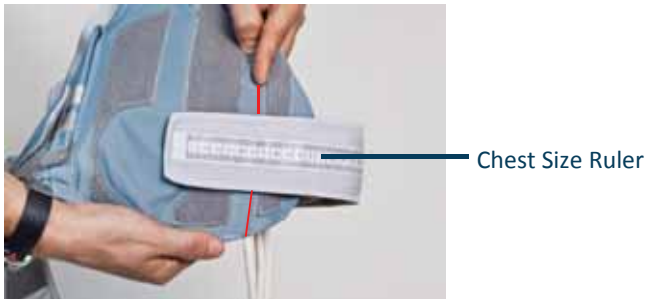



**Figure 11: Chest Size Measurement Ruler**

You may refer to the *Reading Patient Chest Size* section on page 43 for a description of this procedure.

## Pins and Caps for Vest Adjustment Locking and the Detacher Magnet

The vest's adjustable flaps are locked after being adjusted to the patient. This vest adjustment locking is done using the provided pins and caps found in the ReDS System box.


**Figure 12: Vest Locking Pins and Caps**

A detacher magnet is used in order to unlock the pins and caps to allow a change to the vest adjustment:


**Figure 13: Detacher Magnet**

## SensiCloud™ Portal

SensiCloud is a software application intended for storage and display of fluid content measurements collected automatically from ReDS System devices.

The data from the ReDS System is automatically transmitted via a cellular or WiFi data connection to the SensiCloud secure server for healthcare provider review.

### SensiCloud Components

The SensiCloud consists of a secured cloud-based server hosting the system database and the SensiCloud Portal application.

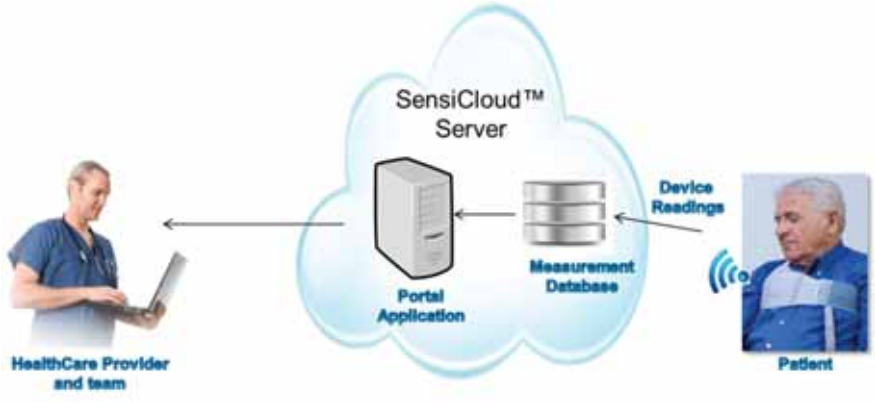



**Figure 14: SensiCloud Components**

The following are the main functions available in SensiCloud:

- Enrolling patients in the SensiCloud Portal, which associates them with the healthcare provider using the system to view their measurements.
- Providing a graphical/tabular view of all available fluid readings of his/her associated patients.
- Setting up lung fluid level thresholds and receiving automatic system notifications (via email and/or text messages) triggered by those user-defined thresholds.
- Monitoring patients' compliance via missed daily readings indicators.
- Enabling automatic measurement reminder notifications to patients.

# 2 Setting Up

This chapter describes how to adjust the sensor vest to fit a specific patient and other general setup procedures that must be performed one time prior to using the ReDS System.

**CAUTIONS:**

- To ensure proper and dependable usage of the ReDS System, read all the instructions provided in this user manual before using the ReDS System.
- Do not operate the ReDS System without proper training. For additional information, contact support.

## General Setup

The following steps need only be performed once before using the ReDS System for the first time.

### Step 1: Assembling the Cart

This step is optional. If no cart is needed, skip to Step 2 on page 25.

► **To assemble the cart:**

- Assemble the cart stand wheels, basket and handle according to the assembly instructions provided in the cart box, with the handle being positioned at a distance of 1 cm from the top of the pole, and the basket positioned 78cm above floor, both facing backwards (opposite to the VESA mounting plate).
- Mount the Bedside Console on the VESA mounting plate, shown below. Use the provided screws and a standard Phillips screwdriver.

**Figure 15: Bedside Console VESA Mounting Plate**

## Step 2: Adjusting the Bedside Console

The tilt of the console display can be adjusted. For Cart configuration, use the lever on its back.

### ► To adjust the tilt of the Bedside Console (Cart configuration) display:

1. Turn the black lever on the cart's back clockwise to release the console's hinge.
2. Tilt the console to the angle that suits you.
3. Turn the lever counter-clockwise to lock the Bedside Console in position.

**NOTE:**

Lifting the black lever allows it to turn without releasing or locking the console's hinge.

### ► To adjust the tilt of the Bedside Console (Tabletop configuration) display:

- Tilt the screen gently to the angle that suits you.

**CAUTION:**

Place the Bedside Console on a flat and stable surface to prevent tipping and falling.

## Step 3, Setting Up Communication

This step is optional. If the ReDS System is to be used in a Standalone mode (meaning without the SensiCloud™) skip this step.

### ► To set up communication:

Connect the cellular modem (or the wireless adaptor if using Wi-Fi) to the back of the console. Use the white straps to secure in place. The cellular modem is provided within the ReDS System package.

**CAUTION:**

- The use of USB accessories other than those specified may result in increased electromagnetic interference or decreased electromagnetic immunity of the ReDS System.

For additional information about communication troubleshooting, you may refer to *Chapter 7, Troubleshooting* on page 86.

**NOTE:**

'Transmission to cloud' is ON by default to allow for cellular communication to the SensiCloud. If Wi-Fi is used, "Wi-Fi" should be selected accodingly. It should be turned OFF when neither cellular communication nor Wi-Fi are available or if no communication is required ("Standalone"). See Chapter 7 System Configuration or contact support for more information.

## Patient Setup

This section describes how a healthcare provider should adjust the sensor vest. Each sensor vest must be adjusted for a specific patient before it is used to measure that patient.

The sensor vest adjustment procedure need only be performed once for each patient. After the sensor vest is adjusted for a specific patient, use this sensor vest for all his/her future measurements. In multiple patient use, the sensor vest adjustment must be repeated for each patient.

**CAUTION:**

When using the device with multiple patients make sure to use the vest with proper disposable infection control garments to protect patients. Please refer to chapter 4 for additional information.

If the sensor vest adjustment is modified for any reason, the adjustment procedure must be repeated in its entirety.

**CAUTION:**

Each sensor vest is only intended to be used by the patient for whom it was set up.

## Patient Setup Workflow

The following provides an overview of the steps for setting up a sensor vest for a new patient and a reference to the sections of this user manual that provide detailed instructions.

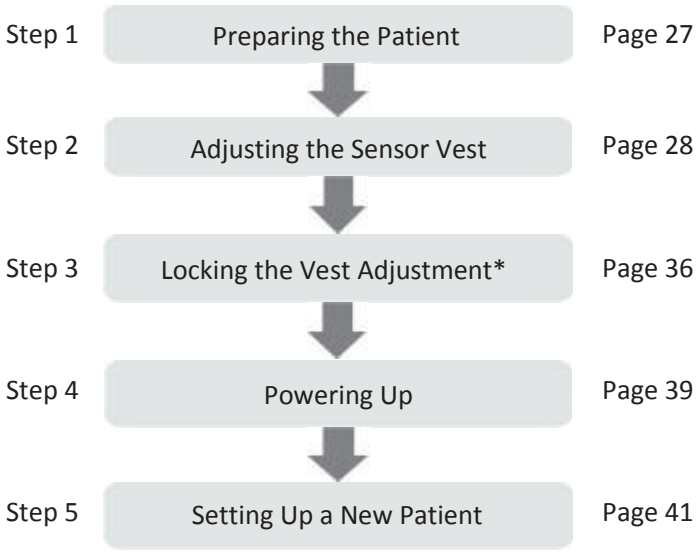



**Figure 16: Patient Setup Workflow**

* Locking the vest adjustment may be performed later as part of the device assignment to patient workflow, or, if the ReDS System is used for taking readings of multiple patients, may be skipped altogether.

# Step 1: Preparing the Patient

### ► To prepare the patient:

- Make sure the patient is dressed in plain light clothing.
- Avoid using over a bra.

**CAUTION:**

To ensure high quality measurements, use the device over plain, light clothing such as a t-shirt or an undershirt. Metal elements under the sensors should be avoided, such as jewelry. Avoid using device over a bra.

## Step 2: Adjusting the Sensor Vest

Adjusting the sensor vest involves the following:

- Loosening the flaps and the Fastening Strap.
- Positioning the front of the sensor vest.
- Setting the back piece height.
- Centering the back piece.
- Tightening the side flaps and fastening the strap.
- Performing verification steps.

Follow the procedure below for complete details.

**CAUTIONS:**

When considering whether to use the ReDS System, take the following patient-related considerations into account:

- Physical deformities in the thorax area that may prevent application or correct adjustment of the sensor vest.
- Recent surgery in the torso area.
- Surgical wounds, healing tissue or recent skin grafts or flaps on the thorax.
- Burns, open wounds or skin infections on the thorax.

Pay attention to the sensor vest cable in order to avoid entanglement, strangulation or pulling the Bedside Console.

### ▶ To loosen the flaps and the Fastening Strap in order to prepare the sensor vest for adjustment:

1. Open the Right Fastening Flap and then reattach it to its maximum opening position, as shown below:

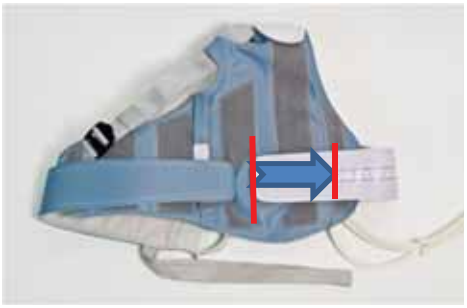


**Figure 17: Opening the Right Fastening Flap**

2. Open the Left Fastening Flap and reattach it to its maximum opening position, as shown below:

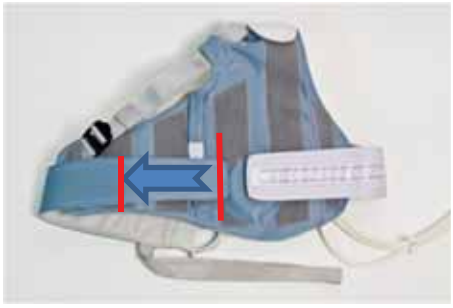


**Figure 18: Opening the Left Fastening Flap**

3 Tilt the black plastic buckle of the Fastening Strap on the back of the sensor vest and pull to loosen the Fastening Strap, as shown below:


**Figure 19: Loosening the Fastening Strap**

4 Open the fastening shoulder flap and then reattach it to its maximum opening position, as shown below:


**Figure 20: Opening the Fastening Shoulder Flap**

► **To put the sensor vest on the patient:**

**CAUTION:**

When using the device with multiple patients make sure to use the vest with proper disposable infection control garments to protect patients. Please refer to chapter 4 for additional information.

**NOTES:**

- When adjusting the vest, a standing posture is preferable. If a standing posture is not possible, then have the patient sit upright in a chair with no backrest or a bed with his/her feet on the floor.
- Adjustment should be done while the patient's shoulders are relaxed and the patient is upright.

1 Put the sensor vest on the patient's shoulder so that the red sensor is positioned on the front-right side of the chest.


**Figure 21: Positioning the Red Sensor**

2 Place the sensor vest so that the Positioning Reference Points are vertical and aligned with the sternum. The upper Positioning Reference Point (Figure 8) is just below the patient's suprasternal (Jugular) notch and the bottom Positioning Reference Point rests below the patient's breastbone (sternum), as shown below:


**Figure 22: Positioning the Sensor Vest During Adjustment**

3 Ask the patient to hold the sensor vest steady in its current position and close the buckle with the left-side flap. Have the patient hold the closed buckle and verify that it is centered on his/her sternum.

4 Stand behind the patient and center the back center strip over the spine. Then adjust the back piece height and the shoulder fastening flap such that:

- **For shorter patients of height up to and including 165 cm (5' 5"):** The lower, **S** labeled height marker on the Back Center Strip (Figure 6) covers the C7 vertebra.
- **For taller patients of height greater than 165 cm (5' 5"):** The higher, **T** labeled height marker on the Back Center Strip (Figure 6) covers the C7 vertebra.

0

**NOTE:**

When adjusting the flap, make sure that the patient's shoulders are relaxed and that the patient is upright.


**Figure 23: Using the Back Center Strip to Position the Sensor Vest**

**NOTE:**

To locate the C7 Vertebra:

- While the patient's head is tilted forwards and downwards, use two fingers to feel for the most prominent vertebra. That vertebra is the C7 vertebra.
- Position the height indicator marker against the C7 vertebra, and make sure that the height indicator is kept in position when the patient raises his/her head

5. Tighten the shoulder flap to secure the correct height.
6. While the patient is holding the front buckle steady on the sternum, carefully center the back of the sensor vest by aligning the lower end of the Back Center Strip with the patient's spine. To verify, use your fingers to feel the spinal column in the lower part of the vest near the back sensor. Once centered, hold the back piece in place.0

**Figure 24: Centering the Back of the Sensor Vest**

7 While holding the sensor vest back piece flat against the body with one hand, use your other hand to attach the Left Fastening Flap.


**Fig0ure 25: Tightening the Left Fastening Flap**

8 While holding the sensor vest back piece flat against the body with one hand, use your other hand to tighten the Right Fastening Flap around the patient's chest so that it fits snugly, but is not uncomfortably tight. For patient comfort, make sure that the side flaps (left and right flaps) are not pressed up too tightly into the armpit.

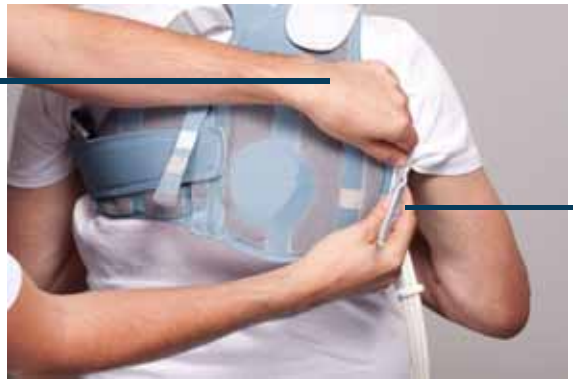



**Figure 26: Tightening the Right Fastening Flap**

9 Verify that the back center strip is still centered on the patient's spinal column (as in step 6). If necessary, make minor adjustments to the side (right/left) straps.

**10** Read the patient's chest size, as described in the *Reading Patient Chest Size* section on page 43. If the chest size value is 10 or less, repeat steps **4 – 8**, but this time do it while aligning the center strip about a finger width to the right of the spine.

**NOTE:**

The vest adjustment supports ruler chest dimension values of 2.5cm to 25cm. Please do not use the ReDS System if the measured ruler values exceed this range. For additional information, you may contact support.

**11** Tighten the fastening strap (shown below) so that it is slightly tense and the back piece below is nearly separated from the patient's back, as shown below:


**Figure 27: Tightening the Fastening Strap**

**12** To verify proper adjustment of the sensor vest, remove the sensor vest completely from the patient and then have the patient put it back on.

**13** While the patient is upright, verify that the sensor vest is positioned properly, as described below:

- Make sure that the sensor vest fits snugly, but is not uncomfortably tight.
- **Verify that the back of the vest is properly positioned, as follows:**
  - The correct marker on the back center strip is placed over the C7 vertebra (Figure 23).
  - The lower end of the back center strip is exactly aligned with the spinal column of the patient (Figure 24), or is a finger width to the right of the spine for patients with Chest Size ruler value of less than 10.
  - The vest lies flat against the body with no creases or folds.

- **Verify that the front of the vest is properly positioned, as follows:**
  - The upper Positioning Reference Point is in place (Figure 22).
  - The Front Sensor is entirely below the clavicle bone, such that the upper edge of the sensor is not touching it.

**Figure 28: Verifying Front Sensor's Position**

  - Instruct the patient to lie back in a reclined position, either lying close to supine or sitting, in an adjustable bed, a reclining chair, or on a regular bed supported by pillows.
  - Make sure the patient does not roll or slide against the bed or chair when getting into position.
  - Verify again that the front of the vest is properly positioned, as described above.

**14** If necessary, correct the adjustment according to the following:

- If the Front Sensor is touching the clavicle bone when the patient is lying back, repeat the entire adjustment procedure. This time, place the upper Positioning Reference Point roughly 2 – 3 cm lower.
- If the vest back piece is too low or too high, repeat steps **4 – 13**.
- If the position of the vest's back center strip needs to be adjusted relative to the spine (to the left or right), have the patient hold the front piece in place, release one flap and tighten the opposite flap until it is in place. If this is not sufficient for centering, use the shoulder flap to shift the back piece right or left relative to the front chest piece.
- After any readjustment, repeat the verification steps **12 – 13**.

**15** Fill in the patient's information on the sensor vest label card and insert it into the designated place on the inside of the sensor vest, as described on page 21.

**CAUTION:**

After completing the adjustment procedure described above, lock the vest adjustment using the provided pins and caps. Do not alter the vest adjustment as this may result in low quality measurements.

## Step 3: Locking the Vest Adjustment

After completing the adjustment procedure including the verification steps, the sensor vest adjustment should be locked to ensure that both intentional and unintentional alterations to the vest's proper fit to the patient are avoided.

### ▶ To lock the vest adjustment:

**NOTES:**

- Make sure the vest fits properly according to verification steps (12-14 above) prior to locking the vest adjustment.

1. Place the adjusted sensor vest on your desk or other flat surface available.
2. Locate the pins and caps in your ReDS System box and place them on your desk or other flat surface.


**Figure 29: Locating the Pins and Caps**

**CAUTION:**

Exercise caution when locking and unlocking the vest adjustment to avoid pinching or pinpricking.

3 Take one pin and pierce through one of the eyelets and the shoulder flap. Pierce through the eyelet which is the closest to the shoulder, from the inside of the vest out, so that the pin will be pointing away from the body. Note that you only need to use one of pin per flap.

**Figure 30: Piercing Through the Shoulder Flap**

Cover the pin with a cap making sure to insert the pin all the way into the hole in the cap. Try pulling on the cap to make sure it is locked in place.

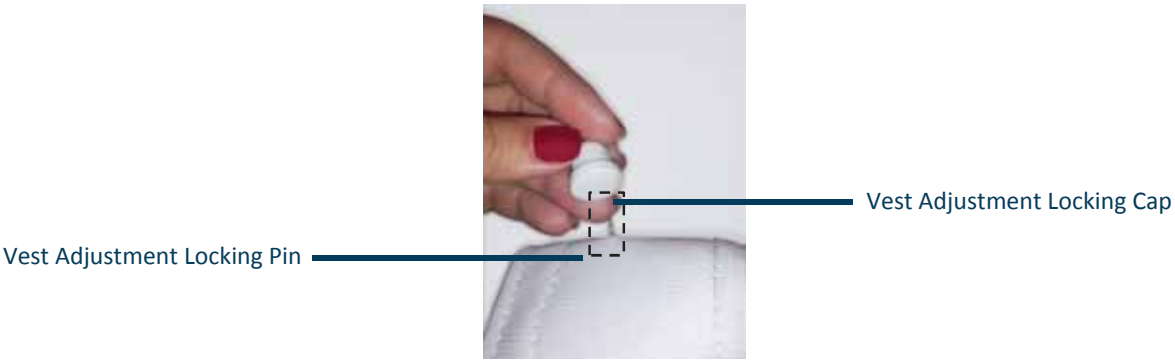



**Figure 31: Placing the Cap**

4 Take another pin and pierce through the right flap. Pierce through the eyelet which is the closest to the center of the strap, from the inside of the vest out, so that the pin will be pointing away from the body. Cover the pin with a locking cap making sure to insert the pin all the way into the hole in the cap. Try pulling on the cap to make sure it is locked in place. Note that you only need to use one pin to lock the flap

5 Take the third pin and pierce through the left flap. Pierce through the eyelet from the inside of the vest out, so that the pin will be pointing away from the body. Cover the pin with the last locking cap making sure to insert the pin all the way into the hole in the cap. Try pulling on the cap to make sure it is locked in place.

6 The vest adjustment is locked and ready to use.

**NOTE:**

- The vest has 3 adjustable flaps: Shoulder Flap, Left Flap and Right Flap. Make sure you locked all three.

### ► To unlock the vest adjustment:

After the vest adjustment is locked, it is ready for use by the patient for whom it was adjusted. The vest adjustment should not be changed throughout the use of the device by the patient. However, in case the vest needs to be re-adjusted, the vest should be unlocked first in the following way:

**CAUTION:**

- Magnetic Field
- Persons with medical implants KEEP BACK 30in. (76cm) from the unlocking magnet
- Interaction with metallic objects may produce Pinch Hazard.
- To avoid damage, keep magnetic media such as computer disks (including the ReDS System Console), credit cards and tapes away from the unlocking magnet.

1 Place the unlocking magnet on your desk

2 Bring one of the caps onto the center of the magnet. Press the pin down against the magnet to release it from the cap and then lift the vest. The cap will remain on the magnet and the pin will now be exposed.

**Figure 32: Detaching the Cap**

3 Carefully remove the pin from the vest and place away from the magnet.

**Figure 33: Removing the Pin**

4 Repeat for the remaining two caps and pins.

5 The vest can now be re-adjusted.

## Step 4: Powering Up

**WARNING!**

- This system should not be operated if there is any visible physical damage to any of its parts (Sensor Vest, Bedside Console, power supply or cables), such as cracks, breaks, tears and so on.
- The ReDS System should not be used in the vicinity of RF emitters such as magnetic resonance imaging (MRI) machines, computed tomography (CT) machines, RF diathermy devices, RFID devices and electromagnetic security systems such as metal detectors, as this may result in increased electromagnetic interference to the ReDS System.

### ► To power up the ReDS System:

1. Plug in the Power Supply to a standard power outlet. The blue LED (light) inside the **ON/OFF** power button lights up (Figure 1).
2. Briefly press the **ON/OFF** button on the top left of the console (Figure 1) to power on the console. Wait one minute, the console's start screen is then displayed, as shown below:


**Figure 34: Start Screen**

**NOTE:**

When used at home, the system should remain plugged into the power outlet at all times. The console has a screensaver, as shown below:

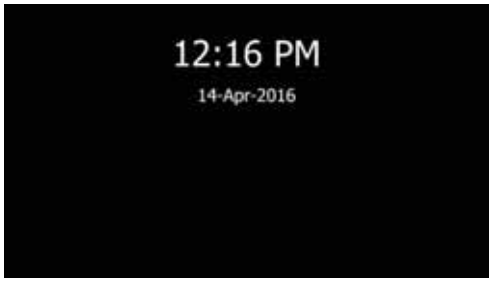



**Figure 35: Screensaver**

## Step 5: Setting Up a New Patient

A new patient must be set up as described below when using the system for the first time.

### ► To set up a new patient:

1. In the Start screen (Figure 34), tap **Start** → **Select Patient** → **New Patient**. The following screen is displayed:


**Figure 36: Patient Management Screen**

2. Read the patient's chest size, as described in the *Reading Patient Chest Size* section on page 43.
3. In the **Chest Size Ruler** field, enter the value read using the Chest Size ruler.
4. Double check the Chest Size Ruler value you have entered before proceeding.

5 In the **Patient ID** field, enter the patient ID.

6 Tap **Save**.

## Enrolling a New Patient in SensiCloud

**NOTES:**

This step is optional. You can set up the patient in the SensiCloud™ system now or at any other time in the future. Alternatively, you can use the ReDS System™ in Standalone mode (meaning without the SensiCloud™).

For full instructions for use and details about the SensiCloud please refer to Chapter 4: *The SensiCloud Portal*, page 60.

### ► To set up a new patient in the SensiCloud:

- In the Patient List screen, which is displayed after log in, press the **Add New Patient** button, the New Patient screen is displayed:

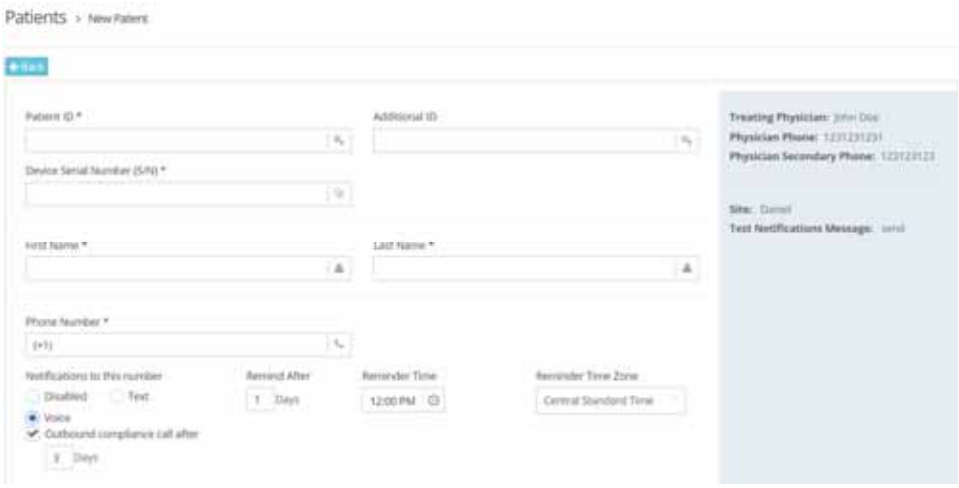



**Figure 37: Enrolling a New Patient**

- Fill in the patient information. Fields highlighted by an asterisk (*) are mandatory.
- In the **Device Serial Number** field, enter the serial number of the ReDS System used to measure this patient. The serial number of the ReDS System is written on the back of the Bedside Console.
- In the **Phone Number** fields, enter the patient's primary and secondary phone numbers.

- Set notifications  for the patient. If enabled, the primary phone number will be used for sending automatic measurement reminder messages to the patient (please use the appropriate international prefix number).
- Make sure all information is correct and tap the **Save** button.
- The new patient record is then displayed in the Patient List.

**CAUTION:**

Verify that the patient is assigned to the correct physician and that the phone number provided for contact is also correct. This can be easily done by viewing the Patient Details screen, which can be accessed from the Patient Graph View.

Verify successful setup and connectivity by performing a test measurement and viewing the results under the patient's graph view in the SensiCloud. For more information about how to view measurements results in SensiCloud you may refer to the *Using the SensiCloud* section on page 64.

## Reading Patient Chest Size

This procedure uses the vest's integrated Chest Size ruler.

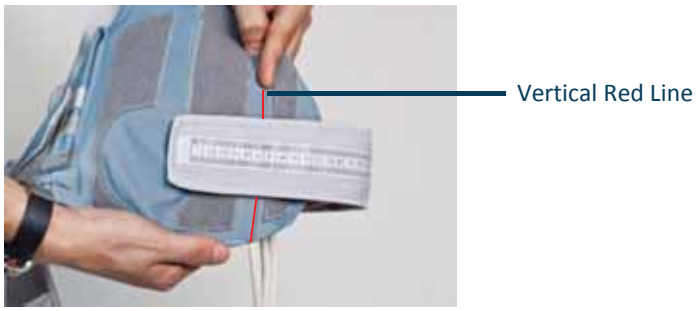



**Figure 38: Chest Size Measurement Ruler**

### ► To read the patient's chest size:

Look at which number the vertical red line crosses the Chest Size ruler. Note for example in the shown picture the chest size is 5.5 (the redline has cleared the 5$^{th}$ rectangle and an additional half of the 6$^{th}$ box). Choose the closest whole number marker or half box marker (i.e no need for higher accuracy than 0.5).

**CAUTION:**

- To ensure accurate measurements make sure to read and enter the chest size ruler value accurately.

# 3 Taking a Measurement

This chapter describes how to measure a patient using the ReDS System.

This chapter assumes that a sensor vest has already been adjusted for the patient to be measured, as described in *Chapter 2, Setting Up* on page 24.

**CAUTIONS:**

- To use the ReDS System correctly and dependably read all instructions in this user manual before using it.
- Before taking the measurement of a specific patient, check that you are using his/her personalized sensor vest by checking the label on the sensor vest, as described on page 21.
- Each sensor vest is adjusted for a specific patient. Do not use the sensor vest for any patient other than the one for which it was adjusted, as this may result in low quality measurements.
- Do not use the vest in case the vest adjustment locking pins are exposed.
- When using the device with multiple patients make sure to use the vest with proper disposable infection control garments to protect patients. Please refer to chapter 4 for additional information.

**NOTE:**

When the device is used for single patient monitoring, it is recommended to perform the measurement procedure described in this chapter early in the day (before 10 am) and in a consistent time and measurement position.

# Taking a Measurement – Workflow

The following provides an overview of the steps for taking a measurement using the sensor vest and a reference to the section of this user manual that provides detailed instructions.

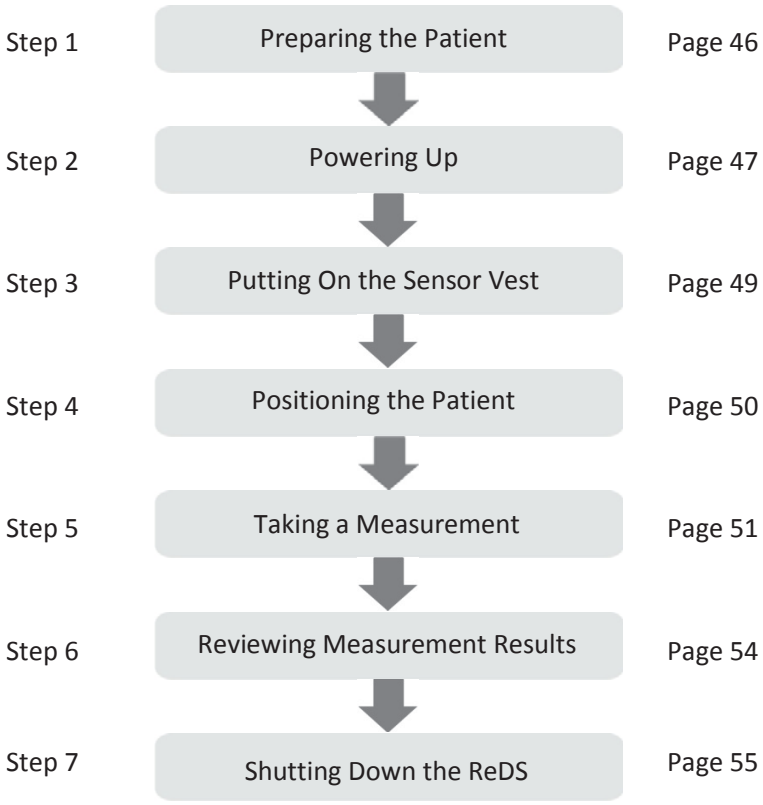



**Figure 39: Taking a Measurement – Workflow**

# Step 1: Preparing the Patient

► **To prepare the patient:**

- Make sure the patient is dressed in plain light clothing.
- Avoid using over a bra.

**CAUTION:**

To ensure high quality measurements, use the device over plain, light clothing such as a t-shirt or an undershirt. Metal elements under the sensors should be avoided, such as jewelry. Avoid using device over a bra.

## Step 2: Powering Up

**WARNING!**

- This system should not be operated if there is any visible physical damage to any of its parts (Sensor Vest, Bedside Console, power supply or cables), such as cracks, breaks, tears and so on.
- The ReDS System should not be used in the vicinity of RF emitters such as magnetic resonance imaging (MRI) machines, computed tomography (CT) machines, RF diathermy devices, RFID devices and electromagnetic security systems such as metal detectors, as this may result in increased electromagnetic interference to the ReDS System.

### ► To power up the ReDS System:

1. Plug in the Power Supply to a standard power outlet.

**NOTE:**

The system should remain plugged into the power outlet. The console has a screen saver. When the screen saver is displayed, simply tap the screen to redisplay. When the screen is completely black (off), then power on the ReDS System, as described above.

If the system is unplugged or if power is down, the following message will be displayed on the screen: “Power cord disconnected”

2. Press the **ON/OFF** button on the top left of the console (Figure 1) to power on the console. The blue LED (light) inside the button lights up and within one minute the following screen is displayed, as shown below:


**Figure 40: Start Measurement Screen**

3 The system is now ready to take measurements.

# Step 3: Putting On the Sensor Vest

► **To put the sensor vest on:**

**CAUTION:**

When using the device with multiple patients make sure to use the vest with proper disposable infection control garments to protect patients. Please refer to chapter 4 for additional information.

1 Pick up the sensor vest, slide the patient's right arm through the armhole and put the vest on the shoulder as close as possible to the neck, as shown below:

**Figure 41: Inserting the Right Arm into the Armhole**

2 Hold the sensor vest so that the upper Positioning Reference Point is just below the patient's suprasternal (Jugular) notch and the bottom Positioning Reference Point rests below the patient's breastbone (sternum), as shown below:


**Figure 42: Positioning the Sensor Vest for Measurement**

3 Grab the left flap. Make sure the flap is lying flat against the body and is not twisted.

4 While holding the sensor vest in place, fasten the buckle, as shown below:


**Figure 43: Fastening the Buckle**

## Step 4: Positioning the Patient

Position the patient as described below, and make sure the patient does not move, talk, drink, or use a cell phone while taking a measurement.

### ► To position the patient:

1 Instruct the patient to lie back in a reclined position, close to supine, in an adjustable bed, a reclining chair, or on a regular bed supported by pillows.

2 The patient should recline backwards into position and avoid rolling or sliding against the bed or chair while getting into position, as this may shift the vest's position.

3 Ensure that the patient is leaning back so that the back sensor is pressed against his/her back.

4 Ensure that the patient's arms are resting at his/her sides.

5 Ensure that the Front Sensor is entirely below the clavicle bone, such that the upper edge of the sensor is not touching it. Use your hand to feel both the upper edge of the front sensor and the patient's clavicle, as shown below:

**Figure 44: Verifying that the Front Sensor is Not Touching the Clavicle Bone**

**NOTE:**

If the patient's position requires correcting, ask the patient to sit back up, re-position and then recline back.

## Step 5: Taking a Measurement

The following screen is displayed:


**Figure 45: Start Measuring Screen**

**NOTE:**

If the screen is not displayed, the screen saver may be active. Simply tap the screen to redisplay the screen above. If the screen is completely black (off), then power on the ReDS System by pressing the **ON/OFF** button, as described in the *Step 2, Powering Up* section on page 47.

### ► To start measuring:

1. Tap the **Yes** button in the screen shown above (Figure 45). The following screen is displayed:


**Figure 46: Putting the Sensor Vest On**

2. If the sensor vest is not already on the patient, then put it on, as described in the *Step 3, Putting On the Sensor Vest* section on page 49.

3. Tap the screen to start the actual measurement process. The following screen is displayed while the red chest sensor inflates:


**Figure 47: Measurement Progress Screen**

**NOTE:**
If needed, tap the screen to abort the measuring process.

4. Wait while the measurement is performed. The red chest sensor in the front will start to inflate. The measurement takes 90 seconds.

**NOTE:**
The patient should not move, talk, drink, or use a cell phone during this time, as this may result in low quality measurement.

- Tapping the screen at any point during the measurement deflates the red chest sensor and stops the measurement process immediately.

- If a technical failure occurs, the measurement terminates immediately and a relevant message is displayed and sounded. Try again. You may refer to *Chapter 7, Troubleshooting* on page 86. Contact support if a problem persists.
- If the patient is uncomfortable, remove the sensor vest at any time to abort the measurement procedure.

**5** Wait until the measurement process ends automatically and the red chest sensor deflates. After a successful measurement the following screen is displayed, together with a message indicating the data transmission status (transmitting, transmitted successfully, transmission failed):


**Figure 48: Measurement Results**

**NOTE:**

If the measurement was not successful, then the following message is displayed: *Low quality measurement. Please remove the vest and try again.*

You may refer to page 54 for more information.

If the measurement was successful and if you are using the SensiCloud, the results are transmitted at this stage. After a successful transmission, the following message is displayed: ***Your measurement was transmitted successfully***. In any case of transmission failure, a message will be shown on screen and the results will be saved on the device until transmitted successfully. For additional information regarding data transmission, you may refer to *Chapter 7, Troubleshooting* on page 86.

**6** Remove the sensor vest. Place the sensor vest next to the Bedside Console or in the auxiliary basket if using a cart. This completes the measurement session.

Refer to the *Step 6, Reviewing Measurement Results* section on 54 for a description of the results.

### Unsuccessful Measurement

If the measurement was not successful, then the following message is displayed: *Low quality measurement. Please remove the vest and try again.*

Verify that the instructions in this chapter were followed correctly. It is recommended to check that the back sensor is pressed against the back, and that the patient does not move or talk during the measurement process. For additional information you may refer to *Chapter 7, Troubleshooting* on page 86.

Re-run the measurement process.

If this is the first time that the sensor vest is being used after it was adjusted, then repeated unsuccessful measurements may indicate that the sensor vest was not fitted properly. In this case, re-adjust the sensor vest by following the instructions in *Chapter 2, Setting Up* on page 24 and then re-run the measurement process described in this chapter.

If the problem occurs three times in a row, remove the sensor vest and contact support.

## Step 6: Reviewing Measurement Results

After a successful measurement process, the following is displayed on the Bedside Console screen:


**Figure 49: Measurement Ended**

The fluid content parameter is displayed in Ohm (Ω) units. When viewing fluid content by Ohm units, the display range is 177 Ω (low fluid content) to 70 Ω (high fluid content). The normal lung fluid content ranges roughly from 150 Ω to 105 Ω.

The results may also be displayed in percent units (%), representing the volume of fluid in the lung out of the total lung volume. The display range for the fluid content parameter is 15% (low fluid content) to 60% (high fluid content). The normal lung fluid content ranges roughly from 20% to 35%.

Tap the **Start** button to perform another measurement.

**CAUTION:**

The ReDS System fluid reading is intended to be used as an adjunct parameter to standard clinical assessment methods

## Step 7: Shutting Down the ReDS System*

*Perform the following only when the ReDS System is not going to be used for some time.

► **To shut down the ReDS System:**

1 Briefly push the **ON/OFF** button and wait for the shutdown process to complete.

2 Unplug the Bedside Console from the power outlet.

3 Store the sensor vest, as described in the *Storage* section on page 90.

# Step 8: Packing the ReDS System

If traveling with the ReDS System is required, please use the original device package to re-pack:

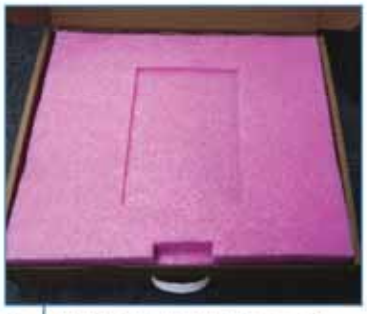
1 Remove sleeve and open package.
Remove top foam cover.

2 Remove this foam part.

3 Place device in package.
The metal base goes where the foam part was.

4 Return foam part over the metal base, and tilt screen all the way back.

5 Fold cable, and place vest on top of it.



6 Place the top foam cover and close the package (note the position of the small groove next to the carrying handle)

# 4 Multi-patient Use of the ReDS System in a clinical setting

This chapter describes how to use the ReDS System with multiple patients.

## Overview

The system may be used for monitoring of a single patient over a period of time (see chapter 5 next). The device might also be used by a health care provider, in the hospital or hospital like facilities, to obtain readings of multiple patients.

When used in a hospital or hospital like facilities with multiple patients, healthcare professionals should follow recommendations for standard precautions and/or institutional infection control guidelines designed to minimize the risk of transmission of pathogens, as well as the instructions provided in this chapter.

## Multi-patient Use Instructions

**CAUTION:**

- Stop using the device if there is a reason to suspect that it has been contaminated.
- When using the device with multiple patients, make sure to use the vest with proper disposable infection control garments to protect patients.

## ► Perform the following steps for each new patient:

1. Set up a new patient record (make sure to delete previously measured patient records, see step 4 below) as instructed on page 41

**NOTES:**

There is no need to lock the vest adjustment in this use case, as this is used to prevent alternations made by the patient during home use.

2. Before setting up the vest and before applying it to take a measurement ('Setting Up' process described in chapter 2, and to the 'Taking a Measurement' process described in chapter 3), apply a protective garment over the patient's upper body (e.g. disposable jacket, isolating gown, cape, or any other disposable garment that is cleared for clinical use in infection control) so that it separates it from the vest. After the vest is applied over the patient, apply an additional protective layer so that it covers the front of the vest from potential excretions (saliva, mucus etc.)
3. Dispose the used infection protective garments after use.
4. Delete the patient record when completing work with current patient:

**CAUTION:**

Make sure to delete the patient record when completing work with current patient and create a new patient record with the updated ruler value for the next patient to avoid using a wrong ruler value.

a. Tap the **Select Patient** button in the System Settings screen

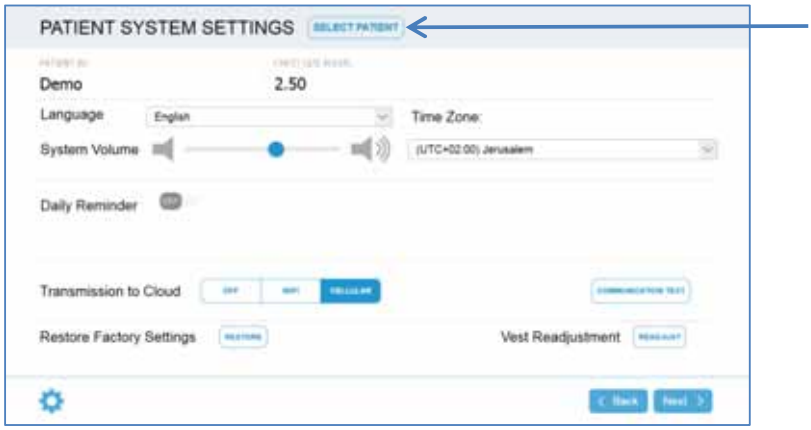



**Figure 50: System Setting Screen**

b. In the **Patient List screen** tap the row of the patient you wish to delete and then tap the **Delete** button:

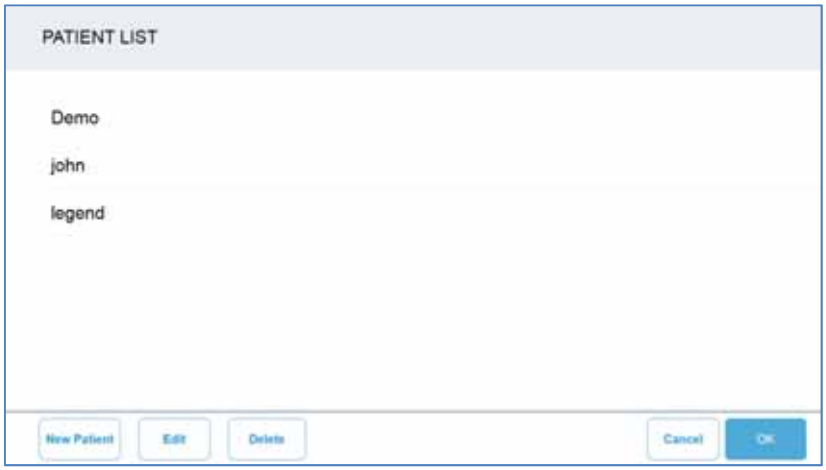



**Figure 51: Patient list Screen**

c. Approve the deletion by tapping **OK** in the confirmation pop up

5 Start again from step 1 above for every new patient.

► **At least once a week, perform a thorough visual inspection of the device:**

a. Detach the 3 flaps of the vest
b. Inspect the garment of the vest for any tears or opening of seams (both internal and external sides)
c. Inspect the Bedside Console, Power Supply and the Cables (power cable and vest cable) for any visible physical damage (cracks, breaks)

**WARNING!**

This system should not be operated if there is any visible physical damage to any of its parts (Sensor Vest, Bedside Console, power supply or cables), such as cracks, breaks, tears and so on.

# 5 The SensiCloud™ Portal

This chapter describes how to use of the SensiCloud Portal to monitor, record and review the thoracic fluid status of your monitored patients.

This chapter contains the following sections:

- **SensiCloud Overview,** page below, describes the main functions of the SensiCloud Portal.
- **SensiCloud Main Screens,** page 61, describes the three main screens of the SensiCloud Portal.
- **Using the SensiCloud Portal,** page 64, describes how to manage and track your patients using the SensiCloud Portal.
- **SensiCloud Troubleshooting,** page 72, describes how to troubleshoot various SensiCloud Portal problems.

## SensiCloud Overview

The SensiCloud enables quick and easy access to your patients' data through a simple user interface. The SensiCloud provides the following functions:

- Enrolling patients in the SensiCloud Portal.
- Pairing a specific ReDS System device (by serial number) to a patient in the system to enable collection of measurements.
- Providing healthcare providers with a graphical or tabular view of all the available fluid readings of their associated patients.
- Setting up lung fluid level thresholds and receiving automatic system notifications (via email and/or text messages) triggered by those user-defined thresholds.
- Enabling physician acknowledgement of notifications.
- Monitoring patients' compliance via missed daily readings indicators.
- Enabling automatic measurement reminder notifications to patients.
- Recording of textual time-stamped notes per patient.

### Connecting over the Internet

All SensiCloud Portal users should use an active internet connection and one of the following (or newer) browser versions: Internet Explorer 11, Chrome 35 or Firefox 30. You may contact support for technical compatibility and assistance.

## SensiCloud Main Screens

The following are the three main screens of the SensiCloud Portal:

### Patient List

The Patient List enables a  physician or healthcare provider to display a concentrated tabular view of all patients. For each patient this screen shows the last measurement value and graphical indicators of threshold parameter-related notifications and missed readings (indicating the number of days since a reading has been successfully received).

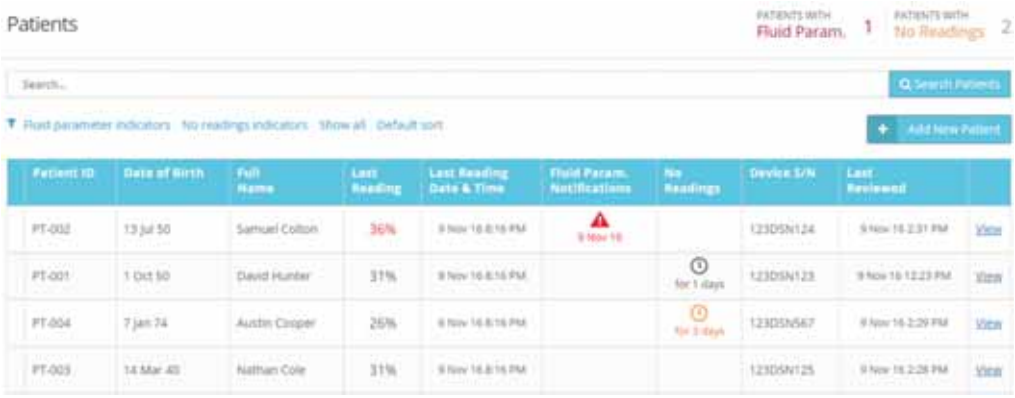



**Figure 52: Patient List**

For additional details and historical readings, you can click the **View** link in the right most column on each line or on the patient ID to display the Patient Graph View, described below.

## Patient Graph View

The Patient Graph View displays the patient's historical readings in a graphical or tabular view. This view enables you to adjust thresholds that trigger notifications and to acknowledge received notifications. Time stamped notes may be recorded for general purposes.

**Figure 53: Patient Graph View**

## My Account

The **My Account** screen enables you to enter your details and to define your notification message preferences. This defines the timing and type of automatic messages sent to you. Messages are sent once a day, if your predefined notification threshold for one or more of the monitored patients is exceeded. The notification message reminds you to log into the system, and may be chosen to be received in the form of email, text message or both, and also may be disabled completely or during weekends and federal holidays.

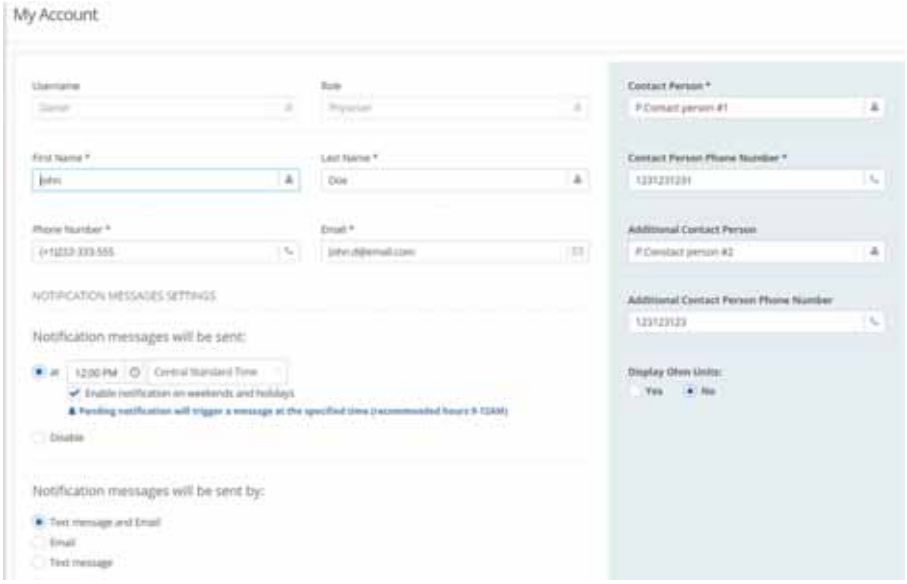



**Figure 54: My Account Screen**

# Using the SensiCloud

This chapter describes how you can manage and track your patient's fluid readings using the SensiCloud System.

**NOTE**

- In cases where the SensiCloud™ service is unavailable, a healthcare provider may contact the patient to inquire about his/her fluid readings.
- When using the SensiCloud Portal, it is recommended to assess the patient's measurements at the same time each day, preferably in the late morning after most patients have completed their lung fluids measurements.

## SensiCloud Portal Login

Log in using your personal user name and password

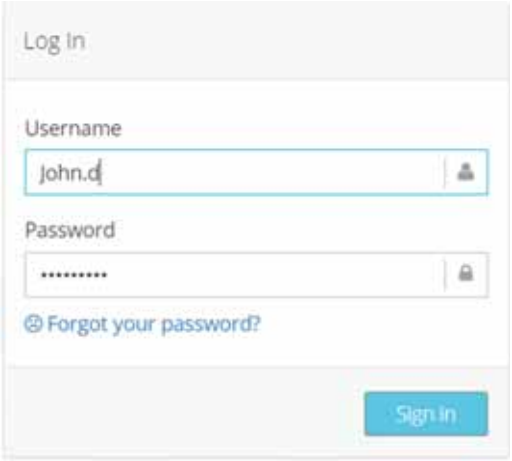



**Figure 55: Login Screen**

## Enrolling a New Patient using the SensiCloud

► **To set up a new patient using the SensiCloud:**

- In the Patient List screen, which is displayed after log in, press the **Add New Patient** button, the New Patient screen is displayed:

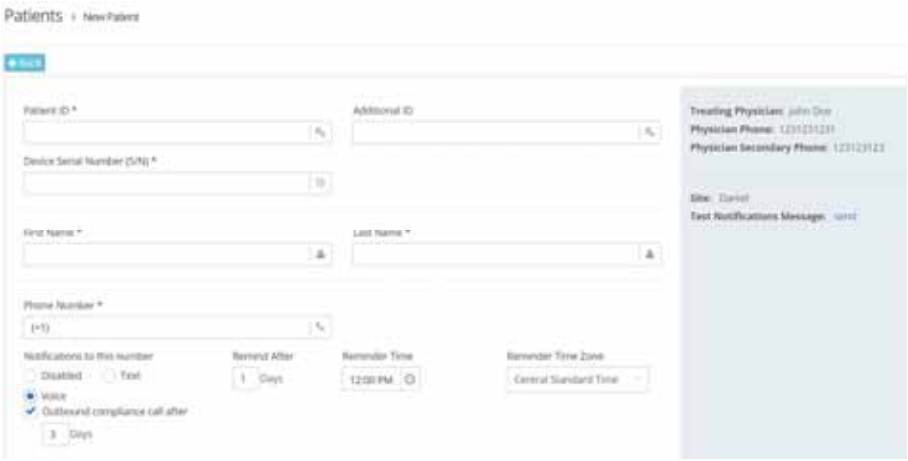



**Figure 56: Enrolling a New Patient**

- Fill in the patient information. Fields highlighted by an asterisk (*) are mandatory.
- In the **Device Serial Number** field, enter the serial number of the ReDS System used to measure this patient. The serial number of the ReDS System is written on the back of the Bedside Console.
- Enter the patient's primary and secondary phone numbers in the **Phone Number** fields.
- Set reminder notifications ON/OFF for the patient. If ON, Voice or text messages can be selected. The primary phone number will be used for sending automatic measurement reminder messages to the patient (please use the appropriate international prefix number, press on the ℹ icon for proper phone number formats).
- Make sure all information is correct and tap the **Save** button.
- The new patient record is then created and displayed in the Patient List.

⚠ **CAUTION:**

Verify that the patient is assigned to the correct physician and that the phone number provided for contact is also correct. This can be easily done by viewing the Patient Details screen, which can be accessed from the Patient Graph View.

**CAUTION:**

Verify successful setup and connectivity by performing a test measurement and viewing the results under the patient's graph view in the SensiCloud. For more information about how to view measurement results in SensiCloud, refer to the *Using the SensiCloud* section on page 64.

## Editing Patient Details

► **To edit patient details:**

1. **Log in** to the SensiCloud, as described above. The Patient List screen is then displayed.
2. Select the patient whom you wish to edit by clicking either the **View** link in the right most column or the patient ID.
3. Click the **View Patient Details** button on the right corner of the screen. The Patient Details screen is displayed:

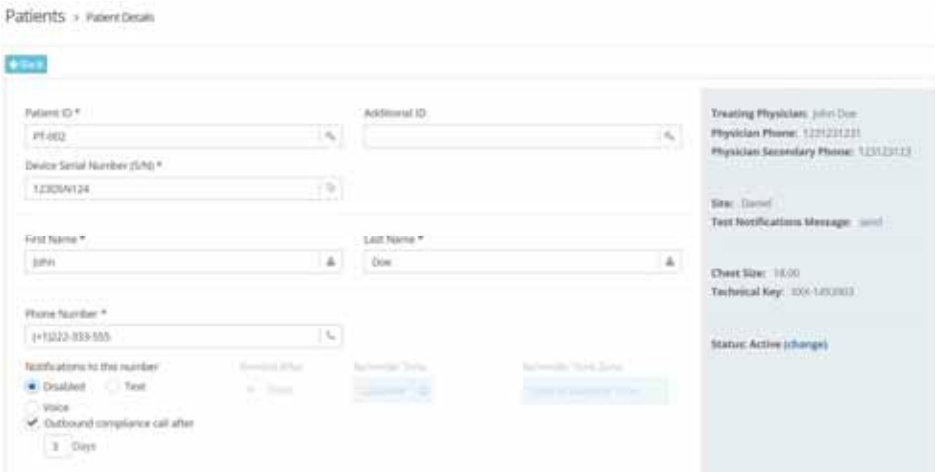



**Figure 57: Editing Patient Details**

4. Edit the information and when done click the **Save** button

## Suspending a Patient

Suspending a patient is useful where you need to pause monitoring of a patient for a limited time.

**NOTE**

- Suspending a patient will disable reminder notification messages to that patient.
- If a reading is received for a suspended patient, the system automatically changes the status for this patient back to Active.
- Suspended patients will be displayed in the Active Patient List in Gray.

### ► To suspend a patient:

1. **Log in** to the SensiCloud, as described above. The Patient List screen is displayed.
2. Select the patient whom you wish to suspend by clicking either the **View** link in right most column or the **patient ID**.
3. Click the **View Patient Details** button on the upper right corner of the screen. The Patient Details screen is displayed:

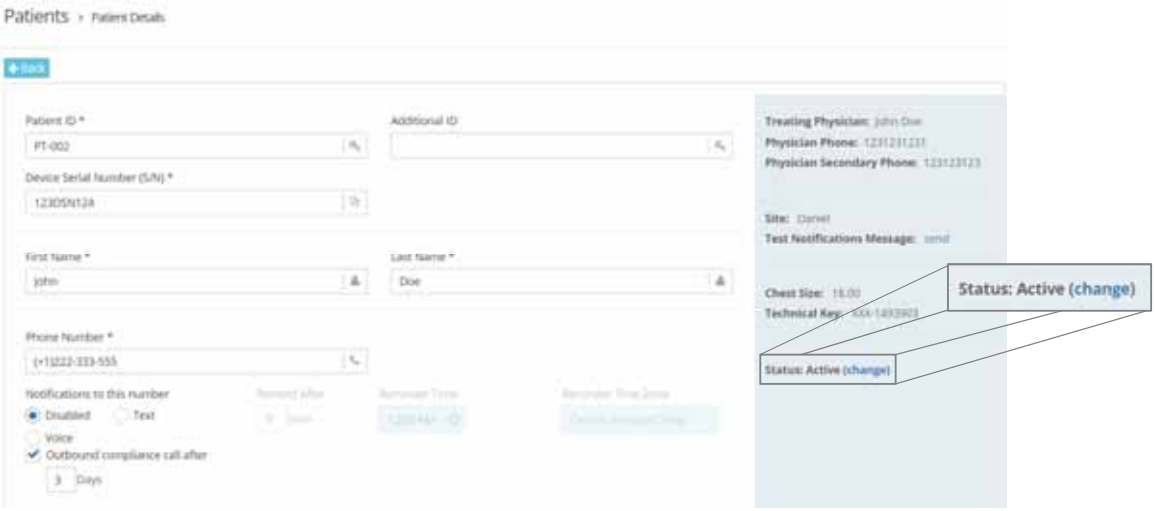



**Figure 58: Suspending a patient**

4. Click the **(change)** button located next to the 'Status'
5. Click 'OK' to confirm or 'Cancel'.
6. Tap **Save**.

**NOTE**

To change a patient back to active, repeat the above steps.

## Archiving a Patient

Archiving a patient may be used for archiving the data for patients who are no longer being monitored. Doing so will remove him/her from the active patient list, and will disable all notifications related to that patient. 'Archived' patients' data is displayed in the 'Archived Patients' list in the Patient List screen. Archived patients are not visible to Administrative Users.

**NOTE**

- Archiving a patient will disable reminder notification messages to that patient.

## ► To Archive a Patient:

1. **Log in** to the SensiCloud, as described above. The Patient List screen is displayed.
2. Select the patient whom you wish to archive by clicking either the **View** link in right most column or the **patient ID**.
3. Click the **View Patient Details** button on the upper right corner of the screen. The Patient Details screen is displayed:

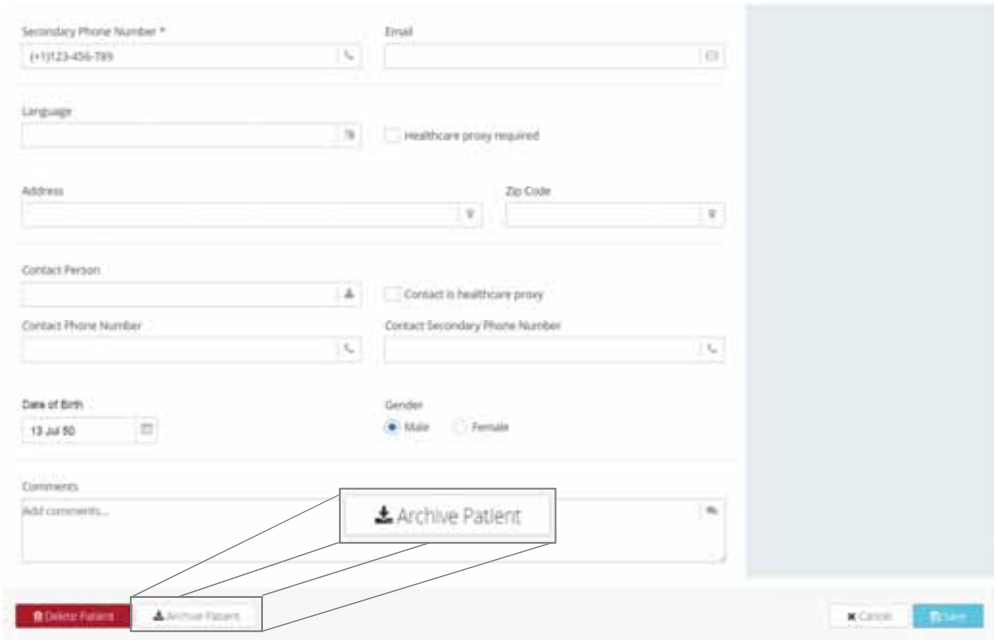



**Figure 59: Archiving a patient**

4. Click the **Archive Patient** button located at the bottom
5. Click **Yes, Archive Patient** to confirm or **No, go back to patient screen** to cancel.
6. Tap **Save**.

**NOTE**

To change a patient back to active, repeat the above steps, this time the button will change its name to 'Mark as Enrolled'. You will need to provide the device serial number.

## Viewing the Patients List

After login or completion of a New Patient Enrollment (as described above), the Patient List is displayed showing all active patients.


**Figure 60: Patient List – Default Sort**

By default the table is sorted as follows:

- Patients that have both missed readings notifications and active fluid parameter notifications are displayed at the top of the list.
- This is followed by patients that have active fluid parameter notifications.
- This is followed by patients that have missed reading notifications.
- This is followed by patients that had a fluid parameter notification which was acknowledged but their last reading result still exceeds the predefined thresholds.
- This is followed by the rest of the patients, meaning patients with no fluid parameter notifications and no missed readings.

Clicking a column header sorts the entire table according to the selected parameter. To return to default, click the Default sort button

Clicking either the **View** link in right most column of each line or the patient ID will display the Patient Graph View described below. The time and date when a healthcare provider last viewed a patient's Graph View is displayed in the "Last Reviewed" column.

Last Reading results are provided both in Ohm (Ω) units and in percent units (%).

Pressing the Archived Patients button on the top will show all the patients that were archived.

## Reviewing the Patient Graph View

**NOTE**

In cases where the SensiCloud™ service is unavailable, a healthcare provider may contact the patient to inquire about his/her fluid readings.

The Patient View screen displays the current and historical readings in a graphical or tabular view. Tabular view is available by pressing the “Table View” tab.

Hovering over a measurement displays its timestamp and fluid content value.

You can use the Zoom tool and then click and drag anywhere on the plot area, to pan to your region of interest.

You can record textual time-stamped notes per patient. All your recorded notes will be displayed in a chronological order in addition to notes recorded for the patient by other users, including administrative users.

### ► To record a note:

1. Click the **Add New Note** button.
2. Type your note into the free-text field. Select note type from the drop menu. For notes of type ‘Marker', a triangular time marker will be displayed in the plot area according to their post time and date (see figure 58).
3. For notes of type ‘Marker’ you may adjust the note timestamp if necessary.
4. Click the **Save** button to record the note.

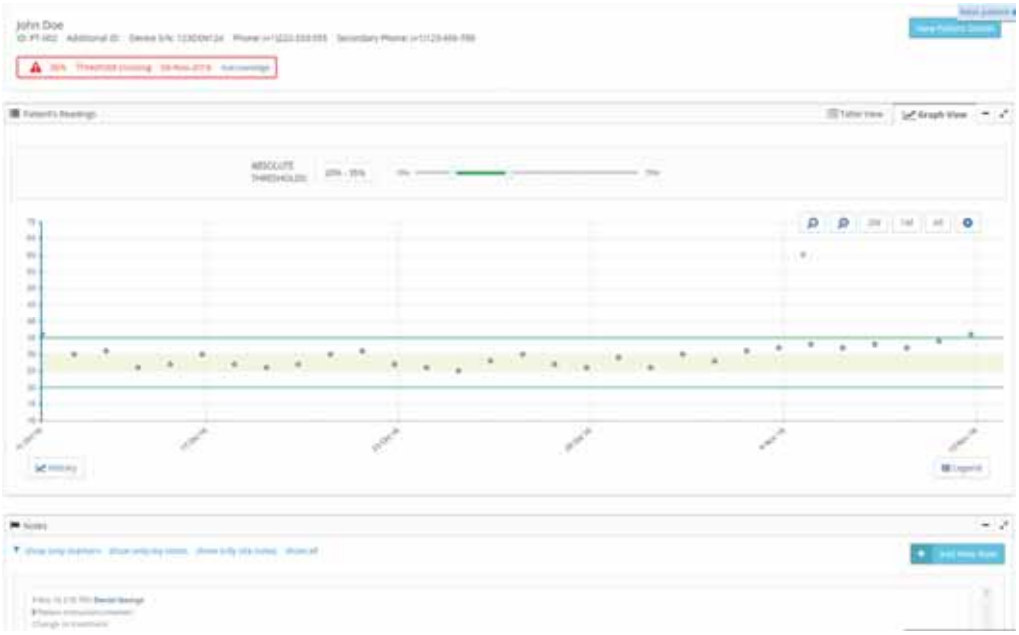


**Figure 61: Patient Graph View**

## Setting the Lung Fluid Threshold per Patient

► **To set the lung fluid thresholds for a patient:**

1. Click either the **View** link in the right most column of each patient row or the patient ID to access Patient Graph View.
2. You can set the lower and upper thresholds by either dragging the slider handles to the left or right or by typing the new threshold in the threshold value textbox (see Figure 62). The center of the range is indicated graphically by a green zone. In the event that a reading is received and it is higher than the upper threshold OR lower than the lower threshold, a notification for the patient will be triggered. You may change your notification preferences under 'My Account' screen.

**NOTE**

Thresholds settings affect triggering of notifications as indications in the patient list as well as notification messages sent by emails or text messages. The default setting for the thresholds range is 20%-35%. Note that selecting a wide threshold range will cause notifications not to be triggered.

**CAUTION:**

The healthcare provider should review patient data as needed, irrespective of the notification functionality provided by the SensiCloud Portal.

**NOTE**

For convenient follow up, every threshold change for a patient automatically generates a time-stamped note that contains the information about the change. This note will be shown both in the notes list on the bottom of the page as well as in the plot area according to the time and date in which the change was made.

## Viewing and Acknowledging Notifications

As described in the *My Account* section above notification will appear in the Patient List and in the Patient Graph View for each reading that is outside defined thresholds. In addition this will trigger a notification via a daily email, text message, or both, as defined under *My Account*.

In the Patient Graph View screen an active notification that has been triggered should be acknowledged by clicking on the Acknowledge text in the red notification box.

Notifications that have not been acknowledged will trigger additional daily reminder messages.

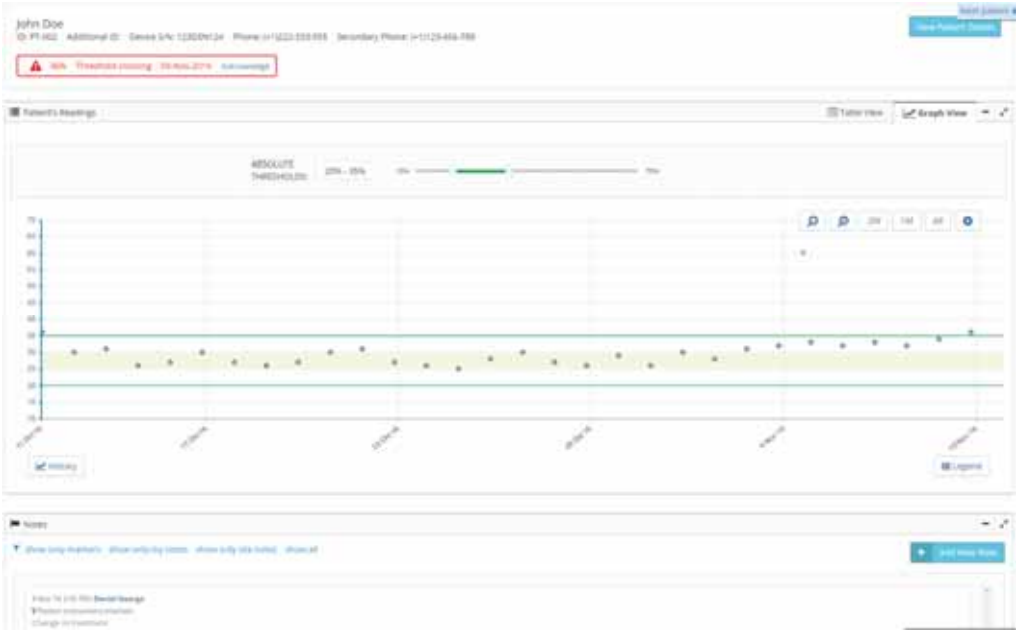


**Figure 62: Patient Graph View**

## Administrative User

The cloud portal also provides functionality for centrally monitoring system use, monitoring patient compliance and performing system administration tasks. These functions may be used by healthcare providers or by administrative users supporting the healthcare providers' workflow.

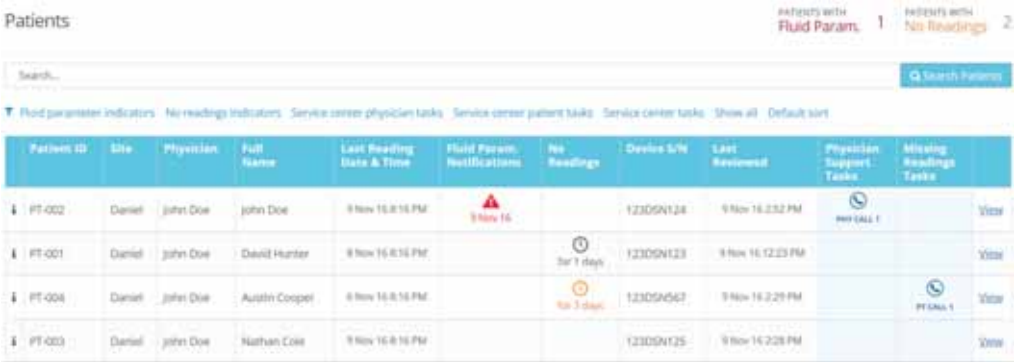
## Patient List

The main screen of the administrative user is the patient list which in this case contains all patients from all sites and physicians to whom the administrative service is provided.

The user can monitor indicators of missing readings (*Missing Readings* indicator) for non-compliant patients, as well as indicators of patients' fluid reading related notifications status (*Fluid Param Notifications* indicator). The cloud portal also presents the administrative user with two additional indicators:

- The *Physician Support Tasks* indicator shows up when the attending physician has not acknowledged the *Fluid Parameter Notification* in a timely manner.
- The *Missing Readings Tasks* indicator shows up when the patient has consistently failed to take her/his readings as required.

These task indicators may be used by the administrative user as a reminder to contact either the attending physician or patient and provide additional support.




**Patients List - Administrative User View**

For an administrative user, the patient list provides the following information: Patient ID, treating physician and site, last reading transmission time, notification indicators, time and date of last Patient Graph review by the caring physician, Physician Support Tasks indicator, Missing Readings Tasks indicator and device serial number.

The list is sorted first by site, enabling the administrative user to easily review a selected site's patients. Within each site, the list is then sorted by physician and for each physician, the patients are displayed according to the default sort described in 'Viewing the Patients List' on page 66.

Searching the table is available by the following information types: Patient ID, Site, Physician, Full Name and Device SN.

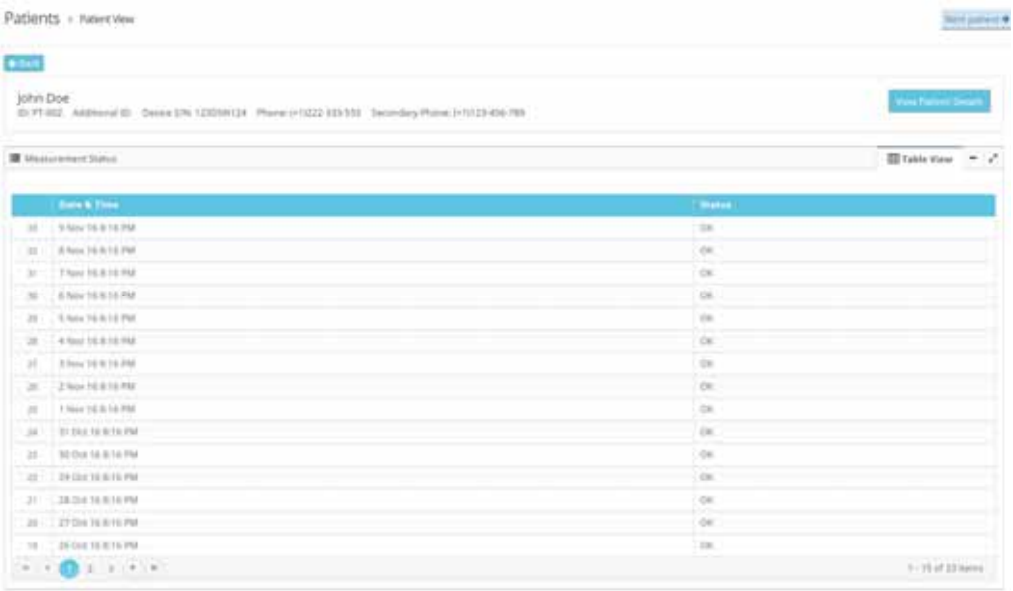
### Tool tip

Pressing the ℹ icon available next to each patient ID will display the available contact information.

## Patient View

Pressing either the 'View' button or the patient ID of each patient on the list will show the patient view screen. In this screen all patient measurements are shown in a tabular view, without the actual results. Timestamp and the validity of each measurement performed by the patient are shown in each line. Each measurement can have one of the following status types:

1. OK – Valid measurement.
2. QF – Quality Feedback. Measurement of low quality for which a result could not been calculated.
3. Stopped by user – Measurement that was stopped before it has been completed. Results are not calculated.
4. Error – Measurement that was not successful due to a technical malfunction.



Additionally, notes recorded by administrative users for the viewed patient are shown below the table.  My Account

"My Account" screen enables the administrative user to provide and edit his personal details.

## SensiCloud Troubleshooting

The following describes how to troubleshoot various system problems. If a problem cannot be solved contact support.

| Problem | Potential Causes | Action Required |
|---|---|---|
| SensiCloud Portal is inaccessible | SensiCloud server failure, communication problems. | Wait a few minutes and try again. If the problem persists, contact support. |
| Unable to login to SensiCloud | Wrong user name, password, or both. | Enter your user name and password again.  Passwords are case sensitive.<br>In case you forgot your password, press 'forgot your password' and follow the instructions on screen. |
| | Your account has been locked due to multiple retries to connect with wrong authentication details | Contact support for unlocking your account. |

# 6 Assigning ReDS System to a Patient for Home Use

**CAUTION:**

Make sure to provide the patient with the **Patient's User Manual** and the **Patient's Quick Reference Guide** (provided with each device).

This chapter discusses the main steps and issues that healthcare professionals should communicate to patients when prescribing the ReDS System for home use It also discusses the main tasks that the healthcare professional should practice with the patient.

This chapter assumes that a sensor vest has already been adjusted for the patient by the healthcare provider, as described in *Chapter 2, Setting Up* on page 24.

The training session consists of two parts.

- Part one reviews the ReDS System manual, including its intended use and safety instructions.
- Part two is a tutorial in which the patient practices the key tasks required for proper ReDS System operation.

# Training the Patient – Workflow

The following provides an overview of the steps for training a patient to use the ReDS System. A reference is provided to the section of this user manual that provides detailed instructions.

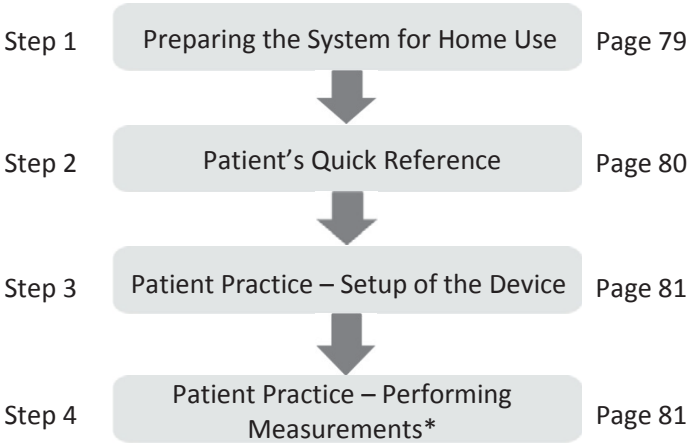



**Figure 63: Taking a Measurement – Workflow**

* Locking the vest adjustment may be performed after this step, see Page 36.

# Step 1: Prepare the System for Home Use

► **To prepare the system for home use:**

1. If using the SensiCloud, make sure that communication is set up by checking that the USB cellular modem is inserted into the back of the Bedside Console. Use the white straps to secure in place. The USB cellular modem is provided with the ReDS System package. For additional information about communication troubleshooting, you may refer to *Chapter 7, Troubleshooting* on page 86. Note that Wi-Fi solutions for connectivity are also available in cases of cellular coverage problems. For further information regarding these options please contact support.

2 Set the measurement reminder time, the preferred audio volume, the time-zone and select system language as described in the *Configuration* section on page 83.

## Step 2: Patient's Quick Reference Guide Review

Introduce the ReDS System to the patient and review the following sections in the Quick Reference Guide:

- Important Safeguards:
  - Read each warning and caution with the patient.
  - Make sure that each of the warnings and cautions are clear to the patient.
- Setting Up the ReDS System for Use:
  - Review each step with the patient
  - Discuss considerations for optimal Bedside Console positioning (i.e. at the patient's right hand side when in measurement position).
- Taking a measurement
- Guide the patient where to find troubleshooting and contact information

**Checkpoint:**

After reviewing each chapter with the patient, make sure that the patient understands the main points that were explained and that he/she feels confident enough to continue.

## Step 3: Patient Practice – Setup of the Device

Work with the patient to practice setting up of the device:

- Take the device out of the box and position it in place:
  - The Bedside Console should be placed on a flat and stable surface.
  - It is preferable to place the Bedside Console on the right hand side of the patient.
- Connect the USB cellular modem to the port.
- Plug the device into the power outlet.
- Turn on the system.

After completing these procedures, ask the patient to perform them again, but without your assistance.

**Checkpoint:**

Ensure that the system is in place, turned on and ready for use. If this checkpoint is OK, then continue to *Step 3, Practice – Performing Measurements* on page 81.

## Step 4: Patient Practice – Performing Measurements

**NOTE:**

Instruct the patient to perform the measurement procedure described in this chapter early in the day (before 10 am) and in a consistent time and measurement position.

Work with the patient to practice performing a measurement:

- Apply the vest correctly on the body:
  - Make sure that the patient puts the vest on the shoulder as close as possible to the neck.
  - The patient can use the auxiliary strap to grab/catch the left flap.
  - Make sure that the patient places the upper Positioning Reference Point just below the suprasternal notch.
  - For easier buckle fastening, the patient should hold the buckle and slide the two parts toward each other, as shown below:

**Figure 64: Fastening the Buckle**

- Instruct the patient to get into the correct measurement position. Make sure the patient reclines backwards avoiding rolling or sliding against the bed or chair while getting into position and that the back sensor is pressed against the back rest. Instruct him/her not to move or talk during measurement.
- Have the patient use the user interface to perform a measurement.

After completing these procedures, ask the patient to perform them again, but without your assistance.

**Checkpoints:**

- Ensure that the vest is applied correctly over the patient's thorax.
- Ensure that the patient understands the interactive user interface and succeeded in initializing a measurement.
- Ensure that the patient gets into the correct measurement position without rolling or sliding against the bed or chair and that he/she was not moving or talking during measurement.
- If using the SensiCloud, verify that the measurement results appear on SensiCloud as expected.

**CAUTION:**

Have the patient repeat the practice session as needed until all checkpoints have been achieved.

Once training is completed successfully, pack the system for the patient. Make sure to put the patient's manual, quick reference guide and contact card in the ReDS System box and remove the healthcare provider manual and quick reference guide. Note that the USB cellular modem may be left connected to the console.

# 7 System Configuration and Transmission to Cloud

This chapter describes the system configuration and Transmission to Cloud options.

## Configuration

The Configuration screen enables you to configure the ReDS System.

► **To configure the ReDS System:**

1 In the Main screen (Figure 34), tap the **Start** button.

The following screen is displayed:

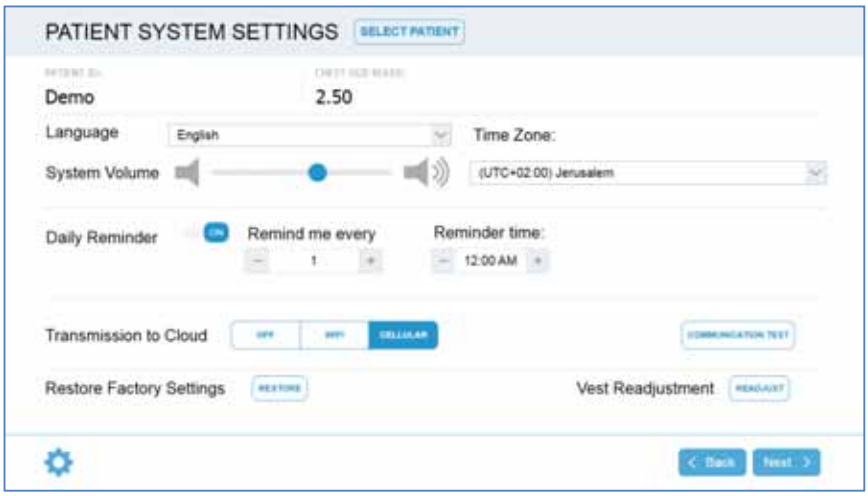



**Figure 65: System Configuration Screen**

2 Use the options in this screen, as follows:

- **Language:** Select the language of the Bedside Console screen interface.
- **System Volume:** Select the volume of the sounds and alerts made by the Bedside Console.
- **Time Zone Selection:** Select your correct time zone (default time zone is CST)
- **Measurement Reminder Scheduling:** Disable, enable, and set time for the measurement reminder.
- **Transmission to Cloud:** Disable, or enable and select Wi-Fi or Cellular. Also test communications with the SensiCloud by pressing the Test button. A success/failure message will follow. For more details on Transmission to Cloud see next section.

## Transmission to Cloud

The device enables easy synchronization of results and other data to the SensiCloud Portal (via either cellular / Wi-Fi communication).

The 'Transmission to Cloud' feature allows automatic transmission of measurement results. It is controlled through the **OFF / WiFi / Cellular buttons** as shown below:

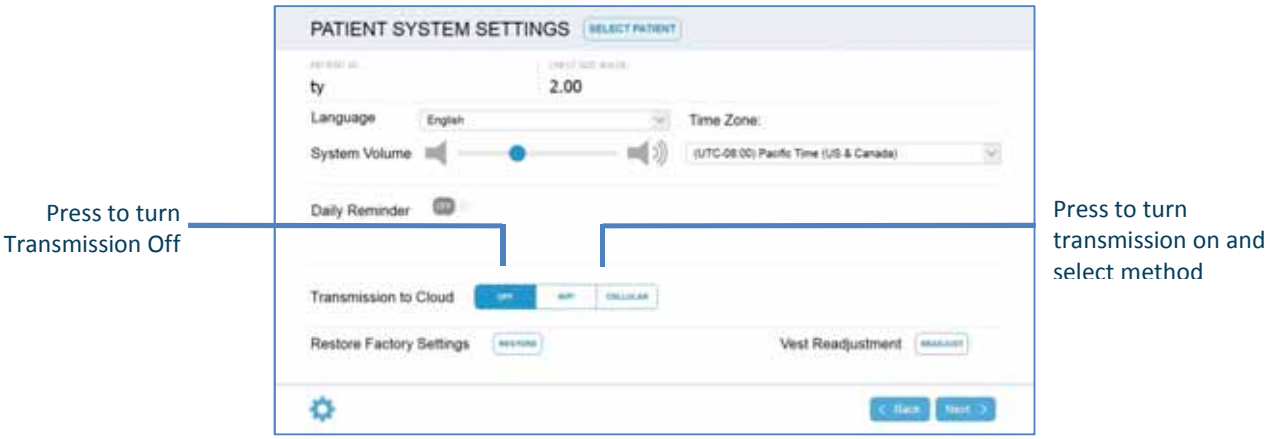



**Figure 66: Transmission to Cloud: Wi-Fi, Cellular, OFF Selection**

**NOTE:**

'Transmission to cloud' is ON by default to allow for cellular communication to the SensiCloud. If Wi-Fi is used, "Wi-Fi" should be selected accodingly. It should be turned OFF when neither cellular communication nor Wi-Fi are available or if no communication is required ("Standalone"). See Chapter 7 System Configuration or contact support for more information.

**NOTE:**

In order to allow successful transmission of all data, do not disconnect the system from the power outlet until the system announces that the transmission has ended. Disconnecting during data transmission aborts the process and requires the data to be sent again.

## Signal Strength Indicator

The cellular signal strength as received by the device's USB cellular modem is indicated in the form of a cellular signal bars indicator. Use the indicator to troubleshoot cellular coverage issues.

Similarly, if using Wi-Fi, standard Wi-Fi strength indicator is displayed. Additionally, the blinking blue led on the USB adapter is another indication of a good signal and working connection.

# 8 Troubleshooting

This chapter describes how to troubleshoot various system problems. If a problem cannot be solved, contact support.

**Table 1: Troubleshooting**

| Problem | Potential Causes | Action Required |
|---|---|---|
| System is unresponsive | No power<br>System is off | Make sure the power supply is properly plugged into a working outlet. Press the **ON/OFF** button. In some cases charging of up to 15 minutes will be required |
| | System malfunction | Press and hold the **ON/OFF** button for five seconds, release it, and then press it again. |
| Message displayed: "Low quality measurement" | 1. Patient slid or rolled on the bed or chair while lying back and the vest has moved.<br>2. Vest was applied over multiple layers of clothing or thick clothing.<br>3. Sensor-vest positioning reference points were not centered on the breastbone when the vest was applied.<br>4. Patient was moving or talking during measurement | 1. Remove the sensor vest.<br>2. Make sure patient is wearing light clothing.<br>3. Reapply the sensor vest according to the instructions making sure shoulder strap is close to the neck.<br>4. Guide patient into position and ensure the patient is not rolling or sliding against the bed or chair.<br>5. Re-run the measurement and make sure movement and talking during the measurement are avoided.<br>6. If the problem repeats more than twice, contact support. |

| Problem | Potential Causes | Action Required |
|---|---|---|
| Message displayed: "System Malfunction" | Technical malfunctions | 1. Press and hold the **ON/OFF** button for five seconds, release it and then press it again. The system restarts.<br>2. If the malfunction persists, stop using the system and contact support. |
| Message displayed: "Data Transmission Failure" | USB Cellular modem is not connected | Connect your USB cellular modem to the USB port on the back of the console.<br>If the USB cellular modem is already connected, disconnect it and then reconnect. |
| | Bad or no cellular reception | Change the console position to improve cellular reception. Use the signal reception indicator available on screen to verify that the minimal quality of service is available (indicated by at least one bar). |
| | Wi-Fi issues (If using Wi-Fi) – LED on the Wi-Fi adapter not flashing | Make sure that the USB Wi-Fi adaptor is connected to the USB port on the back of the console. If the USB Wi-Fi adaptor is connected, disconnect it and then reconnect. |
| | | Make sure that the Wi-Fi router is within 30 feet of the device |
| | | Restart the router by turning it off, waiting for two minutes and then turning it back on. If the problem persists, contact support. |

# A Labeling

This appendix shows the label that is attached to the ReDS and describes the symbols that appear on them. Note that the labels shown here are for reference only.

## System Labels

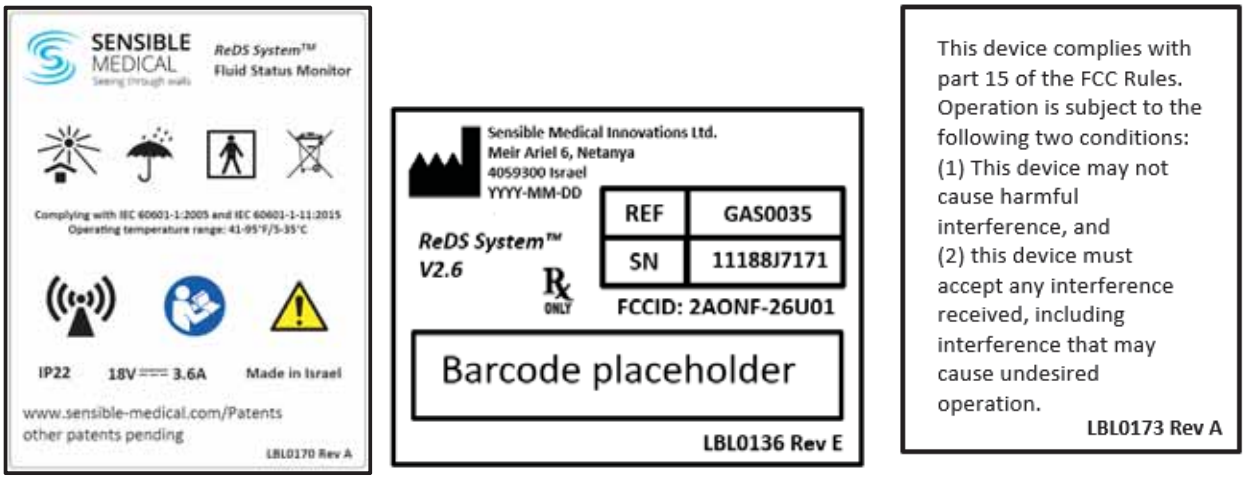
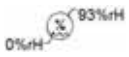
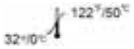
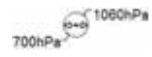



**Figure 67: System Identification Labels Samples**

# Labeling Symbols

**Table 2: Labeling Symbols**

| Symbol | Description |
|---|---|
| Fluid Status Monitor | Intended Purpose |
| ReDS System | Product Commercial Name |
| V2.6 | Model ID |
|  | Federal law restricts this device to sale by or on the order of a physician |
|  | Follow instructions for use |
|  | Keep dry |
|  | Keep away from sunlight |
|  | Degree of protection against electric shock (Type BF) |
|  | Waste of electrical and electronic equipment |
| **IP22** | Protected against solid objects greater than 12.5 mm<br>Protected against dripping water when tilted up to 15° |
|  | General warning |
|  | Manufacturer |
|  | Storing and shipment allowed humidity range |
|  | FCC ID Number |

| Symbol | Description |
|---|---|
|  | Manufacturer commercial logo |
|  | Non-ionizing radiation |
|  | UDI (Unique Device Identifier) |
|  | Magnetic Field |
|  | Catalog number |
|  | Serial number |
|  | Electrostatic sensitive devices |
|  | Direct Current |
| LBL0315 Rev. A | Label number and revision |
| Made in Israel | Country of origin where the product was manufactured or assembled |
| Meir Ariel 6,<br>Netanya<br>4059300 Israel | Manufacturer address |
|  | Storing and shipment allowed temperatures |
|  | Storing and shipment allowed pressure range |
| | |

# B Handling

This appendix describes how to store, clean and maintain the ReDS System.

## Storage

Store the sensor vest indoors in a dry and protected place, preferably in its shipping box.

Between measurements, it is recommended to leave the Bedside Console plugged into a power outlet.

Storage and shipment conditions are as follows:

- Temperature: 32°F to 122°F
- Relative Humidity: 0% – 93% non-condensing
- Atmospheric Pressure: 700 hPa to 1060 hPa

Gather loose cables (sensor vest cable and power cable) by wrapping them around the Bedside Console. When using the Cart configuration, use the utility basket to store the sensor vest, the power supply and their cables.

## Cleaning

If soiled or if cleaning is needed:

- The device should be wiped clean using an approved medical grade 70% alcohol disinfectant or equivalent tuberculocidal disinfectant.
- The screen should be cleaned using a standard computer screen-cleaning solution.

# Maintaining

- No user maintenance is required for the ReDS System. This device must only be serviced by Sensible Medical Innovations Ltd. qualified personnel.
- There are no user-serviceable parts inside the ReDS System.
- Contact support in case of battery malfunction.
- The ReDS System can be used multiple times on a specific patient. After this patient no longer requires it, the ReDS System must be returned. Contact support for more information.

# C Technical Information

This appendix provides ReDS System technical specifications and other technical information.

## Technical Specifications

**Table 3: Technical Specifications**

| Electrical Requirements | |
|---|---|
| | 100–240 VAC, 50/60 Hz<br>0.75 A @ 100 VAC<br>0.35 A @ 240 VAC |
| **Sensor Electromagnetic Information** | |
| Operating Frequency | 0.95-2 GHz |
| Frequency Band | 0.95-2 GHz |
| Type of Modulation | Stepped CW |
| Type of Modulating Signal | NA |
| Frequency of Modulating Signal | NA |
| Effective Radiated Power | -20dBm (0.01 milliwatt) or lower |
| Bandwidth of the Receiving Section | 0.95-2 GHz |
| **Mechanical** | |
| sensor vest Weight | 4 lbs |
| Bedside Console Weight – Cart | 31.2 lbs ± 10% |
| Bedside Console Weight – Tabletop | 7.2 lbs ± 10% |

| | |
|---|---|
| Bedside Console Height – Cart | 48.23 inches ± 10% |
| Bedside Console Height – Tabletop | 10.83 inches ± 10% |
| Sensor Vest Materials, Internal | PL - PU FR Coating |
| Sensor Vest Materials, External | 100% PL |
| **Display Parameters** | |
| Fluid Content Display Range | 70 Ω -177Ω, 15%–60% |
| Accuracy | ± 7% |
| **Cellular Wireless Connectivity** | |
| Cellular Connectivity Options | GSM, GPRS, EDGE, HSPA, UMTS, LTE, CDMA |
| Cellular Frequency Bands | 700, 800, 850, 900, 1700, 1800, 1900, 2100 or 3500 MHz |
| Data Rate (Uplink) | 60Kbps – 75Mbps |
| Minimal Required Quality of Service | Minimal signal strength of one bar in the cellular signal strength indicator |
| Effective Radiated Power | 20dBm - 34 dBm (0.1 Watt - 2.5 Watt) |
| FCC Compliant | Yes, Class B |
| **Wi-Fi Wireless Connectivity** | |
| Protocol options | IEEE 802.11b/g/n |
| Frequency Bands | 2.4Ghz or 5Ghz |
| Data Rate | 1mbps to 300mbps |
| Minimal Required Quality of Service | An active Wi-Fi connection indicated by Link/Activity LED indicator |
| Effective Radiated Power | 10 dBm - 30 dBm (0.01 Watt - 1 Watt) |
| Security | WEP, WPA or WPA2 |
| FCC Compliant | Yes, Class B |
| Range | Up to 30 feet from Wi-Fi router |
| **Auxiliary Battery Specifications** | |
| Type | Li-polymer, 7.4V, 29.6Wh |
| Battery Operating Conditions | See ‘Operating Conditions’ next |

| Operating Conditions | |
|---|---|
| Operating Temperature | 41°F to 95°F |
| Humidity | 15%–93% Non-condensing |
| Atmospheric Pressure | 700 hPa–1,060 hPa |
| **Storage and Shipment** | |
| Temperature | 32°F to 122°F |
| Relative Humidity | 93% Non-condensing |
| **Ingress Protection** | |
| Sensor Vest | IP22 |
| Bedside Console | IP22 |

# Classification and Standards

**Table 4: Classification and Standards**

| | |
|---|---|
| Degree of Protection Against Electric Shock | BF |
| Degree of Protection Against the Presence of Flammable Anesthetic Mixtures | Not for use with flammable anesthetics |

### FCC Compliance Statements

- FCC Part 15.21 Statement

  Changes or modifications not expressly approved by Sensible Medical Innovations Ltd. could void the user's authority to operate the equipment.

- FCC Receivers and Class B Digital Statement

  This device complies with FCC Rules Part 15. Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference that may be received or that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the system.
- Increase the separation between the system and receiver.
- Connect the system into an outlet on a circuit different from that to which the receiver is connected.
- Consult the manufacturer, distributor or an experienced radio/TV technician for help.

## Guidance and Manufacturer's Declaration—Electromagnetic Immunity and Emissions

The ReDS System V2.6 is intended for use in the electromagnetic environment described below. The user of the system should ensure that it is used in such an environment.

**NOTES:**

- The ReDS System requires special precautions regarding EMC and must be used according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment can affect the ReDS System.
- Other equipment may interfere with the ReDS System, even if that other equipment complies with CISPR emission requirements.

**Table 5: Electromagnetic Emissions for All ME Equipment and ME Systems**

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The ReDS System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in ReDS System nearby electronic equipment. |
| RF Emissions CISPR 11 | Class B | The ReDS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/Flicker Emissions IEC 61000-3-3 | Complies | |

**Table 6: Electromagnetic Immunity for All ME Equipment and ME Systems**

| Immunity Test | IEC 60601 Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Electrostatic Discharge (ESD), IEC 61000-4-2 | 6kV contact<br>8kV air | 6kV contact<br>8kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. |
| Electrical fast transient/burst, IEC 61000-4-4 | 2 kV for power supply lines<br>1 kV for input/output lines | 2 kV for AC power supply lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge, IEC 61000-4-5 | 1kV line to line<br>2kV line to earth | 1kV line to line<br>2kV line to earth | Mains power quality should be that of a typical commercial or hospital environment. |

| Immunity Test | IEC 60601 Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | For 0–5 cycles:<br><5% $U_T$ (> 95% dip in $U_T$)<br><br>For 5 cycles:<br>40 % $U_T$ (60% dip in $U_T$)<br><br>For 25 cycles:<br>70 % $U_T$ (30% dip in $U_T$)<br><br>For 5 seconds:<br><5% $U_T$ (>95% dip in $U_T$) | For 0–5 cycles:<br><5% $U_T$ (>95% dip in $U_T$)<br><br>For 5 cycles:<br>40% $U_T$ (60% dip in $U_T$)<br><br>For 25 cycles:<br>70 % $U_T$ (30% dip in $U_T$)<br><br>For 5 seconds:<br><5% $U_T$ (>95% dip in $U_T$) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |

**NOTE:**

$U_T$ is the AC mains voltage prior to application of the test level.

**Table 7: Electromagnetic Immunity**

| Immunity Test | IEC 60601 Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| | | | Portable and mobile RF communications equipment should be used no closer to any part of ReDS System (including cables) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter (see below). |
| Conducted RF, IEC 61000-4-6 | 3 Vrms 150 kHz to 80 MHz | $[V_1]$ = 3 Vrms | **Recommended separation distance:** d = 1.2√P |
| Radiated RF, IEC 61000-4-3 | 10 V/m 80 MHz to 2.5 GHz | $[E_1]$ = 10 V/m | **Recommended separation distance:** d = 0.35√P, 80 – 800 MHz range<br><br>d = 0.7√P, 800 – 2,500 MHz range |

**NOTES:**

- ReDS System at 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- **P** is the maximum output power rating of the transmitter, in watts (W), according to the transmitter manufacturer and **d** is the recommended separation distance, in meters (m).
- Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]
- Interference may occur in the vicinity of equipment marked with the following symbol: 

- [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 ReDS System is used exceeds the applicable RF compliance level above, the ReDS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ReDS System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 8: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ReDS System for Non-life-supporting ME Equipment and ME Systems**

| Rated Maximum Output Power of Transmitter (in Watts) | Separation Distance According to Frequency of Transmitter (in Meters) | | |
|---|---|---|---|
| | 150 kHz to 80 MHz Outside ISM Bands $d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz $d = 0.35\sqrt{P}$ | 800 MHz to 2,500 GHz $d = 0.7\sqrt{P}$ |
| The ReDS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the ReDS System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ReDS System as recommended below, according to the maximum output power of the communications equipment. | | | |
| 0.01 | 0.12 | 0.035 | 0.07 |
| 0.1 | 0.38 | 0.11 | 0.22 |
| 1 | 1.2 | 0.35 | 0.7 |
| 10 | 3.8 | 1.1 | 2.2 |
| 100 | 12 | 3.5 | 7.0 |

**NOTES:**

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- For transmitters rated at a maximum output power not listed above, the recommended separation distance **d** ( in meters [m]) can be determined 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.

**ReDS™ System User Manual**

SENSIBLE MEDICAL
Seeing through walls

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℞ ONLY Federal law restricts this device to sale by or on the order of a physician