



SOZO System Instructions for Use



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For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed U.S. by email at tsu@impedimed.com or by phone at: 877 247 0111 option 4



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, either a Samsung Galaxy Tab A (Models SM-T510 or SM-T580), or an iPad Airmini, comes with the SOZO system. It communicates with the SOZO Device using *Bluetooth*^{®1} technology.

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 and the Tablet user guide.

1.1.2 SOZOapp

The SOZOapp for Android is pre-installed on the Tablet. For customers choosing an iPad interface, contact ImpediMed Technical Support for download instructions. Note that screenshots throughout this Instructions for Use are based on the Android SOZOapp. The iPad SOZOapp screens will look nearly identical. Please note that instructions in this User Guide are for SOZOapp and MySOZO versions 3.0.1 and later. Not all functionality in later versions is present in earlier ones.

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:

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

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

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 license**-ImpediMed grants a separate license for each type of Assessment. Once an Assessment is licensed, the Clinic has access to that Assessment for all current and previous measurements. The availability of the Assessment license is viewable in MySOZO and the SOZOapp.
- 2.0.4 **At-risk limb**-The limb at risk of developing lymphedema.
- 2.0.5 **Bilateral**-A type of L-Dex Assessment for a patient who has both arms or both legs at risk of lymphedema. The SOZO system compares each arm with each leg.
- 2.0.6 **Bioimpedance**-The measure of impedance of the human body to an alternating electric current.
- 2.0.7 **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.
- 2.0.8 **BIS**-Bioimpedance Spectroscopy.
- 2.0.9 **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.
- 2.0.10 **Clinic**-A customer of ImpediMed, such as a hospital or medical facility, which uses the SOZO system.
- 2.0.11 **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.
- 2.0.12 **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 or not to accept or reject measurements. The SOZO software helps determine the quality of measurements as high, medium or low quality.
- 2.0.13 **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.
- 2.0.14 **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 lymphedema, if the right arm is at-risk of lymphedema, then the left arm is the contralateral limb.

- 2.0.15 **Dominant limb**-The limb which the patient uses the most. For example, for a right-handed patient, the right arm is the dominant limb.
- 2.0.16 **ECF**-Extracellular fluid. Extracellular fluid is all the fluid that is not contained within the cells. ECF is usually expressed as a volume (liters or pints).
- 2.0.17 **Electrode Plates**-See "Electrodes."
- 2.0.18 **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.
- 2.0.19 **Fluid Analysis Assessment**- Also referred to as "Fluid Analysis," 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 the Fluid Analysis User Guide.
- 2.0.20 **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).
- 2.0.21 **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).
- 2.0.22 **Fluid Analysis User Guide**-LBL-525-2, the Fluid Analysis Assessment Instructions for Use.
- 2.0.23 **Hex Key**-A tool which comes with the SOZO system for assembling the SOZOsupport Stand
- 2.0.24 **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.
- 2.0.25 **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 (liters or pints).
- 2.0.26 **Ipsilateral limb**-The limb on the same side of the patient's body. For purposes of L-Dex Assessment of a patient with bilateral lymphedema, 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 lymphedema 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.
- 2.0.27 **Impedance**-The measure of the total opposition of a circuit or part of a circuit to an electrical current.
- 2.0.28 **L-Dex®**-The Lymphedema Index, a numeric value used in L-Dex Assessment
- 2.0.29 **L-Dex Assessment**- also referred to as "L-Dex," 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 lymphedema, using certain patient measurements taken with the SOZO Device. Indications for Use and Instructions for Use of the L-Dex Assessment is in the L-Dex User Guide.
- 2.0.30 **L-Dex score**-The measurement parameter for the L-Dex Assessment.
- 2.0.31 **L-Dex User Guide**- LBL-525-1, the L-Dex Assessment Instructions for Use.

- 2.0.32 **Licensed Assessments**-Assessments for which a Clinic has purchased a license
- 2.0.33 **Measurements**-Measurement data taken by the Clinician of the patient using the SOZO Device. Measurements are the inputs in the SOZO assessment process.
- 2.0.34 **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.
- 2.0.35 **Parameter**-A clinically meaningful output based upon measurements
- 2.0.36 **Product**-The SOZO Device, including all hardware components of the SOZO Device, except for any hardware component which is a "Consumable."
- 2.0.37 **Patient**-The individual who is being measured with the SOZO Device.
- 2.0.38 **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°).
- 2.0.39 **R**-Resistance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).
- 2.0.40 **Rinf**-Rinfinity. Rinf is the impedance measured at an infinite frequency.
- 2.0.41 **R0**-The impedance measured at a frequency of 0 kHz.
- 2.0.42 **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).
- 2.0.43 **SOZOapp**-The app pre-installed on the Tablet which provides the User with access to the SOZO system.
- 2.0.44 **SOZOconnect Cable**-The hardware component of the SOZO Device used to connect the SOZOtouch with the SOZOstep.
- 2.0.45 **SOZOcradle**-The hardware component of the SOZO Device which holds the Tablet in place.
- 2.0.46 **SOZO Device**-The commercially available medical device manufactured by ImpediMed, which uses Bioimpedance Spectroscopy to perform different types of Assessments of patient fluid levels.
- 2.0.47 **SOZOsupport Stand**-The hardware component of the SOZO Device upon which the patient stands for the taking of SOZO measurements.
- 2.0.48 **SOZOstep**-A hardware component of the SOZO Device upon which the patient stands (places their feet) for connection to the SOZO Device.
- 2.0.49 **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.
- 2.0.50 **SOZOtouch**-A hardware component of the SOZO Device upon which the patient places their hands for connection to the SOZO Device.
- 2.0.51 **Tablet**- Samsung tablet, provided to the ImpediMed customer as part of the SOZO system, with the SOZOapp pre-installed.

- 2.0.52 **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 (liters or pints) or a percentage of total mass (e.g. 60% of mass is TBW).
- 2.0.53 **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 the Tissue Analysis User Guide.
- 2.0.54 **Tissue Analysis User Guide**-LBL-525-3, the Tissue Analysis Assessment Instructions for Use.
- 2.0.55 **Unilateral**-A type of L-Dex Assessment for a patient with one arm or one leg at risk for lymphedema.
- 2.0.56 **User Device**-A device, including a PC, laptop or mobile device, used by the User to access MySOZO.
- 2.0.57 **Xc**-Reactance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).
- 2.0.58 **Z**-Impedance, which is the measure of the total opposition to an electric current. See and compare with bioimpedance.

3.0 Introduction to the SOZO System

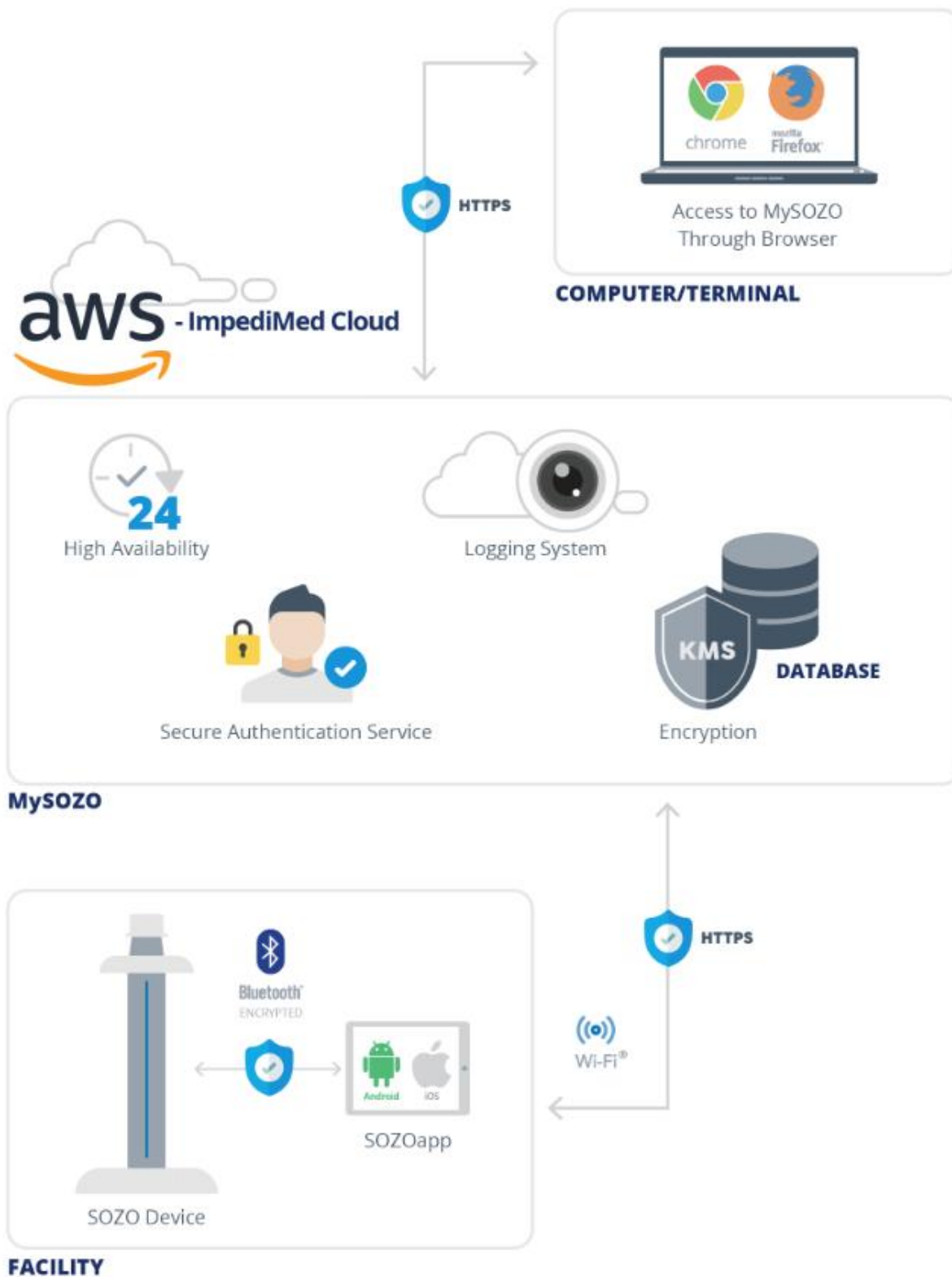
The SOZO system is a medical device system comprised of hardware and software. The SOZO system hardware components are the SOZO Device and the Tablet. SOZO system software is made up of the SOZOapp and MySOZO. Users may access the SOZO system through the SOZOapp on the Tablet, or by the internet through 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 lymphedema 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 lymphedema 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.²

All other patients may also benefit from the SOZO Fluid and Tissue Analysis, to monitor and track clinically relevant parameters of their body composition, such as fat mass (FM), fat free mass (FFM) and skeletal muscle mass (SMM).

² 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.









3.4 Assessment Licenses

Clinicians use the SOZO system to perform measurements and assessments on patients. As an ImpediMed customer, a Clinic must purchase a separate license for each Assessment. A Clinic may purchase a license 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 licenses, ImpediMed makes licensed 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 as well as 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.
IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.

4.2 Intended Use



Ensure that you have read and understand this entire User Guide, and all instructions for use within this User Guide, 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.

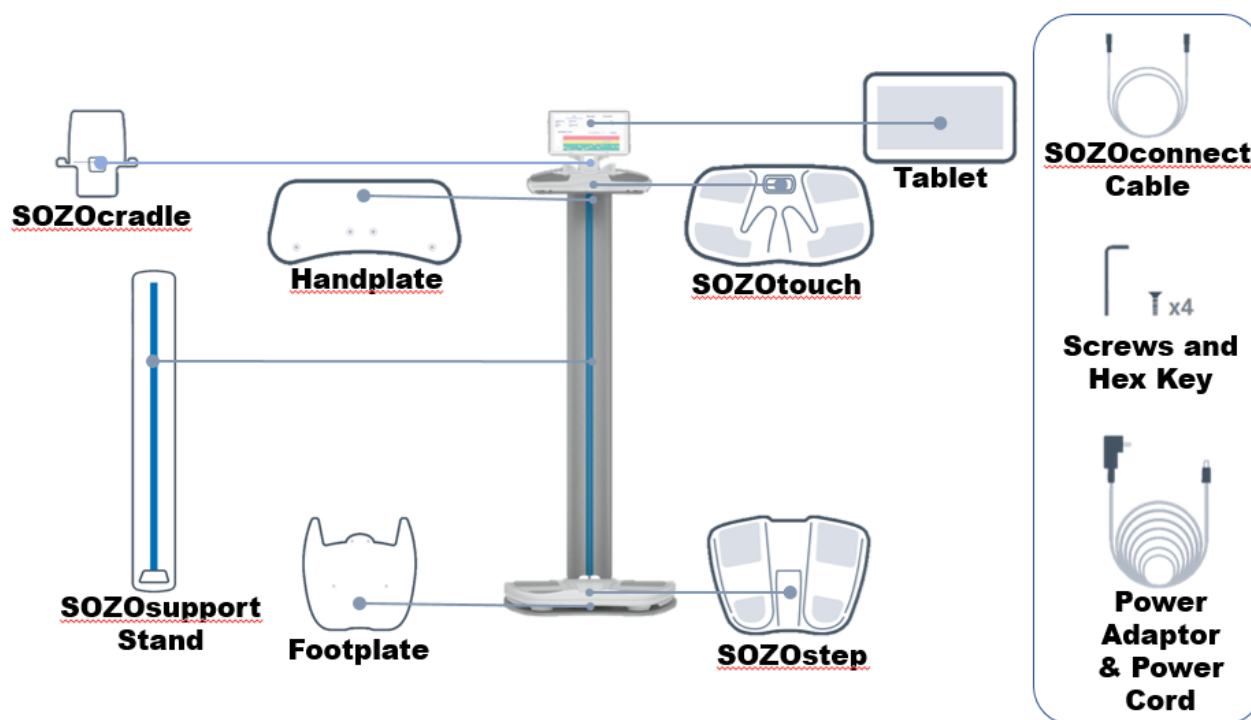
5.0 SOZO Device Assembly

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

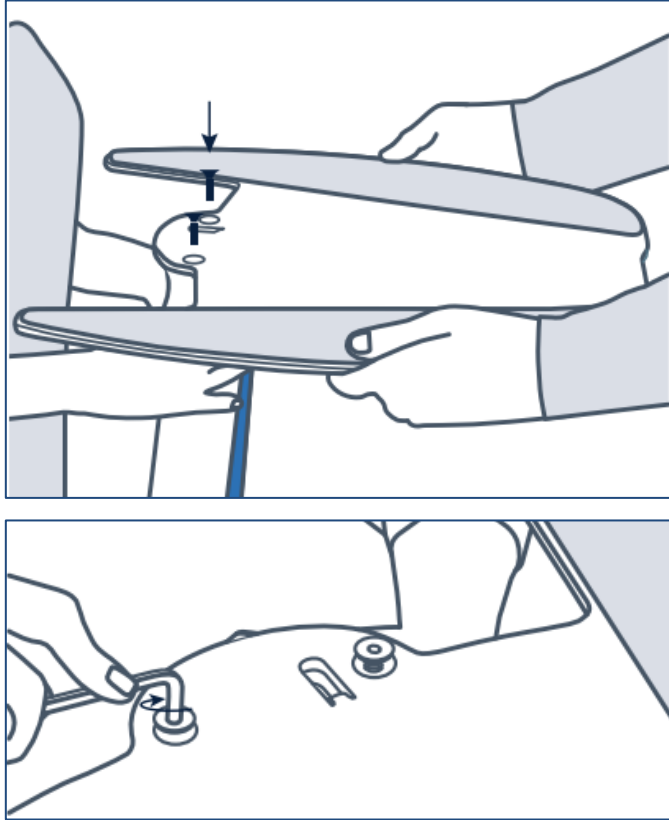
Before assembly, identify the SOZO Device components shown below.



5.1.2 Assembly Process

5.1.2.1 Step One: Attach Footplate to SOZOsupport Stand

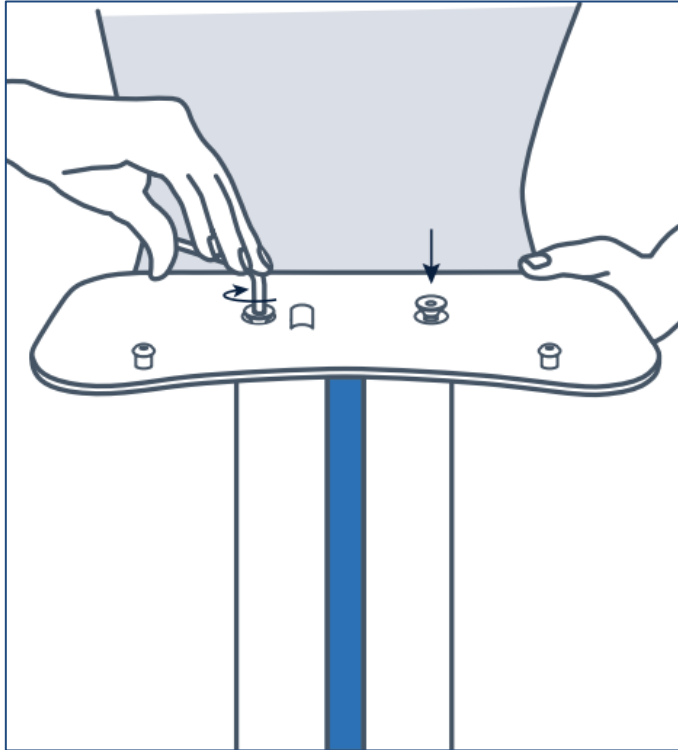
Using the Hex Key, screw the Footplate into the base of the SOZOsupport Stand.



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

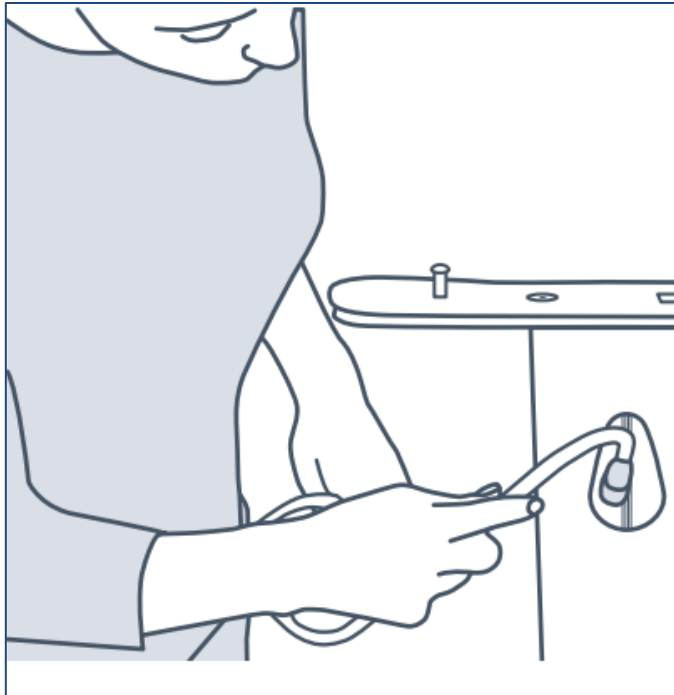
Using the Hex Key, attach the Handplate with the remaining screws.



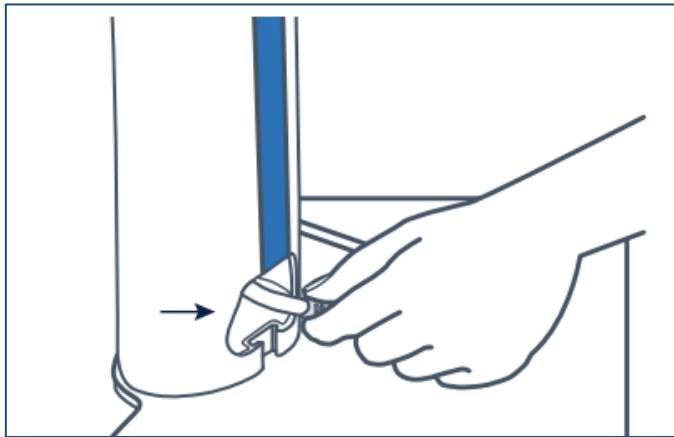
Once the Footplate and Handplate are connected to the SOZOsupport Stand, the large drop hole should be near the top opposite of the blue stripe as shown in Step Three.

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.



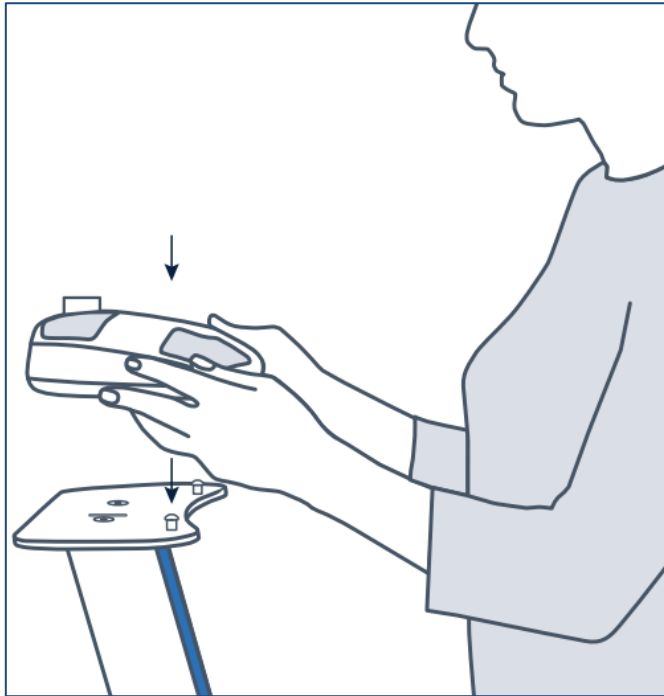
Feed the SOZOconnect Cable out of the front hole at the base of the SOZOsupport Stand.



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

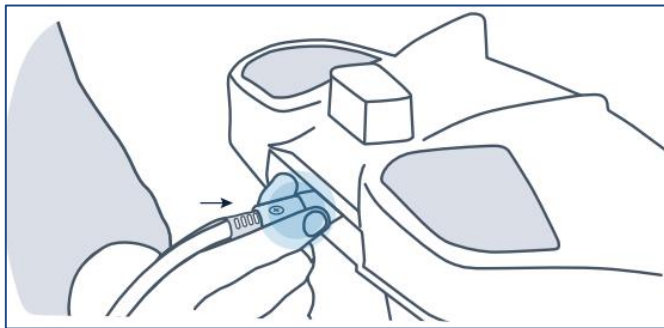
5.1.2.4 Step Four: Attach SOZOt看ch to Handplate

Place the SOZOt看ch onto the mounting screws and push forward to lock into place.



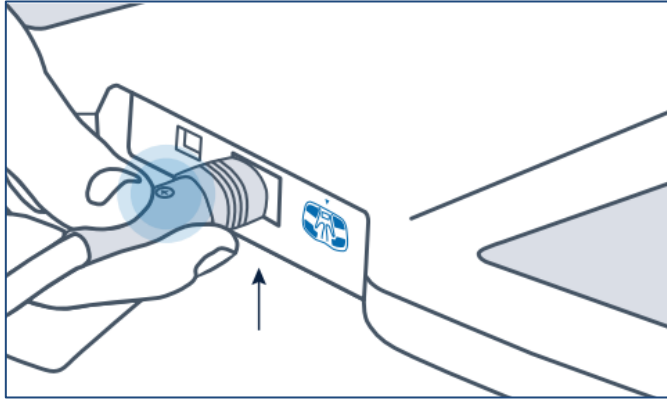
5.1.2.5 Step Five: Attach SOZOconnect Cable to SOZOtouch

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



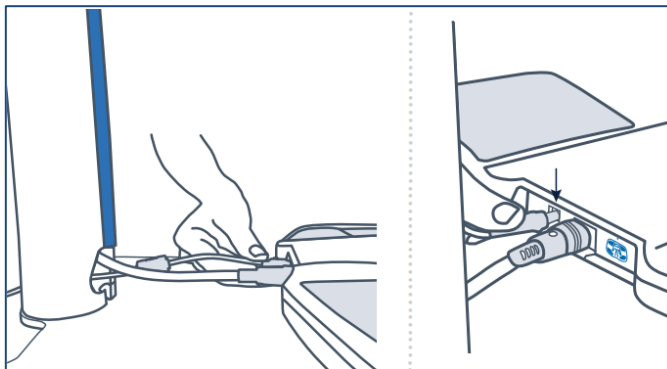
5.1.2.6 Step Six: Attach SOZOconnect Cable to SOZOstep

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

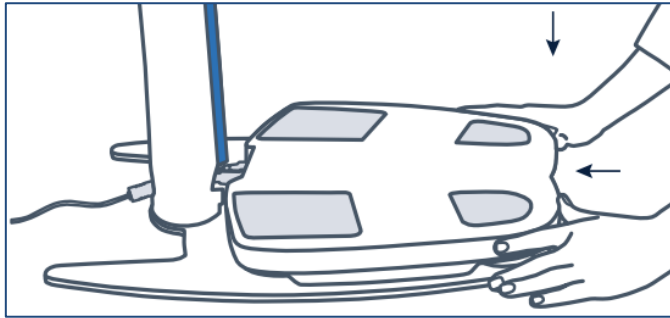
Before starting this step, make sure that the SOZOconnect Cable is plugged into both the SOZOtouch and the SOZOstep. Locate the power support port on the back of the SOZOstep. Feed the corresponding end of the Power Cord through the openings in the bottom of the SOZOsupport Stand and connect it to the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



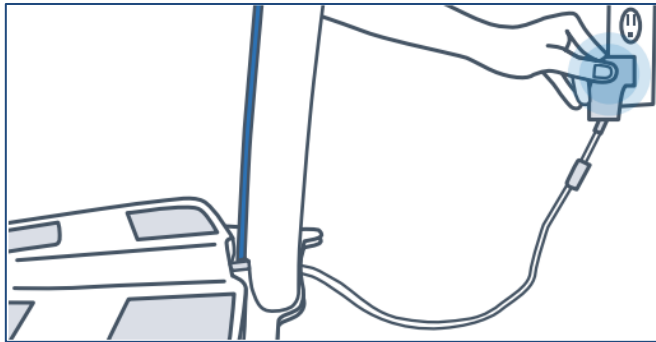
Before using the SOZO Device for the first time, make sure to follow all steps for start-up of MySOZO in [Section 6.0 MySOZO](#) and the SOZOapp, [Section 8.0 Using the SOZOapp](#).

5.1.2.8 Step Eight: Attach SOZOstep to the Footplate

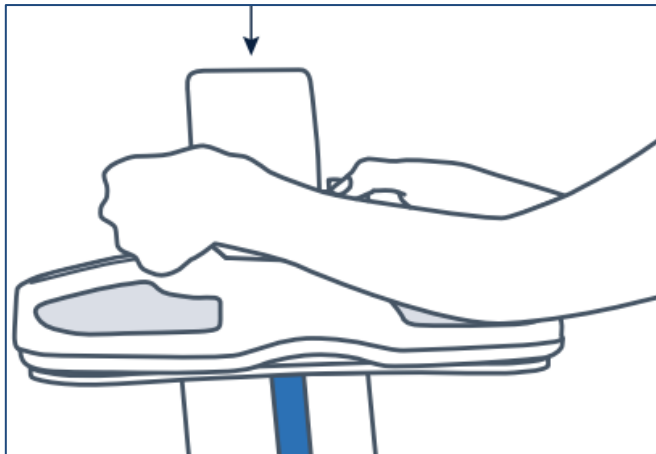
Place the SOZOstep onto the mounting screws and push forward to lock into place.



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 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.

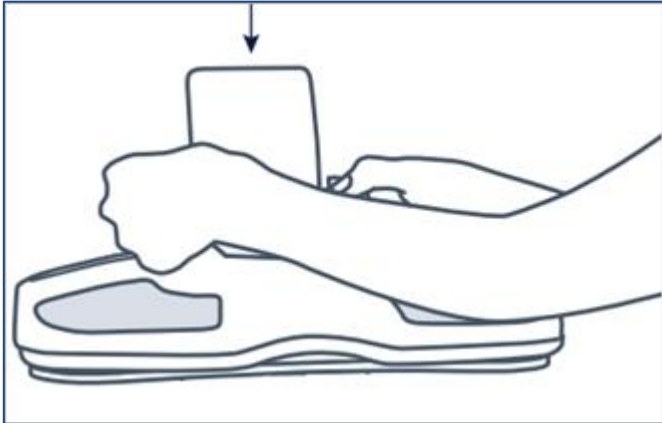
5.2.1 Attach SOZOtouch to SOZOstep with SOZOconnect Cable

Connect the SOZOtouch to the SOZOstep with the SOZOconnect Cable by repeating [Section 5.1.2.5 Step Five: Attach SOZOconnect Cable to SOZOtouch](#), and [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 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 authorization and licenses 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.

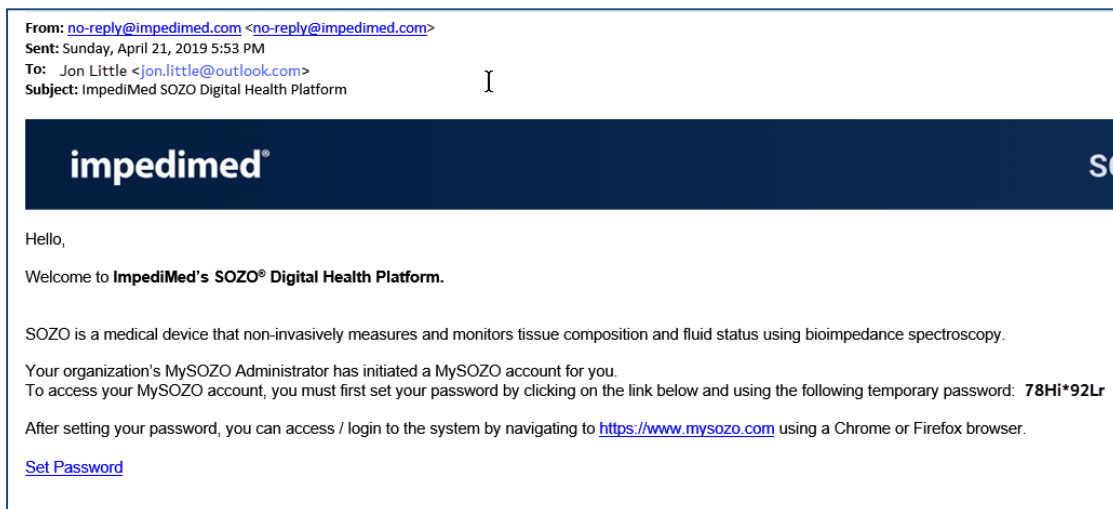
6.2 All MySOZO Users (Administrators and Clinicians)

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**.



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**.

impedimed

SOZO® Digital Health Platform

Set New Password

Email Address
Johnsmith@gmail.com

Temporary Password

New Password

Confirm New Password

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. Cannot be one of the last 3 passwords used

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

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

impedimed[®]

SOZO[®] Digital Health Platform

Login To Your Account

Email Address

Email Address

Password


Password

Language

English (US) ▾

Login

Having trouble logging in or need to reset your password?



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

impedimed[®]

SOZO Digital Health Platform

Reset Password

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

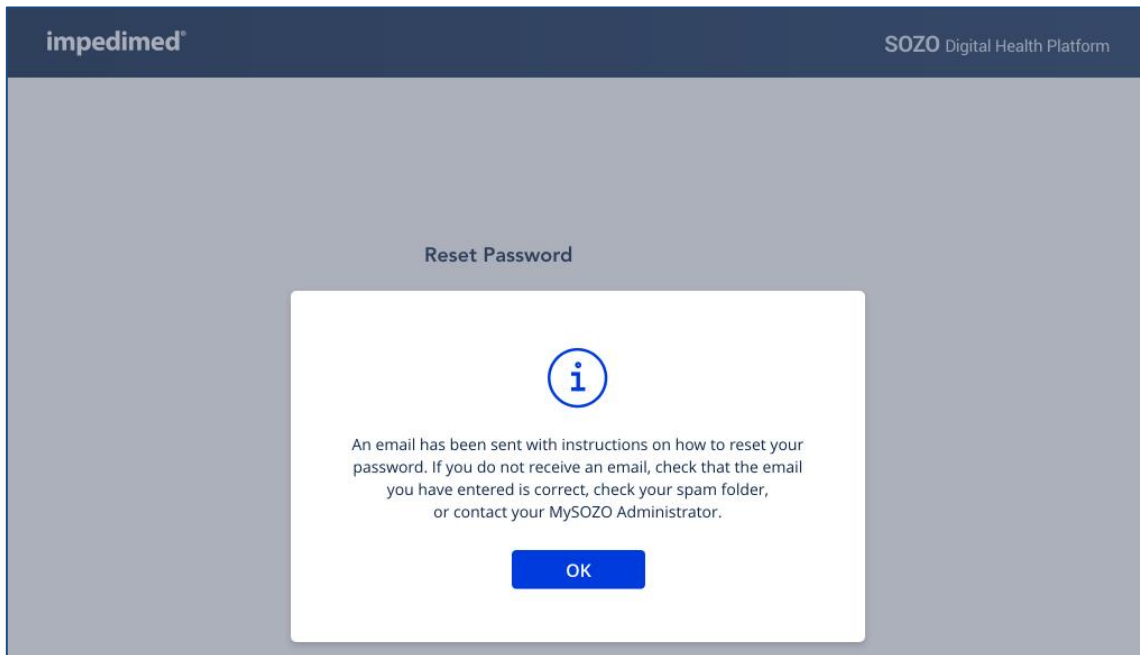
Email Address

Email Address

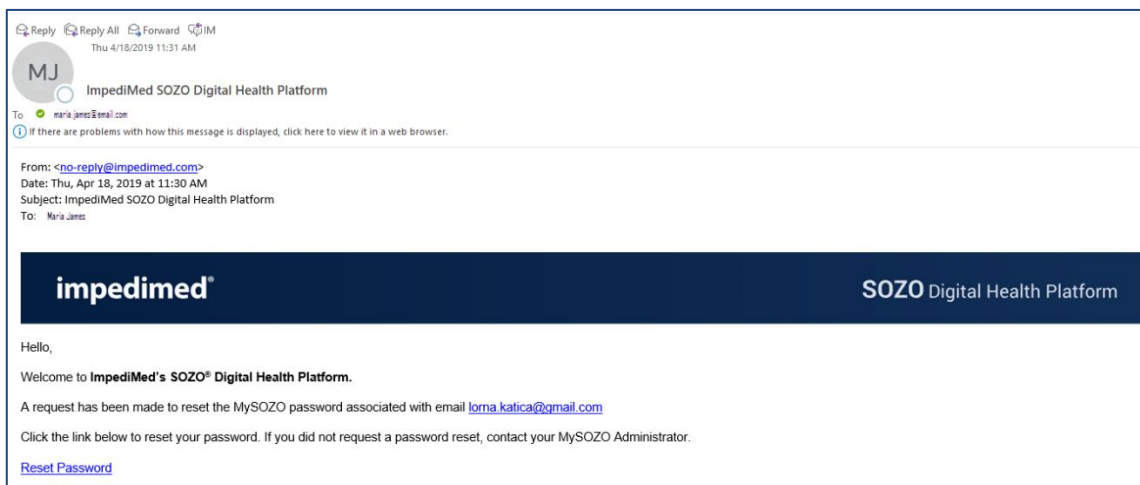
Submit

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

A user with an Administrator role has authority to manage MySOZO User accounts, adjust certain SOZO system-wide settings, create and edit Groups, and export Audit Logs. A user with an Administrator role can be created or added by another existing user with an Administrator role. Users 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	Phone Number	Email Address	User Role	Select
Smith	John	+1 7605852100	jsmith@hotmail.com	Admin Clinician	<input type="checkbox"/>
Iverson	George	+1 7608049245	giverson@yahoo.com	Clinician	<input type="checkbox"/>
Jackson	Jessica	+1 7386037007	jjackson@gmail.com	Clinician	<input type="checkbox"/>
Jasper	Tim	+1 7326012258	tjasper@hotmail.com	Clinician	<input type="checkbox"/>
Lackowski	Daren	+1 8772470111	dlackowski@gmail.com	Admin Clinician	<input type="checkbox"/>
Orange	Robert	+1 7386037009	rorange@gmail.com	Clinician	<input type="checkbox"/>
Rademan	Jeremy	+1 7326012295	jrademan@yahoo.com	Clinician	<input type="checkbox"/>
Saballos	Britney	+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.

The screenshot shows the MySOZO Admin interface. At the top, there's a dark blue header with 'MySOZO Admin' on the left, 'Admin' and 'Clinician' toggle buttons in the center, and a user profile section on the right showing 'John Smith' with a 'My Profile' dropdown, 'User List' button, 'Help' button, and 'Log Out' button. Below the header is a navigation bar with icons and labels for 'CREATE USER', 'EDIT USER PROFILE', 'DELETE USER', 'PATIENT GROUPS', 'EXPORT AUDIT LOGS', and 'SETTINGS'. The main content area is titled 'User List' and features a search bar labeled 'Search User' with a magnifying glass icon. Below the search bar is a table with the following data:

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

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. If an Administrator also has Clinician rights, they can toggle between Administrator and Clinician screens by clicking the ‘Admin’ or ‘Clinician’ toggle.

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.

MySOZO Admin
Admin
Clinician
John Smith

CREATE USER

EDIT USER PROFILE

DELETE USER

PATIENT GROUPS

EXPORT AUDIT LOGS

SETTINGS

User List

Search User

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

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.

MySOZO Admin

Admin

Clinician

John Smith

CREATE USER

EDIT USER PROFILE

DELETE USER

PATIENT GROUPS

EXPORT AUDIT LOGS

SETTINGS

User List

Search User

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

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 Admin
John Smith

Help


Technical Support

<div>NORTH AMERICA</div> <div>Email: tsu@impedimed.com</div> <div>Phone: USA/Canada (toll free): +1 877 247 0111 option 4</div>	<div>ALL OTHERS</div> <div>Email: ts@impedimed.com</div> <div>Phone: +61 7 3860 3700</div>
--	--

More Information

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

ImpediMed Regulatory Information




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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: <http://www.impedimed.com/patents/>



+B277SFT025V309*

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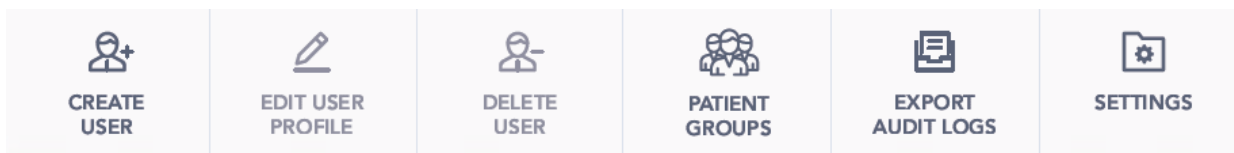
6.3.2.5 Log Out

Log Out Icon

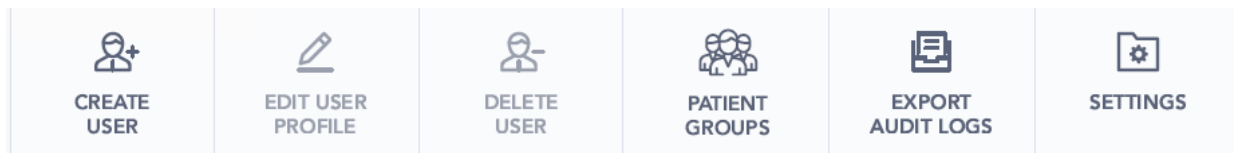


To log out of MySOZO at any time, click the **Log Out** icon on the upper right.

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 (note that in MySOZO v3.1.0, both choices can be selected). 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 and/or Clinician. When done, click **Create User**.

MySOZO Admin John Smith

CREATE USER EDIT USER PROFILE DELETE USER PATIENT GROUPS EXPORT AUDIT LOGS SETTINGS

User Details

First Name Required

Middle Name

Last Name Required

Email Address Required

Country Code

Phone Number

User Role
☒ 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 Admin John Smith

CREATE USER EDIT USER PROFILE DELETE USER PATIENT GROUPS EXPORT AUDIT LOGS SETTINGS

User Details

First Name Michael

Middle Name

Last Name Simpson Required

Email Address msimpson@impedimed.com Required

Country Code

Phone Number

User Role
☐ Administrator ☐ Clinician

Create User

The email entered already exists for another clinician or administrator. The email used must be unique.

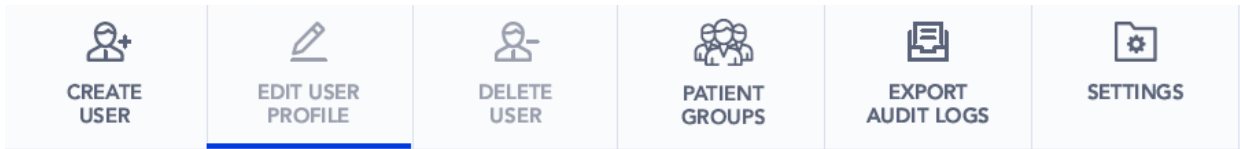
Cancel Continue to Edit



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



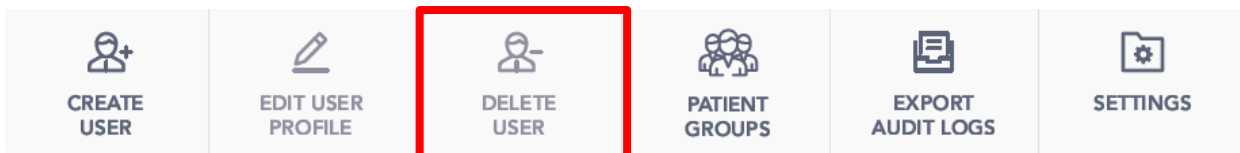
An Administrator may edit a User profile by clicking the **Edit User Profile** tab. On the “User Details” screen, the Administrator may change User information.

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.

A screenshot of the 'MySOZO Admin' interface. The top navigation bar shows 'Admin' and 'Clinician' tabs, with 'John Smith' logged in. Below the navigation bar is a row of icons for 'CREATE USER', 'EDIT USER PROFILE', 'DELETE USER', 'PATIENT GROUPS', 'EXPORT AUDIT LOGS', and 'SETTINGS'. The 'EDIT USER PROFILE' tab is active. The main content area is titled 'User Details' and contains a form with the following fields: 'First Name' (Michael, Required), 'Country Code' (United States (+1), dropdown), 'Middle Name' (Steward), 'Phone Number' (234578042136), 'Last Name' (Simpson, Required), 'User Role' (Administrator and Clinician checkboxes), 'Email Address' (jsmith@hotmail.com, Required), and a 'Save Changes' button. A 'Change Email' button is located at the bottom right of the form.

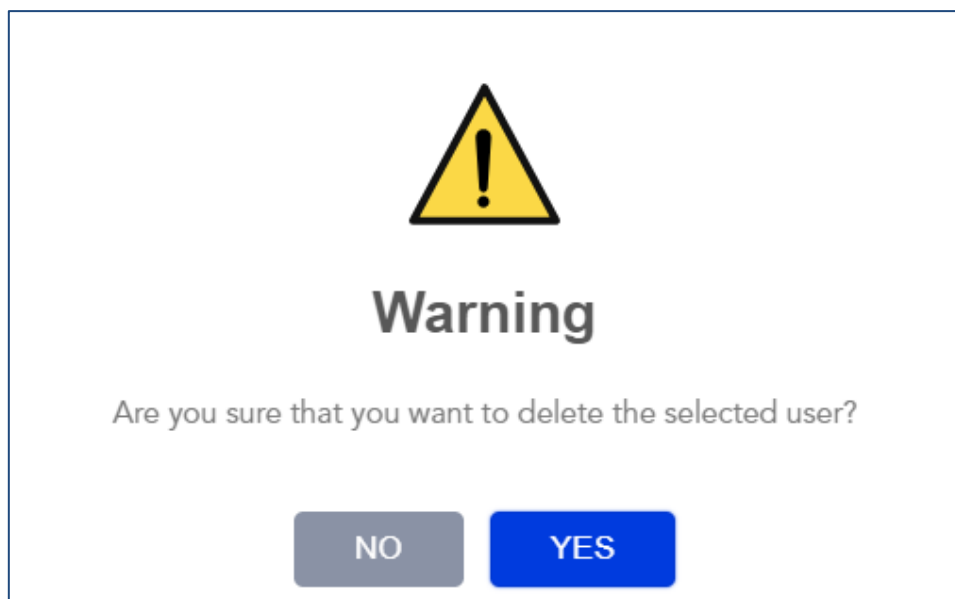
Only an Administrator may edit a User’s email address. A Clinician may edit their own email address but does not have authority to change another User’s email address.

6.3.3.3 Delete User

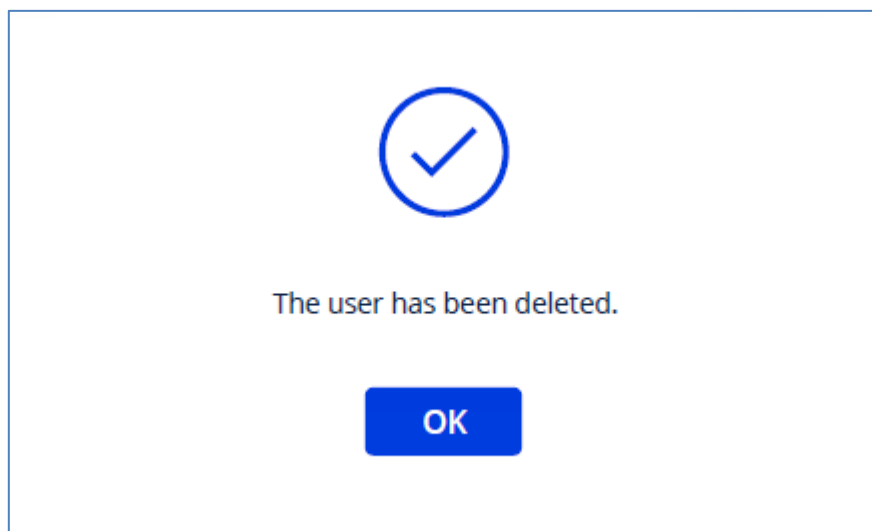


To delete a User, on the “User List” Administrator home page, select the box next to the User to be deleted and click **Delete User** tab.

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



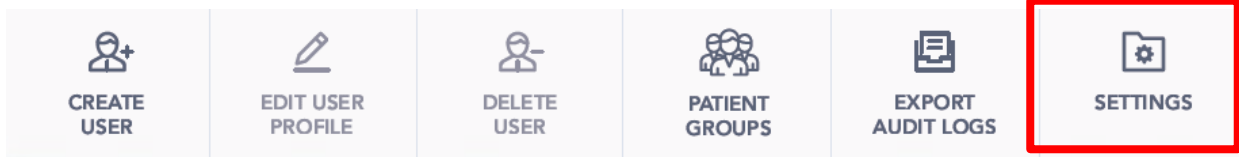
MySOZO confirms deletion of the User. Click **OK**.



6.3.3.4 Restore User

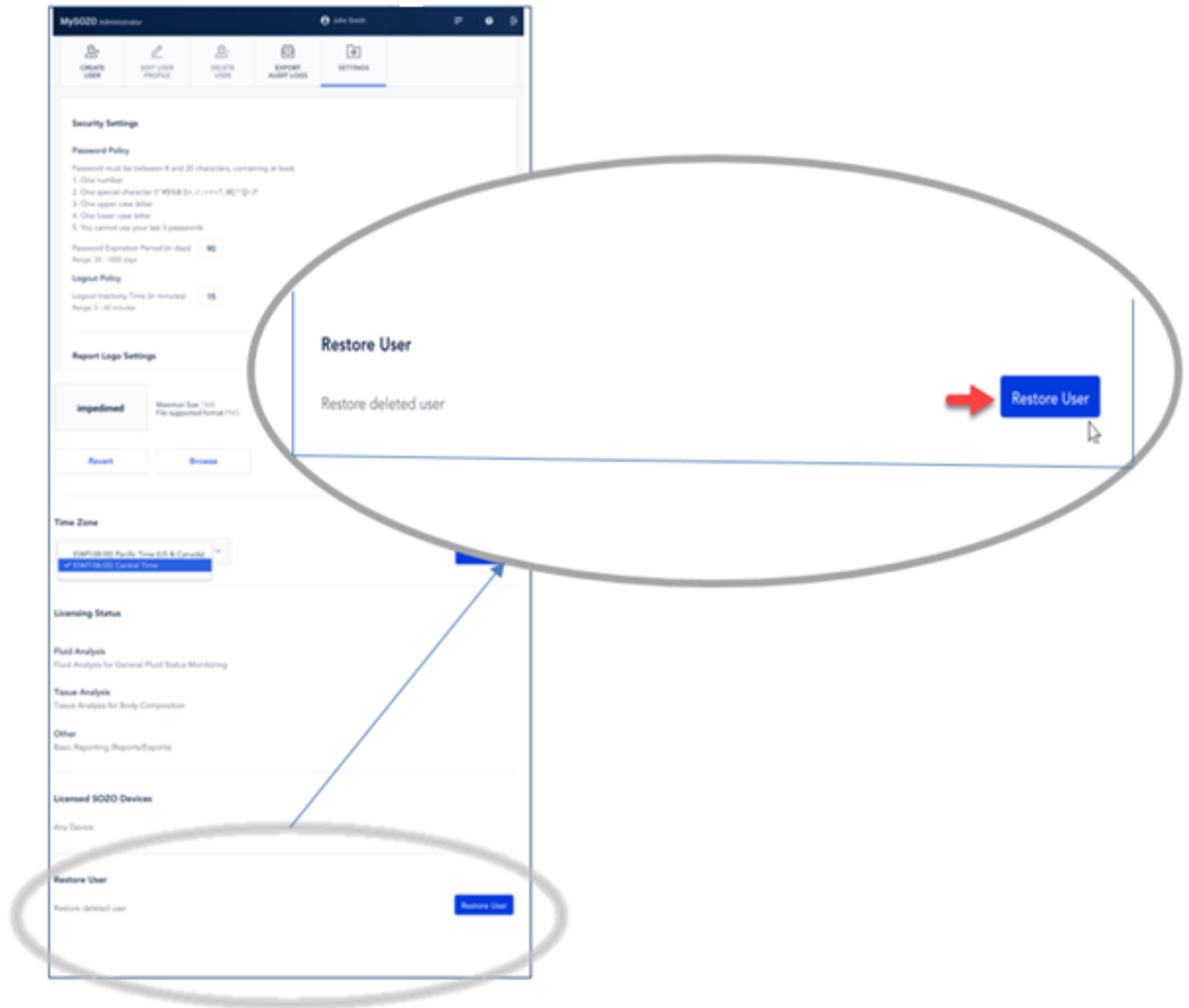
MySOZO stores deleted User accounts. If a User is accidentally deleted, the User may be restored. To restore a deleted User:

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

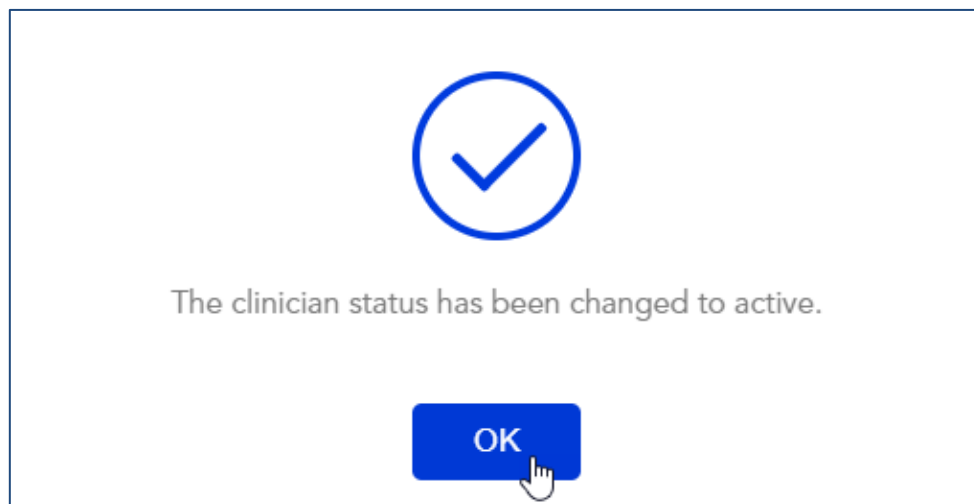
Under “Deleted Users” screen, select the User to restore and click **Restore**.

MySOZO Administrator				Test Admin			
Deleted Users				Search User...			
Last Name	First Name	Middle Name	Phone Number	Email Address	User Role		
Jones	Mary			mary.jones@email.com	Clinician	Restore	

Click **Yes** on Warning.



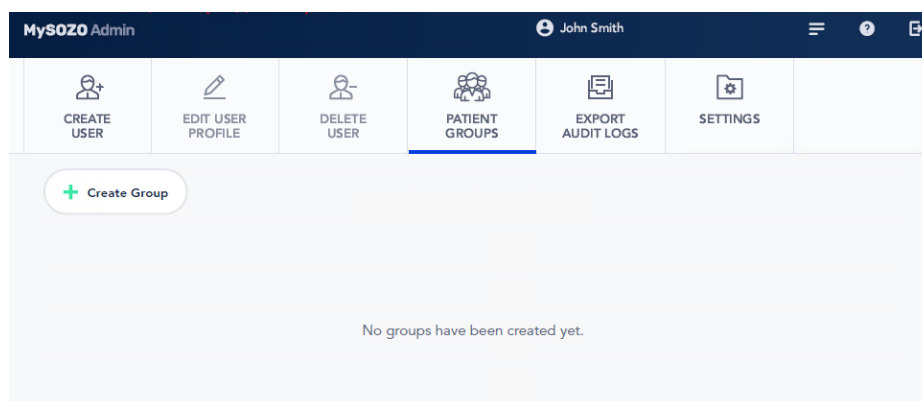
MySOZO confirms that the user status has been changed to active. Click **OK**.



6.3.3.5 Patient Groups

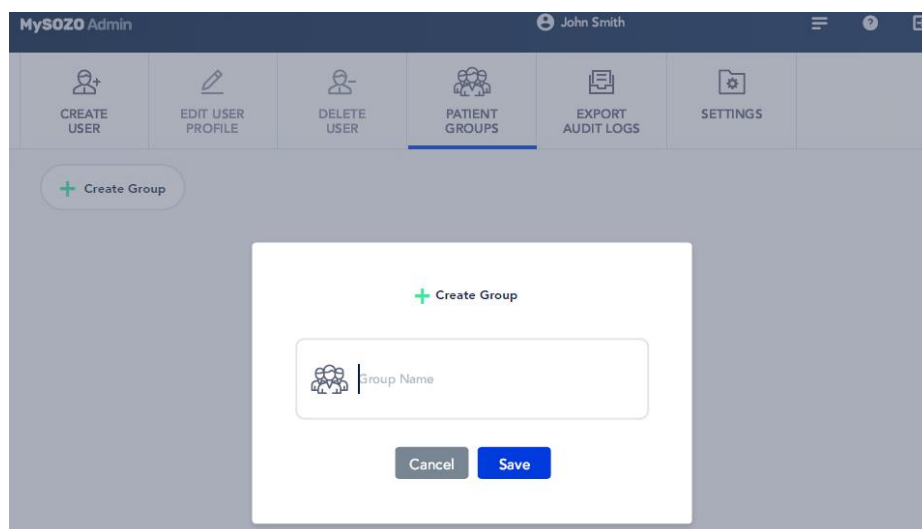


Version 3.1.0 of MySOZO allows an Administrator to create Groups of patients. Individuals with Administrator access may create and name Groups for use in the facility. To manage Patient Groups, click the Patient Groups tab to bring up the following screen:



6.3.3.5.1: Create Group

Clicking Create Group will bring up the following pop-up:

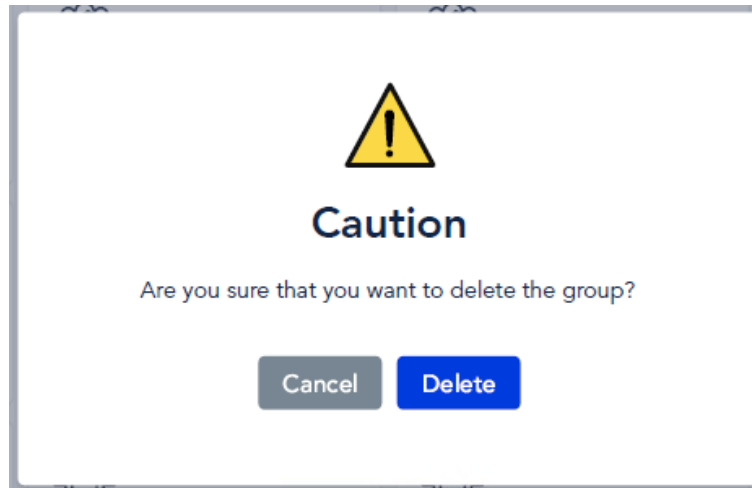


6.3.3.5.2: Rename/Delete Group

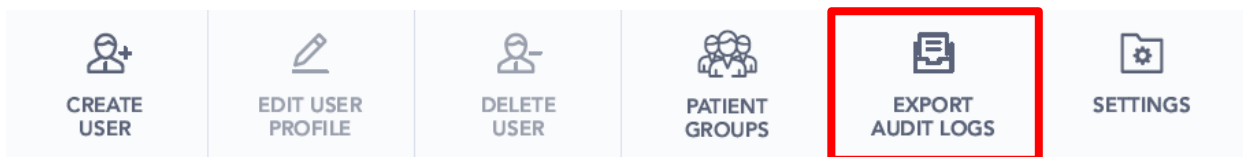
If a Group needs to be renamed or deleted, this can be performed in the Patient Groups tab. Each Group has a pen symbol (denoting 'rename') and a trash can symbol (denoting 'delete') as follows:



Deleting the Group will result in the following pop-up which to confirm the deletion:

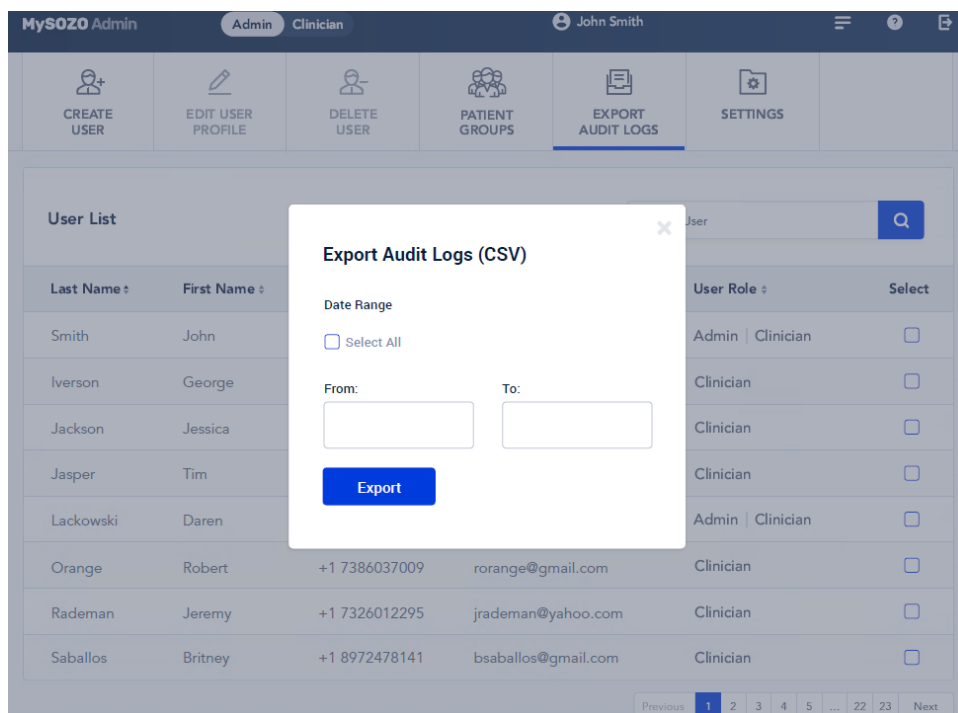


6.3.3.6 Export Audit Logs

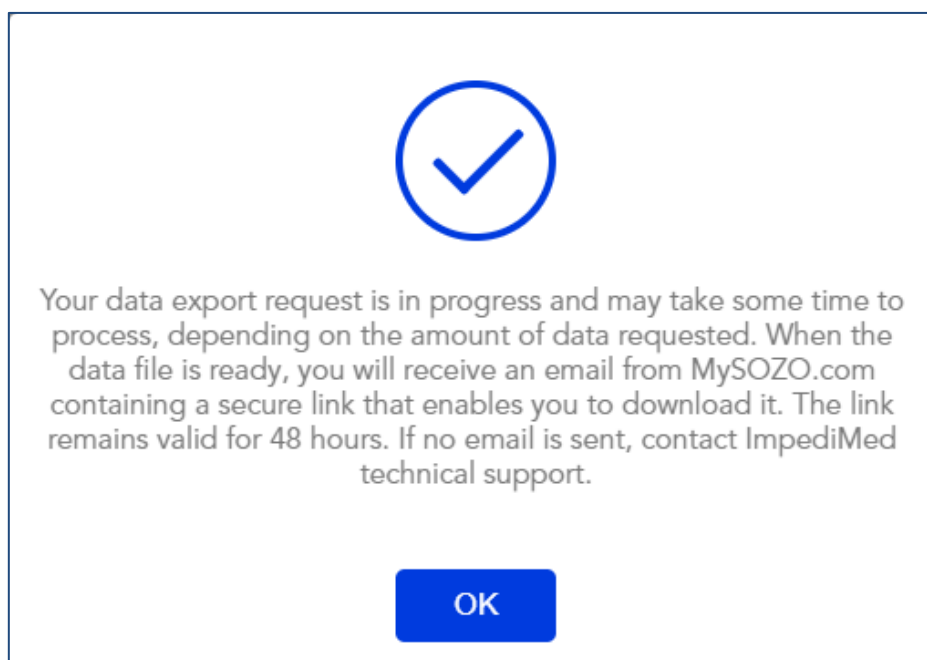


An Administrator may need to review audit logs to assist in an audit or investigation. Audit logs may be exported directly from MySOZO. Audit logs include identity of Users who have viewed certain MySOZO pages or information, identity of Users who have retrieved data, and Users' log in and log out dates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

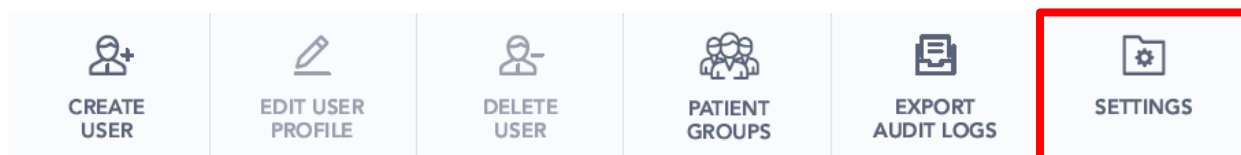
Enter the date range in the "Export Audit Logs (CSV)" pop-up and click **Export**.



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.



6.3.3.7 Settings



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

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 licenses. When finished, click **Save**.

MySOZO Admin John Smith

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

Security Settings

Password Policy

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 Expiration Period (in days) **90**
Range: 30 - 1000 days

Logout Policy

Logout Inactivity Time (in minutes) **15**
Range: 5 - 60 minutes

Save

6.4 MySOZO Clinician

A MySOZO user with a role of Clinician has authority to manage patient profiles, add or remove patients from Groups, view / take patient measurements, and export data or reports.

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 shows the MySOZO Clinician interface. At the top, there's a header with 'MySOZO Clinician', 'Admin' and 'Clinician' tabs, and a user profile for 'John Smith'. Below the header is a navigation bar with icons and labels for 'PATIENT DASHBOARD', 'CREATE PATIENT', 'DELETE PATIENT', 'PATIENT GROUPS', 'EXPORT', 'REPORT', and 'SETTINGS'. The main content area is titled 'Patient List' and features a search bar labeled 'Search Patient' with 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, there is a pagination control showing 'Previous', '1', '2', '3', '4', '5', '...', '22', '23', and 'Next'.

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.

This screenshot is similar to the previous one, showing the MySOZO Clinician interface. The 'Search Patient' field and the magnifying glass search icon are highlighted with a red rectangular box to draw attention to them.

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. If an Administrator also has Clinician rights, they can toggle between Administrator and Clinician screens by clicking the 'Admin' or 'Clinician' toggle. (Compare with icon designating log in of an Administrator in MySOZO Administrator [Section 6.3.2.1 Logged in Status](#)).

6.4.3.2 Clinician User Profile Icon



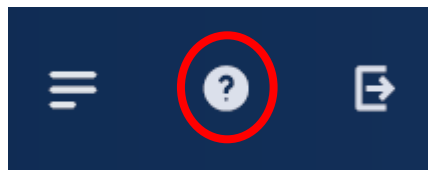
The **User Profile** icon allows the Clinician to edit their profile.

6.4.3.3 Patient List Icon



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

6.4.3.4 Help (Question Mark) Icon



Click the question mark icon for help.

6.4.3.5 Log Out Icon



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

6.4.4 Clinician Main Menu

 PATIENT DASHBOARD	 CREATE PATIENT	 DELETE PATIENT	 PATIENT GROUPS	 EXPORT	 REPORT	 SETTINGS
---	--	--	--	--	---	---


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

6.4.4.1 Patient Dashboard

 PATIENT DASHBOARD	 CREATE PATIENT	 DELETE PATIENT	 PATIENT GROUPS	 EXPORT	 REPORT	 SETTINGS
---	--	--	--	--	---	---

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	 PATIENT GROUPS	 EXPORT	 REPORT	 SETTINGS
---	--	--	--	--	---	---

Patient List						
					Search Patient	
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"/>

Click **Patient Dashboard** tab. The "Patient Details" screen appears.

MySOZO Clinician John Smith

PATIENT DASHBOARD HISTORY RESULTS EDIT PROFILE

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 Lymphedema
- ✓ HF-Dex for Heart Failure
- ✓ Fluid Analysis for ESRD
- ✓ 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 PATIENT GROUPS EXPORT REPORT SETTINGS

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

MySOZO Clinician John Smith

PATIENT DASHBOARD **CREATE PATIENT** DELETE PATIENT PATIENT GROUPS EXPORT REPORT SETTINGS

Patient Details

First Name Required	Country Code
<input type="text"/>	<input type="text"/>
Middle Name	Phone Number
<input type="text"/>	<input type="text"/>
Last Name Required	Address
<input type="text"/>	<input type="text"/>
Email Address Required	City
<input type="text"/>	<input type="text"/>
<input type="checkbox"/> Not Provided	State
Medical Record Number (MRN) Required	<input type="text"/>
<input type="text"/>	Country
	<input type="text"/>

The Clinician must enter first name, last name, Medical Record Number (“MRN”), date of birth, sex and height. The MRN must be unique to each patient in your database.



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 “Lymphedema Settings.”

Assessment Type

- ☐ L-Dex Analysis for Lymphedema
- ☐ HF-Dex for Heart Failure or ☐ Fluid Analysis for General Fluid Status Monitoring
- ☐ Fluid Analysis for ESRD
- ☐ Tissue Analysis for Body Composition

Lymphedema Settings

Required

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

Also, the clinician may optionally assign the patient to a predefined ‘group’. If grouping has been set up in your facility (only available with SOZOapp v3.1.0 or later), a list of available groups will appear at the end of patient setup. Check the box for each group the patient is to be assigned to.

Patient Groups

- | | | | |
|-------------------------------------|-------------------------------------|-------------------------------------|-------------------------------------|
| <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name |
| <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name |
| <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name | <input type="checkbox"/> Group Name |

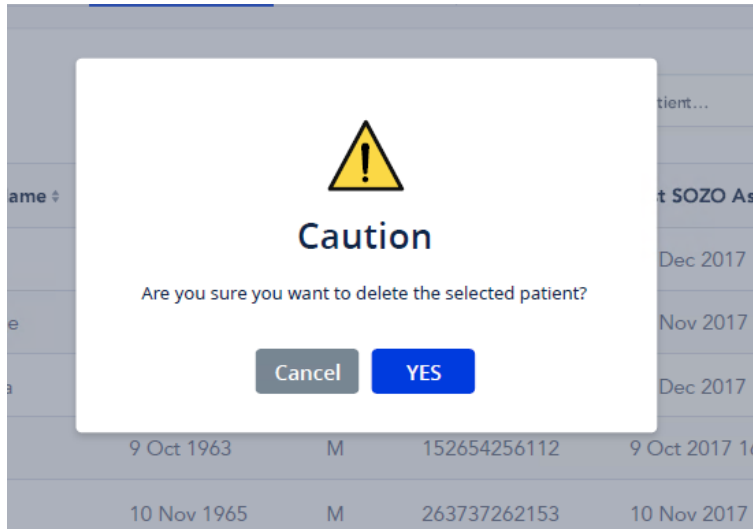
Create Patient

When done, click **Create Patient**.

6.4.4.3 Delete Patient



To delete a patient, first select the patient from the “Patient List” and click the ‘Delete Patient’ icon. 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 at a later date. 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**

Restore Patient

Restore deleted patient

Restore

Note that if the deleted patient shares details with other patients in the facilities’ MySOZO database, alerts will pop up alerting

6.4.4.5 Merge Patient

In the event that more than one profile has been created for a patient, all data may be merged under one patient profile.

To merge two profiles, click **Settings** tab on the Clinician Main Menu from within MySOZO.com.



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

Merge Patients

Merge active patients

Merge

Note that during merging, the source patient's measurements will be added to the destination patient and the source patient will be deleted. All results will be recalculated based on the destination patient's profile. This change is permanent and not reversible.

Clicking on 'Merge' will bring up the following screen:

The screenshot displays the 'Merge Patients' interface. At the top left, the title 'Merge Patients' is followed by an information icon. Below the title, there are two main columns: 'Source Patient' on the left and 'Destination Patient' on the right. Each column has a search bar at the top with the placeholder text 'Search Patient' and a magnifying glass icon. Between the two columns, there is a central area containing a document icon with a right-pointing arrow and a 'Preview' button. The 'Source Patient' and 'Destination Patient' columns are currently empty, indicating no patients have been selected for merging.

Search for the redundant patient's profile in the Source column, and select the appropriate patient. Repeat the search for the destination patient's profile in the Destination column, and

select the appropriate patient. Click on 'Preview' to continue to the next screen.

Merge Patients ⓘ

Anderson

Q

Source Patient

First Name	David
Last Name	Anderson
Email Address	danderson@gmail.com
MRN	254366577387276 ⓘ
Date of Birth	28 June 1966
Sex	Male
Height	188 cm

Assessment Type

Lymphedema Settings

Groups

Assessment

☐ Unilateral ☐ Bilateral

Body Element

☐ Arm ☐ Leg

Risk Limb

☐ Left ☐ Right

Limb Dominance

☐ Left ☐ Right

Anderson

Q

Destination Patient

Assessment Type

Lymphedema Settings

Groups

☒ Group A

☒ Group B

☒ Group C

☒ Group D

Confirm Merge

Cancel

Verify that the source and destination patients are correct. Click 'Confirm Merge' if correct, otherwise click 'Cancel' to go back to the prior screen. One final popup alerts the user that the change is not reversible,



Caution

Are you sure that you want to merge the selected patients?

This change will be permanent and not reversible.

Cancel

Merge

After clicking 'Merge', the Source patient will be deleted, all their measurement data will be integrated with the Destination patient. The additional data will be recalculated based on the Destination patient profile.

6.4.4.6 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 Clinician interface. On the left is a 'Patient List' table with columns for 'Last Name' and 'First Name', listing patients like Smith, Iverson, Jackson, etc. On the right is a table for 'SOZO Assessment' with columns for date, time, and a checkbox. Overlaid on top is the 'Export Settings' pop-up. This pop-up has sections for 'USER DATA TO EXPORT' (radio buttons for Selected Patients, All Patients, Groups), 'PATIENT GROUPS' (a dropdown menu), 'ASSESSMENT TYPE' (checkboxes for L-Dex, HF-Dex, ESRD, Fluid Analysis, Tissue Analysis, Hy-Dex, and Report Summary), 'DATE RANGE' (a 'Select All' checkbox and 'From'/'To' date pickers), 'DATA FORMAT' (radio buttons for Row per patient and Row per measurement), and 'ADDITIONAL SETTINGS' (checkboxes for Show De-identified Patient ID, Show Patient Identifying Details, Show Additional Patient Details, Show Device/Measurement Info, and Show Group Details). At the bottom of the pop-up are 'Cancel' and 'Export' buttons.

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



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 received, contact ImpediMed technical support.

OK

6.4.4.7 Patient Report:



A Clinician may create a patient report from MySOZO in the form of a PDF, 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**. The history graphs available to be printed will depend on the assessment types that have been chosen for the patient.

Report Settings

ASSESSMENT TYPE

☒ L-Dex ☐ Fluid Analysis

☐ HF-Dex ☐ Tissue Analysis

☐ ESRD

HISTORY GRAPHS

☐ L-Dex ☐ FM

☐ HF-Dex ☐ FM % of Weight

☐ TBW ☐ SMM

☐ TBW % of Weight ☐ SMM % of Weight

☐ ECF ☐ Protein & Minerals

☐ ECF % of TBW ☐ Protein & Minerals % of Weight

☐ ECF, TBW, Weight ☐ Phase Angle

☐ ICF ☐ BMR

☐ ICF % of TBW ☐ BMI

☐ Hy-Dex ☐ Weight

☐ FFM

☐ FFM % of Weight

DATE RANGE

☐ Select All From: To:

Cancel **Create Report**

6.4.4.8 Settings



Under the **Settings** tab, the Clinician may restore a deleted patient ([Section 6.4.4.4 Restore Patient](#)), merge multiple patient profiles ([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, centimeters or inches, and liters or pints. When finished, click **Save**.

MySOZO Clinician John Smith

PATIENT DASHBOARD CREATE PATIENT DELETE PATIENT PATIENT GROUPS EXPORT REPORT **SETTINGS**

Measurement Units

kg ☒ lbs cm ☒ ft in liters ☒ pints **Save**

Licensing Status

L-Dex
L-Dex for Unilateral Lymphedema
L-Dex for Bilateral Lymphedema

HF-Dex
HF-Dex for Heart Failure

ESRD
Fluid Analysis for ESRD

Fluid Analysis
Fluid Analysis for General Fluid Status Monitoring

Tissue Analysis
Tissue Analysis for Body Composition

Other
Basic Reporting (Reports/Exports)

Licensed SOZO Devices
Any Device

Software Information ●
MySOZO version 3.0.1
New software update is available.
[Release Notes](#)

Time Zone
(GMT-06:00) Central Time

Restore Patient **Restore**
Restore deleted patient

Merge Patients **Merge**
Merge active patients

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.

MySOZO Clinician John Smith

PATIENT DASHBOARD HISTORY RESULTS EDIT PROFILE

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

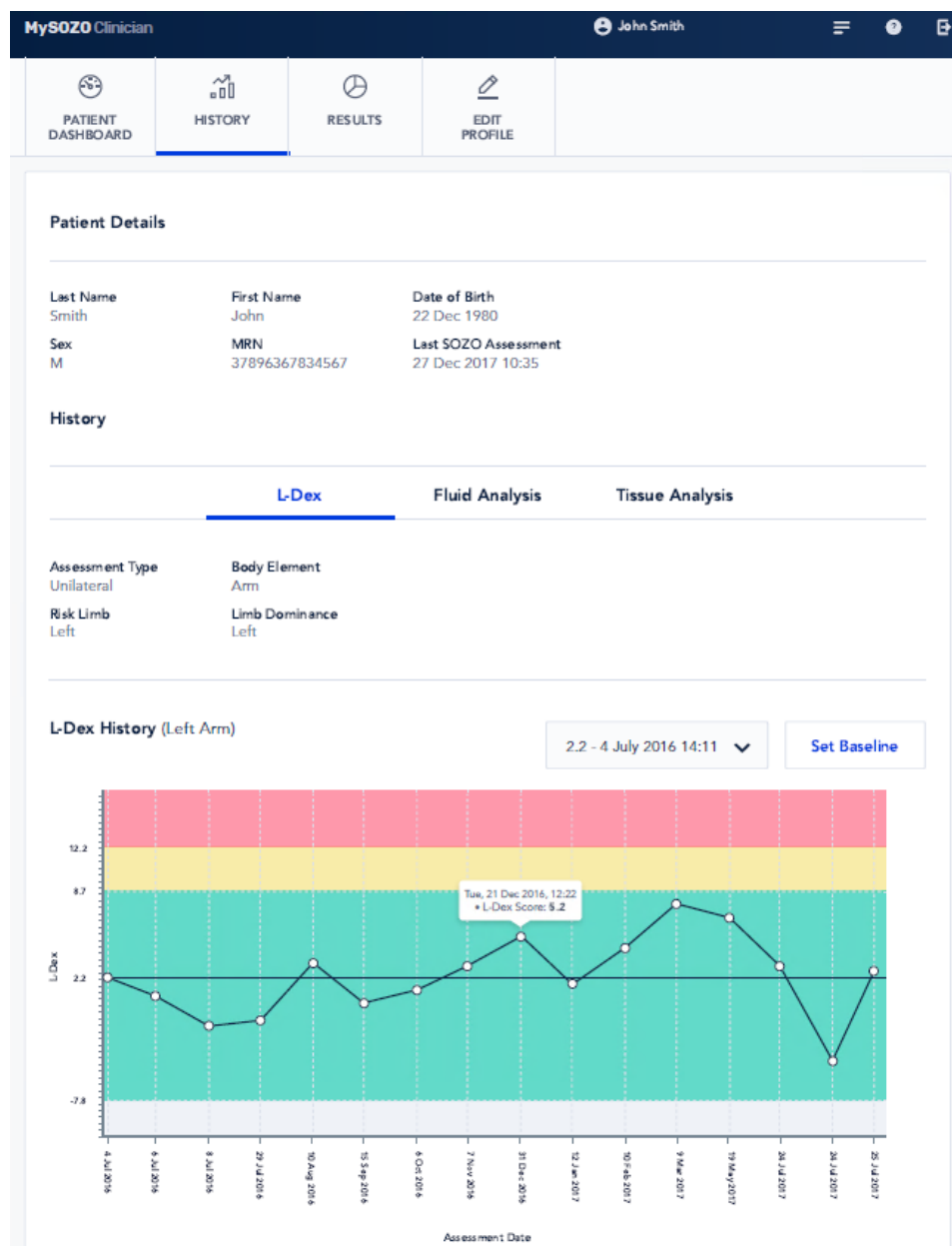
Assessment Type

- ✓ L-Dex Analysis for Lymphedema
- ✓ HF-Dex for Heart Failure
- ✓ Fluid Analysis for ESRD
- ✓ Tissue Analysis for Body Composition

6.4.5.2 Measurement History

PATIENT DASHBOARD HISTORY RESULTS EDIT PROFILE

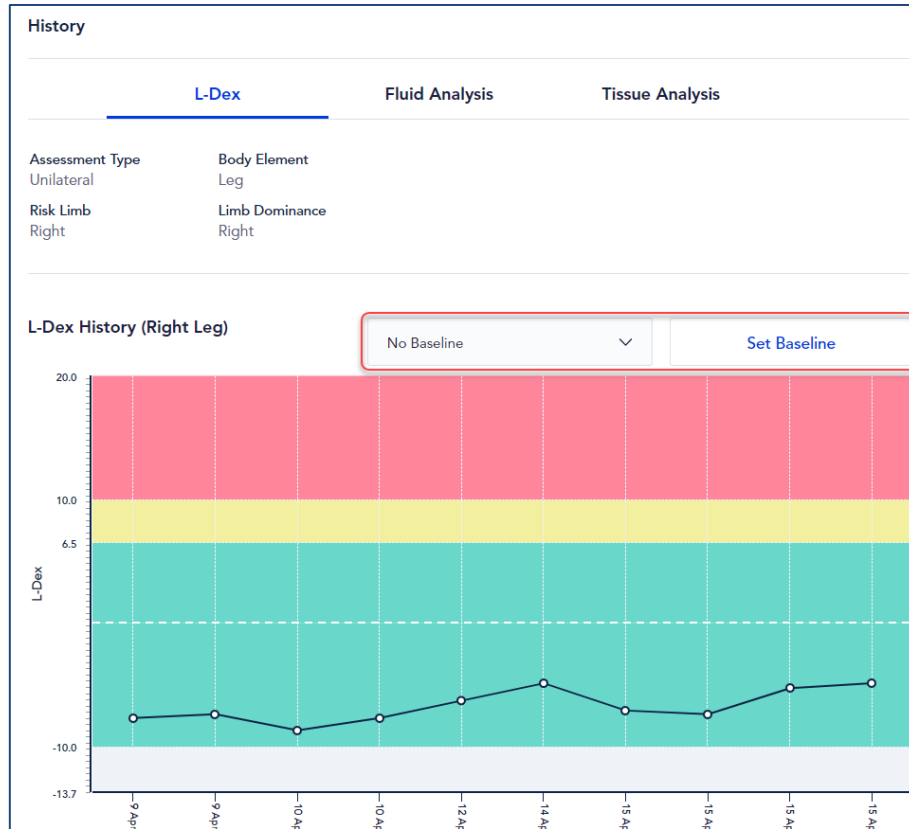
History displays graphs of patient measurements taken over time. Click the **History** tab to see “Patient Details.” Beneath “History” is a list of Assessments. Click each Assessment to view a graph of the history of patient measurements. A blue line shows which Assessment was selected.



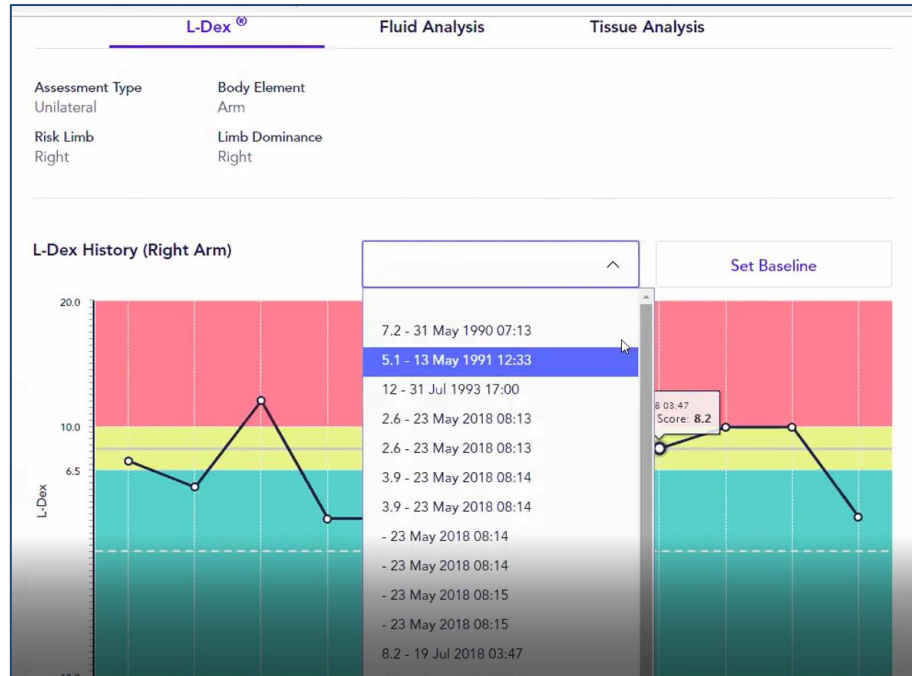
Only the measurement history of licensed Assessments appears in **History**.

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 the **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.

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

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



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



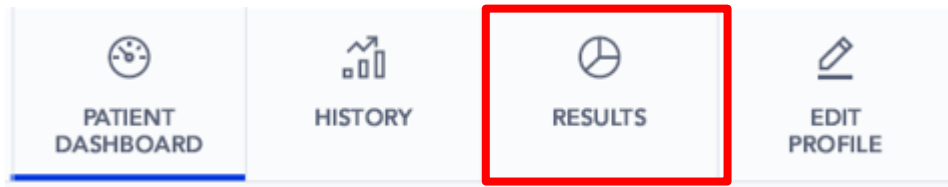
6.4.5.2.3.2 Example of Fluid Analysis History



6.4.5.2.3.3 Example of Tissue Analysis History



6.4.5.3 Measurement Results Viewable by Clinician in MySOZO



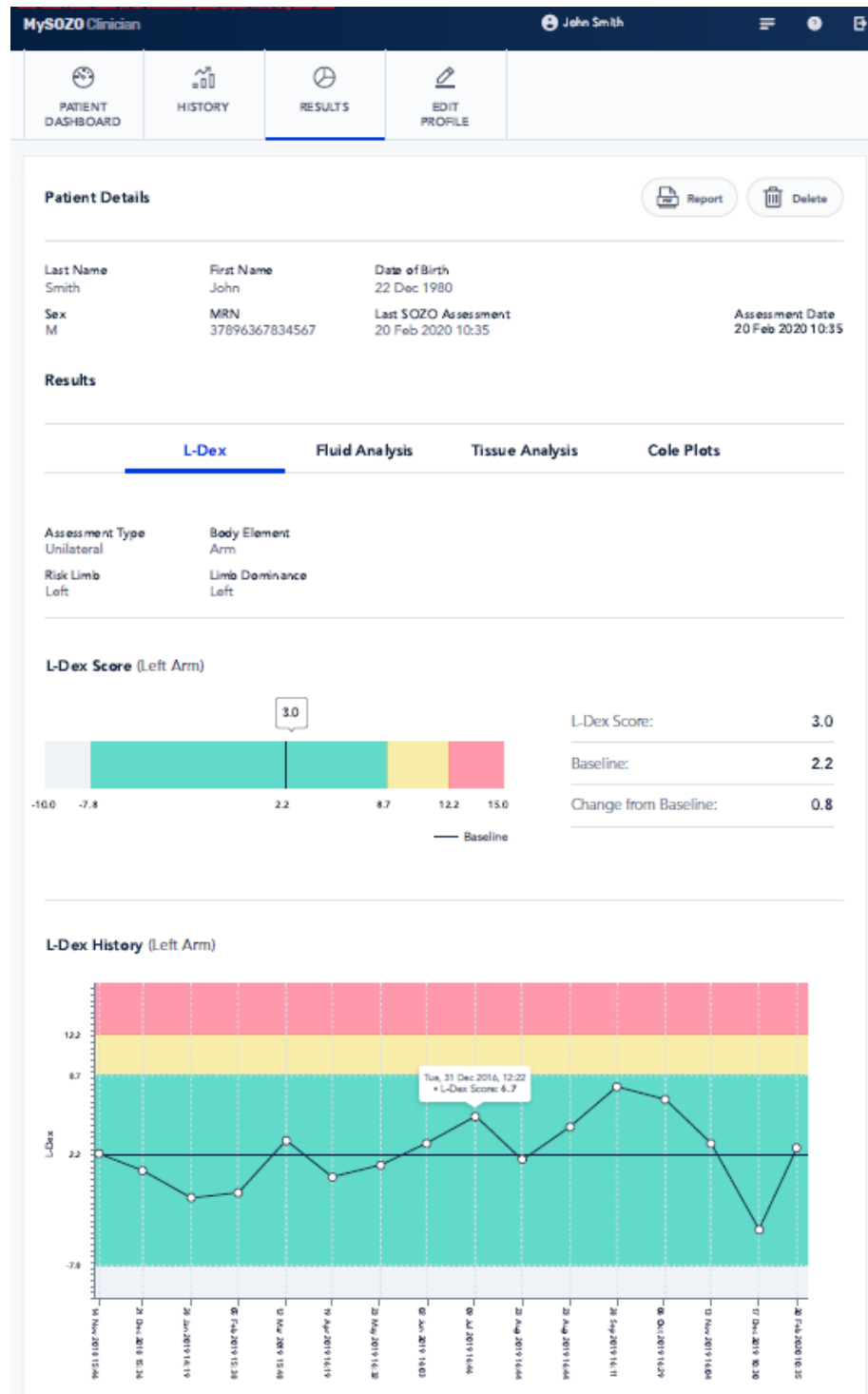
Click **Results** tab. “Patient Details” has identifying patient information and a list of measurement dates.

MySOZO Clinician John Smith

PATIENT DASHBOARD	HISTORY	RESULTS	EDIT PROFILE
Patient Details			
Last Name Smith	First Name John	Date of Birth 22 Dec 1980	
Sex M	MRN 37896367834567	Last SOZO Assessment 13 Apr 2017 12:35	
Select Measurement Date			
27 Dec 2017 10:29			
28 Dec 2017 10:15			
29 Dec 2017 09:35			
30 Dec 2017 18:23			
4 Jan 2018 12:11			
7 Jan 2017 17:45			

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 L-Dex Example



6.4.5.3.2 Fluid Analysis Example

MySOZO Clinician
John Smith

PATIENT DASHBOARD

HISTORY

RESULTS

EDIT PROFILE

Report

Delete

Patient Details

Last Name

Smith

First Name

John

Date of Birth

22 Dec 1980

Sex

M

MRN

37896367834567

Last SOZO Assessment

20 Feb 2020 10:35

Assessment Date

20 Feb 2020 10:35

Results

L-Dex

Fluid Analysis

Tissue Analysis

Cole Plots

Total Body Water (TBW)

Total Body Water

41.0 Liters

50% of Weight

Fluid Distribution

Extracellular Fluid (ECF)

15.5 Liters

Intracellular Fluid (ICF)

21.4 Liters

TBW

42.0%

% of TBW

58.0%

Extracellular Fluid (ECF):

42.0%

Intracellular Fluid (ICF):

58.0%

Hy-Dex Analysis

Less Hydrated

More Hydrated

31.4

Current:

31.4

Change from previous:

-

Change from Baseline:

-

-100

-75

-50

-25

0

25

50

75

100

-4 SD

-3 SD

-2 SD

-1 SD

mean

+1 SD

+2 SD

+3 SD

+4 SD

Hy-Dex is a bi-directional scale that displays a person's fluid status as compared to a dataset from an average population. Hy-Dex is only intended for use with healthy patients and should not be used to diagnose or treat a medical condition.

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6.4.5.3.3 Tissue Analysis Example

MySOZO Clinician

John Smith

PATIENT DASHBOARD

HISTORY

RESULTS

EDIT PROFILE

Report

Delete

Patient Details

Last Name
Smith

First Name
John

Date of Birth
22 Dec 1980

Sex
M

MIDN
37896367834567

Last SOZO Assessment
20 Feb 2020 10:35

Assessment Date
20 Feb 2020 10:35

Results

L-Dex

Fluid Analysis

Tissue Analysis

Cole Plots

Tissue Analysis

Fat Free Mass (FFM)

53.0 kg

66% of Weight

Fat Mass (FM)

32.0 kg

33% of Weight

Skeletal Muscle Mass (SMM)

29.3 kg

24.8% of Weight

Weight

• Total Body Water (TBW):

36.9 Liters

• Protein & Mineral:

13.5 kg

• Fat Mass:

34.6 kg

Metabolic Report

Basal Metabolic Rate (BMR)

1465.3 cal/day

Active Tissue Mass (ATM)

27.6 kg

Extracellular Mass (ECM)

22.8 kg

Weight

• Fat Mass (FM):

27.2%

• Active Tissue Mass (ATM):

36.1%

• Extracellular Mass (ECM):

36.7%

Note: ATM + ECM = FFM

Other

Phase Angle

5.3°

Body Mass Index (BMI)

24.0 kg/m²

Weight

80.2 kg

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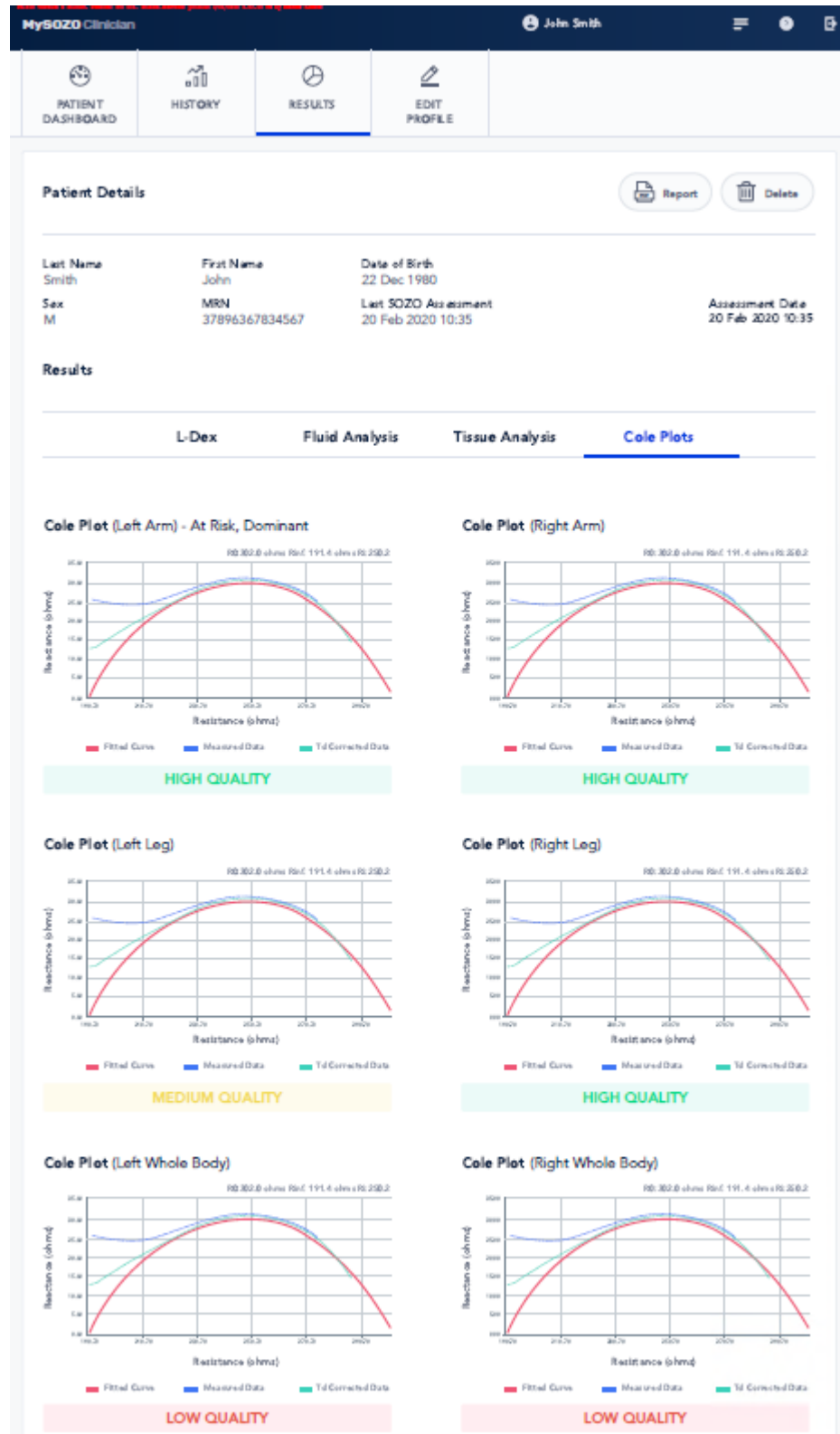
Assessment-specific charts, such as a weight breakdown chart for Tissue Analysis, may be displayed, as shown below.

6.4.5.3.3.1 Weight Breakdown Chart in Tissue Analysis



6.4.5.3.4 Cole Plots Example

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

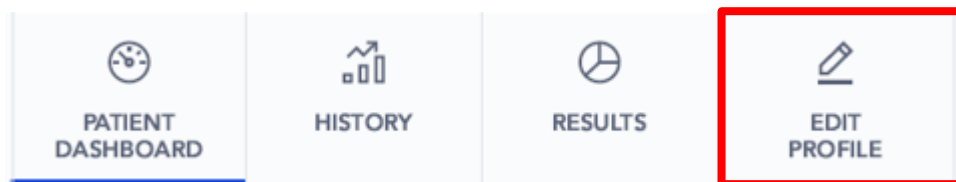


For more about reviewing Cole plots in the SOZOapp, see [Section 8.6.2.4 Reviewing Cole Plots After Measurement](#).



If the Right Whole Body Cole plot is low quality, measurements for the HF-Dex assessment type will not be displayed.

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 Clinician
John Smith

PATIENT DASHBOARD
HISTORY
RESULTS
EDIT PROFILE

Patient Details

First Name Required <input type="text" value="John"/>	Country Code <input type="text" value="United States (+1)"/>
Middle Name <input type="text" value="George"/>	Phone Number <input type="text" value="6932197540"/>
Last Name Required <input type="text" value="Smith"/>	Address <input type="text" value="5900 Pasteur Ct."/>
Email Address Required <input type="text" value="jsmith@impedimed.com"/>	City <input type="text" value="Carlsbad"/>
<input type="checkbox"/> Not Provided	State <input type="text" value="California"/>
Medical Record Number (MRN) Required <input type="text" value="366736228734"/>	Country <input type="text" value="United States"/>
Date of Birth Required <input type="text" value="22 Dec 1980"/>	Postal Code <input type="text" value="CA 90210"/>
Sex Required <input type="text" value="Male"/>	
Height (cm) Required <input type="text" value="192"/>	

Assessment Type

☒ L-Dex Analysis for Lymphedema
 ☒ HF-Dex for Heart Failure
 or
 ☐ Fluid Analysis for General Fluid Status Monitoring
 ☐ Fluid Analysis for ESRD
 ☐ Tissue Analysis for Body Composition

Lymphedema Settings Required

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

Patient Groups

<input checked="" type="checkbox"/> Group Name	<input checked="" type="checkbox"/> Group Name	<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name
<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name
<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name	<input type="checkbox"/> Group Name

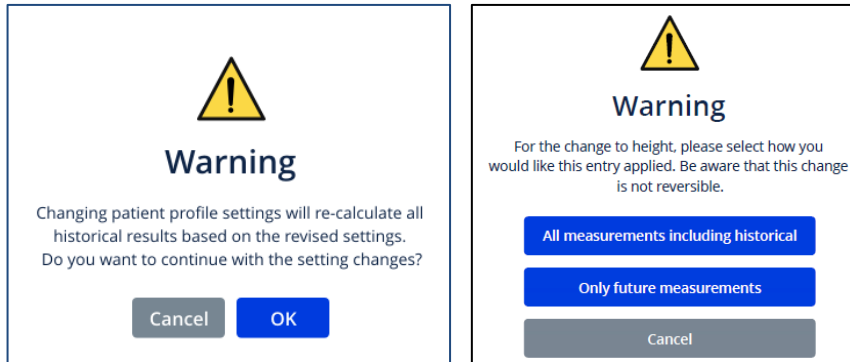
Save Changes

6.4.5.4.1 Patient Weight May Not Be Modified

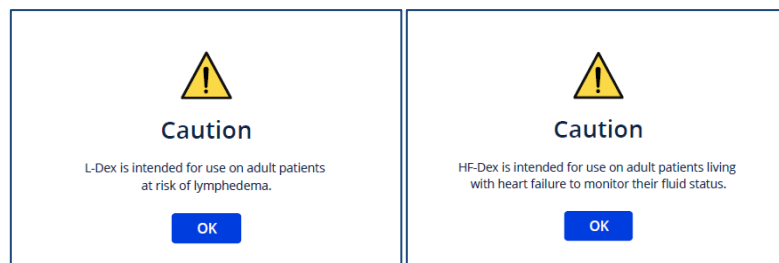
Weight is important for measurement accuracy. [See Section 8.6.2.2.2 Entering Weight](#). The Clinician enters the patient weight at the time of measurement, which is valid for that measurement only. After measurement, weight may not be modified.

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 SOZO software version 3.1.0 and later, adding a new Assessment to the patient profile triggers a Caution about the intended use of that Assessment. Read and make sure that you understand the instructions for use for: L-Dex in the L-Dex Assessment User Guide; HF-Dex in the HF-Dex User Guide; ESRD in the ESRD User Guide. Similar warnings are presented in 3.0.1 software.



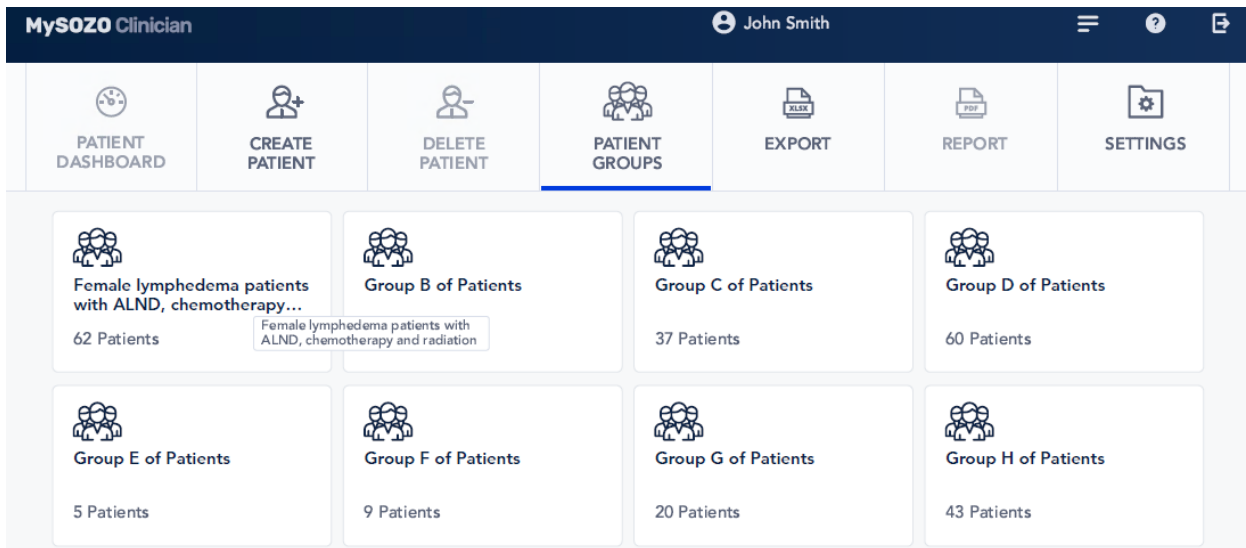
For more about Assessments, see [Section 9.0 Assessments](#).

6.4.6 Patient Groups

In MySOZO version 3.1.0 and later, patients can be assigned to predefined groups within your SOZO database. Administrator access is required to manage group creation. Clinician access is required to add and remove patients from groups. Note that the full set of patient grouping functions are only available through MySOZO, not SOZOapp.

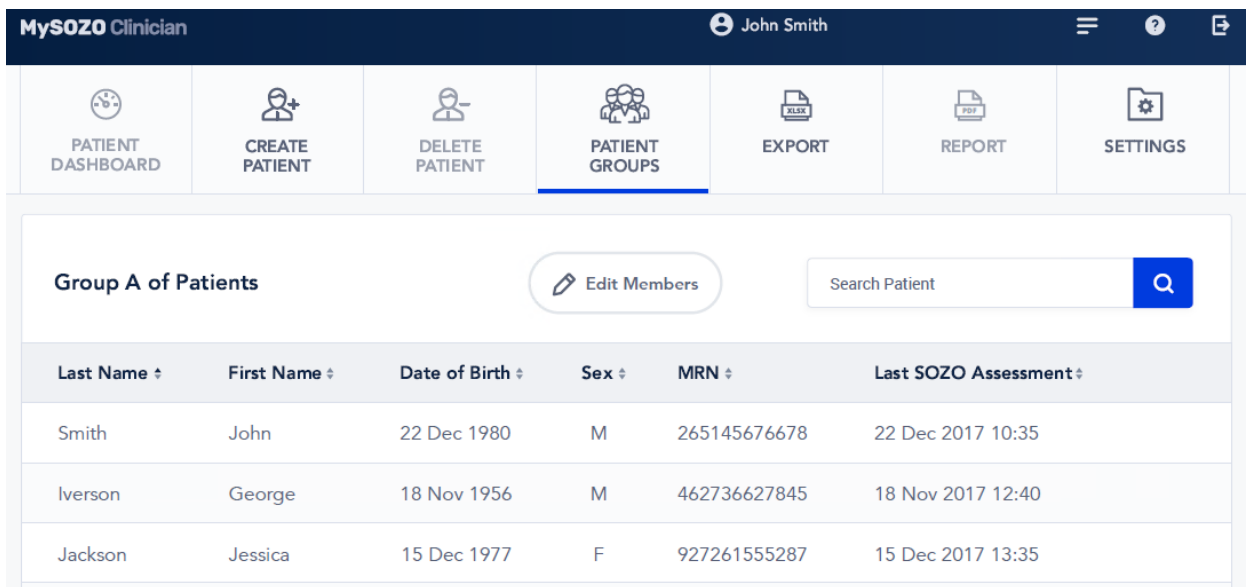


To access grouping features, click the Patient Groups tab. This will bring up all currently available groups within your facility:



Note that if the Patient Groups tab is empty, only individuals with Administrator permissions can create or name them.

Clicking on one of the groups will bring up the list of patients currently assigned to that group:



To modify patients within the group, click on 'Edit Members' to bring up the following screen:

MySOZO Clinician
John Smith

PATIENT DASHBOARD

CREATE PATIENT

DELETE PATIENT

PATIENT GROUPS

EXPORT

REPORT

SETTINGS

Search Patient

Patients

David Anderson
Date of Birth: 28 Jun 1966
Sex: Male
MRN: 254366577387276
Last SOZO Assessment: 28 Jun 2019, 16:00

☐

John Smith
Date of Birth: 28 Jun 1966
Sex: Male
MRN: 254366577380000
Last SOZO Assessment: 25 Feb 2018, 12:05

☐

Steven Anderson
Date of Birth: 25 Jun 1970
Sex: Male
MRN: 465667673877300
Last SOZO Assessment: 28 Feb 2019, 17:56

☐

Matthew Anderson
Date of Birth: 28 Mar 1956
Sex: Male
MRN: 900984766788898

☐

Add →

← Remove

Search Patient

Group: Lymphedema patients with ALND

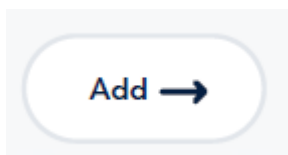
Michael Morrison
Date of Birth: 28 Jun 1966
Sex: Male
MRN: 254366577387276
Last SOZO Assessment: 28 Jun 2019, 16:00

☐

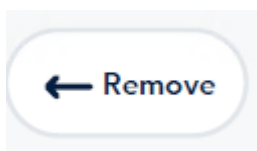
Martin Smith
Date of Birth: 28 Jun 1966
Sex: Male
MRN: 254366577380000
Last SOZO Assessment: 25 Feb 2018, 12:05

☐

Patients can be added to the group by selecting or searching for patients in the left hand column and checking the box next to their profile. Selecting at least one patient will highlight the 'Add' button. Click the 'Add' button to add patients to the group.



Similarly, checking the boxes next to the names in the right hand column will highlight the 'Remove' button to allow removal of patients from a group.



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 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 section 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). [Section 5.0](#) SOZO Device Assembly provides instructions for system configuration for standing and seated positions.



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

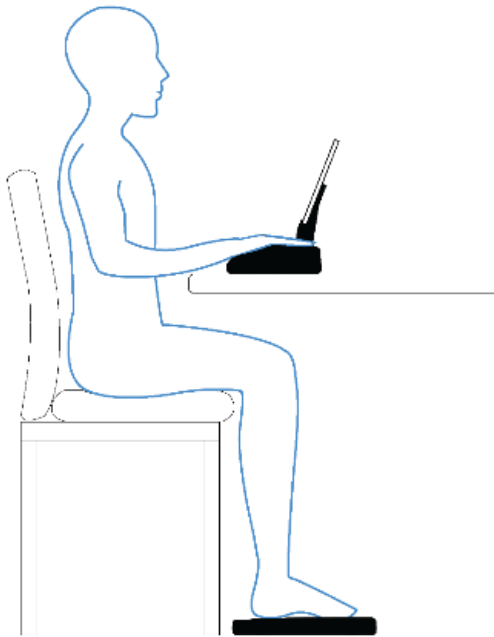
When standing on the SOZO Device, ImpediMed strongly recommends using the SOZOsupport Stand provided with the system.

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®*. On android tablets, once *Bluetooth®* is enabled, the Tablet scans for connection to the SOZO Device and a device may be paired. On iOS tablets, the SOZO Device is paired to the tablet from within the app itself and the available devices will be shown on the home page.

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**.

impedimed®

SOZO Digital Health Platform

Set New Password

Email Address
Johnsmith@gmail.com

Old Password

New Password

Confirm New Password

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**.

SOZOapp

John Doe

Log Out

CREATE PATIENT

PAIR DEVICE

SELF-TEST

SETTINGS

Device name

Select a device

Refresh

Patient List

Search Patient...

Q

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

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

My Profile

Save

User Details

First Name

Required

John

Middle Name

Required

Michael

Last Name

Required

Doe

Email Address

Required

jsmith@impedimed.com

Change Email

Country Code

United States (+1)

Phone Number

760-585-2100

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

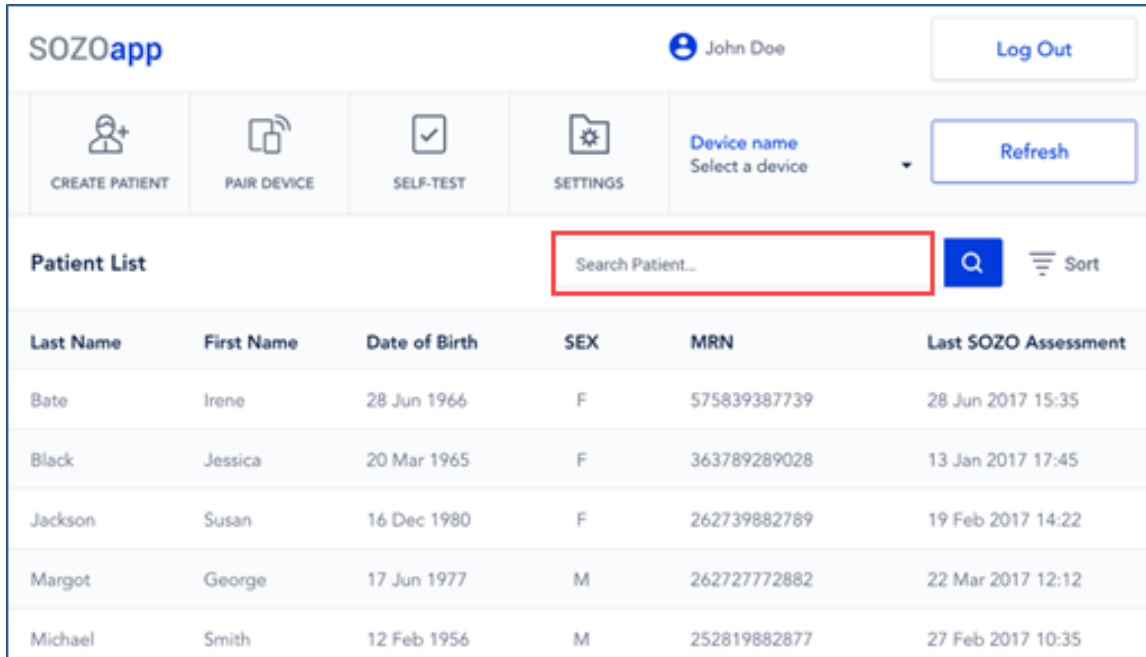
Search Patient...

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

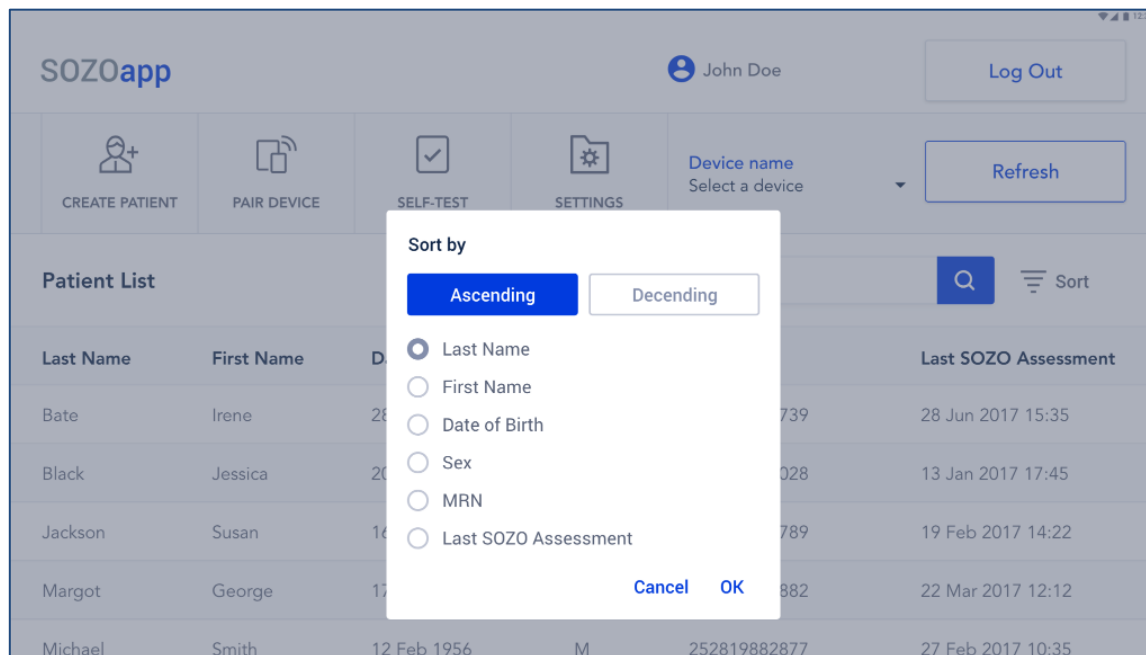
The Clinician may search for a patient in the “Patient List.”



The screenshot shows the SOZOapp interface. At the top, there's a header with the SOZOapp logo, a user profile for John Doe, and a Log Out button. Below the header is a navigation bar with icons for CREATE PATIENT, PAIR DEVICE, SELF-TEST, and SETTINGS. To the right of the navigation bar is a 'Device name' dropdown menu and a Refresh button. The main section is titled 'Patient List' and features a search bar (highlighted with a red box) and a Sort icon. Below the search bar is a table with patient 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

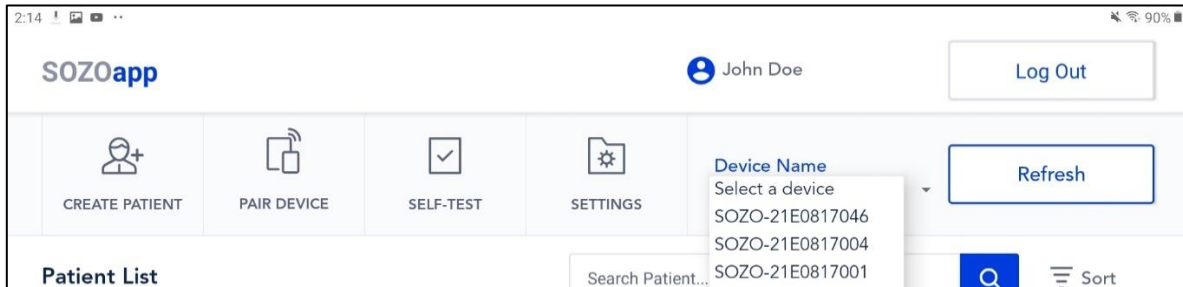
Type the patient's name into **Search Patient** field. A search may be done using the sort feature. Tap the **Sort** icon and select criteria for sorting, which are ascending or descending order, date of birth, sex, MRN or last SOZO Assessment.



The screenshot shows the same SOZOapp interface as before, but with a 'Sort by' dialog box open. The dialog box has two tabs: 'Ascending' (selected) and 'Descending'. Below the tabs are five radio button options: 'Last Name' (selected), 'First Name', 'Date of Birth', 'Sex', and 'MRN'. At the bottom of the dialog are 'Cancel' and 'OK' buttons. The background shows the 'Patient List' table and the 'Sort' icon that was tapped.

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-xxxxxxxx or iOS_SOZO-xxxxxxxx). When pairing with an iOS device such as an iPad, only devices that have identification starting with IOS will be available for connection. When pairing with an Android device such as a Samsung tablet, use the device identification that does not start with IOS. If a device is chosen that starts with IOS, the android SOZOapp will not be able to communicate with the SOZO device. If this occurs, chose a SOZO device with a identification that does not start with IOS or navigate into the Bluetooth settings menu to unpair the SOZO Device.

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. . If using the iOS SOZOapp, the SOZO Device will only be recalled if the SOZO Device is also powered on when the user logs in. 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.

John Doe

Log Out

CREATE PATIENT

PAIR DEVICE

SELF-TEST

SETTINGS

Device name

Select a device

Refresh

Patient List

Search Patient...

Q

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

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

Settings

Help

Get Help

Firmware Update

Update

Measurement Units

kg

lbs

cm

ft in

liters

pints

Save

Licensing Status

View

Software Information

SOZOapp version 3.1.0

Software version is up to date.

Release Notes

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

Update

Time Zone

UTC(-8:00) Pacific Time

Restore Patient

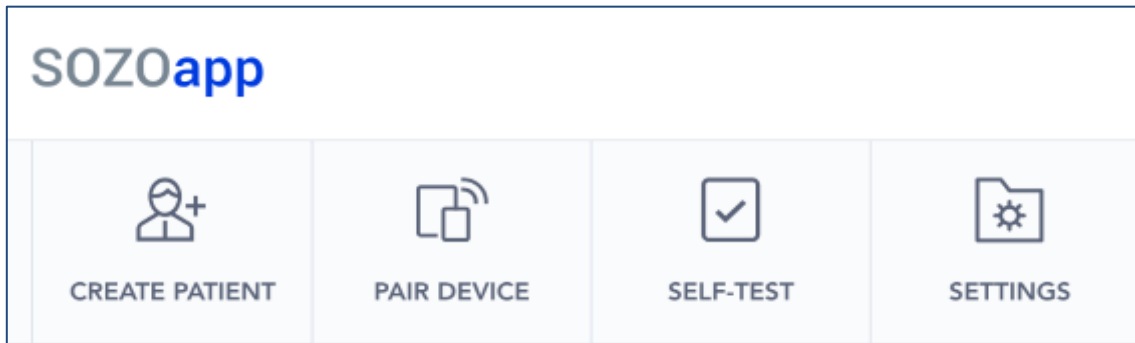
Restore deleted patient

Restore Patient

8.4.1.2 Using the Self-Test to Confirm Device Status

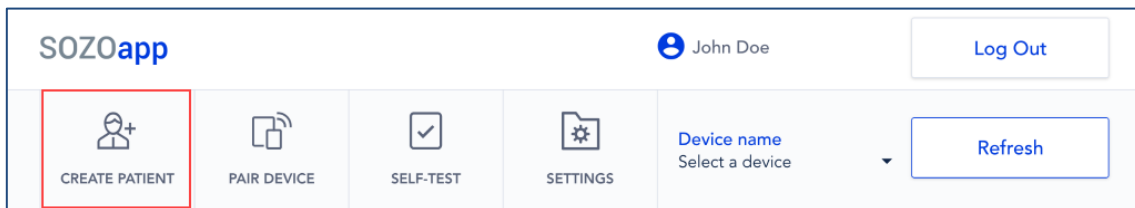
The status of the SOZO Device may also be confirmed by a self-test. To run the self-test, tap the **Self-Test** tab from the SOZOapp Main Menu. If the SOZO Device emits a clicking sound, and the Self-Test is shown as successful, the Device Status is confirmed.

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.

A screenshot of the 'Create Patient' form. The title 'Create Patient' is at the top left, and a 'Create' button is at the top right. The form is titled 'Patient Details' and contains several input fields: 'First Name' (Required), 'Middle Name', 'Last Name' (Required), 'Email Address' (Required), 'Country Code' (dropdown menu with 'United States (+1)' selected), 'PI' (dropdown menu with 'Afghanistan (+93)' selected), 'A' (dropdown menu with 'Argentina (+54)' selected), 'City', 'State', and 'Medical Record Number (MRN)' (Required). There is also a checkbox labeled 'Not provided'.

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. Select the types that apply. Note that not Assessments are available in all geographic regions where SOZO is sold, and may not be available for licensing.

Height

Required

Assessment Type

☐ L-Dex Analysis for Lymphedema

☐ HF-Dex for Heart Failure or ☐ Fluid Analysis for General Fluid Status Monitoring

☐ Fluid Analysis for ESRD

☐ Tissue Analysis for Body Composition



Adding a new Assessment to the patient profile triggers a Caution about the intended use of that Assessment. Read and make sure that you understand the instructions for use for: L-Dex in the L-Dex Assessment User Guide; and HF-Dex in the HF-Dex Assessment User Guide.

8.5.1.3 Lymphedema Settings

For patients at risk of lymphedema, scroll down to “Lymphedema 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).

Lymphedema Settings

Assessment

☐ Unilateral ☐ Bilateral

Body Element

☐ Arm ☐ Leg

Risk Limb

☐ Left ☐ Right

Limb Dominance

☐ Left ☐ Right

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

Create Patient

Create

Patient Details

First Name

Required

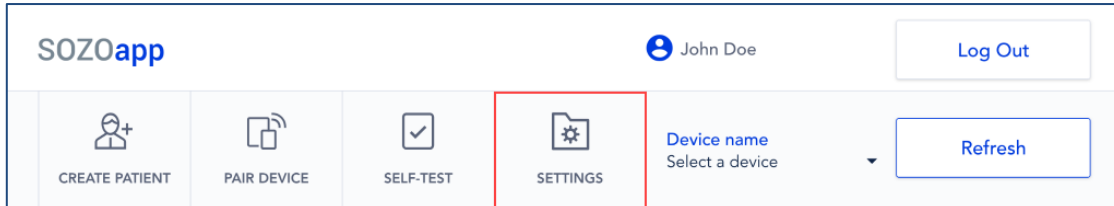
Country Code

8.5.2 Delete Patient

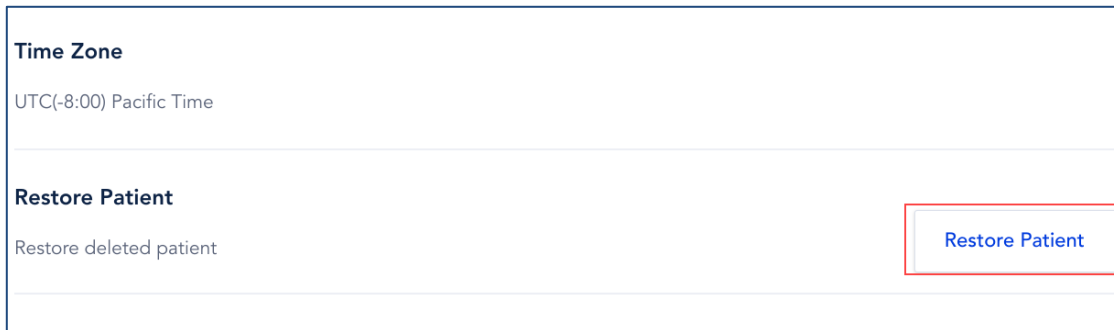
A patient may only be deleted by the Clinician from MySOZO. See MySOZO [Section 6.4.4.3 Delete Patient](#).

8.5.3 Restore Patient



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




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



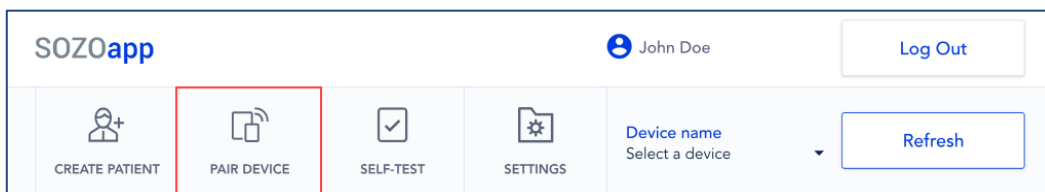
From the “Deleted Patients List,” select the patient to restore.

Restore Patients					
Deleted Patients List					
				Search Patient...	 
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**.

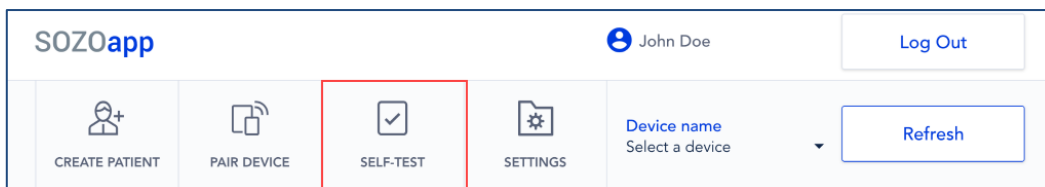
Restore Patients					
Deleted Patients List					
Search Patient...				Q	Sort
Last Name	First Name	Date of Birth	SEX	MRN	Last SOZO Assessment
Bate	Irene	<div>  <p>Caution</p> <p>Are you sure you want to Restore the selected patient?</p> <p>Cancel Restore Patient</p> </div>			
Black	Jessica				
Jackson	Susan				
Margot	George				
Michael	Smith				
Simpson	Andrew				
		27 Jan 1957	M	387763899938	12 Jun 2017 12:50

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.

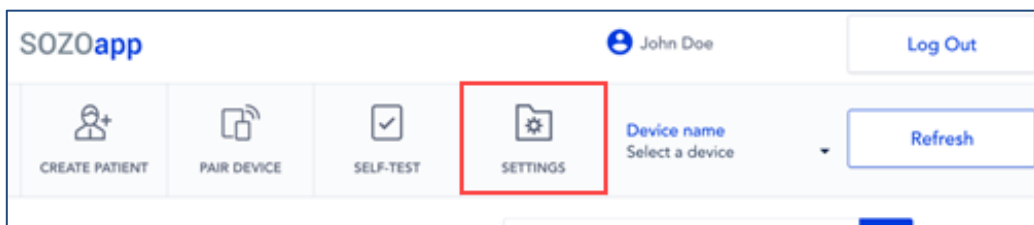
8.5.5.1 Optional for Device Status Confirmation

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

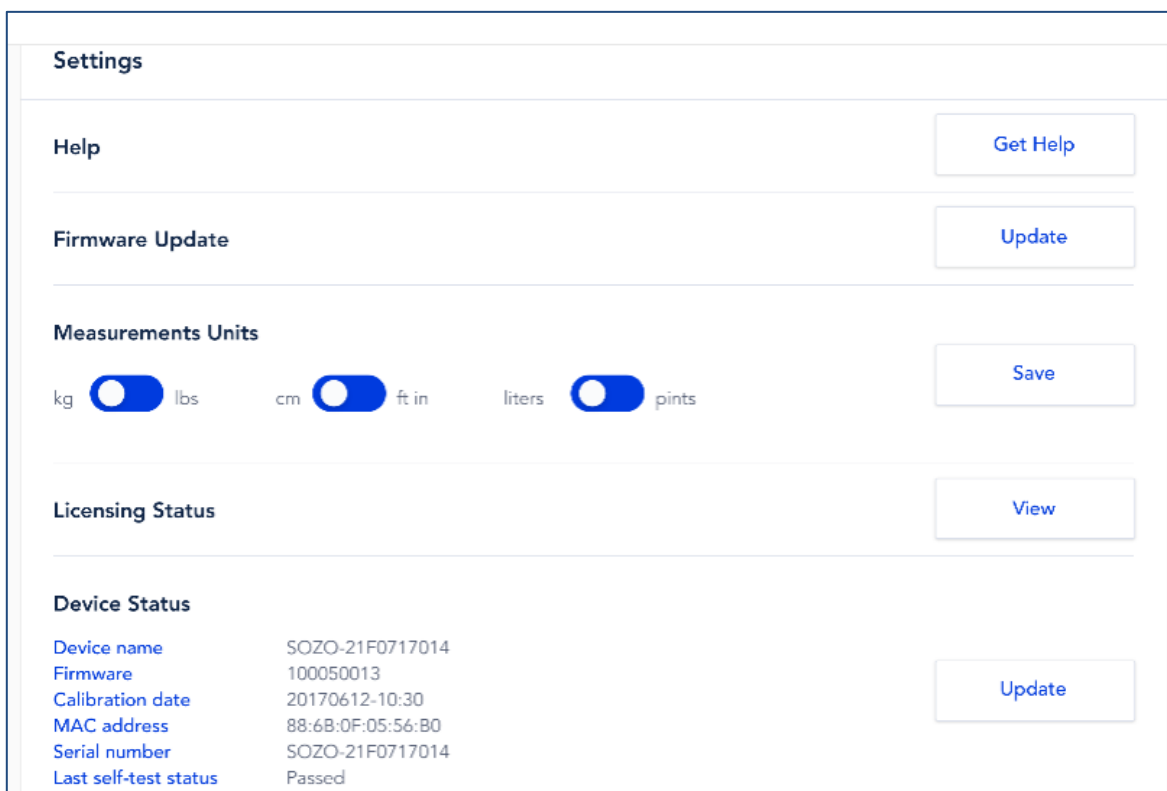
A self-test is mandatory preparation for taking measurements. It should be run daily before taking the first measurement of the day. See [Section 8.6.2.1 Self-Test](#).

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.



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

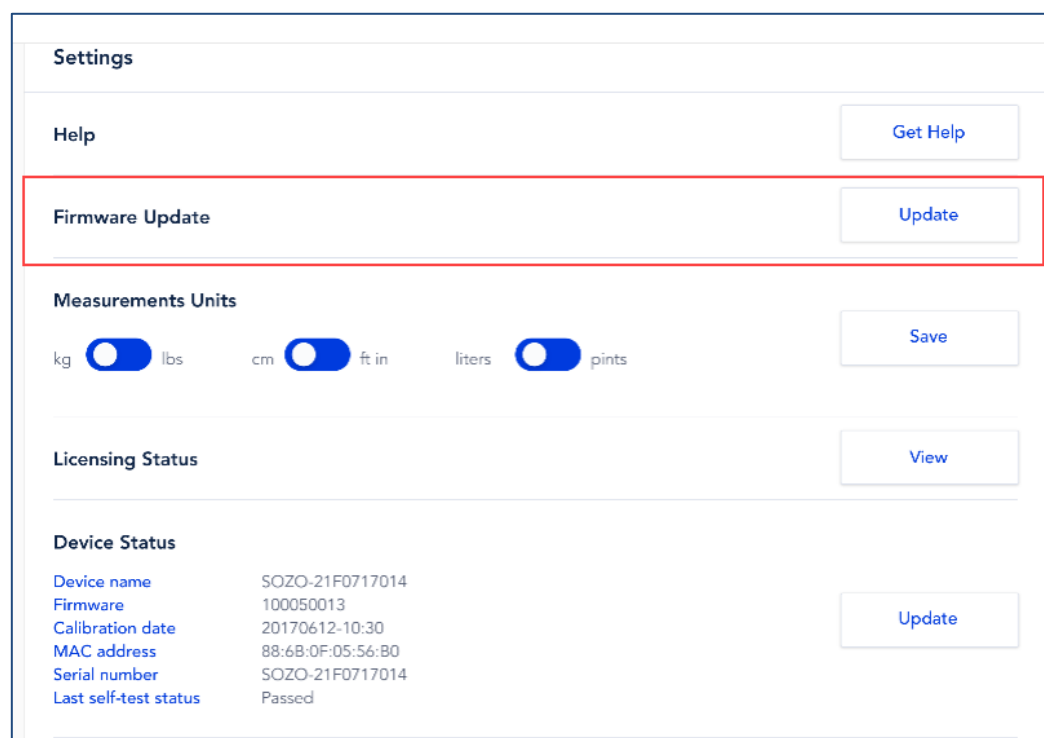
8.5.5.1 Adjusting Units of Measure

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, centimeters to inches and liters to pints. When done, tap **Save**.



8.5.5.2 Firmware Update

The SOZO Device software, or “firmware,” may be updated by tapping the **Update** button on the Settings screen and following the prompts. This process may take a few minutes and the tablet or SOZO Device should not be turned off during this time. After completion of the firmware update, the firmware version should be checked by updating the device status to show the desired firmware version. The firmware functionality may be updated through the Android SOZOapp versions 3.1.0 or higher.



8.5.5.3 Licensing Status

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

Settings

Help

Get Help

Firmware Update

Update

Measurements Units

kg

lbs

cm

ft in

liters

pints

Save

Licensing Status

View

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

Update

8.5.5.4 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”.

Settings

Device Status

Device name

Not retrieved

Firmware

Not retrieved

Calibration date

Not retrieved

MAC address

Not retrieved

Serial number

Not retrieved

Last self-test status

Not retrieved

Update

Software Information

SOZOapp version 3.0.1

Software version is up to date.

Release Notes

Time Zone

(PDT) Pacific Time (US and Canada);Tijuana

The SOZOapp will always be the most compatible version with the SOZO system. If the android SOZOapp version is not the most current version, it will be automatically updated. If the iOS SOZOapp version is not the most current version, the user will be notified upon login and the SOZOapp will not progress past the login screen. If this occurs, contact your IT support or ImpediMed technical support for a compatible version of the SOZOapp.

8.6 Taking Measurements

The SOZO Device supports various types of measurements for each Assessment, such as measurements for the detection of lymphedema, 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 the specific Assessment User Guides, including the L-Dex, Fluid Analysis and Tissue Analysis User Guides.






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
--	--	--	---	---

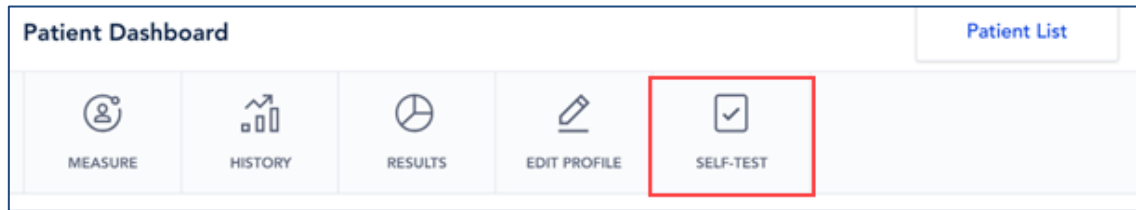
Patient Details

Last Name Smith	First Name John	Date of Birth 28 Jun 1966
Sex M	MRN 273666378899387626	Last SOZO Assessment 24 Feb 2018 16:11

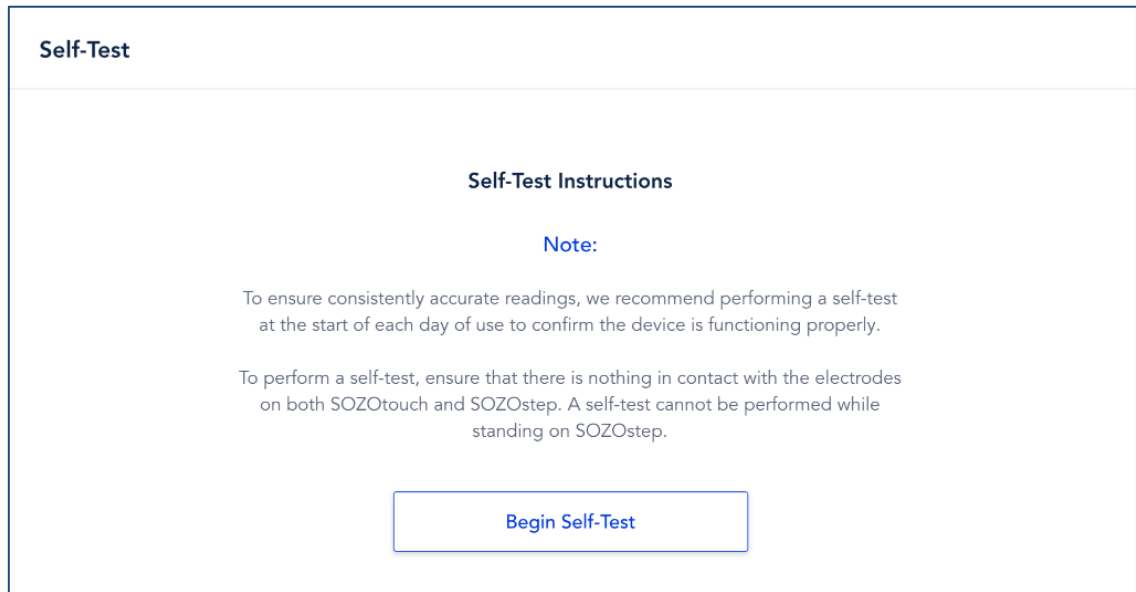
Assessment Type

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

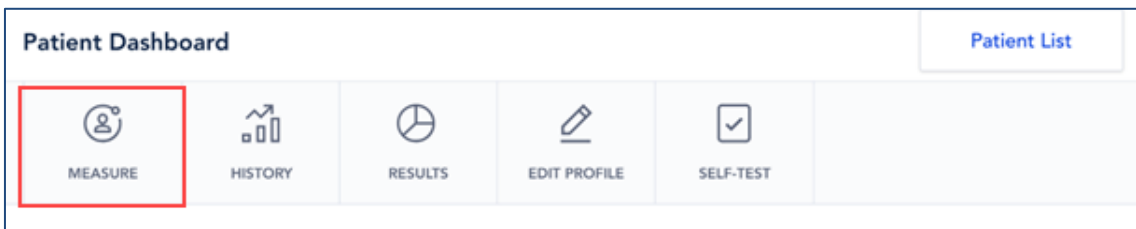
8.6.2.1 Self-Test



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**.



8.6.2.2 Preparing to Take Measurements



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)

Note: If the patient has an active implantable device (e.g. pacemaker or defibrillator), reference the IFU for additional instructions.

Tutorial

Start Measurement

8.6.2.2.3 Tutorial on Foot and Hand Placement

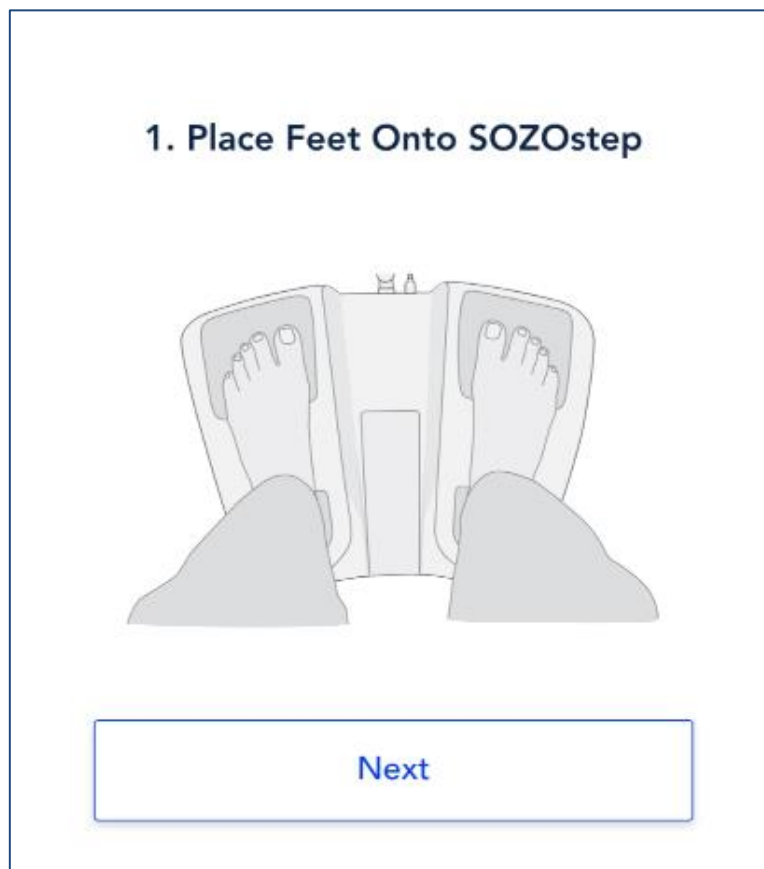
The Tutorial presents illustrations of correct foot and hand placement onto the electrodes.

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 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)

Note: If the patient has an active implantable device (e.g. pacemaker or defibrillator), reference the IFU for additional instructions.

Tutorial

Start Measurement

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

Start Measurement

Start

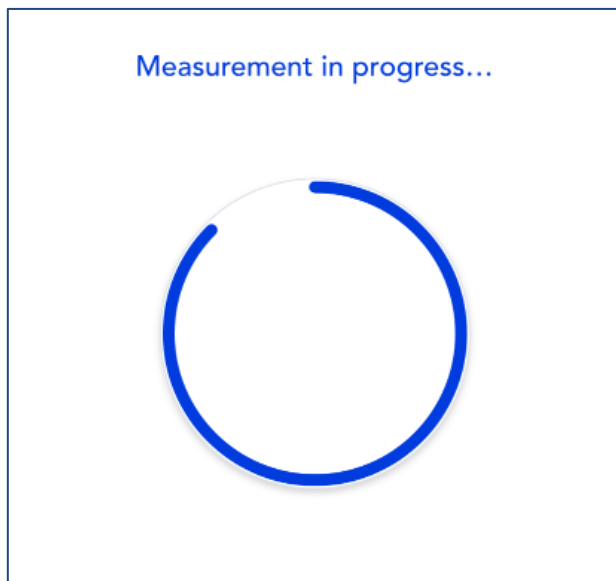
Measurement will start in...

5

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.

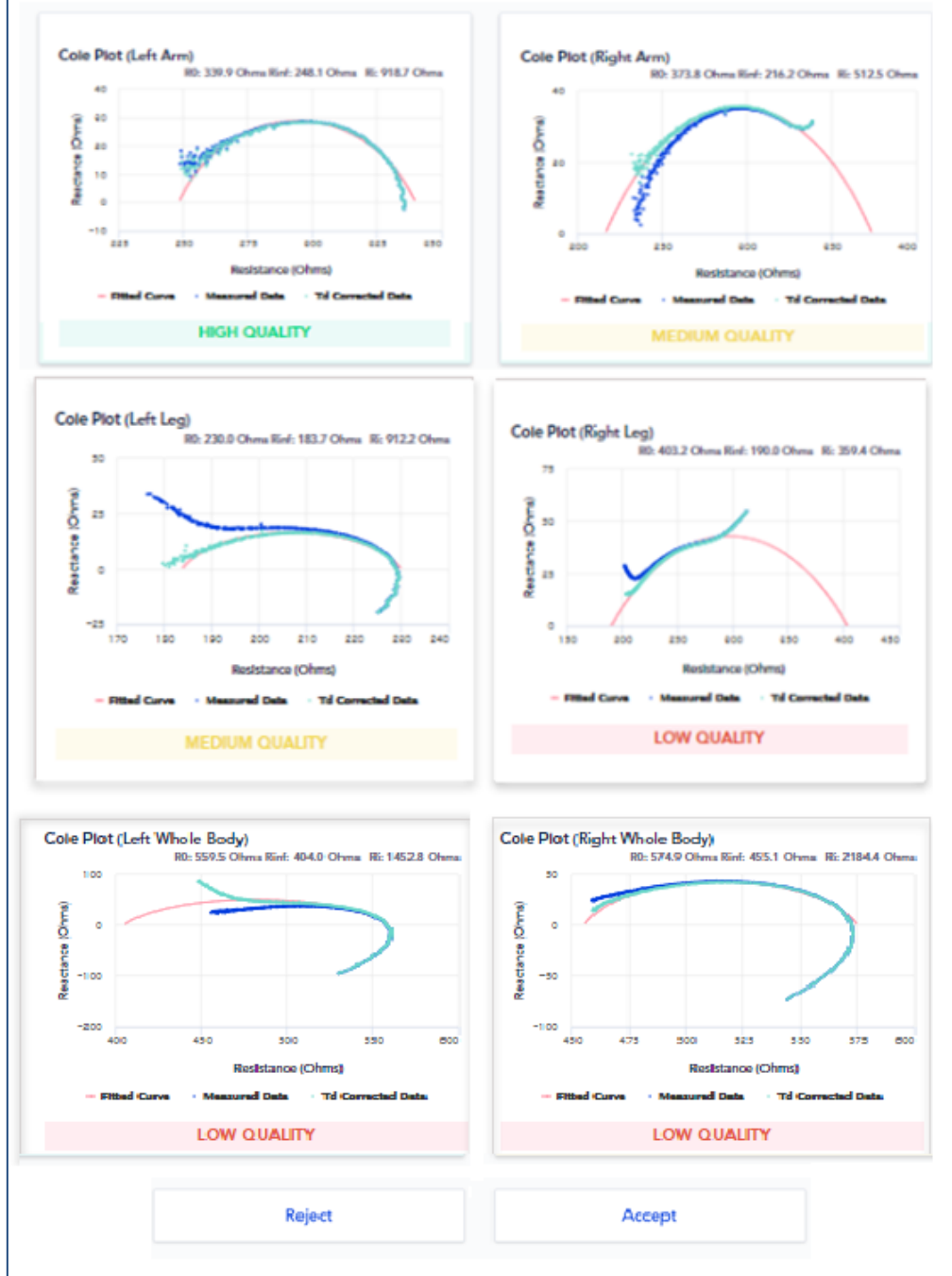
8.6.2.4.1 Considering Cole Plots in Deciding to Accept or Reject Measurements

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.



Measurement quality is important to ensure accuracy in results. For HF-Dex, the patient's Right Whole Body measurement must be a high (preferred) or medium quality. If a patient's Right Whole Body Cole plot was assessed to be low quality (“red”), the measurement should be retaken. If the measurement is accepted with a “red” RWB Cole plot, HF-Dex and ESRD outputs will not be presented.

Accept or Reject Cole Plots



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.”

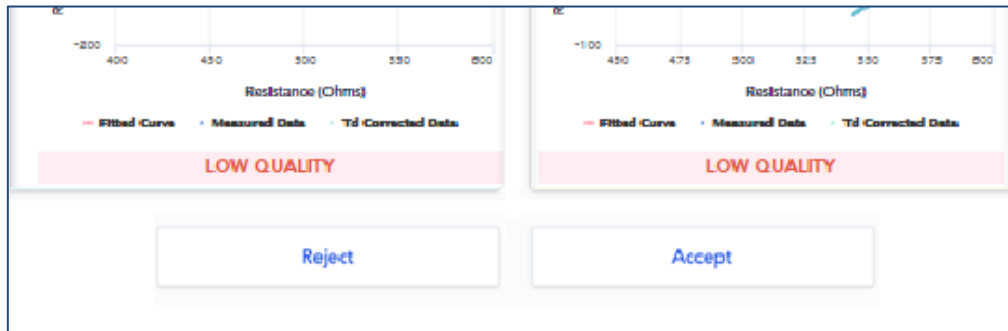


If, on the other hand, Measured Data is extremely scattered or does not form a semi-circle, the Cole plot may be medium quality or low quality. During the brief measurement period some measurement errors may occur if, for example, the patient shifts their hands or feet. Other errors, such as a sharp 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 of 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.



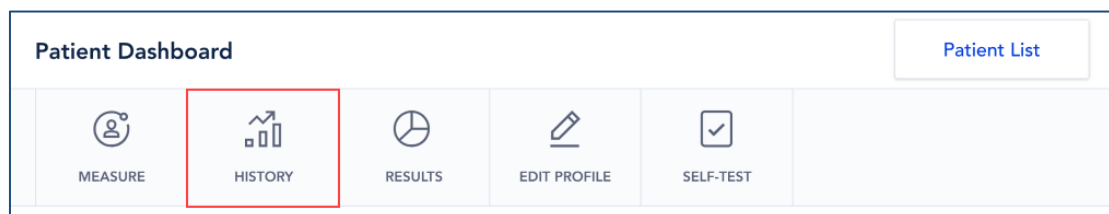
The Clinician cannot accept or reject some, but not all, Cole plots. If they tap **Accept**, all Cole plots are accepted. If **Reject** is tapped, all Cole plots are rejected.

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 licensed 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.

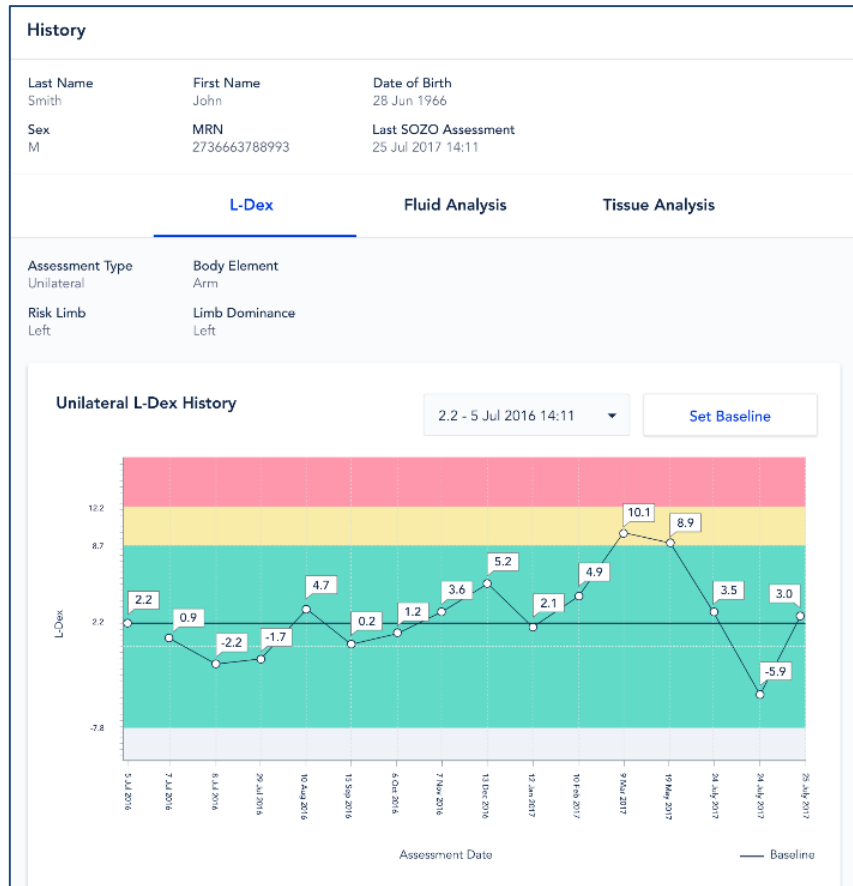


Only historical measurements for licensed Assessments will appear under History. Therefore, the Clinician will only be able to view licensed Assessments.

8.6.2.5.1 Examples of Historical Measurements

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

8.6.2.5.1.1 Example of L-Dex History

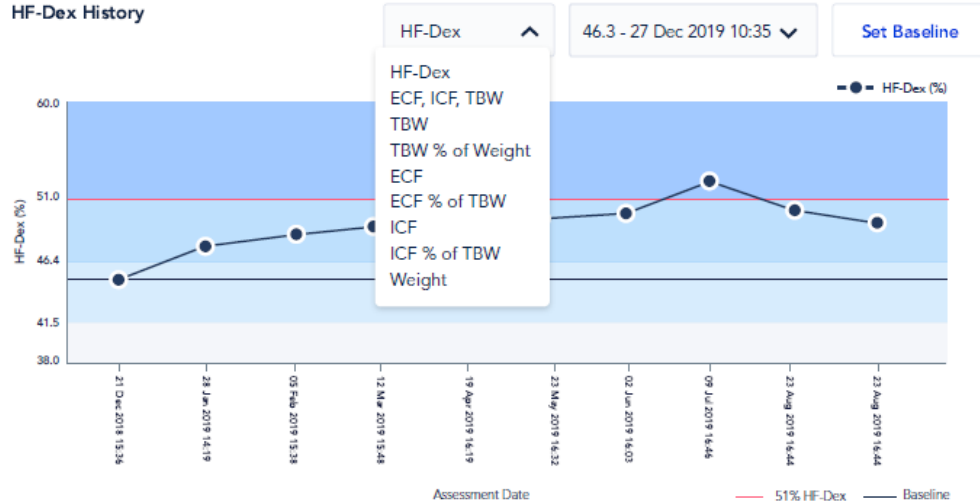


8.6.2.5.1.2 Example of HF-Dex History

History

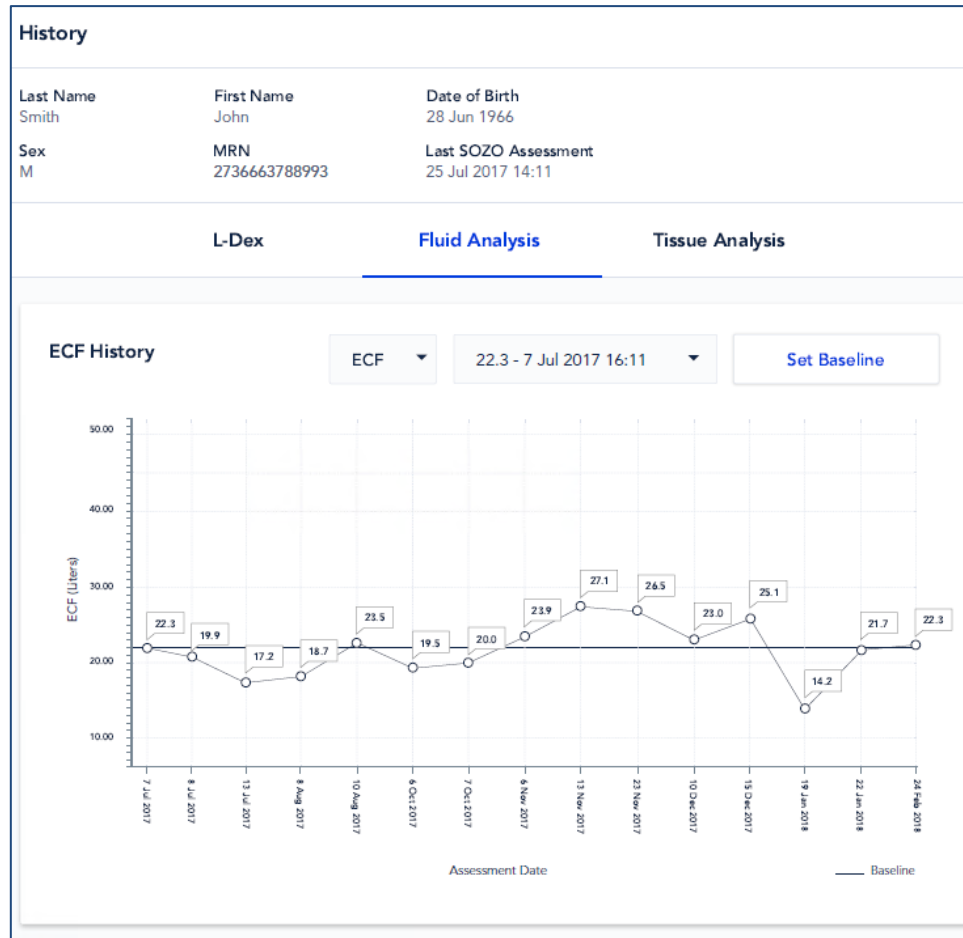
L-Dex **HF-Dex** ESRD Tissue Analysis

HF-Dex History



The HF-Dex scale is a tool to assist in monitoring fluid status in patients with heart failure who have fluid management problems, and should be used in conjunction with other clinical data. HF-Dex values in the light blue reference range are consistent with normal fluid volumes, based on data collected from healthy individuals who do not have heart failure. Values in the dark blue reference range may indicate signs of fluid overload. Values in the medium blue range indicate an elevated fluid volume. Values in the gray range require additional investigation.

8.6.2.5.1.3 Example of Fluid Analysis History



8.6.2.5.1.4 Example of Tissue Analysis History



8.6.2.5.2 Setting a Baseline

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

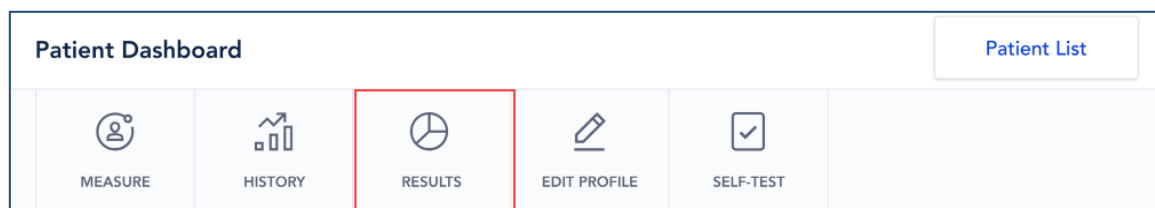


If the Clinician chooses not to set a baseline, the field next to “Set Baseline” may be left blank.

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 the L-Dex User Guide, the Fluid Analysis User Guide and the Tissue Analysis User Guide.

8.6.2.6 Results



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

Results

Last Name Smith	First Name John	Date of Birth 28 Jun 1966
Sex M	MRN 2736663788993	Last SOZO Assessment 25 Jul 2017 14:11

Select Measurement Date

25 Jul 2017 14:11

22 Jun 2017 19:53

17 Apr 2017 14:43

15 Feb 2017 18:11


8 Jan 2017 15:55

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.

Deleting a measurement:

In MySOZO and SOZOapp version 3.1.0 and later, individual measurements may be deleted. If, for example, low quality Cole plots were accepted and the clinician desires to remove them by navigating to the result screen of the measurement to be deleted and selecting the trash can icon in the upper right hand corner of the screen:

Results

 Delete

Last Name Smith	First Name John	Date of Birth 28 Jun 1966	
Sex M	MRN 2736663788993	Last SOZO Assessment 25 Jul 2017 14:11	Assessment Date 28 Jun 2017 10:35

Clicking on Delete will bring up a confirmation pop-up.



Deleting individual measurements is permanent. The data cannot be recovered.

8.6.2.6.1 Example of L-Dex Results

Results

Delete

Last Name Smith	First Name John	Date of Birth 28 Jun 1966	
Sex M	MRN 2736663788993	Last SOZO Assessment 25 Jul 2017 14:11	Assessment Date 28 Jun 2017 10:35

L-Dex

Fluid Analysis

Tissue Analysis

Cole Plots

Assessment Type Unilateral	Body Element Arm
Risk Limb Left	Limb Dominance Left

L-Dex Score (Left Arm)



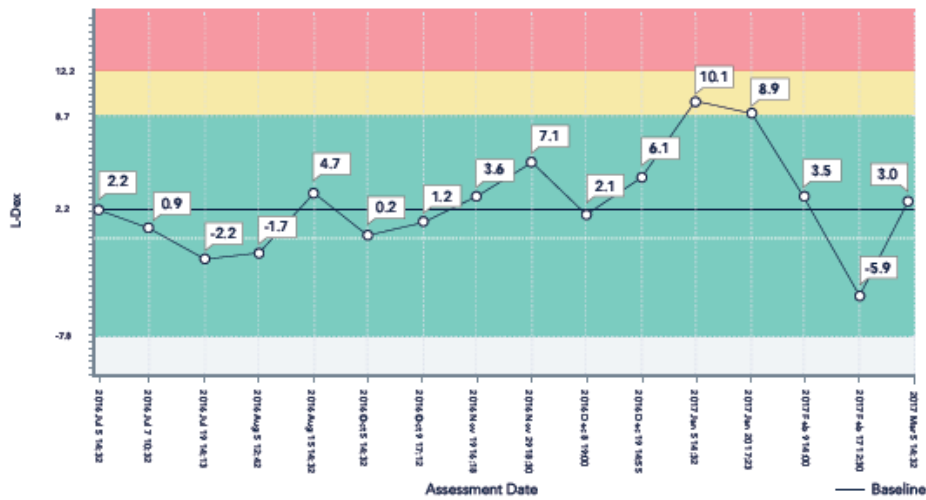
L-Dex Score: 3.0

Baseline: 2.2

Change from baseline: 0.8

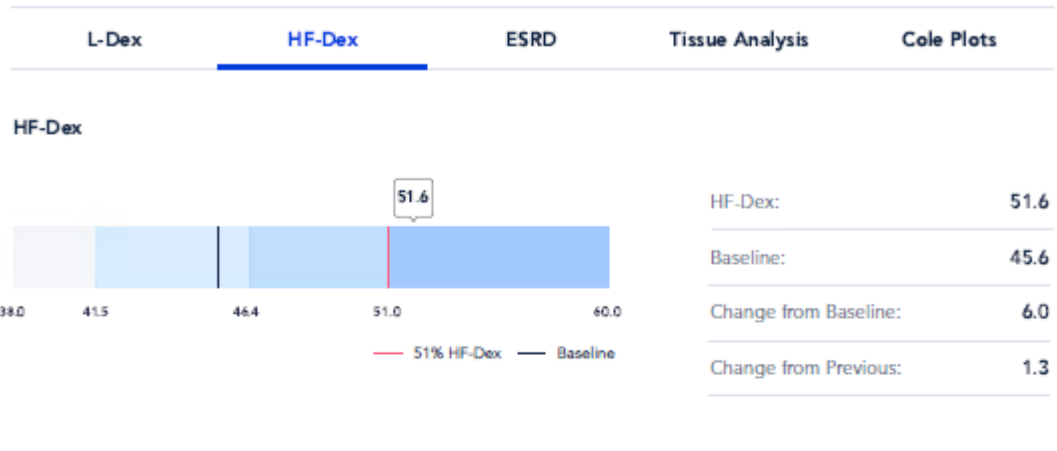
— Baseline

Unilateral L-Dex History



8.6.2.6.2 Example of HF-Dex Results

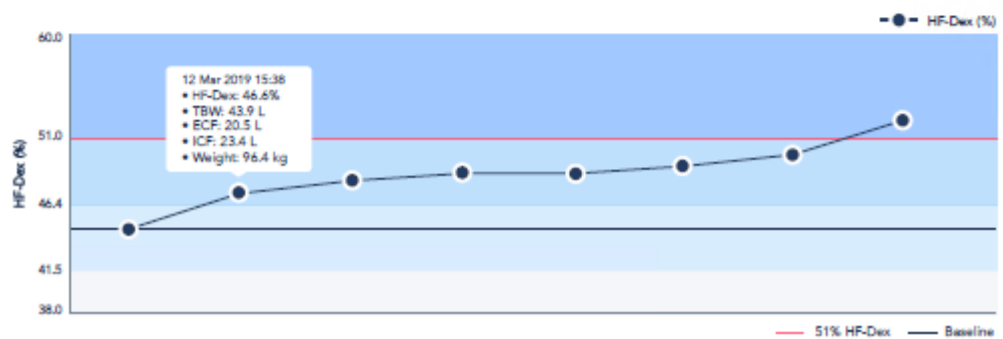
Results



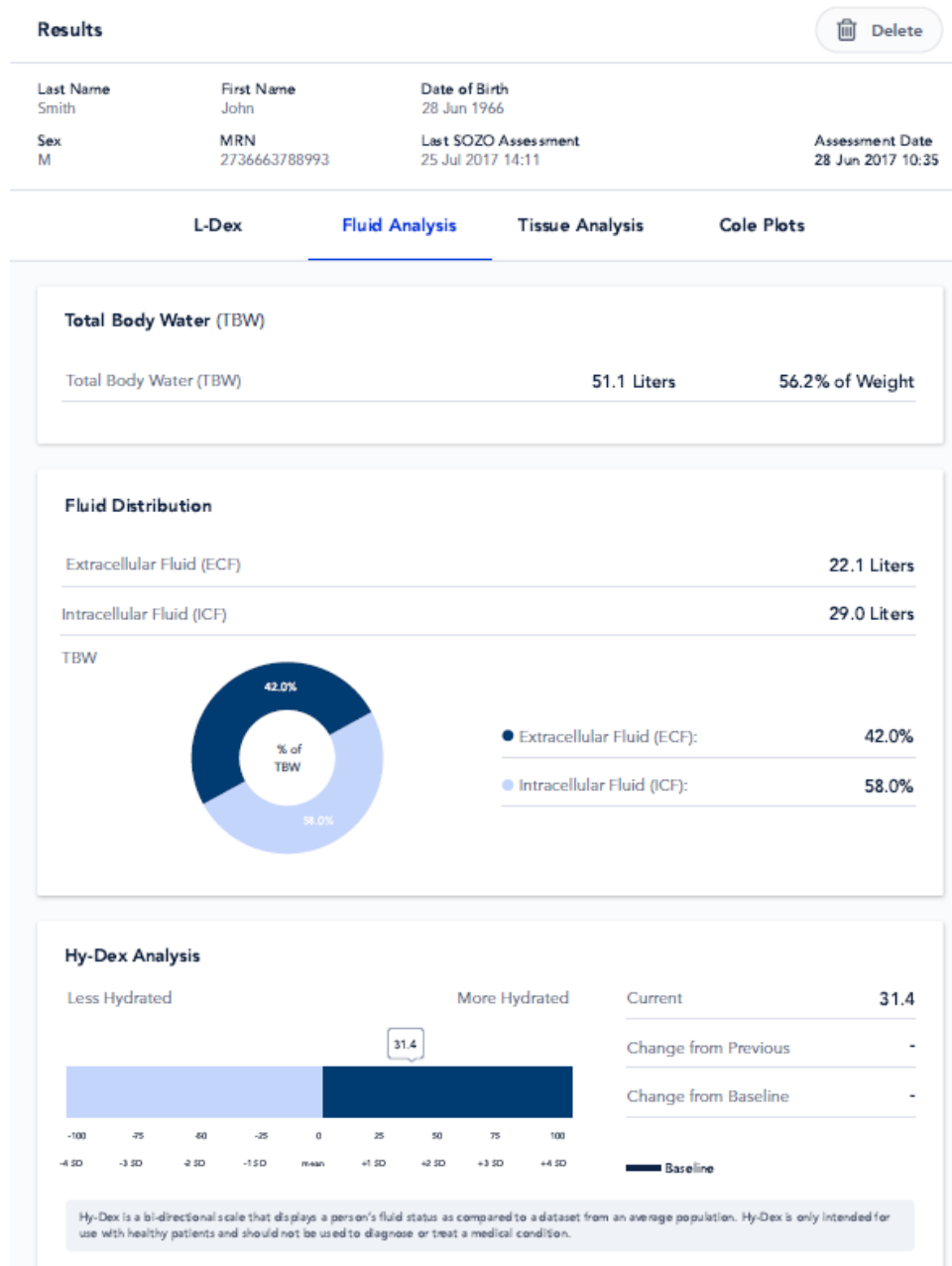
Fluid Analysis & Weight

Total Body Water (TBW)	44.0 Liters	46.3% of Weight
Extracellular Fluid (ECF)	22.7 Liters	51.6% of TBW
Intracellular Fluid (ICF)	21.3 Liters	48.4% of TBW
Weight	95.0 kg	

History



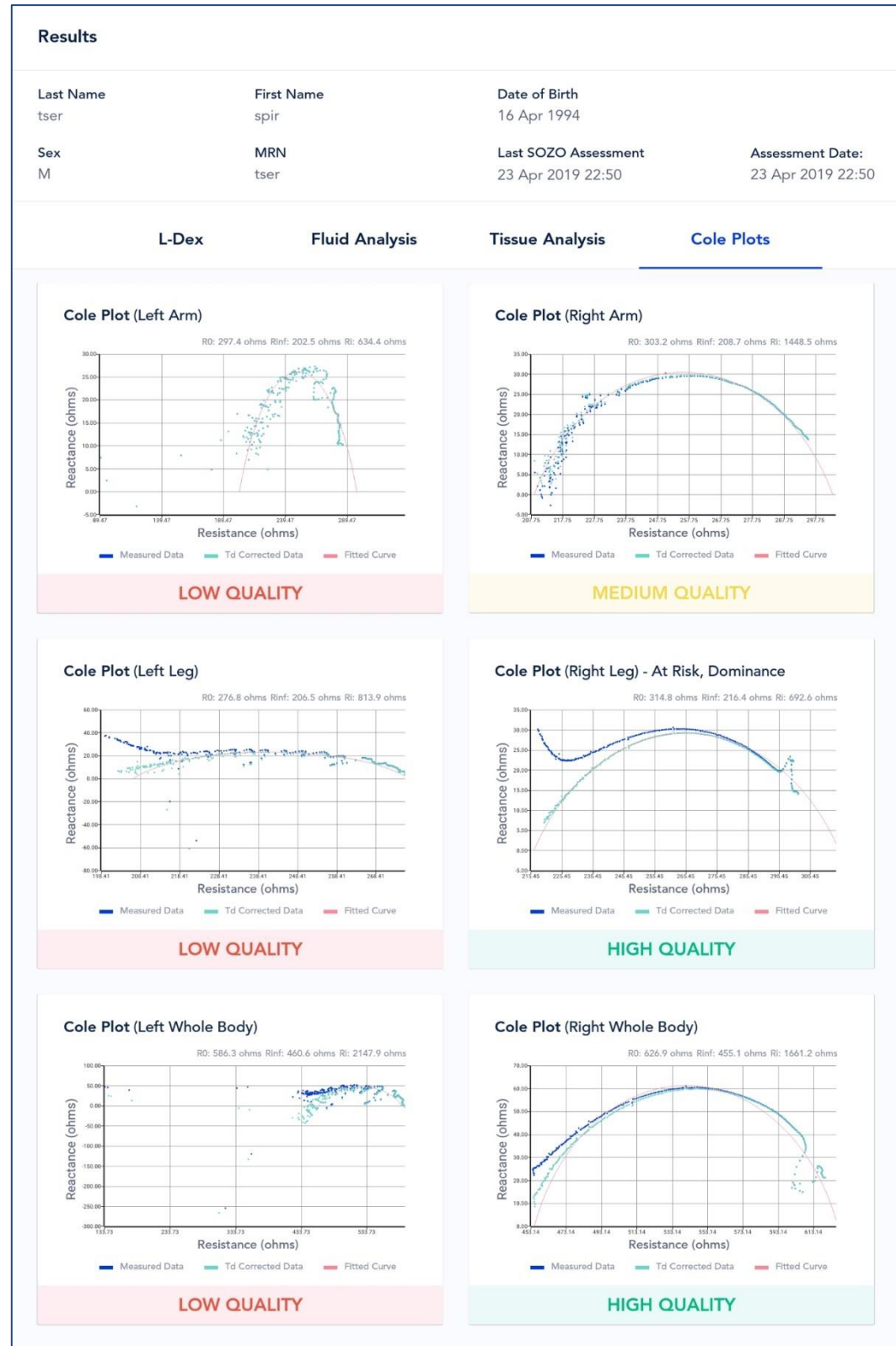
8.6.2.6.3 Example of Fluid Analysis Results



8.6.2.6.4 Example of Tissue Analysis Results



8.6.2.6.5 Example of Cole Plots



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](#).

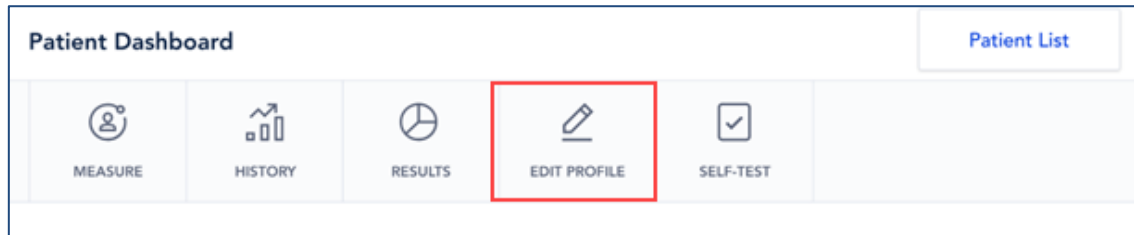
8.6.2.6.5 Impact of Licensing Additional Assessments on Results

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 licenses, the new Assessments may be added to a patient's history. After a new Assessment is licensed, the Clinician may add the newly licensed 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.

8.3.2.4.2 Impact of Cancellation of Assessment License on Results

If a Clinic cancels an Assessment license, 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 Lymphedema settings. All licensed 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

John

Middle Name

Michael

Last Name

Required

Smith

Email Address

Required

jsmith@hotmail.com

☐ Not provided

Medical Record Number (MRN)

Required

2736663788993

Date of Birth

Required

28 June 1966

Sex

Required

Male

Height

Required

187

Country Code

United States (+1)

Phone Number

760-585-2100

Address

5900 Pasteur Ct.

City

Carlsbad

State

California

Country

United States

Postal Code

CA 90210

Assessment Type

☒ L-Dex Analysis for Lymphedema
 ☒ HF-Dex for Heart Failure
 or
 ☐ Fluid Analysis for General Fluid Status Monitoring
 ☐ Fluid Analysis for ESRD
 ☐ Tissue Analysis for Body Composition

Lymphedema Settings

Required

Assessment

☒ Unilateral
 ☐ Bilateral

Body Element

☒ Arm
 ☐ Leg

Risk Limb

☒ Left
 ☐ Right

Limb Dominance

☒ Left
 ☐ Right

Patient Groups

☒ Group Name
 ☐ Group Name
 ☐ Group Name
 ☒ Group Name
 ☐ Group Name
 ☐ Group Name
 ☐ Group Name
 ☐ Group Name
 ☐ Group Name
 ☐ Group Name
 ☐ Group Name

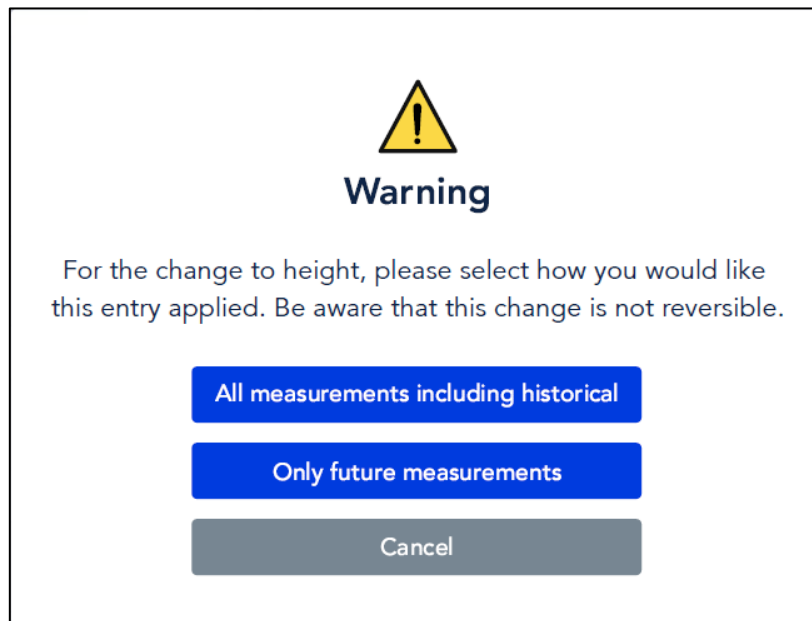
If an email address is not provided, leave the email field blank and tap the “Not Provided” box.

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 gray out the patient L-Dex settings, which will not be saved.

9.0 Assessments

The SOZO Device supports the following Assessment Types:

- 1) L-Dex
- 2) HF-Dex
- 3) Fluid Monitoring & Analysis
- 4) Tissue Analysis

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

Some Assessment Types may also 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. Go to www.impedimed.com to download the Assessment-specific instructions for use, including the L-Dex Assessment User Guide (LBL-525-1), the HF-Dex User Guide (LBL-525-2), or the Fluid & Tissue Analysis User Guide (LBL-525-3), or contact ImpediMed technical support for a printed copy.

10.0 Troubleshooting

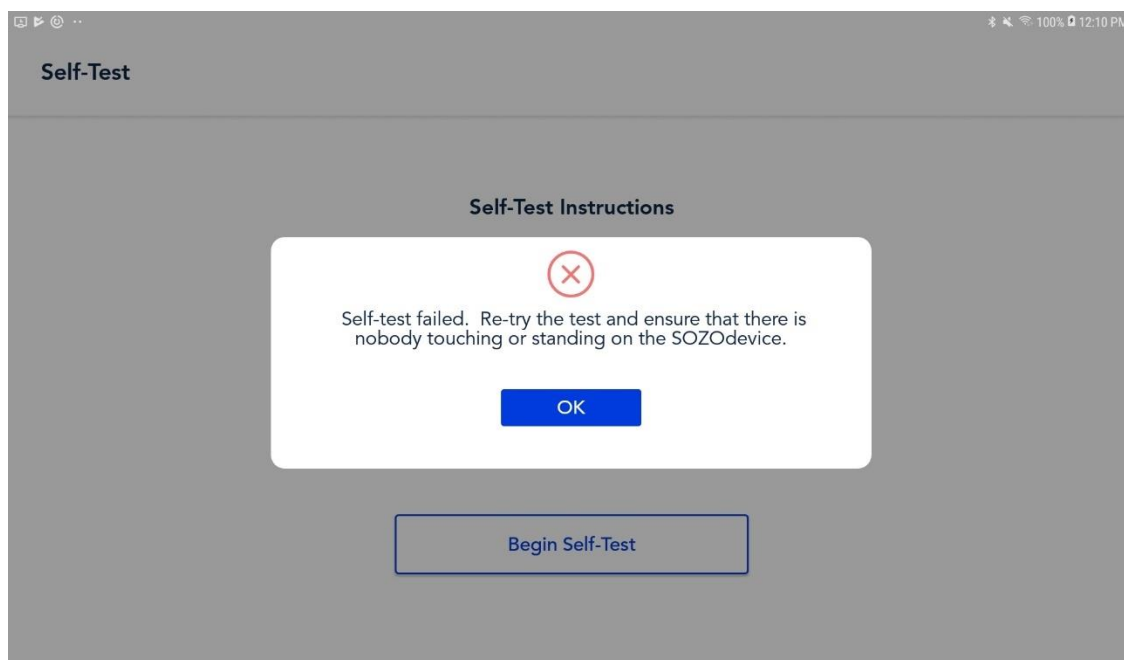
10.1 SOZOapp Error Messages

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 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

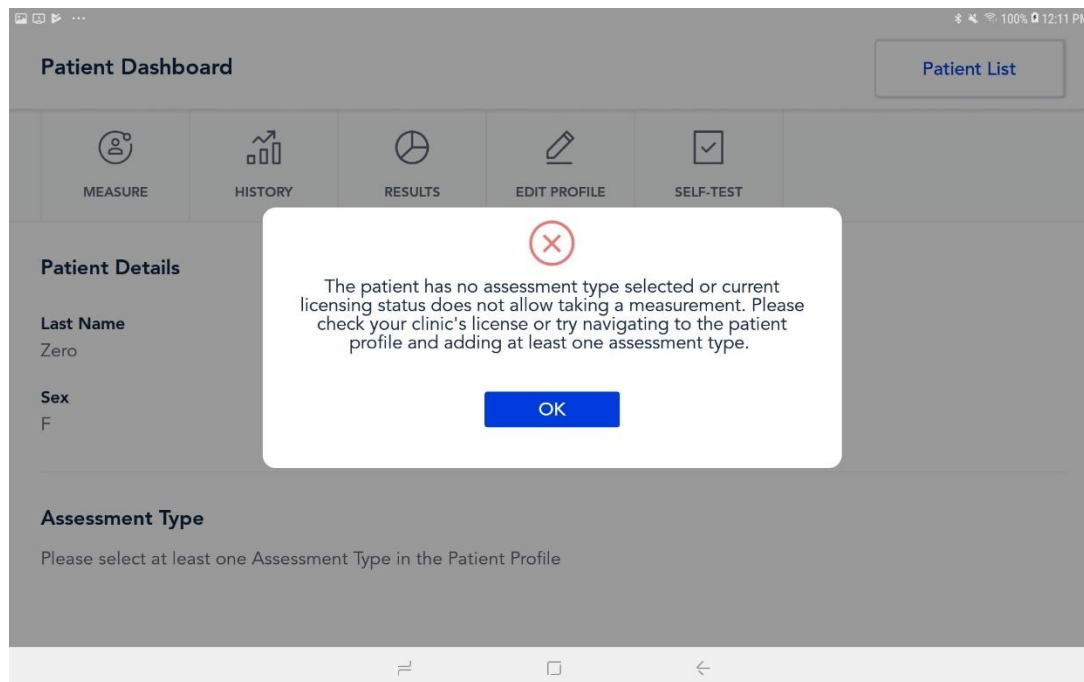
10.1.2 Patient Profile

10.1.2.1 Assessment Type

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

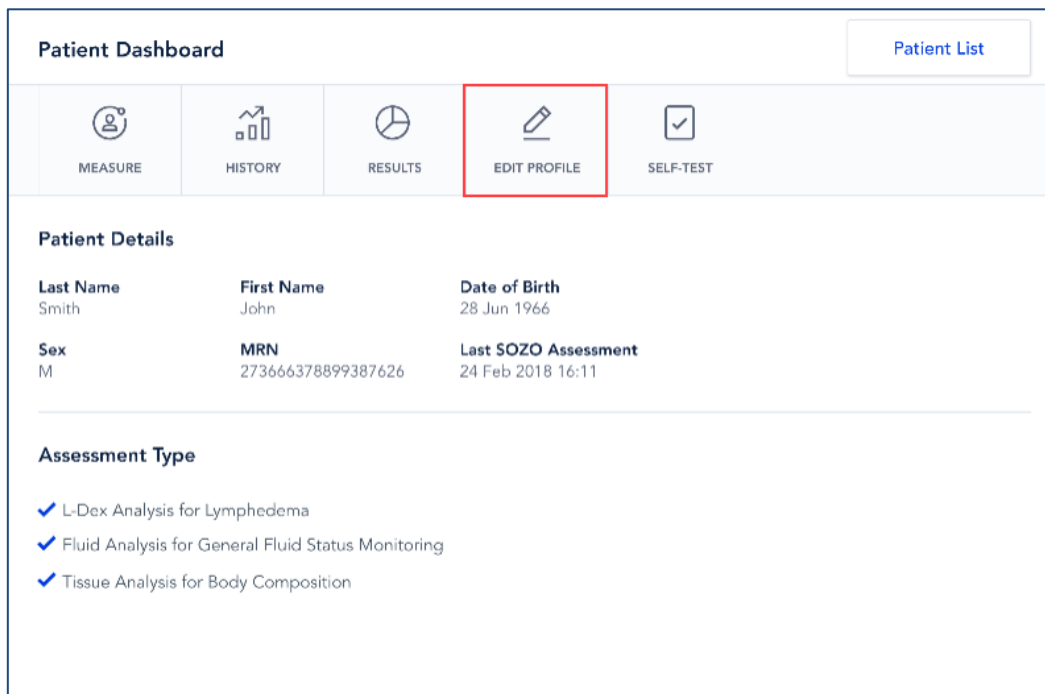
10.1.2.1.1 Error Message

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



10.1.2.1.2 Resolution

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



Choose Assessment Type under “Patient Details.”

Profile

Save

Patient Details

First Name

Required

John

Middle Name

Michael

Last Name

Required

Smith

Email Address

Required

jsmith@hotmail.com

☐ Not provided

Medical Record Number (MRN)

Required

2736663788993

Date of Birth

Required

28 June 1966

Sex

Required

Male

Female

Height (ft)

(in)

Required

4

0.4

Country Code

Australia (+61)

United States (+1)

Afghanistan (+93)

Albania (+355)

Algeria (+213)

Andorra (+376)

Angola (+244)

Argentina (+54)

5900 Pasteur Ct.

City

Carlsbad

State

California

Country

United States

Postal Code

CA 90210

Assessment Type

☒ L-Dex Analysis for Lymphedema

☒ HF-Dex for Heart Failure or ☐ Fluid Analysis for General Fluid Status Monitoring

☐ Fluid Analysis for ESRD

☐ Tissue Analysis for Body Composition

Lymphedema Settings

Required

10.1.2.2 Lymphedema Settings

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

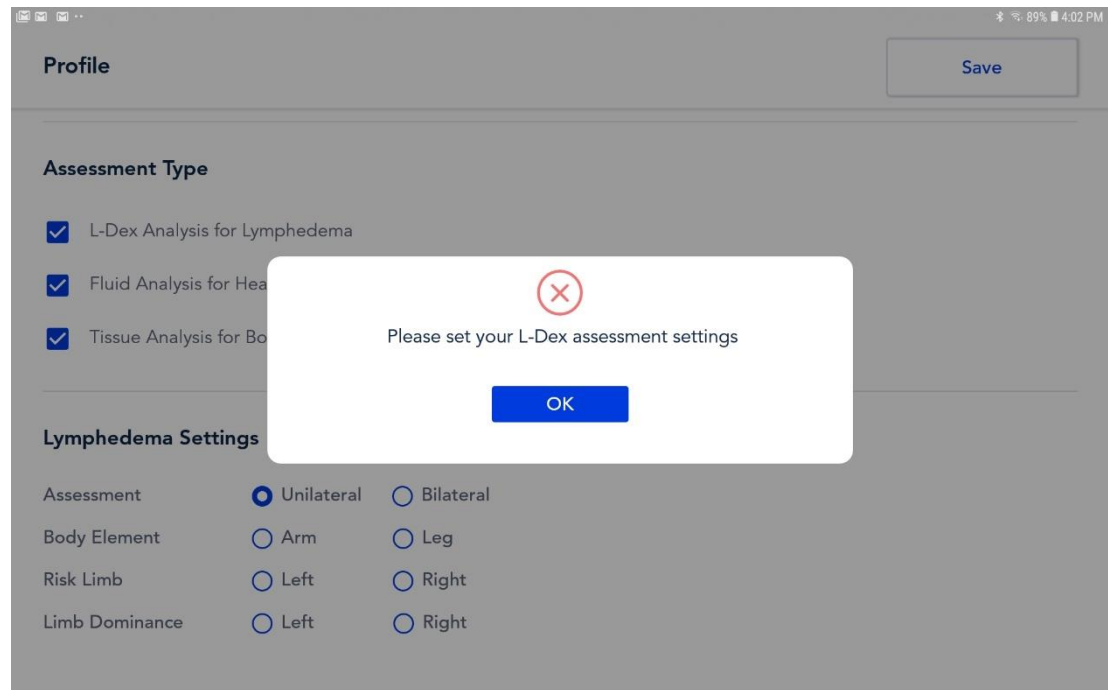
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LBL-525 REV H

10.1.2.2.1 Error Message

“Please set your L-Dex assessment settings.”



10.1.2.2.2 Resolution

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



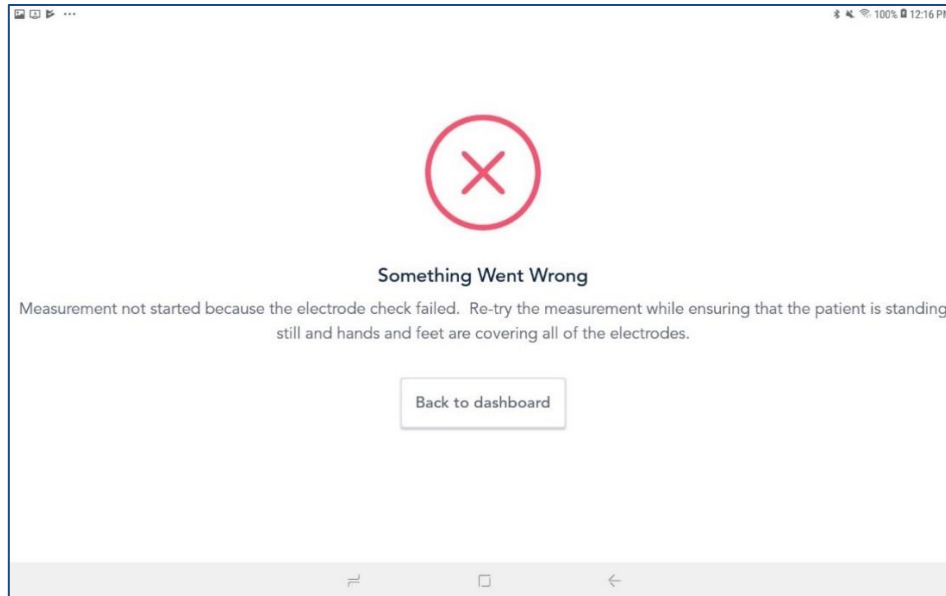
If “Bilateral” is selected as the “Assessment Type,” after arm or leg is chosen as the “Body Element,” “Left and “Right” are both automatically selected as “Risk Limb.”

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

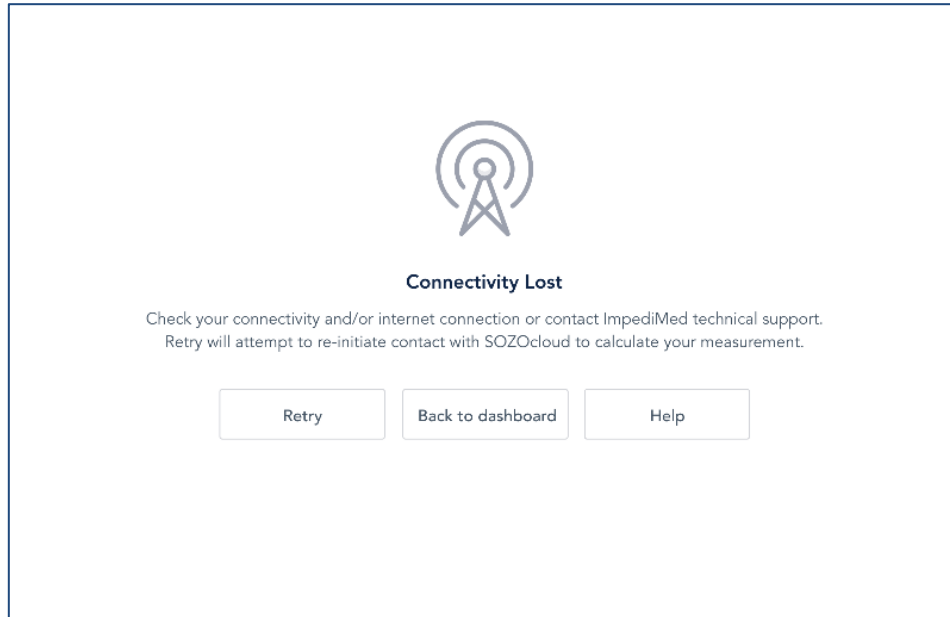
Ensure that the patient is standing on the SOZO Device before tapping ***Measure***.

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 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 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 license is not available.	Check the assessment types chosen for the patient and adjust accordingly. Check available licenses and contact ImpediMed technical support if unable to resolve.
Historical results for an assessment type are available, but current results are not shown.	License for the assessment type is not active.	Check active licenses. Contact ImpediMed technical support if license status is not correct.
No SOZO devices are selectable even after device is paired via Bluetooth.	Device is not licensed.	Check license status. Contact ImpediMed technical support if license 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.
Logging in to SOZOapp/MySOZO (cont'd)		
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.
"There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support."	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/Tablet to MySOZO.com. Potential issue with disruption of WiFi signal.	Take another measurement. Move location of SOZO Device if it is in an area with other equipment that emits electromagnetic signals. Check the WiFi signal near the tablet and troubleshoot as appropriate. 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). If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. Verify SOZO hardware is powered on by pushing button and verifying blue light at back of unit is illuminated. Turn off and restart the Tablet and the SOZO Device. If error persists, contact ImpediMed technical support

"Possible device connection problem" or "There is a Bluetooth connection problem..." or "Pairing failed, Please try again"	Tablet Bluetooth has been turned off or SOZO Device Bluetooth has malfunctioned.	Confirm Tablet Bluetooth is turned on and that the proper SOZO device is selected. 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 using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. 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
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 the manufacturer'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

SOZO Help Email: tsu@impedimed.com

12.6 Components and Accessories

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

Definition of Products:

SOZO System.

ImpediMed shall deliver to Customer the products and services referenced in the Quotation (collectively, the “**SOZO System**”), subject to availability of the SOZO System, which may consist of Hardware, Software, and SOZO Services. “**Hardware**” refers to tangible equipment such as the SOZO® device, support stand, tablet and accessories/Peripherals. “**Software**” refers to all forms of software, whether pre-installed, embedded (e.g., firmware), in read only memory, or found on any other media or other form and specifically includes the mySOZO app installed on the Hardware, but specifically excludes the SOZO Services. “**SOZO Services**” refers to the ImpediMed’s cloud based SOZO software platform delivered on a software-as-a-service (SaaS) basis, including as available through mySOZO.com.

Limited Warranty:

(a) Hardware. Subject to the exceptions and upon the conditions set forth herein, ImpediMed warrants that for a period of twelve (12) months after the date of purchase of the Hardware, or such longer period identified in the Quotation if Customer has purchased an extended warranty, the Hardware will be free from material defects in material and workmanship (“**Warranty Period**”). Customer acknowledges that the Hardware is subject to use and safety guidelines and instructions for use contained in the accompanying instructions for use or other user manual and Documentation. Customer agrees to use the Hardware solely in accordance with the Documentation accompanying the Hardware. ImpediMed shall not be liable for a breach of the warranty set forth in this Section unless Customer follows ImpediMed’s warranty return procedures communicated to Customer in connection with this Agreement, and ImpediMed also verifies that the Hardware is defective and that the defect developed under normal and proper use. Moreover, ImpediMed shall not be liable for a breach of the warranty set forth in this Section if: (i) Customer makes any further use of such Hardware after giving such notice; (ii) the defect arises because Customer failed to follow ImpediMed’s oral or written instructions as to the storage, installation, commissioning, handling, use, care or maintenance of the Hardware; (iii) Customer alters or repairs such Hardware without the prior written consent of ImpediMed; (iv) repairs or modifications are made by persons other than ImpediMed’s own service personnel, or an authorized representative’s personnel, unless such repairs are made with the written consent of ImpediMed in accordance with procedures outlined by ImpediMed; or (v) the defect is caused, in whole or in part, by normal wear and tear, accident, abuse, improper voltage, other improper use or use not in accordance with our specifications or instructions, and/or any other improper care or handling.

(b) Software. Subject to the exceptions and upon the conditions set forth herein, during the Subscription Term ImpediMed warrants that, from the date of shipment or the date of electronic availability, as applicable, the Software will conform to the applicable Documentation for such Software.

(c) SOZO Services. Subject to the exceptions and upon the conditions set forth herein, during the Subscription Term ImpediMed warrants that the SOZO Services will perform substantially in accordance with the Documentation.

(d) **EXCEPT FOR THE WARRANTIES EXPRESSLY SET FORTH IN THIS SECTION 16, THE SOZO SYSTEM IS PROVIDED “AS-IS” AND IMPEDIMED MAKES**

NO WARRANTIES WHATSOEVER WITH RESPECT TO THE SOZO SYSTEM OR ANY COMPONENTS THEREOF, INCLUDING ANY (A) WARRANTY OF MERCHANTABILITY; (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; (C) WARRANTY OF TITLE; (D) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD-PARTY; (E) WARRANTY THAT THE SOFTWARE OR SOZO SERVICES WILL BE UNINTERRUPTED, ERROR-FREE, OR THAT DEFECTS CAN BE CORRECTED; OR (F) WARRANTY THAT ANY DATA WILL NOT BE LOST OR DAMAGED; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.

(e) Products manufactured by a third-party and third-party software ("**Third-Party Products**") may constitute, contain, be contained in, incorporated into, attached to or packaged together with, the SOZO System. Third-Party Products are not covered by the warranty in this Section. For the avoidance of doubt, **IMPEDIMED MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO ANY THIRD-PARTY PRODUCT, INCLUDING ANY (A) WARRANTY OF MERCHANTABILITY; (B) WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE; (C) WARRANTY OF TITLE; (D) WARRANTY THAT THE PRODUCTS ARE FDA APPROVED, OR OTHERWISE APPROVED, SCIENTIFIC OR MEDICAL DEVICES; (E) WARRANTY THAT THE PRODUCTS HAVE BEEN TESTED FOR SAFETY OR EFFICACY; OR (F) WARRANTY AGAINST INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF A THIRD-PARTY; WHETHER EXPRESS OR IMPLIED BY LAW, COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE OF TRADE OR OTHERWISE.** Notwithstanding the foregoing, in the event of the failure of any Third-Party Products, ImpediMed will assist (within reason and at ImpediMed's sole discretion) Customer (at Customer's sole expense) in obtaining, from the respective third-party, any (if any) adjustment that is available under such third-party's warranty.

(f) **NO HARDWARE RETURNS WILL BE ACCEPTED AFTER THE WARRANTY PERIOD HAS EXPIRED, UNLESS AN EXTENDED WARRANTY HAS BEEN PURCHASED PRIOR TO THE CONCLUSION OF THE INITIAL TWELVE (12) MONTH PERIOD.** After the Warranty Period has expired, ImpediMed may, in its sole discretion, repair nonconforming Hardware at current industry-standard rates for parts ("**Part**"), labor and transport. ImpediMed warrants that for a period of twelve (12) months after the shipment of a replacement or new Part, the Part will be free from material defects in material and workmanship, subject to the restrictions and limitations described in this Section. Subject to the requirements above, with respect to any such Hardware during the Warranty Period, ImpediMed shall, in its sole discretion, either: (i) repair or replace such Hardware (or the defective part), using new or refurbished Hardware or Parts; or (ii) credit or refund the price of such Hardware at the pro rata contract rate, provided that, if ImpediMed so requests, Customer shall, at Customer's expense, return such Hardware to ImpediMed. All warranty, diagnostic, and repair services are provided without any obligation of confidentiality or non-disclosure on the part of ImpediMed, its employees or agents. Therefore, before delivering any Hardware to ImpediMed, Customer should back up or store any related data or information and purge the Hardware of any information that could be considered confidential, including information related to the identity of a patient or "Protected Health Information," as that term is defined in 45 C.F.R. § 160.103. For any non-conforming Software or SOZO Services, ImpediMed's entire liability and Customer's exclusive remedies under the warranties described in this Section shall be for ImpediMed, at its option, to use reasonable efforts to remedy such defects or performance failure pursuant to the SOZO Support Policy.

(g) **THE REMEDIES SET FORTH HEREIN SHALL BE CUSTOMER'S SOLE AND EXCLUSIVE REMEDY AND IMPEDIMED'S ENTIRE LIABILITY FOR ANY BREACH OF THE LIMITED WARRANTY SET FORTH IN THIS SECTION. Representations and warranties made by any person, including representatives of ImpediMed, which are inconsistent or in conflict with the terms of this warranty, as set forth above, shall not be binding upon ImpediMed.**

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 (Android), ~45 seconds (iOS).
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 one year.

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	The SOZO Device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

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 th 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.

Immunity test	4 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
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 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% Ur for 1 cycle	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds ----- 0% Ur for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% Ur for 1 cycle	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.
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 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms (Outside ISM)</p> <p>6Vrms (In ISM and amateur Bands)</p> <p>150 kHz to 80 MHz</p> <p>10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz</p>	<p>(V1) = 3Vrms (V2) = 6Vrms</p>	<p>Portable and mobile communications equipment should be separated from the SOZO by no less than the distances calculated/listed below:</p> <p>$D = (3.5/V1)(\text{Sqrt } P)$ $D = (12/V2)(\text{Sqrt } P)$</p> <p>$D = (12/E1)(\text{Sqrt } P)$ 80 to 800 MHz</p> <p>$D = (23/E1)(\text{Sqrt } P)$ 800 MHz to 2.7 GHz</p> <p>where P is the max power in watts and D is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

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 ± 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



HF-Dex™ Assessment Module Instructions for Use



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Pinkenba Qld 4008
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EC	REP
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For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed U.S. by email at tsu@impedimed.com or by phone at: + 877 247 0111 option 4.

MediMark Europe Sarl
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France






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/>

HF-Dex Assessment

Safety Instructions

These symbols are provided to guide you in the use of this product safely and correctly, and to prevent risk and injury to you and others. For more safety instructions and other symbols, see User Guide, “SOZO System Instructions for Use.”

Symbol	Definition
	WARNING! Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
	Follow instructions for use.
	Note

HF-Dex for Heart Failure

Indications for Use

The SOZO® HF-Dex module is intended for adult patients living with heart failure.

This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

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 the main User Guide, LBL-525, “SOZO System Instructions for Use.” All warnings, contraindications and precautions apply. In addition, consider the following when using SOZO to take HF-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.

In order to use the HF-Dex module, the facility will require a license for the module. The patient will additionally need to have the module selected in their profile. After doing so, HF-Dex module results will be presented after every measurement.



Measurement quality is important. Specifically, the patient’s Right Whole Body measurement will need to be of a medium or high quality. If a patient’s Right Whole Body Cole plot was assessed to be low quality (“red”), the measurement should be retaken. If a low quality measurement is accepted, HF-Dex outputs will not be presented. The following error message will instead be displayed.



This result cannot be provided due to low measurement quality “red”. For this measurement to be shown, the Right Whole Body Cole Plot (found in the Cole plot review screen after the measurement) must be medium quality “yellow” or high quality “green”.

HF-Dex Assessment Results

HF-Dex Scores

The HF-Dex score is a tool to assist in the clinical assessment of fluid status on a patient with heart failure by a medical provider. The results screen will display the patient’s HF-Dex score on a scale, with measurements displayed over time from oldest (left) to newest (right). The HF-Dex score is the patient’s ECF/TBW %, compared to clinical data in the following manner:

Light Blue range: HF-Dex values in the light blue reference range are consistent with healthy individuals who do not have heart failure.

Medium Blue range: Patients whose HF-Dex score falls into the medium blue range have a raised score that is above the reference range for healthy individuals who do not have heart failure. Elevated scores can be caused by many factors that are not necessarily indicators of heart failure or decompensation.

Dark Blue range: Patients whose HF-Dex score falls into the dark blue range have a higher score that compares to levels in a decompensated heart failure population. Clinical data shows that patients with elevated scores should be carefully monitored. Decisions regarding the patient's management should be made in conjunction with other clinical data.

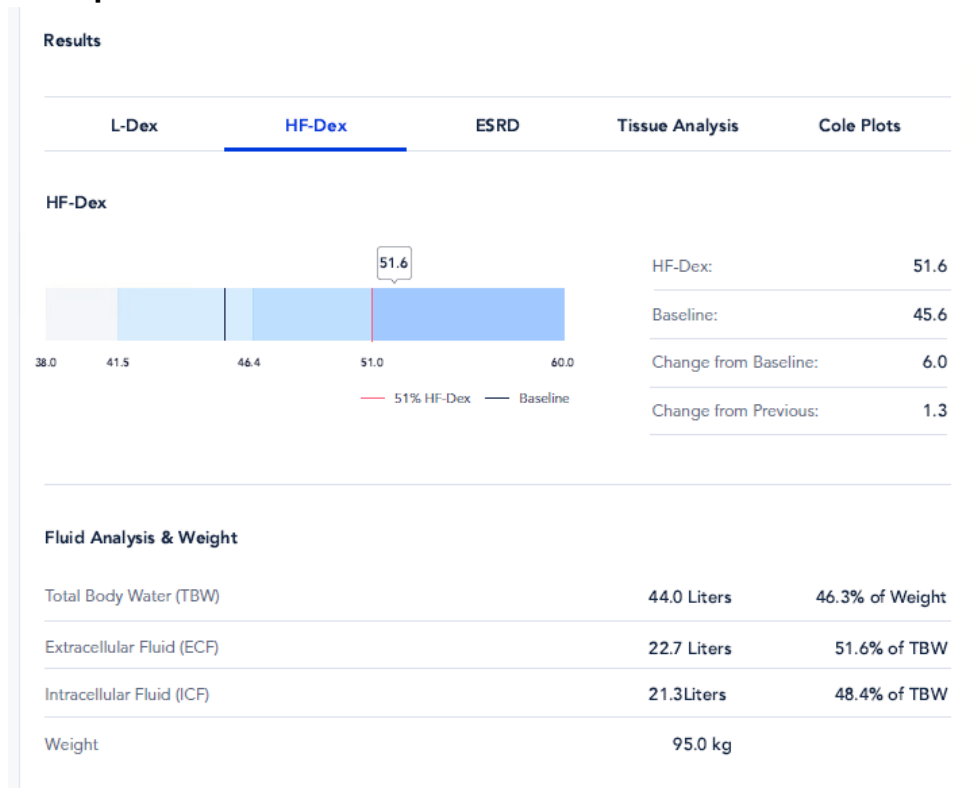
Grey range: HF-Dex values in the grey range may indicate a fluid imbalance for other causes (such as dehydration) or potential issues with measurement accuracy, and requires additional investigation.

Additional information presented includes the patient's baseline HF-Dex score, change vs. baseline, and change from previous HF-Dex score.

When reviewing measurements, the following outputs can also be selected and measurements over time observed in graph form:

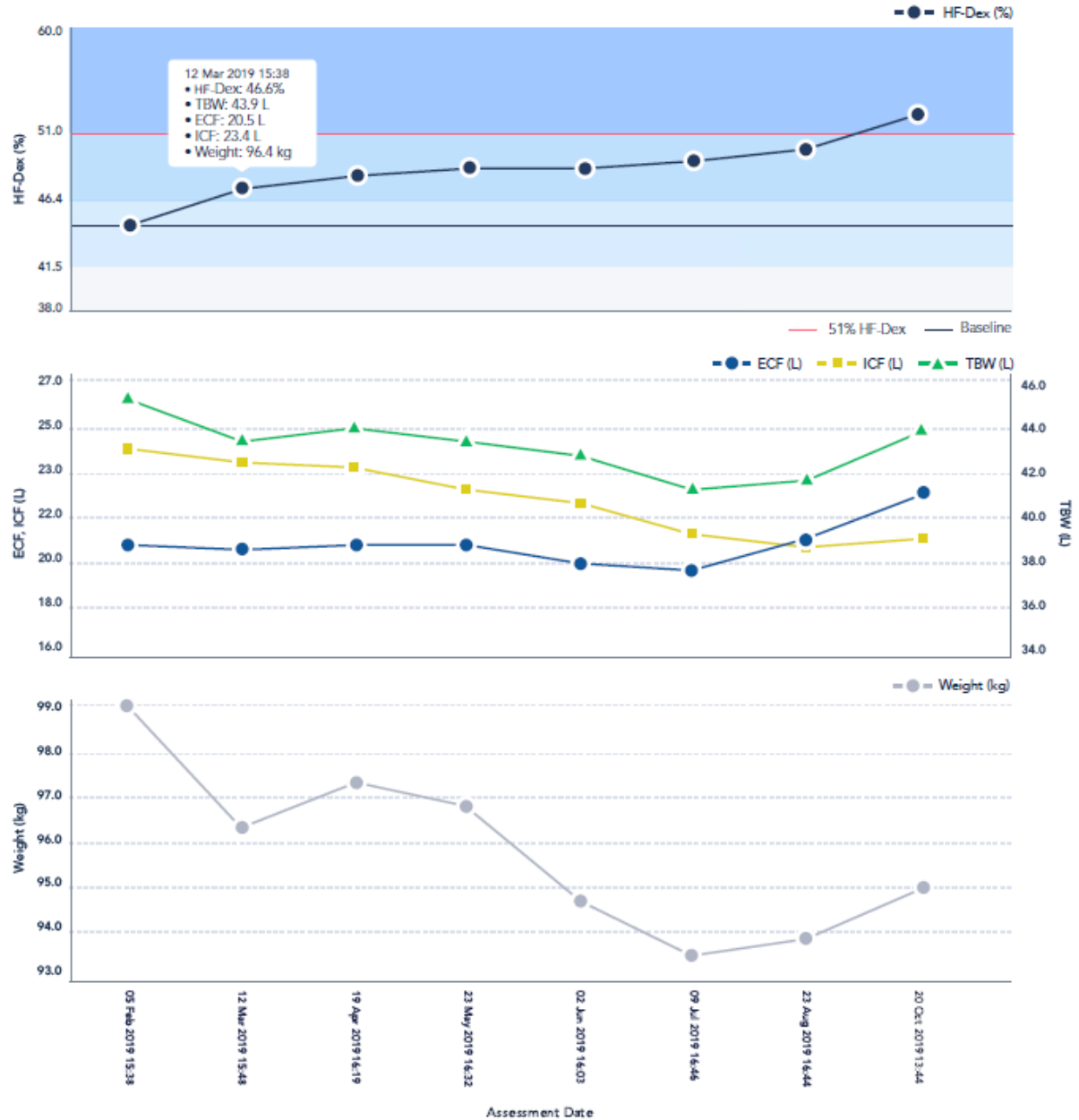
- Total Body Water (TBW)
- TBW as a % of weight
- Extracellular Fluid (ECF)
- ECF as a % of TBW
- Intracellular Fluid (ICF)
- ICF as a % of TBW
- Weight

Example of HF-Dex Results



At the bottom of the results screen, the patient's HF-Dex, TBW, ICF, ECF scores as well as weight will be shown on history graphs similar to the following:

History



Results and historical measurements of the patient may also be viewed in MySOZO. For more information about HF-Dex results, see the main User Guide, "SOZO System Instructions for Use."

Availability of Assessment Type

Only Assessment Types licensed to your facility are available for you to review. For more about licensing of Assessments Types, see the main User Guide, “SOZO System Instructions for Use.” The available Assessment Types for a given user is displayed in the SOZOapp and MySOZO. Licensed Assessments are displayed in the SOZOapp and MySOZO.

Recommended Measurement Frequency

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