SENSIBLE MEDICAL
Seeing through walls

ReDS™ Pro System Healthcare Provider User Manual

ReDS™ Pro System V2.7

RA-24629 Rev. D

February 2020

About This Manual

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

This manual describes the ReDS Pro System V2.7. It applies to healthcare providers (HCPs) who are using the device to monitor patients.

This manual contains the following chapters:

- **Chapter 1, Introducing the ReDS Pro System,** page 14, introduces the ReDS Pro System and describes its components.
- **Chapter 2, Setting Up,** page 22, describes general setup procedures to be performed before using the ReDS Pro System or that can be changed when needed.
- **Chapter 3, Taking a Measurement,** page 31, describes how to adjust the sensor unit to fit a specific patient and how to measure a patient using the ReDS Pro System.
- **Chapter 4, The SensiCloud™ Portal,** page 62, describes how to use of the SensiCloud Portal to monitor the thoracic fluid status of multiple patients.
- **Chapter 5, Troubleshooting,** page 84, 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 87, shows the labels that are attached to the ReDS Pro System components and describes the symbols that appear on them.
- **Appendix B, Handling,** page 89, describes how to store, clean and maintain the ReDS Pro System.
- **Appendix C, Technical Information,** page 98, provides ReDS Pro System technical specifications and other technical information.

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Legal Notice

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

Support and Contact Information

Sensible-Medical Innovations Ltd.

6 Meir Ariel St.

Netanya, Israel 4250364

Website: www.sensible-medical.com

Email: info@sensible-medical.com

	this system contains electrical and electronic components that 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 Pro System, read all the instructions provided in this user manual before using the ReDS Pro System.

WARNINGS!

1. The ReDS Pro 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 or its auxiliary equipment should not be operated if there is any visible physical damage to any of its parts (Sensor Unit, Bedside Console, Carrying Case, Package, Chest Size Ruler, Power Supply or cables), such as cracks, breaks, tears, stuck parts, deformations 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, lithotripsy, and electrocautery devices, and RFID devices and electromagnetic security systems such as anti-theft systems and metal detectors, as this may result in increased electromagnetic interference to the ReDS System.

   To avoid possible interference from such hospital environment emitters, the ReDS System should not be used in the vicinity of, or during procedures involving devices which deliver energy. In addition, avoid using RFID devices (such as asset or patient tracking RFID devices) in proximity to the device while taking a reading.
9. In case you are using a single device for multiple patients, use the SensiCloud only for device level readings back up, as described in the *Device Level Readings Back Up Using the SensiCloud* section on page 82.
10. Do not leave the Carrying Case inside the car to maintain storage and shipment conditions as indicated in the label.

CAUTIONS:

1. Do not operate the ReDS Pro System without proper training. For additional information, and in case additional training is needed, contact support.
2. In case of user discomfort, abort the operation of this system by using the console or by removing the Sensor Unit.
3. Federal law (USA) restricts this device to sale by or on the order of a physician.
4. Pay attention to the sensor unit cable in order to avoid entanglement, strangulation or pulling the Bedside Console.
5. Pay attention when operating the Sensor Unit around the patient to avoid physical impact to the patient.
6. When using the table stand mount, place the Bedside Console on a flat and stable surface to prevent tipping and falling.
7. 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.
8. Avoid exposing the system to liquids, as this may cause device damage.
9. This system should only be serviced by qualified personnel.
10. Remove the unit before performing defibrillation to avoid system damage or ineffective defibrillation therapy.
11. The ReDS Pro System fluid reading is intended to be used as an adjunct parameter to standard clinical assessment methods.
12. When considering using the ReDS Pro 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 Unit.
    - 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.

13. In the following cases, remove the Sensor Unit, unplag and connect the power supply and restart the system:
    - HW malfuction message is displayed on screen.
    - Device is not responding.
    - A measurement that does not stop automatically within 4 minutes of starting.

    In case of Recurring device malfunction contact support.

    When connecting the USB modem(or any other specified device) to reduce risk of damage to the system, do not touch the system's USB port

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

14. The ReDS Pro System should not be used adjacent to, or stacked with, other electronic equipment. See Table 7 for minimal separation distances.
15. The system is intended for indoor use and storage. Avoid exposing to high or low temperatures, humidity and pressure conditions (see *Appendix C*, *Technical Information* on page 98) as this may cause system malfunctions.
16. Stop using the device if there is a reason to suspect that it has been contaminated.
17. After every patient use (and before packing), clean and disinfect the Sensor Unit. See the *Step 6: Cleaning and Disinfection* section on page 61 for more information.
18. To avoid patient mix up, when it is not the first time the patient is being enrolled and measured, make sure you are selecting the correct patient from the list, according to the unique patient ID and/or other patient details.
19. Avoid using the system if you feel that the Sensor Unit arm is too loose, stuck, or if the chest sensor does not inflate.
20. Avoid hanging, pulling or holding the device from the back-positioning tool, but rather hanging it from the sensor-unit-arms.
21. 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.
22. To ensure accurate measurements, make sure to use the provided chest size ruler and to enter read value accurately .
23. Exporting reports from the system may contain patient PHI (protected health information). Consider adding report password.
24. Do not connect devices to this system’s USB ports, except as instructed in this manual.
25. Do not connect any unauthorized USB devices to the USB port. Please consult with your institution's IT/bioengineering department to get guidance on which USB devices are authorized, and how to use them.
26. Do not use the device over bare skin.

27. Packing inside the Carrying Case should be done according to the instructions. Wrong packing may damage the device.

1 Introducing the ReDS Pro System

This chapter introduces the ReDS Pro System and describes its components.

Overview

The ReDS Pro System is a non-invasive device consisting of a Bedside Console connected to a wearable unit that is used for the measurement of lung fluid. A measurement session lasts about 45 seconds. Measurement results are in percent units (%), representing the volume of fluid in the lung out of the total lung volume.

The system may be used by a healthcare provider to obtain readings for multiple patients. Each time the device is used, it must be set up and properly positioned on the patient to be measured.

Indications for Use

ReDS Pro is intended for use by qualified healthcare practitioners, 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. The ReDS Pro System is indicated for patients:

- With fluid management problems.
- Taking diuretic medication.
- Living with heart failure.
- Recovering from a 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 unit) is 39 or less.

Contraindications

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

System Components

The ReDS Pro System consists of the following components:

- **Bedside Console** (with cart mounting), page 15
- **Sensor Unit,** page 18

Bedside Console

The following describes the components of the Bedside Console.

Figure 1: Front of Bedside Console

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 to the power supply.

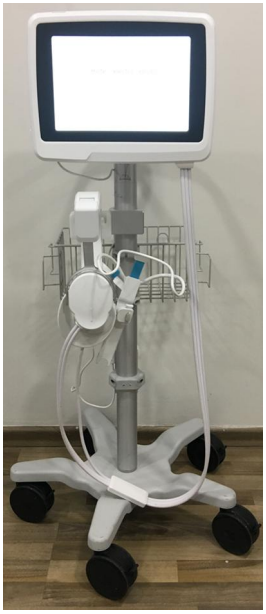


Figure 2: Bedside Console Mounted on Cart

Figure 3: Bedside Console Mounted on Table

Wireless Connectivity

The Bedside Console has a cellular USB modem inside that transmits the readings to a secured cloud server. 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 Huawei modem, model MS2372 FCC ID: QISMS2372h-517 or another equivalent qualified modem.

NOTE:

The option to transmit readings to the cloud server can be disabled using the **Transmission to Cloud** setting, as described on page 26.

Alternatively, a Wi-Fi solution for connectivity is also available in cases of cellular coverage problems. Wi-Fi technology supported is one or more of the 802.11 technologies IEEE 802.11a/b/g/n/ac and the operating frequency band is either 2.4 GHz or 5 GHz. The Wi-Fi adapter complies with FCC Class B limits. If needed, a router may also be provided. If needed, a router may also be provided. If using Wi-Fi, connect only to an approved and secure network using WPA2. For further information regarding Wi-Fi options, contact support team. The team will support you in selecting and setting up the Wi-Fi network.

CAUTIONS:

- Do not connect devices to this system's USB port, except as instructed in this manual.
- Do not connect any unauthorized USB devices to the USB port. Please consult with your institution's IT/bioengineering department to get guidance on which USB devices are authorized, and how to use them.

NOTE:

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

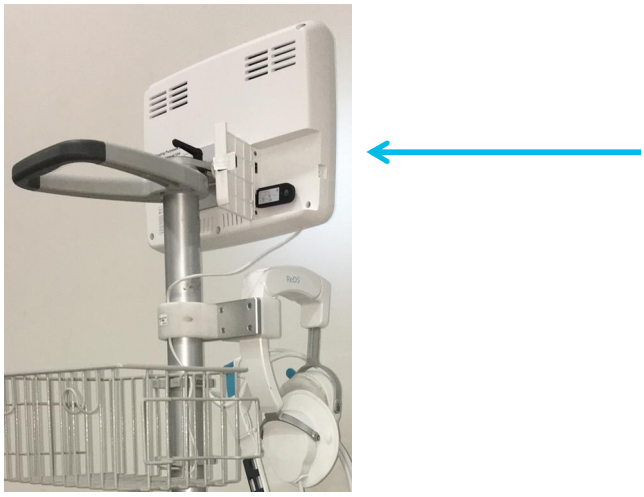


Figure 4: USB Port for Cellular Modem

Sensor Unit

The Sensor Unit consists of two sensors (Back and Chest) and a positioner. One sensor is placed on the patient's chest and another on the patient's back. The chest sensor inflates during measurement for better contact with the patient's upper-right chest through light clothing. The back sensor is positioned on the upper-right part of the patient's back. The Sensor Unit is connected by a non-detachable cable to the Bedside Console.

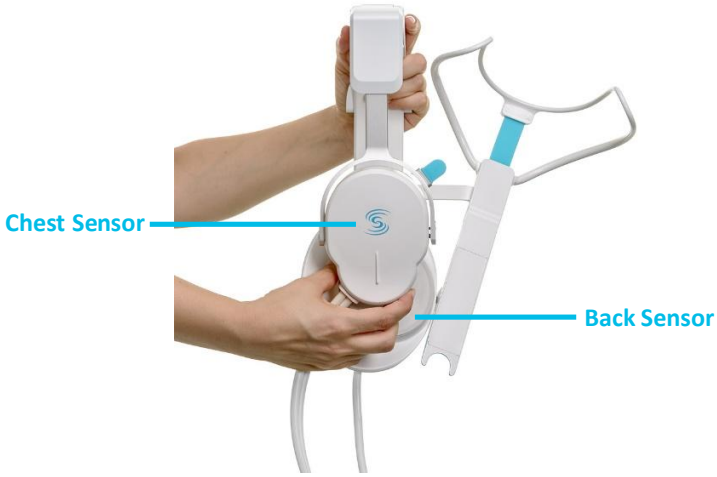


Figure 5: Sensor Unit – Sensors

The Sensor Unit's positioner is a collar-like apparatus. It is used to properly position the sensors on the patient's thorax.

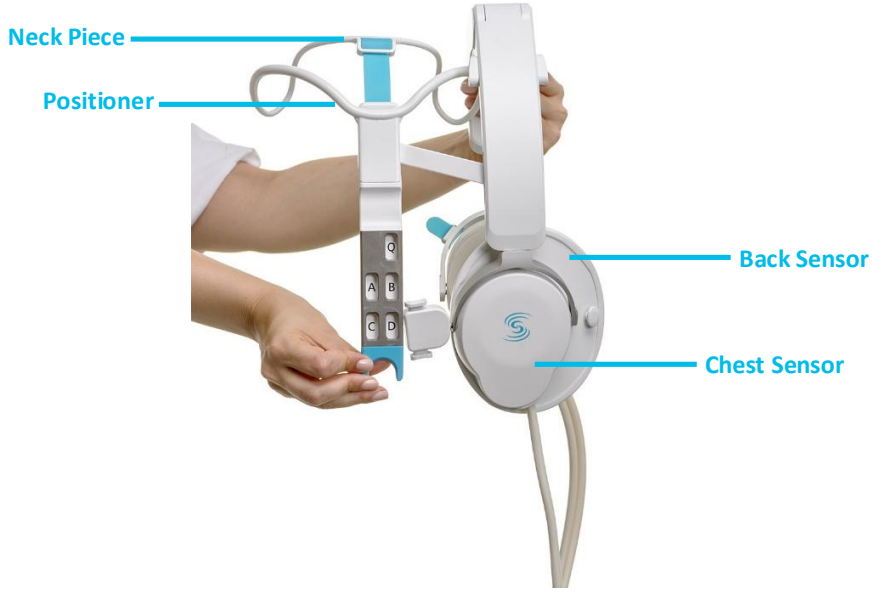


Figure 6: Sensor Unit – Positioner

Auxiliary Equipment

- **Chest Size Rulers,** page 20
- **Portable Cart Accessory,** page 16 **or;**
- **Table stand accessory** page 16 and **Carrying case,** page 20
- **Cellular Modem,** page 17

Chest Size Ruler

The detachable, retractable Chest Size ruler is used to measure the chest size when the Sensor Unit is applied on the patient.

Figure 7: Chest Size Measurement Ruler

Carrying Case

The carrying case is used to hand- carry the ReDS™ Pro System in the use case of a traveling nurse.

See instructions for packing the ReDS Pro System in the carrying case in page **Error! Bookmark not defined.**

SensiCloud™ Portal

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

The data from the ReDS Pro System is automatically transmitted via a cellular or Wi-Fi 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.

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.

- Performing technical and administrative tasks by Sensible service team for supporting healthcare provider's work.

Available for single patient per device use only:

- 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 measurement activity via missed readings indicators.
- Enabling automatic measurement reminder notifications.

2 Setting Up

This chapter describes general setup procedures to be performed before using the ReDS Pro System or that can be changed as needed.

For instructions about measuring a patient, see *Chapter 3*, *Taking a Measurement* on page 31.

CAUTIONS:

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

General Setup

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

Step 1: 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.

Step 2, Setting Up Communication

This step is optional. If there is no need for cloud support, then you can skip this step.

► **To set up communication:**

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

For additional information about communication troubleshooting, see *Chapter 5, Troubleshooting* on page 84.

NOTE:

The system is set up by default to send measurements to the cloud. For more details, see page 26.

Step 3: Powering Up

WARNING!

- This system should not be operated if there is any visible physical damage to any of its parts (Sensor Unit, Bedside Console, power supply or cables), such as cracks, breaks, tears, stuck parts, deformations 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, lithotripsy, and electrocautery devices, and RFID devices and electromagnetic security systems such as anti-theft systems and metal detectors, as this may result in increased electromagnetic interference to the ReDS System.

  To avoid possible interference from such hospital environment emitters, the ReDS System should not be used in the vicinity of, or during procedures involving devices which deliver energy. In addition, avoid using RFID devices (such as asset or patient tracking RFID devices) in proximity to the device while taking a reading.

► **To power up the ReDS Pro System:**

1 Plug in the power supply to a standard power outlet. The blue light on the power supply should light up.

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.
If the System Password is configured, you will be asked to enter the password.
When the screen is completely black (off), then power on the ReDS Pro System, as described above.
If the system is unplugged or if power is down, the following message displays on the screen: *Power cord disconnected.*
To go back to screensaver mode, press the lock sign on the top left of the screen.

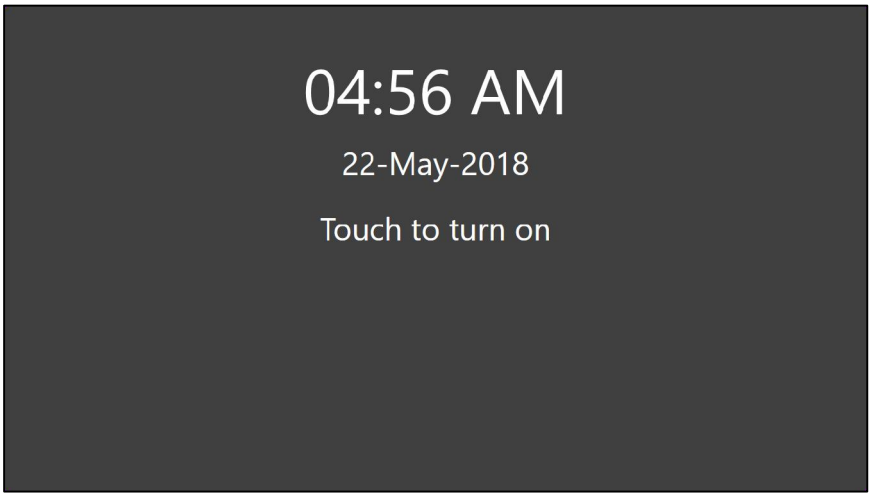


Figure 8: Screensaver

2 Briefly press the blue ON/OFF button on the top left of the console (see

Figure 1) to power on the console. After one minute roughly, the console's Start screen displays, as shown below:

Figure 9: Start Screen

The system is now ready for use.

Settings

The *System Settings* screen enables you to configure the ReDS Pro System.

► To set up the ReDS Pro System:

1 In the *Start* screen (see Figure 9), click the cog wheel icon on the bottom left. The following screen displays:

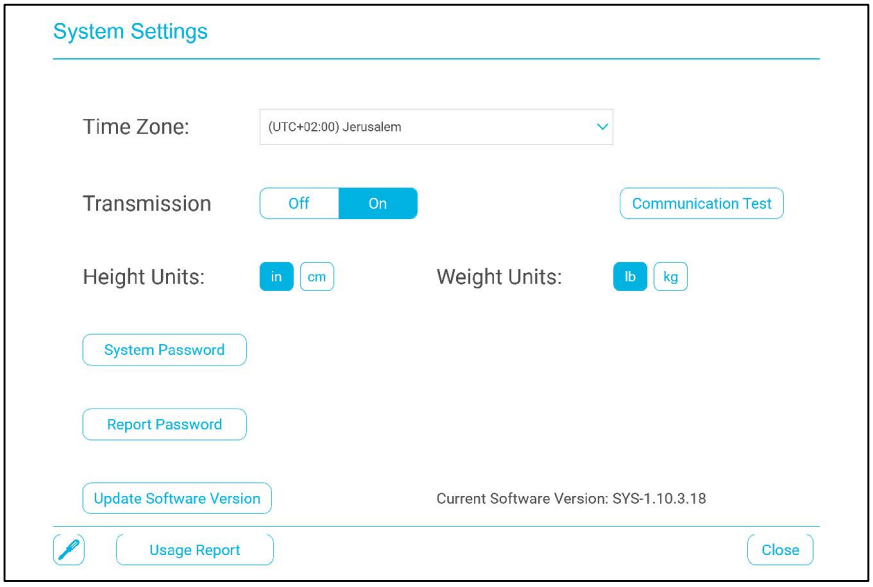


Figure 10: System Settings Screen

2 Use the options in this screen, as follows:

- **Time Zone:** Select your correct time zone (the default time zone is CST).
- **Transmission:** The device enables easy synchronization of results and other data to the cloud (via either cellular or Wi-Fi communication). When this feature is enabled, measurement results are automatically transmitted to the cloud.

NOTE:

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

NOTE:

Transmission mode is set to ON by default. The system recognizes whether Cellular or Wi-Fi is used. It should be turned OFF when neither cellular communication nor Wi-Fi are available or if no communication is required (Standalone). If needed, you may contact support for more information.

- **Communication Test button:** If the system is set up to communicate via a cellular or Wi-Fi connection, tapping this button verifies the connection. A success or failure message displayed.
- **Wi-Fi Configuration:** To connect to a Wi-Fi network, make sure the Transmission button is set to ON, choose one of the available networks from the list, then tap Connect, type the password in the "Connect to a network" popup, and tap Connect.

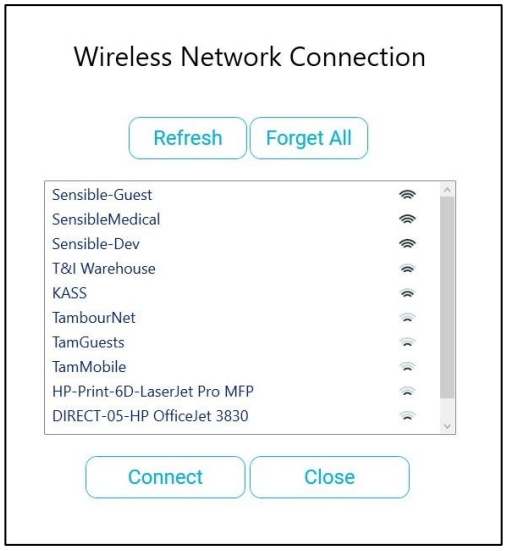


Figure 11: Wireless Network Connection popup

Figure 12: Enter Password

- **Height Units:** The system can be set to either the Imperial or Metric System. Select **in** for Inches or **cm** for Centimeters.
- **Weight Units:** The system can be set to either the Imperial or Metric System. Select **lb** for Pounds or **kg** for Kilograms.
- **System Password:** to set a system password, type a password in the box. A password conformation is needed. To lock the system, use the lock icon on the top left corner of the screen.

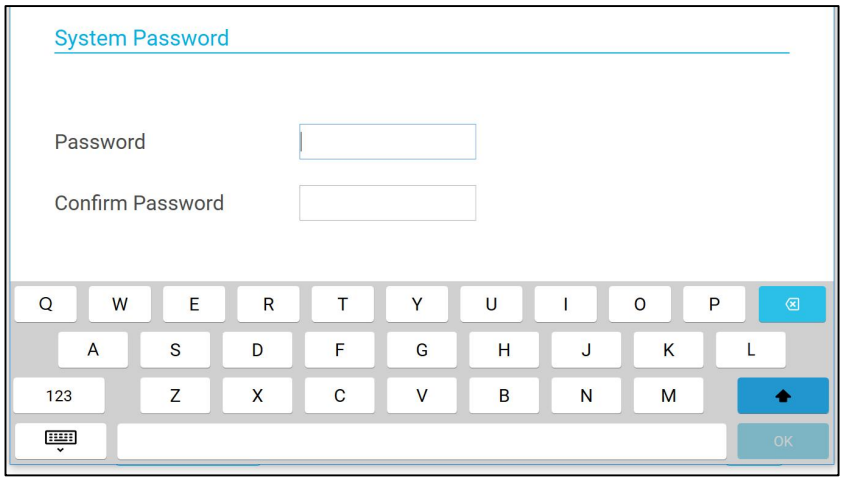


Figure 13: System Password Screen

To unlock the system, type the system password. Unlocking the system with the System password will be required also after a timeout.

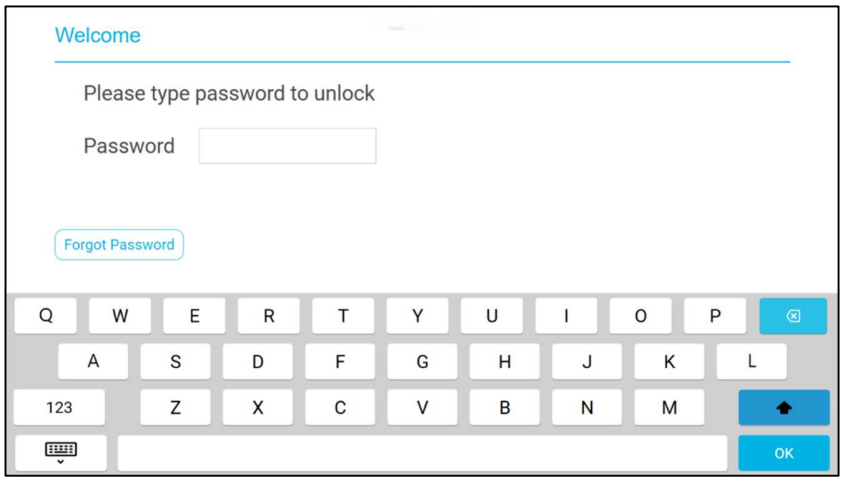


Figure 14: Enter Password Screen

Use the “forgot my password” button to contact support in case of forgotten password.

Figure 15: Password Recovery Screen

Call Sensible service and indicate the password recovery code. The service representative will provide the new password to enter in the new password field.

NOTE:

System Password is empty by default. If a password is set, it will be required for unlocking and using the system.

- **Report Password:** to set a report password for the usage report (see page 62), type a password in the box. A password confirmation is needed. For unlocking the reports generated from the system type the Report password.

NOTE:

Report Password is empty by default, once it is set, it will be required for unlocking and viewing the reports generated by the system.

- **Software Upgrade-** to start a software upgrade process, insert the designated USB thumb drive and tap the SW Upgrade button. A popup with the software upgrade password will display on screen.

NOTE:

Software Upgrade of the device should be performed only by a hospital authorized user and according to the manufacturer instructions

Signal Strength Indicator

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

Similarly, if using Wi-Fi, a 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.

You can also use 'Communication Test' in the 'Settings' screen to validate cellular or Wi-Fi connectivity.

3 Taking a Measurement

This chapter describes how to adjust the Sensor Unit to fit a specific patient and how to measure a patient using the ReDS Pro System.

When used in a hospital or hospital-like facilities with multiple patients, healthcare providers 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.

CAUTIONS:

- To use the ReDS™ Pro System correctly and dependably, read all instructions in this user manual before using it.
- After every patient use (before packing), clean and disinfect the Sensor Unit. See the *Cleaning and Disinfection* section on page 61 for more information.

Taking a Measurement – Workflow

The following provides an overview of the steps for setting up the Sensor Unit and taking a measurement, and a reference to the sections of this user manual that provide detailed instructions.

NOTE:

Make sure to power up the ReDS Pro system before performing the workflow below. See the *Step 3: Powering Up* section on page 23 for details.

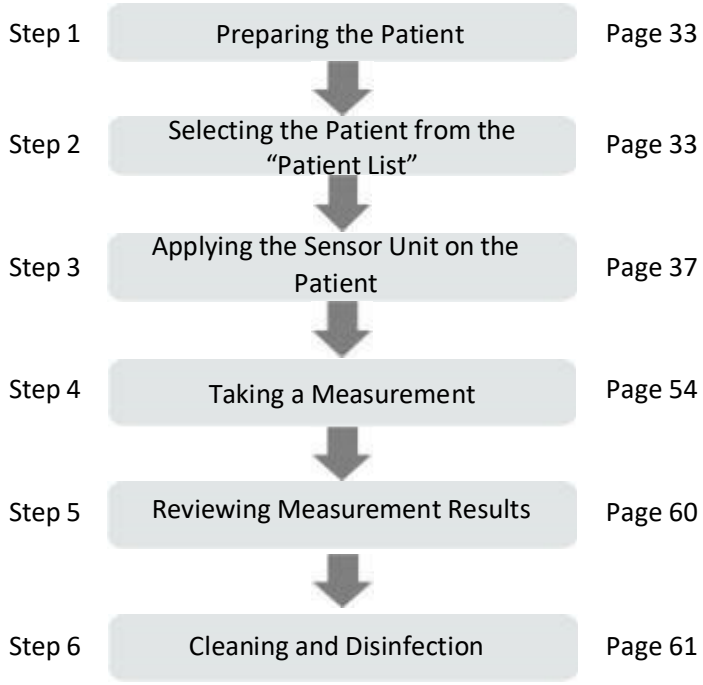


Figure 16: Measurement Flow

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 the device over a bra.
- Do not use the device over bare skin

Step 2: Selecting the Patient

After a patient record has been created, it displays in the patient list. To select the patient to be measured, you should first check whether that patient already exists in the patient list. If he/she does not, then you must create a patient record for that patient.

For enrolling the patient in SensiCloud™ (optional), please see *Chapter 4, The SensiCloud™ Portal* on page 62.

NOTE:

When working in Anonymous mode, select a patient from the list according to the unique Patient Number.

CAUTION:

To avoid patient mix ups, make sure that you select the correct patient, according to the unique patient ID and other patient details.

► To select a patient:

1 In the *Start* screen (see Figure 9) tap **Start**.

The following screen displays:

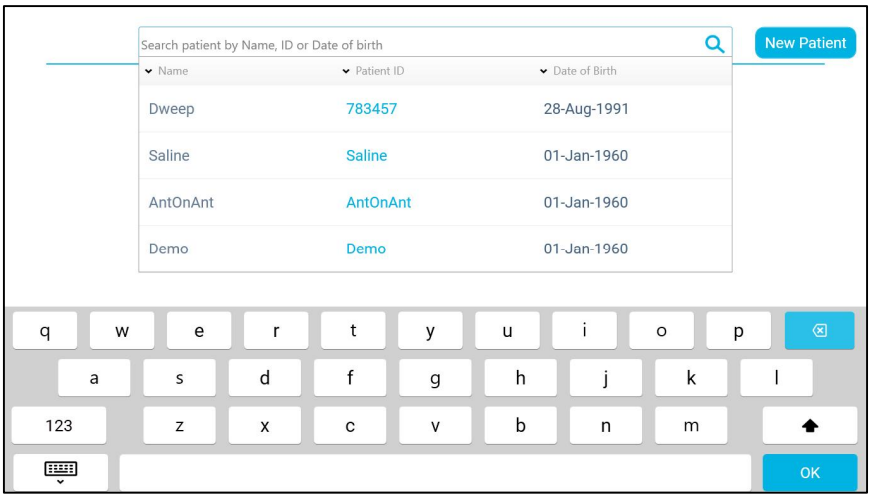


Figure 17: Patient List Screen

This screen lists all patients currently defined in the system. If the patient already appears in the list, tap his/her patient row to select that patient and then proceed to *Step 3: Applying the Sensor Unit on the Patient* on page 37.

For reviewing patient's previous measurements, tap on "History" button.

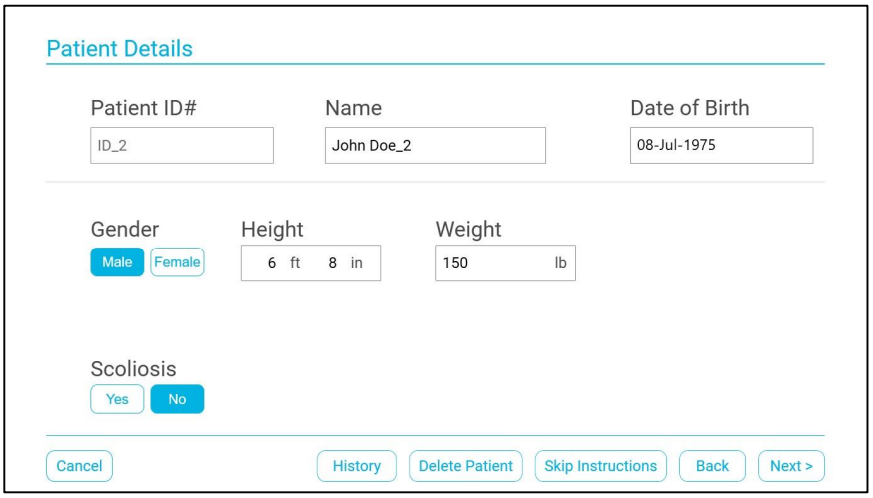


Figure 18: Patient History Screen

Patient's measurements are presented in the table below:

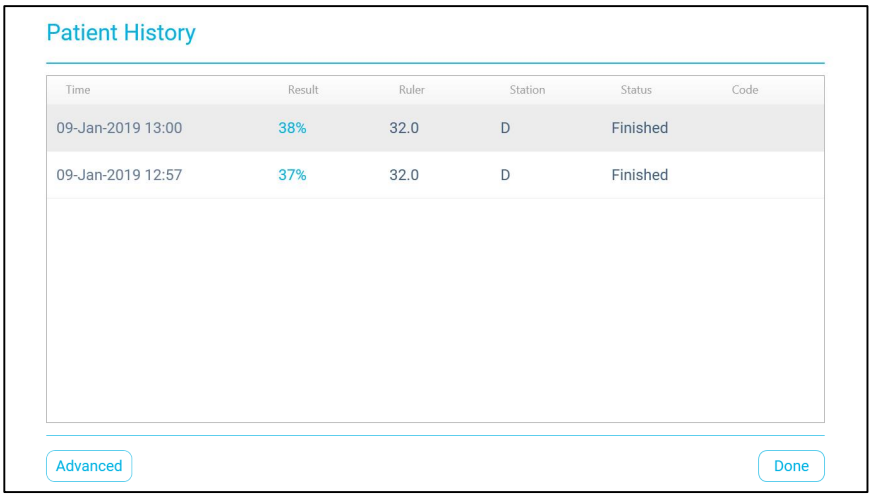


Figure 19: Patient History Screen

NOTE:

- You can type in part of the patient's name or ID to filter the patient list.
- When working in Anonymous mode, the **Patient Name**, **Patient ID #** and **Date of Birth** fields are not presented.

If the patient does not appear in the list, click the **New Patient** button and then proceed to step 2 below. The following screen displays:

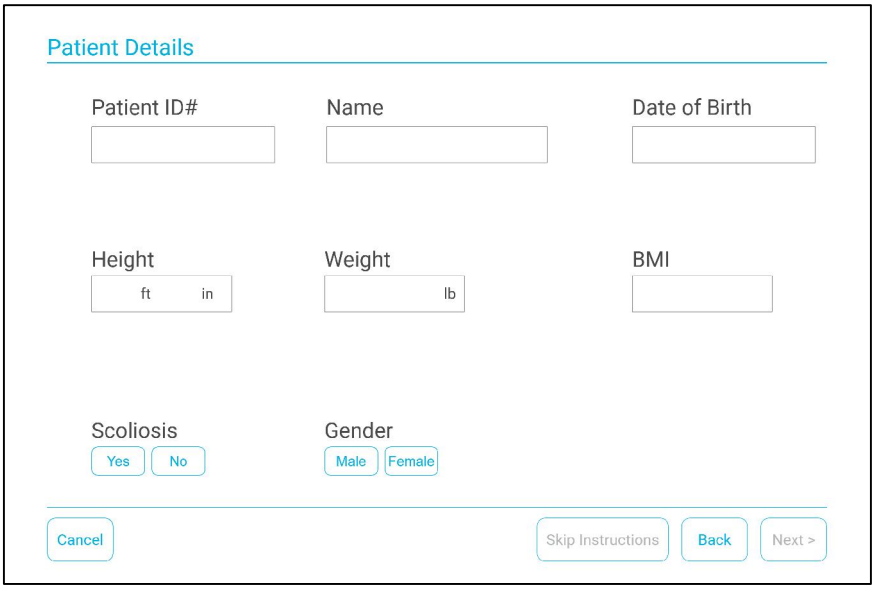


Figure 20: Patient Details Screen

2 Enter the following for the patient:

- Patient Name
- Patient ID #
- Date of Birth
- Gender
- Patient Height
- Patient Weight
- Scoliosis

Use the keyboard at the bottom of the screen, where needed, to make your entries.

After entering Patient Height and Patient Weight, patient's BMI will automatically be calculated and displayed in the BMI field on screen.

NOTE:

Make sure to enter **Patient Height** and **Patient Weight** in the correct fields on screen.

NOTE:

When working in Anonymous mode, the **Patient Name**, **Patient ID #** and **Date of Birth** fields are not presented.

NOTE:

You can move directly to the *Verification* screen from the *Patient Details* screen (see Figure 20), and skip the intermediate steps in the wizard. To do so, tap the **Skip Instructions** button in the *Patient Details* screen. Then, enter and verify patient values in the *Verification* screen.

Step 3: Applying the Sensor Unit on the Patient

This section describes how to apply the Sensor Unit on the patient, and adjust it for that patient, in order to take a measurement. The Sensor Unit is typically used to measure multiple patients. Therefore, it must be adjusted each time to measure the current patient.

WARNING!

This system or its auxiliary equipment should not be operated if there is any visible physical damage to any of its parts (Sensor Unit, Bedside Console, Carrying Case, Package, Chest Size Ruler, Power Supply or cables), such as cracks, breaks, tears, stuck parts, deformations and so on.

CAUTION:

After every patient use (and before packing), clean and disinfect the Sensor Unit. See the *Cleaning and Disinfection* section on page 61 for more information.

CAUTIONS:

When considering whether to use the ReDS Pro 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 Unit.
- 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.

CAUTION:

- Pay attention to the Sensor Unit cable in order to avoid entanglement, strangulation or pulling the Bedside Console.
- Pay attention when operating the Sensor Unit around the patient to avoid physical impact due to uncontrolled release of the sensor arm.

The procedure for placing and positioning the Sensor Unit on the patient and taking a measurement uses a guided wizard. During a measurement session, measurements are taken in two different positions.

Instruct the patient to remain still for the duration of the measurement procedure.

▶ To apply the Sensor Unit on the patient:

CAUTION:

After every patient use (and before packing), clean and disinfect the Sensor Unit. See the *Cleaning and Disinfection* section on page 90 for more information.

1 In the *Patient Details* screen, tap **Next**. The following popup window displays:

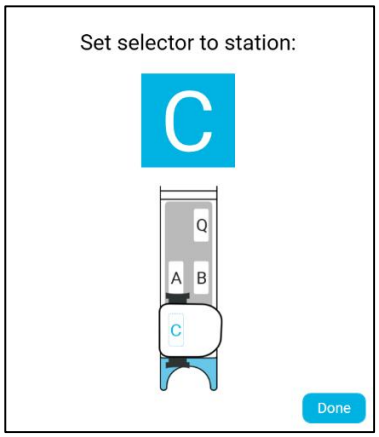


Figure 21: Setting the Station

The popup window indicates which station to set the selector to (A/B/C/D) on the positioner, based on the patient's anatomy. The personal details that were entered in the *Patient Details* screen are used for this purpose.

To properly set the selector, do the following:

- Hold the Sensor Unit in your hand.
- Release the selector station, as follows:
  - Press the two buttons on the selector sides.

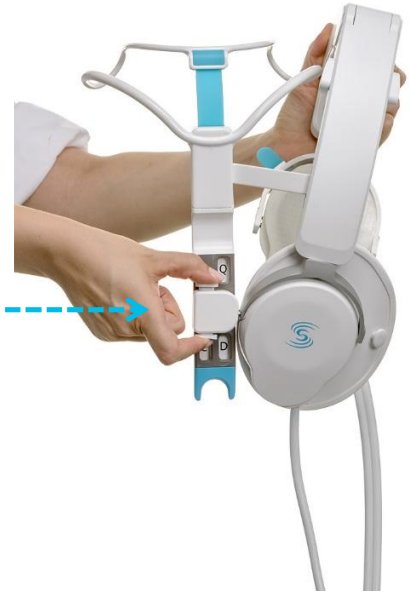


Figure 22: Setting the Selector – 1

- Pull out the selector away from the positioner so that it is no longer connected.

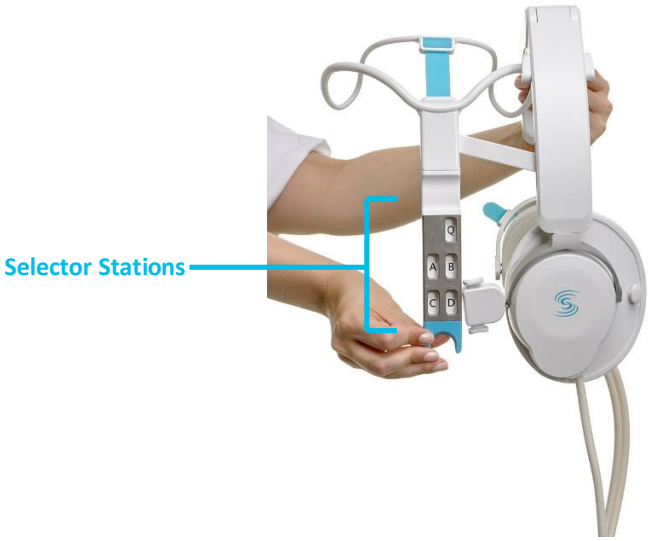


Figure 23: Setting the Selector – 2

- Reattach the selector to the selector station, as shown in Figure 21: Setting the Station (A, B, C, D or Q), by clicking the selector socket back onto the A, B, C or D station. You only need to push it into place. There is no need to

press the buttons.

Figure 24: Setting the Selector – 3

2 Tap **Done** once you have set the selector station on the positioner. The *Positioning* screen displays:

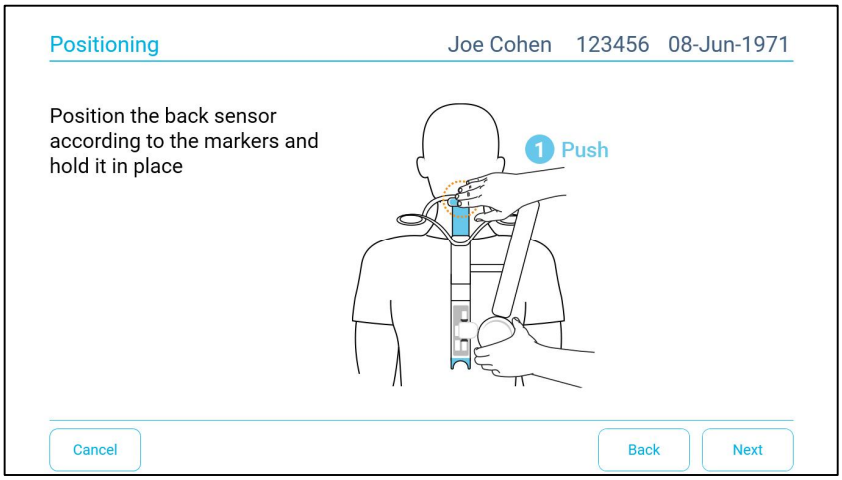


Figure 25: Positioning Screen – 1

In this step, the Sensor Unit is applied on the patient.

3 Have the patient sit in a high-back chair, all the way back. Apply the Sensor Unit to the patient. To do so, hold the back sensor in one hand and the chest (front) sensor with the other hand. While standing close to the patient, have the patient lean forward and place the chest and back sensors on the patient's right side.

Figure 26: Placing the Sensor Unit on the Patient

The following screen and GIF display:

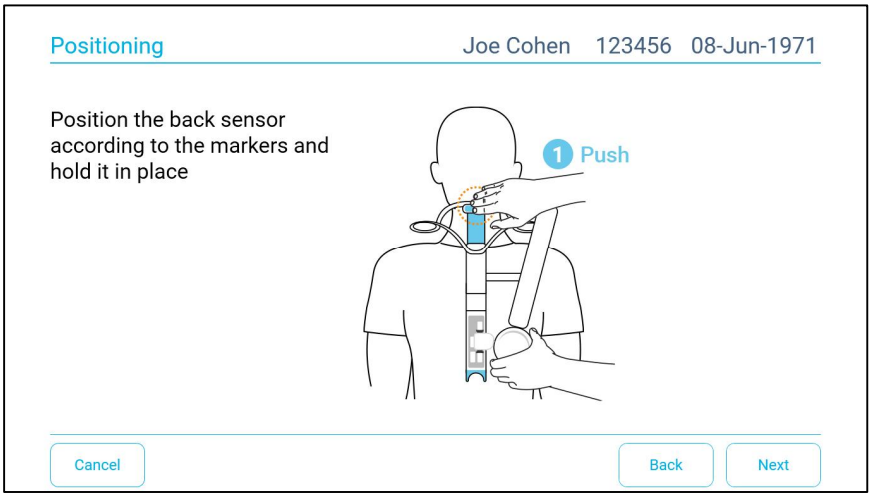


Figure 27: Positioning Screen – 2

In this step, you position the back sensor on the patient.

Before doing so, ensure that the patient is sitting in a high-back chair. Positioning of the back sensor is made with the patient seated all the way back on the chair, while leaning forward. The patient's shoulders should be relaxed.

NOTE:

Alternatively, the patient can be seated on an adjustable bed that provides back support. The bed must be adjusted to a tilted position where the patient can sit back, and have support for his/her back.

4 While holding the back sensor with your left hand, position it on the patient, as follows:

- Use your right hand to push the blue marker forwards against the patient's neck.

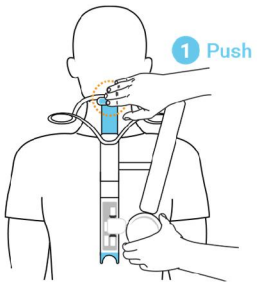


Figure 28: Positioning the Back Sensor – 1

Figure 29: Positioning the Back Sensor – 2

- Slide the sensor down until the positioner collar touches the patient's shoulders.

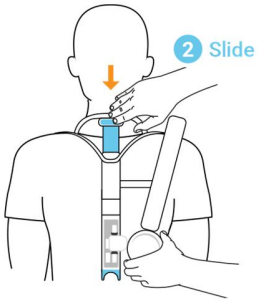


Figure 30: Positioning the Back Sensor – 3

Figure 31: Positioning the Back Sensor – 4

- Hold the neck piece in place on the patient's neck to secure the height.

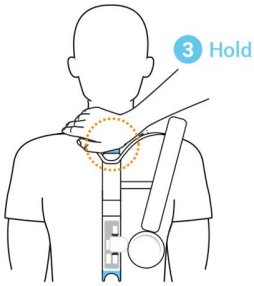


Figure 32: Positioning the Back Sensor – 5

Figure 33: Positioning the Back Sensor – 6

- Align the spine notch with the patient's spine. To locate it, use one finger of one hand to feel where the spine is through the semi-circle groove at the bottom of the positioner, as shown in Figure 34. Use your other hand to hold the positioner in place. Using the same hand as the one used to find the spine, move the back sensor so that the semi-circle groove is on the spine. Then, move that hand to hold the sensor and let go with the other hand.

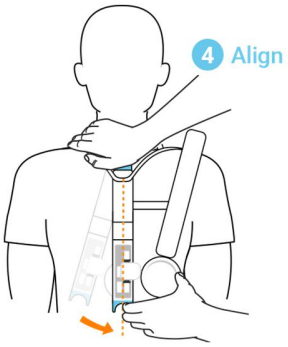


Figure 34: Positioning the Back Sensor – 7

Figure 35: Positioning the Back Sensor – 8

- While still holding the back sensor in place, have the patient sit up and then recline back, pressing the back sensor against the backrest. Do not remove your hand that is holding the sensor until the patient sits back, in order to keep the sensor in place.

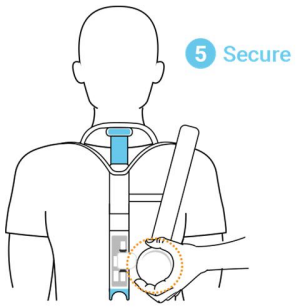


Figure 36: Positioning the Back Sensor – 9

Figure 37: Positioning the Back Sensor – 10

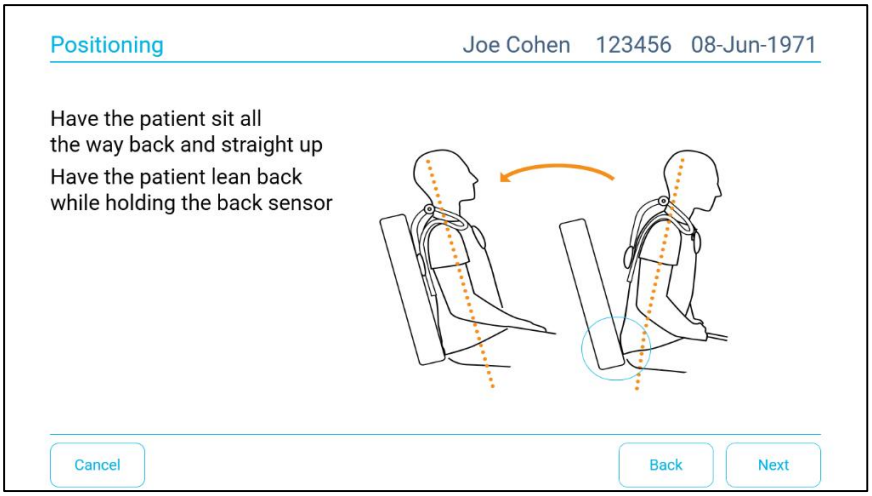


Figure 38: Have the patient lean back – 1

Figure 39: Have the patient lean back – 2

5 After you have positioned the back sensor, tap **Next**. The following screen displays:

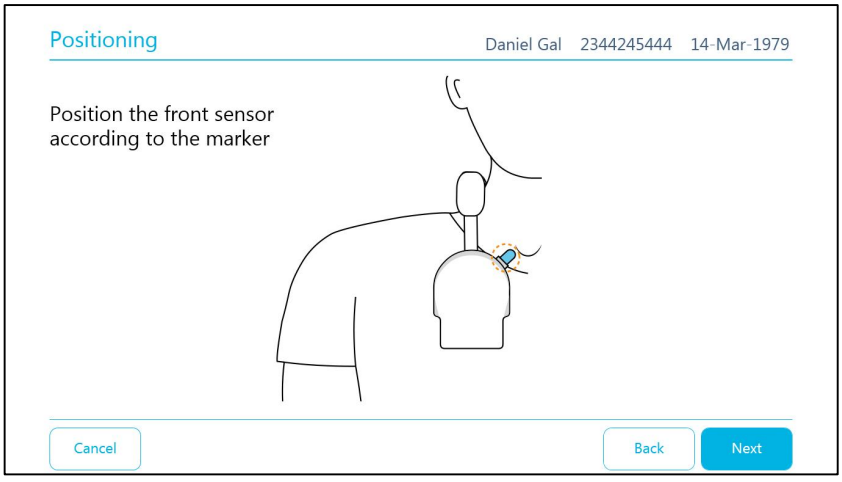


Figure 40: Step 2 Screen – 3

In this step, you position the chest (front) sensor on the patient. Make sure that the patient remains sitting back in the chair while positioning the chest sensor.

6 Position the chest sensor according to the alignment marker, adjusting the front sensor slider as needed. To properly position the sensor, use your finger to find the patient's Supra-Sternal notch. Then, position the marker tab so that it reaches the patients' Supra-Sternal notch. Check if the sensor positioning requires additional adjustment to ensure the front sensor is positioned just to the right of the sternum and just below the clavicle, as shown below:

Figure 41: Alignment Marker on Chest Sensor

Figure 42: Locating the Supra-sternal Notch

7 While the patient maintains position, attach the supplied Chest Size Ruler to the hook at the back of the Sensor Unit.

Figure 43: Attaching the Chest Size Ruler – 1

8 Have the patient slightly lift his/her right arm. Pull the Chest Size Ruler tightly under the right arm and across the chest sensor.

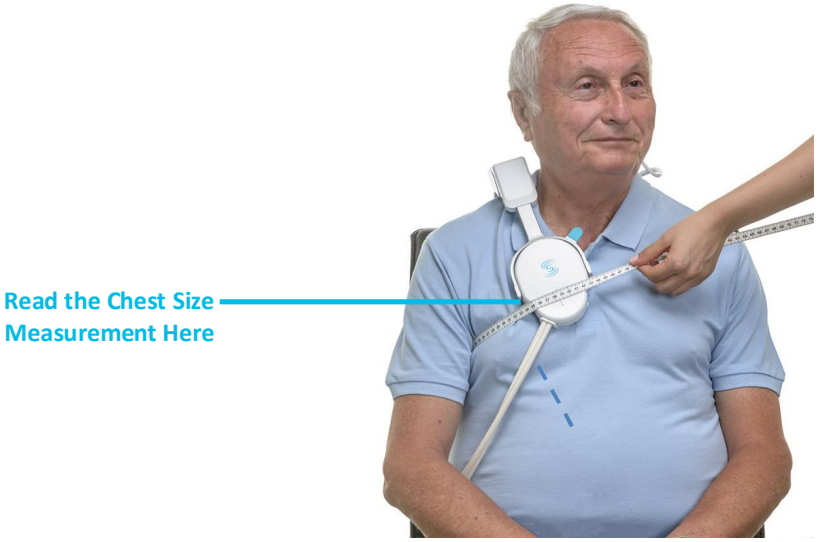


Figure 44: Reading the Chest Size Ruler Value – 2

9 Read the value of the Chest Size Ruler, which crosses the bold reference line on the chest sensor, and enter it in the **Enter chest size ruler** field.

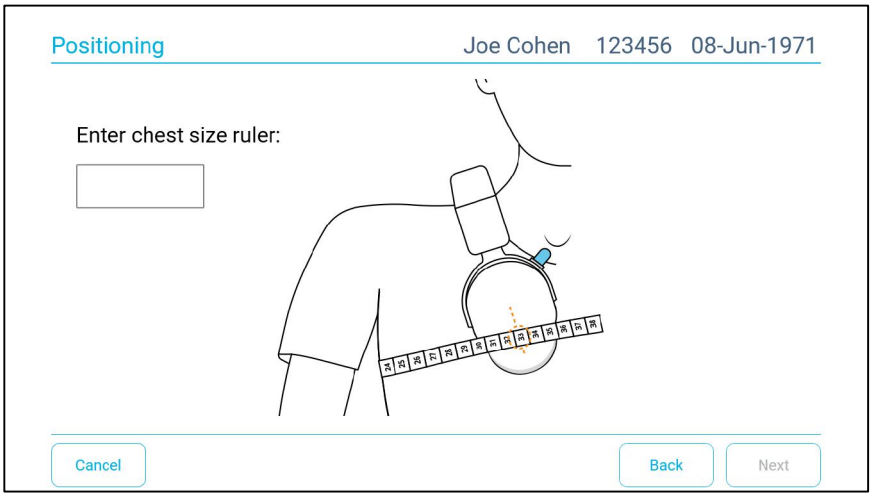


Figure 45: Positioning the Chest Sensor – 1

NOTE:

The Sensor Unit adjustment supports ruler chest dimension values of 17.5 cm to 47 cm. Do not use the ReDS Pro System if the measured ruler values exceed this range.

CAUTION:

To ensure accurate measurements, make sure to read and enter the chest size ruler value accurately.
Avoid using the system if you feel that the Sensor Unit arm is too loose, stuck or if the chest sensor does not inflate.

10 Tap **Next**. The *Verification* screen displays:

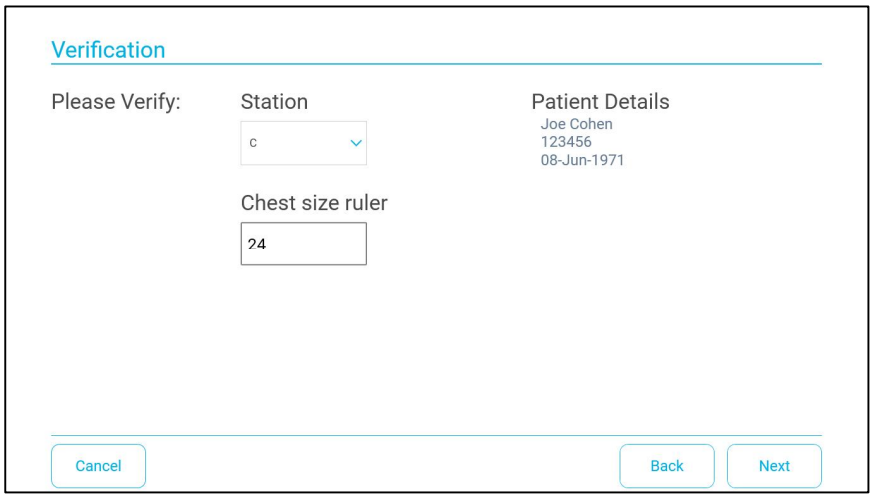


Figure 46: Verification Screen

This screen displays a summary of what was entered in the wizard screens.

NOTE:

- You can move directly to the *Verification* screen from the *Patient Details* screen (see Figure 20), and skip the intermediate steps in the wizard. To do so, tap the **Skip Instructions** button in the *Patient Details* screen. Then, enter or verify patient values in the *Verification* screen.
- At this point, in some cases you may be requested to set the Station Selector to a different station. If this is required, it will be explicitly stated on the screen.

11 Verify that the values that you entered are correct, or change them if necessary.

12 Tap **Next**. The following screen displays:

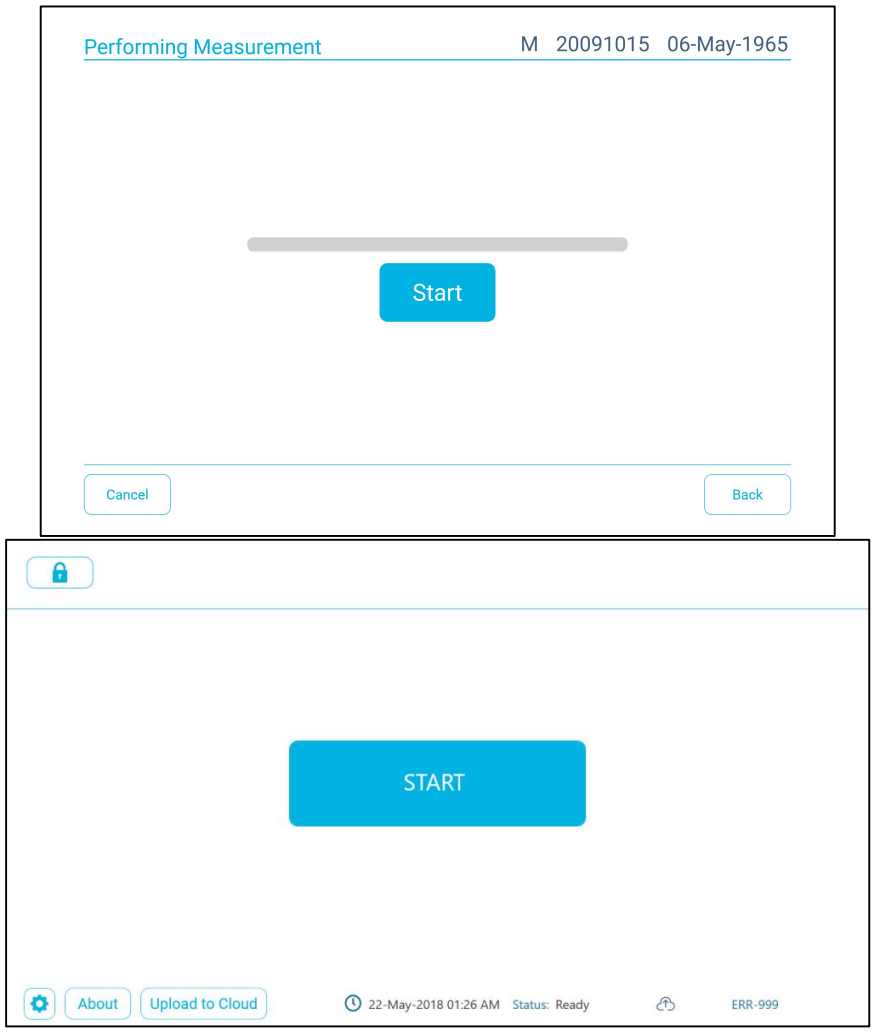


Figure 47: Step 3 Screen – 1

You are now ready to take measurements for the patient.

Step 4: Taking a Measurement

1 In the *Performing Measurement* screen (see Figure 47), tap **Start** to start the actual measurement process. The following screen displays:

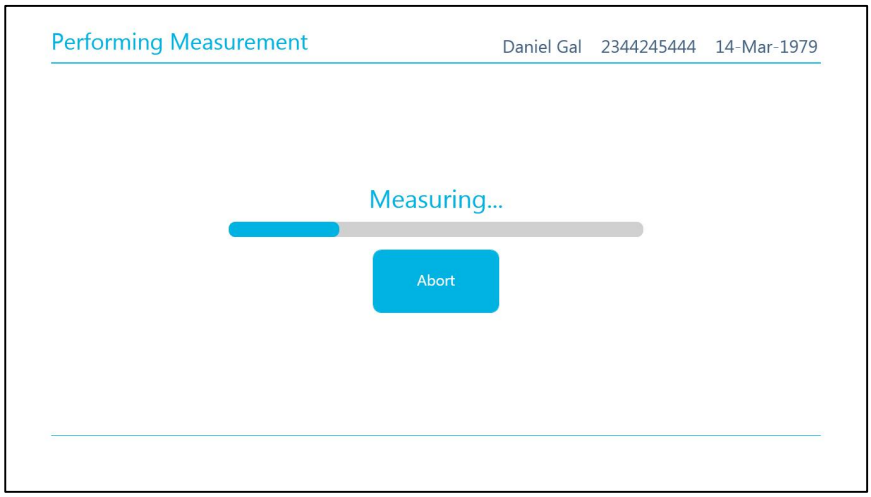


Figure 48: Measurement Screen

NOTE:

If needed, tap the **Stop** button to abort the measuring process.

2 The chest sensor in the front will start to inflate. The measurement takes 45 seconds.

NOTE:

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

- Tapping the **Stop** button on the screen at any point during the measurement deflates the chest sensor and stops the measurement process immediately.
- If a technical failure occurs, the measurement terminates immediately and a relevant message is displayed. Try again. You may refer to *Chapter 5, Troubleshooting* on page 84. Contact support if a problem persists.
- If the patient is uncomfortable, remove the Sensor Unit at any time to abort the measurement procedure.

3 Wait until the measurement process ends automatically and the chest sensor deflates. After a successful measurement, the following screen displays, showing the measurement result:

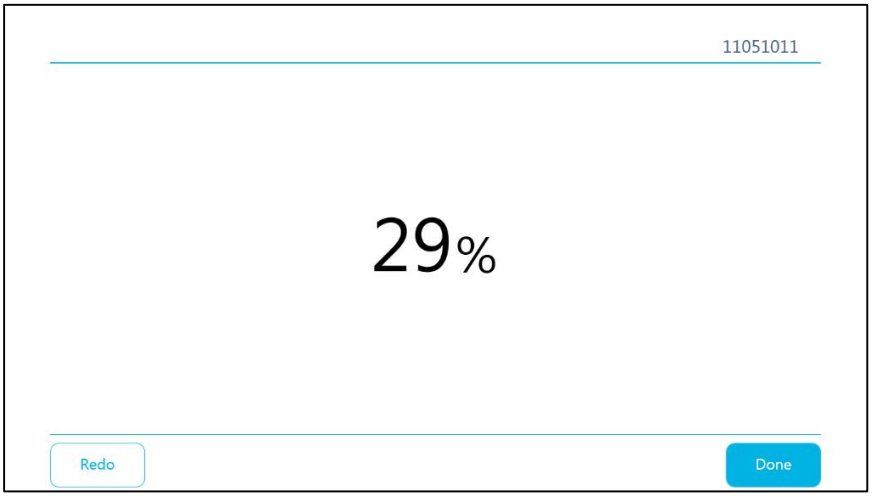


Figure 49: Measurement Result

Press Done to complete the measurement flow.

4 The device may be configured to include a second measurement part taken at the Q station (for quality purposes). In this case, please follow the instruction below to complete the measurement.

Move the back sensor to the second measurement position (Q station).

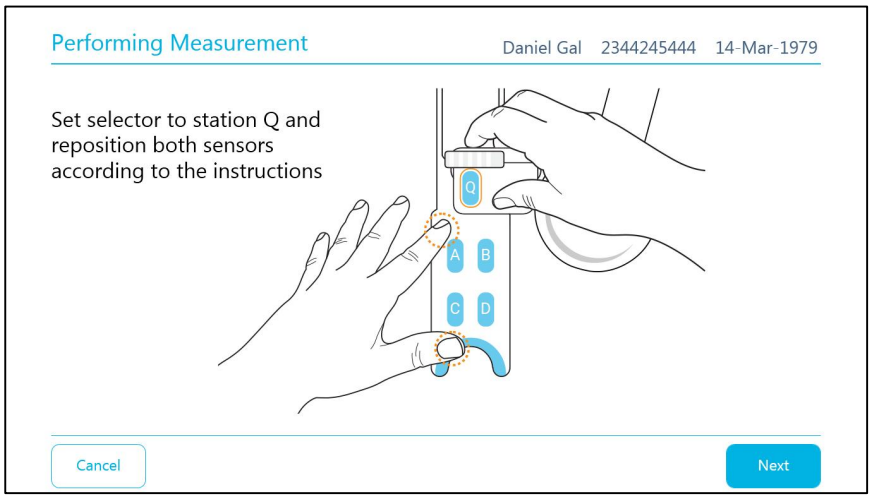


Figure 50: Step 3 Screen – 2

Do the following to position the back sensor for the second measurement:

- Have the patient lean forward.
- Push the slider to the right and remove the selector from the positioner. Then, snap it into place onto the Q selector station.

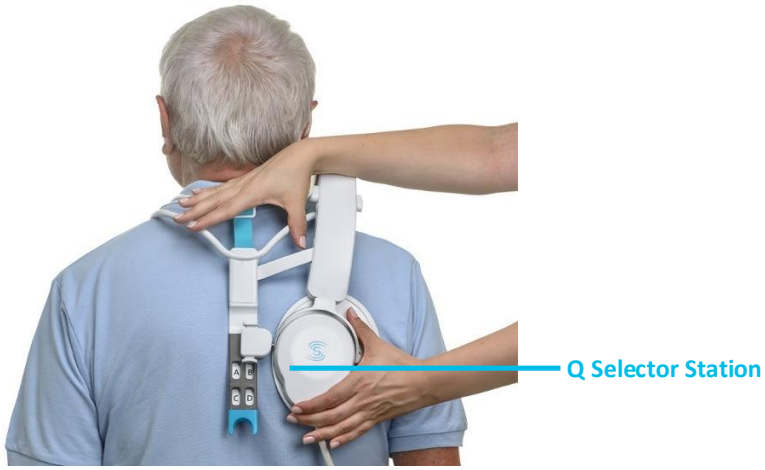


Figure 51: Positioning the Back Sensor for the Second Measurement

- Reposition the back and chest sensors on the spine and the neck. See page 43 for more details.
- Have the patient sit upright and recline back against the backrest in the chair while holding the back sensor in place.

5 Tap **Next**. The following screen displays:

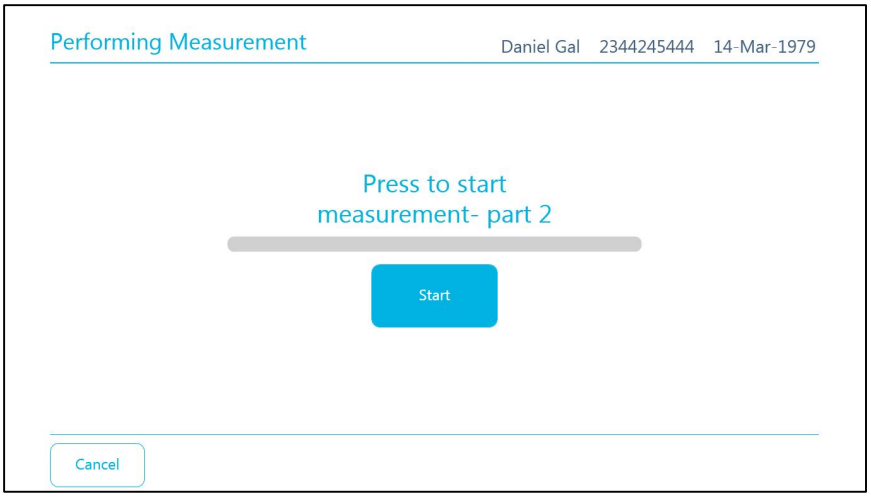


Figure 52: Measuring Part 2 Screen – 1

6 Tap **Start** to take the measurement in the second position. The following screen displays:

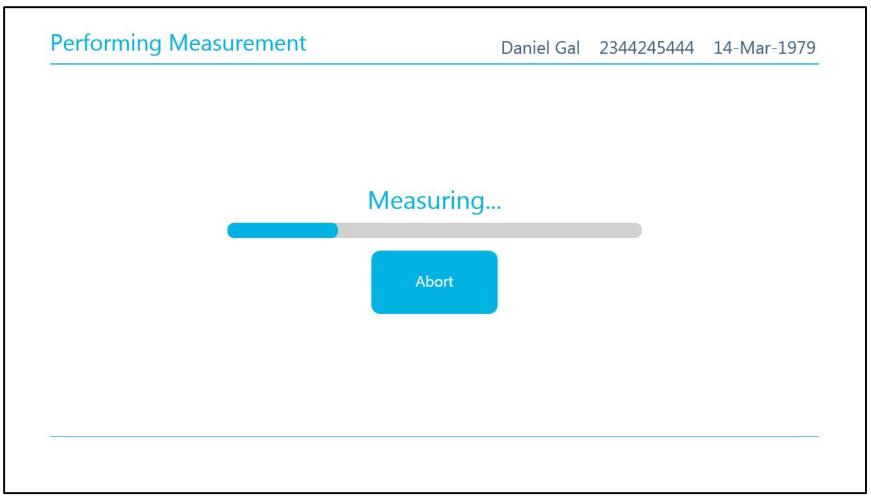


Figure 53: Measuring Part 2 Screen – 2

7 Wait until the measurement process ends automatically and the chest sensor deflates. After a successful measurement, the following screen displays, showing the measurement result:

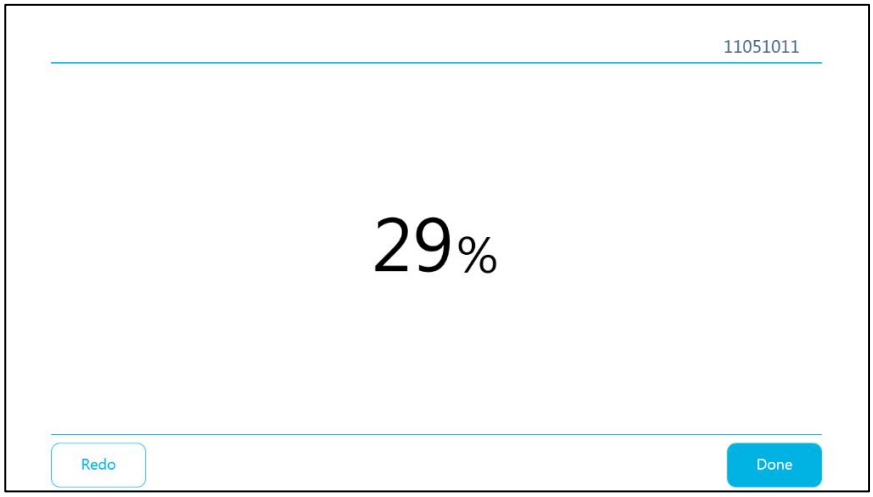


Figure 54: Measurement Result

Press Done to complete the measurement flow.

Unsuccessful Measurement

If the measurement was not successful, then the following message is displayed: *Low Quality.*

Unsuccessful measurements may indicate that the Sensor Unit was not fitted properly. In this case, re-adjust the Sensor Unit by following the instructions in the *Step 3: Applying the Sensor Unit on the Patient* section on page 37 and then re-run the measurement process described in this chapter.

Take care to hold the unit's back sensor carefully when positioning that sensor on the patient. The back sensor must be held in place until the patient is instructed to lean back in the chair, to ensure that it remains positioned properly. The patient should be instructed to sit up straight as much as possible while you hold the back sensor, until the patient leans back in the chair.

Verify that the instructions in this chapter were followed correctly. It is recommended to check that the back sensor is pressed against the back, that the sensors do not move during the measurement and that the patient does not move or talk during the measurement process. For additional information, you may refer to *Chapter 5, Troubleshooting* on page 84.

Re-run the measurement process.

If the problem occurs three times in a row, remove the Sensor Unit and contact support.

Step 5: Reviewing Measurement Results

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

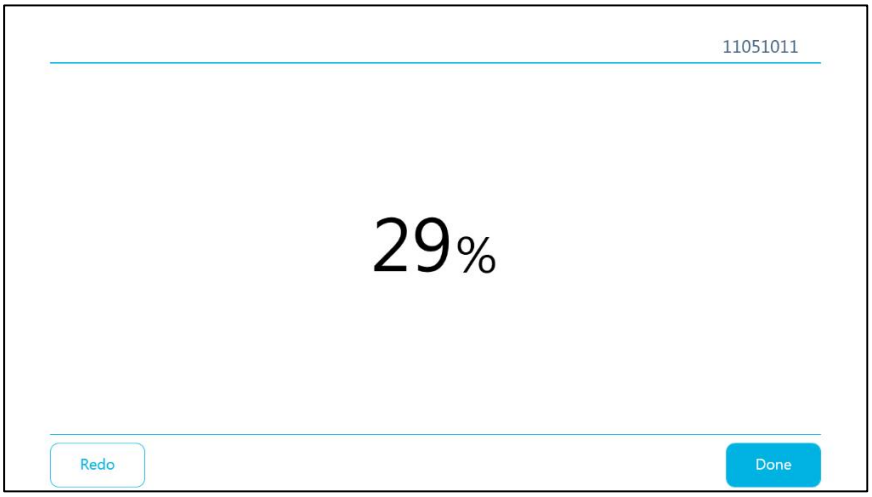


Figure 55: Measurement Results

The fluid content parameter is 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%.

Press Done to complete the measurement flow. Tap the **Redo** button to perform another measurement with the same patient.

CAUTION:

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

Step 6: Cleaning and Disinfection

Remove the Sensor Unit from the patient. To do so, remove both sensors from the patient using one hand on the chest sensor and the other hand on the back sensor. After every patient use, clean and disinfect the Sensor Unit, See the *Cleaning and Disinfection* section on page 90 for more information. Hang the Sensor Unit on the designated hanger on the cart. If you are using a table stand mount, make sure that the Sensor Unit is placed in a secure and protected position. This completes the measurement session.

Shutting Down the ReDS Pro System

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

► **To shut down the ReDS Pro 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. Hang the Sensor Unit on the designated place on the cart, so that it cannot be harmed.

4 Generating Reports from The ReDS™ Pro System

Usage Report

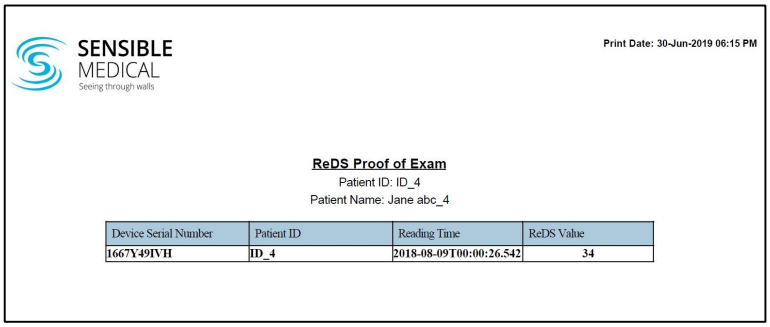
The *Usage Report* screen enables you to generate reports of the measurements taken from the ReDS Pro System.

The following provides instructions for report generating from the system.

Insert a USB thumb drive to the designated place in the back of the console, disconnect the Cellular modem of Wi-Fi adapter if needed. Contact support regarding the USB thumb drive use.

Use the options in this screen, as follows:

- Date Range: To generate a report that includes all measurements in the specified range, choose a date range, or either use the “All” button to generate reports with all existing measurements.
- Report type: choose a report type from the following options:
    - **Proof of Exam** report, a separate report for each measurement taken in the ReDS Pro System, which includes the following data: Device SN, Patient ID, Reading Time, and ReDS Value.


SENSIBLE MEDICAL
Seeing through walls

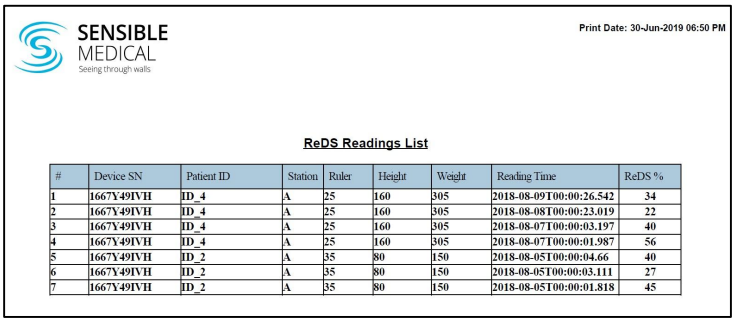
Print Date: 30-Jun-2019 06:15 PM

ReDS Proof of Exam
Patient ID: ID_4
Patient Name: Jane abc_4

Device Serial Number	Patient ID	Reading Time	ReDS Value
1667Y49IVH	ID_4	2018-08-09T00:00:26.542	34

Figure 56: Proof of Exam report sample

- **List of Readings** report- contains a list of measurements taken in the ReDS Pro System, according to the filters which were chosen. The report includes the following data: Device SN, Patient ID, Station, Ruler, Height, Weight, Reading Time, and ReDS Value.



SENSIBLE MEDICAL
Seeing through walls

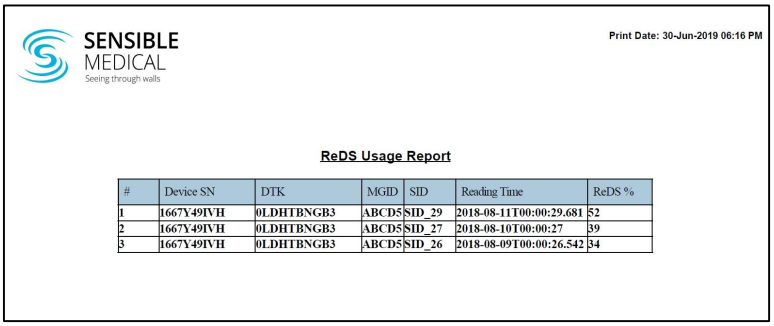
Print Date: 30-Jun-2019 06:50 PM

ReDS Readings List

#	Device SN	Patient ID	Station	Ruler	Height	Weight	Reading Time	ReDS %
1	1667Y49IVH	ID_4	A	25	160	305	2018-08-09T00:00:26.542	34
2	1667Y49IVH	ID_4	A	25	160	305	2018-08-08T00:00:23.019	22
3	1667Y49IVH	ID_4	A	25	160	305	2018-08-07T00:00:03.197	40
4	1667Y49IVH	ID_4	A	25	160	305	2018-08-07T00:00:01.987	56
5	1667Y49IVH	ID_2	A	35	80	150	2018-08-05T00:00:04.66	40
6	1667Y49IVH	ID_2	A	35	80	150	2018-08-05T00:00:03.111	27
7	1667Y49IVH	ID_2	A	35	80	150	2018-08-05T00:00:01.818	45

Figure 57: List of Readings report sample

- **Usage report**- contains a list of measurements taken in the ReDS Pro System, according to the filters which were chosen. The report includes the following data: Device SN, Reading Time, ReDS Value and further technical details involving the measurement.



SENSIBLE MEDICAL
Seeing through walls

Print Date: 30-Jun-2019 06:16 PM

ReDS Usage Report

#	Device SN	DTK	MGID	SID	Reading Time	ReDS %
1	1667Y49IVH	0LDHTBNGB3	ABCD5	SID_29	2018-08-11T00:00:29.681	52
2	1667Y49IVH	0LDHTBNGB3	ABCD5	SID_27	2018-08-10T00:00:27	39
3	1667Y49IVH	0LDHTBNGB3	ABCD5	SID_26	2018-08-09T00:00:26.542	34

Figure 58: List of Usage Report sample

- Filter by patient- this option is valid only when choosing the Proof of Exam report type. Click on Filter by Patient and choose a patient from the patient list, tap the patient row to select a certain patient.

Once the report type is configured, click on Generate report to generate report

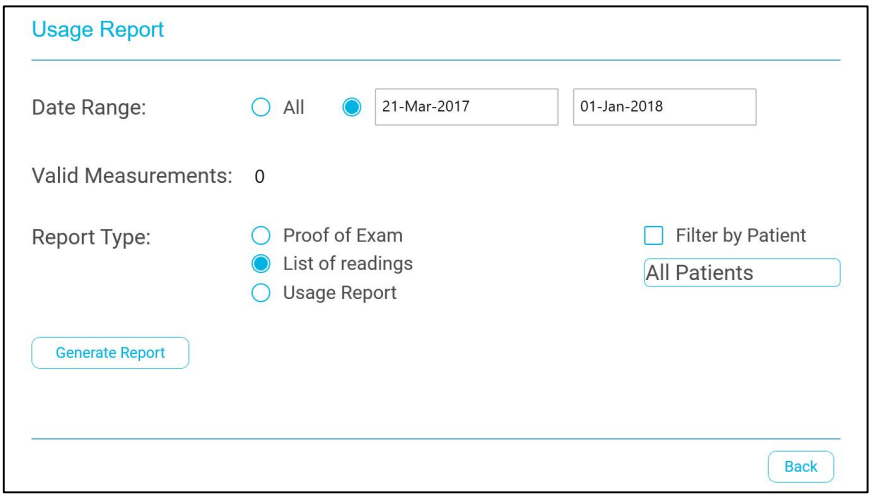


Figure 59: Measurement Workflow

NOTE

To add encryption to the Proof of Exam and List of Readings reports, enter password in Report Password field, see page 26. In case a password was added, a password would be required for viewing those reports.

NOTE

- After the report generation was completed, disconnect the USB thumb drive, and reconnect the cellular modem of WiFi adapter (in case the transmission is set to Cellular or WiFi)
- Do not connect or disconnect the USB thumb drive during active measurement

CAUTION:

You are about to export reports that might contain patient PHI (protected health information) from the system. Consider adding report password, see page 26

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,** below, describes the main functions of the SensiCloud Portal.
- **SensiCloud Main Screens,** page 66, describes the three main screens of the SensiCloud Portal.
- **Using the SensiCloud Portal,** page 70, describes how to manage and track your patients using the SensiCloud Portal.
- **SensiCloud Troubleshooting,** page 83, describes how to troubleshoot various SensiCloud Portal problems.

SensiCloud Overview

The SensiCloud provides the following functions:

- Device level readings backup.
- Performing technical and administrative tasks by Sensible service team for supporting healthcare provider's work.

  When using a device allocated to a single patient:

  The SensiCloud enables quick and easy access to your patients' data through a simple user interface.
- Enrolling patients in the SensiCloud Portal.
- Pairing a specific ReDS Pro 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 measurement activity via missed readings indicators.
- Enabling automatic measurement reminder notifications.
- 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

When using a device allocated to a single patient, for patient specific management through the SensiCloud portal, follow the sections below.

WARNING!

In case you are using a single device for multiple patients, use the SensiCloud only for device level readings back up, as described in the *Device Level Readings Back Up Using the SensiCloud* section on page 82.

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).

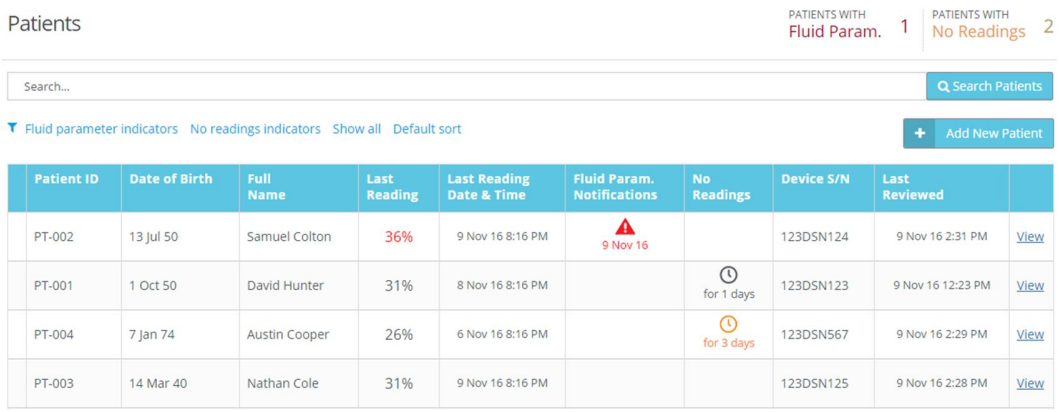


Figure 60: Patient List

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.

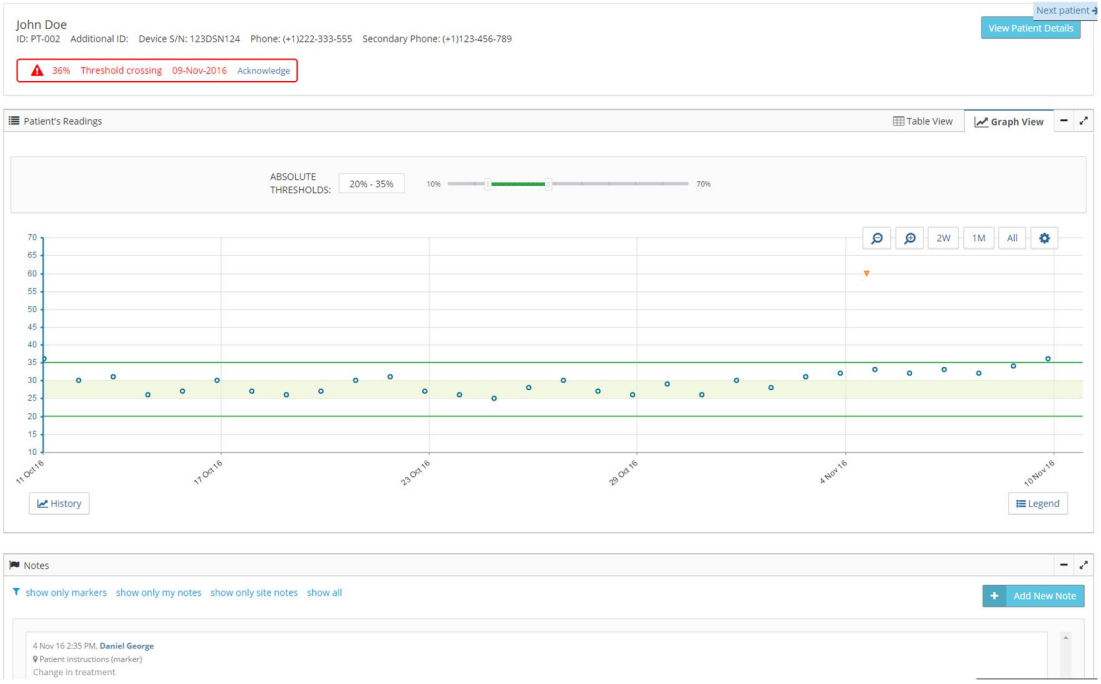


Figure 61: Patient Graph View

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.

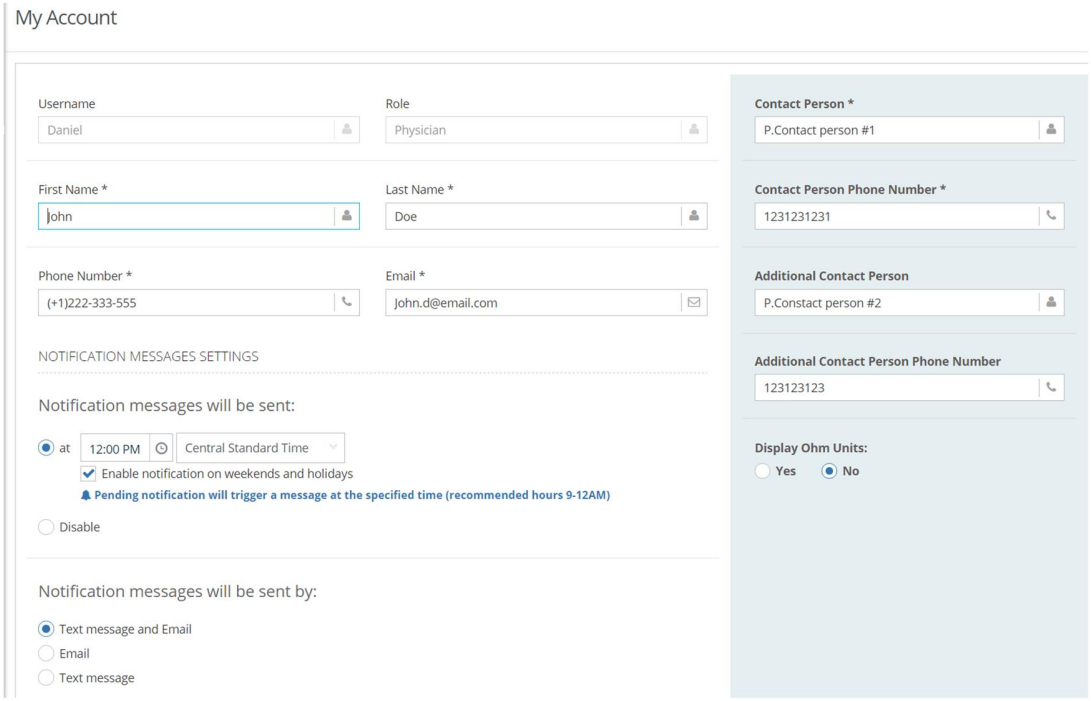


Figure 62: My Account Screen

Using the SensiCloud

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

NOTE

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

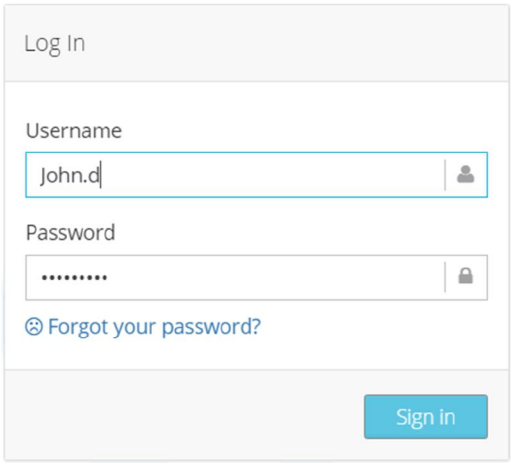


Figure 63: Login Screen

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 logging in, press the **Add New Patient** button, the New Patient screen is displayed:

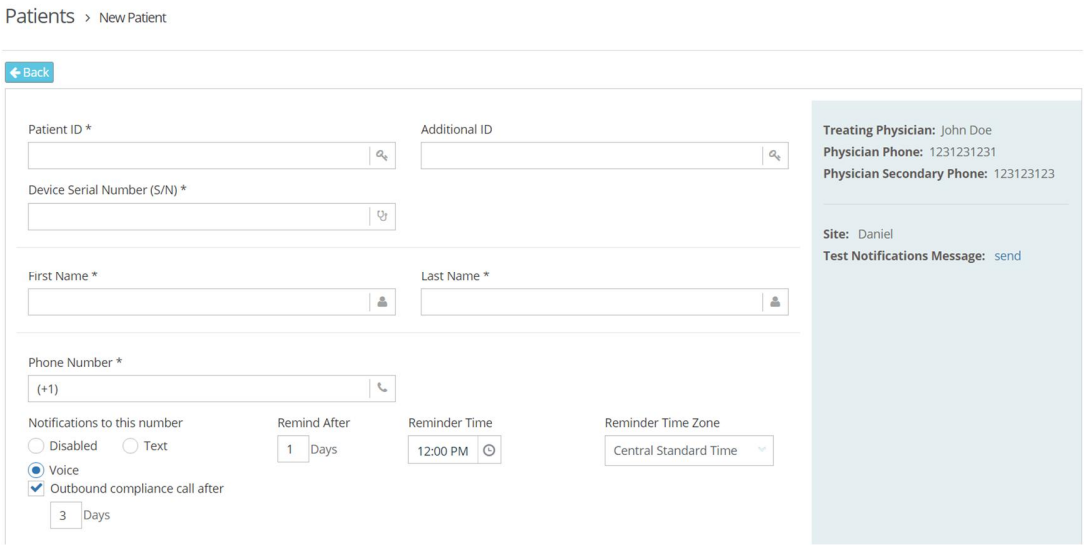


Figure 64: Enrolling a New Patient

- 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 Pro System used to measure this patient. The serial number of the ReDS Pro 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 70.

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:

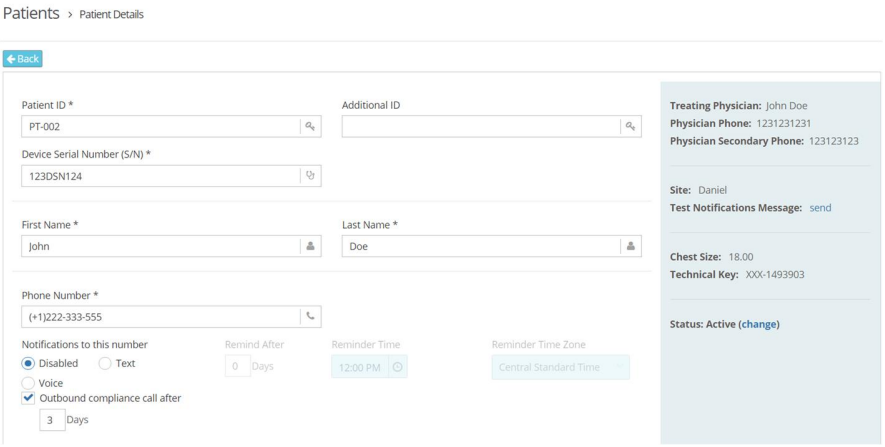


Figure 65: Editing Patient Details

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:

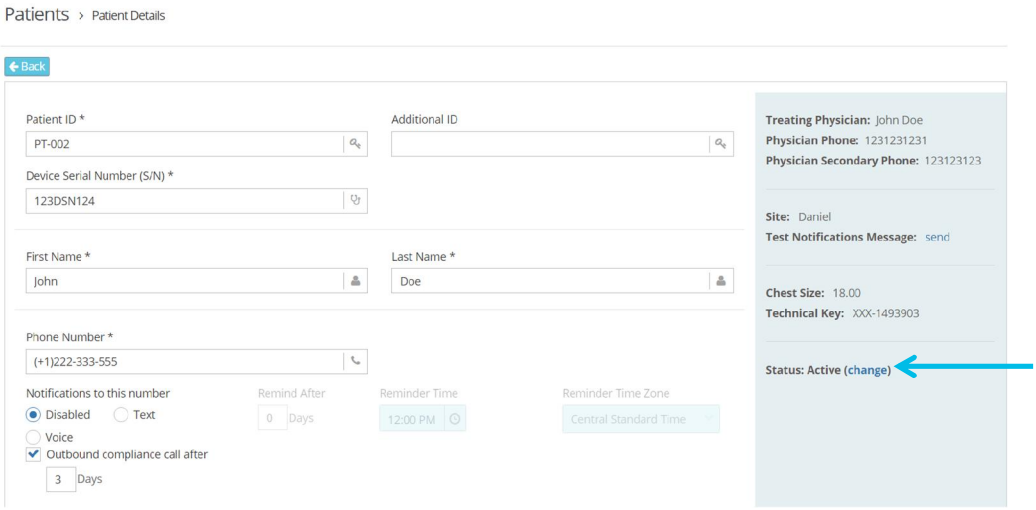


Figure 66: Suspending a patient

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:

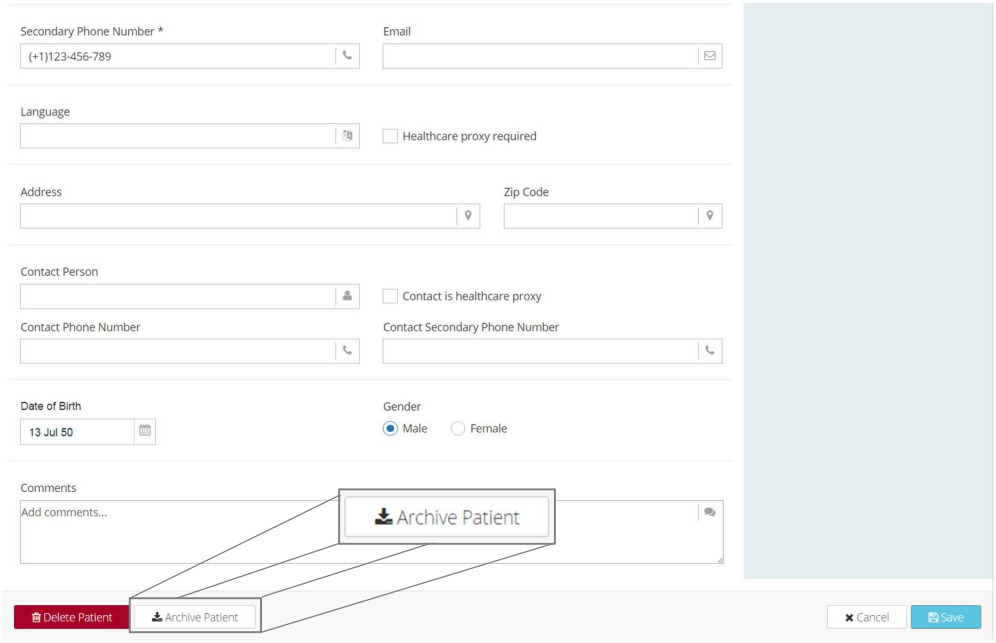


Figure 67: Archiving a patient

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.

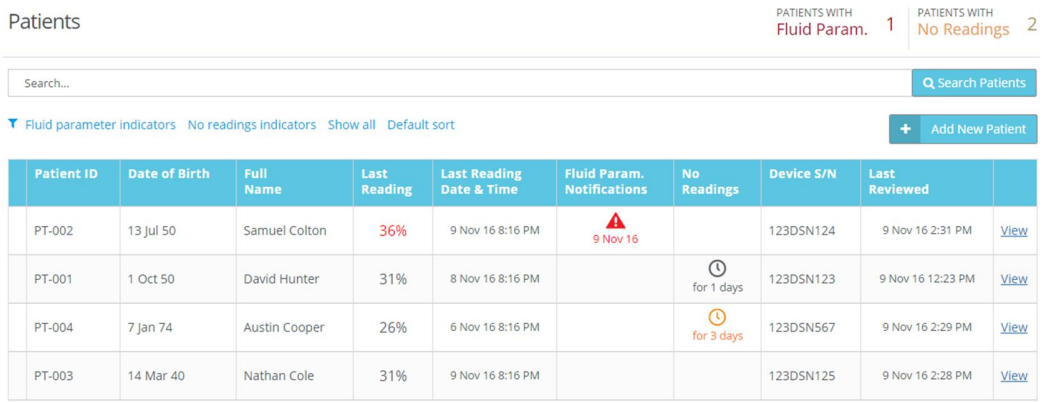


Figure 68: Patient List – Default Sort

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 in percent units (%).

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

Reviewing the Patient Graph View

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.
3. For notes of type ‘Marker’ you may adjust the note timestamp if necessary.
4. Click the **Save** button to record the note.

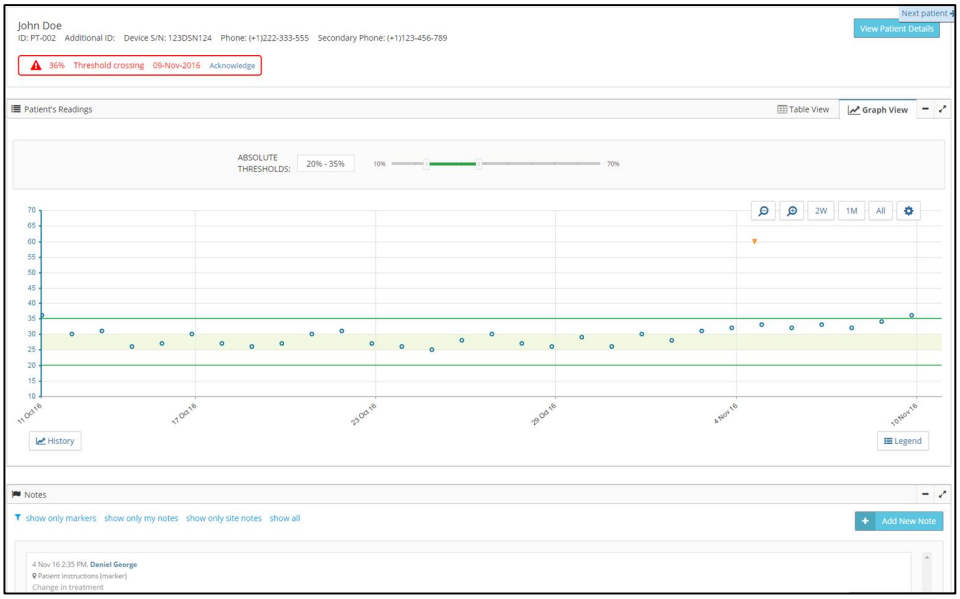


Figure 69: Patient Graph View

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 70). 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.

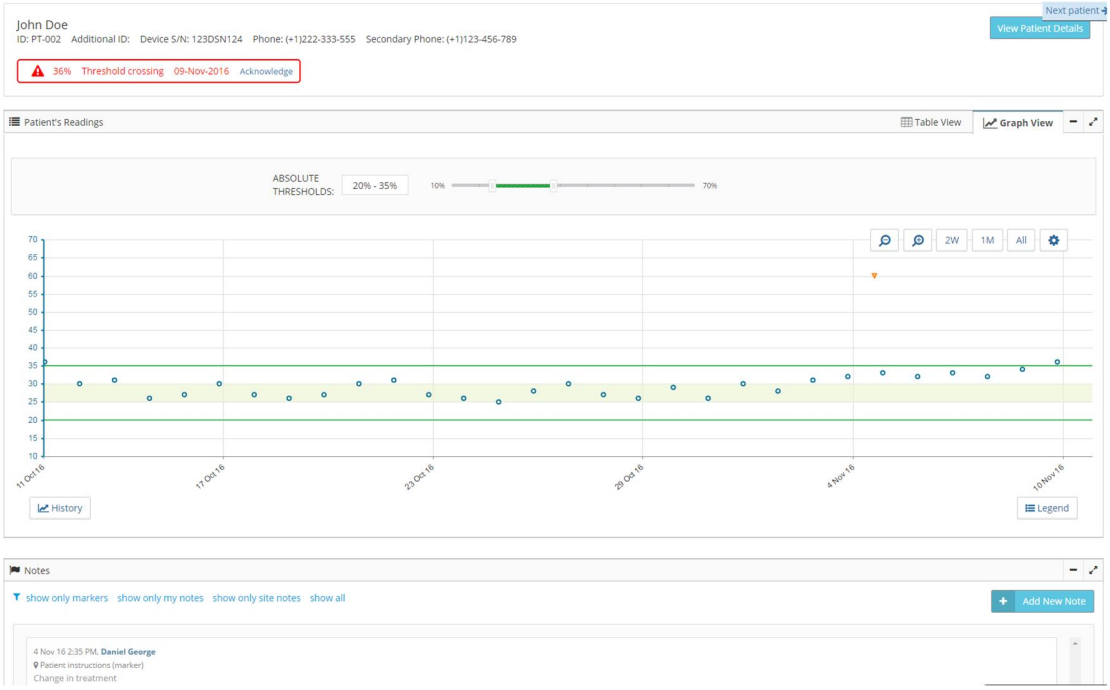


Figure 70: Patient Graph View

Administrative User

The cloud portal also provides functionality for centrally monitoring system use, monitoring measurement activity 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), 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 readings are not taken over an extended period.

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.

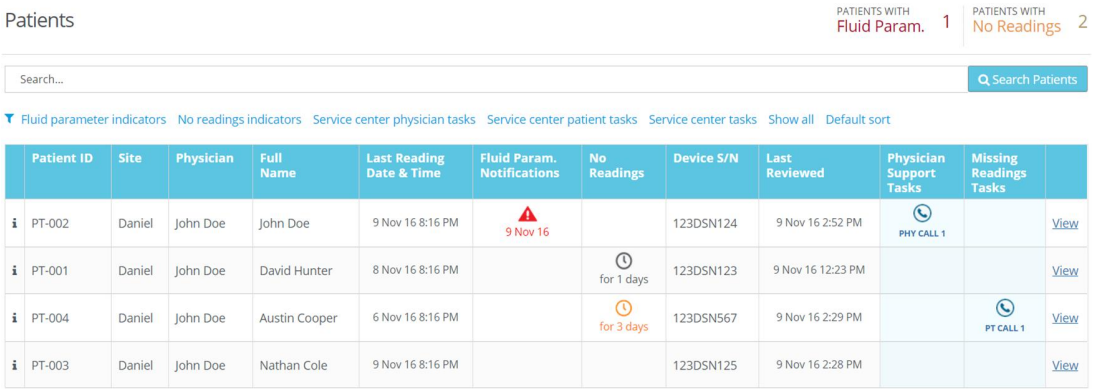


Figure 71: Patients List - Administrative User View

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 76.

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:

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

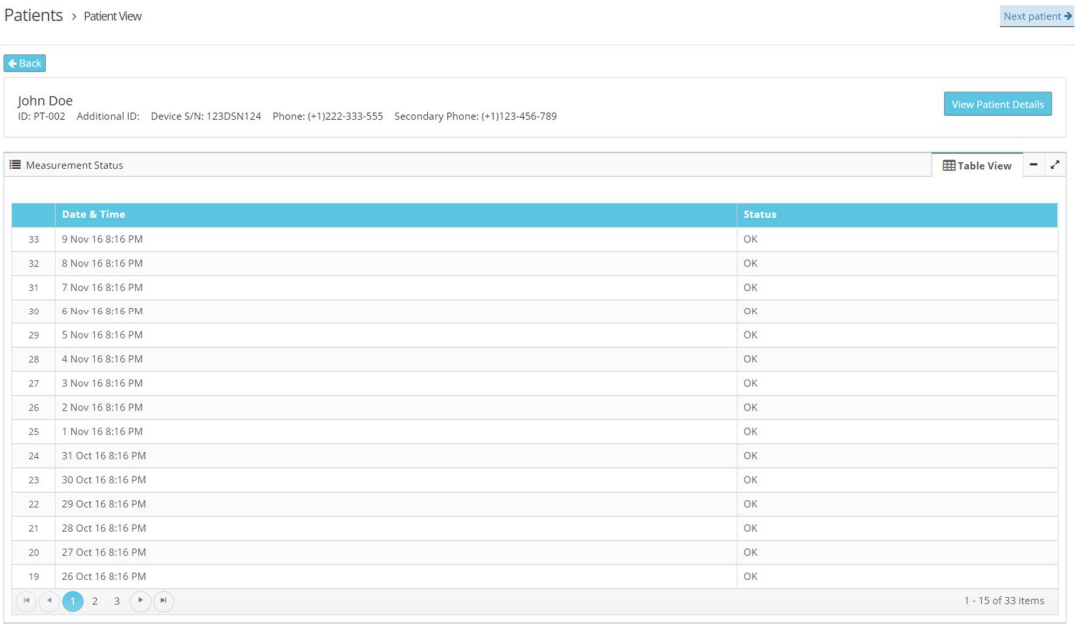


Figure 72: Patient View

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.

Device Level Readings Back Up Using the SensiCloud

For device level readings back up, using the SensiCloud portal, follow the section below.

► To set up a new device using the SensiCloud:

- Use the Patient Identifier field to recognize a device.
- In the **Device Serial Number** field, enter the serial number of the ReDS Pro System you are using. The serial number of the ReDS Pro System is written on the back of the Bedside Console.
- Make sure all information is correct and tap the **Save** button.
- Use the tabular view (see figure 71) to view logs of measurements taken from the device.

Patient ID	Date of Birth	Full Name	Last Reading	Last Reading Date & Time	Fluid Param. Notifications	No Readings	Device S/N	Last Reviewed	
Clinic name 1		Hospital Floor	54%	3 Aug 18 12:33 PM	17 Apr 18	for 2 days	1670W90UMZ	19 Jun 18 3:17 AM	View
Clinic name 2		Rochester Regional Ehealth	49%	31 Jul 18 3:31 PM	4 Apr 18	for 5 days	1746U86VDB	26 Jul 18 3:24 PM	View
Clinic name 3		Heart Failure Clinic	48%	3 Aug 18 2:39 PM	25 May 18	for 2 days	1734HPVSJH	31 Jul 18 2:44 PM	View
Clinic name 4		Traveling Nurses	47%	31 Jul 18 2:29 PM	30 Jul 18	for 5 days	1183FH1KGL	31 Jul 18 2:20 PM	View
Clinic name 5		Hospital Floor	47%	23 May 18 9:59 AM	4 Dec 17	for 74 days	1467EXDVNF	19 Jul 18 11:29 AM	View
Clinic name 6		Heart Failure Clinic	47%	20 Jun 18 3:51 PM	5 Jun 18	for 46 days	13342HP9RS	19 Jun 18 3:22 AM	View

Figure 73: Tabular View

CAUTION:

Verify successful setup and connectivity by performing a test measurement and viewing the results under the patient's tabular view in the SensiCloud. For more information about how to view measurement results in SensiCloud, refer to the *Using the SensiCloud* section on page 70.

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. 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 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. 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 is required.
	System malfunction.	Press and hold the **ON/OFF** button for five seconds, unplug and reconnect the device. Press shortly on the **ON/ OFF** button.
	Forgotten password	Use the “forgot my password” button to contact support. Contact Support, and indicate the password recovery code. The service representative will provide the new password to enter in the new password field.

Problem	Potential Causes	Action Required
Message displayed: *Low quality measurement*	1. Patient slid or rolled on the bed or chair while lying back and the unit has moved. 2. Unit was applied over multiple layers of clothing or thick clothing. 3. Sensor Unit positioning markers were not positioned properly on the back and front when the unit was applied. See the *Step 3: Applying the Sensor Unit on the Patient* section on page 37 for details. 4. Patient was moving or talking during measurement.	1. Remove the Sensor Unit. 2. Make sure that the patient is wearing light clothing. 3. Make sure that all patient details are correct, including the Chest Size Ruler value. 4. Reapply the Sensor Unit according to the on-screen instructions, making sure that the markers are properly positioned. 5. Guide the patient into position and ensure that the patient is not rolling or sliding against the bed or chair. 6. Re-run the measurement process and make sure that movement and talking during the measurement are avoided. 7. If the problem repeats more than twice, contact support. 8. Click the **Redo** button at the end of a measurement to display the *Patient Details* screen. In that screen, verify that all information was entered correctly.
Message displayed: *System Malfunction*	Technical malfunctions.	1. Press and hold the **ON/OFF** button for five seconds, unplug and reconnect the device. Press shortly on the **ON/ OFF** button. 2. If the malfunction persists, stop using the system and contact support.

Problem	Potential Causes	Action Required
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. 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 the Start screen to verify that the minimal quality of service is available (indicated by at least two bars). You can also use 'Communication Test' in the 'Setting' screen to validate cellular or Wi-Fi connectivity.
	Wi-Fi issues (if using Wi-Fi) – LED on the Wi-Fi adapter not flashing.	Make sure that the USB Wi-Fi adapter is connected to the USB port on the back of the console. If the USB Wi-Fi adapter 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.

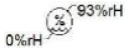
A Labeling

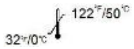
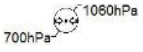
This appendix shows the label that is attached to the ReDS Pro System and describes the symbols that appear on it.

Labeling Symbols

Table 2: Labeling Symbols

Symbol	Description	Symbol	Description
Fluid Status Monitor	Intended purpose		Manufacturer commercial logo
ReDS Pro System	Product commercial name		Non-ionizing radiation
V2.7	Model ID		Unique Device Identifier (UDI)
Rx ONLY	Federal law restricts this device to sale by or on the order of a physician	FCCID	FCC ID Number
	Follow instructions for use	REF	Catalog number
	Keep dry	SN	Serial number
	Keep away from sunlight		
	Degree of protection against electric shock (Type BF)	⎓	Direct current
	consult instruction for use		
IP22	Protected against solid objects greater than 12.5 mm Protected against dripping water when tilted up to 15°	Made in Israel	Country of origin where the product was manufactured or assembled

Symbol	Description
	General warning
	Manufacturer
	Storing and shipment allowed humidity range
	Cart Basket Max. Load allowed

Symbol	Description
Meir Ariel 6, Netanya 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 Pro System.

General

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

- Check the mechanical arms and inflatable sensor to check for cracks, breaks, tears, deformations or jammed parts.
- Inspect the Bedside Console, power supply and the cables (power cable and unit cable) for any visible physical damage (cracks, breaks).

WARNING!

This system or its auxiliary equipment should not be operated if there is any visible physical damage to any of its parts (Sensor Unit, Bedside Console, Carrying Case, Package, Chest Size Ruler, Power Supply or cables), such as cracks, breaks, tears, stuck parts, deformations and so on.

Storage

Store the Sensor Unit indoors in a dry and protected place, preferably in its transported package

If you are not using the carrying case, between measurements, it is recommended to leave the Bedside Console plugged into a power outlet.

Storage and shipment conditions are as follows:

- **Temperature:** 32–122°F
- **Relative Humidity:** 0–93% non-condensing
- **Atmospheric Pressure:** 700–1,060 hPa

Gather loose cables (Sensor Unit cable and power cable) by wrapping them around the Bedside Console. When using the cart configuration, use the hanger to store the Sensor Unit, and the utility basket to store the power supply and cables.

Cleaning and Disinfection

CAUTION:

Stop using the device if there is a reason to suspect that it has been contaminated.

General Cleaning

If the Console and/or cable and/or Chest Size Ruler are soiled or if cleaning is needed:

- The console, cable and the Chest Size Ruler 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.

Cleaning and Disinfection of the Sensor Unit

After every patient use (and before packing and/or if the Sensor Unit is soiled):

- Use a new Super Sani-Cloth or equivalent germicidal wipe (see note below) to clean soil off all surfaces of the sensor unit until no visible soil appears. Pay close attention to grooves and sensors.
- Use a new Super Sani-Cloth wipe or equivalent germicidal wipe (see note below) to thoroughly wet the sensor unit, if the wipe starts to dry replace it with a new one and continue.
- For effective disinfection, treated surfaces should remain wet for a total of three minutes (i.e. three minute contact time).
- Use a lint free cloth dampened (after squeezing) with distilled water to wipe all surfaces of the sensor unit and leave to air dry.

Use Super Sani-Cloth wipes, or equivalent germicidal wipes in accordance with the manufacturer's instructions (please note associated manufacturer's warnings).

NOTE:

- Equivalent germicidal wipe should contain the following active ingredients:
- N-Alkyl(68%C12, 32%C14) dimethyl ethylbenzyl ammonium chlorides 0.25%
- N-Alkyl(60%C14,30%C16,5%C12,5%C18) dimethyl benzyl ammonium chlorides 0.25%
- Isopropyl Alcohol 55.0%

Maintaining

- No user maintenance is required for the ReDS Pro System. This device must only be serviced by Sensible-Medical Innovations qualified personnel.
- There are no user-serviceable parts inside the ReDS Pro System.
- Contact support in case of battery malfunction.
- The ReDS Pro System must be returned upon concluding its use. Contact support for more information.

Packaging for Shipment

► **To maintain the ReDS Pro System:**

1. Place the hanger in the upper-right slot. Place the three Chest Size Rulers in the designated left slot. Place the USB and the Wi-Fi dongle in the lower- left slot.
2. Set the station selector to station **B**.
3. Place the sensor unit in the left slot. Place the inside foam between the two sensors.
4. Loop the RF cable in the right slot, loop the power cord in the bottom slot. Place the power adapter in the lower-right slot.
5. Place the Bedside Console over the cable in the right slot facing up, such that the cable exiting the console is pointing down towards the power supply.

Figure 74: System inside the package

6 Place the packaging foam covers over the Sensor Unit and the Bedside Console.

Transporting the ReDS Pro with a Carrying Case configuration

To transport the ReDS Pro System by car for example in the use case of a traveling nurse, use the provided Sensible Carrying case according to the following instructions:

► Unpacking of the ReDS Pro System

1. Place the carrying case on the floor, unzip the case and pull up the handle. Place the top strap over the handle in order to hold the carrying case open.
2. detach the two straps on bottom of the left corner of the carrying case which holds the Sensor Unit arm.
3. Take the stations selector out from the strap on the center of the buffer.
4. Take the Sensor Unit out from the trolley.
5. Take the power supply and cable out from the power supply's pocket.
6. Open the two buckles.
7. Lift the buffer and attach the strap to the top side of the trolley
8. Take out the bedside console from the carrying case
9. Open the table stand before using the bedside console.

► Packing the ReDS Pro in the carrying case:

1. Place the carrying case on the floor, unzip the case and pull up the handle. Place the top strap over the handle in order to hold the carrying case open.

Figure 75: Left: Carrying Case handle and zippers open Right- strap over handle

2. Lift the buffer and attach the strap to the top of the carrying case (top side).Slide the table stand's back leg into the sleeve at the back of the carrying case, make sure that the sleeve holds the leg inside. Tilt the Bedside console backwards until it reaches to the back of the carrying case.

Figure 76: Sleeve

3. To close the buffer, attach the Velcro connected to the bottom of the buffer, to the carrying case floor.

Figure 77: Buffer consented to the case floor

4. Attach the buckles around the buffer.

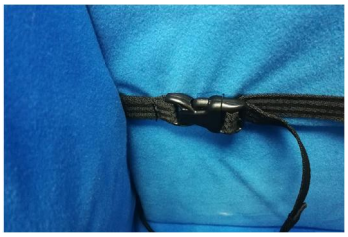


Figure 78: buckles connected

5. loop the power cable around the power supply and place the power supply inside the power supply's pocket

Figure 79: Power supply inside the pocket

6. Disconnect the stations selector and place the sensor's separator between the front and the back sensor

Figure 80: Station selector is disconnected. The separator is between the sensors

7. Place the right side of the neck piece inside the Sensor Unit arm.

Figure 81: Neck piece inside the Sensor Unit arm

8. Place the Sensor Unit inside the bag, see figure below for correct orientation

Figure 82: Neck piece inside the Sensor Unit arm

9. Insert the station selector in the shown orientation into the straps on the center of the buffer

Figure 83: Neck piece inside the Sensor Unit arm

10. Attach the two straps on bottom of the left corner of the carrying case around the Sensor unit arm. Make sure the straps are tightened.

Figure 84: Straps around the Sensor unit arm

11. Release the top strap from the handle, and bring it back to the front

12. Close and zip the carrying case.

NOTES:

- The label attached on the back of the carrying case indicates allowed usage conditions.
- Avoid exposing the carrying case to heavy rain.
- Pack and unpack the system from the carrying case while placed on the floor.

WARNING!

- Do not leave the Carrying Case inside the car to maintain storage and shipment conditions.
- This system or its auxiliary equipment should not be operated if there is any visible physical damage to any of its parts (Sensor Unit, Bedside Console, Carrying Case, Package, Chest Size Ruler, Power Supply or cables), such as cracks, breaks, tears, stuck parts, deformations and so on.

CAUTION:

Packing inside the Carrying Case should be done according to the instructions above. Wrong packing may damage the device.

C Technical Information

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

Technical Specifications

Table 3: Technical Specifications

Electrical Requirements	
	100–240 VAC, 50/60 Hz 0.30 A @ 100 VAC 0.13 A @ 240 VAC
Sensor Electromagnetic Information	
Operating Frequency	[957, 958, 1242, 1243, 1256, 1257, 1292, 1293, 1294, 1295, 1428, 1429, 1430, 1431, 1629, 1635, 1636, 1655, 1656, 1657, 1711, 1712, 1716, 1717, 1718] MHz
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 Unit Weight	3.1 lbs
Bedside Console Weight – Cart	37.9 lbs ± 10%
Bedside Console Weight – Tabletop	9.0 lbs ± 10%

Bedside Console Height – Cart	46.65 inches ± 10%
Bedside Console Height – Tabletop	10.51 inches ± 10%
Sensor Unit Materials	PA 12, PU, PC-ABS
Display Parameters	
Fluid Content Display Range	15%–60%
Accuracy	± 7%
Cellular Wireless Connectivity	
Cellular Connectivity Options	GSM, GPRS, EDGE, HSPA, UMTS, LTE, CDMA
Cellular Frequency Bands	700, 800, 850, 900, 1,700, 1,800, 1,900, 2,100 or 3,500 MHz
Data Rate (Uplink)	60 Kbps – 75 Mbps
Minimum Required Quality of Service	Minimum signal strength of two bars in the cellular signal strength indicator
Effective Radiated Power	20–34 dBm (0.1–2.5 Watt)
FCC Compliant	Yes, Class B
Wi-Fi Wireless Connectivity	
Protocol Options	IEEE 802.11b/g/n/ac
Frequency Bands	2.4 GHz or 5 GHz
Data Rate	1–300 Mbps
Minimum Required Quality of Service	An active Wi-Fi connection indicated by the Link/Activity LED indicator
Effective Radiated Power	10–30 dBm (0.01–1 Watt)
Security	WPA2
FCC Compliant	Yes, Class B
Range	Up to 30 feet from the Wi-Fi router
File Encryption	
File system encryption	AES256
Auxiliary Battery Specifications	
Type	Li-ion; 7.57 V ; 5,702 mAh

Battery Operating Conditions	See *Operating Conditions* below
Operating Conditions	
Operating Temperature	41–95˚F
Humidity	15%–93% Non-condensing
Atmospheric Pressure	700–1,060 hPa
Storage and Shipment	
Temperature	32–122˚F
Relative Humidity	0-93% Non-condensing
Ingress Protection	
Sensor Unit	IP22
Bedside Console	IP22
Expected service life	
Expected service life of the system	5 years

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 ID: 2AONF-27C01

► **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 Pro System V2.7 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 Pro 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 Pro System.
- Other equipment may interfere with the ReDS Pro System, even if that other equipment complies with CISPR emission requirements.
- The use of accessories, transducers and cables other than those provided may result in increased emissions or decreased immunity of the ReDS Pro System.
- The ReDS Pro System should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the ReDS Pro System should be observed to verify normal operation.
- In case of electromagnetic disturbances, device operation may be temporarly distrupted and error may appear on screen.

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

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 2	The ReDS Pro System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions CISPR 11	Class B	The ReDS Pro 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	8kV contact 15kV air	8kV contact 15kV 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 100 kHz repetition frequency	2 kV for power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment – Guidance
Surge, IEC 61000-4-5	0.5&1kV	0.5& 1kV (belongs to class II equipment without any grounded interconnections according to Section 36.202.5(b)(4) of EN/IEC 60601-1-2 4th edition)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	For 0.5 cycles: 0% U_T (> 95% dip in U_T) at 0°,45°,90°,135°,180°,225v,270°, and 315° For 1 cycle: 0% U_T (> 95% dip in U_T) For 25 cycles: 70 % U_T (30% dip in U_T) For 25 cycles: 0% U_T (> 95% dip in U_T)	For 0.5 cycles: 0% U_T (> 95% dip in U_T) at 0°,45°,90°,135°,180°,225v,270°, and 315° For 1 cycle: 0% U_T (> 95% dip in U_T) For 25 cycles: 70 % U_T (30% dip in U_T) For 25 cycles: 0% 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.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment – Guidance
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE:

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 Pro System (including cables) than the recommended separation distance (see below).
Conducted RF, IEC 61000-4-6	3Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz to 80 MHz 80 % AM @ 1 kHz	$[V_1]$ = 6 Vrms 150 kHz to 80 MHz	**Recommended separation distance:** **d= 30 cm**
Radiated RF, IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ = 10 V/m	**Recommended separation distance:** **d= 30 cm**

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment – Guidance
Proximity fields from RF wireless technologies, IEC 61000-4-3	9- 28 V/m According to Table 9 in IEC 60601-1-2 4th edition	[E_1] = 9- 28 V/m According to Table 9 in IEC 60601-1-2 4th edition	**Recommended separation distance:** **d= 30 cm**

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.
- **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 Pro System is used exceeds the applicable RF compliance level above, the ReDS Pro 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 Pro System.
- [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

SENSIBLE
MEDICAL
Seeing through walls

Sensible-Medical Innovations Ltd.

6 Meir Ariel St. Netanya, Israel
4250364

℞ ONLY

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