



# **SOZO System Instructions for Use**



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For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.

For patent(s) and/or patent application(s) see: <https://www.impedimed.com/patents/>

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# 1.0 Minimum Requirements

## 1.1 Tablet

The Tablet, a Samsung Galaxy Tab A (Models SM-T510 or SM-T580) comes with the SOZO system. It has *Bluetooth*<sup>1</sup> communication with the SOZO Device.

### 1.1.1 Tablet Function

The Tablet is the primary user interface for the SOZO Device. Clinicians use the Tablet for all SOZO functions, including management of patient profiles, and the entry of patient measurements and data for SOZO Assessments. For product details on the Tablet, review [www.samsung.com](http://www.samsung.com) and the Tablet user guide.

### 1.1.2 SOZOapp

The SOZOapp for Android is pre-installed on the Tablet.

## 1.2 User Devices

Users may access MySOZO with any device, including a PC, laptop, or mobile device, with internet access and a Google Chrome or Mozilla Firefox web browser. For internet requirements, see [Section 1.3 MySOZO](#).

## 1.3 MySOZO

MySOZO communicates with the SOZO system through the internet. The minimum and recommended requirements for internet access are:

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<sup>1</sup> *The Bluetooth<sup>®</sup> word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by ImpediMed is under licence. Other trademarks and trade names are those of their respective owners.*



**MySOZO Minimum and Recommended Requirements**

Component	Requirements
Internet Speed	Minimum>15 Mbps download, 5 Mbps/ upload Recommended>25Mbps download, 5 Mbps upload
Web Browser	Google Chrome, Mozilla Firefox

## 2.0 Glossary

- 2.0.1 **Administrator**-MySOZO User authorized to manage Clinician and Administrator accounts and perform SOZO system-wide administrative functions. The Administrator has exclusive authority to adjust certain SOZO system-wide settings through MySOZO.
- 2.0.2 **Assessment**-An assessment of measurements taken of the patient, which is an output of the SOZO system. Different types of Assessments are available to the ImpediMed customer and viewable on the SOZOapp and MySOZO, including L-Dex®, Fluid Analysis and Tissue Analysis.
- 2.0.3 **Assessment licence**-ImpediMed grants a separate licence for each type of Assessment. Once an Assessment is licenced, the Clinic has access to that Assessment for all current and previous measurements. The availability of the Assessment licence is viewable in MySOZO and the SOZOapp.
- 2.0.4 **ATM**-Active Tissue Mass. Active Tissue Mass includes all metabolically active tissues in the body. Also, sometimes referred to as “Body Cell Mass” (BCM), these tissues include muscle, organs, and nervous tissue. This is expressed as a mass (kg or lb) and as a percentage of total mass.
- 2.0.5 **At-risk limb**-The limb at risk of developing lymphoedema.
- 2.0.6 **Bilateral**-A type of L-Dex Assessment for a patient who has both arms or both legs at risk of lymphoedema. The SOZO system compares each arm with each leg.
- 2.0.7 **Bioimpedance**-The measure of impedance of the human body to an alternating electric current.
- 2.0.8 **Bioimpedance Spectroscopy**-The technology used by the SOZO Device to accurately measure body water volumes of the patient, based upon bioimpedance parameters over a frequency range of 3 - 1000 kHz using 256 frequencies.
- 2.0.9 **BIS**-Bioimpedance Spectroscopy.
- 2.0.10 **BMR**-Basal Metabolic Rate. Basal Metabolic Rate is the amount of energy used by a person's body when at rest. ImpediMed uses the Mifflin-St. Jeor equation to calculate BMR. BMR is expressed in calories per day.
- 2.0.11 **Clinic**-A customer of ImpediMed, such as a hospital or medical facility, which uses the SOZO system.
- 2.0.12 **Clinician** -The primary User of the SOZO system, and an authorized User of MySOZO and the SOZOapp. The Clinician uses the SOZO Device to: take and record measurements of patients; view and evaluate measurements and Assessments over time; and assess patient progress.
- 2.0.13 **Cole plots** -The SOZO measurement data is displayed in the form of a complex impedance plot, commonly called a Cole plot. The X axis is the resistance value and the Y axis is the reactance value of the measurement at each of the 256 frequencies measured. Cole plots are reviewed when determining whether to accept or reject measurements. The SOZO software helps determine the quality of measurements as high, medium or low quality.

- 2.0.14 **Consumable**-A hardware component of the SOZO Device which the ImpediMed customer uses recurrently and which eventually wears out, gets used up or is discarded. For example, the Tablet sleeve is a consumable.
- 2.0.15 **Contralateral limb**-The limb located on the other side of the patient's body. For purposes of the L-Dex Assessment of a patient with unilateral lymphoedema, if the right arm is at-risk of lymphoedema, then the left arm is the contralateral limb.
- 2.0.16 **Dominant limb**-The limb which the patient uses the most. For example, for a right-handed patient, the right arm is the dominant limb.
- 2.0.17 **ECF**-Extracellular fluid. Extracellular fluid is all the fluid that is not contained within the cells. ECF is usually expressed as a volume (litres or pints).
- 2.0.18 **ECM**-Extracellular Mass. Extracellular Mass includes all metabolically inactive tissues in the body (e.g. bone, blood plasma). This is expressed as a mass (kg or lb) and a percentage of total mass.
- 2.0.19 **Electrode Plates**-See "Electrodes."
- 2.0.20 **Electrodes**-Stainless steel plate components of the SOZOtouch (where the patient places their hands), and of the SOZOstep (where the patient places their feet), which drive and sense electrical current for the performance of Bioimpedance Spectroscopy.
- 2.0.21 **Fluid Analysis Assessment**- Also referred to as "Fluid Analysis," the Fluid Analysis Assessment is performed by the SOZO Device of certain fluid levels of patients living with heart failure. Indications for Use and Instructions for Use of the Fluid Analysis Assessment is in [Section 9.3.2 Fluid Analysis](#).
- 2.0.22 **FM**-Fat Mass. Fat mass is the amount of mass a person has that is made up of fat. FM is typically measured in kilograms (kg) or pounds (lb) and is also expressed as a percentage of total mass (e.g. 24% body fat).
- 2.0.23 **FFM**- Fat-Free Mass. Fat Free Mass is the amount of mass a person has that contains no fat. FFM includes bone, muscle, connective tissue, organs, and body water. FFM is typically measured in mass (kg or lb) or expressed as a percentage of total mass (e.g. 60% fat free mass).
- 2.0.24 **Fluid Analysis**-The Fluid Analysis Assessment, as described in [Section 9.3.2 Fluid Analysis](#).
- 2.0.25 **Hex Key**-A tool which comes with the SOZO system for assembling the SOZOsupport Stand
- 2.0.26 **Hy-Dex®**-Hydration Index. A bi-directional "open-ended" scale that displays a person's fluid status as compared to a dataset from an average population. Can be used as a tool to assist a clinician or user in assessing their fluid status or hydration.
- 2.0.27 **ICF**-Intracellular fluid. Intracellular fluid is all the fluid that is contained within the cell membranes of the body. ICF is usually expressed as a volume (litres or pints).
- 2.0.28 **Ipsilateral limb**-The limb on the same side of the patient's body. For purposes of L-Dex Assessment of a patient with bilateral lymphoedema, SOZO compares R0 impedance of the at-risk limbs with the R0 impedance of the unaffected ipsilateral limbs. For example, if the patient has bilateral lymphoedema in both legs, the left arm is the unaffected ipsilateral limb to the at-risk left leg, and the right arm is the unaffected ipsilateral limb to the at-risk right leg.

- 2.0.29 **Impedance**-The measure of the total opposition of a circuit or part of a circuit to an electrical current.
- 2.0.30 **L-Dex®**-The Lymphoedema Index, a numeric value used in L-Dex Assessment. See also “L-Dex Assessment.”
- 2.0.31 **L-Dex Assessment**-Also referred to as “L-Dex,” the L-Dex Assessment is based upon L-Dex values, derived from the ratio of impedance for the unaffected limb and the at-risk limb, of the body fluid levels of patients at risk of lymphoedema, using certain patient measurements taken with the SOZO Device. Indications for Use and Instructions for Use of the L-Dex Assessment are set forth in [Section 9.3.1 L-Dex® for Lymphoedema](#).
- 2.0.32 **L-Dex score**-The measurement parameter for the L-Dex Assessment.
- 2.0.33 **Licensed Assessments**-Assessments for which a Clinic has purchased a licence.
- 2.0.34 **Measurements**-Measurement data taken by the Clinician of the patient using the SOZO Device. Measurements are the inputs in the SOZO assessment process.
- 2.0.35 **MySOZO**-The central cloud-based hub for the SOZO system that computes and stores Assessments based on raw measurement data taken from the SOZO Device. Users may access MySOZO via the internet.
- 2.0.36 **Parameter**-A clinically meaningful output based upon measurements.
- 2.0.37 **Product**-The SOZO Device, including all hardware components of the SOZO Device, except for any hardware component which is a “Consumable.”
- 2.0.38 **Patient**-The individual who is being measured with the SOZO Device.
- 2.0.39 **Phi**-Phase Angle. Phase Angle is the arctangent of resistance/reactance of a person's cell membrane at a 50 kHz frequency. Phase Angle is expressed as a degree (e.g. 5.5°).
- 2.0.40 **R**-Resistance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).
- 2.0.41 **Rinf**-Rinfinity. Rinf is the impedance measured at an infinite frequency.
- 2.0.42 **R0**-The impedance measured at a frequency of 0 kHz.
- 2.0.43 **SMM**-Skeletal Muscle Mass. Skeletal Muscle Mass includes all muscle mass that mechanically acts on bones to create movement. It does not include cardiac or smooth muscle. Expressed as mass (kg or lb).
- 2.0.44 **SOZOapp**-The app pre-installed on the Tablet which provides the User with access to the SOZO system.
- 2.0.45 **SOZOconnect Cable**-The hardware component of the SOZO Device used to connect the SOZOtouch with the SOZOstep.
- 2.0.46 **SOZOcradle**-The hardware component of the SOZO Device which holds the Tablet in place.
- 2.0.47 **SOZO Device**-The commercially available medical device manufactured by ImpediMed, which uses Bioimpedance Spectroscopy to perform different types of Assessments of patient fluid levels.
- 2.0.48 **SOZOsupport Stand**-The hardware component of the SOZO Device upon which the patient stands for the taking of SOZO measurements.

- 2.0.49 **SOZOstep**-A hardware component of the SOZO Device upon which the patient stands (places their feet) for connection to the SOZO Device.
- 2.0.50 **SOZO system**-The commercially available medical device system manufactured by ImpediMed, also referred to as the SOZO Digital Health Platform in the SOZOapp, which uses Bioimpedance Spectroscopy to perform various Assessments of patient fluid levels. The SOZO system is comprised of hardware-the SOZO Device and the Tablet, and software - MySOZO and the SOZOapp.
- 2.0.51 **SOZOtouch**-A hardware component of the SOZO Device upon which the patient places their hands for connection to the SOZO Device.
- 2.0.52 **Tablet**- Samsung tablet, provided to the ImpediMed customer as part of the SOZO system, with the SOZOapp pre-installed.
- 2.0.53 **TBW**-Total Body Water. Total Body Water is the total water within a person's body, including both intracellular and extracellular fluid. This is expressed as a volume (litres or pints) or a percentage of total mass (e.g. 60% of mass is TBW).
- 2.0.54 **Tissue Analysis Assessment**-The Assessment, also referred to as "Tissue Analysis," performed by the SOZO Device of the body composition of the patient, designed to estimate various body composition parameters, including Total Body Water (TBW), Fat-free Mass (FFM) or Fat Mass (FM), Basal Metabolic Rate(BMR), Skeletal Muscle Mass (SMM), Phase Angle (Phi), Body Mass index (BMI), and the Hydration Index (Hy-Dex®) Analysis. Indications for Use of the Tissue Analysis Assessment is in [Section 9.3.3.1](#) Indications for Use.
- 2.0.55 **Tissue Analysis**-See "Tissue Analysis Assessment."
- 2.0.56 **Unilateral**-A type of L-Dex Assessment for a patient with one arm or one leg at risk for lymphoedema.
- 2.0.57 **User Device**-A device, including a PC, laptop or mobile device, used by the User to access MySOZO.
- 2.0.58 **Xc**-Reactance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).
- 2.0.59 **Z**-Impedance. Impedance is the measure of the total opposition to an electric current. See and compare with "Bioimpedance."

## **3.0 Introduction to the SOZO System**

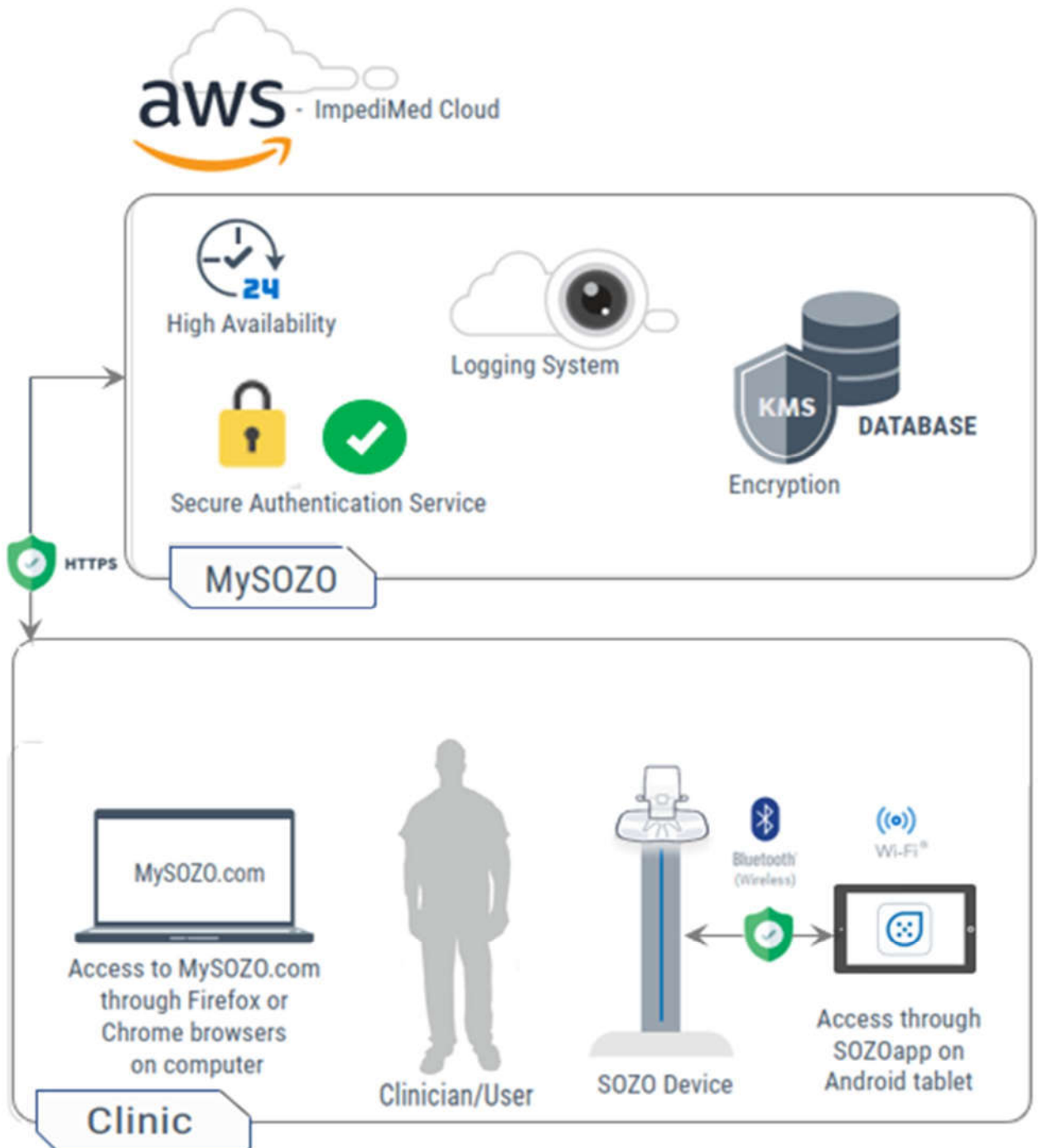
The SOZO system is a medical device system comprised of hardware and software. The SOZO system hardware components are the SOZO Device and the Tablet. SOZO system software is made up of the SOZOapp and MySOZO. Users may access the SOZO system through the SOZOapp on the Tablet, or by the internet through MySOZO.com.

### **3.1 Bioimpedance Spectroscopy (BIS)**

BIS is the only non-invasive technology available for accurate measurement of body water volumes in a clinical setting. Bioimpedance parameters are measured over a frequency range of 3 - 1000 kHz using 256 frequencies. Extracellular, intracellular and total body water are calculated from comparison of data collected from frequency range. With additional patient-specific data, further calculations determine other body composition results. Graphs allow evaluation of quality of measurements in the form of a Cole plot.

The SOZO system offers a rapid, non-invasive measurement of impedance which is used to determine fluid levels for monitoring of a variety of conditions, allows long-term patient monitoring and provides reports to support clinical and research practices.

## 3.2 SOZO System Overview



### 3.3 The SOZO Device

The SOZO Device is a medical device which uses ImpediMed's patented Bioimpedance Spectroscopy (BIS) for fast non-invasive measurement of fluid levels in human patients. ImpediMed's BIS technology provides a user-friendly platform to take quick, accurate patient measurements for assessment of patient body water volume, including extracellular fluid, intracellular fluid and total body water. The SOZOapp is a software application on the Tablet and provides the main user interface for the SOZO system. The SOZO Device and SOZOapp are used in conjunction with MySOZO, a cloud-based system.

The SOZO Device may assist with early detection of lymphoedema by giving an "early warning" of patient fluid status change. It may also be used to monitor fluid levels in patients living with heart failure. The SOZO system may be an integral part of a treatment plan for a lymphoedema and heart failure patient. Using the SOZO system, a Clinician may also monitor patient progress, including using the establishment of a baseline to track patient historical measurements.<sup>2</sup>

Healthy patients may also benefit from the SOZO Tissue Analysis Assessment, which monitors various parameters of body composition, such as fat mass (FM), fat free mass (FFM) and skeletal muscle mass (SMM).

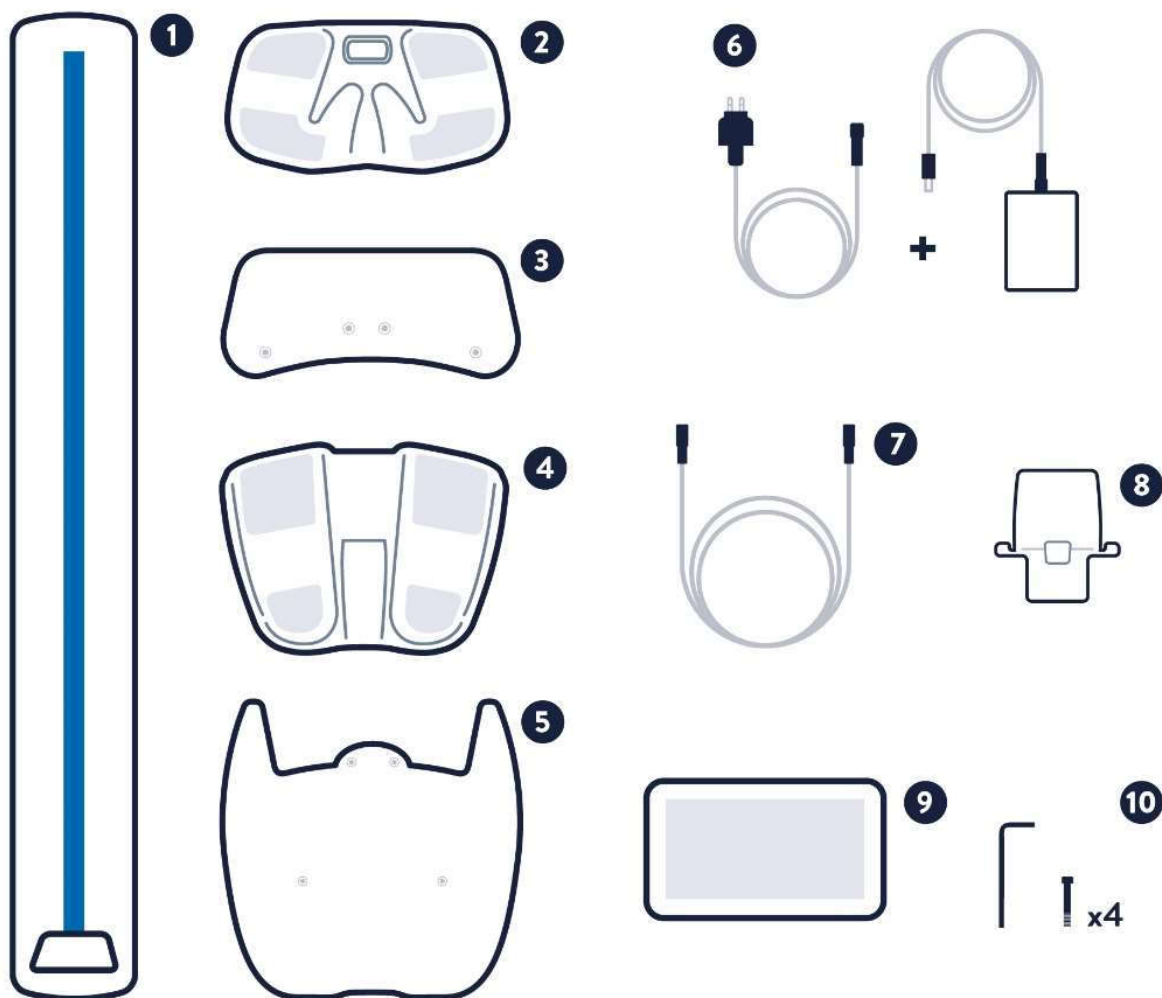
---

<sup>2</sup> Setting a baseline is not required for all Assessments. For the L-Dex Assessment, the Clinician may decide not to set a baseline. See 8.6.2.5.2 Setting a Baseline.



### 3.3.1 SOZO Device Hardware Components

The SOZO Device has the hardware components shown below.



- (1) SOZOsupport Stand
- (2) SOZOtouch
- (3) Handplate
- (4) SOZOstep
- (5) Footplate
- (6) Power Adaptor and Power Cord
- (7) SOZOconnect Cable
- (8) SOZOcradle
- (9) Tablet
- (10) Screws and Hex Key for SOZOsupport Stand

For more on SOZO Device components and how to assemble the SOZO Device, [see Section 5.1.2 Assembly Process](#).









## **3.4 Assessment Licences**

Clinicians use the SOZO system to perform measurements and Assessments on patients. As an ImpediMed customer, a Clinic must purchase a separate licence for each Assessment. A Clinic may purchase a licence to use one, some, or all Assessments offered in their geographic region by ImpediMed, depending upon the needs of the Clinic and its patients. Once the Clinic purchases Assessment licences, ImpediMed makes licenced Assessments available on the SOZOapp and MySOZO.

# 4.0 Safety Instructions

## 4.1 Signs and Symbols

The warning signs and the symbols below are listed in order to use this product safely and correctly and to prevent risk and injury to you and others.

Symbol	Definition
	Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
	What you should NOT do.
	An action that must be followed.
	Follow instructions for use.
	Note
	For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.
	This device is rated BF as per IEC60601-1. This device meets the standard IEC60601-1-2.
	This is a Class 2 medical device.
<b>IP21</b>	Protected from touch by fingers and objects greater than 12 millimetres. Protected from condensation.

## 4.2 Intended Use



Ensure that you have read and understand this entire User Guide, including all instructions for use, before using the SOZO Device. No other specific skill or training is required to take measurements using the SOZO Device.

The SOZO Device is a medical device intended for clinical use by operators who have read this User Guide. The SOZO Device is intended for use, under the direction of the operator, for the non-invasive monitoring and management of fluid levels in patients. This includes use under direction of a physician in patients with fluid management problems in a variety of medically accepted clinical applications.

## 4.3 Contraindications



The SOZO Device should not be used by:

- Patients with cardiac arrhythmia with pacemakers or other implanted electronic equipment.
- Patients undergoing external defibrillation.

## 4.4 Warnings



Pregnant patients:

While the use of bioimpedance technology in pregnant patients has been shown to have had no adverse effects, the SOZO Device has yet to be clinically validated for use with that population group.

## 4.5 Precautions



Ensure that you have read and understand these entire instructions for use document before using the SOZO Device. No other specific skill or training is required to take measurements using the SOZO Device.



Do not allow the SOZO Device to come in contact with any liquids.



Only use the Power Adaptor supplied with the SOZO Device. The use of any other Power Adaptor may expose the patient to the risk of electrocution.



Do not use or operate the SOZO Device in the presence of strong electromagnetic fields. This Medical Device may interfere with other Medical Devices in its vicinity.

Devices or other sources can potentially cause interference problems:



- Example 1: Heat from a radiant heater.
- Example 2: Moisture from a nebuliser.
- Example 3: Devices generating large electromagnetic fields such as MRI or DXA.



Keep away from small children or animals. Strangulation due to cables may occur and small parts may be inhaled or swallowed.



Avoid using on subjects with metal allergies. Allergic reactions may be caused by the stainless steel used in the electrodes of the SOZO Device.



Avoid using accessories, detachable parts and materials not described in the instructions for use, interconnecting the SOZO Device with other equipment not described in the instructions for use, or modifying the SOZO Device in any way.



The use of accessories, transducers, and cables other than those specified may result in increased Emissions or decreased Immunity of the SOZO Device.



Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in ches) to any part of the SOZO system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



Degraded sensors and electrodes, or loosened electrodes, can degrade performance or cause other problems.



Ensure that all data collected from the SOZO Device is assessed under supervision of a physician when managing a chronic disease



The SOZO Device has a maximum weight capacity of 170 kg (375 lbs). Do not use the SOZO Device in a standing position if patient weight exceeds 170 kg (375 lbs).



The SOZO Device is intended for indoor use only. Do not use outdoors

## 4.6 Use and Storage Conditions

### 4.6.1 Environmental Operating Conditions

The SOZO Device must be operated in the following conditions:

- A temperature range of +5°C to +40°C (+41°F to +104°F)
- A relative humidity range of 15% to 93%, non-condensing
- An atmospheric pressure range of 700 hpa to 1060 hpa

The SOZO Device has been validated against applicable electrical safety standards for use in both clinical and home environments.

### 4.6.2 Environmental Transport and Storage Conditions

The SOZO Device must be transported and stored in the following conditions:

-25°C (-13°F) without relative humidity control and +70°C (158°F) at a relative humidity up to 93%, non-condensing.

If the unit has been stored at the extremes of these temperature ranges, allow it to return to within its operating temperature conditions (approximately 35 minutes) before installing or using.

## 4.7 Location for Use

When used with the stand accessory, the SOZO Device should be placed on a flat, stable surface near a standard power outlet, with room on either side to allow free access to the electrodes. If the system is configured for seated use, place at a non-metal desk that allows comfortable access from a seated position to the SOZOstep and SOZOtouch components. For seated use, a non-metal chair should be used.



Do not place SOZO Device on any object or material made of metal, other than the SOZOsupport Footplate and Handplate.



The SOZO Device should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the SOZO Device should be observed to verify normal operation in the configuration in which it will be used.



Using the SOZO Device on carpet may cause static electricity, which could damage the equipment. If installing the SOZO Device on carpet is unavoidable, please use the SOZOsupport Stand, or an antistatic mat.



Various environmental factors environment may interfere with the SOZO Device performance including: the effects of lint, dust, light (including direct sunlight), as well as pets, pests, or children.



Do not use in the presence of flammable anaesthetic gasses or in an oxygen-rich environment.



Surface temperature may exceed 47° C (117° F) in normal use. Do not use SOZO Device if it is hot to the touch. Disconnect the SOZO Device by unplugging the Power Adaptor and call ImpediMed Technical Support.

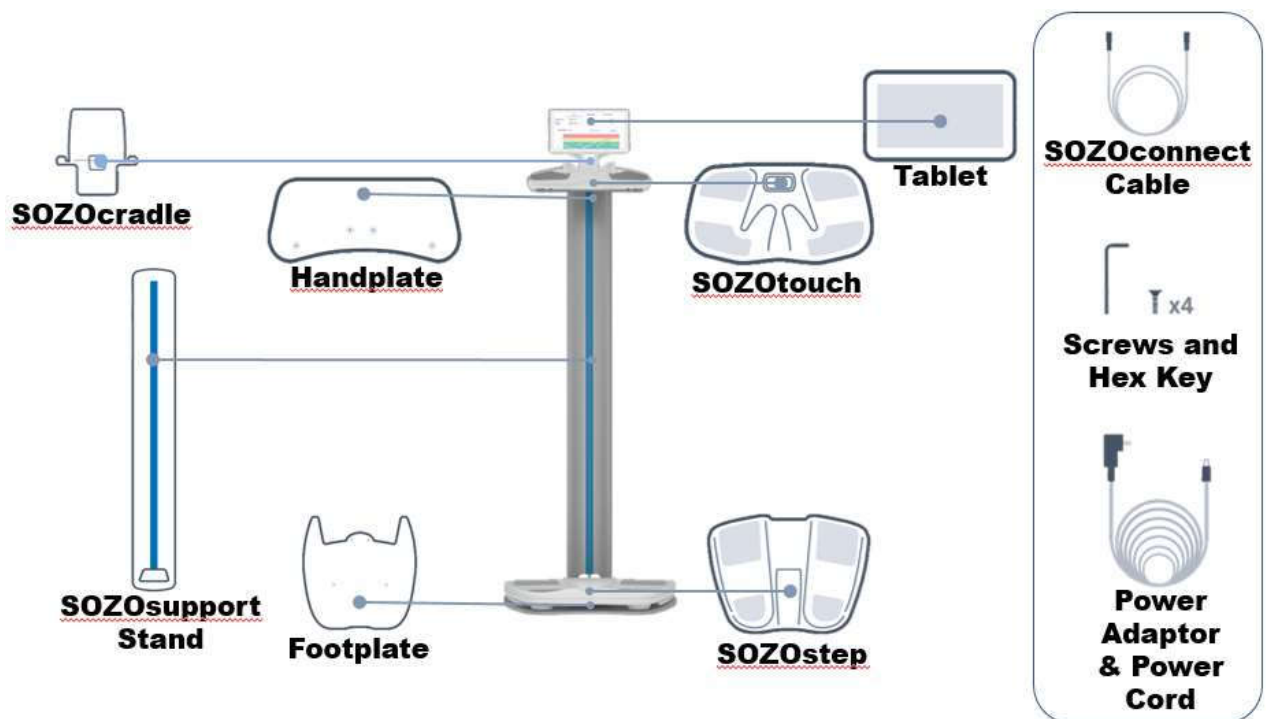
# 5.0 SOZO Device Assembly

## 5.1 SOZO Device with SOZOsupport Stand

Most patients stand during measurement, which requires assembly of the SOZO Device with the SOZOsupport Stand. Follow these steps to assemble the SOZO Device with the SOZOsupport Stand.

### 5.1.1 Identify SOZO Device Components

Before assembly, identify the SOZO Device components shown below.

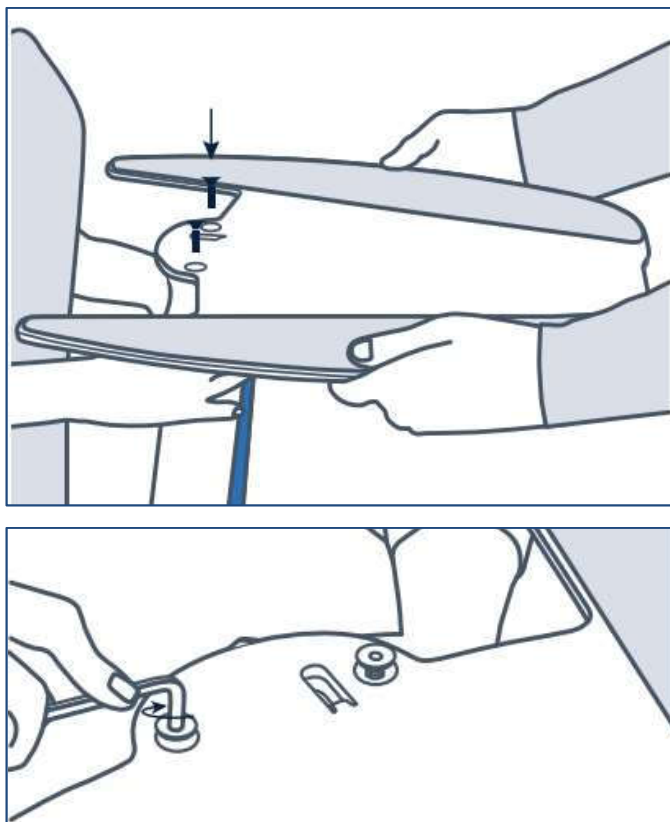




## 5.1.2 Assembly Process

### 5.1.2.1 Step One: Attach Footplate to SOZOsupport Stand

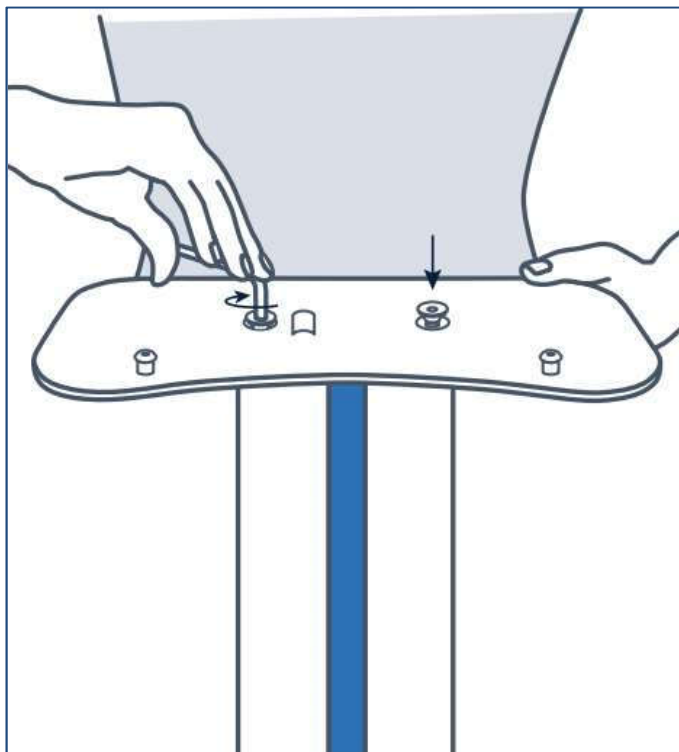
Using the Hex Key, screw the Footplate into the base of the SOZOsupport Stand.



To make the process quicker, easier and safer, have two people assemble the SOZOsupport Stand. The first person can hold the SOZOsupport Stand with the base upward. While the second person holds the Footplate on the SOZOsupport Stand, the first person attaches the Footplate using the Hex Key.

### 5.1.2.2 Step Two: Attach Handplate to SOZOsupport Stand

Screw the Handplate into the top of the SOZOsupport Stand.



#### **5.1.2.2.1 Position Handplate**

Place the Handplate on the top of the SOZOsupport Stand with the mounting screws facing up.

#### **5.1.2.2.2 Attach Handplate**

Using the Hex Key, attach the Handplate with the remaining screws.



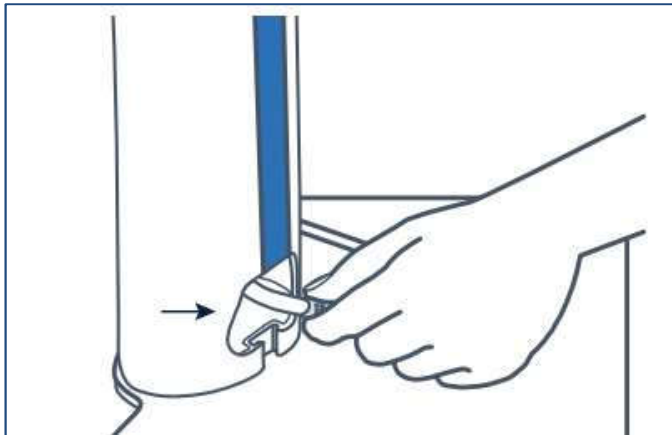
Once the Footplate and Handplate are connected to the SOZOsupport Stand, the large drop hole should be near the top opposite of the blue stripe as shown in Step Three.

### 5.1.2.3 Step Three: Lace SOZOconnect Cable Through SOZOsupport Stand

Feed the SOZOconnect Cable into the droplet hole on the back of the SOZOsupport Stand.



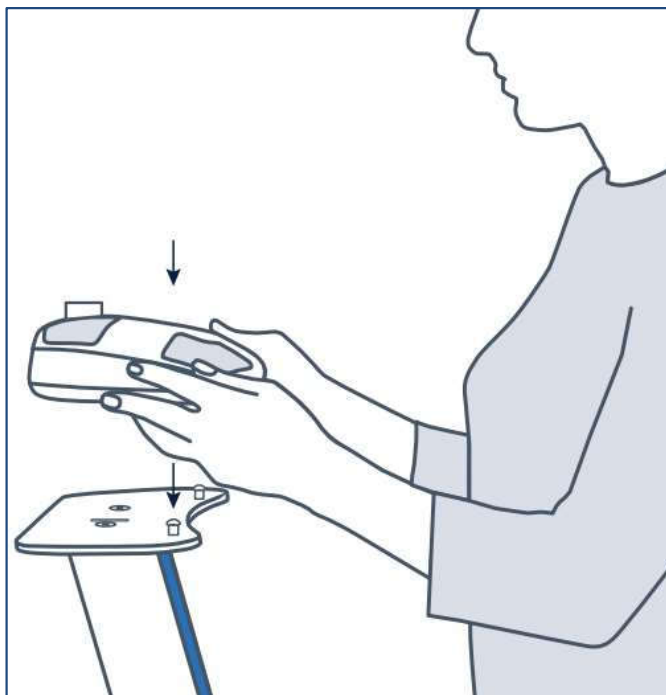
Feed the SOZOconnect Cable out of the front hole at the base of the SOZOsupport Stand.



Either end of the SOZOconnect Cable may be used to connect the SOZOtouch and SOZOstep.

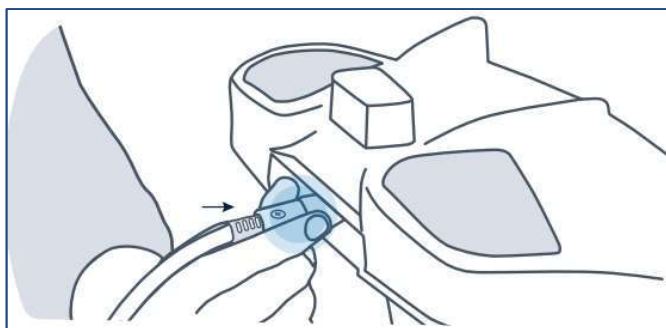
#### 5.1.2.4 Step Four: Attach SOZOtouch to Handplate

Place the SOZOtouch onto the mounting screws and push forward to lock into place.



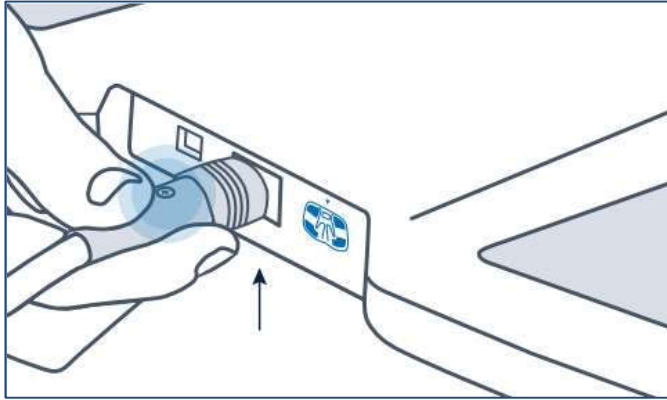
#### 5.1.2.5 Step Five: Attach SOZOconnect Cable to SOZOtouch

Make sure that the screw on the SOZOconnect Cable is facing upwards before attaching it to the SOZOtouch.



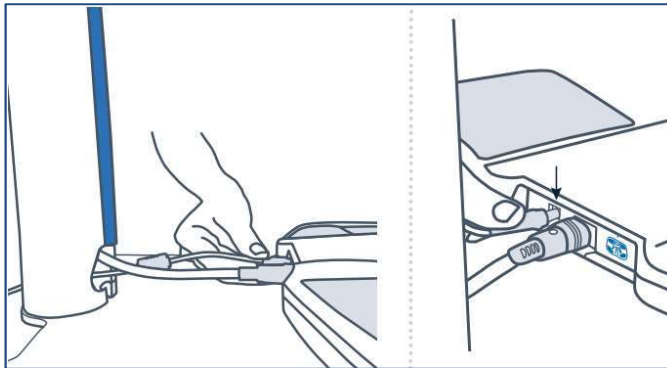
#### 5.1.2.6 Step Six: Attach SOZOconnect Cable to SOZOstep

Make sure that the screw on the SOZOconnect Cable is facing upwards before attaching it to the SOZOstep.



#### 5.1.2.7 Step Seven: Connect Power Cord to SOZOstep

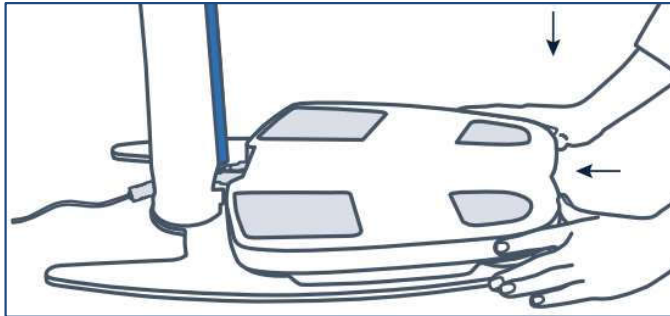
Before starting this step, make sure that the SOZOconnect Cable is plugged into both the SOZOtouch and the SOZOstep. Locate the power support port on the back of the SOZOstep. Feed the corresponding end of the Power Cord through the openings in the bottom of the SOZOsupport Stand and connect it to the port.



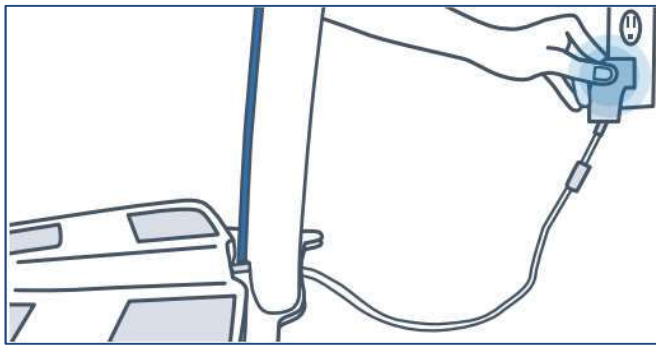
Before using the SOZO Device for the first time, make sure to follow all steps for start-up of MySOZO in [Section 6.2.1 First Time Set-Up](#) and the SOZOapp, [Section 8.2 Start-Up](#).

#### 5.1.2.8 Step Eight: Attach SOZOstep to the Footplate

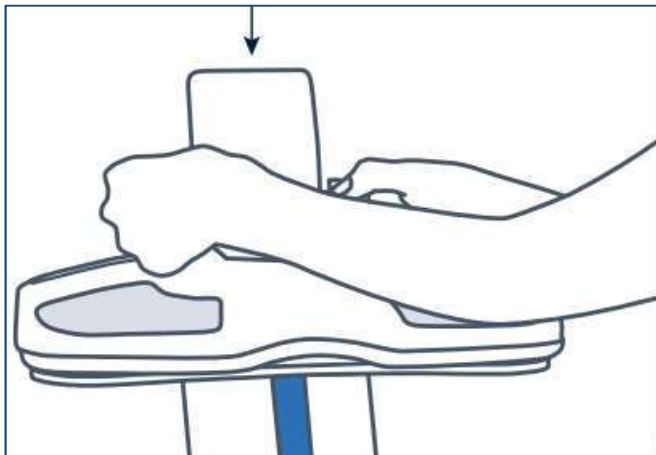
Place the SOZOstep onto the mounting screws and push forward to lock into place.



Once the SOZOstep is in place, plug the Power Cord into the wall outlet.



#### 5.1.2.9 Step Nine: Attach SOZOcradle to SOZotouch



Once the SOZOcradle is secure, place the Tablet in a landscape position on the SOZOcradle

Observe the following warnings while assembling the SOZO Device.



Only use the Power Adaptor supplied with the SOZO Device. The use of any other Power Adaptor may expose the patient to the risk of electrocution.



Ensure that the SOZOconnect Cable is plugged in to the Handplate and Foot plate before connecting the Power Cord. If the SOZO Device must be moved, ensure that the Power Cord is disconnected before moving or uninstalling the system.



When plugging the Power Cord into the wall outlet, the SOZO system will automatically run a self-test to ensure functionality. Do not touch the stainless-steel electrodes when a self-test is running.

For more information on setting up the SOZO system with the SOZOsupport Stand, visit [www.impedimed.com](http://www.impedimed.com) or contact ImpediMed technical support, per [Section 12.5 Technical Support](#).

## 5.2 SOZO Device without SOZOsupport Stand



To use the SOZO Device while the patient is sitting, follow the instructions for use in [Section 7.2.3 Seated Position](#).

Sometimes, a patient is unable to stand during measurement. In that case, follow the steps below to assemble the SOZO Device without the SOZOsupport Stand.

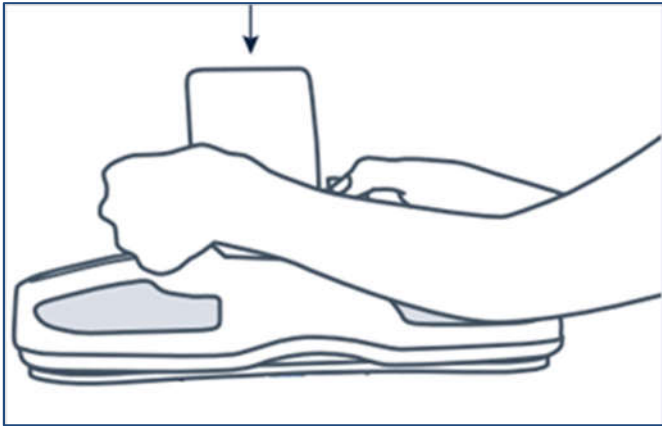
### 5.2.1 Attach SOZOtouch to SOZOstep with SOZOconnect Cable

Connect the SOZOtouch to the SOZOstep with the SOZOconnect Cable by repeating Step Five, [Section 5.1.2.5 Step Five: Attach SOZOconnect Cable to SOZOtouch](#), and Step Six, [Section 5.1.2.6 Step Six: Attach SOZOconnect Cable to SOZOstep](#). The SOZOconnect Cable port is the same for the Handplate and Footplate.

Place the SOZOtouch on a level surface and at a comfortable height, such as on a table or desk, so that the patient may place their hands on the SOZOtouch while they are sitting down.

Place the SOZOstep on a level surface beneath and in alignment with the SOZOtouch. Ensure that the SOZOstep is positioned in such a way that the power supply can be easily connected and disconnected.

### 5.2.2 Connect SOZOcradle



Confirm that the SOZotouch is stationary and on a level surface. Place the SOZOcradle onto the SOZotouch with the ledge of the holder facing the SOZotouch stainless steel electrodes.

For clinical use, the SOZOcradle can be reversed with the ledge of the holder facing away from the electrodes. Place the Tablet onto the ledge of the SOZOcradle, so that the SOZOcradle is holding the Tablet.

### 5.2.3 Connect Power Supply

Locate the power supply port on the back of the SOZOstep and plug the corresponding end of the Power Cord into that port.

Take the remaining end of the power supply cable and plug it into the nearest wall outlet. The SOZO Device may be safely turned off by unplugging the Power Adaptor.



Only use the Power Adaptor that is supplied with the SOZO Device. The use of any other Power Adaptor may expose the patient to the risk of electric shock.



Ensure that the connector cable is plugged in to both the SOZotouch and SOZOstep assemblies before connecting the power supply. If the SOZO Device must be moved, ensure that the power supply is disconnected before moving or uninstalling the system.



Ensure that nothing is in contact with the SOZotouch or SOZOstep electrodes when applying power.

For more information on setting up the SOZO system without the SOZOsupport Stand, visit [www.impedimed.com](http://www.impedimed.com) or contact ImpediMed technical support, per [Section 12.5 Technical Support](#).

**Setup of SOZO Device Complete.**



## 6.0 MySOZO

MySOZO allows the User to access the SOZO system from any User Device with internet access, provided that the User Device has a Google Chrome or Mozilla Firefox web browser.

[See Section 1.3 MySOZO Minimum Requirements.](#)

MySOZO is accessed through a web portal, MySOZO.com. SOZO accounts and patient data, including patient measurement data and Assessment results, may be viewed in MySOZO. MySOZO updates its patient data and accounts by interfacing with the SOZOapp. MySOZO interfaces with the SOZOapp to allow a Clinician to take measurements, view past results and manage their patients.

A MySOZO account must be created before you may begin using the SOZOapp on the Tablet or access MySOZO.com.

### 6.1 Introduction

After the Clinic purchases the SOZO system, ImpediMed will establish the initial authorisation and licences and create the first Clinic Administrator. Once the initial Clinic Administrator has been created by ImpediMed, additional Administrators and Clinicians may be added by Clinic. All Users, whether they are Administrators or Clinicians, are identified by their email address.

It is easy to begin. There is no need to install any software. Users log into MySOZO.com on a User Device with internet access.

### 6.2 All MySOZO Users (Administrators and Clinicians)

The below steps, including Login, password set-up, and reset for forgotten password or expiration, apply to all MySOZO Users.

#### 6.2.1 First Time Set-Up

##### 6.2.1.1 Email with Temporary Password

For a new User, ImpediMed sends the User an email, as shown in example below, with a temporary password. In email, the User clicks **Set Password**.

From: [no-reply@impedimed.com](mailto:no-reply@impedimed.com) <[no-reply@impedimed.com](mailto:no-reply@impedimed.com)>  
Sent: Sunday, April 21, 2019 5:53 PM  
To: Jon Little <[jon.little@outlook.com](mailto:jon.little@outlook.com)>  
Subject: ImpediMed SOZO Digital Health Platform

**impedimed**

SO

Hello,

Welcome to **ImpediMed's SOZO® Digital Health Platform**.

SOZO is a medical device that non-invasively measures and monitors tissue composition and fluid status using bioimpedance spectroscopy.

Your organization's MySOZO Administrator has initiated a MySOZO account for you.

To access your MySOZO account, you must first set your password by clicking on the link below and using the following temporary password: **78Hi\*92Lr**

After setting your password, you can access / login to the system by navigating to <https://www.mysozo.com> using a Chrome or Firefox browser.

[Set Password](#)

### 6.2.1.2 Set New Password

After the User clicks the email link, the “Set New Password” screen appears. The User enters the Temporary Password that was provided in the email and sets and confirms a new password and clicks **Submit**.

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SOZO® Digital Health Platform

#### Set New Password

Email Address

jon.little@outlook.com

Temporary Password

Temporary Password

New Password

New Password

Confirm New Password

Confirm New Password

**Submit**

The password must be between 8 and 20 characters containing at least:

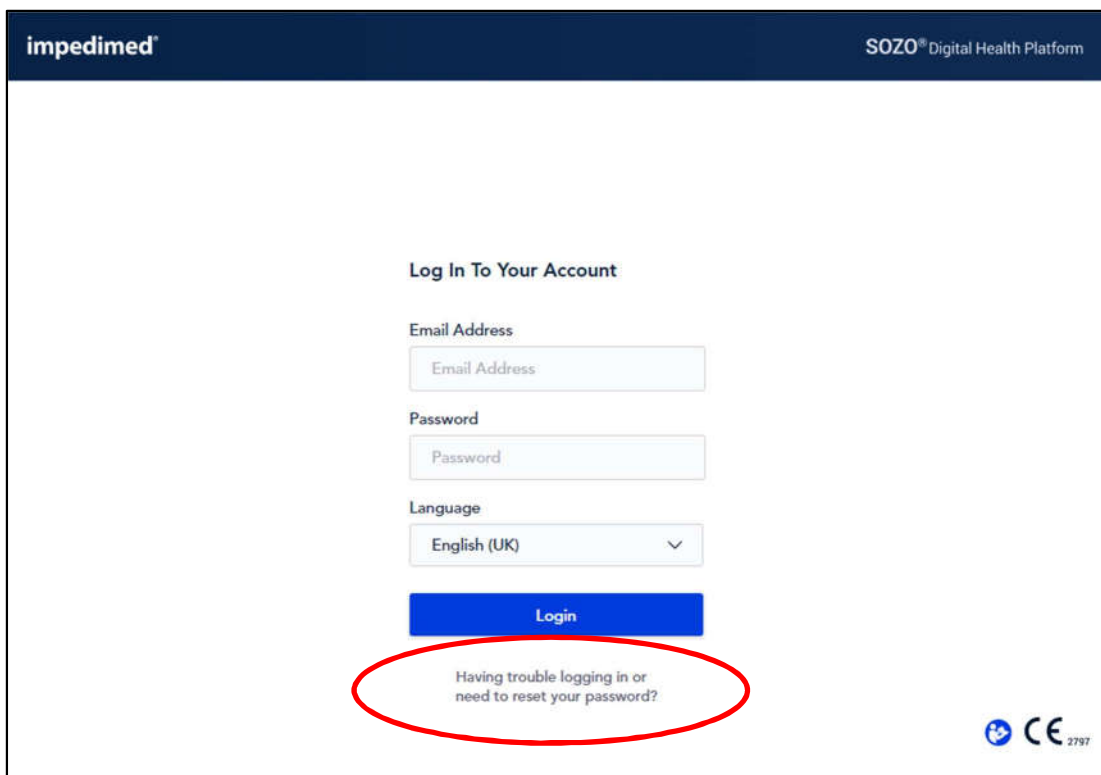
1. One number
2. One special character (!"#\$%&'()\*+,-./:;<=>?\_@[]^{}~)\*
3. One upper case letter
4. One lower case letter

### 6.2.1.3 User Password Privacy

Only the User has access to their password. No other User may see or have access to the User's password.

## 6.2.2 Password Reset

If you have trouble logging in or forget your password, click the message below the **Login** button.



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SOZO® Digital Health Platform

Log In To Your Account

Email Address

Password

Language

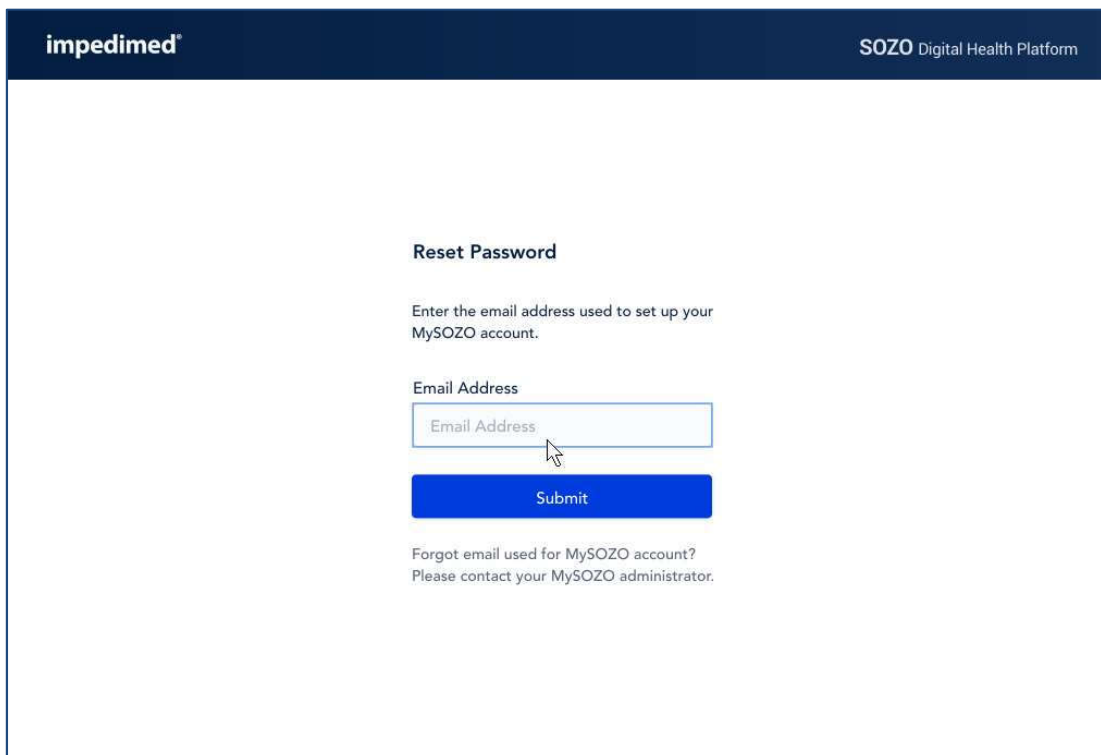
English (UK)

Login

Having trouble logging in or need to reset your password?

CE 2797

On the next screen, enter email address for the MySOZO account.



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SOZO Digital Health Platform

Reset Password

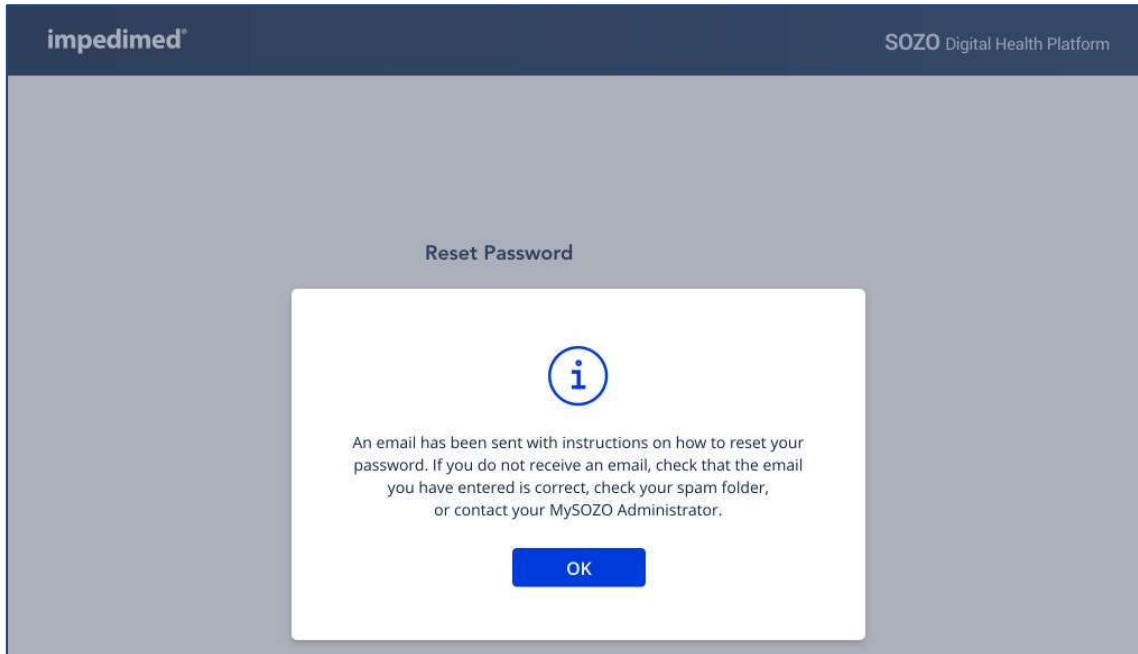
Enter the email address used to set up your MySOZO account.

Email Address

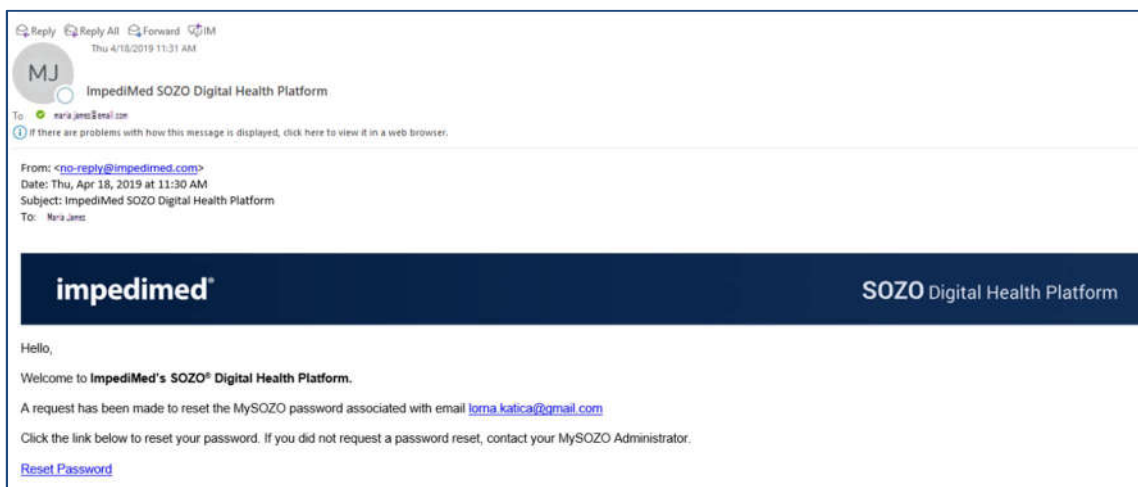
Submit

Forgot email used for MySOZO account?  
Please contact your MySOZO administrator.

A pop-up notifies the User to expect a password reset email from ImpediMed.



After ImpediMed sends the email with password reset instructions, click **Reset Password** link in the email.



Create and confirm the new password on the “Set New Password” screen.

### Set New Password

Email Address

eric.johnson@outlook.com

New Password

New Password

Confirm New Password

Confirm New Password

Submit

The password must be between 8 and 20 characters containing at least:

1. One number
2. One special character (!"#\$%&'()\*+,-./:;<=>?\_@[]^{}~)\*
3. One upper case letter
4. One lower case letter
5. Can not be one of the last three passwords used.


## 6.2.3 Password Expiration

Your password will expire within a time period set by your Clinic. A pop-up will warn you about upcoming password expiration. To reset your password, click **Reset Now**.

impedimed® SOZO Digital Health Platform

Login to Your Account

Email Address



Your password will expire in 5 days.  
Do you want to reset it now?

[Reset Later](#) [Reset Now](#)

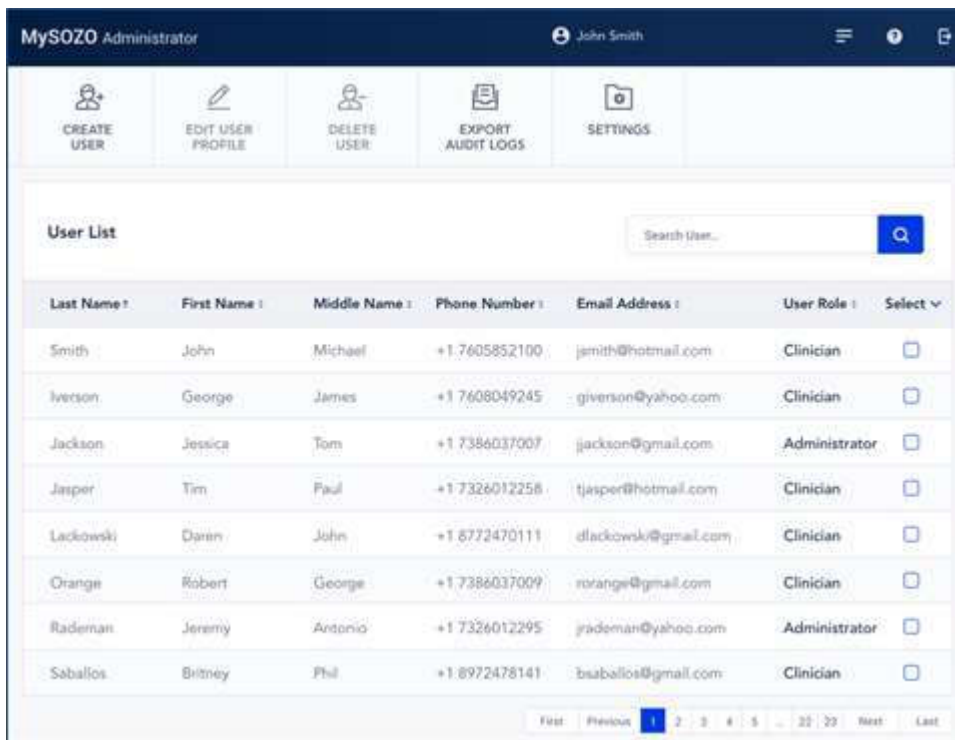
Having trouble logging in or  
need to reset your password?

## 6.3 MySOZO Administrator

An Administrator has exclusive authority to manage MySOZO User accounts, adjust certain SOZO system-wide settings and export Audit Logs. The Clinic sets up ImpediMed Administrator accounts. Administrators are identified by their email address.

### 6.3.1 Administrator Home Page

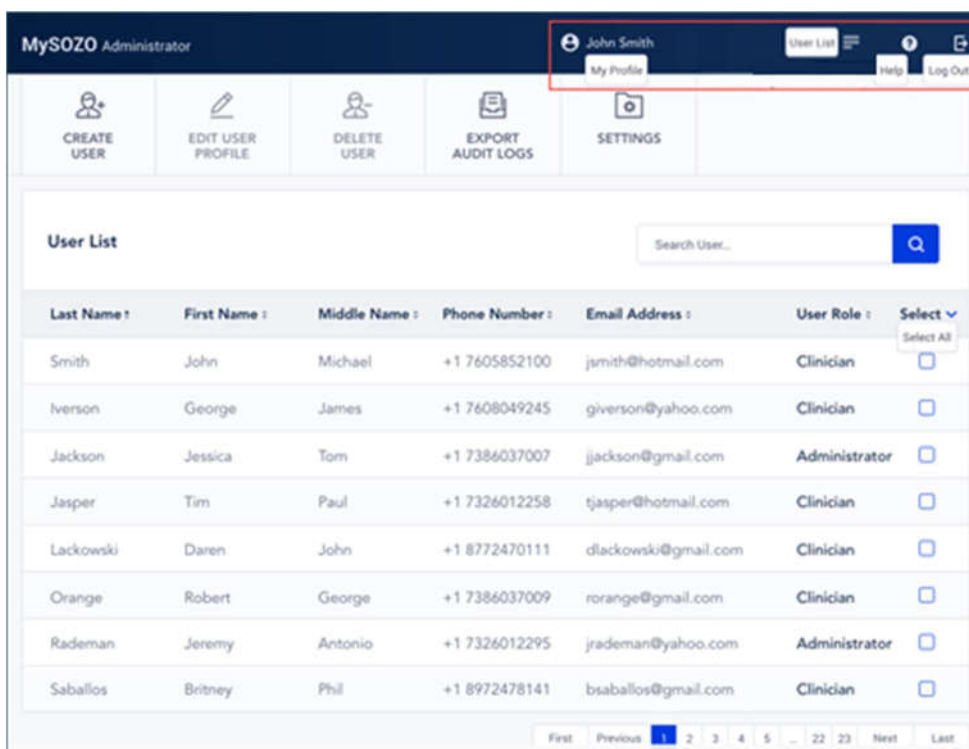
As Administrator, log in and set password per log in process for all users, per [Section 6.2.1 First Time Set-Up](#). Login leads to the MySOZO Administrator home page, which displays the User List.



Last Name :	First Name :	Middle Name :	Phone Number :	Email Address :	User Role :	Select ▾
Smith	John	Michael	+1 7605852100	jsmith@hotmail.com	Clinician	<input type="checkbox"/>
Iverson	George	James	+1 7608049245	giverson@yahoo.com	Clinician	<input type="checkbox"/>
Jackson	Jessica	Tom	+1 7386037007	jackson@gmail.com	Administrator	<input type="checkbox"/>
Jasper	Tim	Paul	+1 7326012258	tjasper@hotmail.com	Clinician	<input type="checkbox"/>
Lackowski	Darin	John	+1 6772470111	dlackowski@gmail.com	Clinician	<input type="checkbox"/>
Orange	Robert	George	+1 7386037009	rorange@gmail.com	Clinician	<input type="checkbox"/>
Rademan	Jeremy	Antonio	+1 7326012295	jrademan@yahoo.com	Administrator	<input type="checkbox"/>
Saballos	Britney	Phil	+1 8972478141	bsaballos@gmail.com	Clinician	<input type="checkbox"/>

### 6.3.2 Banner Icons

When logged in as Administrator, the banner icons enable common administrative functions. Roll your mouse over the icons for their description.



### 6.3.2.1 Logged in Status

MySOZO Administrator Icon



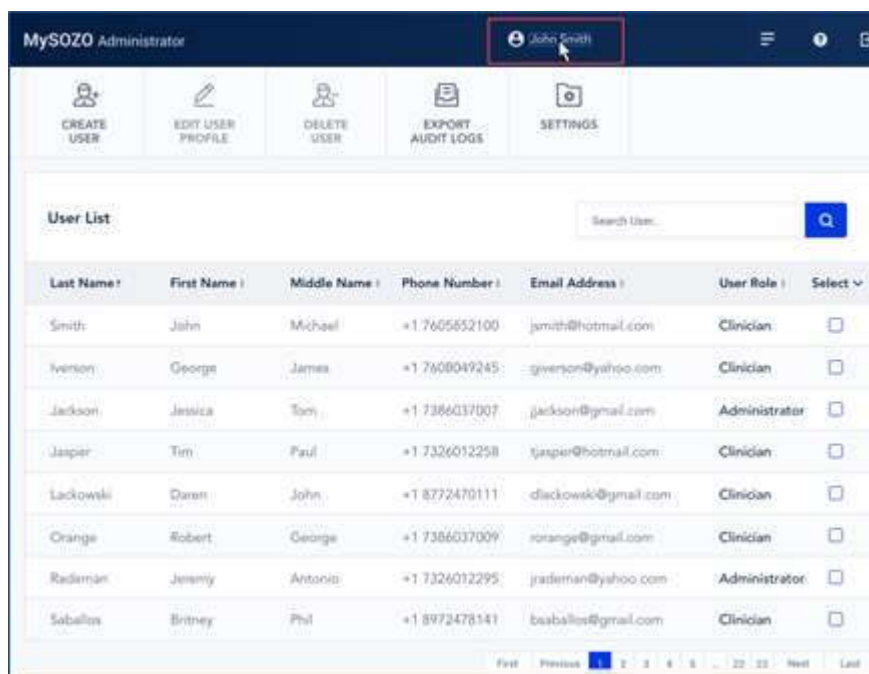
Users may be logged in as an Administrator or Clinician. The “MySOZO Administrator” icon shows that the User is logged in as an Administrator

### 6.3.2.2 Profile of Administrator Logged into MySOZO

User Profile Icon



The name of the User logged into MySOZO appears next to the **User Profile** icon. To review or edit the User profile, click **User Profile** icon.

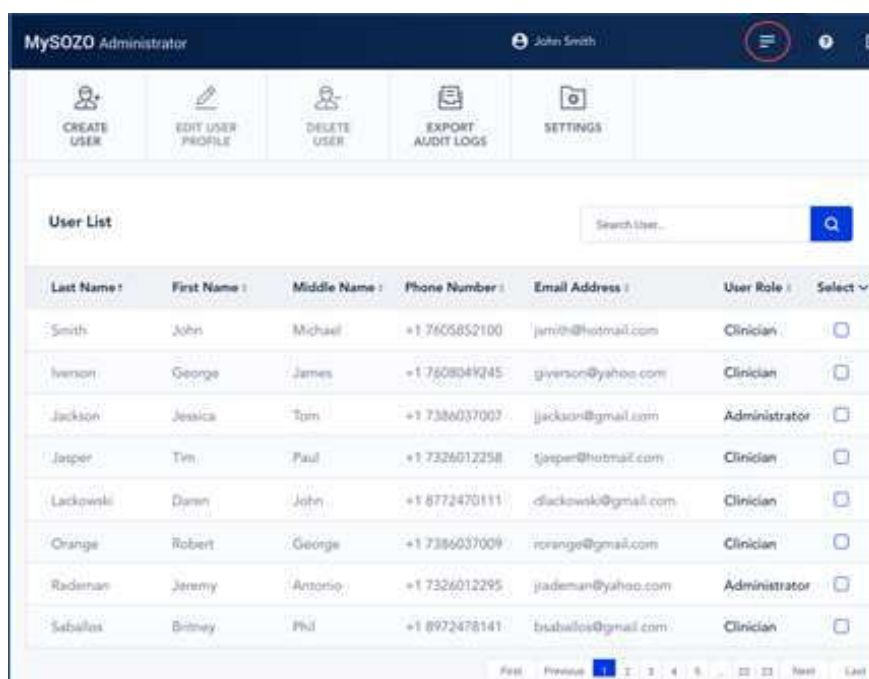


### 6.3.2.3 User List

User List Icon



Click **User List** icon at any time to return to the User List on the MySOZO Administrator home page.



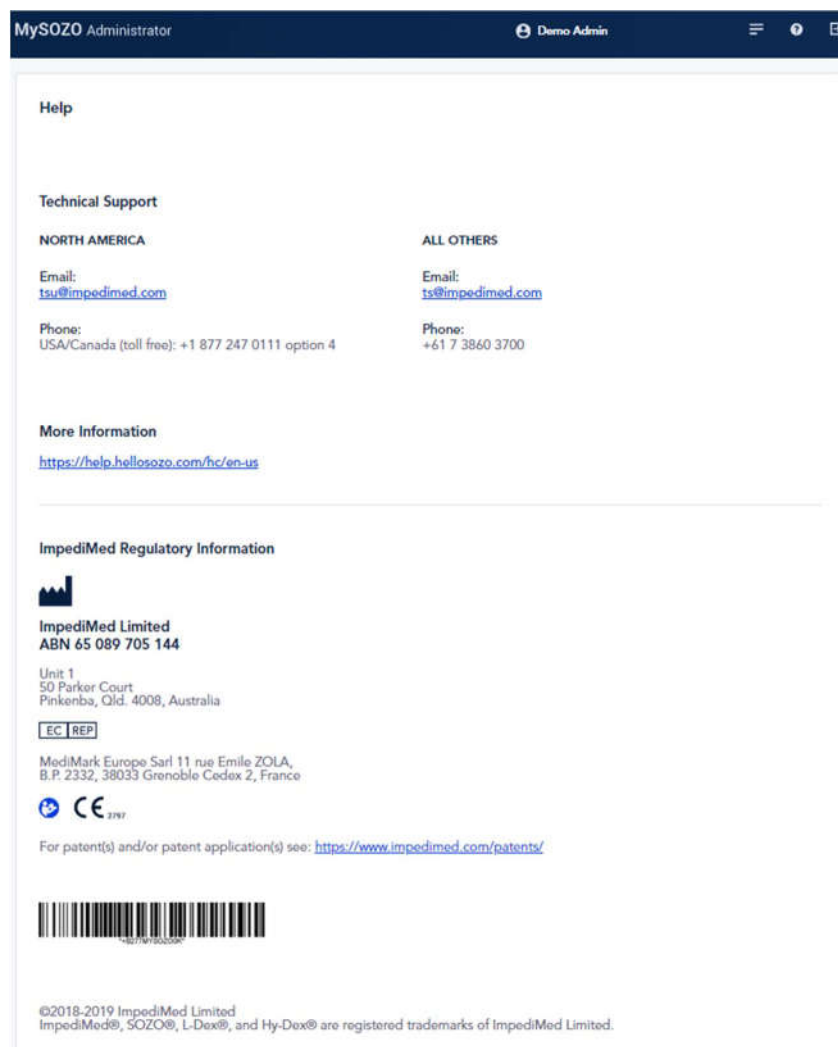


### 6.3.2.4 Help

Help Icon



For assistance with use of MySOZO, click the question mark, which is the **Help** icon. The Help page includes contact information for ImpediMed technical support and product Information.



MySOZO Administrator Demo Admin

#### Help



##### Technical Support


<b>NORTH AMERICA</b>	<b>ALL OTHERS</b>
Email: <a href="mailto:tsu@impedimed.com">tsu@impedimed.com</a>	Email: <a href="mailto:tsu@impedimed.com">tsu@impedimed.com</a>
Phone: USA/Canada (toll free): +1 877 247 0111 option 4	Phone: +61 7 3860 3700

##### More Information

<https://help.hellosozo.com/hc/en-us>

##### ImpediMed Regulatory Information

  
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Unit 1  
50 Parker Court  
Pinkenba, Qld. 4008, Australia  
EC REP  
MediMark Europe Sarl 11 rue Emile ZOLA,  
B.P. 2332, 38033 Grenoble Cedex 2, France  
 2797  
For patent(s) and/or patent application(s) see: <https://www.impedimed.com/patents/>

  
4827191502596

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ImpediMed®, SOZO®, L-Dex®, and Hy-Dex® are registered trademarks of ImpediMed Limited.

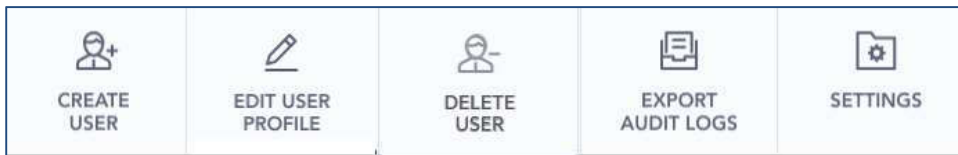
### 6.3.2.5 Log Out

Log Out Icon

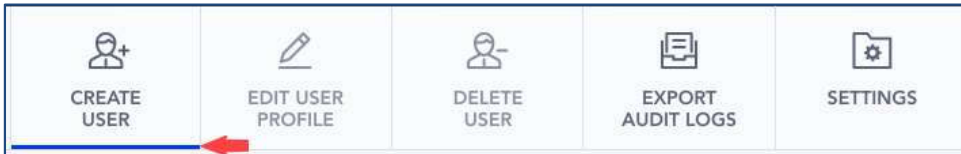


To log out of MySOZO at any time, click **Log Out** icon on the upper right.

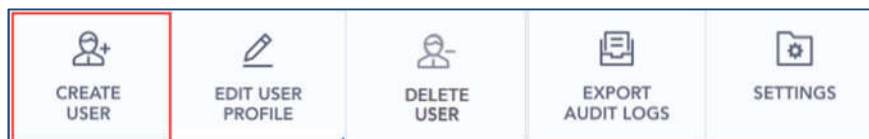
### 6.3.3 MySOZO Main Menu



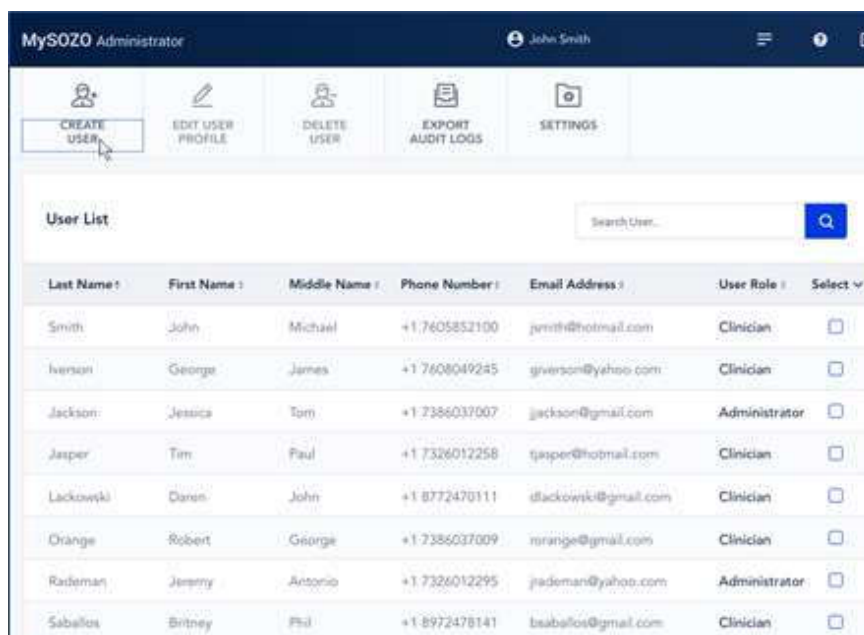
After clicking a Main Menu tab, a blue line appears under the tab to indicate that the User is performing functions inside that tab.



#### 6.3.3.1 Create User



An Administrator creates a User by clicking **Create User** tab. The user is either an Administrator or Clinician. More than one Administrator may be created.



On the “User Details” screen, enter the User’s first name, last name and email address. The remaining fields, including middle name, country code and phone number, are optional. Under “User Role,” select Administrator or Clinician. When done, click **Create User**.

**MySOZO Administrator** John Smith

CREATE USER EDIT USER PROFILE DELETE USER EXPORT AUDIT LOGS SETTINGS

**User Details**

First Name Required Michael Country Code   
 Middle Name Phone Number   
 Last Name Required Simpson User Role   
 Email Address Required ☐ Administrator ☒ Clinician   
 Create User

Every User must have their own email address. If the email is already assigned, a Caution will state that the User already exists.

**MySOZO Administrator** John Smith

CREATE USER EDIT USER PROFILE DELETE USER EXPORT AUDIT LOGS SETTINGS

**User Details**

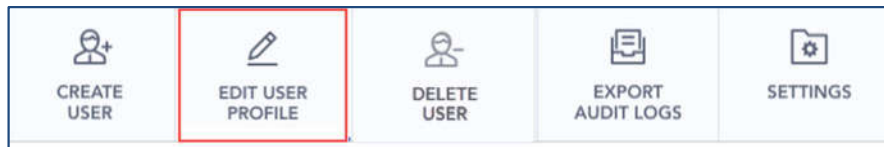
First Name Michael Country Code   
 Middle Name Phone Number   
 Last Name Simpson User Role   
 Email Address Required mrsimpson@impedimed.com ☐ Administrator ☒ Clinician   
 Create User

**Caution**  
 This user already exists in the database.  
 Cancel Continue to Edit



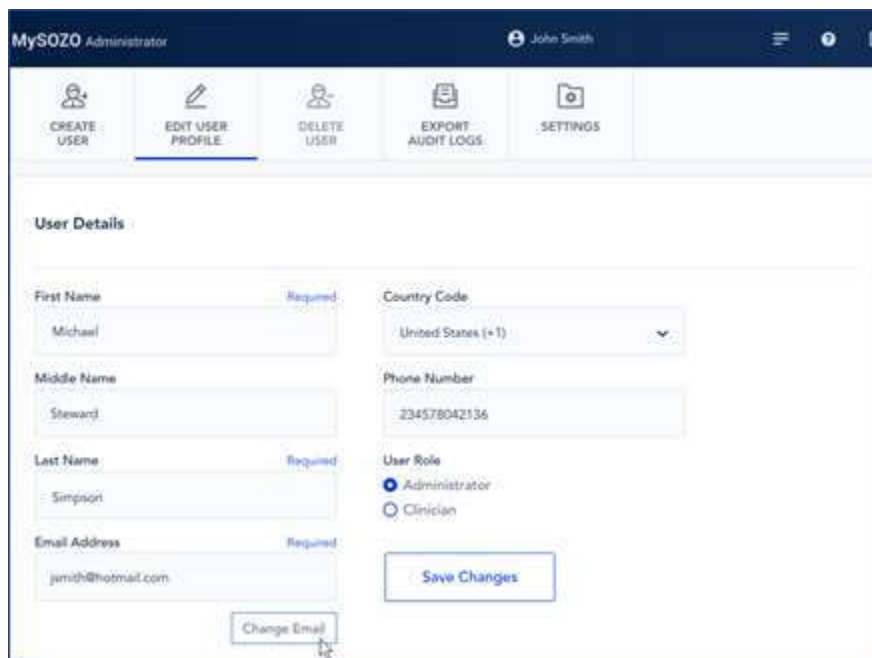
The same email address may not be assigned to more than one User, even when the User is acting as both the Administrator and the Clinician. If this is the case, create the first User as an Administrator with one email address. Then, for the same person, create a second User as the Clinician, and assign a different email address to the Clinician.

### 6.3.3.2 Edit User Profile



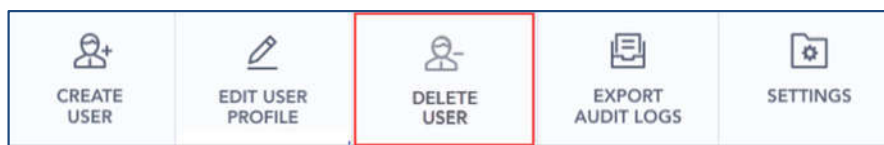
An Administrator may edit a User profile by clicking the **Edit User Profile** tab. On the “User Details” screen, the Administrator may change User information.

The Administrator may edit the User’s email address by clicking **Change Email** at the bottom of the screen. Whenever a User’s email address is changed, the User will receive an email to both the old and the new address notifying them of the change.



Only an Administrator may edit a User’s email address. A Clinician may edit their own email address but does not have authority to change another User’s email address.

### 6.3.3.3 Delete User



To delete a User, on the “User List” Administrator home page, select the box next to the User to be deleted and click **Delete User** tab.

MySOZO Administrator John Smith

CREATE USER EDIT USER PROFILE **DELETE USER** EXPORT AUDIT LOGS SETTINGS

User List

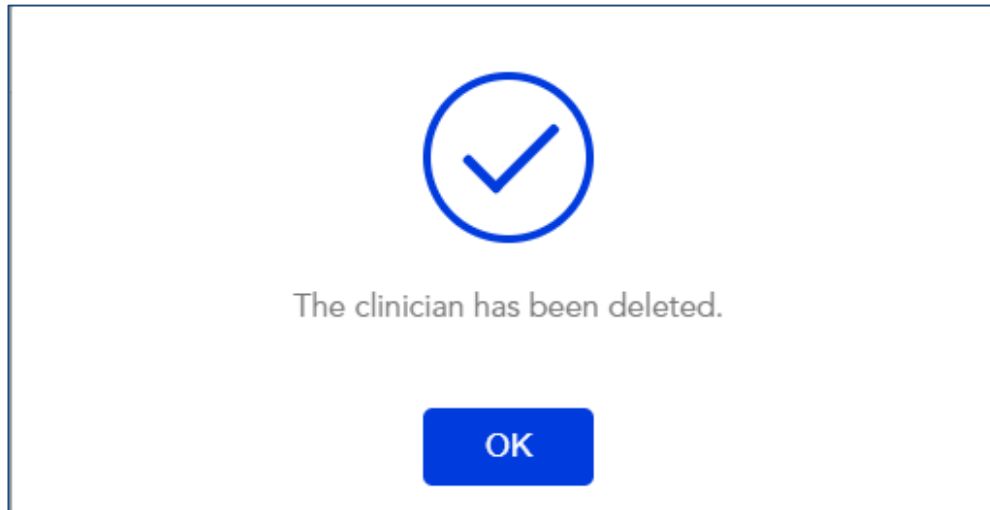
Last Name	First Name	Middle Name	Phone Number	Email Address	User Role	Select
Smith	John	Michael	+1 7605852100	jsmith@hotmail.com	Clinician	<input type="checkbox"/>
Iverson	George	James	+1 7608049245	giverson@yahoo.com	Clinician	<input type="checkbox"/>
Jackson	Jessica	Tom	+1 7386037007	jjackson@gmail.com	Administrator	<input type="checkbox"/>
Jasper	Tim	Paul	+1 7326012258	tjasper@hotmail.com	Clinician	<input type="checkbox"/>
Lackowski	Daren	John	+1 8772470111	dlackowski@gmail.com	Clinician	<input type="checkbox"/>
Orange	Robert	George	+1 7386037009	rorange@gmail.com	Clinician	<input type="checkbox"/>
Rademan	Jeremy	Antonio	+1 7326012295	jrademan@yahoo.com	Administrator	<input type="checkbox"/>
Saballos	Britney	Phil	+1 8972478141	bsaballos@gmail.com	Clinician	<input type="checkbox"/>

First Previous 1 2 3 4 5 ... 22 23 Next Last

Click **Yes** in the Warning pop-up.



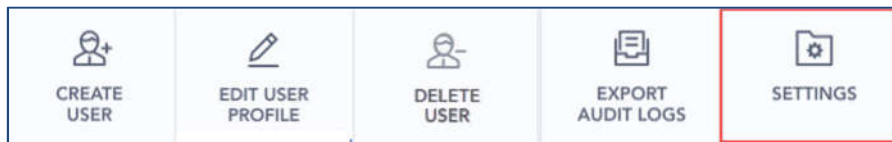
MySOZO confirms deletion of the User. Click **OK**.



#### 6.3.3.4 Restore User

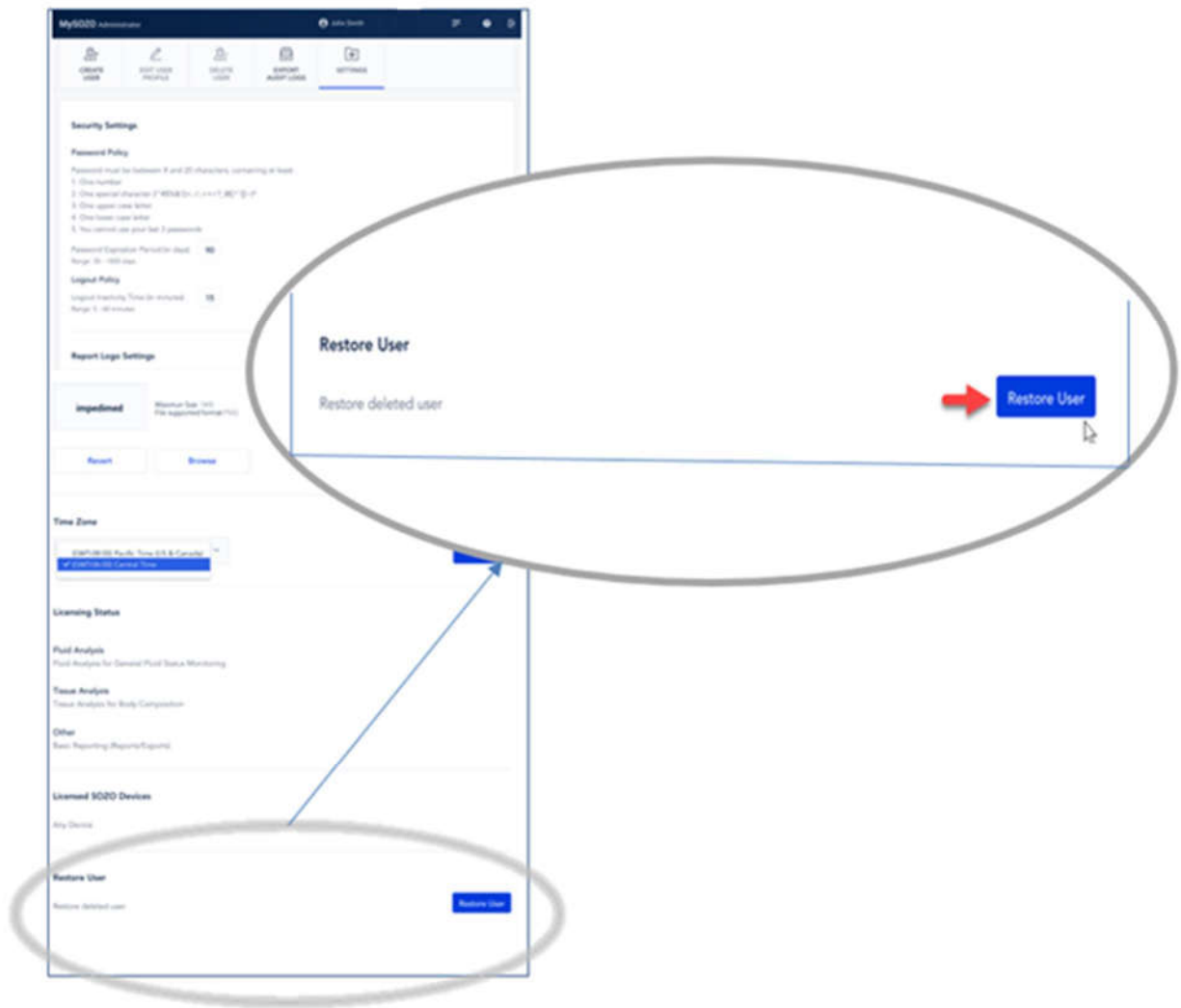
MySOZO stores deleted User accounts. If a User is accidentally deleted, the User may be restored. To restore a deleted User:

##### 6.3.3.4.1 Click *Settings* Tab



##### 6.3.3.4.2 Click *Restore User*

On the "Security Settings" screen, scroll mouse down to the bottom and click ***Restore User***.



#### 6.3.3.4.3 Click Restore

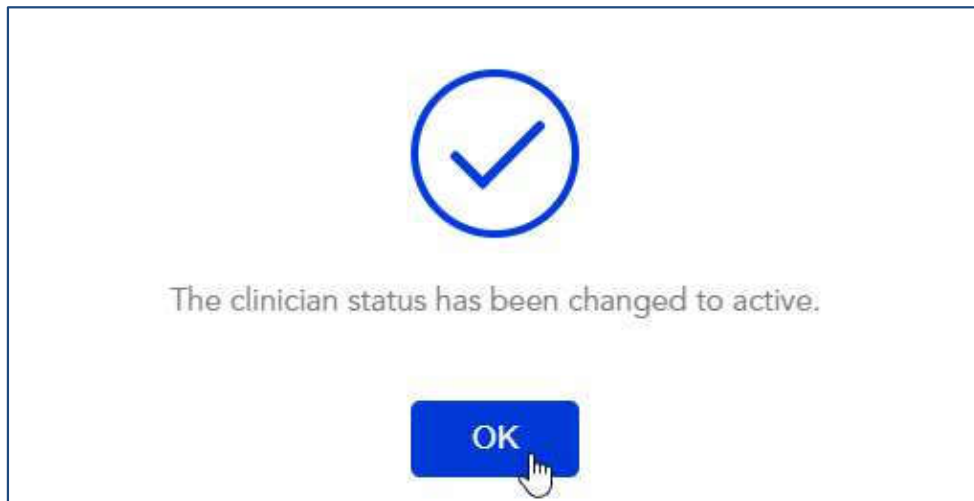
Under “Deleted Users” screen, select the User to restore and click **Restore**.



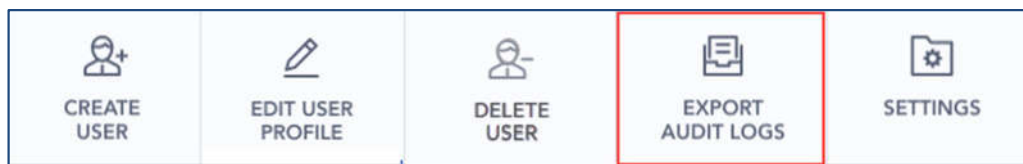
Click **Yes** on Warning.



MySOZO confirms that the user status has been changed to active. Click **OK**.

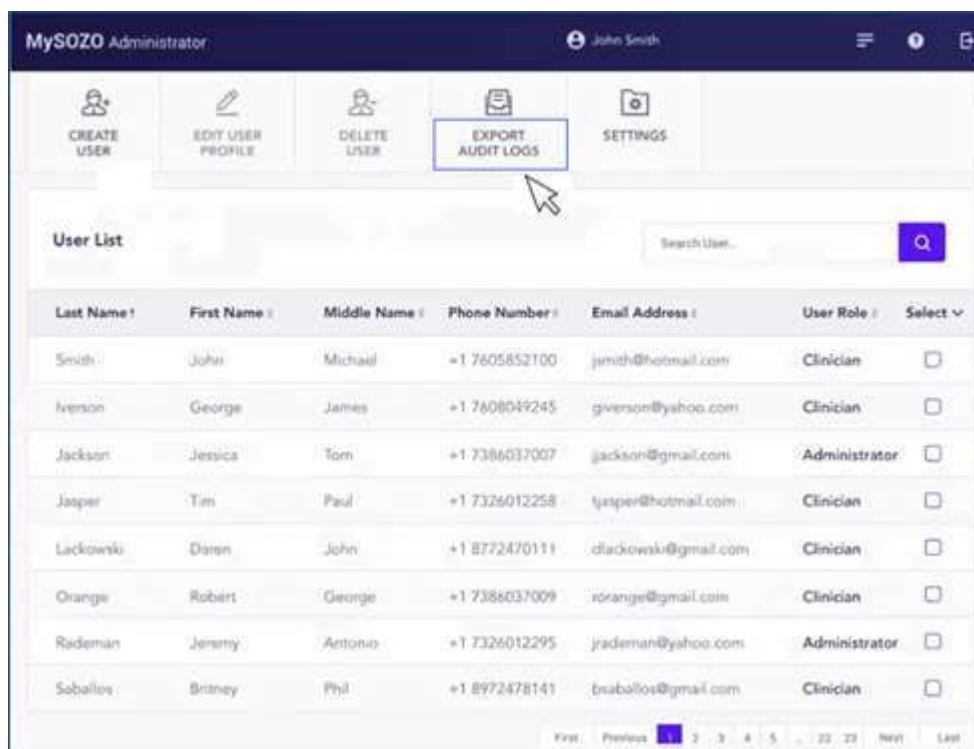


### 6.3.3.5 Export Audit Logs

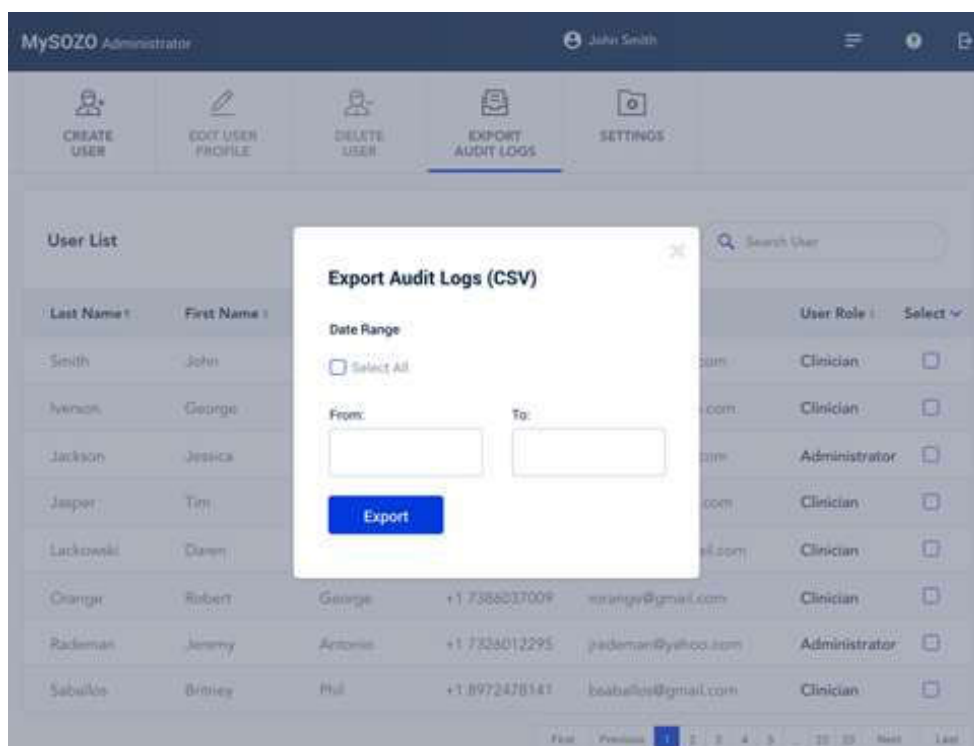


An Administrator may need to review audit logs to assist in an audit or investigation. Audit logs may be exported directly from MySOZO. Audit logs include identity of Users who have viewed certain MySOZO pages or information, identity of Users who have retrieved data, and Users' log in and log out dates and times. To export audit logs, click **Export Audit Logs** tab.





Enter the date range in the “Export Audit Logs (CSV)” pop-up and click **Export**.



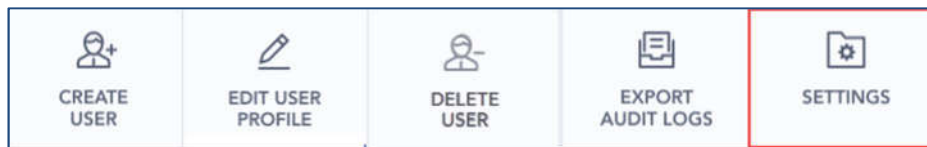
This will trigger a pop-up about the export process. Click **OK**. ImpediMed will send the User an email with a secure link to download data, which is valid for 48 hours.



Your data export request is in progress and may take some time to process, depending on the amount of data requested. When the data file is ready, you will receive an email from MySOZO.com containing a secure link that enables you to download it. The link remains valid for 48 hours. If no email is sent, contact ImpediMed technical support.

OK

### 6.3.3.6 Settings



**Settings** is the last tab on the MySOZO Administrator Main Menu.

**MySOZO Administrator** John Smith

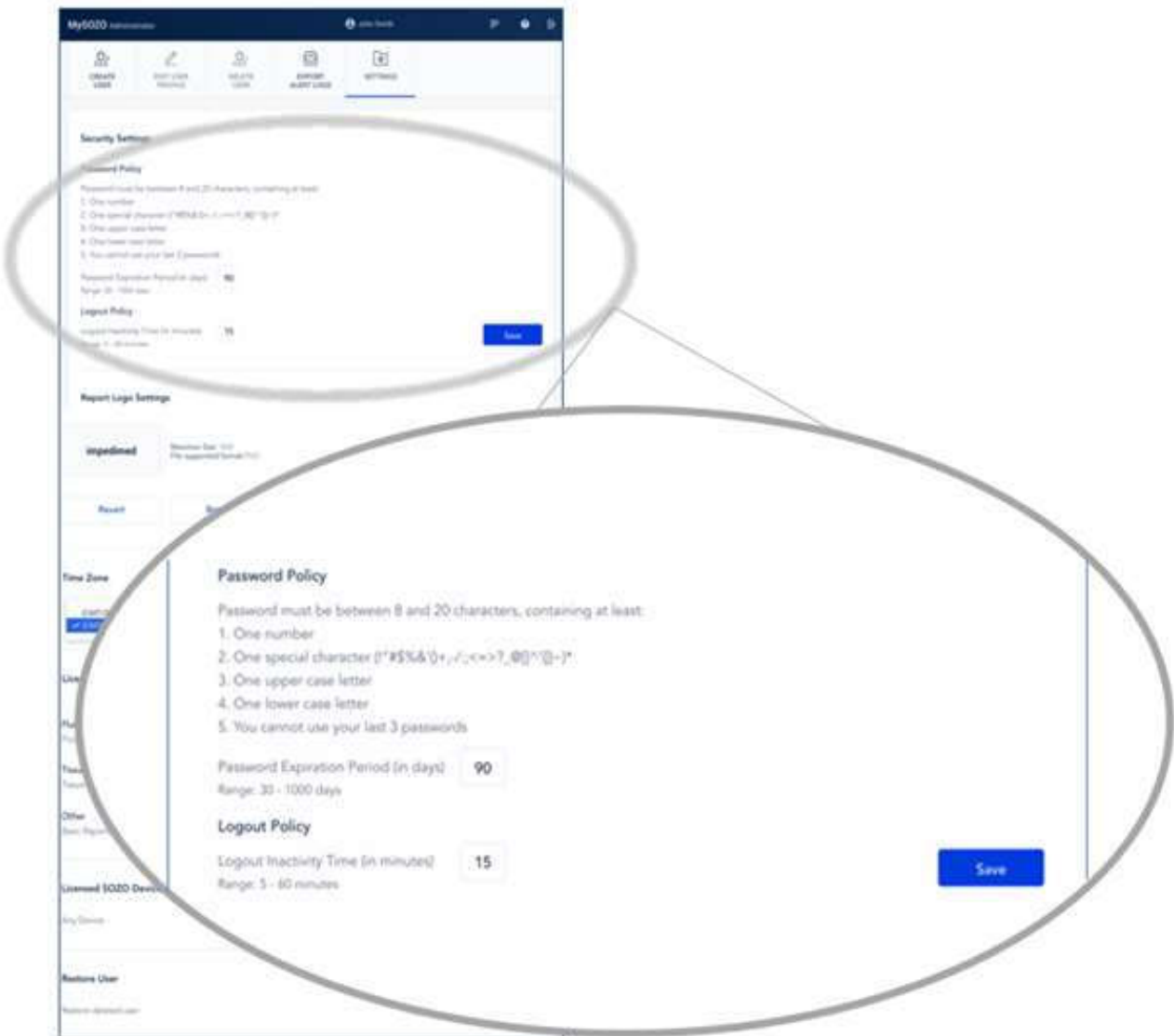
CREATE USER EDIT USER PROFILE DELETE USER EXPORT AUDIT LOGS **SETTINGS**

**User List** Search User...

Last Name	First Name	Middle Name	Phone Number	Email Address	User Role	Select
Smith	John	Michael	+1 7605852100	jasmith@hotmail.com	Clinician	<input type="checkbox"/>
Iverson	George	James	+1 7608049245	giverson@yahoo.com	Clinician	<input type="checkbox"/>
Jackson	Jessica	Tom	+1 7386037007	jackson@gmail.com	Administrator	<input type="checkbox"/>
Jasper	Tim	Paul	+1 7326012258	tjasper@hotmail.com	Clinician	<input type="checkbox"/>
Lackowski	Daren	John	+1 8772470111	dlackowski@gmail.com	Clinician	<input type="checkbox"/>
Orange	Robert	George	+1 7386037009	rorange@gmail.com	Clinician	<input type="checkbox"/>
Rademan	Jeremy	Antonio	+1 7326012295	jrademan@yahoo.com	Administrator	<input type="checkbox"/>
Saballos	Birtney	Phil	+1 8972478141	bsaballos@gmail.com	Clinician	<input type="checkbox"/>

First Previous 1 2 3 4 5 20 25 Next Last

After first log in or any time thereafter, the Administrator may adjust MySOZO system-wide settings. On the “Security Settings” screen, scroll down to change the system-wide settings, which includes password policy, password expiration period, time zone, logout inactivity time, and licences. When finished, click **Save**.



## 6.4 MySOZO Clinician

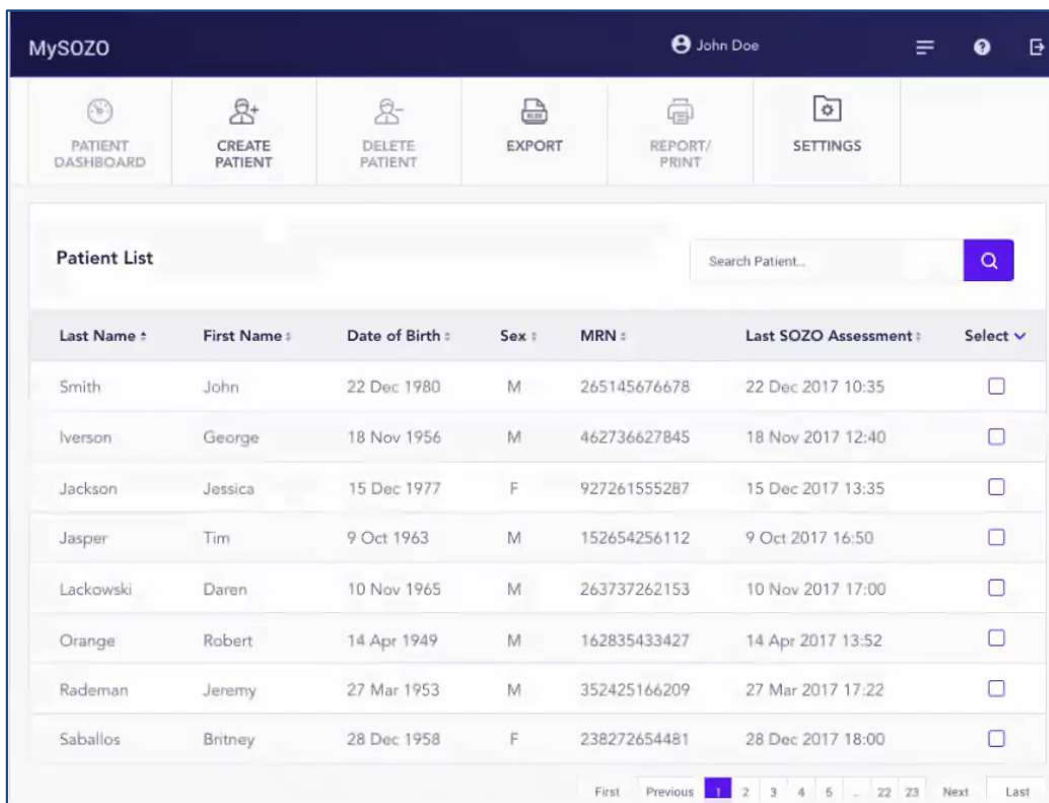
The MySOZO Clinician has exclusive authority to manage patient profiles and view / take patient measurements.

### 6.4.1 Log In

The Clinician follows the same process to log in as all Users per [6.2 All MySOZO Users \(Administrators and Clinicians\)](#).

### 6.4.2 Clinician Home Page

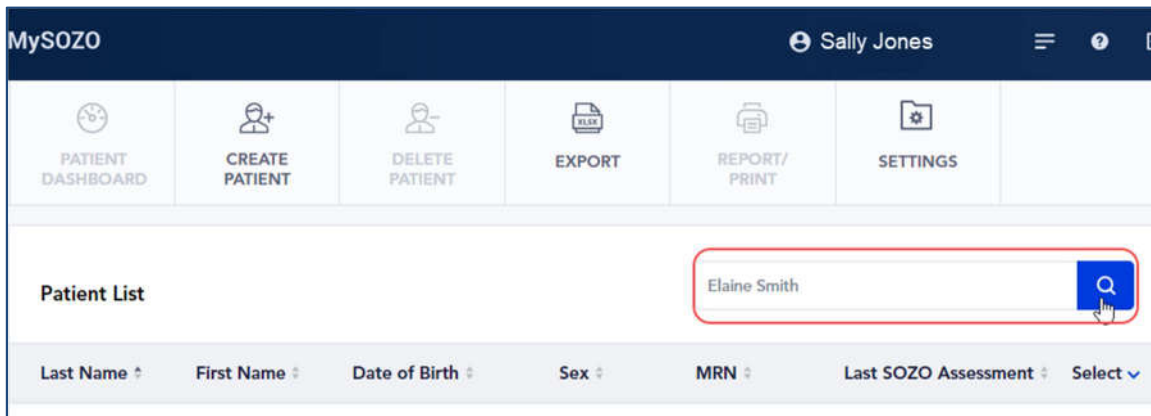
Login leads to the MySOZO Clinician home page, with the “Patient List.”



The screenshot displays the MySOZO Clinician home page. At the top, a dark blue header bar contains the 'MySOZO' logo on the left, the user name 'John Doe' in the center, and a hamburger menu icon, an information icon, and a share icon on the right. Below the header is a navigation bar with six buttons: 'PATIENT DASHBOARD' (with a clock icon), 'CREATE PATIENT' (with a person icon), 'DELETE PATIENT' (with a person icon and a minus sign), 'EXPORT' (with a document icon), 'REPORT/PRINT' (with a printer icon), and 'SETTINGS' (with a gear icon). The main content area is titled 'Patient List' and features a search bar with the placeholder text 'Search Patient...' and a magnifying glass icon. Below the search bar is a table with the following columns: 'Last Name', 'First Name', 'Date of Birth', 'Sex', 'MRN', 'Last SOZO Assessment', and 'Select'. The table contains eight rows of patient data. At the bottom of the table is a pagination control with buttons for 'First', 'Previous', '1' (highlighted), '2', '3', '4', '5', '...', '22', '23', 'Next', and 'Last'.

Last Name	First Name	Date of Birth	Sex	MRN	Last SOZO Assessment	Select
Smith	John	22 Dec 1980	M	265145676678	22 Dec 2017 10:35	<input type="checkbox"/>
Iverson	George	18 Nov 1956	M	462736627845	18 Nov 2017 12:40	<input type="checkbox"/>
Jackson	Jessica	15 Dec 1977	F	927261555287	15 Dec 2017 13:35	<input type="checkbox"/>
Jasper	Tim	9 Oct 1963	M	152654256112	9 Oct 2017 16:50	<input type="checkbox"/>
Lackowski	Daren	10 Nov 1965	M	263737262153	10 Nov 2017 17:00	<input type="checkbox"/>
Orange	Robert	14 Apr 1949	M	162835433427	14 Apr 2017 13:52	<input type="checkbox"/>
Rademan	Jeremy	27 Mar 1953	M	352425166209	27 Mar 2017 17:22	<input type="checkbox"/>
Saballos	Britney	28 Dec 1958	F	238272654481	28 Dec 2017 18:00	<input type="checkbox"/>

To search for a patient, enter the name of the patient in the **Search Patient** field and click the **Search** icon.



### 6.4.3 Banner Icons



Click the Clinician banner icons at any time for common functions of the Clinician in MySOZO.

#### 6.4.3.1 MySOZO Icon



The **MySOZO** icon shows that a Clinician is logged into MySOZO. (Compare with icon designating log in of an Administrator in MySOZO Administrator [Section 6.3.2.1 Logged in Status](#)).

#### 6.4.3.1 Clinician User Profile Icon



The **User Profile** icon allows the Clinician to edit their profile.

#### 6.4.3.1 Patient List Icon



The **Patient List** icon is a shortcut to the Patient List.

#### 6.4.3.2 Help (Question Mark) Icon



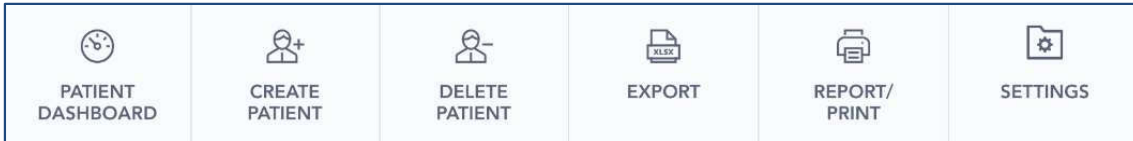
Click the question mark icon for help.

#### 6.4.3.3 Log Out Icon



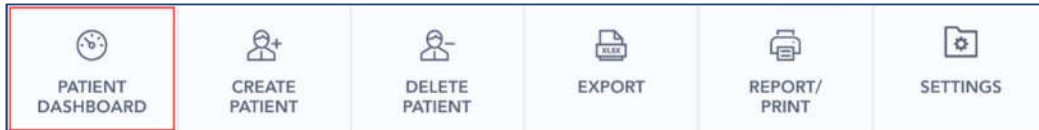
To log out at any time, click the arrow, which is the **Log Out** icon.

#### 6.4.4 Clinician Main Menu



The Clinician Main Menu has the Clinician’s primary MySOZO functions.

##### 6.4.4.1 Patient Dashboard



The Patient Dashboard has detailed information about each patient. To go to the Patient Dashboard, select a patient from the “Patient List.”

PATIENT DASHBOARD	CREATE PATIENT	DELETE PATIENT	EXPORT	REPORT/PRINT	SETTINGS																																																		
<div>Patient List</div> <div>Search Patient... </div> <table><thead><tr><th>Last Name</th><th>First Name</th><th>Date of Birth</th><th>Sex</th><th>MRN</th><th>Last SOZO Assessment</th><th>Select</th></tr></thead><tbody><tr><td>Smith</td><td>John</td><td>22 Dec 1980</td><td>M</td><td>265145676678</td><td>22 Dec 2017 10:35</td><td><input checked="" type="checkbox"/></td></tr><tr><td>Iverson</td><td>George</td><td>18 Nov 1956</td><td>M</td><td>462736627845</td><td>18 Nov 2017 12:40</td><td><input type="checkbox"/></td></tr><tr><td>Jackson</td><td>Jessica</td><td>15 Dec 1977</td><td>F</td><td>927261555287</td><td>15 Dec 2017 13:35</td><td><input type="checkbox"/></td></tr><tr><td>Jasper</td><td>Tim</td><td>9 Oct 1963</td><td>M</td><td>152654256112</td><td>9 Oct 2017 16:50</td><td><input type="checkbox"/></td></tr><tr><td>Lackowski</td><td>Daren</td><td>10 Nov 1965</td><td>M</td><td>263737262153</td><td>10 Nov 2017 17:00</td><td><input type="checkbox"/></td></tr><tr><td>Orange</td><td>Robert</td><td>14 Apr 1949</td><td>M</td><td>162835433427</td><td>14 Apr 2017 13:52</td><td><input type="checkbox"/></td></tr></tbody></table>							Last Name	First Name	Date of Birth	Sex	MRN	Last SOZO Assessment	Select	Smith	John	22 Dec 1980	M	265145676678	22 Dec 2017 10:35	<input checked="" type="checkbox"/>	Iverson	George	18 Nov 1956	M	462736627845	18 Nov 2017 12:40	<input type="checkbox"/>	Jackson	Jessica	15 Dec 1977	F	927261555287	15 Dec 2017 13:35	<input type="checkbox"/>	Jasper	Tim	9 Oct 1963	M	152654256112	9 Oct 2017 16:50	<input type="checkbox"/>	Lackowski	Daren	10 Nov 1965	M	263737262153	10 Nov 2017 17:00	<input type="checkbox"/>	Orange	Robert	14 Apr 1949	M	162835433427	14 Apr 2017 13:52	<input type="checkbox"/>
Last Name	First Name	Date of Birth	Sex	MRN	Last SOZO Assessment	Select																																																	
Smith	John	22 Dec 1980	M	265145676678	22 Dec 2017 10:35	<input checked="" type="checkbox"/>																																																	
Iverson	George	18 Nov 1956	M	462736627845	18 Nov 2017 12:40	<input type="checkbox"/>																																																	
Jackson	Jessica	15 Dec 1977	F	927261555287	15 Dec 2017 13:35	<input type="checkbox"/>																																																	
Jasper	Tim	9 Oct 1963	M	152654256112	9 Oct 2017 16:50	<input type="checkbox"/>																																																	
Lackowski	Daren	10 Nov 1965	M	263737262153	10 Nov 2017 17:00	<input type="checkbox"/>																																																	
Orange	Robert	14 Apr 1949	M	162835433427	14 Apr 2017 13:52	<input type="checkbox"/>																																																	

Click **Patient Dashboard** tab. The “Patient Details” screen appears.

**MySOZO** John Doe

PATIENT DASHBOARD HISTORY RESULTS EDIT PROFILE REPORT/PRINT

**Patient Details**

Last Name Smith	First Name John	Date of Birth 22 Dec 1980
Sex M	MRN 265145676634	Last SOZO Assessment 18 Apr 2018 22:56

**Assessment Type**

- ✓ L-Dex Analysis for Lymphoedema
- ✓ Fluid Analysis for General Fluid Status Monitoring
- ✓ Tissue Analysis for Body Composition

“Patient Details” shows the date of the patient’s last Assessment and the types of Assessments available.

#### 6.4.4.2 Create Patient

PATIENT DASHBOARD **CREATE PATIENT** DELETE PATIENT EXPORT REPORT/PRINT SETTINGS

The Clinician may create a patient in MySOZO by clicking **Create Patient** tab, which leads to “Patient Details.”

**MySOZO** John Doe

PATIENT DASHBOARD CREATE PATIENT DELETE PATIENT EXPORT REPORT/PRINT SETTINGS

**Patient Details**

First Name Required John Country Code   
 Middle Name Phone Number   
 Last Name Required Smith Address   
 Email Address Required City   
☐ Not Provided State   
 Medical Record Number (MRN) Required 23948209384 Country

The Clinician must enter first name, last name, Medical Record Number (“MRN”), date of birth, sex and height. There may be only one MRN per patient.



The Clinician may, but is not required to, enter the patient’s email address. To leave the patient’s email address blank, click the **Not Provided** box under the **Email Address** field.

Scroll down the “Patient Details” page to view “Type of Assessment” and “Lymphoedema Settings.” When done, click **Create Patient**.

**Assessment Type**

☐ L-Dex Analysis for Lymphoedema   
☐ Fluid Analysis for General Fluid Status Monitoring   
☐ Tissue Analysis for Body Composition

**Lymphoedema Settings**

Assessment ☐ Unilateral ☐ Bilateral   
 Body Element ☐ Arm ☐ Leg   
 Risk Limb ☐ Left ☐ Right   
 Limb Dominance ☐ Left ☐ Right

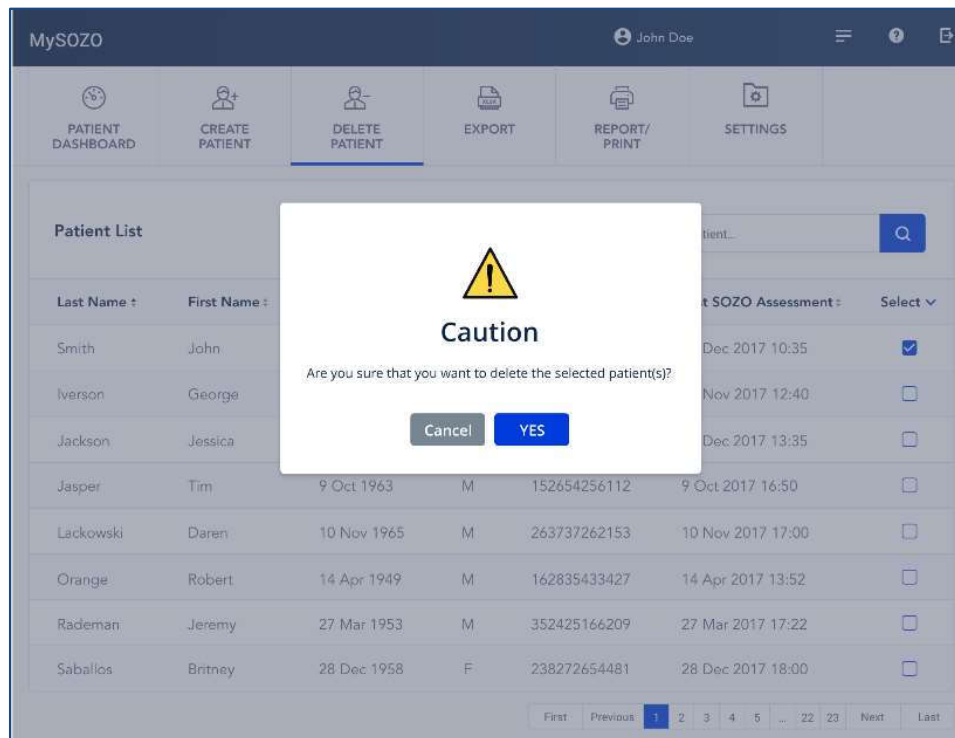
Create Patient



#### 6.4.4.3 Delete Patient



To delete a patient, first select the patient from the “Patient List.” This triggers a Caution. Click **Yes**. This will remove the patient from the patient list and will not allow further measurements to be taken on the patient. However, the patient will remain in the MySOZO database and may be restored later. To fully and permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.

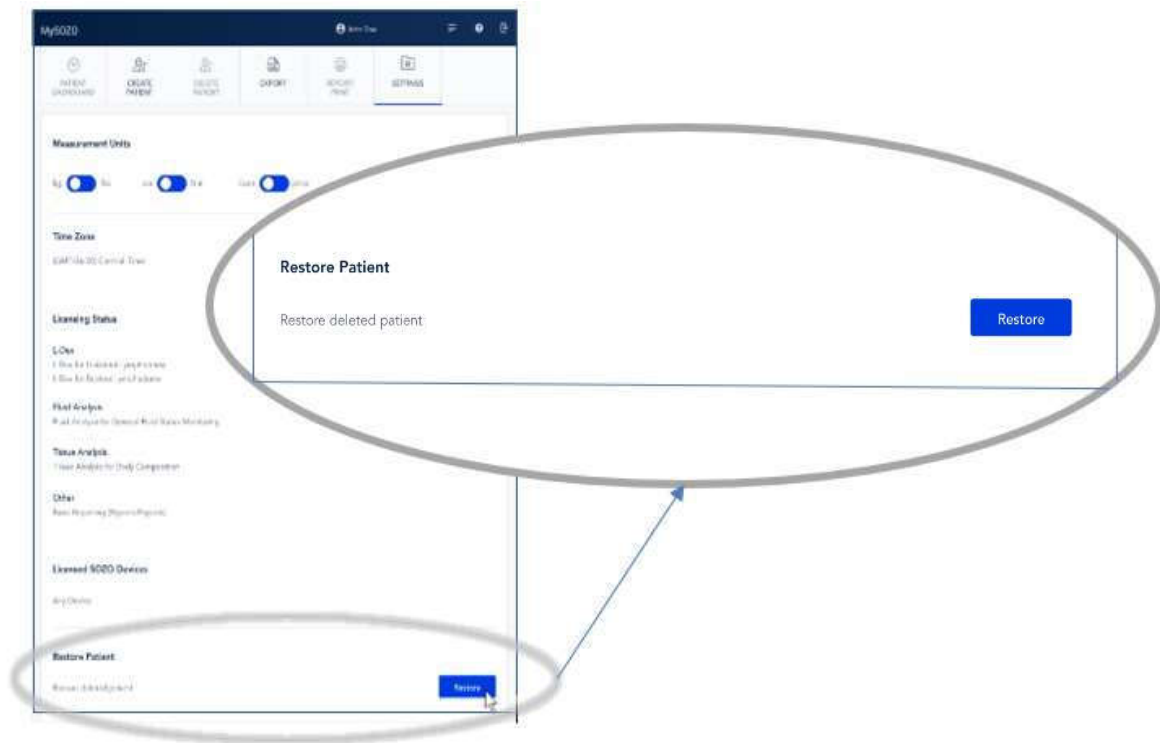


#### 6.4.4.4 Restore Patient

To restore a deleted patient, click **Settings** tab on the Clinician Main Menu.



At the bottom of the “Settings” screen, next to “Restore Patient,” click **Restore**.



#### 6.4.4.5 Export



A Clinician may export patient data from MySOZO.



A Clinician may not export data from the SOZOapp.

To export data, click **Export** tab.



A pop-up displays export settings, which includes Assessment types, date range and data format. When finished, click **Export**.

The screenshot shows the MySOZO Patient List interface. A pop-up dialog box titled 'Export Settings' is open, allowing users to configure data export options. The background interface includes a 'Patient List' table with columns for 'Last Name' and 'First Name', and a 'Patient List' header. The 'Export Settings' dialog box contains the following sections:

- USER DATA TO EXPORT:**
  - ☐ Selected Patients
  - ☐ All Patients
- ASSESSMENT TYPE:**
  - ☐ L-Dex
  - ☐ Fluid Analysis
  - ☐ Tissue Analysis
  - ☐ Hy-Dex
  - ☐ Report Summary
- DATA RESULTS:**
  - ☐ Simplified
  - ☐ Full
- DATE RANGE:**
  - ☐ Select All
  - From:
  - To:
- DATA FORMAT:**
  - ☐ Row per patient
  - ☐ Row per measurement
- ADDITIONAL SETTINGS:**
  - ☐ Show De-identified Patient ID
  - ☐ Show Patient Identifying Details
  - ☐ Show Additional Patient Details
  - ☐ Show Device/Measurement info

An 'Export' button is located at the bottom of the dialog box.

Clicking **Export** triggers a pop-up on the downloading process. Review the instructions and click **OK**.

The screenshot shows a confirmation pop-up message with a large blue checkmark icon at the top. The text inside the pop-up reads:

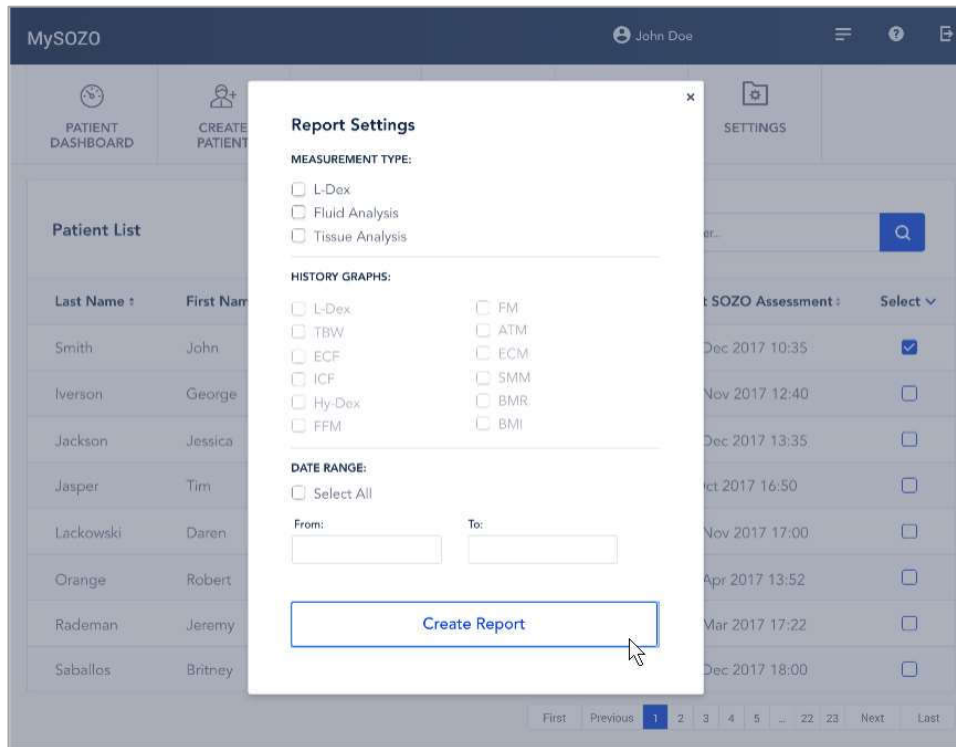
Your data export request is in progress and may take some time to process, depending on the amount of data requested. When the data file is ready, you will receive an email from MySOZO.com containing a secure link that enables you to download it. The link remains valid for 48 hours. If no email is sent, contact ImpediMed technical support.

An 'OK' button is located at the bottom of the pop-up.

#### 6.4.4.6 Patient Report: Report/Print



A Clinician may create a patient report from MySOZO, but not from the SOZOapp. To create a patient report in MySOZO, click **Report/Print** tab. A pop-up with a list of options appears. When finished customizing the patient report, click **Create Report**.



#### 6.4.4.7 Settings: Adjusting Measurement Units



Under the **Settings** tab, the Clinician may restore a deleted patient ([Section 6.4.4.4 Restore Patient](#)) and adjust the measurement units. Under “Measurement Units,” the Clinician may adjust the measurement standard as: kg or lbs, centimetres or inches, and litres or pints. When finished, click **Save**.

MySOZO
John Doe

PATIENT DASHBOARD
CREATE PATIENT
DELETE PATIENT
EXPORT
REPORT/PRINT
SETTINGS

**Measurement Units**

kg lbs
cm ft in
litres pints
Save

**Time Zone**

(UTC-07:00) Pacific Time (US and Canada);Tijuana

**Licencing Status**

**L-Dex®**

L-Dex for Unilateral Lymphoedema
L-Dex for Bilateral Lymphoedema

**Fluid Analysis**

Fluid Analysis for Heart Failure and General Fluid Status Monitoring

**Tissue Analysis**

Tissue Analysis for Body Composition (with Hy-Dex®)

**Other**

Basic Reporting (Reports/Exports)

**Licenced SOZO® Devices**

Any device

**Restore Patient**

Restore deleted patient
Restore

## 6.4.5 Patient Dashboard

Selecting a patient from the Patient List, per [Section 6.4.4.1 Patient Dashboard](#), leads to the Patient Dashboard home page, “Patient Details.”

### 6.4.5.1 Introduction to Patient Dashboard

The Patient Dashboard has its own menu. Each tab is important for the Clinician's role of viewing, recording and evaluating historical measurements and Assessment results.

The screenshot shows the MySOZO Patient Dashboard. At the top, there is a dark blue header with the MySOZO logo on the left, the user name 'Lorna Katica' in the center, and a menu icon on the right. Below the header is a navigation bar with five tabs: 'PATIENT DASHBOARD' (selected, with a clock icon), 'HISTORY' (with a bar chart icon), 'RESULTS' (with a pie chart icon), 'EDIT PROFILE' (with a pencil icon), and 'REPORT/PRINT' (with a printer icon). The main content area is divided into two sections. The first section is titled 'Patient Details' and contains a table with patient information. The second section is titled 'Assessment Type' and contains a list of three assessment types, each with a checkmark icon.

Patient Details		
Last Name	First Name	Date of Birth
Marchant	Lindsey	9 Apr 1952
Sex	MRN	Last SOZO Assessment
M	12345A	14 Apr 2019 18:04

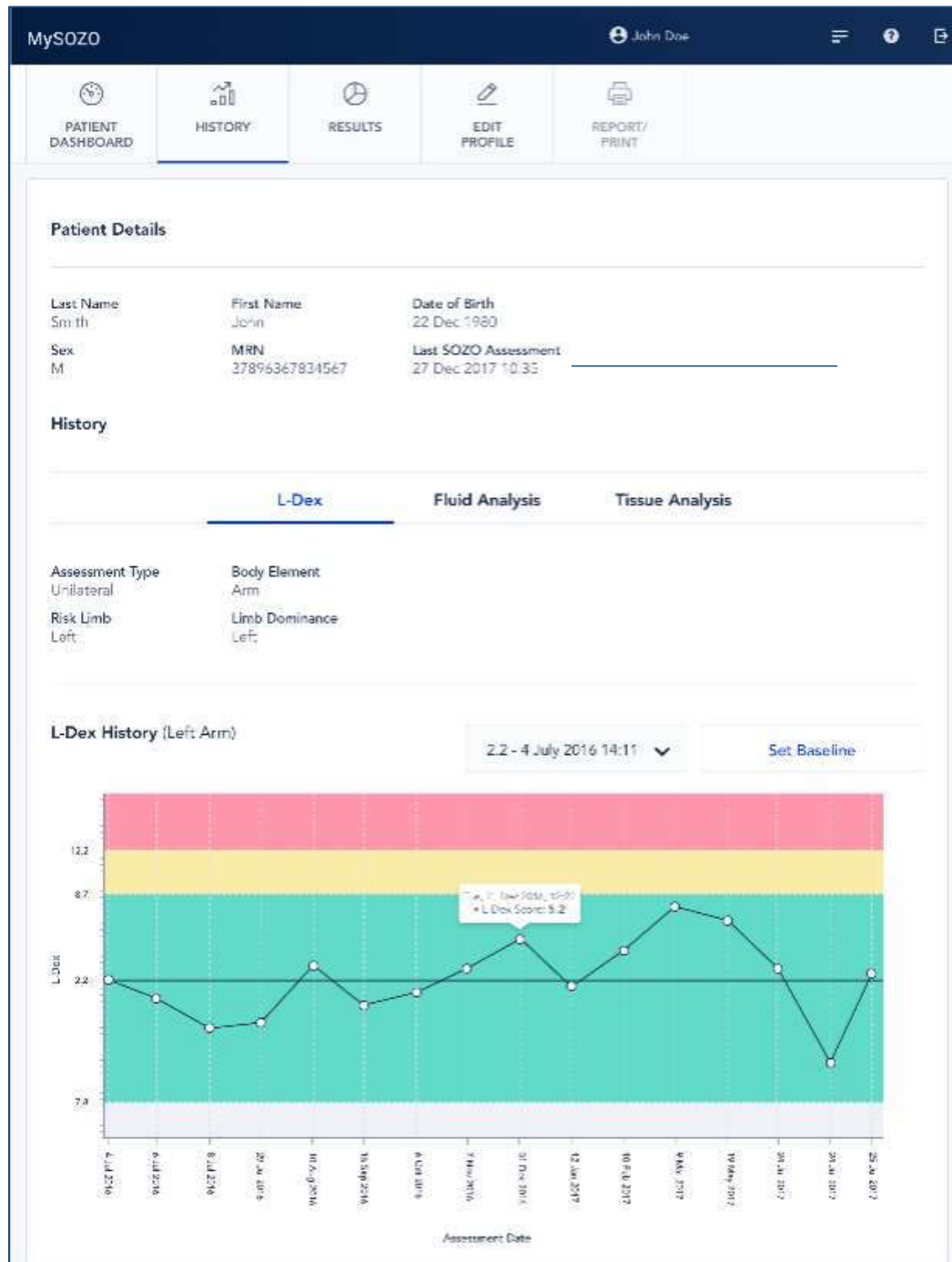
  

Assessment Type
✓ L-Dex Analysis for Lymphoedema
✓ Fluid Analysis for General Fluid Status Monitoring
✓ Tissue Analysis for Body Composition

### 6.4.5.2 Measurement History

This image is a close-up of the navigation tabs from the previous screenshot. The tabs are 'PATIENT DASHBOARD', 'HISTORY', 'RESULTS', 'EDIT PROFILE', and 'REPORT/PRINT'. The 'HISTORY' tab, which features a bar chart icon, is highlighted with a red rectangular border, indicating it is the selected tab.

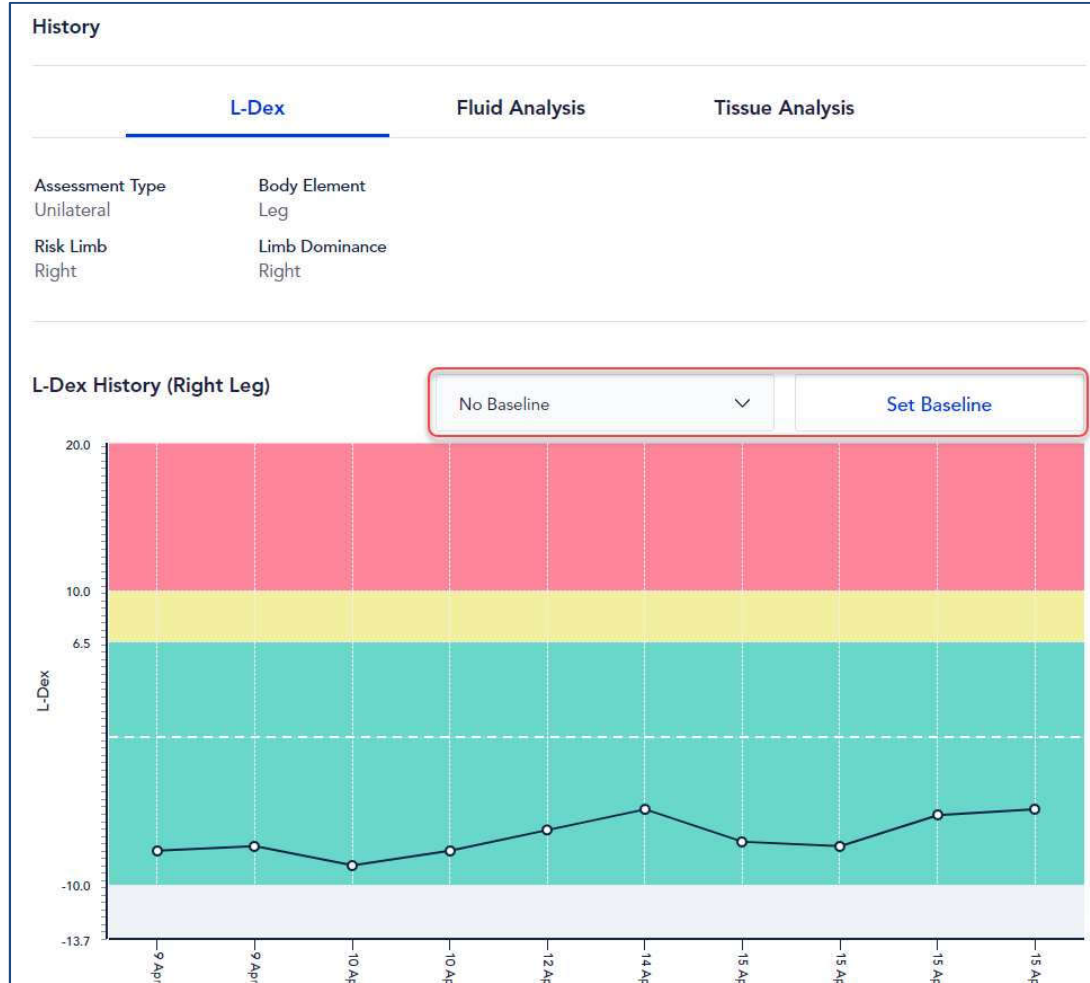
**History** displays graphs of patient measurements taken over time. Click the **History** tab to see "Patient Details." Beneath "History" is a list of Assessments. Click each Assessment to view a graph of the history of patient measurements. A blue line shows which Assessment was selected.



Only licenced Assessments appear in **History**.

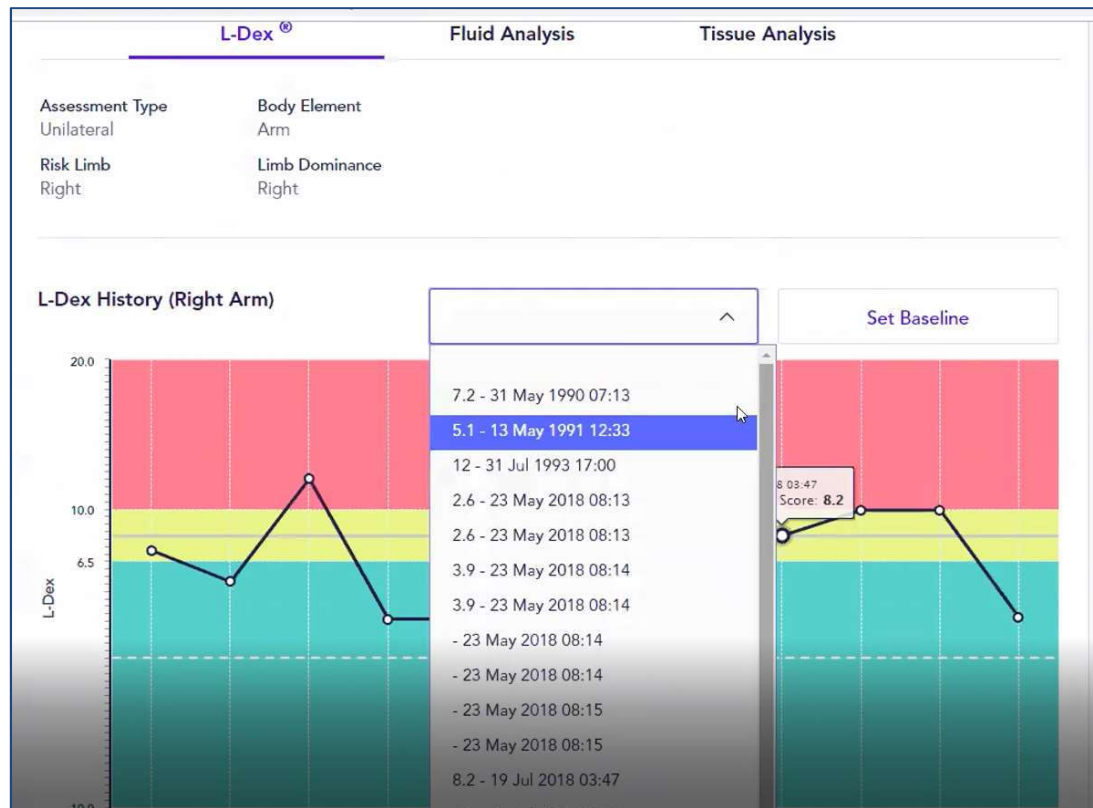
### 6.4.5.2.1 Setting a Baseline

The Clinician may set or remove a measurement baseline for each Assessment type. “No Baseline” appears next to **Set Baseline** if no measurement is chosen as the baseline.





The Clinician may, but is not required to, set a baseline. To set a baseline, the Clinician selects the measurement from the drop-down menu and clicks **Set Baseline**.



To choose the proper measurement as the baseline, the measurement should be:

- (1) High-quality; and
- (2) Taken when the patient is in a normal fluid or “euvoletic” state. Often, this is before treatment has occurred.

Only one parameter may be set as the baseline for each Assessment. The parameter for the L-Dex is the L-Dex score, the Tissue Analysis parameter is the Hy-Dex® score, and the Fluid Analysis parameter is the ECF score.

#### 6.4.5.2.2 Evaluating Measurements Against a Baseline

After setting the baseline, the Clinician may compare patient measurements taken over time against the baseline. From this comparison, the Clinician may identify changes in patient fluid levels, and see if these changes fall within normal or abnormal ranges.

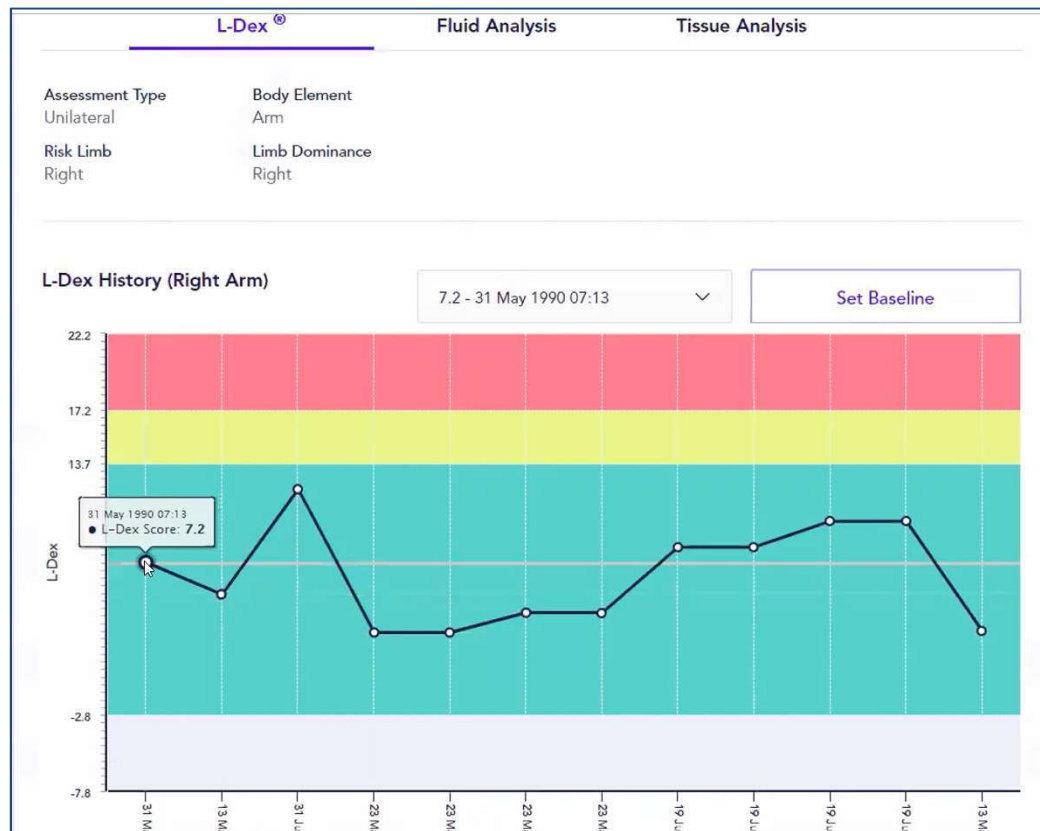
### 6.4.5.2.3 Examples of History of Measurements

Below are examples of measurement history for L-Dex, Fluid Analysis and Tissue Analysis.

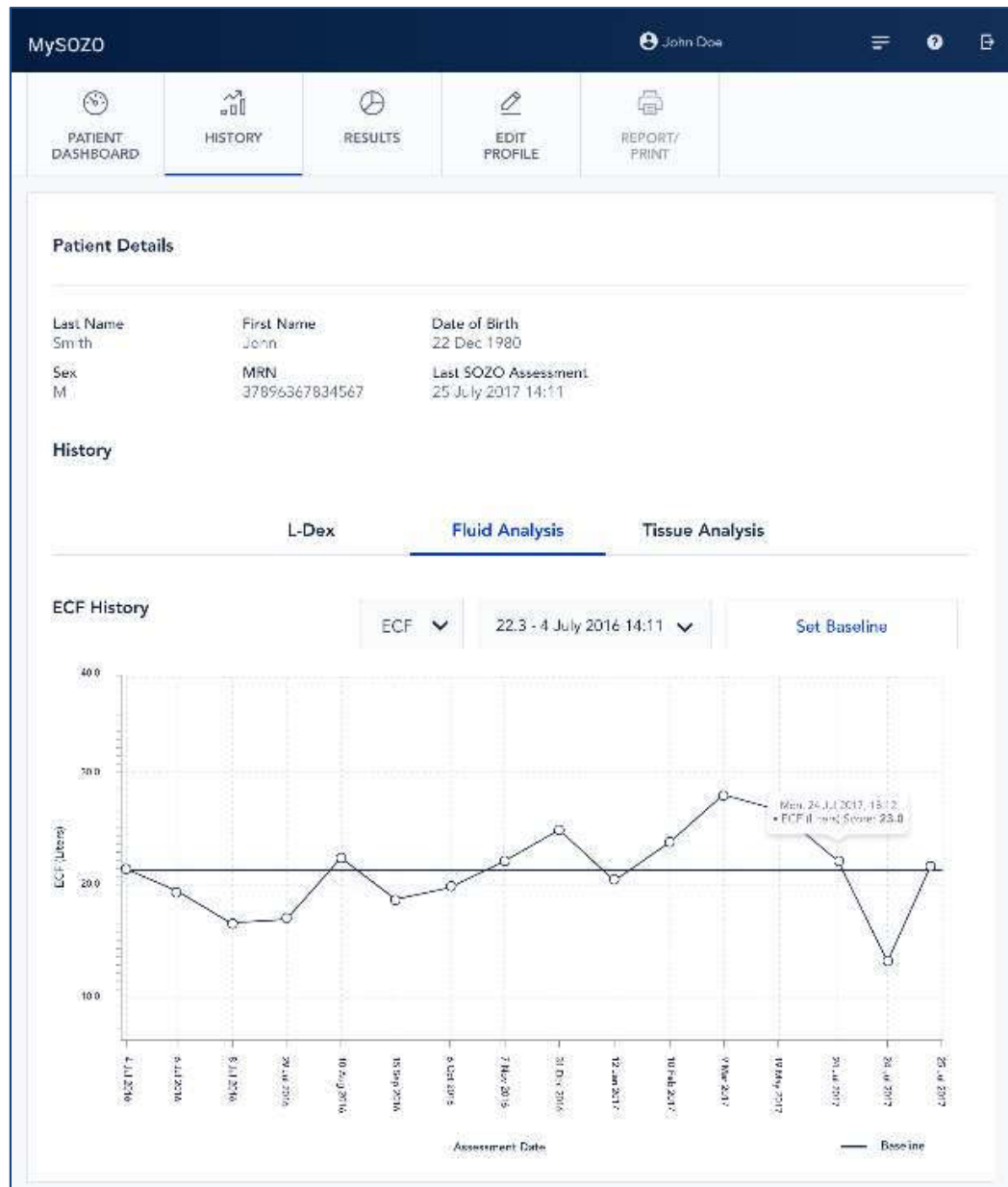
#### 6.4.5.2.3.1 Example of L-Dex History in MySOZO



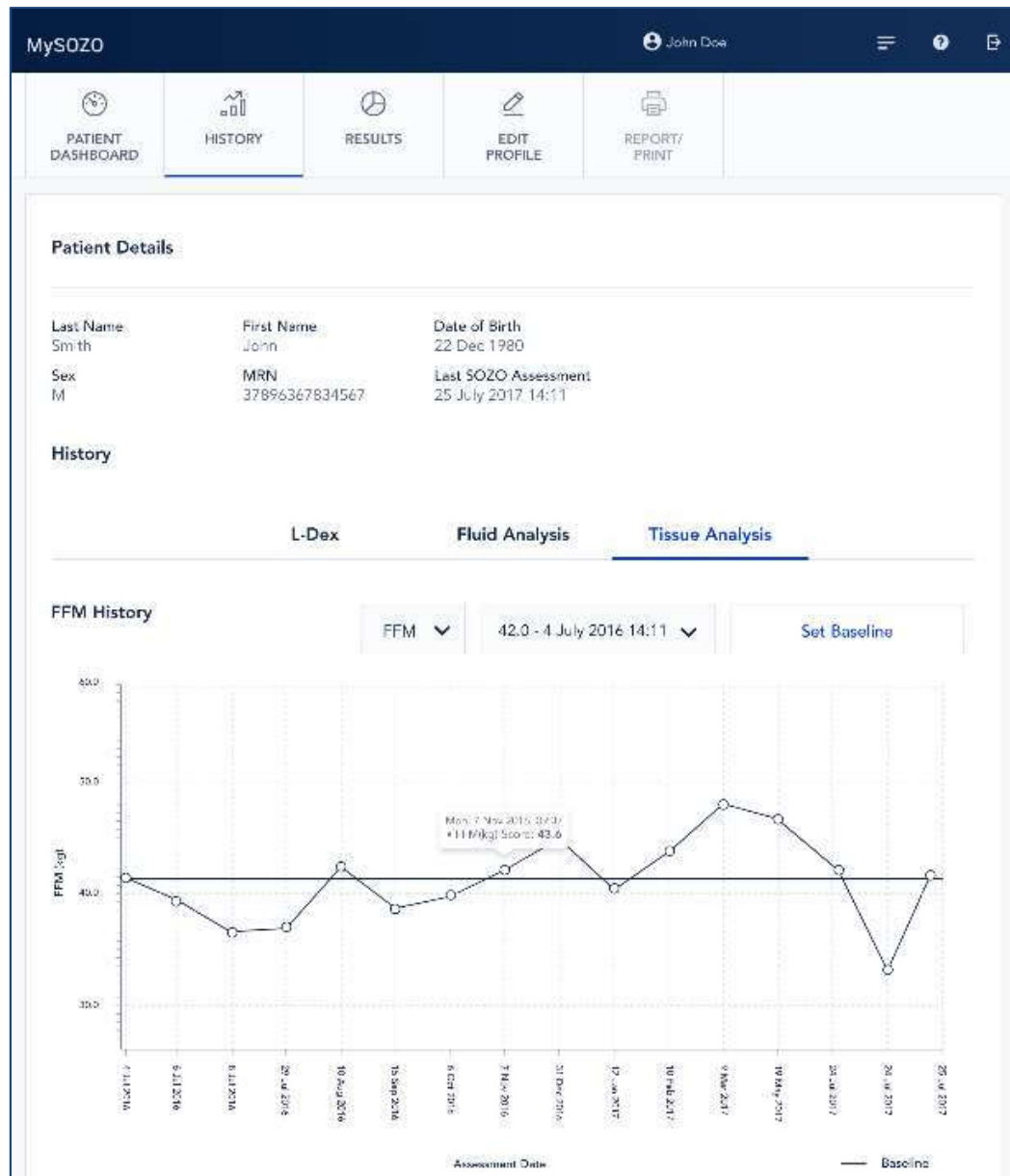
Roll mouse over any data point on the history graph to display the measurement.



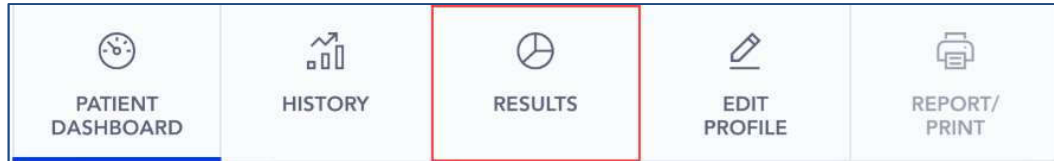
### 6.4.5.2.3.2 Example of Fluid Analysis History in MySOZO



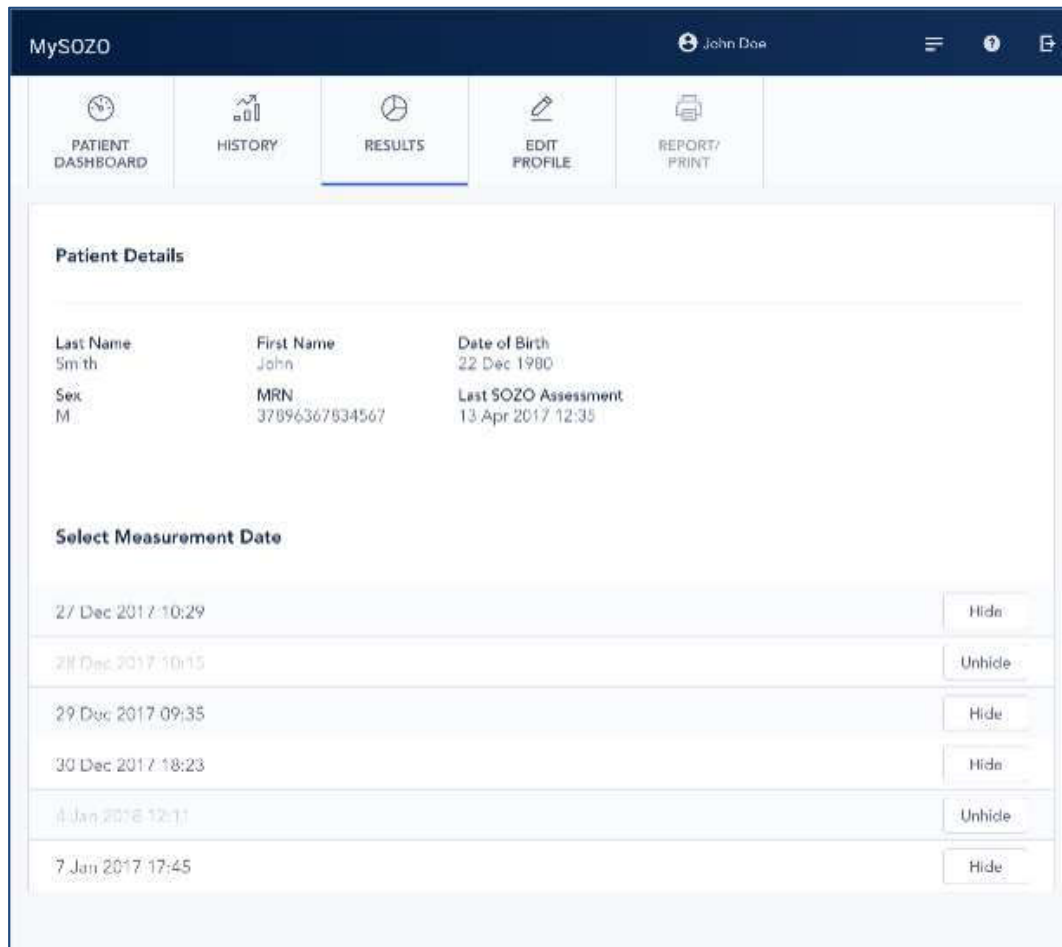
### 6.4.5.2.3.3 Example of Tissue Analysis History in MySOZO



### 6.4.5.3 Measurement Results Viewable by Clinician in MySOZO

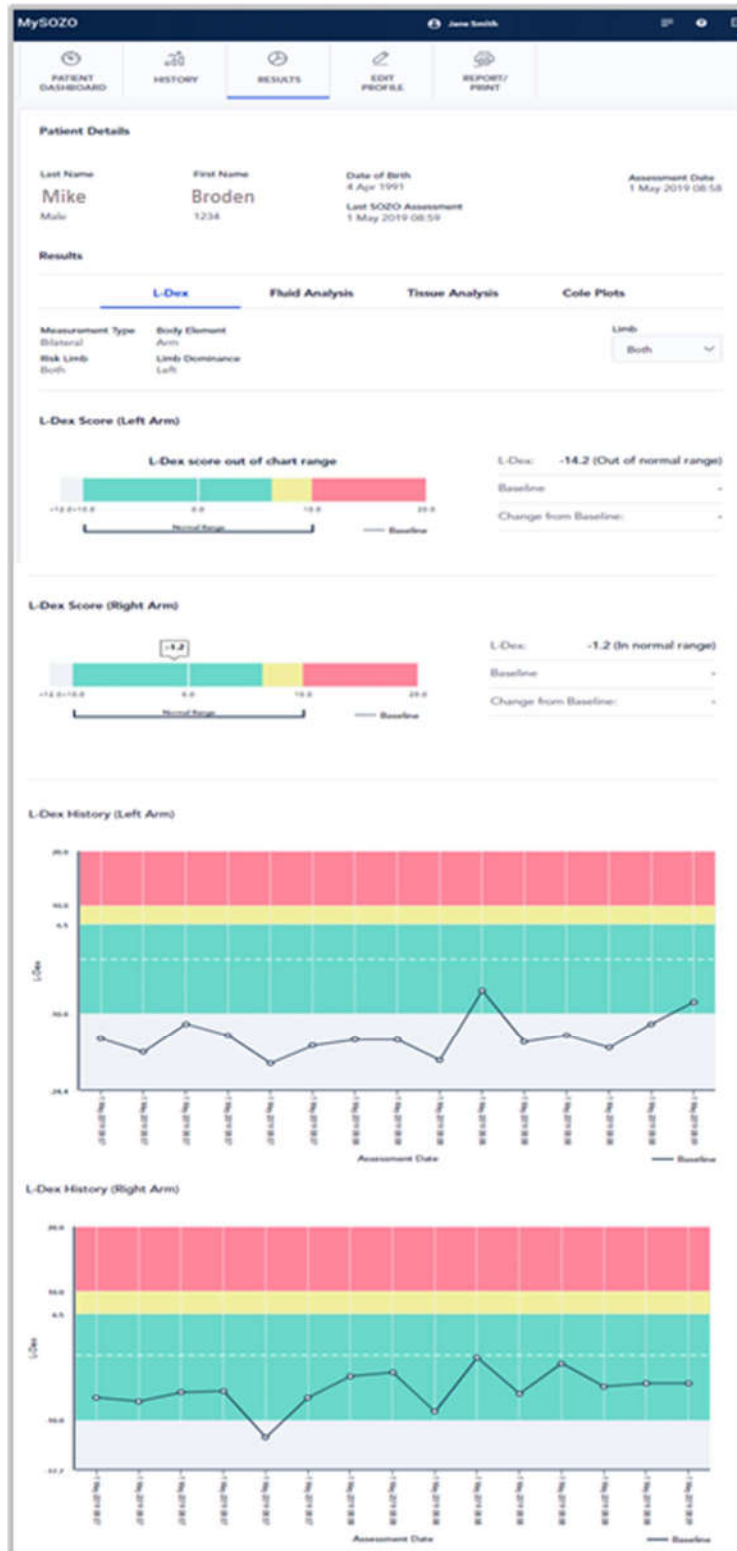


Click **Results** tab. “Patient Details” has identifying patient information and a list of measurement dates.

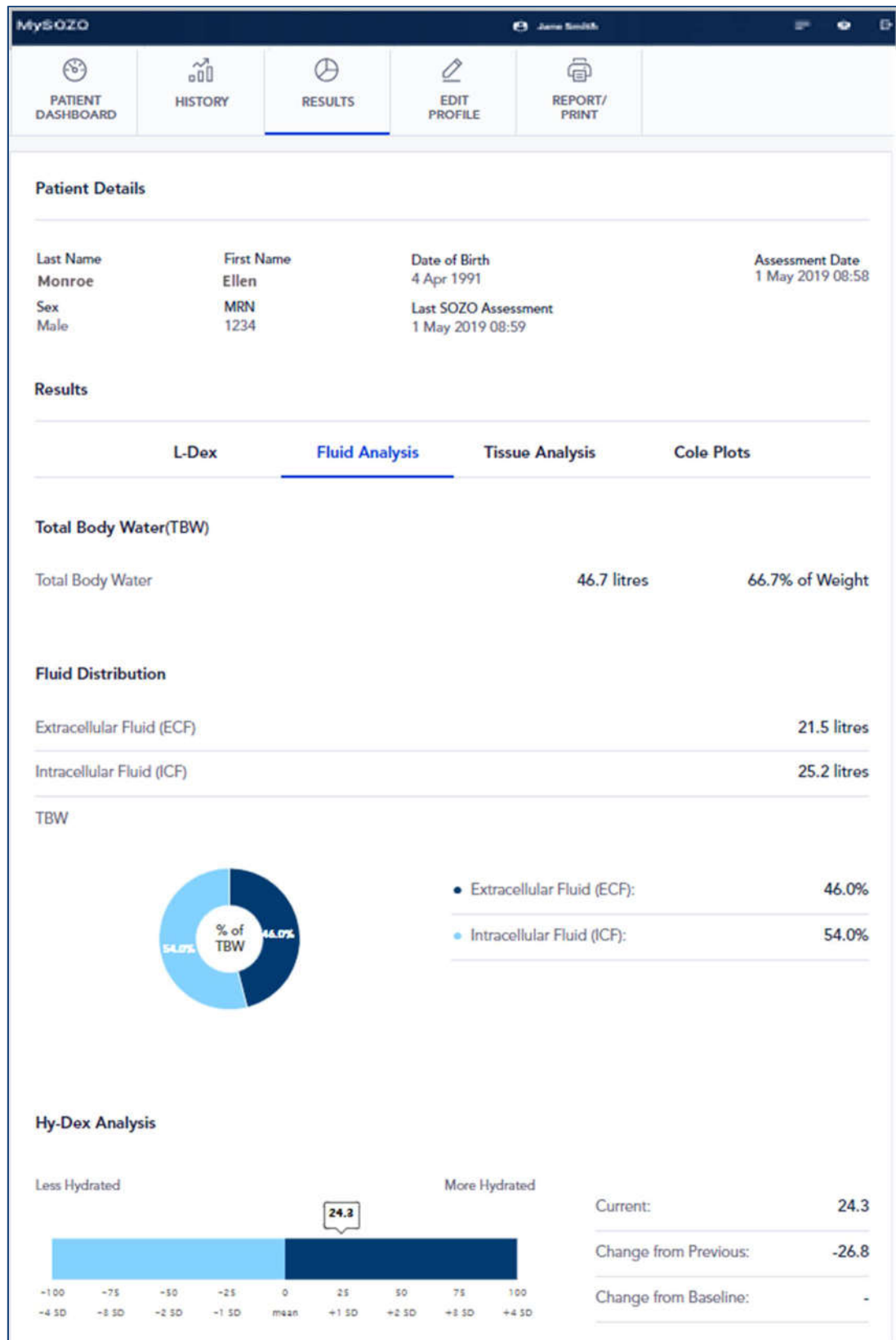


Select a date under “Select Measurement Date.” The results screen appears. Some results may have additional breakdowns of Assessment-specific data. Below are results examples for L-Dex, Fluid Analysis, Tissue Analysis and Cole plots.

### 6.4.5.3.1 Example of L-Dex Results in MySOZO

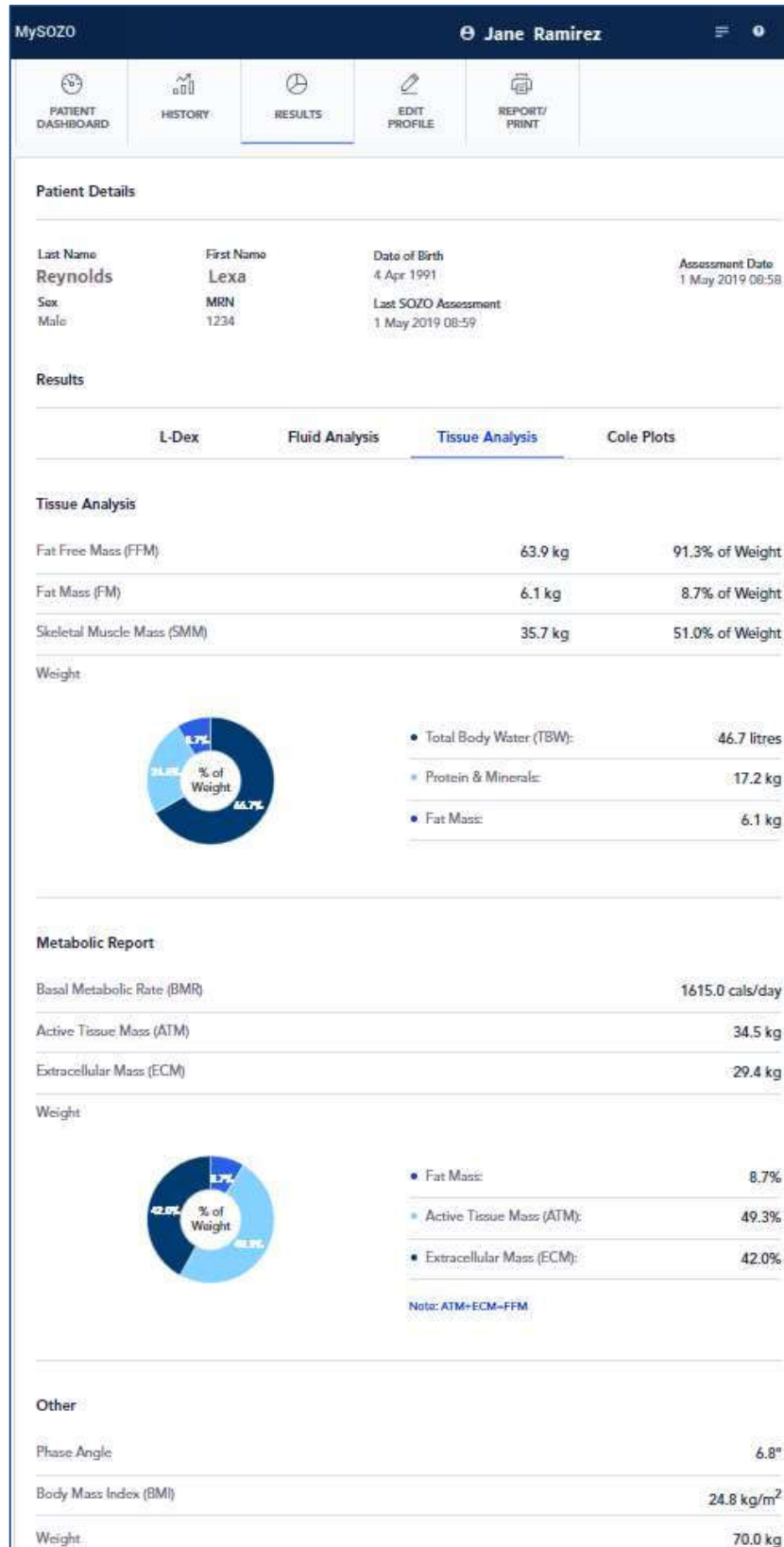


### 6.4.5.3.2 Example of Fluid Analysis Results in MySOZO



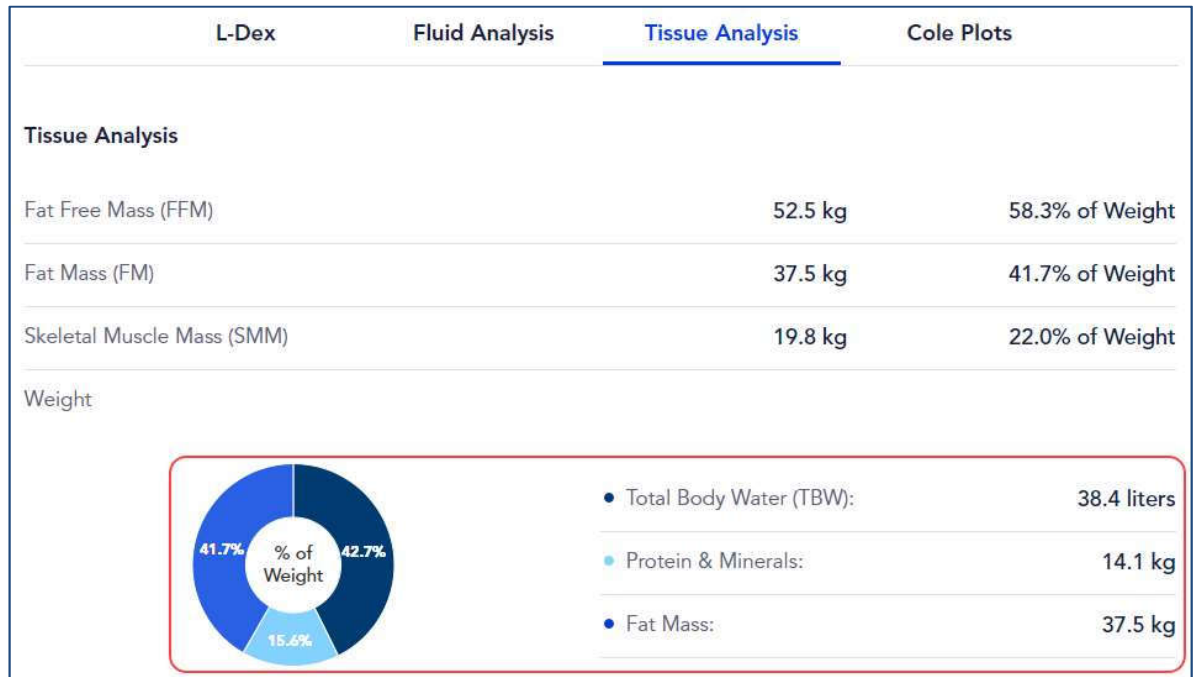


### 6.4.5.3.3 Example of Tissue Analysis Results in MySOZO



Assessment-specific charts, such as a weight breakdown chart for Tissue Analysis, may be displayed, as shown below.

#### 6.4.5.3.3.1 Example of Tissue Analysis Weight Breakdown Chart in MySOZO



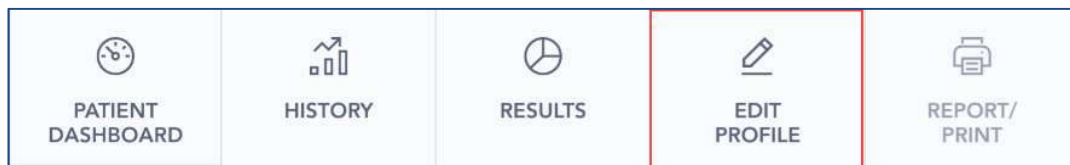
#### 6.4.5.3.4 Example of Cole Plots in MySOZO

The SOZO software helps determine the quality of the Cole plots as high quality (green), medium quality (yellow) or low quality (red).



For more about reviewing Cole plots in the SOZOapp, see [Section 8.6.2.4 Reviewing Cole Plots After Measurement](#).

#### 6.4.5.4 Edit Patient Profile



To edit a patient profile in MySOZO, click **Edit Profile** tab on the Patient Dashboard.

The “Patient Details” screen displays patient personal information, Assessment types and other settings. When done, click **Save Changes** at the bottom of the screen.

MySOZO
Loma Katica

PATIENT DASHBOARD
HISTORY
RESULTS
EDIT PROFILE
REPORT/PRINT

### Patient Details

First Name
Required
Tray

Country Code

Middle Name

Phone Number

Last Name
Required
Edenton

Address

Email Address
Required

City

☒ Not Provided

Medical Record Number (MRN)
Required
Hub1

State

Date of Birth
Required
7 Jun 1966

Country

Sex
Required
Female

Postal Code

Height (cm)
Required
165

### Assessment Type

☒ L-Dex Analysis for Lymphoedema
☒ Fluid Analysis for General Fluid Status Monitoring
☒ Tissue Analysis for Body Composition

### Lymphoedema Settings

Assessment

☒ Unilateral
☐ Bilateral

Body Element

☒ Arm
☐ Leg

Risk Limb

☒ Left
☐ Right

Limb Dominance

☐ Left
☒ Right

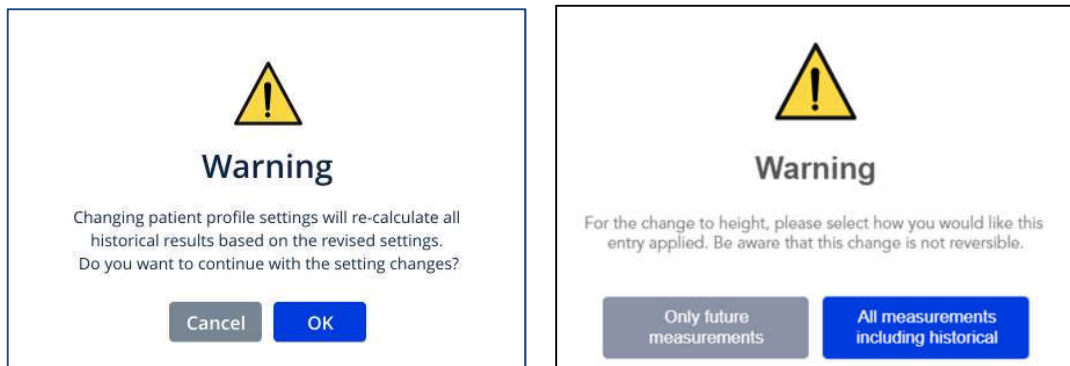
Save Changes

#### 6.4.5.4.1 Patient Weight May Not Be Modified

Weight is important for measurement accuracy. [See Section 8.6.2.2.2 Entering Weight](#). The Clinician enters the patient weight at the time of measurement, which is valid for that measurement only. After measurement, weight may not be modified.

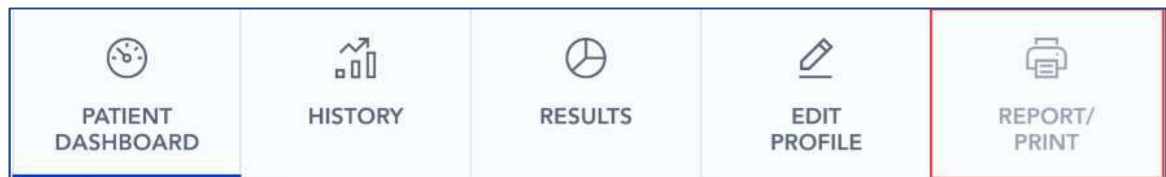
#### 6.4.5.4.2 Warnings and Cautions After Changing Patient Profile

After clicking **Save Changes**, Warnings may appear about potential impact of changes on historical results.



For more about Assessments, see [Section 9.0 Assessments](#).

#### 6.4.5.5 Patient Report: Report/Print



The Clinician may create a patient report in MySOZO by clicking **Report/Print** tab on the Patient Dashboard. The report may be customized by measurement type, history graphs and date range.

When done, click **Create Report**.

MySOZO
John Doe

PATIENT DASHBOARD
CREATE PATIENT

Patient List

Last Name	First Name
Smith	John
Iverson	George
Jackson	Jessica
Jasper	Tim
Lackowski	Daren
Orange	Robert
Rademan	Jeremy
Saballos	Britney

Report Settings

MEASUREMENT TYPE:

☐ L-Dex
☐ Fluid Analysis
☐ Tissue Analysis

HISTORY GRAPHS:

☐ L-Dex
☐ TBW
☐ ECF
☐ ICF
☐ Hy-Dex
☐ FFM

☐ FM
☐ ATM
☐ ECM
☐ SMM
☐ BMR
☐ BMI

DATE RANGE:

☐ Select All

From:
To:

Create Report

SOZO Assessment
Select

Dec 2017 10:35	<input checked="" type="checkbox"/>
Nov 2017 12:40	<input type="checkbox"/>
Dec 2017 13:35	<input type="checkbox"/>
Oct 2017 16:50	<input type="checkbox"/>
Nov 2017 17:00	<input type="checkbox"/>
Apr 2017 13:52	<input type="checkbox"/>
Mar 2017 17:22	<input type="checkbox"/>
Dec 2017 18:00	<input type="checkbox"/>

# 7.0 Preparing the Patient

## 7.1 Introduction

### 7.1.1 Preparing for All Measurements

The Clinician taking measurements on a SOZO Device must make sure that the patient:

- (1) Removes all metal jewellery if possible, including large belt buckles;  
Items above the neck such as earrings are okay.
- (2) Removes any electronics, coins, keys or other metal objects from pockets;
- (3) Removes shoes and socks or stockings or socks;
- (4) Ensures that their feet and hands are clean by wiping with a damp cloth; and
- (5) Remains still during the measurement with elbows away from the body.

### 7.1.2 Preparing for Fluid or Tissue Analysis Measurements

If fluid and/or tissue analysis is intended, make sure that the patient observes the following preparation tips to ensure consistent Fluid Analysis and Tissue Analysis Assessments:

- (1) Empties bladder prior to measurement;
- (2) Avoids exercise for 4 hours prior to measurement;
- (3) Avoids caffeine 2 hours prior to measurement;
- (4) Avoids alcohol for 8 hours prior to measurement; and
- (5) Avoids meals for 8 hours prior to measurement.

### 7.1.3 Taking Measurements Under Similar Conditions

To optimize measurement accuracy, the Clinician should take measurements under similar conditions. Measurements should be taken at the same time of day, and with similar activity level and food and fluid intake.

Read the Indications for Use in Sections [9.3.1.1 Indications for Use](#), [9.3.2.1 Indications for Use](#) and [Tissue Analysis](#) [9.3.3.1 Indications for Use](#) for any indication-specific instructions.



## 7.2 Standing vs. Seated Position



The SOZO system is designed to accommodate patients who may not be able to stand, or who may exceed the maximum weight limitation (up to 375lbs if patient is standing, and up to 750 lbs if patient is sitting). See instructions for system configuration for standing, 5.1 SOZO Device with SOZOsupport Stand, and seated positions, 5.2 SOZO Device without SOZOsupport Stand.

Regardless of whether the patient is standing or seated, to ensure accurate comparison of fluid levels, Clinicians should always take measurements while the patient is in the same position.

### 7.2.1 Optimal Readings

For best results, when taking a reading from a standing position, the patient should stand at rest for a few minutes prior to taking a measurement.

Similarly, when taking a reading from a seated position, the subject should be seated for a few minutes prior to taking a measurement.

### 7.2.2 Standing Position

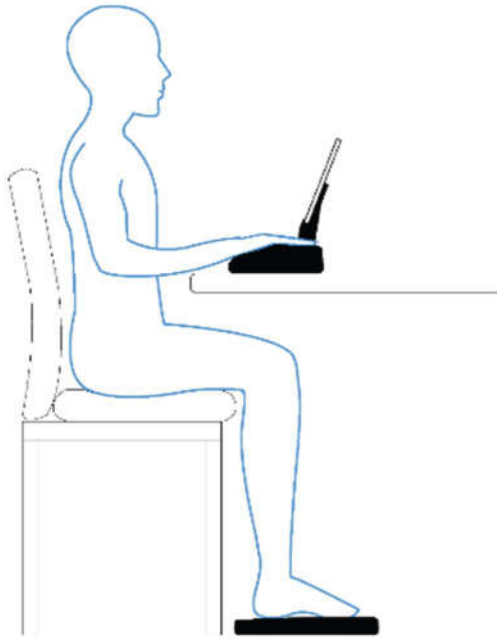
When standing on the SOZO Device, ImpediMed strongly recommends using the SOZOsupport Stand provided with the system.



The patient should:

- distribute body weight evenly on both feet.
- keep arms relaxed with elbows at their side while hands make contact with the electrodes.

### 7.2.3 Seated Position



Do not use a metal chair or table. The patient should:

- Sit fully upright and balanced in the chair with shoulders rolled back.
- Distribute body weight evenly on both hips.
- Bend the knees at a right angle, plus or minus 10 degrees.

# 8.0 Using the SOZOapp

## 8.1 Introduction

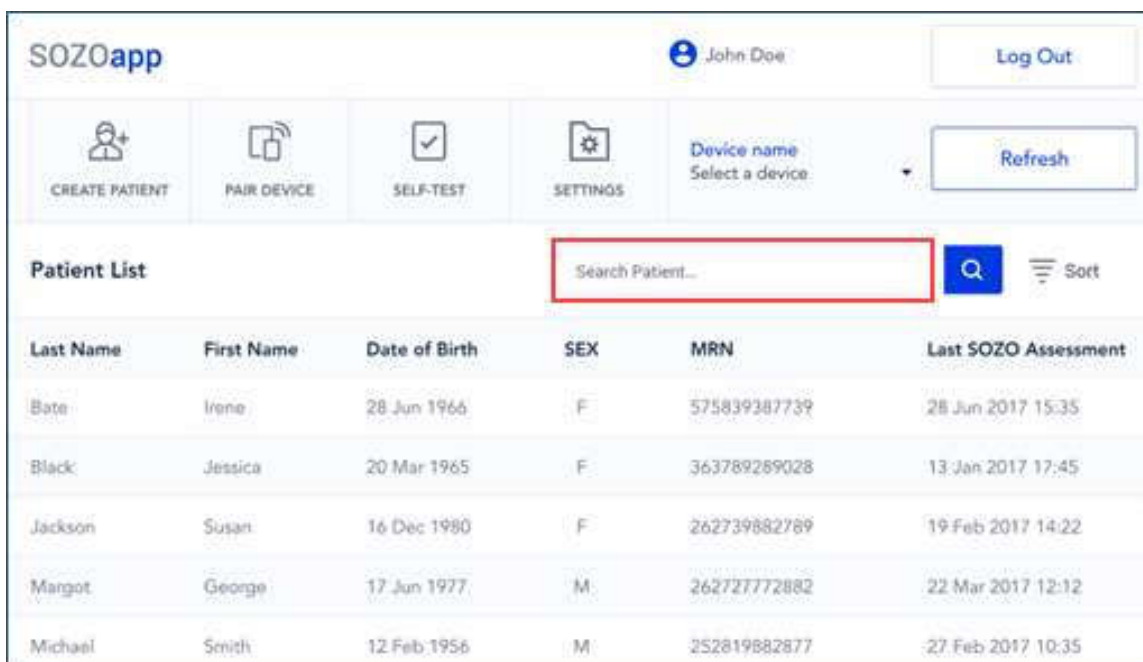
Clinicians may access the SOZO system through MySOZO and the SOZOapp. The SOZOapp allows Clinicians to conduct most SOZO functions, including:

- 1) Management of patient profiles, including adding, editing or selecting patients from a patient list;
- 2) Selecting and configuring Assessments to fit the patient's diagnosis, treatment plan and individual needs;
- 3) Taking and entering patient measurements for various Assessments;
- 4) Considering measurement validity by reviewing Cole plots;
- 5) Evaluating patient progress through comparison of historical measurements against a baseline; and
- 6) Adjust SOZO system-wide settings.

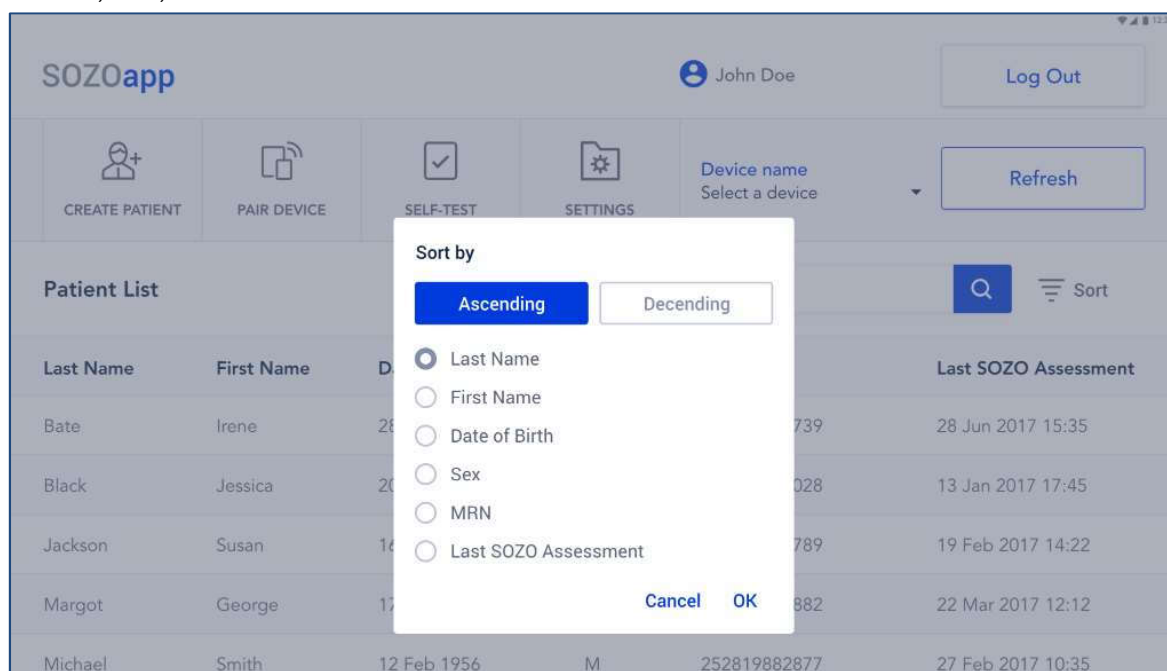
## 8.2 Start-Up

### 8.2.1 Pairing the Tablet with the SOZO Device

Locate Settings on the Tablet and enable Bluetooth®. Once Bluetooth® is enabled, the Tablet scans for connection to the SOZO Device. See [8.3.2 Conducting Patient Search](#)  
[The Clinician](#) may search for a patient in the "Patient List."



Type the patient's name into Search Patient field. A search may be done using the sort feature. Tap the **Sort** icon and select criteria for sorting, which are ascending or descending order, date of birth, sex, MRN or last SOZO Assessment.



#### 8.4 Selecting SOZO Device.

### 8.2.2 Tap SOZOapp

#### SOZOapp



On the Tablet, tap the SOZOapp. If, for any reason, the SOZOapp has been deleted, contact ImpediMed for re-installation. As newer SOZOapp versions are released, the appearance of the SOZOapp icon may change.

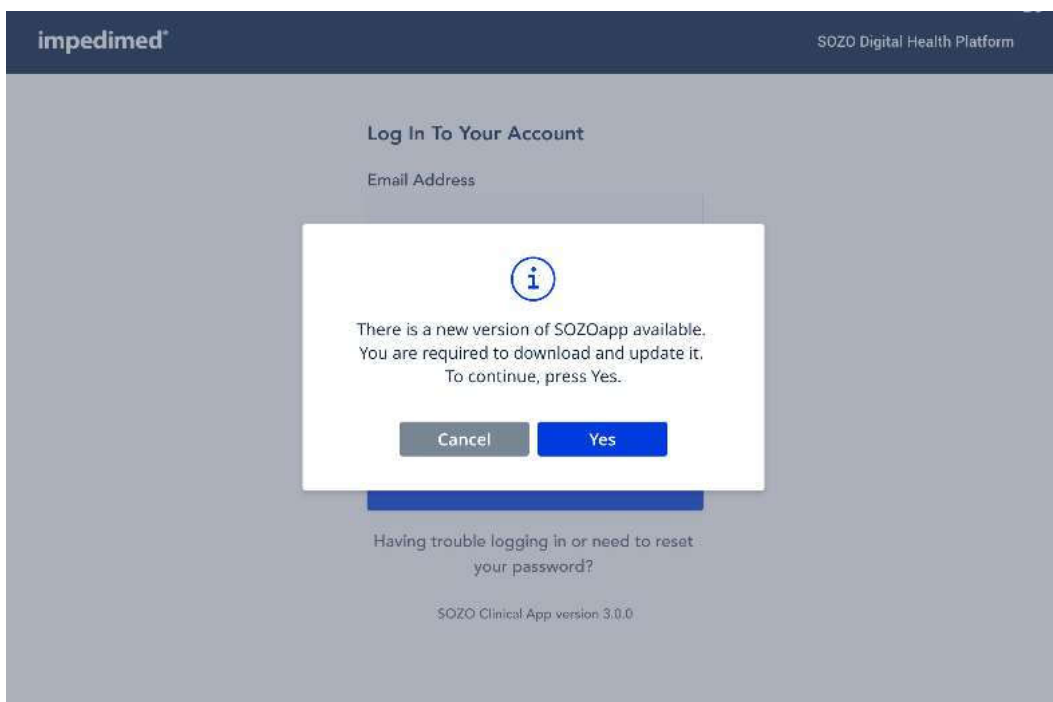
### 8.2.3 Enter Email Address

Under “Log in to Your Account,” enter password, select language and tap **Log In**.



Clinician accounts may not be created in the SOZOapp. Only Administrators may create or edit Clinician accounts through MySOZO. For more information, go to MySOZO Administrator [Section 6.3.3.1 Create User](#).

If there is a newer version of the SOZOapp, the User will be notified.



If you have trouble logging in, you may reset your password by clicking the “Having Trouble” message under **Log In**. ImpediMed will send you an email with a password reset link, which will bring you to the “Set New Password” screen. From the “Set New Password” screen, enter your new password and tap **Submit**.

## 8.3 SOZOapp Home Screen

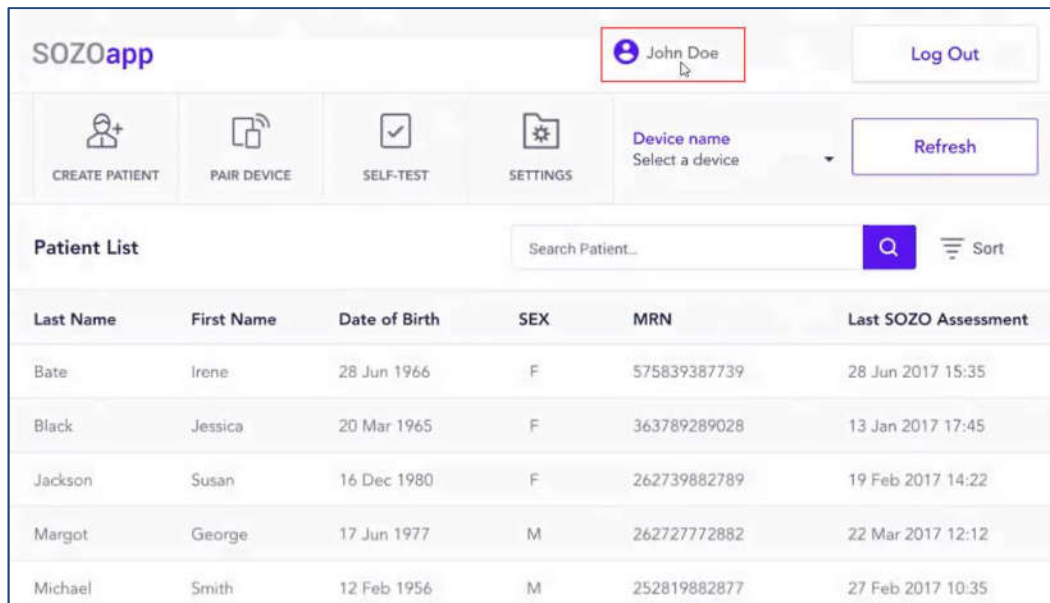
After successful log in, the SOZOapp home screen with “Patient List” appears.

### 8.3.1 SOZOapp Banner Icons

The SOZOapp banner has **User Profile** and **Log Out** Icons.

### 8.3.1.1 User Profile Icon

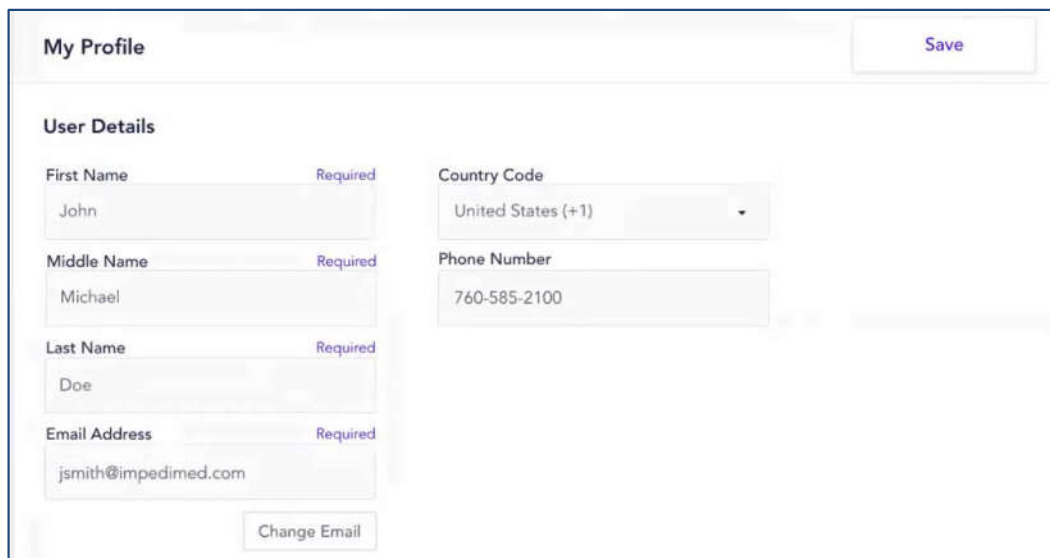
The Clinician may edit their own User profile information at any time by tapping the **User Icon**.



The screenshot shows the SOZOapp home screen. At the top, the 'SOZOapp' logo is on the left, and a user profile icon with the name 'John Doe' is on the right, highlighted with a red box. To the right of the profile icon is a 'Log Out' button. Below the header is a navigation bar with five icons: 'CREATE PATIENT', 'PAIR DEVICE', 'SELF-TEST', 'SETTINGS', and 'Device name Select a device'. A 'Refresh' button is located to the right of the navigation bar. Below the navigation bar is a 'Patient List' section with a search bar and a 'Sort' button. The patient list is a table with the following data:

Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12
Michael	Smith	12 Feb 1956	M	252819882877	27 Feb 2017 10:35

Next, on the “My Profile” screen, review, edit and tap **Save**.



The screenshot shows the 'My Profile' screen. At the top, the title 'My Profile' is on the left, and a 'Save' button is on the right. Below the title is the 'User Details' section. It contains five input fields: 'First Name' (John), 'Middle Name' (Michael), 'Last Name' (Doe), 'Email Address' (jsmith@impedimed.com), and 'Country Code' (United States (+1)). The 'Phone Number' field is also present with the value 760-585-2100. Each input field has a 'Required' label next to it. A 'Change Email' button is located below the email address field.

### 8.3.1.2 Log Out

The User may log out by tapping the **Log Out** icon.

### 8.3.1.3 Patient List

The patient list is on the home screen.

**SOZOapp** John Doe Log Out

CREATE PATIENT PAIR DEVICE SELF-TEST SETTINGS Device name Select a device Refresh

**Patient List** Search Patient... Sort

Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12

### 8.3.2 Conducting Patient Search

The Clinician may search for a patient in the “Patient List.”

**SOZOapp** John Doe Log Out

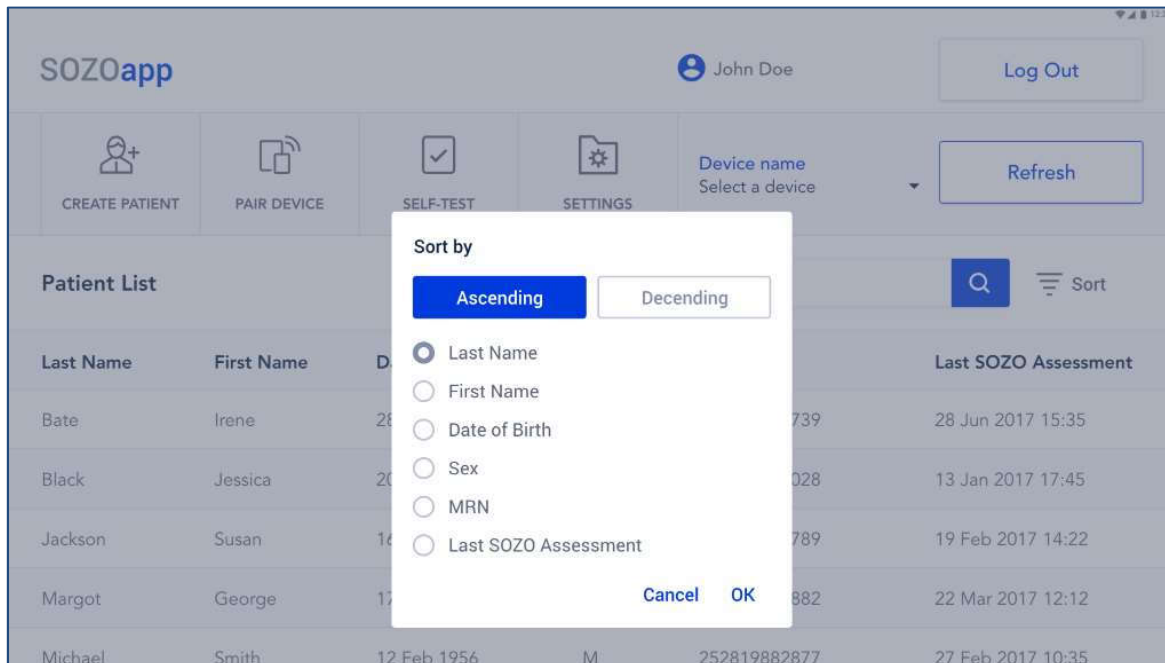
CREATE PATIENT PAIR DEVICE SELF-TEST SETTINGS Device name Select a device Refresh

**Patient List** Search Patient... Sort

Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12
Michael	Smith	12 Feb 1956	M	252819882877	27 Feb 2017 10:35

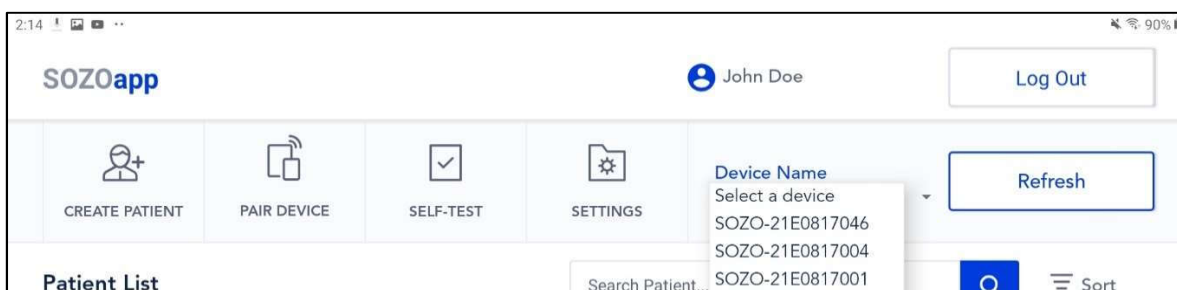
Type the patient’s name into **Search Patient** field. A search may be done using the sort feature. Tap the **Sort** icon and select criteria for sorting, which are ascending or descending order, date of birth, sex, MRN or last SOZO Assessment.





## 8.4 Selecting SOZO Device

From the **Device Name** drop-down menu, select the ImpediMed SOZO Device.



The SOZO Device is identified by serial number (SOZO-xxxxxxxxx). The SOZO Device serial number may be found on the SOZOtouch housing, SOZOstep housing, and the SOZOconnect Cable. The process may be repeated for any new SOZO Devices and must be repeated if either the Tablet or system are replaced. The SOZOapp may only select and work with one SOZO Device at a time.

ImpediMed recommends keeping your SOZO Device together with its paired Tablet. The Tablet may pair with other devices but will only control measurements from the SOZO Device identified under “Device Name.”

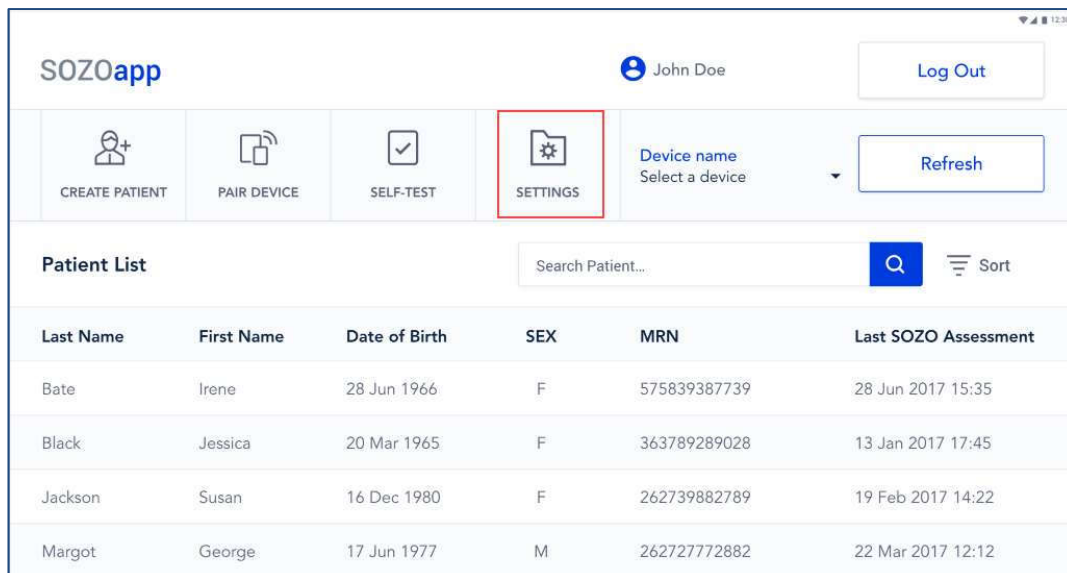
To select the SOZO Device to be used for taking measurements, the SOZOapp recalls the last SOZO Device used and continues pointing to that SOZO Device, even after logging out. Once the SOZO Device is selected, the SOZOapp automatically pairs with the SOZO Device through **Bluetooth®**.

## 8.4.1 Confirming SOZO Device Status

The User should confirm connection to the correct SOZO Device. Confirmation may be done in Settings, or by a self-test.

### 8.4.1.1 Using Settings to Confirm Device Status

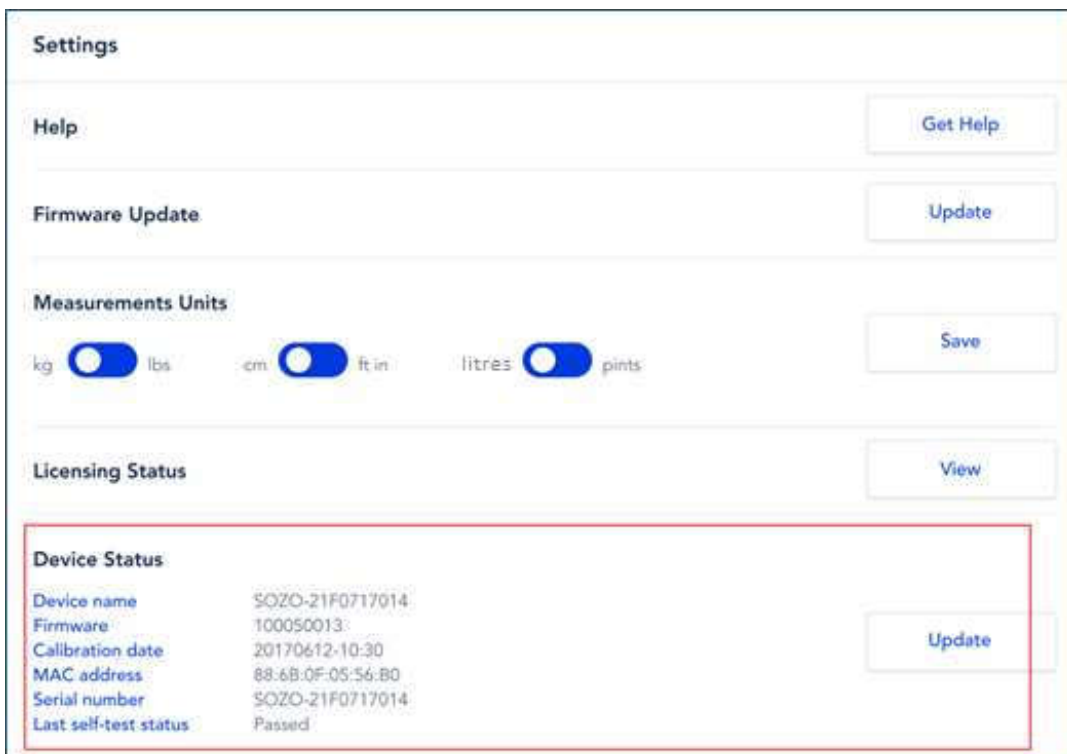
To confirm SOZO Device status, tap the **Settings** tab.



The screenshot shows the SOZOapp main interface. At the top, the app name 'SOZOapp' is on the left, and the user 'John Doe' with a 'Log Out' button is on the right. Below this is a navigation bar with five tabs: 'CREATE PATIENT', 'PAIR DEVICE', 'SELF-TEST', 'SETTINGS' (highlighted with a red box), and 'Device name' (with a dropdown arrow). To the right of the 'Device name' tab is a 'Refresh' button. Below the navigation bar is a 'Patient List' section with a search bar and a 'Sort' button. The patient list contains four entries with columns for Last Name, First Name, Date of Birth, SEX, MRN, and Last SOZO Assessment.

Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12

Next, tap **Update** under SOZO Device Status, and review the details on the “Settings” screen.



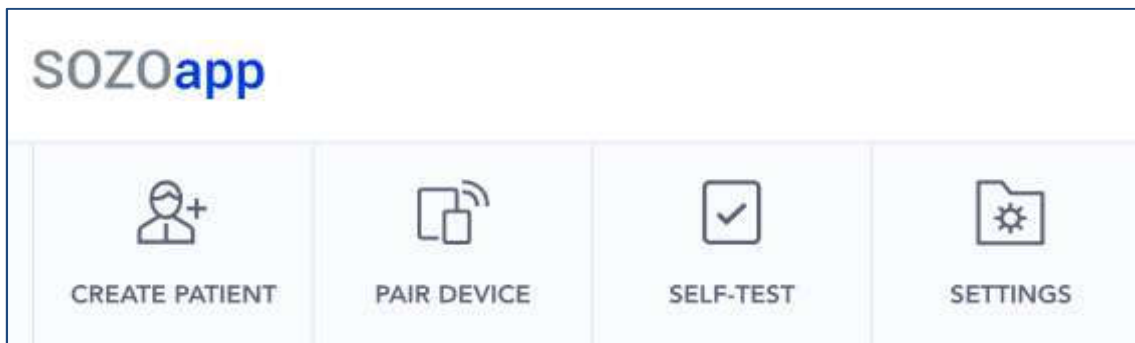
The screenshot shows the 'Settings' screen. It has sections for 'Help' (with a 'Get Help' button), 'Firmware Update' (with an 'Update' button), 'Measurements Units' (with toggle switches for kg/lbs, cm/ft in, and litres/pints, and a 'Save' button), and 'Licensing Status' (with a 'View' button). At the bottom is the 'Device Status' section, which is highlighted with a red box. It contains a list of device details and an 'Update' button.

Device Status	
Device name	SOZO-21F0717014
Firmware	100050013
Calibration date	20170612-10:30
MAC address	88-6B-0F-05-56-B0
Serial number	SOZO-21F0717014
Last self-test status	Passed

#### 8.4.1.2 Using the Self-Test to Confirm Device Status

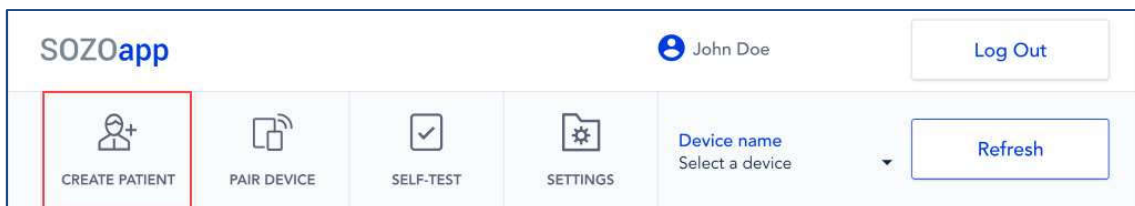
The status of the SOZO Device may also be confirmed by a self-test. To run the self-test, tap the **Self-Test** tab from the SOZOapp Main Menu. If the SOZO Device emits a clicking sound, and the Self-Test is shown as successful, the Device Status is confirmed.

## 8.5 SOZOapp Main Menu



The SOZOapp has a Main Menu, with tabs for Clinician functions.

### 8.5.1 Create Patient



The Clinician may create a new patient by tapping the **Create Patient** tab.

#### 8.5.1.1 Patient Details

On the next screen under "Create Patient" is "Patient Details." Enter the required information. An e-mail may be, but is not required to be, entered. Click the "Not Provided" box if not entering an email address. Duplicate MRN's are not permitted.

Create Patient

Create

Patient Details

First Name

Required

Middle Name

Last Name

Required

Email Address

Required

☐ Not provided

Medical Record Number (MRN)

Required

Country Code

Australia (+61)

✓ United States (+1)

PI

Afghanistan (+93)

Albania (+355)

Algeria (+213)

Andorra (+376)

Angola (+244)

Argentina (+54)

City

State



Do not allow patients to edit patient details. Patients may not create or edit their own patient profiles. The Clinician has the sole authority to create and edit patient profile information.

### 8.5.1.2 Assessment Type

Scroll down the “Create Patient” page for a list of types of Assessments which apply to the patient.

Assessment Type

☐ L-Dex Analysis for Lymphoedema

☐ Fluid Analysis for General Fluid Status Monitoring

☐ Tissue Analysis for Body Composition

Lymphoedema Settings

Assessment

☐ Unilateral

☐ Bilateral

Body Element

☐ Arm

☐ Leg

Risk Limb

☐ Left

☐ Right

Limb Dominance

☐ Left

☐ Right

Create Patient

### 8.5.1.3 Lymphoedema Settings

For patients at risk of lymphoedema, scroll down to “Lymphoedema Settings” and enter the Assessment type (unilateral or bilateral), body element (arm or leg), risk limb (left or right) and dominant limb (left or right).

**Assessment Type**

☐ L-Dex Analysis for Lymphoedema

☐ Fluid Analysis for General Fluid Status Monitoring

☐ Tissue Analysis for Body Composition

**Lymphoedema Settings**

Assessment	<input type="radio"/> Unilateral	<input type="radio"/> Bilateral
Body Element	<input type="radio"/> Arm	<input type="radio"/> Leg
Risk Limb	<input type="radio"/> Left	<input type="radio"/> Right
Limb Dominance	<input type="radio"/> Left	<input type="radio"/> Right

When patient details are complete, tap **Create** on upper right.

**Create Patient** Create

**Patient Details**

First Name Required Country Code

### 8.5.2 Delete Patient

A patient may only be deleted by the Clinician from MySOZO. See MySOZO [Section 6.4.4.3 Delete Patient](#).

### 8.5.3 Restore Patient

The Clinician may restore a deleted patient by tapping the **Settings** tab.

**SOZOapp** John Doe Log Out

CREATE PATIENT PAIR DEVICE SELF-TEST SETTINGS Device name Select a device Refresh

On the “Settings” page, scroll down and tap **Restore Patient**.

Time Zone

UTC(-8:00) Pacific Time

Restore Patient

Restore deleted patient

Restore Patient

From the “Deleted Patients List,” select the patient to restore.

Restore Patients					
Deleted Patients List					
				Search Patient...	Sort
Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12
Michael	Smith	12 Feb 1956	M	252819882877	27 Feb 2017 10:35
Simpson	Andrew	27 Jan 1957	M	387763899938	12 Jun 2017 12:50

On the Caution pop-up, tap **Restore Patient**.

Restore Patients

Deleted Patients List

Search Patient...

Sort

Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	28 Jun 1966	F	575839387739	28 Jun 2017 15:35
Black	Jessica	20 Mar 1965	F	363789289028	13 Jan 2017 17:45
Jackson	Susan	16 Dec 1980	F	262739882789	19 Feb 2017 14:22
Margot	George	17 Jun 1977	M	262727772882	22 Mar 2017 12:12
Michael	Smith	12 Feb 1956	M	252819882877	27 Feb 2017 10:35
Simpson	Andrew	27 Jan 1957	M	387763899938	12 Jun 2017 12:50

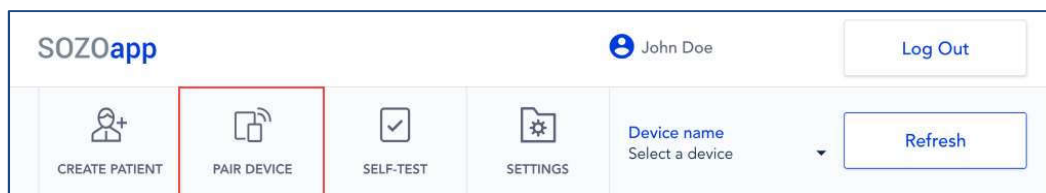
Caution

Are you sure you want to Restore the selected patient?

Cancel

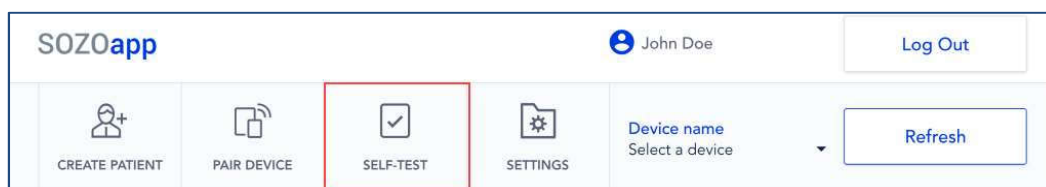
Restore Patient

## 8.5.4 Pairing SOZO Device



The **Pairing Device** tab on the SOZOapp Main Menu is a shortcut to pairing the SOZO Device with the Tablet, usually during initial set-up. To review the steps for pairing, go to [Section 8.2.1 Pairing the Tablet with the SOZO Device](#).

## 8.5.5 Self-Test



Self-tests may be run for different purposes. Run a self-test by tapping **Self-Test** tab.

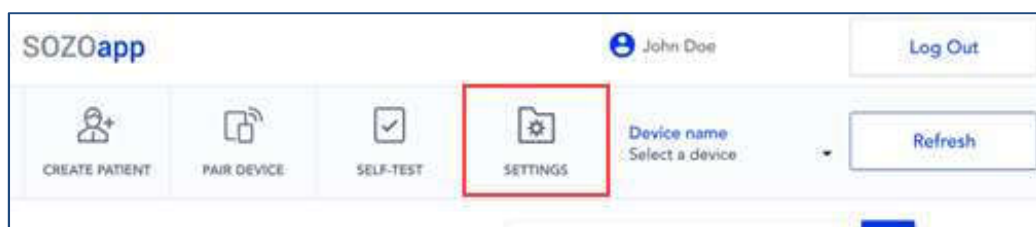
### 8.5.5.1 Optional for Device Status Confirmation

A Self-test is optional to confirm connection to the correct SOZO Device during initial set-up, per [Section 8.4.1.2 Using the Self-Test to Confirm Device Status](#).

### 8.5.5.2 Mandatory Step Before Taking Measurements

A self-test is mandatory preparation for taking measurements. It should be run daily before taking the first measurement of the day. See [Section 8.6.2.1 Self-Test](#).

## 8.5.5 Adjusting SOZO System-Wide Settings from the SOZOapp



The Clinician may change some system-wide SOZO settings in the SOZOapp.

To access Settings, tap **Settings** tab on the SOZOapp Main Menu. The Settings screen appears.

The screenshot shows a 'Settings' application window. It contains several sections: 'Help' with a 'Get Help' button; 'Firmware Update' with an 'Update' button; 'Measurements Units' with three toggle switches for 'kg' (on), 'lbs' (off), 'cm' (on), 'ft in' (off), and 'litres' (on), 'pints' (off), and a 'Save' button; 'Licencing Status' with a 'View' button; and 'Device Status' which lists device information and has an 'Update' button.

Device Status	
Device name	SOZO-21F0717014
Firmware	100050013
Calibration date	20170612-10:30
MAC address	88:68:0F:05:56:80
Serial number	SOZO-21F0717014
Last self-test status	Passed

Under “Settings,” the User has access to configuration and maintenance functions, including help, licencing status, device status, application version, time zone and restore patient, per [Section 8.5.3 Restore](#) .

#### 8.5.5.1 Adjusting Units of Measure

Under **Settings**, the measurement standard for weight, height and water volume may be converted to the preferable standard of the User. Kilograms may be converted to pounds, centimetres to inches and litres to pints. When done, tap **Save**.

This screenshot is identical to the one above, but the 'Save' button in the 'Measurements Units' section is highlighted with a red rectangular border to indicate the action to be taken after changing the units.

#### 8.5.5.2 Firmware Update

The SOZO Device software, or “firmware,” may be updated by tapping **Update** next to “Firmware Update.”



Settings

Help

Get Help

Firmware Update

Update

Measurements Units

kg

lbs

cm

ft in

litres

pints

Save

Licencing Status

View

Device Status

Device name

SOZO-21F0717014

Firmware

100050013

Calibration date

20170612-10:30

MAC address

88:68:0F:05:56:B0

Serial number

SOZO-21F0717014

Last self-test status

Passed

Update

### 8.5.5.2 Licencing Status

By tapping the **View** button, the Clinician may view, but not change, the Clinic's licencing status for various Assessments offered to ImpediMed customers.

Settings

Help

Get Help

Firmware Update

Update

Measurements Units

kg

lbs

cm

ft in

litres

pints

Save

Licencing Status

View

Device Status

Device name

SOZO-21F0717014

Firmware

100050013

Calibration date

20170612-10:30

MAC address

88:68:0F:05:56:B0

Serial number

SOZO-21F0717014

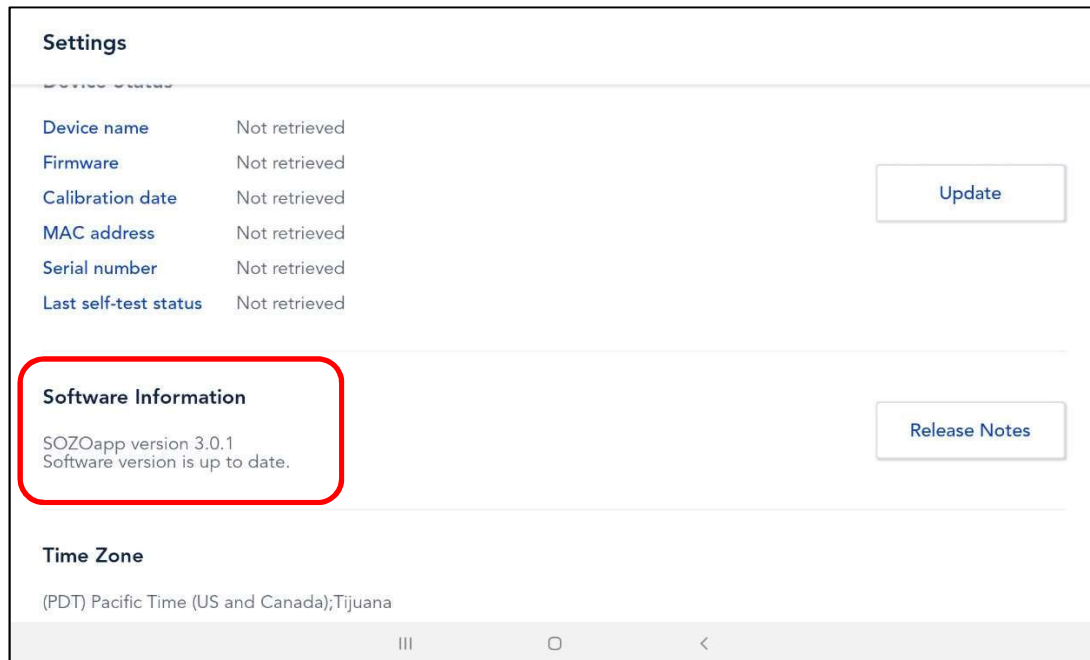
Last self-test status

Passed

Update

### 8.5.5.3 Check SOZOapp Software Version

The User will be notified at log in if a newer SOZOapp version is available. The User may confirm their SOZOapp version under “Software Information” on the Settings screen. The application version may be different than the pictured here. In addition, the user may wish to see major changes in this and the past couple of previous releases by selecting “Release Notes”.



The SOZOapp will always be the most compatible version with the SOZO system. If the SOZOapp version is not the most current version, it will be automatically updated.

## 8.6 Taking Measurements

The SOZO Device supports various types of measurements for each Assessment, such as measurements for the detection of lymphoedema, for monitoring of fluid, and for different body composition outputs. Each of the Assessments, along with indication-specific information and reports are discussed in greater detail below and in Sections 9.3.1 L-Dex® for Lymphoedema, 9.3.2 Fluid Analysis and 9.3.3 Tissue Analysis.

### 8.6.1 Select Patient from Patient List


Select the patient to be measured from the “Patient List” home screen. See **8.3.2 Conducting Patient Search**. To return to Patient List at any time, tap **Patient List** on the upper right.


### 8.6.2 Patient Dashboard


The Patient Dashboard allows navigation through the primary functions of the Clinician.


Patient Dashboard


Patient List


  
MEASURE


  
HISTORY


  
RESULTS


  
EDIT PROFILE


  
SELF-TEST

Patient Details

Last Name

Marchant

First Name

Lindsey

Date of Birth

9 Apr 1952

Sex

M

MRN

12345A

Last SOZO Assessment

14 Apr 2019 18:04

Assessment Type

✓ L-Dex Analysis for Lymphoedema


✓ Fluid Analysis for General Fluid Status Monitoring


✓ Tissue Analysis for Body Composition


### 8.6.2.1 Self-Test


Patient Dashboard


Patient List


  
MEASURE


  
HISTORY


  
RESULTS


  
EDIT PROFILE


  
SELF-TEST

To ensure measurement accuracy, the Clinician must run a self-test before beginning any measurements. Tap **Self-Test** tab on the Patient Dashboard, review the self-test instructions and tap **Begin Self-Test**.

Self-Test

Self-Test Instructions

Note:

To ensure consistently accurate readings, we recommend performing a self-test at the start of each day of use to confirm the device is functioning properly.

To perform a self-test, ensure that there is nothing in contact with the electrodes on both SOZOTouch and SOZOstep. A self-test cannot be performed while standing on SOZOstep.

Begin Self-Test

### 8.6.2.2 Preparing to Take Measurements

Patient Dashboard

Patient List

MEASURE

HISTORY

RESULTS

EDIT PROFILE

SELF-TEST

The Clinician must follow the below steps before starting a measurement. Tap **Measure** tab on the Patient Dashboard.



To ensure patient privacy, do not permit the patient to handle the Tablet while taking SOZO measurements.

### 8.6.2.2.1 Patient Compliance with Pre-Measurement Instructions

After tapping the **Measure** tab, measurement instructions appear. To optimize measurement quality, ensure patient compliance with these instructions. When done, click **Next**.

**Before You Start**  
  
To optimize the quality of the measurement:

- Remove all metal jewelry if possible, including large belt buckles. Items above the neck such as earrings are ok
- Remove any electronics, coins, keys or other metal objects from pockets
- Remove shoes and socks or stockings
- Ensure feet and hands are clean by wiping with a damp cloth
- Remain still during the measurement with elbows away from the body

  
Additional tips to ensure consistent Tissue and/or Fluid Analysis measurements:

- Ensure an empty bladder prior to measurement
- Avoid exercise for 4 hours prior to measurement
- Avoid caffeine for 2 hours prior to measurement
- Avoid alcohol for 8 hours prior to measurement
- Avoid meals for 8 hours prior to measurement

Next

### 8.6.2.2.2 Entering Weight

The Clinician enters the patient's current weight prior to each measurement session.



Accurate weight entry is critical to tissue and fluid analysis. The patient should be weighed immediately prior to the SOZO measurement.

**Enter Weight**  
  
Weight (kg)  
  
  

Tutorial

Start Measurement

### 8.6.2.2.3 Tutorial on Foot and Hand Placement

The Tutorial presents illustrations of correct foot and hand placement onto the electrodes.

#### 8.6.2.2.3.1 Foot Placement

Confirm that the SOZOstep is stationary and on a level surface. Place feet (no stockings/pantyhose or socks) onto SOZOstep and locate heel recesses. Ensure that each foot is flat and in full contact with each electrode plate.



There are two electrode plates for the left foot, and two electrode plates for the right foot.



#### 8.6.2.2.3.2 Hand Placement

Confirm that SOZOtouch is stationary and on a level surface. Place both hands onto SOZOtouch with thumbs securely wrapped around corners of each recess. Make sure each hand is flat and in full contact with each electrode plate.



There are two electrode plates for the left hand, and two electrode plates for the right hand.

## 2. Place Hands Onto SOZOtouch



Next



Surface temperature should not exceed 47° C (117° F) during normal use. Do not use SOZO Device if it is hot to the touch. Disconnect the SOZO Device by unplugging the Power Adaptor and call ImpediMed Technical Support.



Read Intended Use and Precautions before taking measurements with the SOZO Device.

### 8.6.2.3 Start Measurement

If familiar with patient foot and hand placement, skip the Tutorial and tap ***Start Measurement***

Enter Weight

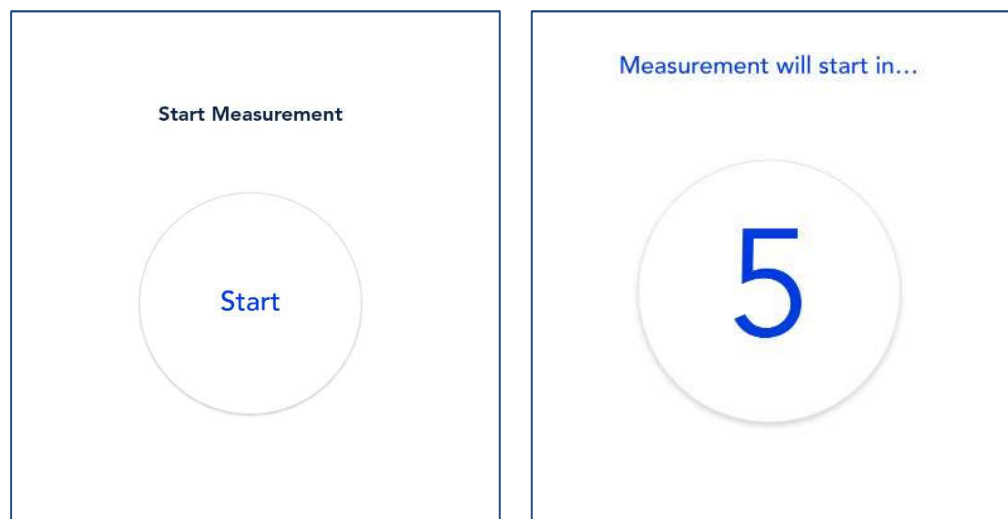
Weight (kg)

110

Tutorial

Start Measurement

This triggers a five-second countdown before the start of the measurement.

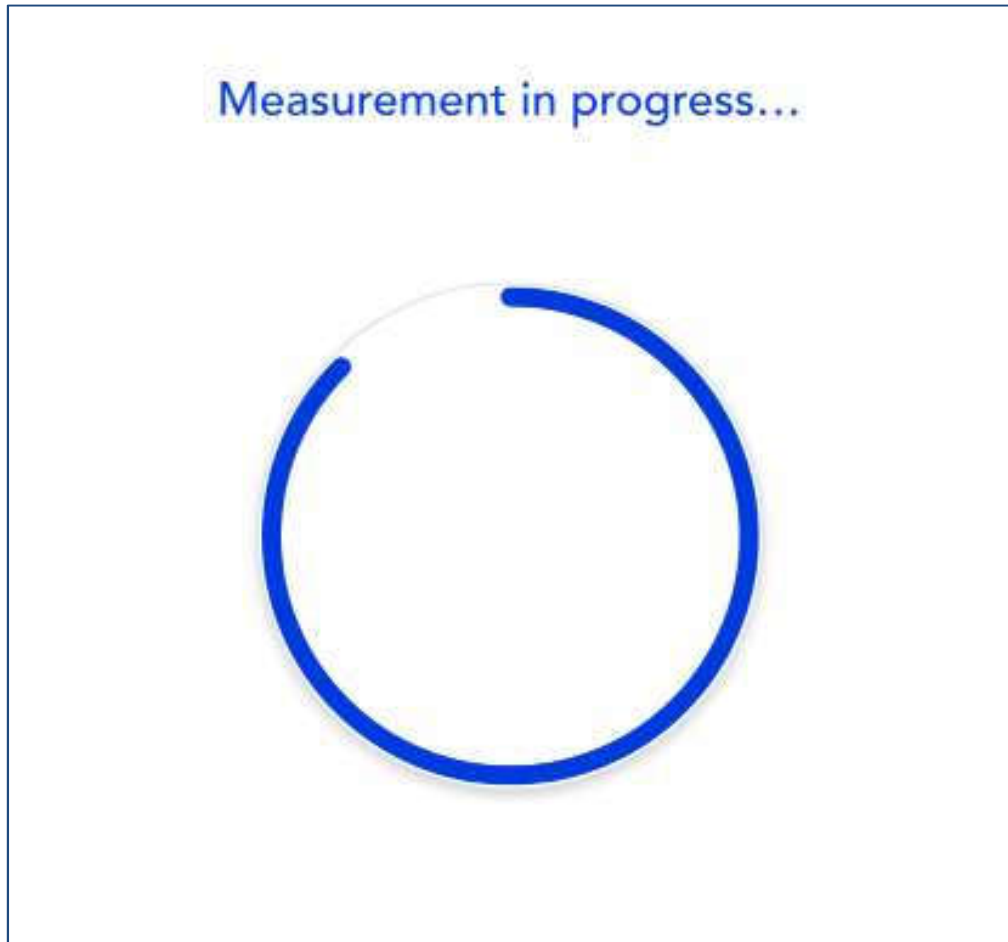


The patient's hands and feet must be firmly placed and held stationary against the electrodes throughout the entire measurement process. The measurement will cancel if no contact is detected.

#### 8.6.2.3.1 Measurement Duration

Once started, the SOZO Device measurement will take approximately 20 seconds. The measurement in progress window remains until the measurement is complete.





The SOZO Device makes audible clicking noises during measurement. These clicking noises indicate that the process is working correctly.

#### **8.6.2.3.2 Losing Connectivity During Measurement**

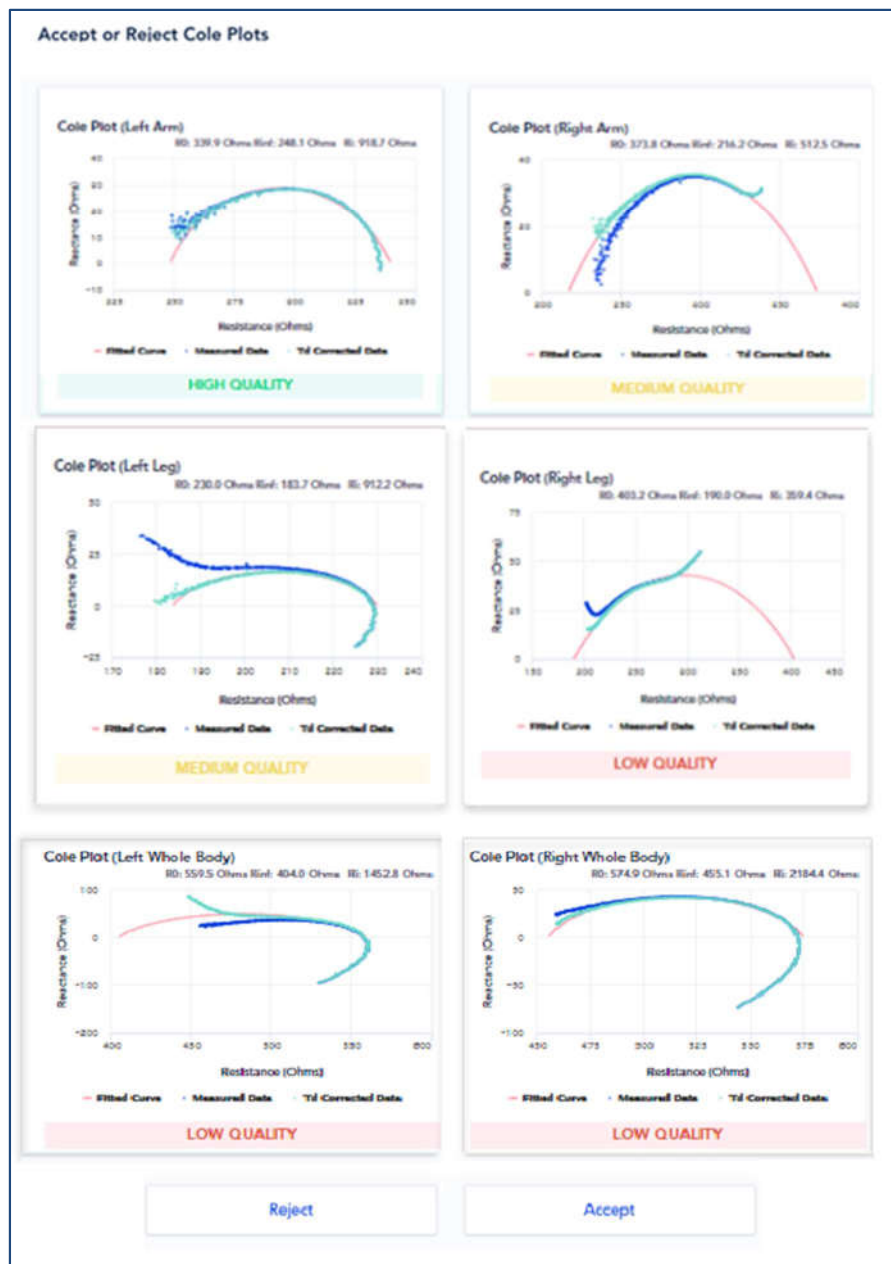
If you lose connectivity while the Measurement is in progress, follow troubleshooting tips in Troubleshooting [Section 10.1.4 Losing Connectivity During Measurement](#).

### 8.6.2.4 Reviewing Cole Plots After Measurement

After the measurement process is complete, the system calculates and assesses the Cole plots. If all 6 Cole plots are assessed as high quality, the Cole plots will be automatically accepted. If any of the 6 Cole plots are assessed as medium or low quality, the next step is to view the Cole plots results, in order to evaluate the validity of the measurements.

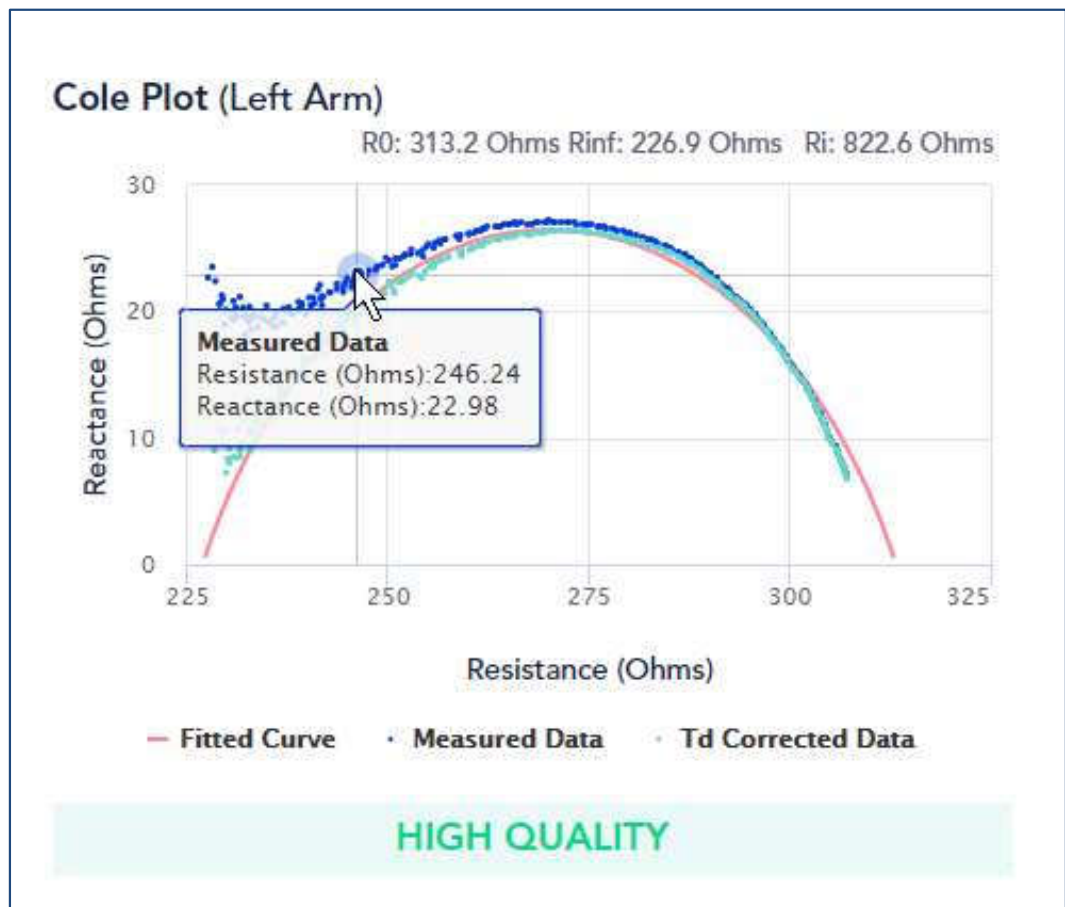
#### 8.6.2.4.1 Considering Cole Plots in Deciding to Accept or Reject Measurements

The SOZO software helps determine the quality of measurements by ranking each Cole plot as “High Quality” (green), “Medium Quality” (yellow) or “Low Quality” (red), as shown below.



#### 8.6.2.4.2 Interpreting Cole Plots

On a Cole plot, the dark blue dots are the raw “Measured Data,” and the light blue dots are “Td Corrected Data,” representing the raw measured data after error correction has been applied. The solid red semi-circle or “Fitted Curve” represents the final curve to which the Td corrected data was fitted. Some degree of “scatter” of Measured Data is acceptable. If Td Corrected Data is consistent with the red Fitted Curve, as shown below, the Cole plot is “High Quality.”



If, on the other hand, Measured Data is extremely scattered or does not form a semi-circle, the Cole plot may be medium quality or low quality. During the brief measurement period some measurement errors may occur if, for example, the patient shifts their hands or feet. Other errors, such as a sharp curve upwards on the right side of the curve may be due to cold, dry, or scaly skin impeding the current at low frequencies. This can usually be improved by cleaning the hands and feet with warm water. A large amount of scattered data may be due to interference from a nearby mobile phone or other piece of operating electrical equipment.

Determination of the quality of a given measurement can only be made at the time of measurement, but Cole plots are also shown when reviewing historical results.

#### 8.6.2.4.3 The Decision to Accept or Reject Measurements

If all the Cole plots are high quality, the measurements are automatically accepted. If, however, one or more of the Cole plots are medium quality or low quality, **Accept** and **Reject** buttons appear at the bottom of the Cole Plots screen. When this occurs, the Clinician must decide to accept or reject the measurements.



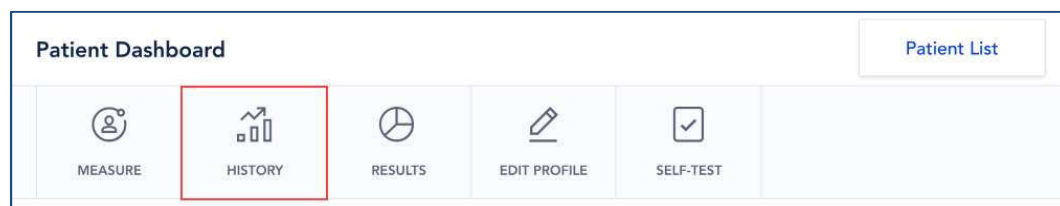
The Clinician cannot accept or reject some, but not all, Cole plots. If they tap **Accept**, all Cole plots are accepted. If **Reject** is tapped, all Cole plots are rejected.

The Clinician does not have to reject the measurements if one or more Cole plots are medium quality or low quality. Instead, the Clinician may still choose to accept the measurements, taking into consideration the quality of each Cole plot, and the facts and circumstances surrounding measurement of the patient.

#### 8.6.2.4.4 Accepting Measurements

Once measurements are accepted, Assessment results are displayed. Only licenced Assessments are available for viewing in the SOZOapp.

#### 8.6.2.5 History



Tap the **History** tab on the Patient Dashboard to display historical measurements of the patient. The History screen appears, displaying summaries of the patient's measurements over time. Tap each Assessment to see historical measurements.

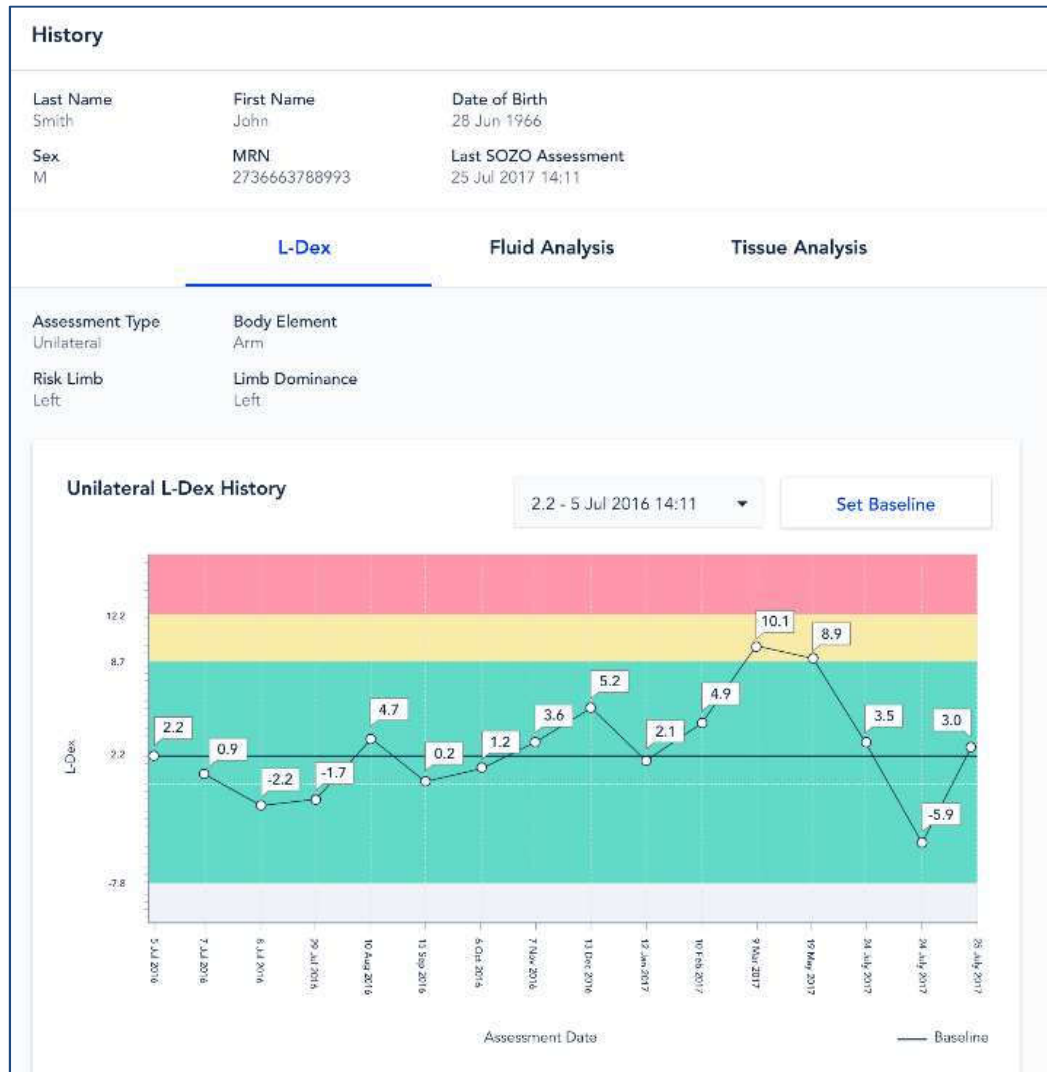


Only historical measurements for licenced Assessments will appear under History. Therefore, the Clinician will only be able to view licenced Assessments.

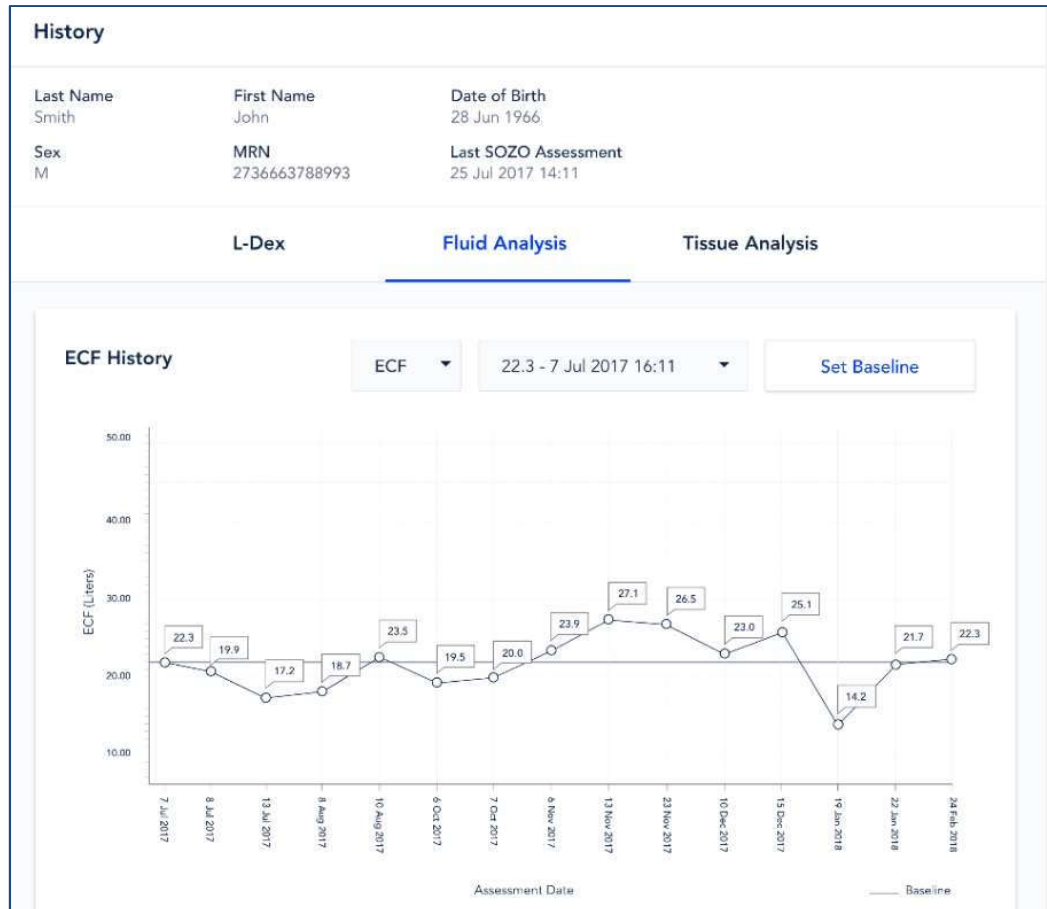
### 8.6.2.5.1 Examples of Historical Measurements

Below are examples of historical measurements for L-Dex, Fluid Analysis and Tissue Analysis.

#### 8.6.2.5.1.1 Example of L-Dex History in SOZOapp



### 8.6.2.5.1.2 Example of Fluid Analysis History in SOZOapp



### 8.6.2.5.1.3 Example of Tissue Analysis History in SOZOapp



### 8.6.2.5.2 Setting a Baseline

The Clinician may, but is not required to, set a baseline for each Assessment.

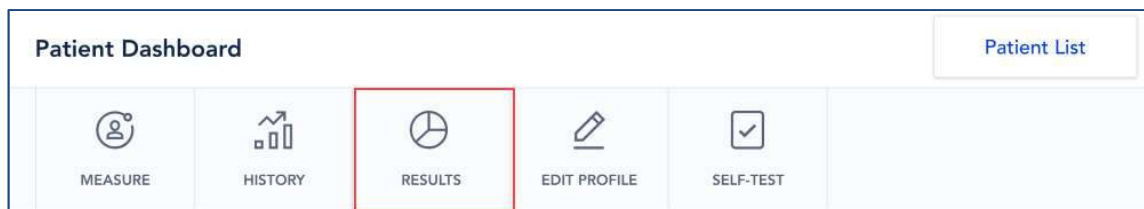


If the Clinician chooses not to set a baseline, the field next to “Set Baseline” may be left blank.

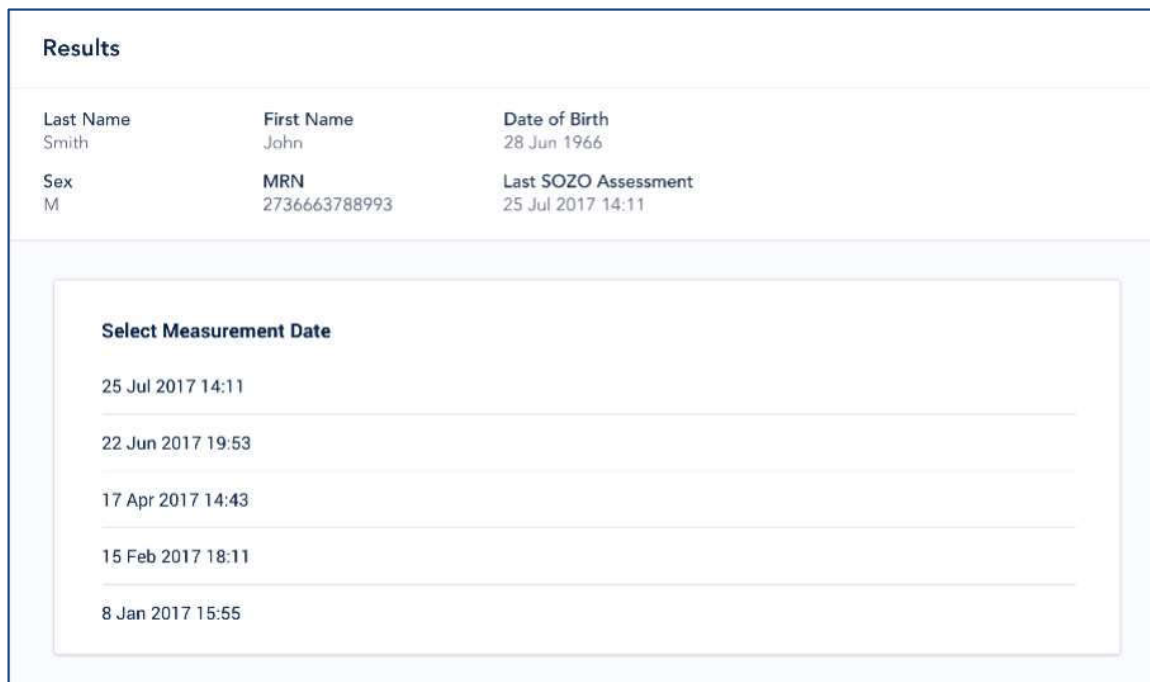
A baseline is a measured value which, in the best clinical judgment of the Clinician, represents the patient’s “normal state.” A baseline is useful for tracking changes over time. For instructions on how to set a baseline, see MySOZO [Section](#)

[6.4.5.2.1 Setting](#) a Baseline. For more information on how a baseline is relevant to each Assessment, see Sections [9.3.1 L-Dex® for Lymphoedema](#), [9.3.2 Fluid Analysis](#) and [9.3.3 Tissue Analysis](#).

### 8.6.2.6 Results



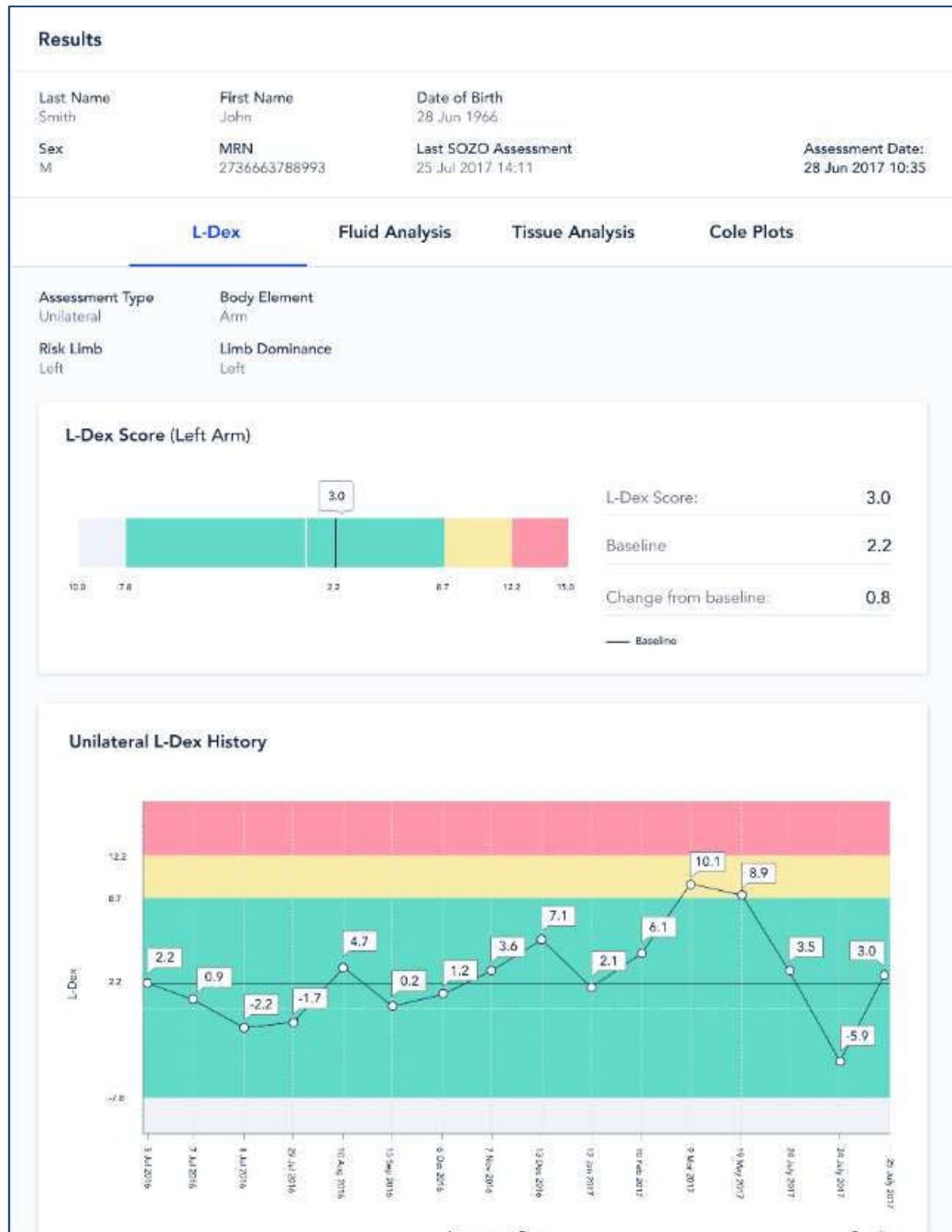
Tap **Results** tab on the Patient Dashboard. The Results screen will display a list of measurement dates.



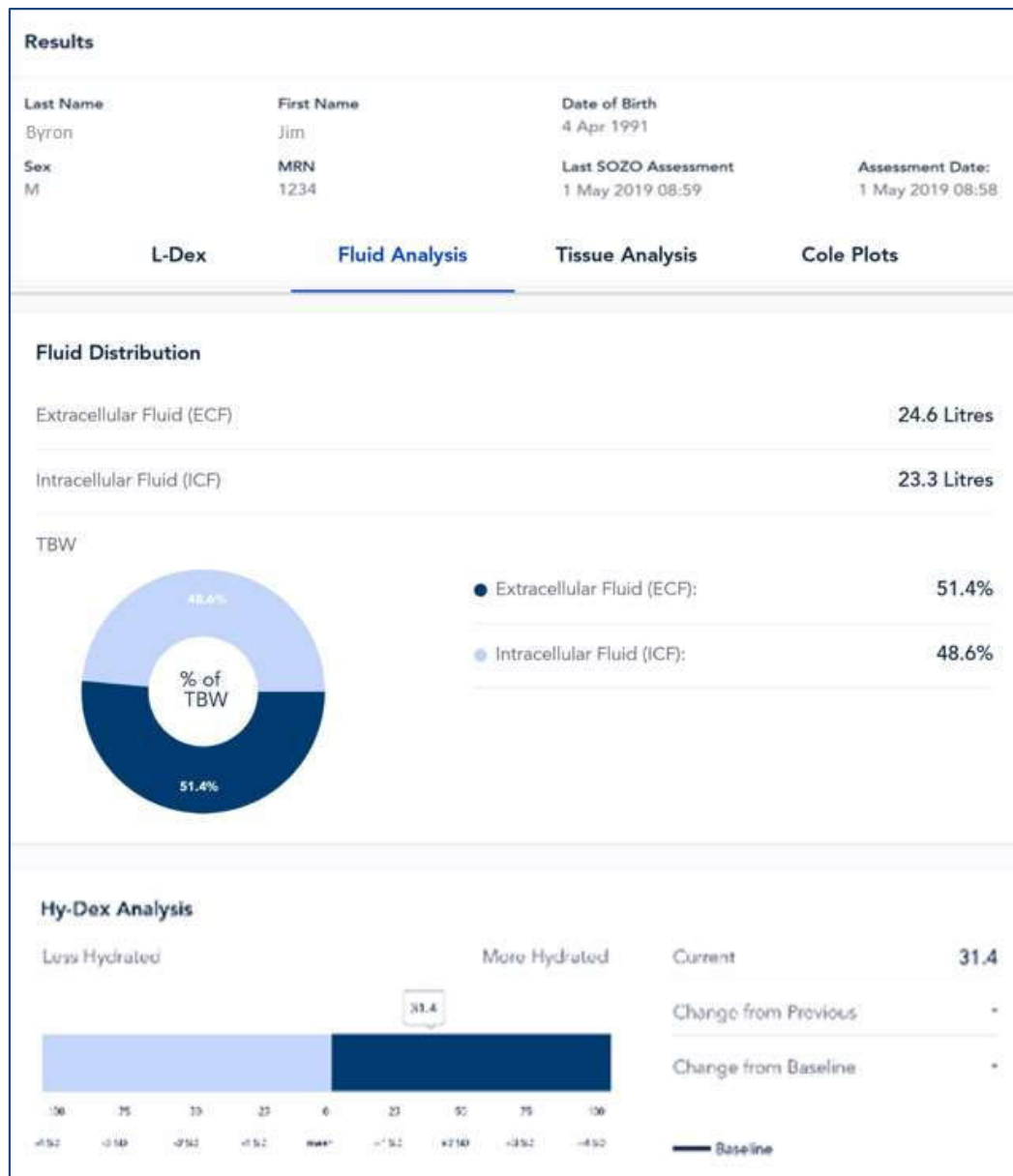
Select a measurement date. A results screen appears with measurement data for that date. For an L-Dex Assessment, this is accompanied by historical trends for the patient. The results page has graphs on selected Assessment types and Cole plots. Examples are shown below.



### 8.6.2.6.1 Example of L-Dex Results in SOZOapp



### 8.6.2.6.2 Example of Fluid Analysis Results in SOZOapp



### 8.6.2.6.3 Example of Tissue Analysis Results in SOZOapp

Last Name <b>Reynolds</b>	First Name <b>Lexa</b>	Date of Birth 4 Apr 1991	Assessment Date 1 May 2019 08:58
Sex Male	MRN 1234	Last SOZO Assessment 1 May 2019 08:59	

**Results**

---

L-Dex
Fluid Analysis
Tissue Analysis
Cole Plots

---

**Tissue Analysis**

Fat Free Mass (FFM)	63.9 kg	91.3% of Weight
Fat Mass (FM)	6.1 kg	8.7% of Weight
Skeletal Muscle Mass (SMM)	35.7 kg	51.0% of Weight

Weight:



- Total Body Water (TBW): 46.7 litres
- Protein & Minerals: 17.2 kg
- Fat Mass: 6.1 kg

---

**Metabolic Report**

Basal Metabolic Rate (BMR)	1615.0 cal/day
Active Tissue Mass (ATM)	34.5 kg
Extracellular Mass (ECM)	29.4 kg

Weight:



- Fat Mass: 8.7%
- Active Tissue Mass (ATM): 49.3%
- Extracellular Mass (ECM): 42.0%

Note: ATM+ECM=FFM

---

**Other**

Phase Angle	6.8°
Body Mass Index (BMI)	24.8 kg/m <sup>2</sup>
Weight	70.0 kg

### 8.6.2.6.4 Example of Cole Plots in SOZOapp



For more about the significance and interpretation of Cole plots, [see Section 8.6.2.4 Reviewing Cole Plots After Measurement](#). Patient historical measurements and results may also be viewed in MySOZO. See: [MySOZO Sections 6.4.5.3 Measurement Results Viewable by Clinician in MySOZO](#); and [Section 6.4.5.2 Measurement History](#).

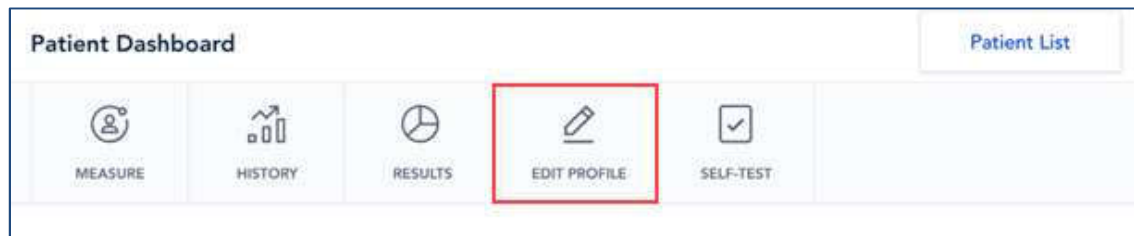
#### 8.6.2.6.5 Impact of Licencing Additional Assessments on Results

When the SOZO Device takes measurements, it collects and stores bioimpedance data categorized by date and time. These are independent of the type of Assessment. If the Clinic decides to purchase additional Assessment licences, the new Assessments may be added to a patient's history. After a new Assessment is licenced, the Clinician may add the newly licenced Assessment types to the patient profile, taking into consideration their intended use. Historical results will be recalculated based on previously collected Measurement data and shown in the applicable history and measurement screens.

#### 8.6.2.6.6 Impact of Cancellation of Assessment Licence on Results

If a Clinic cancels an Assessment licence, the Clinic will no longer be able to take new measurements for that Assessment, and the Clinic will no longer be able to view any previous measurement data for that Assessment type.

#### 8.6.2.7 Edit Patient Profile



To edit a patient profile, tap **Edit Profile** tab on the Patient Dashboard. This displays patient personal data, Assessment types and Lymphoedema settings. All licenced Assessments are available for viewing in the SOZOapp and MySOZO.

Once all changes are made to the patient profile, tap **Save** on upper right.

Profile

Save

Patient Details

First Name

Required

Tray

Middle Name

Last Name

Required

Edenton

Email Address

Required

☒ Not Provided

Medical Record Number (MRN)

Required

Hub1

Date of Birth

Required

7 Jun 1966

Sex

Required

Female

Height (cm)

Required

165

Country Code

Phone Number

Address

City

State

Country

Postal Code

Assessment Type

☒ L-Dex Analysis for Lymphoedema

☒ Fluid Analysis for General Fluid Status Monitoring

☒ Tissue Analysis for Body Composition

Lymphoedema Settings

Assessment

☒ Unilateral

☐ Bilateral

Body Element

☒ Arm

☐ Leg

Risk Limb

☒ Left

☐ Right

Limb Dominance

☐ Left

☒ Right

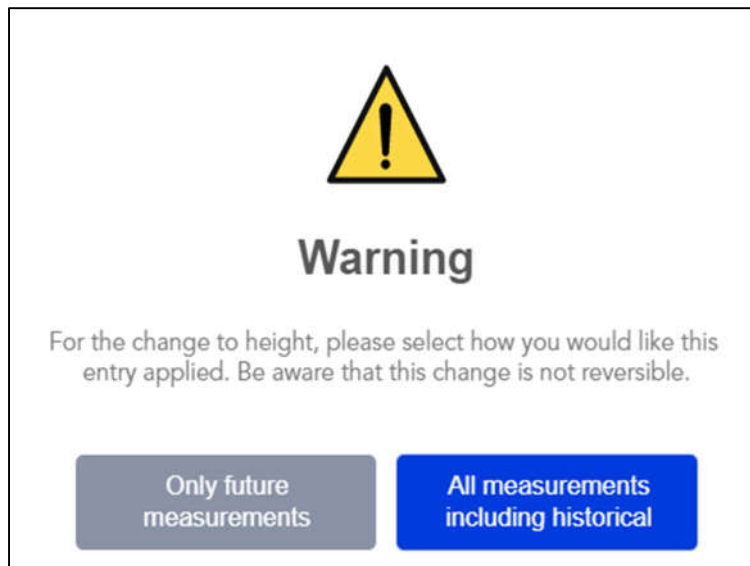
If an email address is not provided, leave the email field blank and tap the “Not Provided” box.

#### 8.6.2.7.1 Select Assessments Appropriate for Each Individual Patient

It is recommended that only the most appropriate and relevant Assessments are selected, taking into consideration the patient diagnosis and the patient's individual needs as determined by their health care provider.

#### 8.6.2.7.2 Warning After Editing Patient's Height on Patient Profile

The below Warning appears after changing the patient's height on their profile.



##### 8.6.2.7.2.1 When to Select “Only future measurements”

In the Warning pop-up, tap **Only Future Measurements** to maintain old Assessments according to previous measurements. This is appropriate for patients whose height have changed due to age or other factors.

##### 8.6.2.7.2.2 When to Select “All measurements including historical”

Tap **All measurements including historical** to recalculate all prior Assessments according to the new height. This is appropriate when patient height has been entered incorrectly and measurements have already been taken. Previous This change is not reversible and if this option is selected, the height cannot be restored back to the height that was entered at the time of measurement.

#### 8.6.2.7.3 Availability of Assessment Specific Data on Patient Profile

L-Dex data (at-risk limb, dominant limb) is shown in the patient profile when the L-Dex Assessment is selected. Please note that deselecting the L-Dex Assessment will grey out the patient L-Dex settings, which will not be saved.

# 9.0 Assessments

## 9.1 Introduction to Assessments

The SOZO Device supports the following types of Assessments:

- 1) L-Dex;
- 2) Fluid Monitoring & Analysis; and
- 3) Tissue Analysis

Depending on licencing, all Assessments and measurements may or may not be available or in MySOZO and the SOZOapp.

Also, some Assessment types may not be available in certain geographic regions. Contact ImpediMed sales or technical support with any inquiries, per [Section 12.5 Technical Support](#). Each Assessment has its own instructions for use providing information on how to use the Assessment and outputs, and Assessment-specific precautions, warnings, and contraindications.

## 9.2 Choosing the Proper Assessments for the Patient

It is recommended that only the most appropriate and relevant Assessment is selected for each patient, taking into consideration the patient's diagnosis and the individual needs of the patient as determined by their health care provider. On deciding which Assessments to select for each patient, take into consideration that:

- L-Dex® aids the Clinician in the assessment of lymphoedema in a patient;
- Fluid Analysis provides fluid monitoring capabilities to support the evaluation of certain clinical conditions including management of heart failure; and
- Tissue Analysis aids in body composition analysis of an individual.

## 9.3 Assessment Specific Instructions for Use

Below are instructions for use, indications for use and guidance for use of each specific type of Assessment.

### 9.3.1 L-Dex® for Lymphoedema

#### 9.3.1.1 Indications for Use

When using the L-Dex Assessment for lymphoedema, the following indications for use apply:



Bioimpedance Spectroscopy is for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular volume differences between the limbs, and is presented to the Clinician on an L-Dex scale as an aid to their clinical assessment of lymphoedema.

The L-Dex Assessment is only indicated for patients who will have, or who have had, lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated.

### 9.3.1.2 Instructions for Use

Ensure that you have read and understand the instructions for use in all sections of this User Guide for setup, installation and use of the SOZOapp, and also ensure that you have read and understand the instructions for use for setup, installation and use of MySOZO and the SOZOapp in all sections of this User Guide. All warnings, contraindications and precautions apply. In addition, consider the following when using the SOZO Device to take L-Dex measurements on a patient:

For a patient who cannot effectively separate their inner thighs, it may be necessary to place insulating material, such as dry clothes, between the patient's legs. Ensure also that the patient's upper arms and elbows are not in contact with their torso.

Prior to taking a measurement, the patient's profile in the SOZOapp must be updated to indicate:

- Unilateral vs. bilateral: whether one arm or one leg is at risk (unilateral), or if both arms or both legs are at risk of lymphoedema (bilateral);
- Body element: whether the arm(s) or leg(s) are at risk of lymphoedema;
- Risk limb: whether the right or left limb is at risk of lymphoedema; and
- Limb dominance: whether the left arm/right arm or left leg/right leg is dominant.



Ensure that you update the patient profile correctly to fit each patient's needs, taking into consideration the relevant facts and circumstances related to measurement, as identified in this User Guide, since this will affect the validity of measurements. Incorrect measurements may impact the accuracy of the L-Dex calculations and may affect the L-Dex assessment based upon L-Dex calculations. For more information about making the correct selections, see instructions for use of the SOZOapp in [Section 8.0 Using the SOZOapp](#), and in [Section 6.0 MySOZO](#).

### 9.3.1.3 The Lymphoedema Index (L-Dex)

The SOZO system displays L-Dex Assessment results based upon patient measurements taken with the SOZO Device. The L-Dex Assessment produces an L-Dex score, which is based on the ratio of the impedance of the unaffected limb(s) to impedance of the at-risk limb(s). Research has established a normal range of L-Dex scores in healthy patients. Normal L-Dex score ranges are presented in the L-Dex assessment results to assist with patient evaluation.

For patients at risk of unilateral lymphoedema in the arm or leg, one L-Dex score will be presented for the at-risk limb. For patients at risk of bilateral lymphoedema, two L-Dex scores will be presented, one for each at-risk limb.

The underlying calculations for unilateral assessments using the SOZO system have not changed from any previous L-Dex devices. The impedance of the extracellular fluid space (R0) of the unaffected limb is compared with the contralateral affected limb. Clinical data has shown this to have “excellent” accuracy when used as a clinical aid to assess unilateral fluid accumulation in the limb following cancer treatment.<sup>3</sup>



When transitioning from L-Dex devices used in a supine position to use of the SOZO system in a sitting or standing position, there may be a one-time shift in L-Dex scores. The shift has been shown to not be significant.

For assessment of patients at risk of bilateral lymphoedema, where fluid accumulation occurs in both arms, or in both legs, simultaneously, the comparison of contralateral limbs is not an option. SOZO uses the R0 impedance of the unaffected ipsilateral limb, instead of the unaffected contralateral limb, for bilateral assessments of fluid increases. Clinical data also has shown that arm R0, when compared to leg R0 for the assessment of fluid accumulation, has “very good” accuracy.<sup>1</sup> For definitions of key terms see [Section 2.0 Glossary](#), and for more discussion of measurement of patients at risk of bilateral lymphoedema, see instructions for use in this User Guide.



If a unilateral patient is subsequently considered to be at risk for bilateral lymphoedema and their profile has been updated, the L-Dex scores for the previously measured limb will be recalculated using this bilateral approach. This may result in a shift in previous L-Dex scores.

For a more on viewing L-Dex Assessment results in the SOZOapp, see [Section 8.6.2.6 Results](#) and for viewing in MySOZO, see [Section 6.4.5.3 Measurement Results Viewable by Clinician in MySOZO](#).

### 9.3.1.4 L-Dex Assessment Results

#### 9.3.1.4.1 L-Dex Scores

The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider. The SOZO system displays the current L-Dex score using the L-Dex scale. The L-Dex scale shows the patient's L-Dex score as either inside or outside of the normal range of L-Dex score for a healthy person.

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<sup>3</sup> SOZO's L-Dex® accuracy was determined using Receiver Operating Characteristic (ROC) curve analysis. Area under the curve (AUC) scores are established using ROC curves which compare the true positive rate (Sensitivity) against the false positive rate (100 minus Specificity) for different cut-off points of a parameter. Each point on the ROC curve represents a sensitivity/specificity pair corresponding to a particular decision threshold. The area under the ROC curve (AUC) is a measure of how well a parameter can distinguish between two groups (diseased/normal). The closer the modelled AUC comes to 1, the better it is. SOZO's L-Dex® accuracy was calculated with an area under the curve (AUC) of 0.95 for unilateral assessment and 0.80 for bilateral assessment.

#### 9.3.1.4.1.1 L-Dex Scores $\leq -10$



*L-Dex scores equal to or less than -10 may be caused by procedural errors. A warning will be displayed stating that the measurement is out of range. Follow the instructions for use to ascertain the accuracy of the measurements in question.*



#### 9.3.1.4.1.2 L-Dex Scores $>10$

*L-Dex scores greater than 10 may indicate the early signs of lymphoedema*



#### 9.3.4.1.3 L-Dex Scores $\Delta \geq +6.5$

*L-Dex scores that have changed +6.5 L-Dex units from the baseline may indicate early signs of lymphoedema.*

#### 9.3.1.4.2 Viewing L-Dex Results

Results of the L-Dex Assessment may be viewed in MySOZO ([See Section 6.4.5.3.1 Example of L-Dex Results in MySOZO](#)) and the SOZOapp. [See Section 8.6.2.6.1 Example of L-Dex Results in SOZOapp.](#)

#### 9.3.1.5 Availability of L-Dex Assessment

The L-Dex Assessment results displays are only available if licenced. See [Section 3.4 Assessment Licences](#).

#### 9.3.1.7 History of Measurements and Results Trends

In addition to the results display screen, the SOZO system also provides a history of patient measurements in graph format, to allow comparison between current results and previous results. This shows increases or decreases in the L-Dex score over time. For more about the history of patient measurements, see [Section 6.4.5.2 Measurement History for measurement history in MySOZO](#), and [Section 8.6.2.5 History for the SOZOapp](#).

##### 9.3.1.7.1 Setting the Baseline

Selection of a baseline – a “normal L-Dex score” for an individual patient – is the optimal way to track changes over time. To set a baseline, navigate to the history chart in the SOZOapp, and select an appropriate baseline measurement, typically within the first few measurements taken, preferably before surgery or other intervention that could impact the lymphatic system.

When a baseline is set, the charts for normal range will reflect a -10 to +10 range around the baseline L-Dex score. If a baseline is not set, the range will centre around an L-Dex score of 0. From this comparison, changes in patient fluid levels may be identified, and evaluated as changes which fall within normal or abnormal ranges. For the L-Dex Assessment, ranges are classified by colour as below normal (grey), normal (green), and abnormal high, broken down into high (yellow) or extremely high (red).

L-Dex ranges are classified by colour as baseline plus two standard deviations and minus three standard deviations (green), plus two to three standard deviations from baseline (yellow), plus three standard deviations from baseline and higher (red), and more than three standard deviations below baseline (grey).

Because each healthy person has a different starting L-Dex score, it is recommended to use a baseline prior to cancer treatment whenever possible to customize the L-Dex scale for the individual. If a patient has already begun treatment and there is no way to determine a healthy baseline, use your clinical judgment in conjunction with other assessments to select the most appropriate baseline. If a patient has already developed lymphoedema and SOZO is being used to track their progress, do not set the baseline, as it will cause confusion with the modified red/yellow/green ranges.

For more information about setting the baseline for an L-Dex Assessment, see [Section 8.6.2.5.2 Setting a Baseline](#).

### **9.3.1.8 Recommended Measurement Frequency for L-Dex**

ImpediMed recommends the following frequency of measurements for patients at risk of unilateral lymphoedema:

Pre-operative baseline

Years 1-3: Every 3 months

Years 4-5: Every 6 months

Year 6+: Annually

## **9.3.2 Fluid Analysis**

### **9.3.2.1 Indications for Use**

The Fluid Analysis Assessment is intended for patients:

- With fluid management problems;
- Taking diuretic medication;
- Living with heart failure;
- Living with end-stage renal disease;
- Recovering from coronary artery disease related event;
- Suffering from recurrent dehydration

The Fluid Analysis Assessment is intended for use under the direction of a physician for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

### **9.3.2.2 Instructions for Use**

Ensure that you have read and understand the instructions for use in all sections of this User Guide, regarding setup, installation, patient preparation and use of the SOZOapp and MySOZO. All warnings, contraindications and precautions apply.

The SOZO system's Fluid Analysis assessment provides a measurement of fluid status. Base impedance decreases when fluid increases and increases when fluid decreases in

the body. Every person has their own baseline value. Fluid status changes should be noted and shared with professional medical clinicians when measurements vary from typical daily values.

The system measures fluid status and is an assessment tool. It is not intended to be a medical diagnostic device. This monitor is intended to be operated by technically qualified medical personnel. The physician, or designated healthcare provider, is responsible for interpreting what assessment, intervention or action is required as a result of changing base impedance values.

Note that the physician may also use the Fluid Analysis assessment to generally monitor fluid levels in healthy patients. For these patients, the assessment cannot be used to diagnose or treat any medical condition.

### **9.3.2.3 Fluid Analysis Results**

At the conclusion of a measurement session, the SOZOapp will present a screen with analysis of the fluid status of the patient, displaying the patient's:

- Total Body Water (TBW);
- Extracellular Fluid (ECF);
- Intracellular Fluid (ICF);
- TBW as a percentage of weight; and
- ECF and ICF distribution (expressed as a percentage of total body water).
- Hydration Index (Hy-Dex) Analysis

#### **9.3.2.3.1 Viewing Fluid Analysis Results**

Fluid Analysis results are viewable in MySOZO (see [Section 6.4.5.3.2 Example of Fluid Analysis Results in MySOZO](#)) and in the SOZOapp. See [Section 8.6.2.6.2 Example of Fluid Analysis Results in SOZOapp](#).

#### **9.3.2.4 Recommended Measurement Frequency for Fluid Analysis**

Measurement frequency should be based on clinical evaluation of the patient's monitoring needs. Daily, weekly or monthly measurements may be appropriate using your best clinical judgment.

### **9.3.3 Tissue Analysis**

#### **9.3.3.1 Indications for Use**

When using the Tissue Analysis Assessment for body composition measurements, the following indications for use apply:

The SOZO Device, which employs Bioimpedance Spectroscopy, is intended to estimate the following body composition parameters:

- Total Body Water (TBW), Extra cellular Fluid (ECF), Intra cellular Fluid (ICF);
- Fat-free Mass (FFM)
- Fat Mass (FM)
- Active Tissue Mass (ATM)
- Extracellular Mass (ECM)
- Basal Metabolic Rate (BMR)
- Skeletal Muscle Mass (SMM),
- Phase Angle (Phi)
- Body Mass Index (BMI)

The SOZO Device measures current, voltage and phase angle (Phi), and from these values calculates resistance (R), reactance (Xc), and impedance (Z), which are used to estimate the above body composition parameters.

Cole plots, along with patient weight, age and gender, are also displayed in the Tissue Analysis Assessment results, which may be viewed in MySOZO and the SOZOapp.

#### **9.3.3.2 Instructions for Use**

Ensure that you have read and understand the instructions for use in all sections of this User Guide. Also ensure that you have read and understand the instructions for use in this User Guide regarding setup, installation, patient preparation and use of the SOZOapp and MySOZO. All warnings, contraindications and precautions apply.

### 9.3.3.3 Tissue Analysis Results

At the conclusion of a SOZO device measurement, the SOZOapp displays results of the Tissue Analysis Assessment. The Tissue Analysis Assessment contains graphs and a wide range of body composition information in preferred units of measure.<sup>4</sup> The following parameters are displayed in the Tissue Analysis assessment:

#### Tissue Analysis

- Fat Free Mass (FFM)
- Fat Mass (FM)
- Skeletal Muscle Mass (SMM)
- Weight

#### Other

- Basal Metabolic Rate (BMR)
- Phase Angle (Phi)
- Body Mass Index (BMI)
- Weight

#### 9.3.3.3.1 Viewing Tissue Analysis Results

Tissue Analysis results are viewable in MySOZO (see [Section 6.4.5.3.3 Example of Tissue Analysis Results in MySOZO](#)) and in the SOZOapp. See [Section 8.6.2.5.1.3 Example of Tissue Analysis History in SOZOapp](#).

### 9.3.3.4 Recommended Tissue Analysis Measurement Frequency

Measurement frequency should be based on clinical evaluation of the patient's monitoring needs. Daily, weekly or monthly readings may be appropriate using your best clinical judgment.

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<sup>4</sup> The standard for measurement of weight, height and water volume may be adjusted to the user's preference for measurement standard in the SOZOapp system-wide settings. The user may set the measurement standard as kg or lbs, centimetres or inches, and litres or pints. For more about adjusting units of measure in the SOZOapp, see [Section 8.5.5.1 Adjusting Units of Measure](#).

# 10.0 Troubleshooting

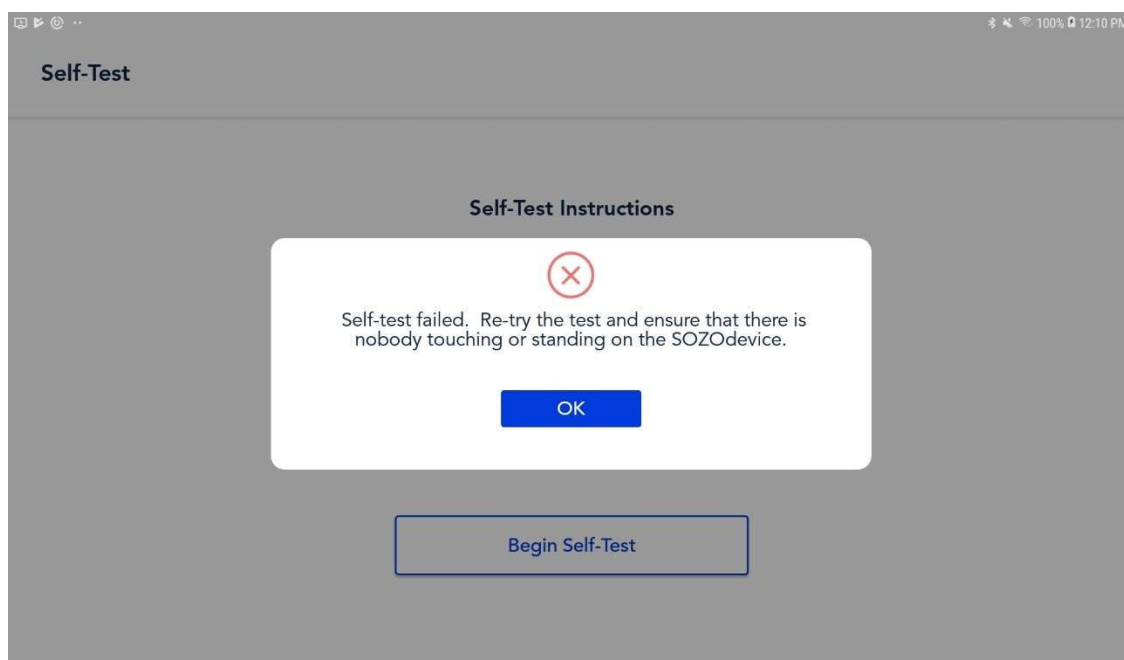
## 10.1 SOZOapp Error Messages

Below are troubleshooting tips for error messages which may appear in the SOZOapp. This is not a complete list of all possible error messages. For a detailed list of troubleshooting issues in the SOZOapp and MySOZO, see [Section 10.2 General Troubleshooting Chart](#).

### 10.1.1 Self-Test

#### 10.1.1.1 Error Message

##### ***“Self-test failed.”***



The ***“Self-test failed”*** error message may appear after running a self-test from the SOZOapp Main Menu or from the Patient Dashboard.

#### 10.1.1.2 Resolutions

Try any one of the below actions to resolve this issue:

- Ensure that nothing is touching the SOZO Device
- Reset the Bluetooth® button on the back of SOZOtouch
- Unplug the SOZO Device from the wall outlet and plug back in

### 10.1.2 Patient Profile

#### 10.1.2.1 Assessment Type

After tapping ***Edit Profile*** tab on Patient Dashboard, changing the Assessment type may trigger an error message.

##### **10.1.2.1.1 Error Message**



***“The patient has no assessment type selected or current licencing status does not allow taking a measurement.”***

The screenshot shows the 'Patient Dashboard' interface. At the top right is a 'Patient List' button. Below it is a navigation bar with five tabs: 'MEASURE' (person icon), 'HISTORY' (bar chart icon), 'RESULTS' (pie chart icon), 'EDIT PROFILE' (pencil icon), and 'SELF-TEST' (checkmark icon). The 'EDIT PROFILE' tab is highlighted. Below the navigation bar, the 'Patient Details' section shows 'Last Name' as 'Zero' and 'Sex' as 'F'. A large white error dialog box is centered on the screen, featuring a red 'X' icon and the text: 'The patient has no assessment type selected or current licensing status does not allow taking a measurement. Please check your clinic's license or try navigating to the patient profile and adding at least one assessment type.' An 'OK' button is at the bottom of the dialog. Below the dialog, the 'Assessment Type' section has a message: 'Please select at least one Assessment Type in the Patient Profile'.

#### 10.1.2.1.2 Resolution

Tap **Edit Profile** tab on Patient Dashboard.

This screenshot shows the 'Patient Dashboard' with the 'EDIT PROFILE' tab highlighted by a red rectangle. The 'Patient List' button is at the top right. The navigation bar shows 'MEASURE', 'HISTORY', 'RESULTS', 'EDIT PROFILE' (highlighted), and 'SELF-TEST'. The 'Patient Details' section displays: 'Last Name' (Marchant), 'First Name' (Lindsey), 'Date of Birth' (9 Apr 1952), 'Sex' (M), 'MRN' (12345A), and 'Last SOZO Assessment' (14 Apr 2019 18:04). The 'Assessment Type' section lists three items, each with a blue checkmark: 'L-Dex Analysis for Lymphoedema', 'Fluid Analysis for General Fluid Status Monitoring', and 'Tissue Analysis for Body Composition'.

Choose Assessment Type under “Patient Details.”

**Patient Details**

First Name Required

Naomi

Middle Name

Last Name Required

Cartworth

Email Address Required

☒ Not Provided

Medical Record Number (MRN) Required

1234

Date of Birth Required

4 Apr 1991

Sex Required

Male

Height (cm) Required

168

Country Code

Australia (+61)

Phone Number

Address

City

State

Country

Postal Code

**Assessment Type**

☒ L-Dex Analysis for Lymphoedema

☐ Fluid Analysis for Heart Failure and General Fluid Status Monitoring

☐ Tissue Analysis for Body Composition

**Lymphoedema Settings**

Assessment

☐ Unilateral ☐ Bilateral

Body Element

☐ Arm ☐ Leg

Risk Limb

☐ Left ☐ Right

Limb Dominance

☐ Left ☐ Right

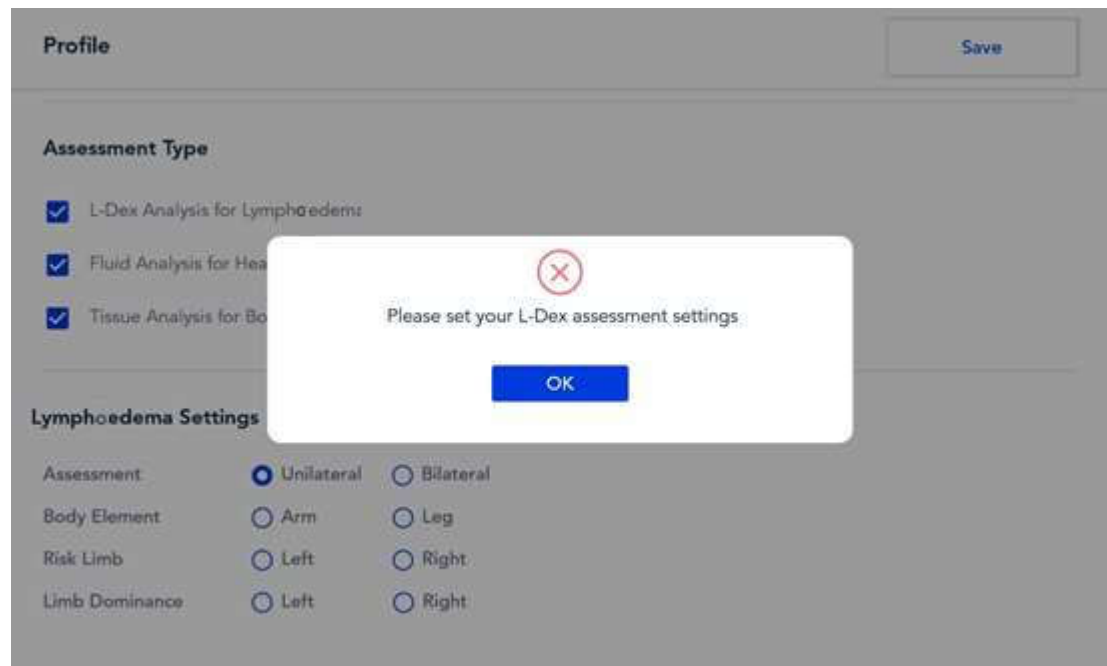
Save Changes

### 10.1.2.2 Lymphoedema Settings

Editing Lymphoedema Settings on the patient profile may trigger an error message.

#### 10.1.2.2.1 Error Message

***“Please set your L-Dex assessment settings.”***



#### 10.1.2.2.2 Resolution

Under “Lymphoedema Settings,” select “Body Element,” “Risk Limb” and “Limb Dominance,” and tap **Save**.



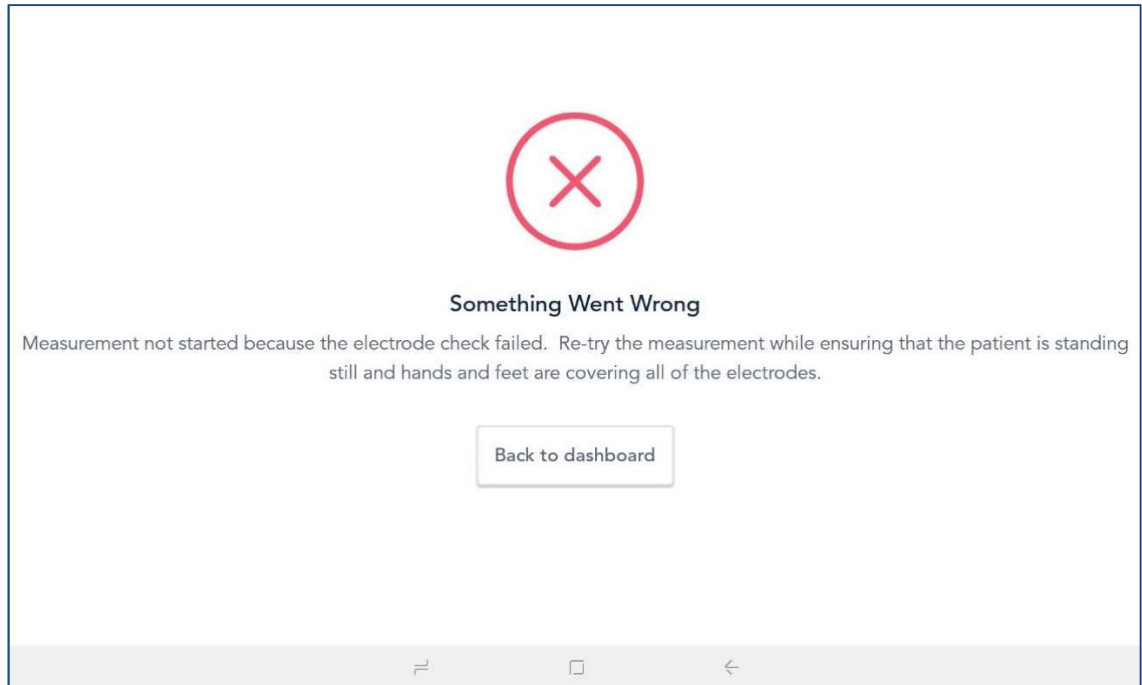
If “Bilateral” is selected as the “Assessment Type,” after arm or leg is chosen as the “Body Element,” “Left and “Right” are both automatically selected as “Risk Limb.”

### 10.1.3 Patient Dashboard

After starting measurement, an error message may appear on the Patient Dashboard.

### 10.1.3.1 Error Message

***“Something Went Wrong. Measurement not started because the electrode check failed.”***



### 10.1.3.2 Resolution

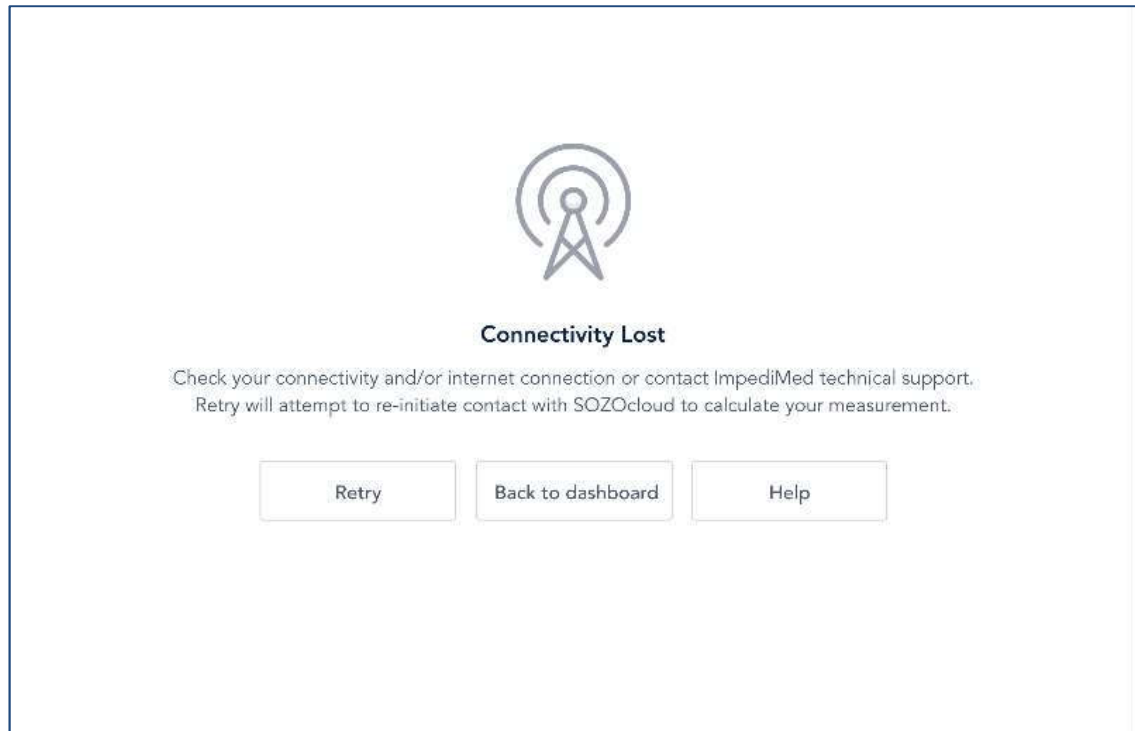
Ensure that the patient is standing on the SOZO Device before tapping ***Measure***.

## 10.1.4 Losing Connectivity During Measurement

If connectivity is lost while measurement is in progress, an error message appears.

### 10.1.3.4.1 Error Message

#### ***“Connectivity Lost.”***



### 10.1.3.4.2 Resolution

To reconnect, tap **Retry**. If this does not establish connectivity, tap **Back to dashboard** to end the measurement. To start over, restart measuring process. See [Section 8.6.2.3 Start Measurement](#).

## 10.2 General Troubleshooting Chart

The General Troubleshooting chart provides guidance for common issues and error messages. In the event that you need additional help, call 877 247-0111, ImpediMed technical support, or you may email ImpediMed at [tsu@impedimed.com](mailto:tsu@impedimed.com) or visit <https://www.impedimed.com>.

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
Form fields have character limits and entry requirements. Various error messages can occur if these field requirements are not met.	User has completed a form field that does not meet minimum/maximum/character type requirements	Enter data in mandatory fields according to requirements described in error message.

SOZO hardware does not emit audible clicks when powering on; LED at back of unit is not emitting a blue light.	Power cord not properly connected or potential hardware failure.	Confirm power cord is properly connected. If cord is correctly inserted, contact ImpediMed technical support.
Self-test fails.	Person/object making contact with electrodes during self-test.	Ensure that no extraneous objects in contact with electrodes during self-test; re-run self-test.
L-Dex; Fluid Analysis; or Tissue Analysis tab is missing from the history or results.	The Assessment type is not chosen, or licence is not available.	Check the Assessment types chosen for the patient and adjust accordingly. Check available licences and contact ImpediMed technical support if unable to resolve.
Historical results for an Assessment type are available, but current results are not shown.	Licence for the Assessment type is not active.	Check active licences. Contact ImpediMed technical support if licence status is not correct.
No SOZO devices are selectable even after device is paired via Bluetooth.	Device is not licenced.	Check licence status. Contact ImpediMed technical support if licence status is incorrect.

Logging in to SOZOapp / MySOZO		
Issue/Error message	Potential Cause	Resolution
"Empty fields. Please enter your username and your password to continue."	User has attempted to log in leaving either username or password blank.	Verify username and password are entered properly.
<b>Logging in to SOZOapp/MySOZO (cont'd)</b>		
Issue/Error message	Potential Cause	Resolution
"Incorrect credential combination. Please check your information and try again."	Incorrect or forgotten username/password.	Verify username and password and attempt to log in again. Continued error: change password with your IT admin.
"Something Went Wrong. There is a Bluetooth connection problem. To resolve, check the tablet settings and ensure that Bluetooth is turned on."	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection.	Check Tablet settings to ensure Tablet is connected to local Wi-Fi network. Otherwise call ImpediMed technical support.
"There is a new version of SOZOapp available. You are required to download and update it to continue using MySOZO. To continue, press Yes".	Logging in to SOZOapp with previous app version after MySOZO or SOZOapp has been upgraded.	Select "Yes" and follow prompts to automatically update SOZOapp to latest version. Note: connection path may need to be reset after update.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	Potential Cause	Resolution
"There are no results matching your search criteria"	Search terms do not identify any patients or clinicians.	Revise search terms.
"Either your connection might have timed out or you need to contact the support team."	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection.	Check Tablet settings to ensure Tablet is connected to local Wi-Fi network. If Tablet is connected, contact your IT admin; otherwise call ImpediMed technical support.
"For security reasons your session has expired" or you have been logged out and see the login page.	User will be logged out automatically based on initial login. The logout time is set by the Clinic administrator.	Log back in with username and password.
"Measurement not started. Electrode check failed"	SOZO hardware verifies that electrodes are connected correctly before taking a measurement. Ensure that correct patient contact is made for all eight electrodes. If any physical damage has occurred to hardware electrode check may also fail.	Power the SOZO Device off and on, ensure correct patient contact and repeat measurement.  If error persists, contact ImpediMed technical support.
"There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support."	Error in sending data from SOZO hardware to Tablet. Potential issue with disruption of Bluetooth signal.	Take another measurement. Move location of SOZO Device if it is in an area with other equipment that emits electromagnetic signals. If error persists, contact ImpediMed technical support.
"Measurement wasn't valid. Please try a new measurement."	Patient is not contacting electrodes cleanly with bare hands/feet; patient preparation steps were not followed.	Ensure that all patient preparation steps have been followed and attempt another measurement. If error persists, contact ImpediMed technical support.

Use of SOZOapp/MySOZO (Clinician) (cont'd)		
Issue/Error Message	Potential Cause	Resolution
"A user with this first name, last name, and date of birth already exists"	When creating new patient, a patient already exists with this combination of first & last names, and DOB	Review existing patient to ensure unnecessary duplication of patient profiles.
"Device not found. Please check your selected device"	SOZOapp is not currently linked to a nearby SOZO Device	Verify that the device chosen is available via Bluetooth by selecting "pair device". If device is selected and error has occurred, ensure that the serial numbers match (if multiple units at your Clinic). Otherwise verify SOZO hardware is powered on by pushing button and verifying blue light at back of unit is illuminated. If error persists, contact ImpediMed technical support
"Possible device connection problem"	Tablet Bluetooth has been turned off.	Confirm Tablet Bluetooth is turned on. Turn off and restart the Tablet and the SOZO Device. Press the Bluetooth reset button on the back of the SOZOtouch panel and verify blue light at back of unit is illuminated. If Bluetooth is enabled on the Tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.
"Self-test unknown error"	Internal error in running self-test; potential hardware failure or firmware/software incompatibility.	Contact ImpediMed technical support
"Self-test failed"	User attempts to run self-test but either device has hardware issue or contact is made with electrodes.	Verify that nothing is touching the electrodes and repeat self-test. If error persists, contact ImpediMed technical support.
"Status retrieved. Please run a self-test and try again."	Unit has not recently run a self-test.	Run a self-test per instructions for use.
No error message, but Clinician notes that patient historical measurement data looks different compared with last review	Patient details have been changed and the measurement results have been recalculated.	Check the patient settings to ensure that they are correct.  Height, age, and L-Dex settings must match historical measurement records to have same measurement results.



Clinic IT Administrator Interfacing with SOZO System		
Issue/Error Message	Potential Cause	Resolution
"The email entered already exists for another clinician or administrator. The email used must be unique."	When creating a new clinician, the selected username is identical to an existing username/email.	Use different username/email.
"Password must be between 8 and 20 characters containing at least: 1. One number 2. One special character !"#\$%&"()*+,-./:;<=>?_@[]^`{ }~ 3. One upper case letter 4. One lower case letter" 5. You cannot use your last 3 passwords."	Password does not meet requirements.	Create password using the listed requirements
"Your passwords do not match. Please re-enter them".	During user password creation, a different password was entered in the confirmation box.	Verify and re-enter passwords.
"Firmware update unknown error"	Unknown error has occurred during SOZO firmware update.	Please contact ImpediMed technical support.
"Firmware update failed"	Update procedure failed.	Attempt to install firmware again. If failure persists, please contact ImpediMed technical support.
Password doesn't work.	Password forgotten.	Review MySOZO set up for instructions on resetting password.

# 11.0 Personal Data

Read our privacy policy located at

<https://www.impedimed.com/privacy-policy/>

# 12.0 Care and Maintenance

## 12.1 The SOZO Device

### 12.1.1 Care

When not in use, the SOZO Device may remain set up and does not need to be uninstalled. If storage is desired, always keep the SOZO Device in its original packaging.

The external enclosure of the SOZO Device should be cleaned between each use with non-bleach-based disinfecting agents or as per your Clinic's policy. ImpediMed does not recommend the use of bleaching agents to clean/disinfect the SOZO Device as that may cause corrosion of the electrodes. The external enclosure of the SOZO device may be cleaned with disinfecting agents such as isopropyl alcohol 70% or Peridox® Concentrate Sporidical Disinfectant and Cleaner for devices that do not display the following label 'Germicide Compatible.'

**SOZO-**  
**[www.impedimed.com/support](http://www.impedimed.com/support)**  
**INTL: +61-7-3860-3700**  
**US: 1-877-247-0111**



SOZO Devices with the 'Germicide Compatible' label located on the side of SOZOtouch may also be cleaned with the following: Cavicide Liquid, Cavicide 1 Liquid, Caviwipes 1, Caviwipes XL, Clinell Liquid, Clinell Wipes, Sani-Cloth Prime, Super Sani Cloth Prime Wipes, and Sani Prime Liquid

The Tablet may require cleaning and disinfection as well. For the Samsung Tablet provided with your SOZO Device, ImpediMed recommends the use of protective disposable Tablet sleeves, to be used and replaced as per your Clinic's policy. The use of a protective sleeve prevents the need to use potentially damaging chemicals on the Tablet itself.



The SOZO Device should not be subjected to ingress of liquid or liquid spillage, impact or excessive heat (direct exposure to sunlight). This can harm the patient, cause damage to the SOZO Device, or give an incorrect reading. The SOZO Device should be used in a dry environment. Contact ImpediMed or an authorized agent for repair.



Do not attempt to sterilize any component or accessory of the SOZO Device.

### **12.1.2 Maintenance**

The SOZO Device does not require any periodic or preventive maintenance other than cleaning and/or disinfecting, in accordance with Section 12.1.1 above. The SOZO Device does not require any periodic calibration.

## **12.2 Self-Test**

To ensure that the SOZO system is operating correctly, run a self-test from the SOZOapp Main Menu, [Section 8.5.5 Self-Test](#), or from the SOZOapp Patient Dashboard, [8.6.2.1 Self-Test](#). ImpediMed recommends that the self-test be performed at the start of the day on which measurements of the patient will be taken.

## **12.3 Repairs**

There are no user-repairable electronic parts within the SOZO Device. Contact ImpediMed or an authorized agent should service or repair of the SOZO Device be required. Do not attempt to use the SOZO Device if it does not appear to be functioning correctly or needs repair.

## **12.4 Tablet Maintenance**

The tablet is shipped partially charged and will need to be charged periodically throughout its use. Please follow Samsung's instructions for use supplied with the Tablet. Although the Tablet will operate at low levels of battery power, ImpediMed recommends charging it upon receipt of the SOZO system

## **12.5 Technical Support**

Australia  
Phone: + 61 7 3860 3700  
Fax: + 61 7 3260 1225

USA  
Phone: (877) 247-0111 Option 2  
Fax: (760) 804-9245

**SOZO Website:** [www.impedimed.com](http://www.impedimed.com)

**SOZO Help Email:** [tsu@impedimed.com](mailto:tsu@impedimed.com)

## 12.5 Technical Support

The following components and accessories are available for separate purchase. Please contact ImpediMed or an authorized agent to purchase replacement parts.

Description
SOZOsupport Stand
SOZOconnect Cable
Power Supply Cable
Tablet
Tablet Sleeves

# 13.0 ImpediMed Product Warranty

**ImpediMed** warrants to the purchaser that in the event of product failure under normal use, due to defects in material or workmanship within the specified period(s) listed below, the device and accessories will be repaired, or at **ImpediMed's** option, replaced. The device and accessories are to be returned to **ImpediMed**, accompanied by proof of purchase, your name, your return address and a statement of the defect. This limited warranty does not apply to products subjected to abnormal use or damaged by accident, misuse, improper voltage, or to products altered or served by anyone other than **ImpediMed** or its authorised agents.

The foregoing limited warranty is exclusive and in lieu of all other warranties whether written, oral, expressed or implied. In particular, **ImpediMed** does not warrant that the product is suitable for the needs of the purchaser, and there are no warranties given as to its fitness for a particular purpose.

**ImpediMed's** representations concerning fitness for purpose or suitability for use by any purchaser do not extend beyond those representations set out in **ImpediMed** literature that may accompany the product.

Depending upon the area of distribution, the following warranty periods will apply:

Australia: **ImpediMed** warrants its devices to be free from defects for a period of twelve months from the date of purchase.

Europe: **ImpediMed** warrants its devices to be free from defects for a period of twenty-four months from the date of purchase.

After the warranty period has expired the device will be repaired at current charge rates for parts, labour and transport. Before returning a product for repair, please contact **ImpediMed** or their authorised distributor for instructions.

In no event will **ImpediMed** be liable for any direct or indirect damages including incidental, consequential or special damages, arising out of or in connection with the use or performance of the product. **ImpediMed** reserves the right to change or discontinue this product without notice.

No representative of **ImpediMed** and no vendor or lessor of the product is authorised to change any of the foregoing terms and conditions, and the purchaser accepts the product subject to all terms and conditions herein, subject always to any contrary provisions which are necessarily implied by statute or law notwithstanding the within terms and conditions.

*Consumables (including tablet sleeves) are excluded from the device warranty.*

# 14.0 Regulatory Statement

FCC ID: QOQBT121


This device complies with Part 15 of the FCC Rules

Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This device complies with the R&TTE Directive.



# 15.0 Product Specifications

Drive AC current	200 micro Amps RMS at a variable frequency of 3 kHz to 1000 kHz.
Frequency Scan	3 to 1000 kHz (256 frequencies)  Scan speed: ~30 seconds to complete a full scan.
Power Supply	24V DC, 1.0A
Dimensions	Hand Plate L=330mm, W=180mm, D=170mm Foot Plate L=450mm, W=320mm, D=40mm
Effective Radiated Power (BT Module)	-18 dBW
Weight	SOZO Device: 10.0 lb/4.5 kg SOZOsupport Stand: 25.5 lb/11.6 kg
Data Displayed	Cole resistance-reactance plot, other outputs dependent on measurement module.
Environmental transport, and storage conditions	- 25 °C without relative humidity control; and + 70 °C at a relative humidity up to 93%, non-condensing;
Environmental operating conditions	a temperature range of + 5 °C to + 40 °C  a relative humidity range of 15% to 93%, non-condensing; and an atmospheric pressure range of 700 hpa to 1060 hpa.
Device (IEC 60601-1) electrical classification	Type BF 
Electromagnetic Compatibility	Meets the requirements of IEC 60601-1-2 and 60601-1-11.
Minimum service life of device and accessories	Minimum service life and associated warranty of parts and accessories is two years.

# 16.0 Safety and Electromagnetic Compatibility (EMC) Information

Guidance and manufacturer's declaration – electromagnetic emissions		
The SOZO device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SOZO device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The SOZO device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO device should assure that it is used in such an environment.			
Immunity test	4 <sup>th</sup> Edition Test Levels	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	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds ----- 0% Ur for	>95% Dip for 0.5 Cycle  60% Dip for 5 Cycles  30% Dip for 25 Cycles  >95% Dip for 5 Seconds ----- 0% Ur for	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SOZO device requires continued operation during power mains interruptions, it is recommended that the SOZO device be powered from an uninterruptible power supply or a battery.

	0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.	0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.	
	0% Ur for 1 cycle	0% Ur for 1 cycle	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/M 50 or 60 Hz	30A/M 50/60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

NOTE Ur is the AC mains voltage prior to application of the test level.

### Guidance and Manufacturer's Declaration – Immunity

The SOZO device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO device should assure that it is used in such an environment.

Immunity test	4 <sup>th</sup> Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms (Outside ISM)  6Vrms (In ISM and amature Bands) 150 kHz to 80 MHz	(V1) = 3Vrms (V2) = 6Vrms	Portable and mobile communications equipment should be separated from the SOZO by no less than the distances calculated/listed below:  $D = (3.5/V1)(\text{Sqrt } P)$ $D = (12/V2)(\text{Sqrt } P)$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz		$D = (12/E1)(\text{Sqrt } P)$ 80 to 800 MHz  $D = (23/E1)(\text{Sqrt } P)$ 800 MHz to 2.7 GHz  where P is the max power in watts and D is the recommended separation distance in meters.  Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).  Interference may occur in the vicinity of equipment containing a transmitter.

Guidance and Manufacturer's Declaration – Immunity						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM $\pm 5$ kHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
870						
930						
1 720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1 845						
1 970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5500						
5785						

## Recommended separation distances between portable and mobile RF communications equipment and the SOZO device

The SOZO device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOZO device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOZO device as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz Non-ISM $D=(3.5/V1)(\text{Sqrt } P)$	Separation (m) 150kHz to 80MHz ISM $D=(12/V2)(\text{Sqrt } P)$	Separation (m) 80 to 800MHz $D=(12/E1)(\text{Sqrt } P)$	Separation (m) 800MHz to 2.7GHz $D=(23/E1)(\text{Sqrt } P)$
0.01	0.116667	0.12	0.12	0.23
0.1	0.368932	0.379473	0.379473	0.727324
1	1.166667	1.2	1.2	2.3
10	3.689324	3.794733	3.794733	7.273239
100	11.66667	12	12	23

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