



# **SOZO<sup>®</sup> System**

## **Instructions for Use**



ImpediMed Limited

ABN 65 089 705 144

Unit 1

50 Parker Court

Pinkenba Qld 4008

Australia

**Phone:** + 61 7 3860 3700

**Fax :** + 61 7 3260 1225

**Email :** [enquiries@impedimed.com](mailto:enquiries@impedimed.com)

Distributed in the United States by:

ImpediMed Inc

5900 Pasteur Court, Suite 125

Carlsbad, CA 92008

(877) 247-0111

[tsu@impedimed.com](mailto:tsu@impedimed.com)

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

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MediMark Europe Sarl

11 rue Emile ZOLA,

B.P. 2332, 38033 Grenoble Cedex 2

France



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# 1 SYSTEM OVERVIEW

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This instructions for use document (IFU) describes the features of the SOZO medical device, including safety, setup, operation, and troubleshooting instructions. It is important to follow the instructions to keep both the hardware and software systems functioning properly.

## 1.1 Bioimpedance Spectroscopy (BIS) Technology

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 impedance data collected over the frequency range. With additional 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.

## 1.2 Introduction to the SOZO® System

The SOZO System 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

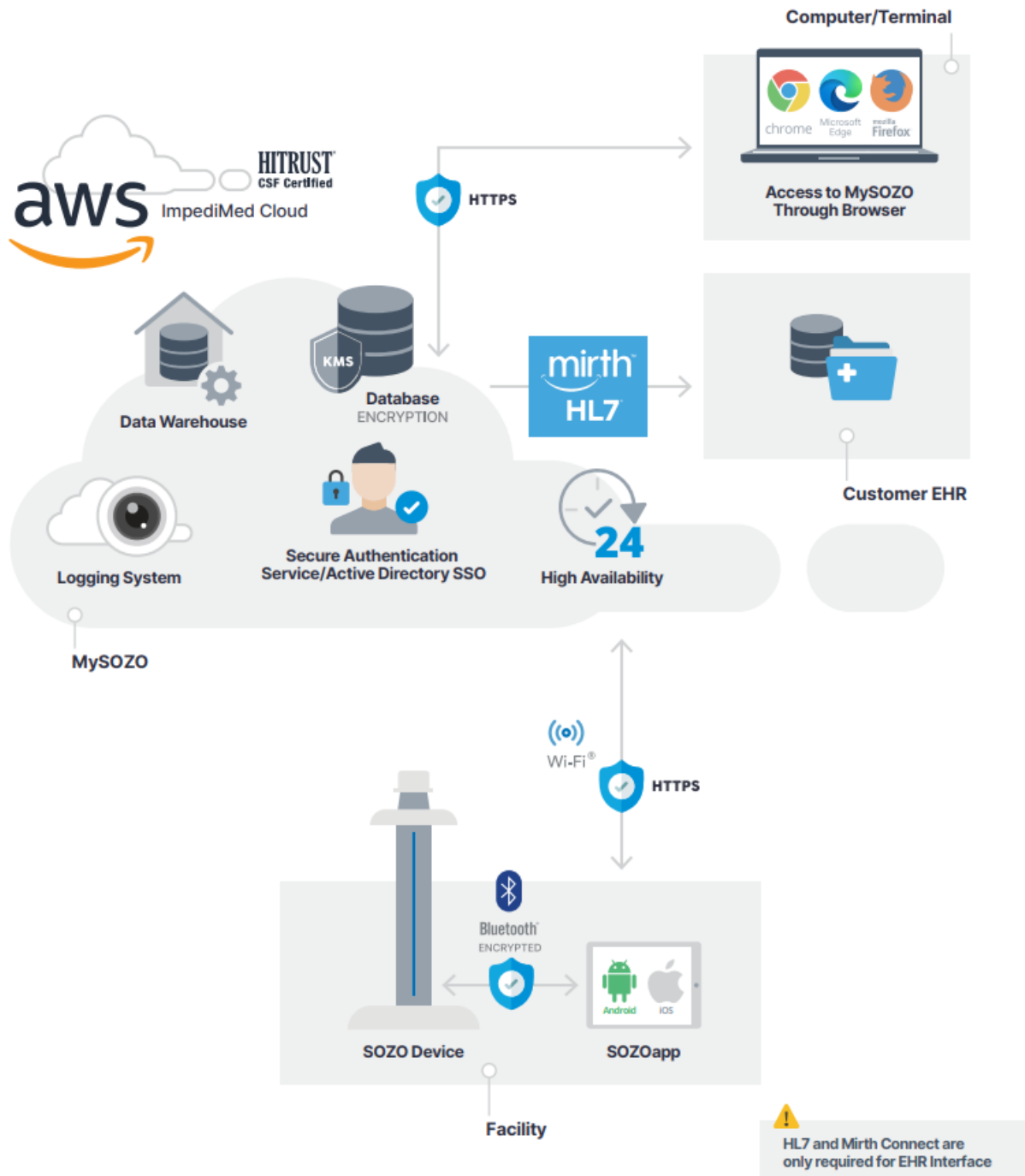
The SOZO System may assist with early detection of lymphedema by giving an "early warning" of patient fluid status change. It may also be used to track fluid levels in patients living with heart failure. The SOZO System may be an integral part of a treatment plan for a lymphedema or a heart failure patient.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

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



### 1.3 The SOZO® System Architecture

The SOZO system is a medical device system made up of hardware and software.



The SOZO system hardware components are the SOZO Device and a Tablet, either a Samsung Galaxy Tablet A (Android) or an Apple iPad (iOS), which communicate using *Bluetooth*<sup>®1</sup> technology.

The SOZO system software is made up of the SOZOapp and MySOZO. The SOZOapp is a software application 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. Users may access and use the SOZO system through the SOZOapp on the Tablet, or access SOZO patient records online at MySOZO.com.

### 1.3.1 Tablet Function

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

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

**iOS:** Contact ImpediMed Technical Support for download instructions.

**Note: screenshots throughout this Instructions for Use are based on the Android SOZOapp and Chrome browser. The iOS SOZOapp screens will look nearly identical. Please note that instructions in this User Guide are for SOZOapp and MySOZO versions 4.1 and later. Not all functionality in later versions is present in earlier ones.**

**Note: Products manufactured by a third-party, such as Tablets, are not covered by ImpediMed's warranty. For further information see Section 14 PRODUCT WARRANTY.**

## 1.4 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.

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## 1.5 Minimum Internet Requirements

Users may access MySOZO.com with any device, including a PC, laptop, or mobile device, with internet access and a Google Chrome, Mozilla Firefox or Chromium-based Edge web browser.

The minimum and recommended requirements for internet access are as follows.

### Minimum and Recommended Requirements

Component	Requirements
Internet Speed	<b>Minimum:</b> >15 Mbps download, 5 Mbps/ upload <b>Recommended:</b> >25Mbps download, 5 Mbps upload
Web Browser	Google Chrome, Mozilla Firefox, Chromium Based Edge

## 1.6 Websites to Whitelist

To be able to take measurements and update the SOZOapp, the tablet will need access to the following websites:









- MySOZO.com
- Updates.MySOZO.com

If the tablet is used on a restricted or managed network, the above websites may need to be whitelisted.

## 2 SAFETY

### 2.1 Signs and Symbols

The warning signs and the symbols below are listed to use this product safely and prevent injury.

Symbol	Definition
	This is an alert to the possibility of a problem with the device associated with its use or misuse that may result in bodily harm or device damage.
	What you should NOT do.
	This information is extremely important and should be followed closely.
	Follow instructions for use.
	A note refers to important information to which the user should pay special attention. Notes provide added insight and helpful information which can be useful to the operator.
	For EU Customers. All products at the end of their life may be returned to ImpediMed for recycling.
	This device is rated BF as per IEC60601-1. This device meets the standard IEC60601-1-2.
	This is a Class 2 medical device.
<b>IP21</b>	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.

## 2.2 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.

## 2.3 Contraindications

2.4 The SOZO Device should not be used by:



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

## 2.5 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.

## 2.6 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 encounter 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.

	<p>Devices or other sources can potentially cause interference problems:</p> <ul style="list-style-type: none"> <li>• Example 1: Heat from a radiant heater.</li> <li>• Example 2: Moisture from a nebulizer.</li> <li>• Example 3: Devices generating large electromagnetic fields such as MRI or DXA.</li> </ul>
	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 inches) 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.

## **2.6.1 Storage Conditions and Use**

### **2.6.1.1 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.

### **2.6.1.2 Environmental Transport and Storage Conditions**







The SOZO Device must be transported and stored within 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.

## 2.6.2 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 on 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.

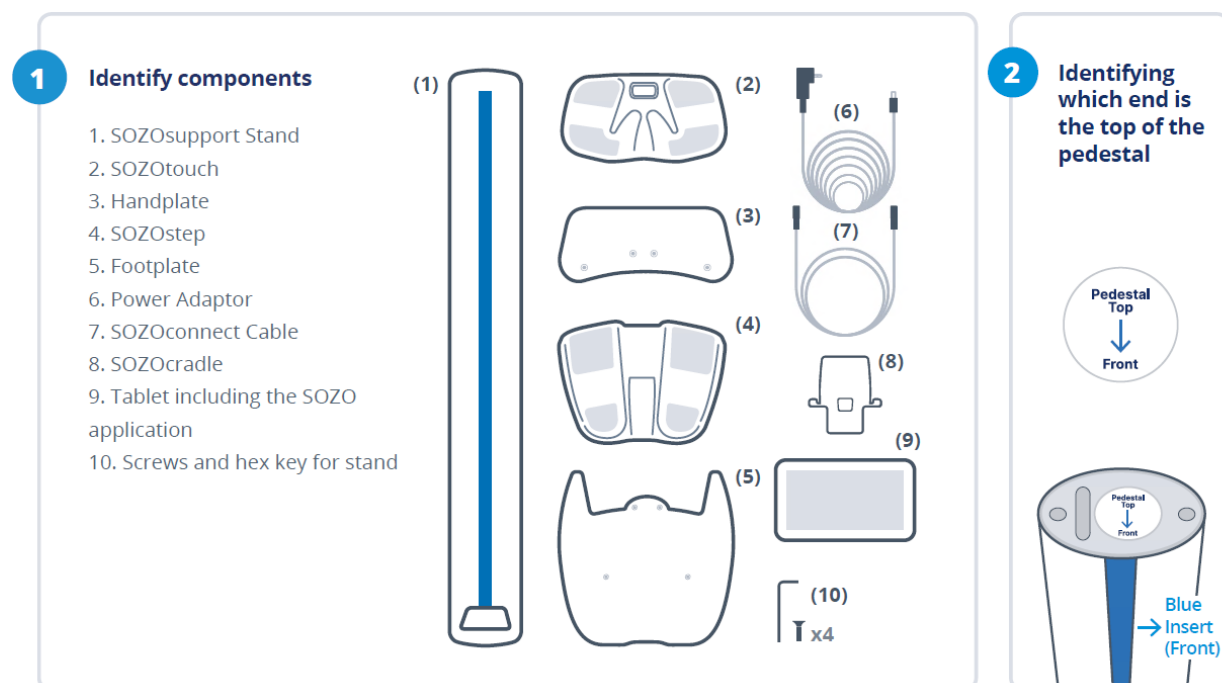
	Do not place SOZO Device on any object or material made of metal, other than the SOZOsupport footplate and Handplate.
	The SOZO Device should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the SOZO Device should be observed to verify normal operation 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 may interfere with the SOZO Device performance including: the effects of lint, dust, light (including direct sunlight), as well as pets, pests, or children. Example: Devices generating large electromagnetic fields such as MRI or DXA.
	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.



## 3 DEVICE ASSEMBLY

### 3.1.1 Identify SOZO® Device Components

Before assembly, identify the SOZO Device components shown below.



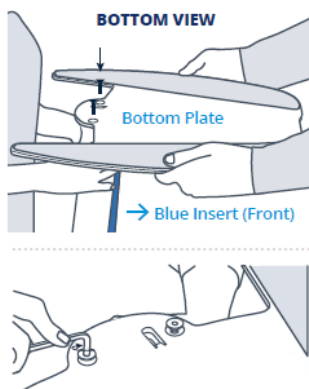
### 3.2 Assembling the SOZO® Device with SOZOsupport Stand

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.

### 3 Screw the footplate (5) into the base of the SOZOsupport Stand (1).

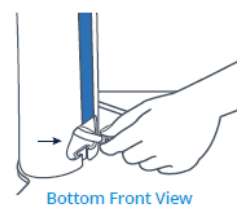
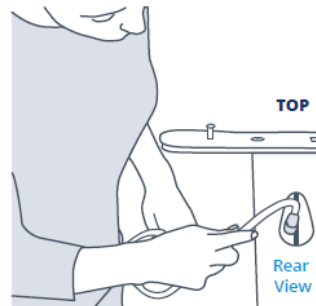
**\*NOTE:** It is recommended that two people take part in assembling the stand in order to make the process quicker, easier and safer.

Have one person hold the stand with the base upward. Have the second person hold the footplate on the stand while the first person attaches the plate using the hex key (10).



### 5 Lace the SOZOconnect cable (7) through the SOZOsupport Stand (1).

Feed the SOZOconnect cable through the droplet hole on the back of the stand and out the front hole at the base of the stand.



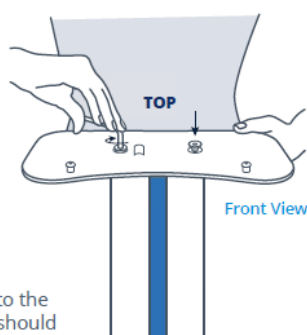
**\*NOTE:** The connector cable port is identical on both the hand plate and foot plate.

### 4 Screw the handplate (3) into the top of the SOZOsupport Stand (1).

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

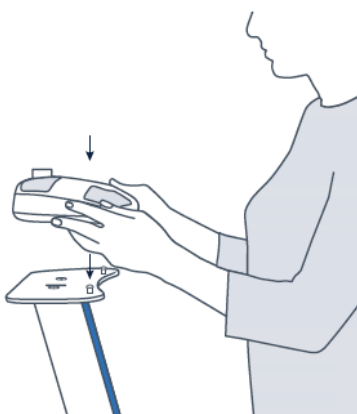
b. Using the hex key (10), attach the handplate with the remaining screws provided.

**\*NOTE:** Once both plates are connected to the SOZOsupport Stand, the large drop hole should be near the top opposite of the blue stripe as shown in top graphic of step 4.



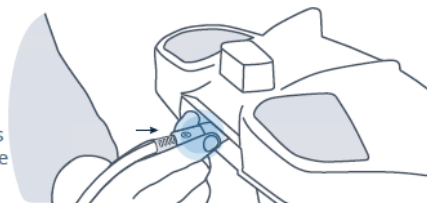
### 6 Attach the SOZOtouch (2) to the handplate (3).

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



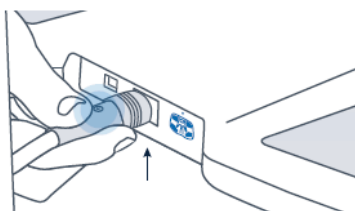
### 7 Attach the SOZOconnect cable (7) to the SOZOtouch (2).

Ensure the screw on the connector cable is facing upwards before attaching it to the SOZOtouch.



### 8 Attach the SOZOconnect cable (7) to the SOZOstep (4).

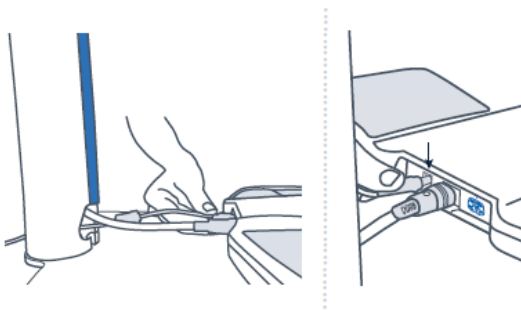
Ensure the screw on the connector cable is facing upwards before attaching it to the SOZOstep.



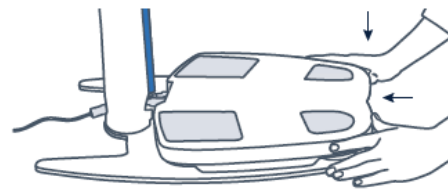
**9****Connect the power cord (6) to the SOZOstep (4).**

**\*NOTE:** Ensure the SOZOconnect cable is plugged into both the SOZOtouch and SOZOstep before connecting the power cord to the SOZOstep.

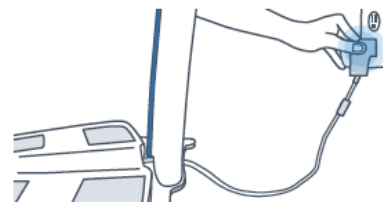
Locate the power supply port on the back of the SOZOstep. Feed the corresponding end of the power supply cable through the openings in the bottom of the stand and connect it into the port.

**10****Attach the SOZOstep (4) to the footplate (5).**

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



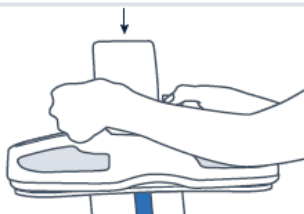
**b.** Once the SOZOstep is in place, plug the power cord into the wall.



**\*NOTE:** Please ensure there is 4 inches or 10 centimeters between the backside of SOZOtouch and any wall.

**11****Attach the SOZOcradle (8) to the SOZOtouch (2).**

Once the cradle is secure, place the tablet (10) in a landscape position on the SOZOcradle.




**12****Set-Up Complete.****NOTES:**

For an easier process, 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.

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

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

**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 Footplate before connecting the Power Cord. If the SOZO Device must be moved, ensure that the Power Cord is disconnected before moving or uninstalling the system.
	When plugging the Power Cord into the wall outlet, the SOZO system will automatically run a self-test to ensure functionality. Do not touch the stainless-steel electrodes when a self-test is running.

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

### **3.3 Assembling the SOZO® Device without the SOZOsupport Stand.**

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

1. Place the SOZOtouch on a level surface at a comfortable height, such as a table or desk, so the patient may place their hands on the SOZOtouch while they are sitting down.
2. 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.
3. 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.
4. Locate the power supply port on the back of the SOZOstep and plug the corresponding end of the Power Cord into that port.
5. 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.

**NOTE:** 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.

To use the SOZO Device while the patient is sitting, follow the [instructions for use](#).



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



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



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

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

## 4 MySOZO

---

### 4.1 Introduction to the MySOZO System

- The MySOZO system is a cloud based system encompassing database storage, encryption, data analysis, secure authentication services and a logging system.
- MySOZO allows the user to access the SOZO system from any user device with internet access and Google Chrome, Mozilla Firefox, or Chromium-based Edge web browsers (“supported browsers”). See MySOZO Minimum Requirements. It is easy to set up, and there is no need to install any software.
- MySOZO is accessed through a web portal, MySOZO.com. SOZO accounts and patient data, including measurement data and assessment results may be viewed in MySOZO.
- The SOZOapp interfaces with MySOZO to access patient data and accounts which allows a clinician to manage their patients. In addition, the SOZOapp interfaces with the SOZO Device to take measurements.
- A MySOZO account must be created before the user can begin using the SOZOapp on the Tablet or access MySOZO.com.
- After the Clinic receives and starts the SOZO system setup, 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 the Clinic Administrators. All users, whether they are Administrators or Clinicians, are identified by their email address.

### 4.2 MySOZO Users (Administrators and Clinicians)

The below steps apply to all MySOZO users. These include sign in, password set-up, and reset for forgotten password or expiration.

## 4.2.1 First Time Set-Up

### 1. New user Email

- a. ImpediMed sends the user an email from [no-reply@impedimed.com](mailto:no-reply@impedimed.com) with a temporary password, as shown in example below  
The user clicks the Password setup link provided in the email.

### 2. Set New Password

- a. After the user clicks the email link, a new browser window opens and the “Set New Password” screen appears. The user enters the Temporary Password that was provided in the email followed by the password and confirmation of the new password. To view the password, click the eye icon.
- b. Ensure the new password meets all letter and character requirements.

Note: 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

- c. To set and confirm the new password, click submit.

**NOTE: Only the user has access to their password. No other user may see or have access to this password.**

1

impedimed®

SOZO Digital Health Platform

**Welcome to MySOZO!**

MySOZO is the online portal for the SOZO Digital Health System by ImpediMed. To begin, start by setting up your password. After your password is setup, you can access MySOZO using a Chrome or Firefox browser at <https://mysozocloud.com>.

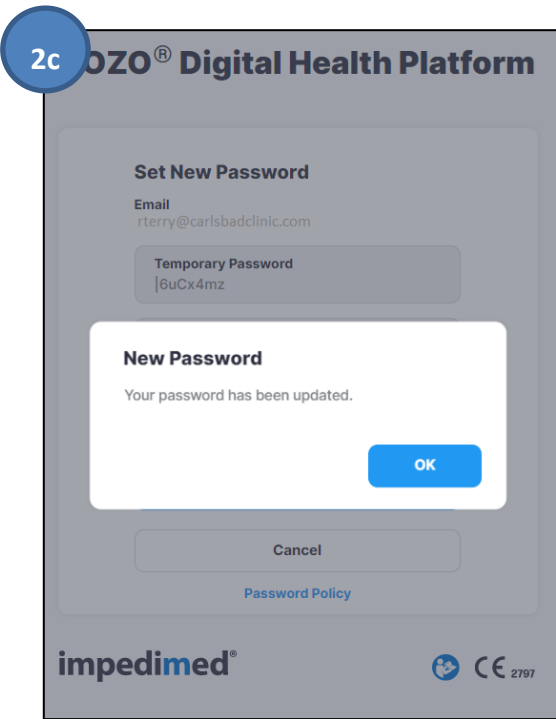
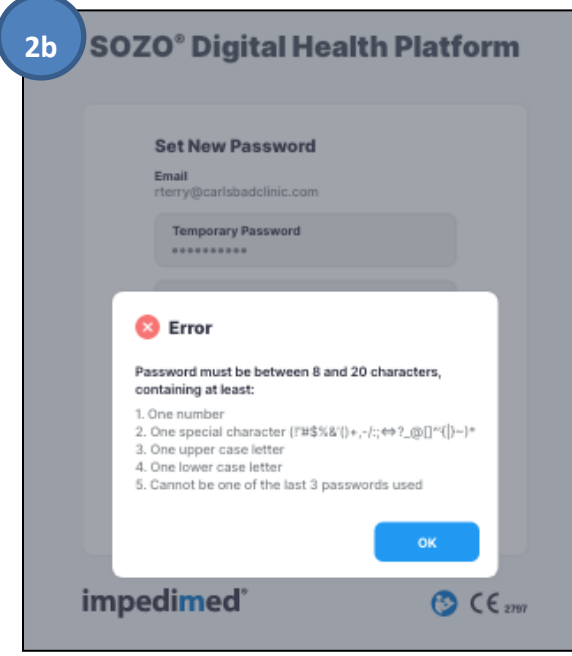
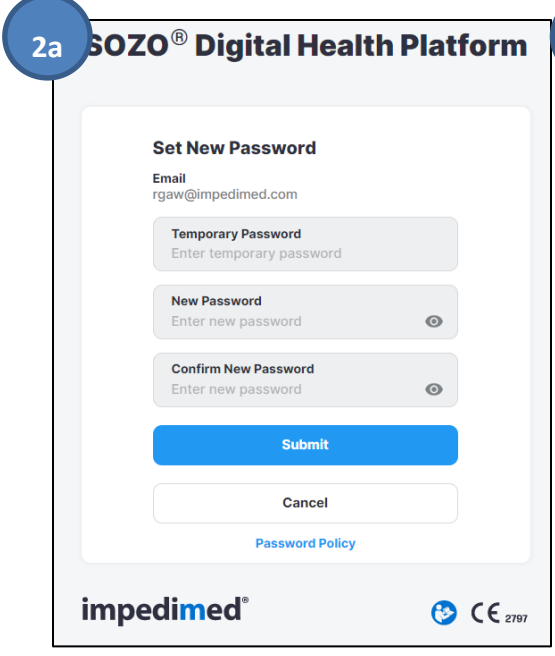
Password setup:  
<https://mysozocloud.com/NewPassword?usernameParameter=rterry@carlsbadclinic.com&newUser=true>

Your temporary password: 0iCY0tb,

If you need any help, we encourage you to contact us at [www.impedimed.com/support](http://www.impedimed.com/support).

Sincerely,  
ImpediMed Customer Experience Team

NOTICE: This email originated from outside of ImpediMed's organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.





## 4.2.2 Password Reset

1. If the user is experiencing trouble signing in or have forgotten their password, click “forgot password”, located underneath the password box on the sign in screen.
2. When prompted, the user will enter the email address for their MySOZO account.
3. A pop-up notifies the user that a password reset email will be sent from ImpediMed if a valid email has been entered.
4. After the user has received the email with password reset instructions, click the Reset Password link in the email. A new browser window opens and the “Set New Password” screen appears.
  - a. Ensure new password meets all letter and character requirements.
  - b. Set and confirm new password. Click submit.

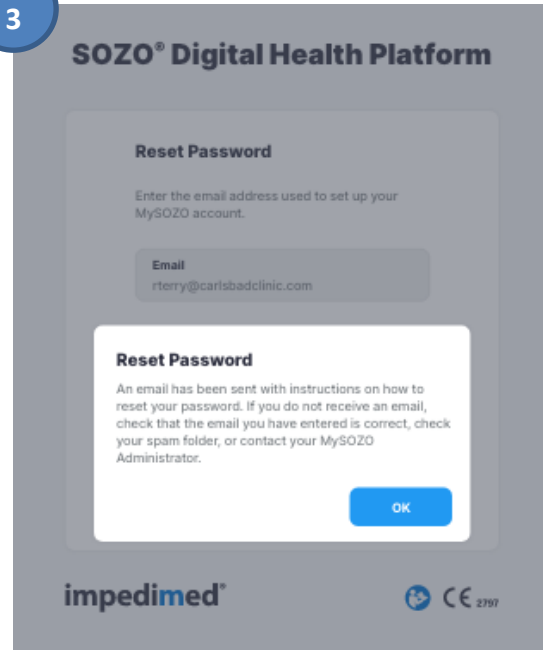
The image displays two screenshots of the SOZO Digital Health Platform interface, illustrating the password reset process.

**Screenshot 1: Sign In Screen**

The Sign In screen features the SOZO Digital Health Platform header. Below the header, the Sign In section includes an Email input field, a Password input field, and a Language dropdown menu (set to English (US)). A blue Sign In button is positioned below the input fields. A link labeled "Forgot password?" is located below the Password input field, circled in red. At the bottom of the Sign In section, there is a link for "Secure sign in with SSO" with a right arrow. The footer displays the impedimed logo and a CE 2797 certification mark.

**Screenshot 2: Reset Password Screen**

The Reset Password screen features the SOZO Digital Health Platform header. Below the header, the Reset Password section includes a prompt: "Enter the email address used to set up your MySOZO account." Below this prompt is an Email input field. A blue Submit button is positioned below the input field. Below the Submit button, there is a link for "Forgot email used for your MySOZO account? Please contact your MySOZO administrator." At the bottom of the Reset Password section, there is a Cancel button. The footer displays the impedimed logo and a CE 2797 certification mark.



4

**impedimed®** **SOZO Digital Health Platform**

A request has been made to reset the MySOZO password associated with [rterry@carlsbadclinic.com](mailto:rterry@carlsbadclinic.com).

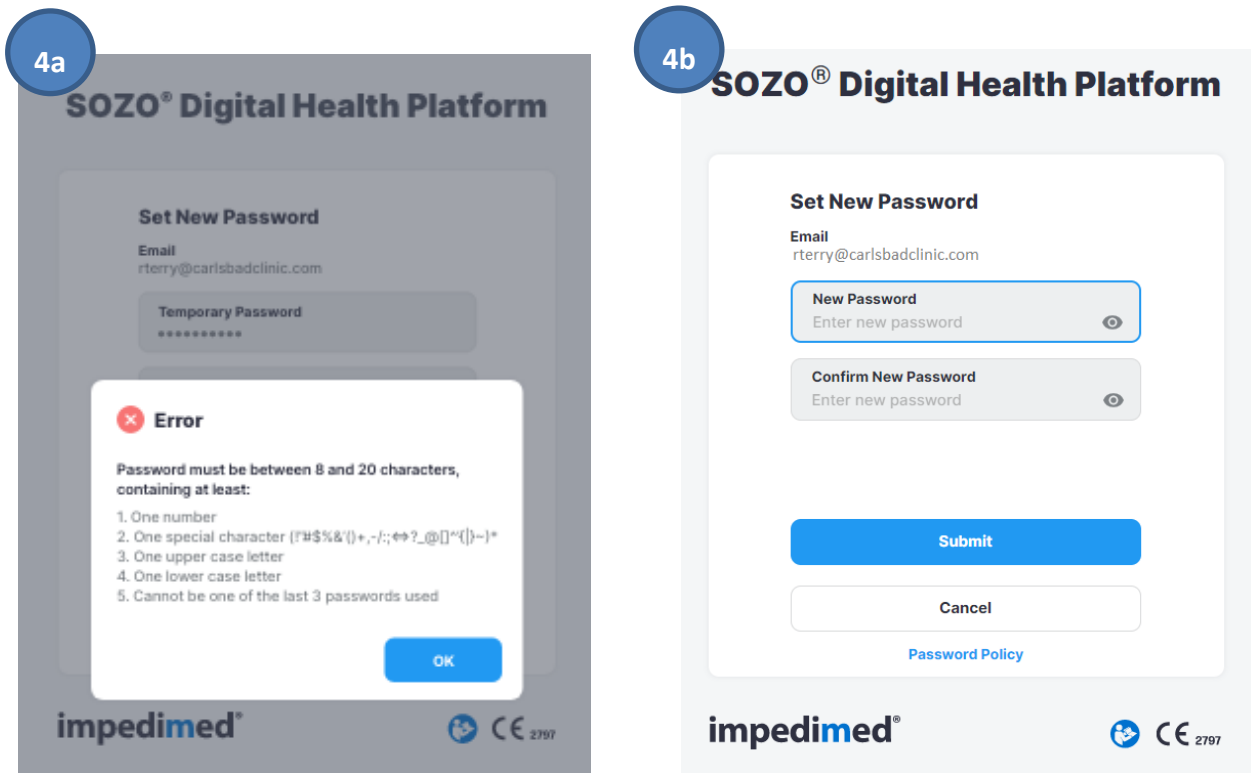
Click this link to reset your password:  
<https://mysozocloud.com/NewPassword?usernameParameter=rterry@carlsbadclinic.com&newUser=false&codeParameter=090732>

If you did not request a password reset, contact your MySOZO Administrator. You can access MySOZO using a Chrome or Firefox browser at <https://mysozocloud.com>.

Sincerely,

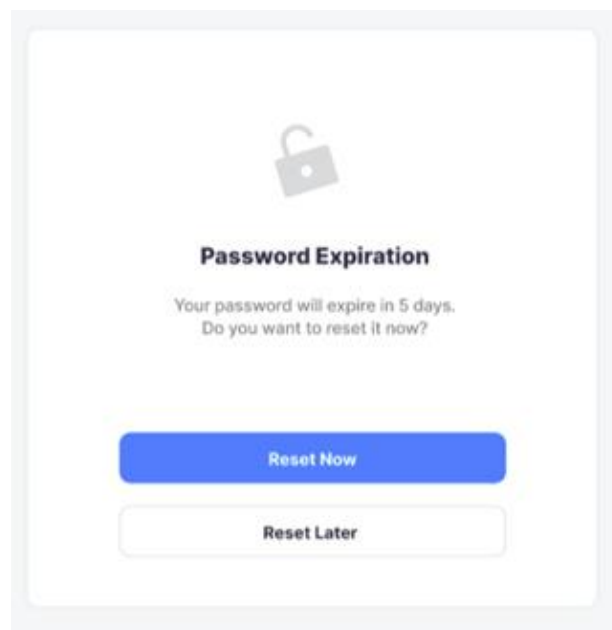
ImpediMed Customer Experience Team  
[www.impedimed.com/support](http://www.impedimed.com/support)

**NOTICE:** This email originated from outside of ImpediMed's organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.



### 4.2.3 Password Expiration

The Clinic Administrator will set the Password Expiration Period in days (30-1000 days). A pop-up will warn the user about upcoming password expiration. To reset the password, click **Reset Now**.



# 5 MYSOZO ADMINISTRATOR

A user with an Administrator role has authority to do the following:

- Manage MySOZO user accounts (create, edit, delete, restore users)
- Create and edit groups
- Create and edit tags
- Adjust SOZO system-wide settings which include security, report logo, time zone and multi-factor authentication settings
- Export Audit Logs.

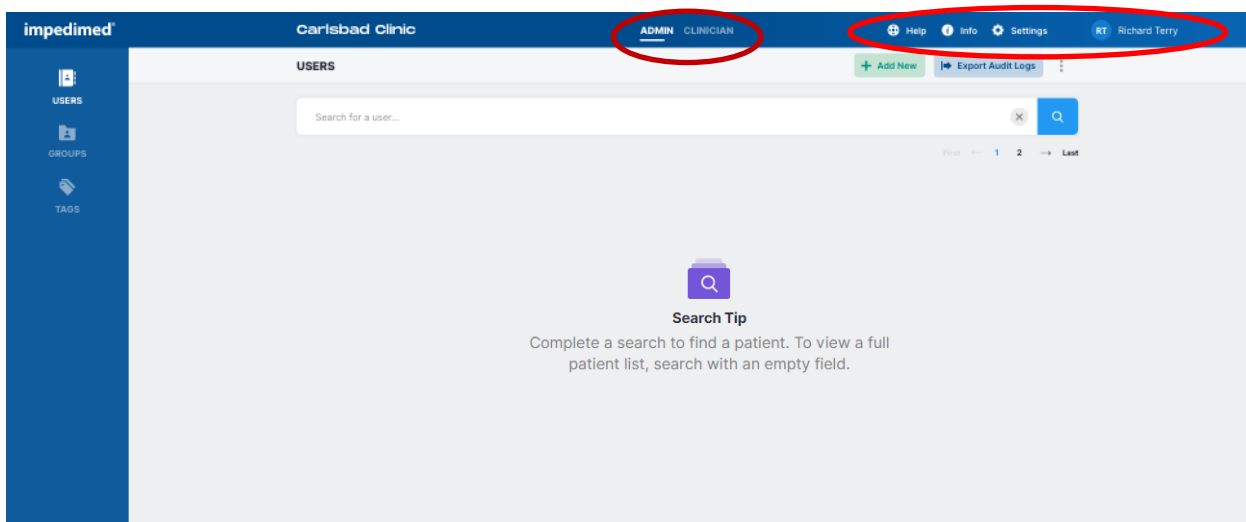
A user with an Administrator role can be created or added by another existing user with an Administrator role. Users are identified by their email address.

## 5.1 Administrator Home Page

For Administrators, set a password and sign in per instructions in the [First Time Set-Up](#) section of the IFU. After signing in the MySOZO Administrator home page will display the User List.

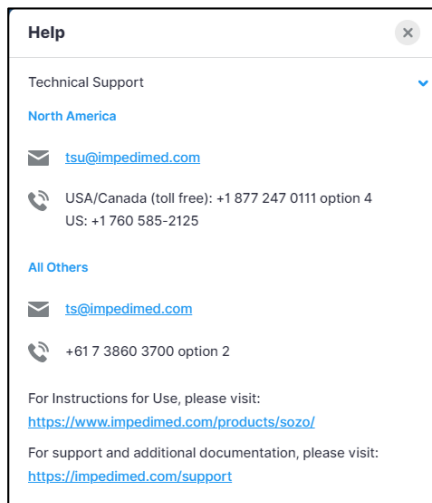
Users may be assigned both Administrator and Clinician roles, and access both functions from the same sign in. The Admin icon is bold and underlined if the user is signed in as an Administrator. If an Administrator also has the Clinician role, they can toggle between Administrator and Clinician screens by clicking **Admin** or **Clinician**.

The banner icons enable common administrative functions.



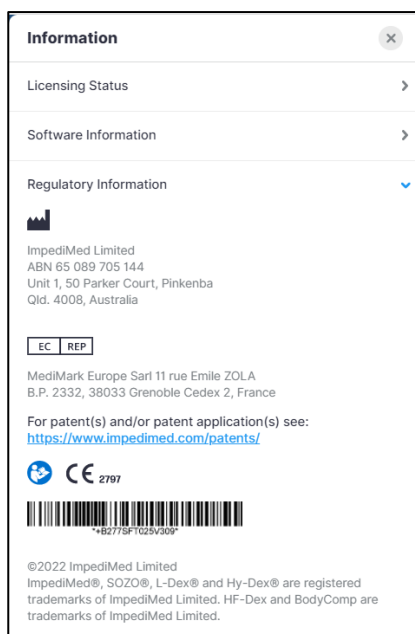
### 5.1.1 Help Icon

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



### 5.1.2 Info Icon

For information about MySOZO, click the **Info** icon. The Information page includes Licensing Status, Software Information and Regulatory Information.



**Licensing Status:** Lists all SOZO modules, active modules are shown with the description underneath, inactive modules are displayed as “Not active”.

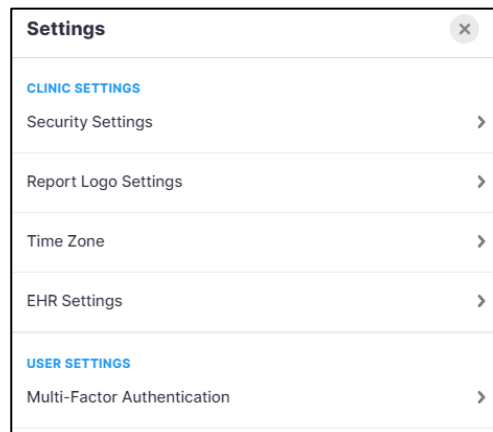
**Software Information:** Displays current mySOZO version and if it is up to date. There is also an option to update if required. Release notes for current and previous versions are listed.

**Regulatory Information:** Provides information regarding the manufacturer, notified body and other important information.

### 5.1.3 Administrator Settings Icon

The Administrator may adjust MySOZO system-wide settings by clicking Settings, located in the top right corner of the home page.

This includes Clinic Settings - Security Settings, Report Logo Settings, Time Zone, EHR Settings and User Settings - Multi-Factor Authentication. If changes have been made, click Save. A success confirmation will appear in the top right corner.



#### 5.1.3.1 Security Settings

In SOZOapp default settings, users set up and maintain individually chosen passwords specific to MySOZO and SOZOapp. Per hospital policy, MySOZO allows a user with Administrator role to configure Single Sign-On (SSO) or Multi-Factor Authentication (MFA) as additional security measures.

##### 5.1.3.1.1 Administrator Multi-Factor Authentication

The Clinic Administrator may elect to implement **Multi-Factor Authentication** for all users within the clinic. Within settings, the Administrator will define the date by which all other users must implement MFA for their account from within settings. On that date, all users will have to implement MFA for their own account after attempting to sign in.

**Settings**

CLINIC SETTINGS

Security Settings

**Multi-Factor Authentication**

☒ Clinic MFA

Date that all users must enable MFA by: 12 May 2023

Password Required

Save

To turn MFA on, the Administrator will need to check Clinic MFA under Security Settings, enter an enable by date, their password and click Save.

Once enabled, MFA will require use of a code generated by a 3<sup>rd</sup> party authenticator app (e.g. Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is set up, activate the MFA for the Clinic Administrator account using the slider under User Settings, Multi-Factor Authentication (see User Multi-Factor Authentication).

#### 5.1.3.1.2 Single Sign On

If your organization is set up for **Single Sign-On (SSO)** users can rely on SSO to sign in instead. Users can work with ImpediMed Technical Support to set up SSO.

**SSO**

☒ I want to have SSO as an authentication server

Domain Name Required

Import SAML file Required

Browse

Password Required

Save

### 5.1.3.1.3 Password and Sign Out Policy

The Clinic Administrator can set the Password Expiration Period here. This defines the length of time which a user's password is valid. After this time period, the user is required to change their password. It can range from 30 to 1000 days.

The Clinic Administrator can also set the Sign out Inactivity Time here. This defines the length of time which a user remains signed into the SOZO system from their initial Sign in or last extension. After this time period, the user is automatically signed out or prompted to extend the session. It can range from 5 to 60 minutes.

**Password Policy**

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. Cannot be one of the last three passwords used.

Password Expiration Period (in days)

Range: 30 - 1000 days

**Sign out Policy**

Sign out Inactivity Time (in minutes)

Range: 5 - 60 minutes

**Save**

### 5.1.3.2 Report Logo Settings


The Clinic Administrator can upload a logo to the SOZO system. This logo will be printed on reports. The maximum size is 1MB and the supported file format is .png.

**Settings** ×

**CLINIC SETTINGS**

Security Settings >

Report Logo Settings ▼



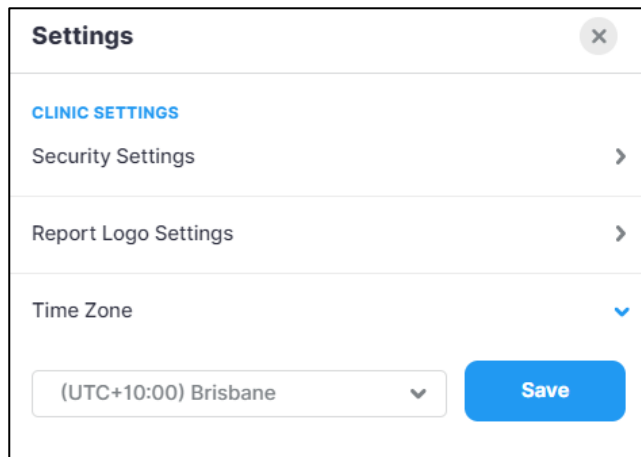
Maximum Size 1MB  
File supported format PNG

**Save**



### 5.1.3.3 Time Zone

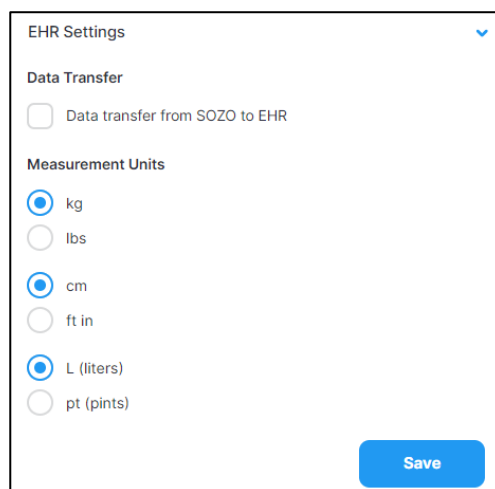
The Clinic Administrator can select the correct time zone here.



The screenshot shows a 'Settings' dialog box with a close button (X) in the top right corner. Under the 'CLINIC SETTINGS' section, there are three items: 'Security Settings', 'Report Logo Settings', and 'Time Zone'. The 'Time Zone' item is expanded, showing a dropdown menu with '(UTC+10:00) Brisbane' selected. A blue 'Save' button is located at the bottom right of the dialog.

### 5.1.3.4 EHR Settings

The Clinic Administrator can work with ImpediMed Technical Support during MySOZO setup or contact ImpediMed Technical Support after the system has been installed, to set up the EHR Interface Settings. Full EHR interface configuration will require additional set-up outside of MySOZO to complete.

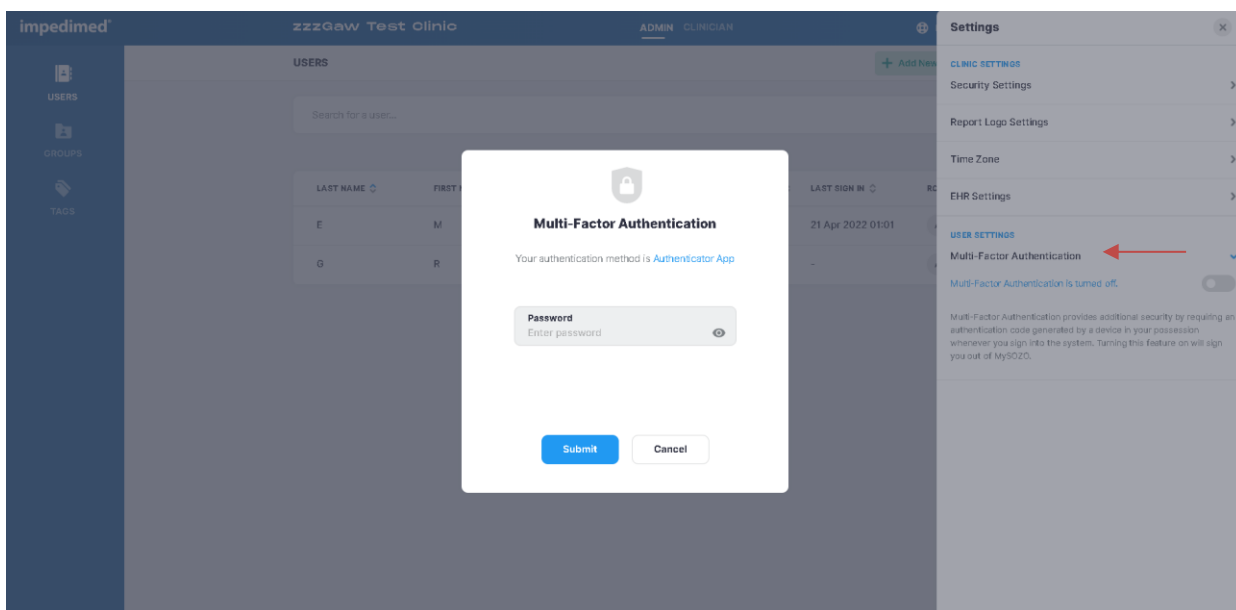


The screenshot shows an 'EHR Settings' dialog box with a close button (X) in the top right corner. It contains two sections: 'Data Transfer' and 'Measurement Units'. In the 'Data Transfer' section, there is a checkbox labeled 'Data transfer from SOZO to EHR' which is currently unchecked. In the 'Measurement Units' section, there are five radio button options: 'kg' (selected), 'lbs', 'cm' (selected), 'ft in', and 'L (liters)' (selected). There is also an option for 'pt (pints)' which is unchecked. A blue 'Save' button is located at the bottom right of the dialog.

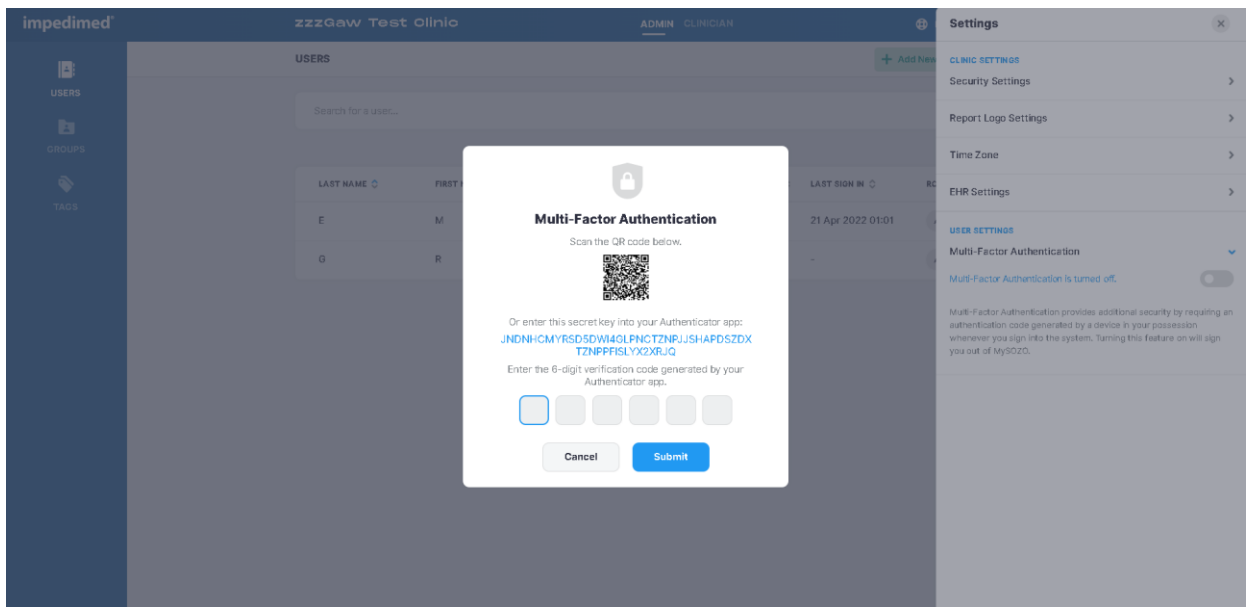
After the EHR interface has been established, the Clinic Administrator can start data transfer to an electronic health record by checking the data transfer box and select the measurement units for the transfer. Contact ImpediMed Technical Support for further details.

### 5.1.3.5 User Multi-Factor Authentication

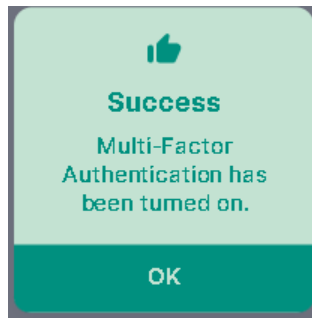
Once enabled by a Clinic Administrator (see Administrator Multi-Factor Authentication), MFA will require use of a code generated by a 3<sup>rd</sup> party authenticator app (e.g. Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is set up, activate the MFA for the Clinic Administrator by using the slider under User Settings, Multi-Factor Authentication. At this point a pop-up will display and the Administrator password is required to be entered.



Next, a pop-up will show displaying a QR code that can be used to link to a third-party authenticator, and first-time entry of the MFA code.



A pop-up will be displayed confirming successful set up.



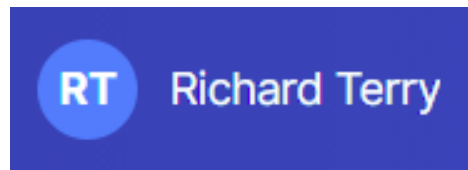
The Administrator will be signed out of the system, and from that point on, will have to use both a password and an MFA code to sign back in.

**Note: once an Administrator has required MFA use by the clinic and the enable date has passed, staff will not be able to sign in to SOZOapp or MySOZO without implementing their own personal MFA.**

An Administrator may elect to turn MFA off for all users. This can be performed from within MySOZO settings, and requires entry of both the user password and an MFA code. After turning MFA off a success message will appear. The user will then be signed out of the system and return to the sign in screen.

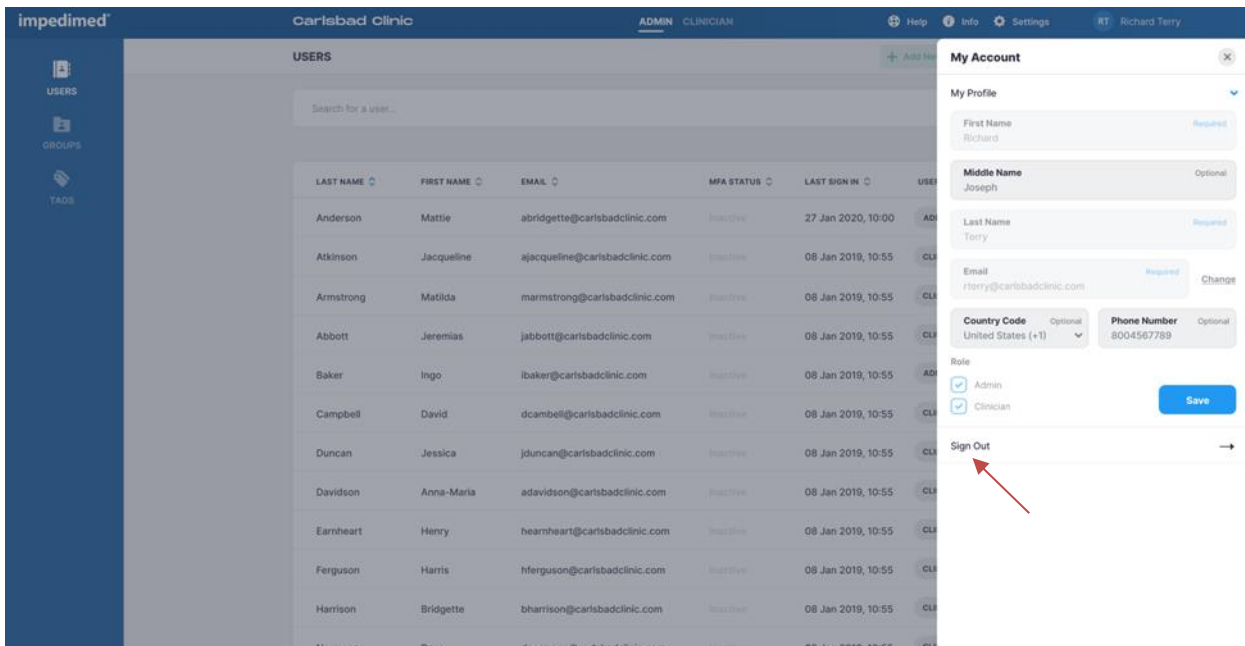
## 5.1.4 Administrator User Profile Icon

The name of the user signed into MySOZO appears next to the User Profile icon.



To review or edit the User profile, click User Profile icon and then select **My Profile**.

To sign out of MySOZO at any time, click the User Profile icon then click the **Sign Out** option in the menu.



The screenshot shows the 'My Account' dropdown menu open over the 'USERS' table. The menu includes options for 'My Profile' and 'Sign Out'. A red arrow points to the 'Sign Out' option.

LAST NAME	FIRST NAME	EMAIL	MFA STATUS	LAST SIGN IN	USER
Anderson	Mattie	abridgette@carlsbadclinic.com	Inactive	27 Jan 2020, 10:00	AD
Atkinson	Jacqueline	ajacqueline@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Armstrong	Matilda	marmstrong@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Abbott	Jeremias	jabbott@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Baker	Ingo	ibaker@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	AD
Campbell	David	dcampbell@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Duncan	Jessica	jduncan@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Davidson	Anna-Maria	adavidson@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Earnheart	Henry	hearnheart@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Ferguson	Harris	hferguson@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Harrison	Bridgette	bharrison@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL
Norena	Dave	dnorena@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CL

**My Account**

**My Profile**

First Name: Richard (Required)

Middle Name: Joseph (Optional)

Last Name: Terry (Required)

Email: rterry@carlsbadclinic.com (Required) Change

Country Code: United States (+1) (Optional) Phone Number: 800-456-7789 (Optional)

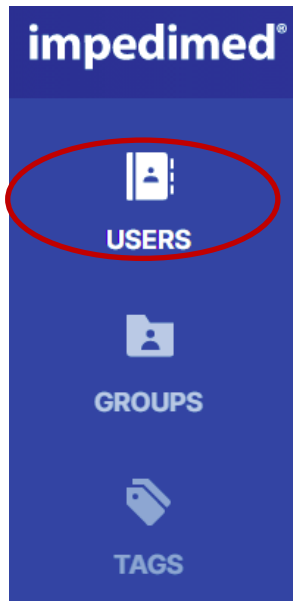
Role: ☒ Admin ☒ Clinician

Save

Sign Out

## 5.2 Administrator User List

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



### 5.2.1 Create New User

An Administrator creates a user by clicking **Add New**. The user may be assigned as an Administrator and/or Clinician. There is no limit to the number of users that can be created.

1. On the **Create User** screen, enter the user's first name, last name, and email address.
  - a. The remaining fields, including middle name, country code, and phone number, are optional.
2. Under **Role** select Administrator and/or Clinician.
3. When done, click **Create** and enter the Administrator password.

**Carlsbad Clinic** ADMIN CLINICIAN Help Info Settings

**USERS** + Add New Export Logs

Search for a user...

**Create User**

**USER DETAILS**

**First Name** Required  
Enter first name

**Middle Name** Optional  
Enter middle name

**Last Name** Required  
Enter last name

**Email** Required  
Enter email

**Country Code** Optional  
Select country code

**Phone Number** Optional  
Enter phone number

**Role** Required

☐ Admin

☐ Clinician

**Create**

LAST NAME	FIRST NAME	LAST SIGN IN	USER ROLE
Anderson	Matt	27 Jan 2020, 10:00	ADMIN CLINICIAN
Atkinson	Jacqueline	08 Jan 2019, 10:55	CLINICIAN
Armstrong	Matt	08 Jan 2019, 10:55	CLINICIAN
Abbott	Jerome	08 Jan 2019, 10:55	CLINICIAN
Baker	Ingrid	08 Jan 2019, 10:55	ADMIN CLINICIAN
Campbell	David	08 Jan 2019, 10:55	CLINICIAN
Duncan	Jessie	08 Jan 2019, 10:55	CLINICIAN
Davidson	Anna	08 Jan 2019, 10:55	CLINICIAN
Earnheart	Henry	08 Jan 2019, 10:55	CLINICIAN

**Create User**

**USER DETAILS**

**First Name** Required  
Enter first name

**Middle Name** Optional  
Enter middle name

**Last Name** Required  
Enter last name

**Email** Required  
Enter email

**Country Code** Optional  
Select country code

**Phone Number** Optional  
Enter phone number

**Role** Required

☒ Admin

☒ Clinician

**Create**

**Password**

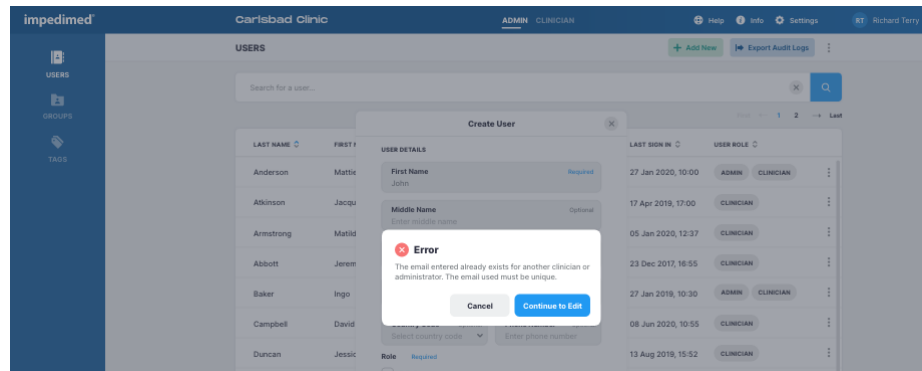
For security reasons in order to create a user your password is required to proceed.

**Password** Required

.....

**Cancel** **Submit**

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



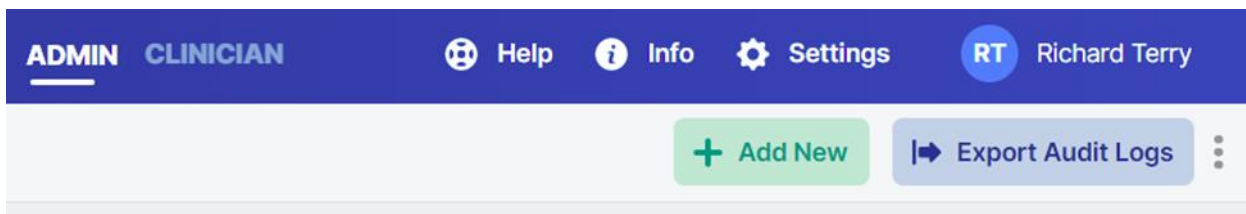
## 5.2.2 Audit Logs

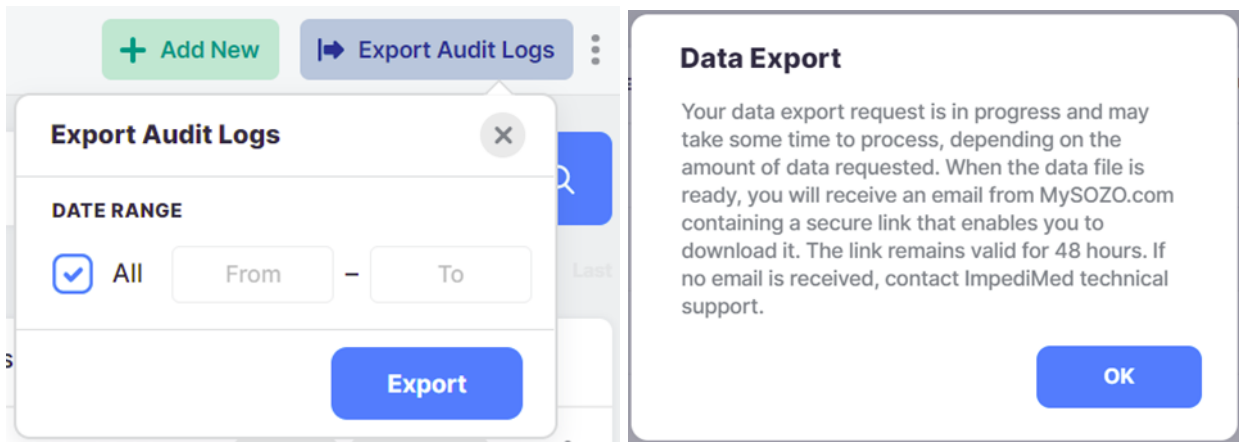
A user with Administrator role may access audit logs of all system access and events, to assist in any audit or investigation. Audit logs may be exported directly from MySOZO.

Audit logs include identity of users who have viewed certain MySOZO pages or information, identity of users who have retrieved data, users' sign in and log out dates and times, date and time of measurements, edits to patient or user profiles.

To export audit logs:

1. Click **Export Audit Logs** in the top right corner.
2. Check **all** to view all audit logs.
  - a. Enter dates in the "To" and "From" box to view audit logs from a specific date range. The default is set to 'all dates'.
3. Click **Apply** to export logs.
4. A pop-up will appear, stating that the data export request is in progress.
5. ImpediMed will send the user an email containing a secure link to download the Audit Logs. The link is valid for 48 hours.





The file will be sent to the email address used to sign in, and can be opened in Notepad. It will contain detailed logs including the date, time and actions undertaken by each user.

### 5.2.3 Edit User

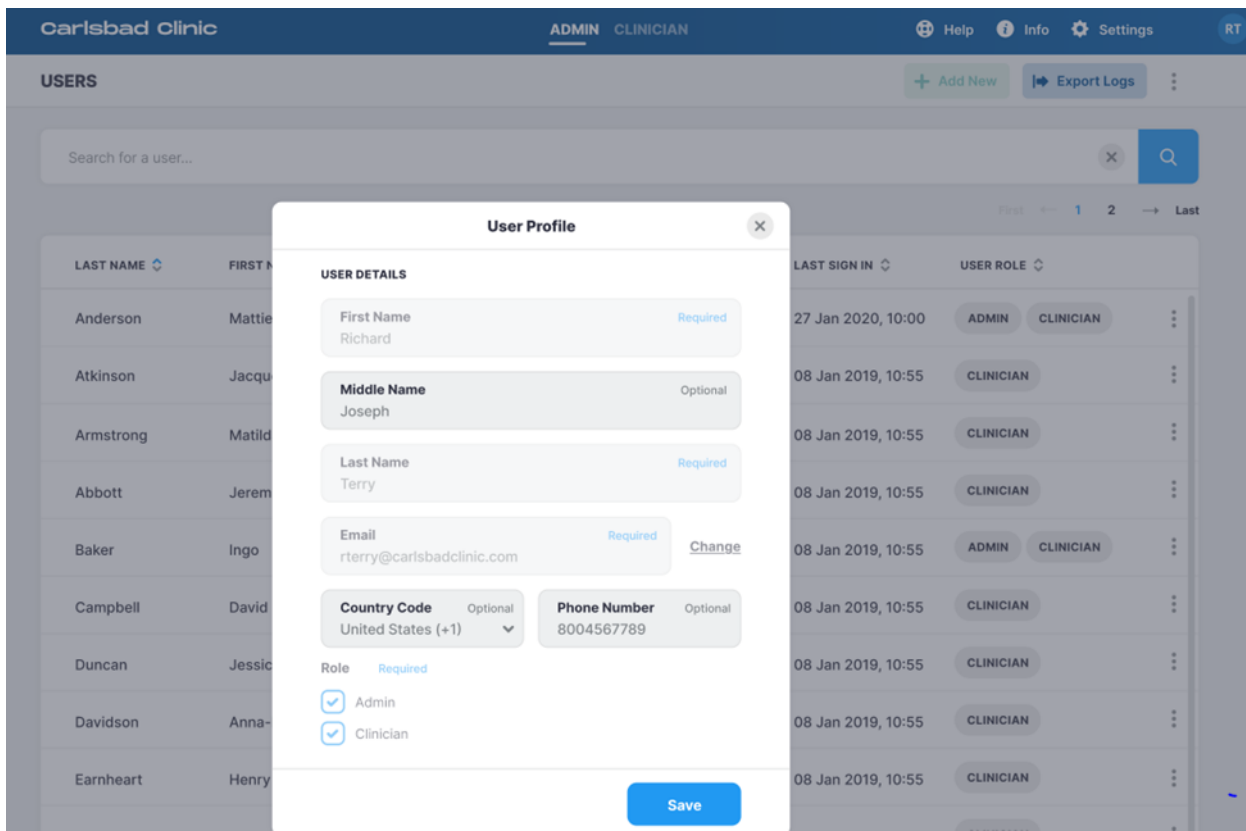
An Administrator may edit a user profile by clicking on the user's name. On the "User Profile" screen the Administrator may update User information.

*The Administrator may edit the user's email by clicking "change". Once a user's email is changed, a notification will be sent to both the old and new email address.*

1. Make updates as needed.
2. Click **Save**.
3. A success confirmation will appear in the top right corner.

**Note: 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.**

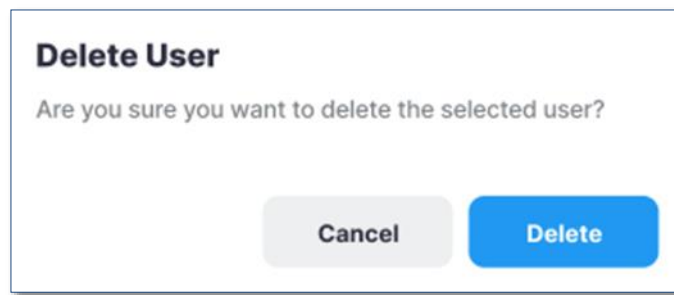




## 5.2.4 Delete User

To delete a user:

1. On the Users List, click on the **three dots** located next to the user's role.
2. Select **Delete**.
3. Click **Delete** in the delete user warning pop-up.
4. A **success** confirmation will appear in the top right corner.



## 5.2.5 Restore User

MySOZO stores deleted user accounts. If a user is accidentally deleted, the user may be restored.

To restore a deleted User:

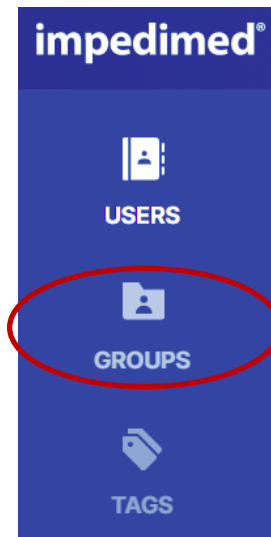
1. On the Users List, click the **three dots** located in the top right corner, next to the **Export Audit Logs** tab.
2. Select **Restore** user.
3. Search the user list for the user profile to be restored.
4. Click the **blue arrow** to restore the user.
5. A restore user warning will pop-up, select **Restore**.
6. A **success** confirmation will appear in the top right corner.

The screenshot displays the 'RESTORE USER' page in the MySOZO application. The page header includes the 'impedimed' logo, 'Carlsbad Clinic' name, and navigation tabs for 'ADMIN' and 'CLINICIAN'. A search bar is present at the top of the user list. The table lists users with columns: LAST NAME, FIRST NAME, EMAIL, MFA STATUS, LAST SIGN IN, and USER ROLE. A red circle highlights the 'three dots' menu icon in the top right corner of the table, which is used to access the 'Restore' option.

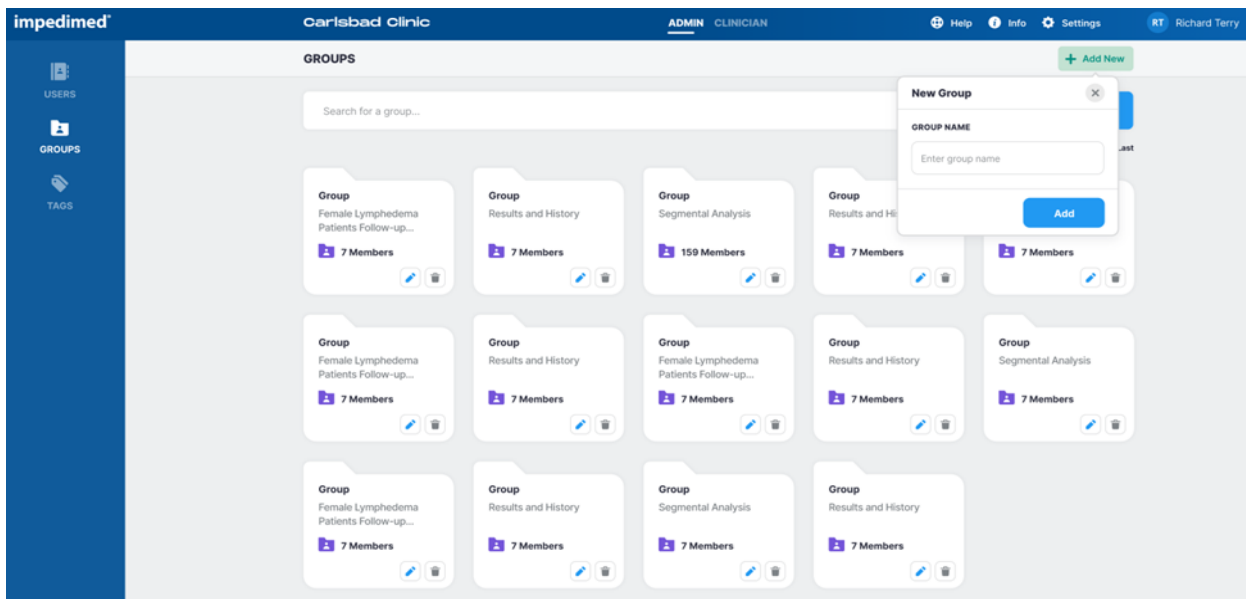
LAST NAME	FIRST NAME	EMAIL	MFA STATUS	LAST SIGN IN	USER ROLE
Anderson	Mattie	abridgette@carlsbadclinic.com	Active	27 Jan 2020, 10:00	ADMIN CLINICIAN
Atkinson	Jacqueline	ajacqueline@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Armstrong	Matilda	marmstrong@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	CLINICIAN
Abbott	Jeremias	jabbott@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Baker	Ingo	lbaker@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	ADMIN CLINICIAN
Campbell	David	dcambell@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Duncan	Jessica	jduncan@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Davidson	Anna-Maria	adavidson@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Earnheart	Henry	hearnheart@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Ferguson	Harris	hferguson@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Harrison	Bridgette	bharrison@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Normann	Dave	dnormann@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Richardson	Nicholas	nricharson@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN

## 5.3 Administrator Patient Groups

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



A user assigned to the Administrator role can create and name groups. Users assigned to a Clinician role may assign/remove Patients to/from the groups. To manage Patient Groups, click the Groups icon to bring up the following screen:



### 5.3.1 Create a New Group

To create a new Patient Group:

1. On the Groups List, click **Add New** in the top right corner.
2. Enter the group name.
3. Click **Add**.
4. The new group folder will appear below with the other group folders.

### 5.3.2 Rename/Delete Group

To rename a Patient Group:

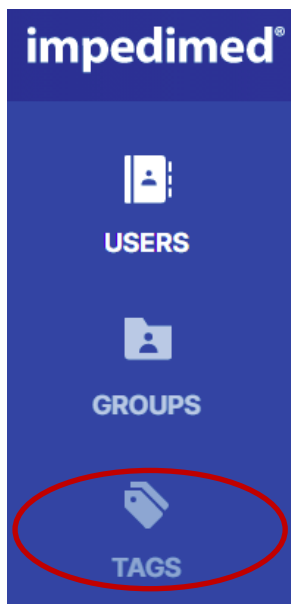
1. On the Groups List, click the **blue pencil** (edit icon) on the folder to be updated.
2. Update the Patient Group name.
3. Click the **blue disk** (save icon).
4. A success confirmation will appear in the top right corner.

To delete a Patient Group:

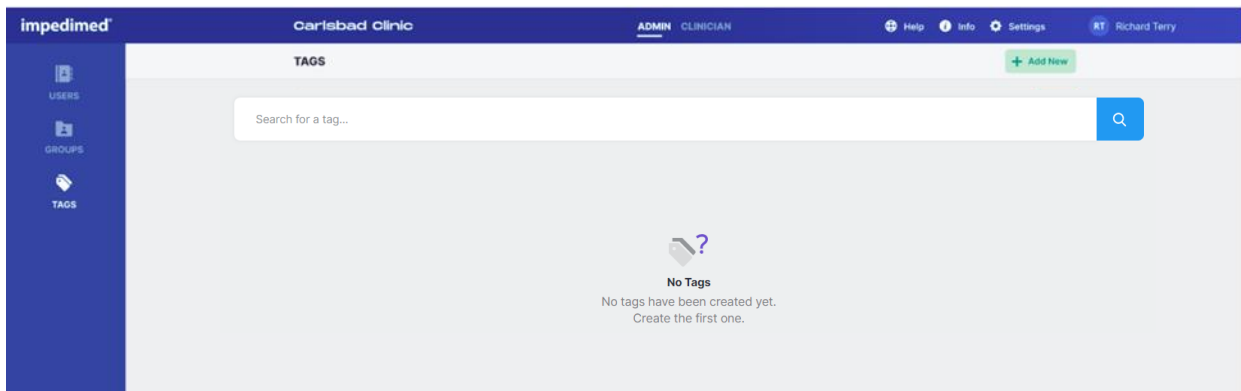
1. On the Groups List, click the **gray trash can** (delete icon) on the folder to be deleted.
2. A delete group warning will pop-up, select **Delete**.
3. A success confirmation will appear in the top right corner.

## 5.4 Administrator Patient Tags

Click **TAGS** at any time to return to the Tag List on the MySOZO Administrator home page.



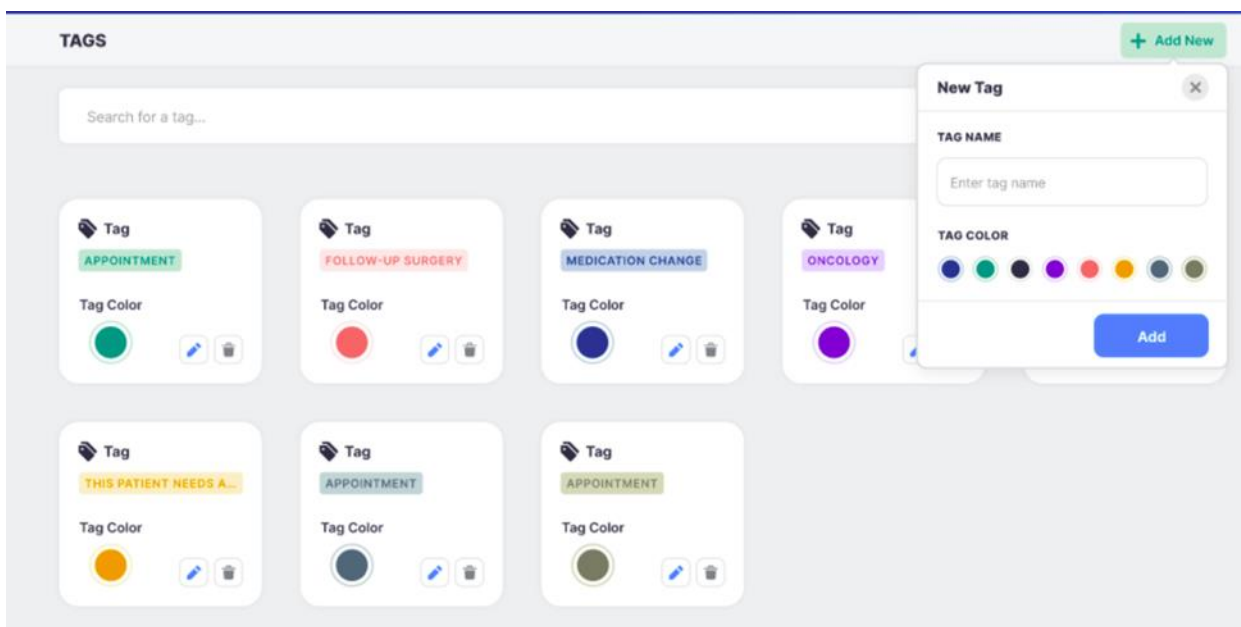
Tags are clinic-defined 48-character color-coded objects that can be attached to a given measurement by a clinician. They allow additional information or notes to be linked to the measurement. The tags used within a clinic can only be managed by a user with an Administrator role.



### 5.4.1 Create a New Tag

To create a new Tag:

1. On the Tags List, click **Add New** in the top right corner.
2. Enter the tag name and select a tag colour.
3. Click **Add**.
4. The new tag folder will appear below with the other tag folders.



## 5.4.2 Rename/Delete Tag

To rename a Tag:

1. On the Tags list, click the **blue pencil** (edit icon) on the tag to be updated.
2. Update the tag name.
3. Click the **blue disk** (save icon).
4. A success confirmation will appear in the top right corner.

To delete a Tag:

1. On the Tags List, click the **gray trash can** (delete icon) on the tag to be deleted.
2. A delete tag warning will pop-up, select **Delete**.
3. A success confirmation will appear in the top right corner.

**Note: when renaming a tag, it will be automatically renamed for all tags used to date. If a tag is deleted, it will remain assigned to all measurements, but will no longer be available to be assigned to a measurement.**

## 6 MYSOZO CLINICIAN

Clinicians may also use MySOZO, primarily for patient record review and assessment. MySOZO cannot be used to take a measurement; this is managed solely by the Clinician directly from the SOZOapp.

A user with a Clinician role has authority to do the following:

- Manage patient profiles
- Remove patients from groups
- View and take patient measurements
- Export data or create reports

### 6.1 Clinician Home Page

Clinicians, prior to signing in for the first time, must set a password and sign in per instructions in the [First Time Set-Up](#) section of the IFU. After signing in, the MySOZO Clinician home page will display the Patient List.

Any user may be assigned to both Clinician and Administrator roles. Users assigned a Clinician role will default to the Clinician role on initial sign in; the icon will be displayed in bold and underlined. If a Clinician also has Administrator rights, they can toggle between Clinician and Administrator screens by clicking **Clinician** or **Admin**.

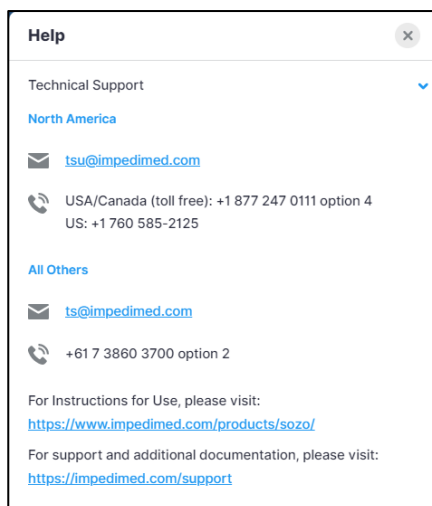
The banner icons enable common administrative functions.

The screenshot displays the MySOZO Clinician Home Page. The top navigation bar includes the 'impedimed' logo, 'Carlsbad Clinic', and a toggle between 'ADMIN' and 'CLINICIAN' (the latter is selected and underlined). To the right of the toggle are icons for Help, Info, Settings, and a user profile for 'Richard Terry'. Below the navigation bar, the 'PATIENTS' section is visible, featuring a search bar with 'all patients' and a table of patient records. The table has columns for LAST NAME, FIRST NAME, DOB, SEX, MRN, and LAST ASSESSMENT. Each row includes a 'Report' button. The table lists 12 patients, all with a last assessment date of 08 Jan 2019, 10:55.

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT	Report
Anderson	Mattie	27 Apr 1956	Female	8004567389-32	08 Jan 2019, 10:55	Report
Atkinson	Jacqueline	30 Aug 1977	Female	8004567389-32	08 Jan 2019, 10:55	Report
Armstrong	Mattida	13 Aug 1939	Female	8004567389-32	08 Jan 2019, 10:55	Report
Abbott	Jeremias	05 Dec 1960	Male	8004567389-32	08 Jan 2019, 10:55	Report
Baker	Ingo	30 Mar 1947	Male	8004567389-32	08 Jan 2019, 10:55	Report
Campbell	David	03 Feb 1958	Male	8004567389-32	08 Jan 2019, 10:55	Report
Duncan	Jessica	25 Mar 1953	Female	8004567389-32	08 Jan 2019, 10:55	Report
Davidson	Anna-Maria	11 Apr 1940	Female	8004567389-32	08 Jan 2019, 10:55	Report
Earnheart	Henry	27 Aug 1970	Male	8004567389-32	08 Jan 2019, 10:55	Report
Ferguson	Harris	29 Apr 1944	Male	8004567389-32	08 Jan 2019, 10:55	Report
Harrison	Bridgette	23 Mar 1955	Female	8004567389-32	08 Jan 2019, 10:55	Report
Normann	Dave	10 Mar 1937	Male	8004567389-32	08 Jan 2019, 10:55	Report
Richardson	Nicholas	17 Dec 1939	Male	8004567389-32	08 Jan 2019, 10:55	Report

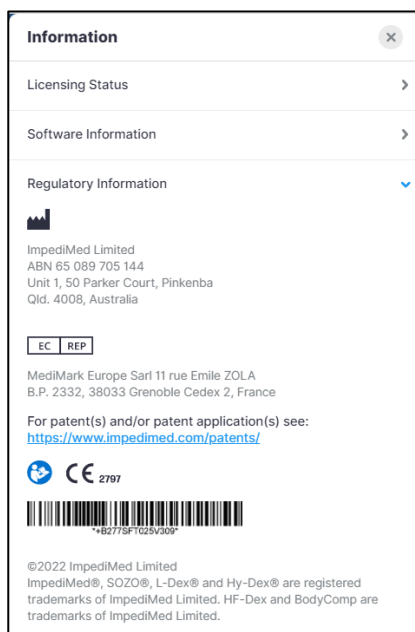
## 6.1.1 Help Icon

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



## 6.1.2 Info Icon

For information about MySOZO, click the **Info** icon. The Information page includes Licensing Status, Software Information and Regulatory Information.





**Licensing Status:** Lists all SOZO modules, active modules are shown with the description underneath, inactive modules are displayed as “Not active”.

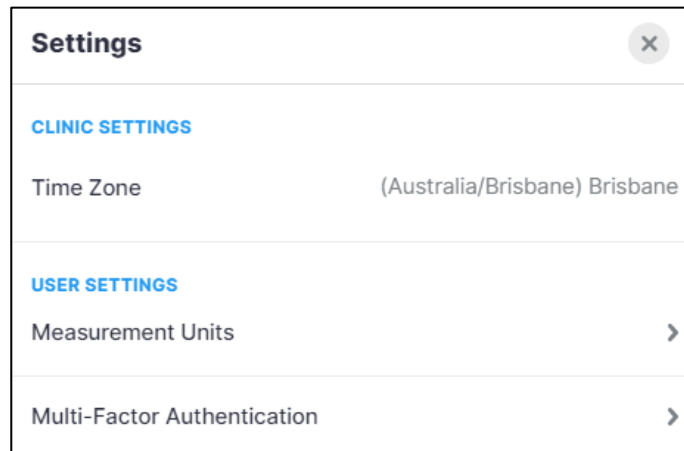
**Software Information:** Displays current mySOZO version and if it is up to date. Release notes for current and previous versions are listed.

**Regulatory Information:** Provides information regarding the manufacturer, notified body and other important information.

### 6.1.3 Clinician Settings Icon

The Clinician may adjust some MySOZO settings by clicking Settings, located in the top right corner of the home page.

These include Clinic Settings – Time zone and User Settings – Measurement Units and Multi-Factor Authentication.



#### 6.1.3.1 Time Zone Settings

The Time Zone currently set for the clinic is displayed here.

#### 6.1.3.2 Measurement Units

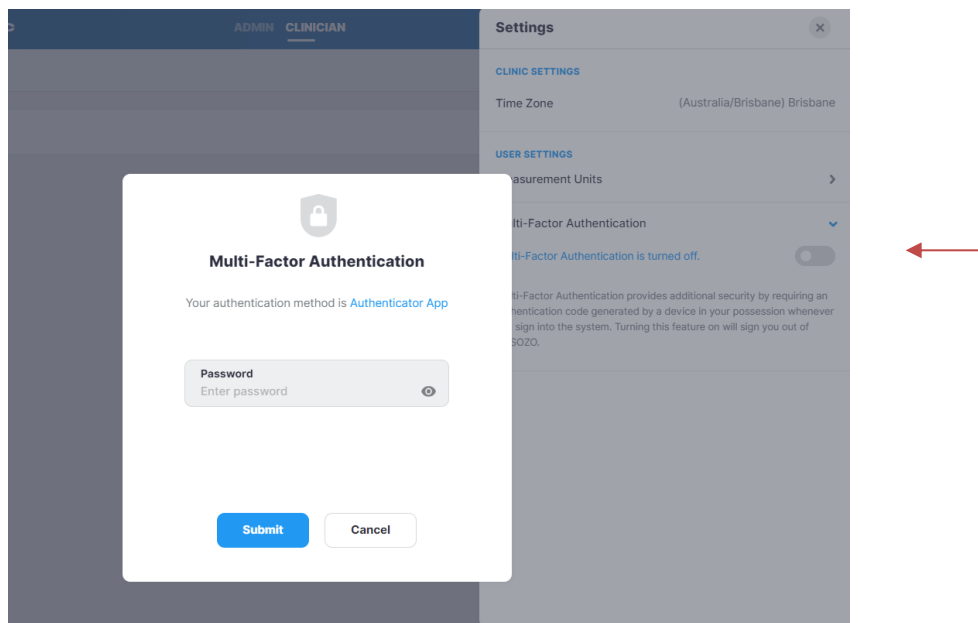
The clinician can adjust preferred display units of measure (kg vs lb; cm vs ft/in; liters vs pints) here. Once changes have been made, click save. A success confirmation will appear in the top right corner.

#### 6.1.3.3 Clinician Multi-Factor Authentication

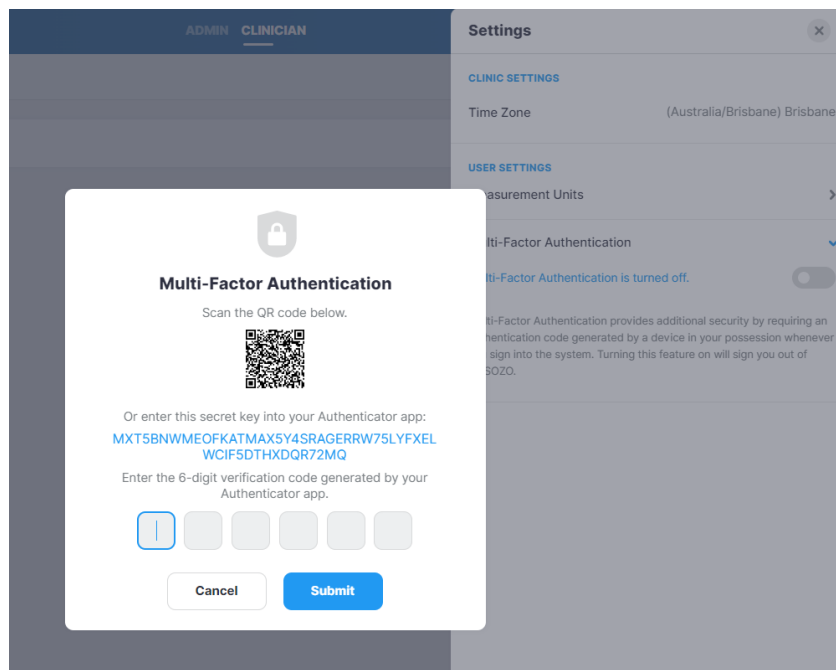
Once enabled by a Clinic Administrator (see Administrator Multi-Factor Authentication), the clinician can elect to have Multi-Factor Authentication turned on for their account prior to the deadline set by the Clinic Administrator.

MFA will require use of a code generated by a 3<sup>rd</sup> party authenticator app (e.g. Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once

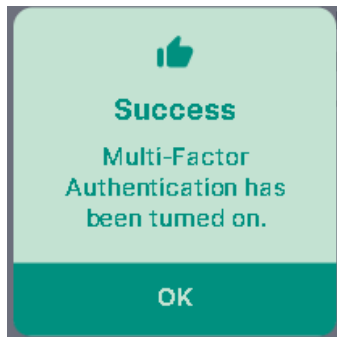
the authenticator app is set up, activate the MFA for the Clinician by using the slider under User Settings, Multi-Factor Authentication. At this point a pop-up will display and the Clinician password is required to be entered.



Next, a pop-up will show displaying a QR code that can be used to link to a third-party authenticator, and first-time entry of the MFA code.



A pop-up will be displayed confirming successful set up.

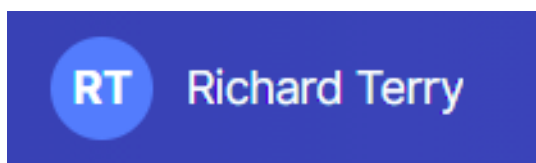


The Clinician will be signed out of the system, and from that point on, will have to use both a password and an MFA code to sign back in.

**Note: once a Clinic Administrator has required MFA use by the clinic and the enable date has passed, Clinicians will not be able to sign in to SOZOapp or MySOZO without implementing their own personal MFA.**

#### 6.1.4 Clinician User Profile Icon

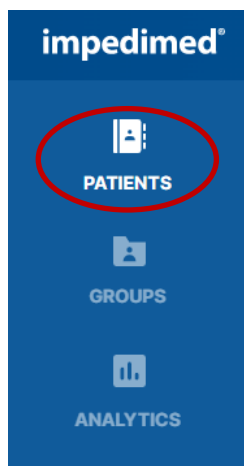
The name of the user signed into MySOZO appears next to the User Profile icon. To review or edit the User profile, click User Profile icon and select **My Profile**.



To sign out of MySOZO at any time, click the User Profile icon then click the **Sign Out** option in the list.

## 6.2 Clinician Patient List

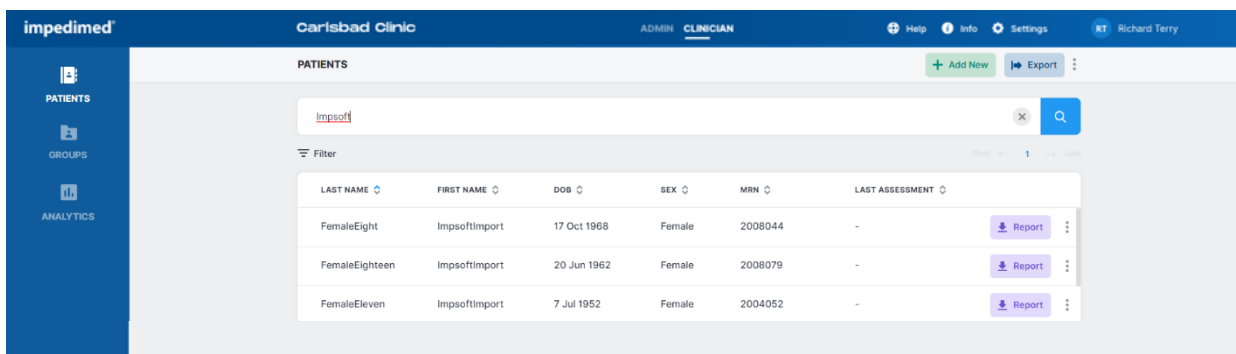
Click **PATIENTS** at any time to return to the Patient List on the MySOZO Clinician home page.



### 6.2.1 Search for Patient

To search for a specific patient, enter the name or medical record number (MRN) of the patient in the **Search Patient** field and click the **Search** icon. This will bring up a list of patients matching the search criteria.

To generate a list of all patients in the clinic, leave the **Search Patient** Field blank and click the **Search** icon.



## 6.2.2 Patient Dashboard

To open the **Patient Dashboard**, navigate to the **Patient List** and search for the desired patient. Click on the patient to open the Patient Dashboard.

The Patient Dashboard has detailed information about each patient which includes name, date of birth, sex, medical record number (MRN), last assessment date, and a list of measurement dates, if any. If any tags have been linked to a patient measurement, or a baseline has been set, they will be shown in the list.

The screenshot shows the ImpediMed Patient Dashboard for a patient named Mattie Anderson. The interface includes a sidebar with navigation options: PATIENTS, GROUPS, and ANALYTICS. The main content area displays patient information and a list of measurements.

**Patient Information:**

- First name: Mattie
- Last name: Anderson
- Date of birth: 27 Apr 1986
- Sex: Female
- Medical record number: 8009007799657
- Last assessment: 12 Mar 2021 17:05

**Measurements Table:**

DATE	BASELINE	TAGS
12 Mar 2021, 17:05		MEDICATION CHANGE, PHYSICAL THERAPY
13 Jan 2021, 17:06	1	RADIATION
30 Feb 2020, 13:30		
02 Feb 2020, 15:50		
10 Dec 2020, 13:45		PHYSICAL THERAPY
07 Nov 2019, 14:00		CHEMOTHERAPY, MEDICATION CHANGE
09 Oct 2019, 17:56	2	
28 Aug 2019, 19:00	1	SURGERY
01 Aug 2019, 13:47		
15 Jul 2019, 12:00		
30 Apr 2019, 15:33		
15 Mar 2019, 13:29		MEDICATION CHANGE
30 Apr 2019, 15:33		

The information is important for the Clinician's role of viewing, recording, and evaluating historical measurements and assessment results. Individual patient reports can be created from the dashboard.

## 6.2.3 Create Patient

A Clinician creates a Patient by navigating to the **Patients List** and clicking **Add New**. There is no limit to the number of patients that can be created.

1. On the **Create Patient** screen, enter the Patient's first name, last name, medical record number (MRN), date of birth, sex, and height.
  - a. The remaining fields, including email address, middle name, country code, and phone number, are optional.
  - b. To leave the patient's email address blank, click the Not Provided box next to the Email Address field.
2. Select the appropriate **Assessment types**.

3. When done, click **Create**.

**Note:** the clinician may optionally assign the patient to a predefined ‘group’. If grouping has been set up in the clinic (only available with SOZOapp v3.1 or later), a list of available groups will appear at the bottom of the create user window. Check the box for each group the patient is to be assigned to.

**Note:** adding a new assessment to the patient profile may trigger a caution about the intended use of that assessment. Ensure you understand the instructions for use for: L-Dex in the L-Dex Assessment User Guide; HF-Dex in the HF-Dex User Guide.

## 6.2.4 Delete Patient

To delete a Patient:

1. Complete a search for a patient to be deleted from the **Patients List**.
2. Click on the **three dots** located next to the patient’s information.
3. Select **Delete Patient**.
4. Click **Delete** in the delete patient warning pop-up.
5. A **success** confirmation will appear in the top right corner.

PATIENTS						<a href="#">+ Add New</a>	<a href="#">Export</a>	
Impsoft								
Filter						First 1 Last		
LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT			
FemaleEight	ImpsoftImport	17 Oct 1968	Female	2008044	-	<a href="#">Report</a>		
FemaleEighteen	ImpsoftImport	20 Jun 1962	Female	2008079	-	<a href="#">Delete Patient</a>		
FemaleEleven	ImpsoftImport	7 Jul 1952	Female	2004052	-	<a href="#">Report</a>		

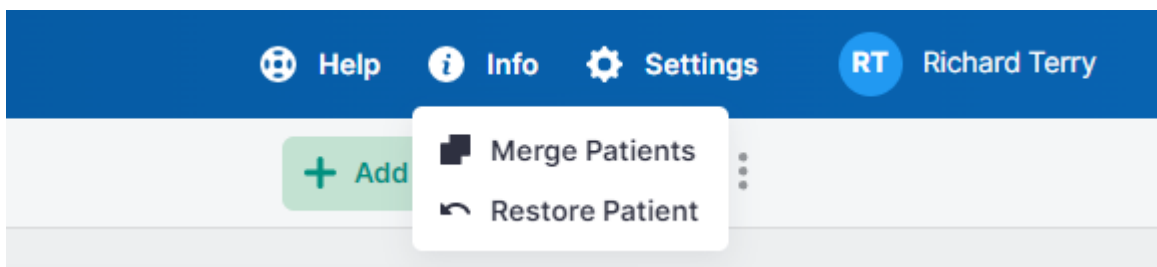
**Note: the patient will remain in the MySOZO database and may be restored. To permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.**

## 6.2.5 Restore Patient

MySOZO stores deleted Patient accounts. If a patient is accidentally deleted, the patient may be restored.

To restore a deleted Patient:

1. Navigate to the **Patients List**.
2. Click the **three dots** located in the top right corner, next to the **Export** button.
3. Select **Restore Patient**.
4. Search the Patients List for the Patient profile to be restored.
5. Click the **blue arrow** to restore the Patient.
6. A restore patient warning will pop-up, select **Restore**.
7. A success confirmation will appear in the top right corner.



## 6.2.6 Merge Patient

When more than one profile has been created for a patient, all data may be merged under one patient profile.

To merge two patient profiles:

1. Navigate to the **Patient List**.
2. Click the **three dots** located in the top right corner, next to the **Export** tab.
3. Select **Merge Patients**.
4. Search the **Source Patient** and **Destination Patient**.
5. **Check** the box for the source patient and destination patient.
6. Select preview to verify all patient information is correct.
7. After review, click **Merge**.
8. A success confirmation will appear in the top right corner.

The screenshot displays the 'Merge Patients' interface in the ImpediMed Carlsbad Clinic system. The interface is split into two main sections: 'Source Patient' and 'Destination Patient'. Each section contains a search bar and a list of patient profiles with checkboxes. A 'Preview' button is located between the two sections. The 'Source Patient' section shows three profiles: 'Arm Bilateral' (checked), 'Arm Unilateral' (unchecked), and 'FemaleEight ImpsoftImport' (unchecked). The 'Destination Patient' section shows three profiles: 'Arm Bilateral' (unchecked), 'Arm Unilateral' (checked), and 'FemaleEight ImpsoftImport' (unchecked). A note at the top of the 'Destination Patient' section states: '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.'

**Note:** 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.

**Note:** if the merged patients have imported L-Dex data from a non-SOZO ImpediMed device such as the L-Dex U400, the imported measurements will not be shown if the patient L-Dex settings are different. For example, if imported U400 data assessed a patient's leg and the data is merged with a patient whose L-Dex profile an arm selected as the at risk limb, then the merged / imported data will not be shown.

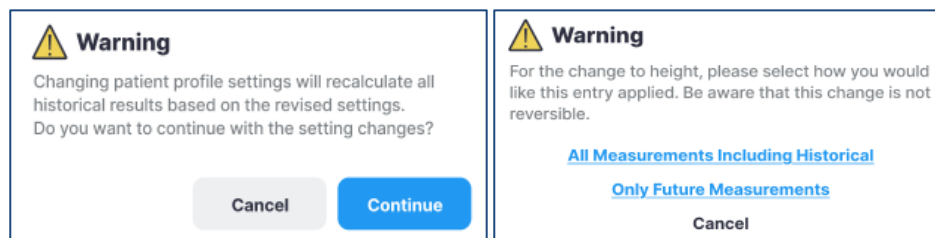
## 6.2.7 Edit Patient Profile

To edit a patient profile:



1. Navigate to the **Patient List**.
2. Search all patients or enter the patients' name.
3. Click the **search** icon.
  - a. Select the patient.
4. From the measurement history screen, a Clinician can click on the Profile icon.
5. Make updates as needed.
6. Click **Save**.
7. A success confirmation will appear in the top right corner.

After making changes to a patient profile warning may appear regarding the potential impact of changes on historical results.



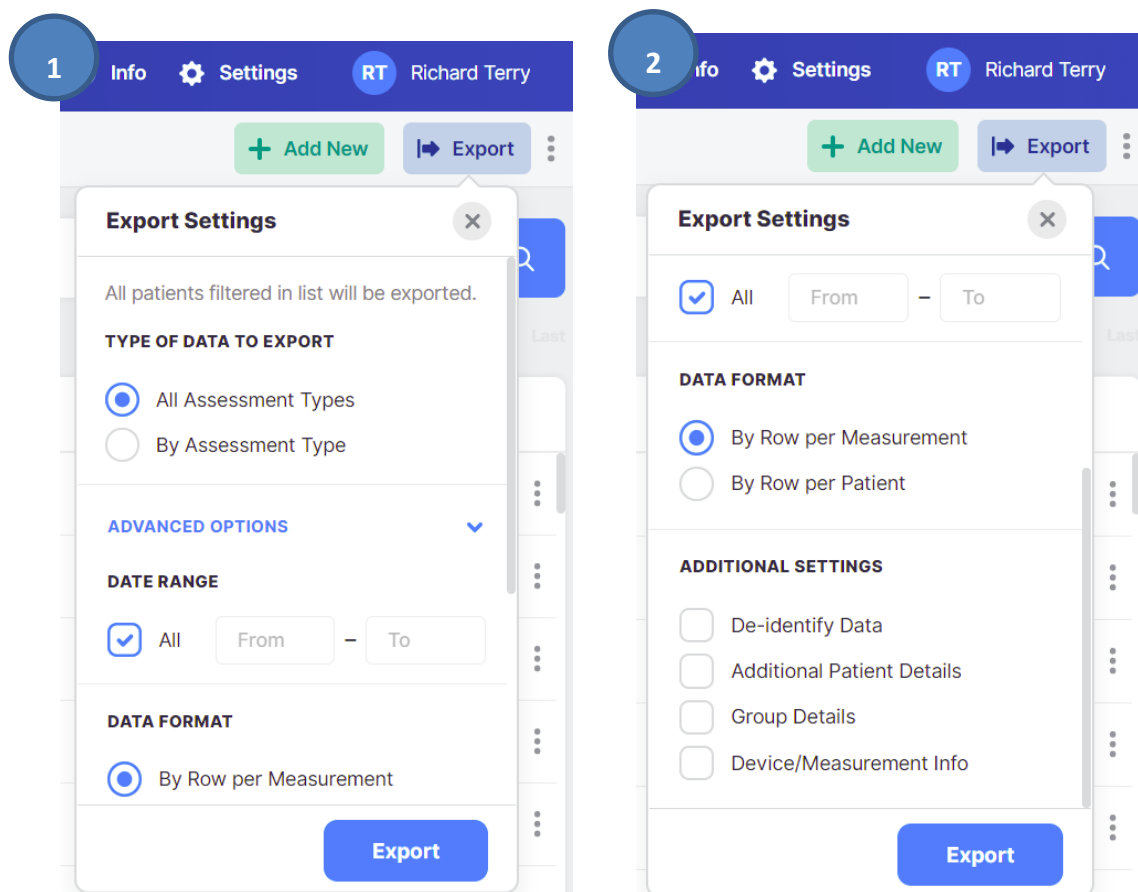
**Note:** when changing certain patient parameters such as height, age or gender, or at-risk/dominant limbs for patients with L-Dex assessments, the software will offer to recalculate all historical measurements. The user may choose which option is most appropriate for the patient. Please consider the following:

- **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.
- **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 the patient's height has been entered incorrectly and measurements have already been taken. This change is not reversible and if this option is selected, the height cannot be restored back to the height that was saved at the time of measurement.
- **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.

## 6.2.8 Export Patient Data

A Clinician may export patient data from MySOZO. To export data, click the Export button on the **Patient List**. A pop-up displays export settings, which includes Assessment types, date range, data format and additional settings. When the settings have been selected, click Export. A pop-up will appear, stating that the data export request is in progress. ImpediMed will send the clinician an email containing a secure link to download the Export Data. The link is valid for 48 hours.

**Note: advanced settings includes a wide range of options that can be scrolled through to customize the patient data export, including whether patient data should be de-identified, additional patient details, whether patients are in a predefined Group, and device/measurement information. The report will only present the options that are selected.**



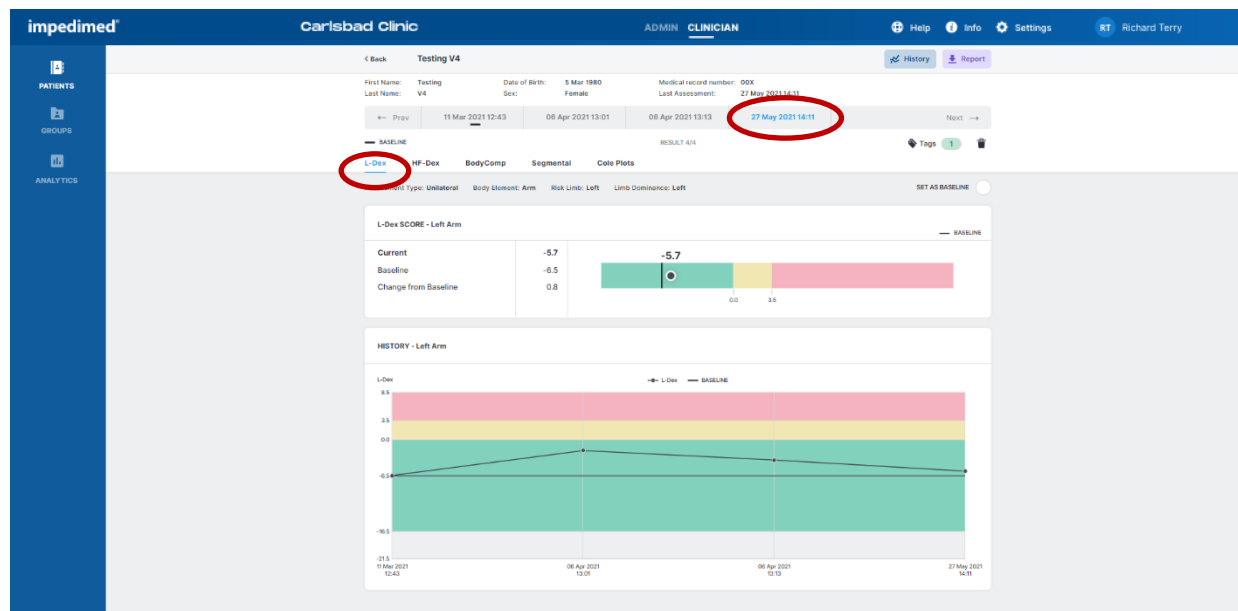


## 6.3 Measurement Dashboard

The **Patient Dashboard** displays a list of all the measurements taken for the patient. The Clinician can click on one of the listed dates to bring up the results from that measurement in the **Measurement Dashboard**.

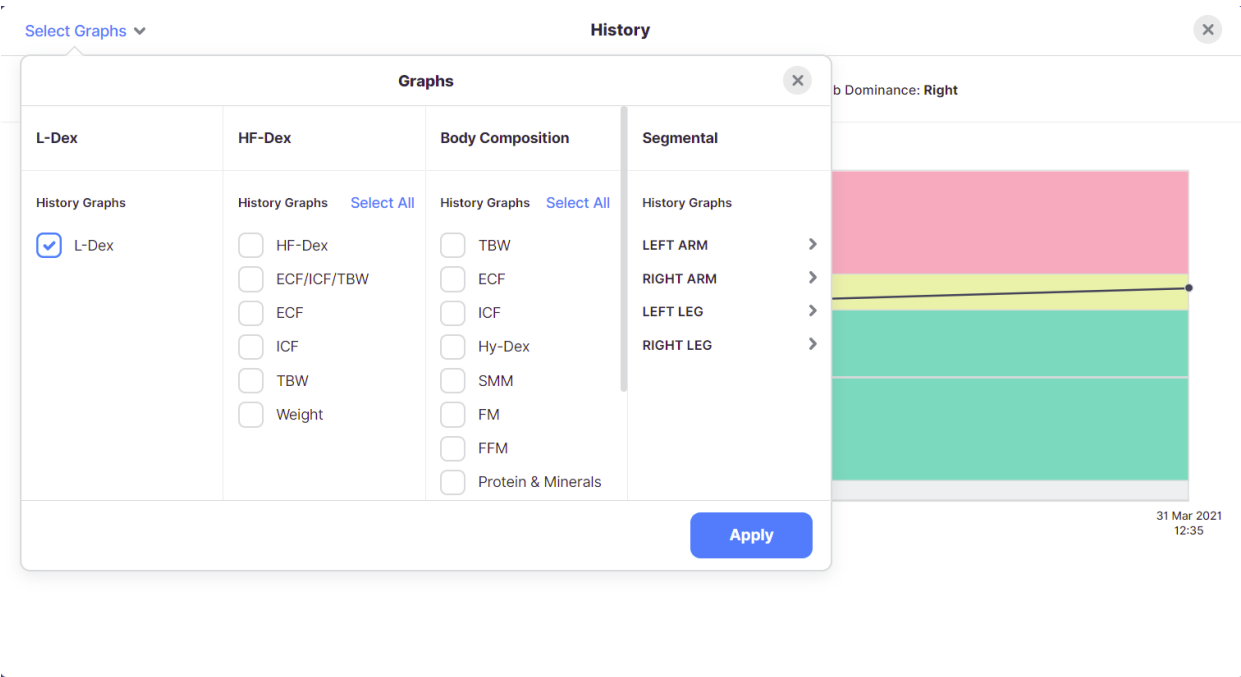
DATE	BASELINE	TAGS
15 Apr 2021, 09:13	2	RED COLE PLOT - SUSP... MEDICATION CHANGE 3 MONTH FOLLOW UP
31 Mar 2021, 12:35		MEDICATION CHANGE
31 Mar 2021, 12:33		3 MONTH FOLLOW UP
22 Mar 2021, 08:13		

The results for one assessment type will initially be displayed, e.g. L-Dex. The Clinician can click on different module types, or different measurement dates, from within the displayed record,. The selected assessment type and measurement date is highlighted in blue.

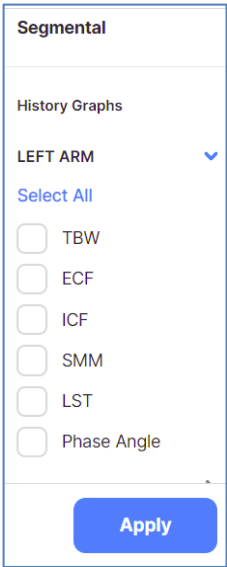


**Note:** only the measurement history of licensed Assessments that have been selected in the patient profile appears in History.

The Clinician may also review summary history graphs for the patient by tapping the 'History' button from the **Measurement Dashboard**. Graphs will be created for each module licensed to the clinic and applied to the patient profile. The popup will allow the user to select specific outputs to be graphed for each module, by selecting the desired outputs under 'Select Graphs' and clicking 'Apply':



Sub-menus are available for each limb's segmental measurements:

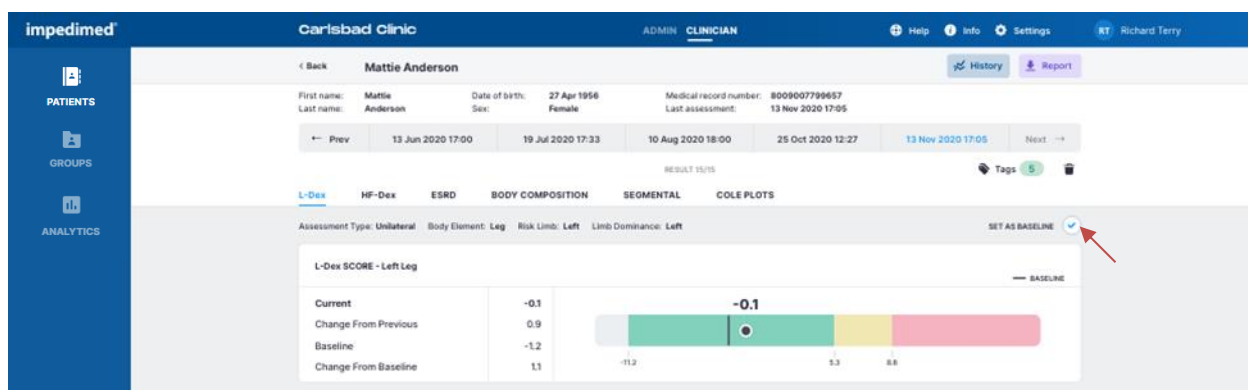


Additionally, many graphs will provide an option to switch between absolute and relative units of measure (liters/pints vs. % TBW)



### 6.3.1 Setting a Baseline

A Clinician may set or remove a measurement baseline for each Assessment type, and for most outputs. To adjust the baseline **check** “SET AS BASELINE”.



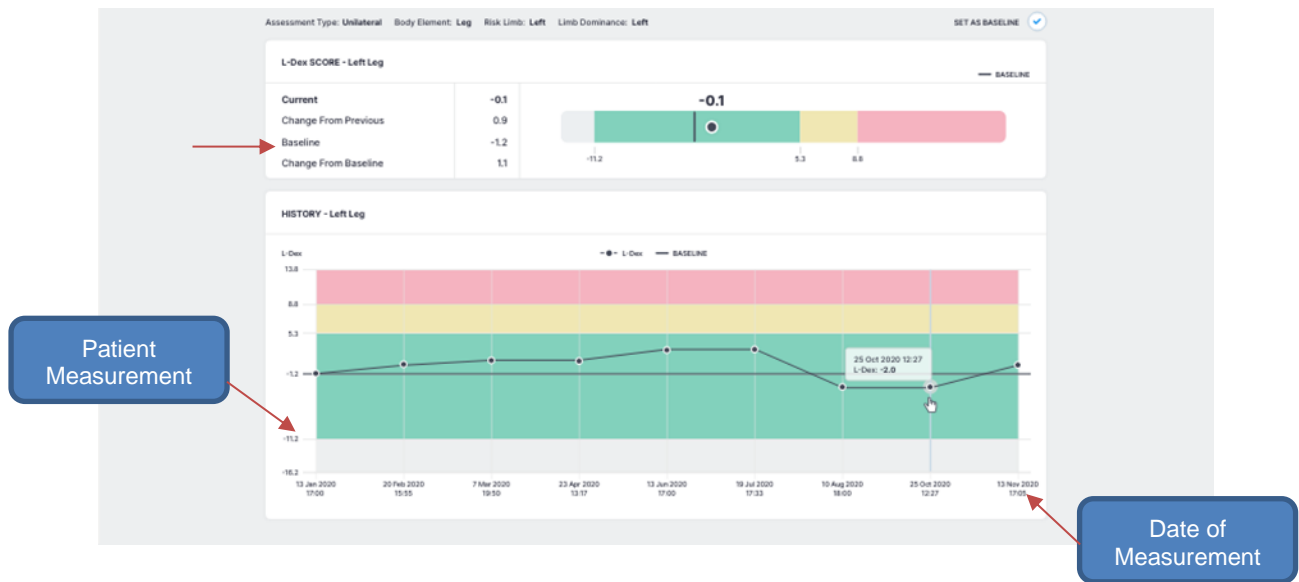
To choose the proper measurement as the baseline, the measurement should be:

- High-quality
- Taken when the patient is in a normal fluid or “euvoletic” state
  - This is often before treatment has occurred

If an incorrect baseline measurement is selected, either de-select the baseline for that measurement, or navigate to the correct measurement and select it as the baseline.

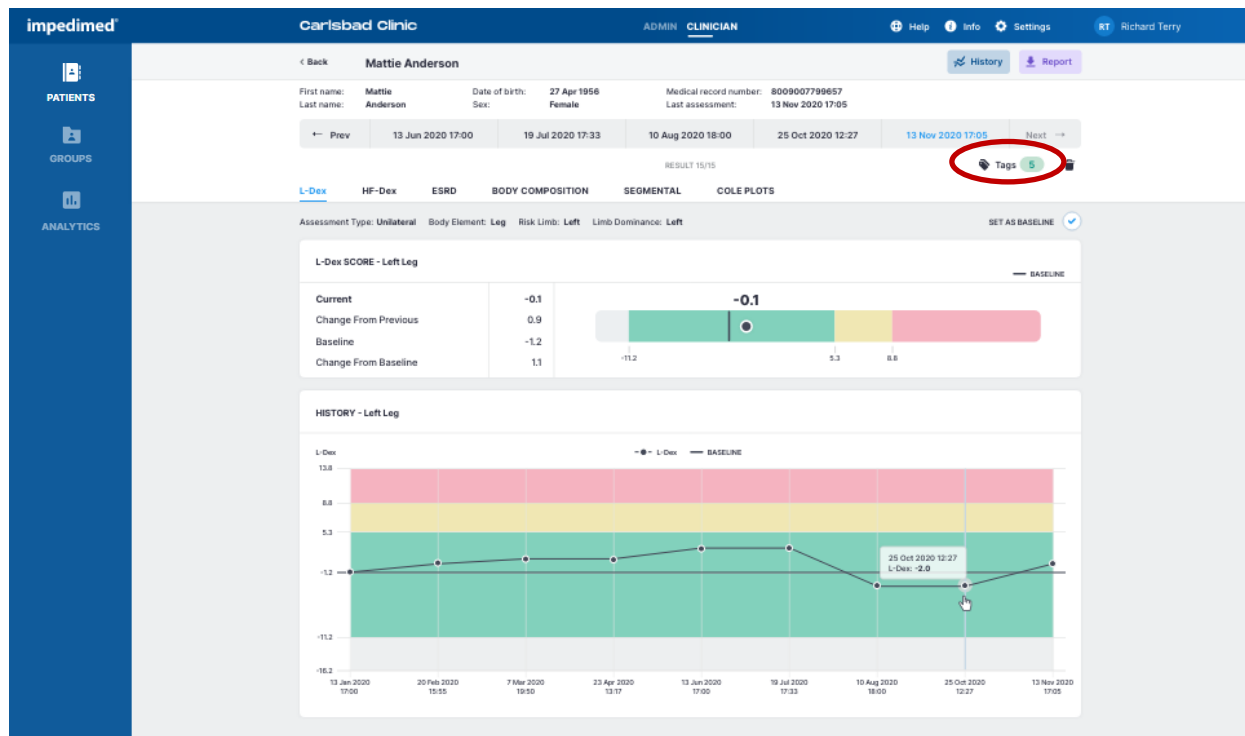
### 6.3.2 Evaluating Measurements Against a Baseline

For any measurement outputs that can have a baseline selected, 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.



### 6.3.3 Adding a Measurement Tag

A Tag can be added to a measurement to provide additional information and notes. These must be created by a Clinic Administrator. The number of Tags linked to a measurement is listed in the top right corner. Multiple Tags can be added to the same measurement.



To add a Tag to a measurement, click the “Tags” icon. Select the Tag to be linked from the drop down menu and add a description if desired. Click the disk icon to save.

### 6.3.4 Cole Plots

The SOZO software helps determine the quality of the Cole Plots by the following:

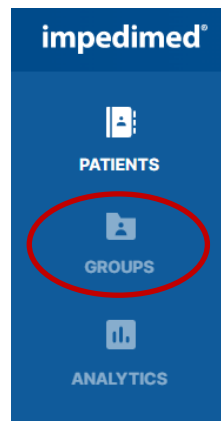
- High quality- green
- Medium quality-yellow
- Low quality-red



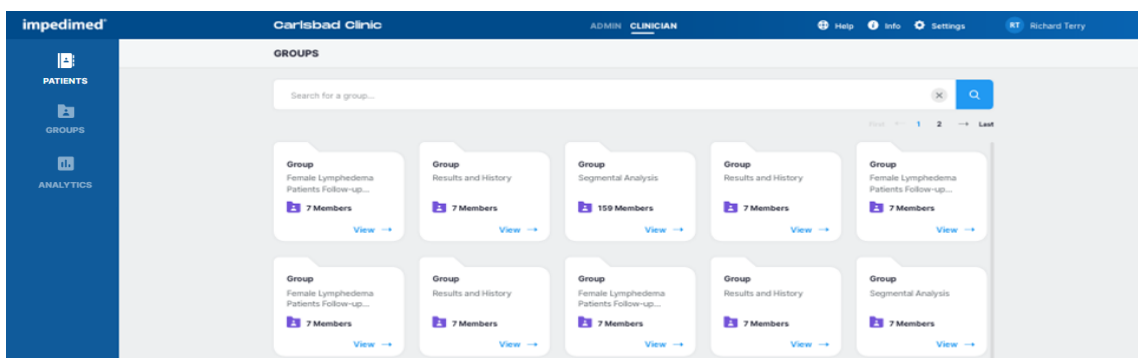
If the Right Whole Body Cole plot is low quality, measurements for the HF-Dex assessment type will not be displayed.

## 6.4 Clinician Patient Groups

Click **GROUPS** at any time to return to the Group List on the MySOZO Clinician home page.



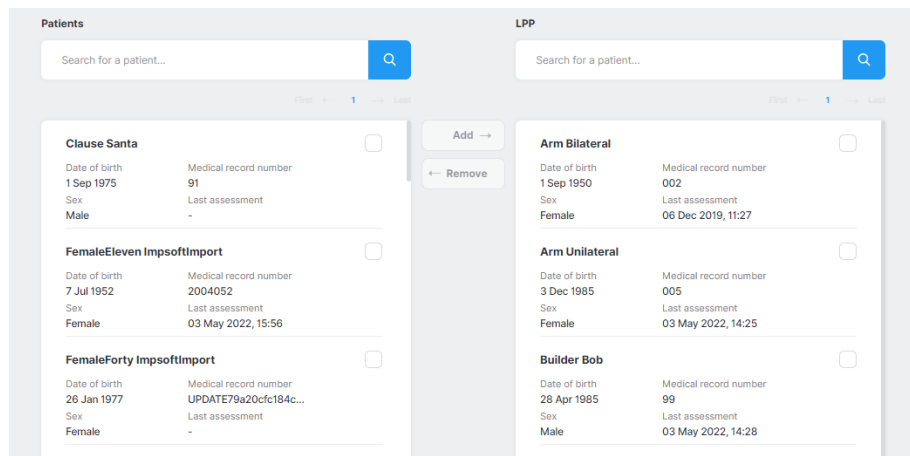
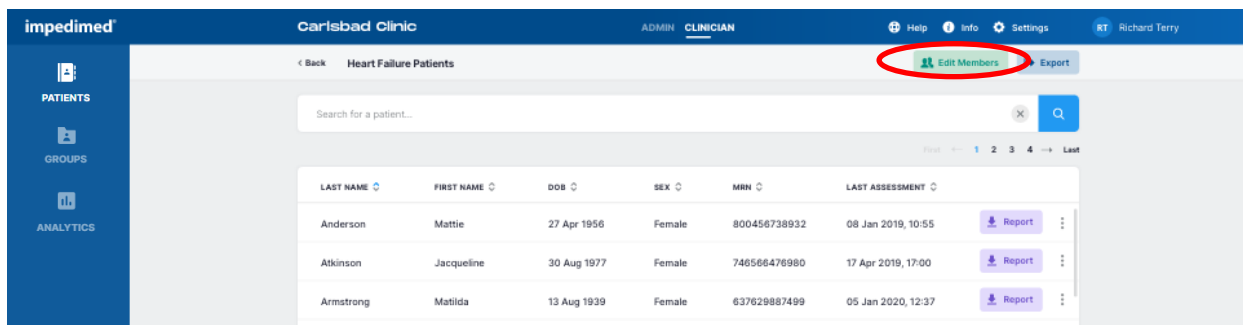
In MySOZO version 4.0 and later, patients can be assigned to predefined groups within the SOZO database. Administrator access is required to manage group creation. Clinician access is required to add or remove patients from groups.





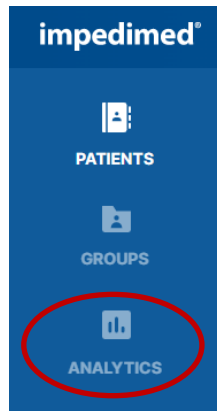
To access grouping features:

1. **Click** the **Groups** List located on the left side panel. This will bring up all current groups within the clinic.
  - a. The full set of patient grouping functions are only available through MySOZO, not SOZOapp.
  - b. If the Patient Groups tab is empty, only individuals with Administrator permissions can create or name them.
2. Select a group by clicking **View** to bring up the list of patients currently assigned to that group.
3. To **modify patients** within the group, click on **Edit Members** located in the top right corner.
  - a. To add a patient to a group search for the patient's name in the left-hand column and **check** 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.
  - b. To remove a patient from a group search for the patient's name in the right-hand column and check the box next to their profile. Selecting at least one patient will highlight the **Remove** button. Click the **Remove** button to add patients to the group.



## 6.5 Clinician Analytics

Click **Analytics** at any time to return to the Analytics page on the MySOZO Clinician home page.



The Clinician Analytics dashboard provides tools to track Lymphedema Assessments and how well the clinic is following the Lymphedema Prevention Program (LPP). Information on protocol compliance and patients in the LPP who have been triggered is provided as well as all patient program management and L-Dex score by demographics. The information in the analytics dashboard is updated hourly.

The **Controls** menu at the top of each tab allows the clinician to display and filter the data as desired.

### 6.5.1 Lymphedema Prevention Program (LPP)

The LPP is supported by the findings of the PREVENT trial<sup>2-3</sup> and McDuff et al<sup>4</sup>. The PREVENT trial followed patients at 3-6 month intervals for 3 years. The study showed that a prospective surveillance program using BIS was able to identify and treat patients for subclinical lymphedema with improved patient outcomes compared to those monitored with tape measure. McDuff found that while the risk of lymphedema is greatest in first 3 years it depends on therapy received with regional lymph node radiation associated with late onset lymphedema. Therefore, they recommended regular intervals for 5 years post treatment.

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<sup>2</sup> Ridner SH, Dietrich MS, Boyages J, et al. A Comparison of Bioimpedance Spectroscopy or Tape Measure Triggered Compression Intervention in Chronic Breast Cancer Lymphedema Prevention. *Lymphatic Research and Biology* 2022.

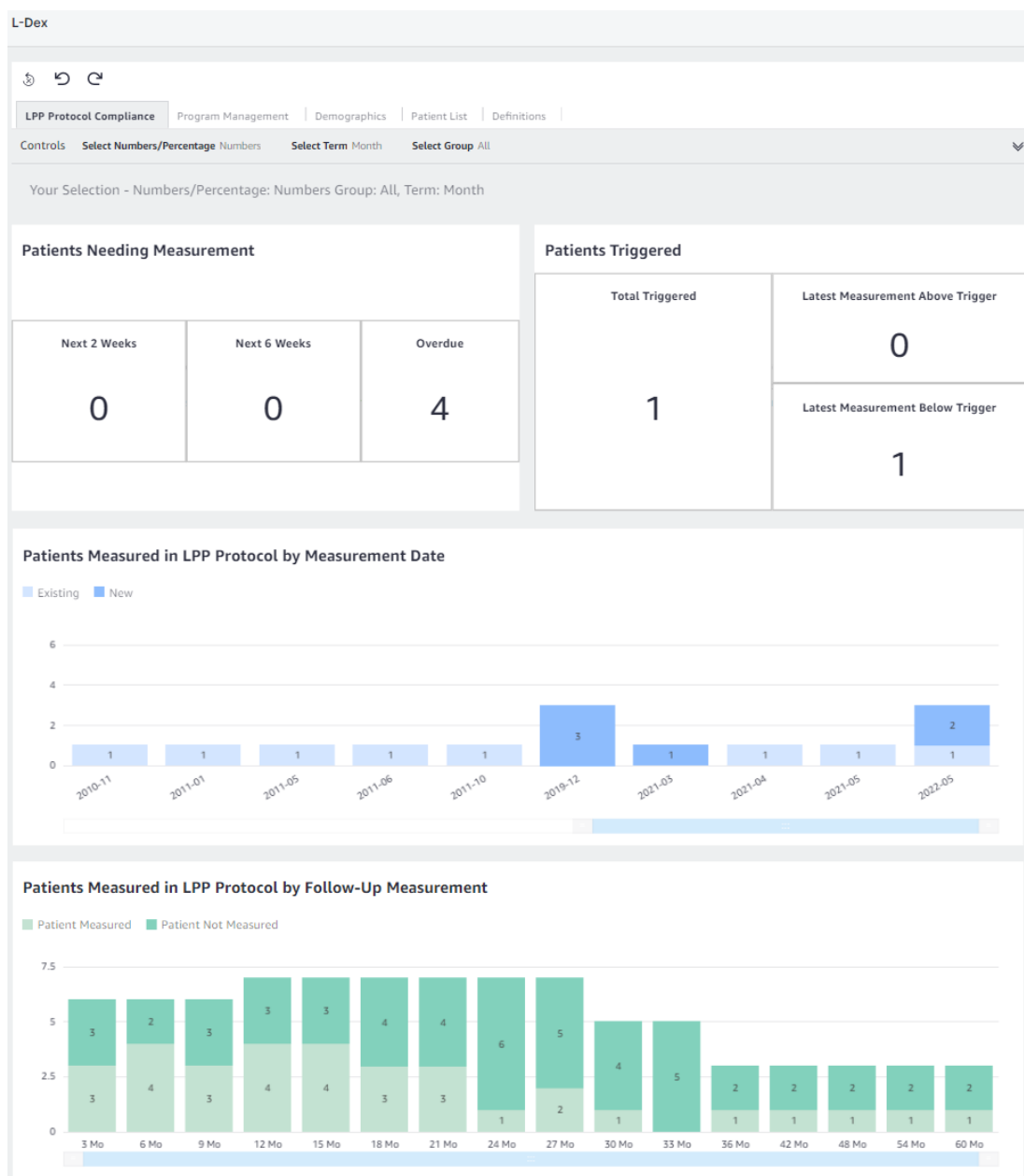
<sup>3</sup> Ridner SH, Dietrich MS, Cowher MS, et al. A Randomized Trial Evaluating Bioimpedance Spectroscopy Versus Tape Measurement for the Prevention of Lymphedema Following Treatment for Breast Cancer: Interim Analysis. *Ann Surg Oncol* 2019.

<sup>4</sup> McDuff SGR, Mina AI, Brunelle CL, et al. Timing of Lymphedema Following Treatment for Breast Cancer: When Are Patients Most At-Risk? *Int J Radiat Oncol Biol Phys* 2018.

## 6.5.2 LPP Protocol Compliance Tab

The LPP Protocol Compliance tab displays the number of patients who require measurements, the number of patients triggered and the compliance to the LPP protocol by date and follow-up measurement.

**Note: this dashboard only includes patients who have a baseline measurement selected and are included in the Lymphedema Prevention protocol as selected in the patient profile by filling out Surgery Date and LPP Start date in the patient profile.**



#### 6.5.2.1 Patients Needing Measurement

This displays the total number of patients in the LPP who are due for their testing in the next 2 weeks, 6 weeks and who are overdue. The due date for a patient is calculated based on the Date of Surgery and the LPP defined frequency within the LPP protocol. Any patient who has taken a measurement in the past 6 weeks is not included in this calculation as they are considered to have already been tested.

**Note: only LPP patients who are within 5 years of treatment are included in this information.**

#### 6.5.2.2 Patients Triggered

This displays the number of patients in the LPP whose L-Dex score has triggered as 6.5 L-Dex units above their baseline.

- **Total Triggered:** The total number of patients whose L-Dex score has ever equalled or exceeded the L-Dex threshold of a 6.5 L-Dex unit increase from baseline in any limb being monitored.
- **Latest Measurement Above Trigger:** The number of patients whose latest L-Dex score is equal to or above 6.5 L-Dex units above their baseline. If a patient has bilateral measurements with two triggers, only one will be counted as a trigger and if any of the latest measurements remain as triggered, it will take precedence. See definitions for further explanation.
- **Latest Measurement Below Trigger:** The number of patients who had previously triggered, but whose latest L-Dex values have fallen to less than 6.5 above their baseline.

**Note: only LPP patients who are within 5 years of treatment are included in this information.**

#### 6.5.2.3 Patients Measured in LPP Protocol by Measurement Date

This provides the number of patients in the LPP protocol who were measured during the selected time period.

**Note: patients with multiple measurements in a single time period will be counted only once. Patients with a measurement in multiple time periods will be counted for each time period where a measurement was taken.**

#### 6.5.2.4 Patients Measured in LPP Protocol by Follow-Up Measurement

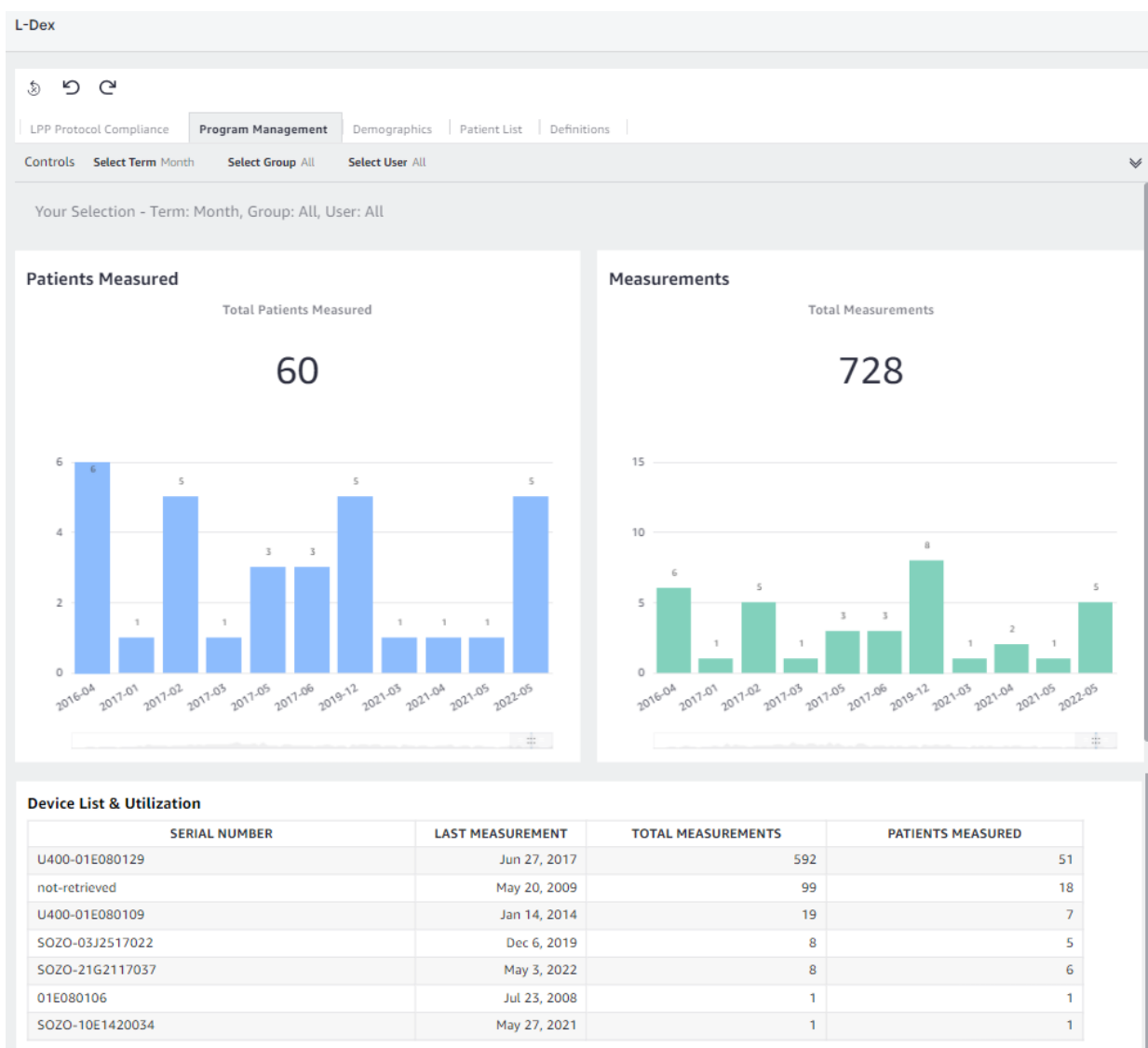
This provides the total number of LPP patients who took a measurement within the target LPP time period vs. those patients who did not take a measurement for each measurement target date. The LPP target dates are defined below and calculated for each patient based on the Surgery Date of the patient, the LPP Protocol Start Date, and the LPP protocol. When calculating compliance, the target LPP time period requires a measurement to be within +/- 6 weeks of the target date to be considered compliant for that time period. Only target dates after the start of the LPP Protocol Start Date are included in the calculation.

#### 6.5.2.5 Further Definitions

- **Surgery Date:** The Surgery Date or first treatment date that had an impact on the Lymphatic system. This date will be used to track when measurements should be started and when the follow up measurements should be taken based on the LPP Protocol. The Surgery date is an optional field that is specified in the patient profile for individual patients but is required for a patient to be included in the Protocol Compliance analytics.
- **LPP Protocol Start Date:** The date that the clinic starts to track the patient within the LPP program. This date will be used to calculate compliance with the LPP protocol for target measurement follow up. This date is typically the same as the Surgery Date. However, if a patient starts the LPP program after the surgery has taken place, any time between the Surgery Date and the LPP start date will not be included for compliance. The LPP Protocol Start Date is an optional field that is specified in the patient profile for individual patients but is required for a patient to be included in the Protocol Compliance analytics.
- **Start Date:** Surgery Date is used as the starting date for the LPP protocol
- **End Date:** 5 years from the Surgery Date
- **Testing Frequency:**
  - First 3 years from Surgery Date (Years 1-3): Every 3 months starting with the Surgery Date.
  - Years 4-5: Every 6 months based on the Surgery Date.
- **Triggered:** A patient is in triggered status once any L-Dex value has increased 6.5 or more from the baseline L-Dex value. Once a patient is in triggered status, he or she will always remain as triggered status as long as the measurement is not deleted, or the baseline is not changed.
- **Latest Measurement Above Trigger:** This output shows if the patient is still measuring L-Dex values 6.5 or more based on their latest measurement. Only patients who have already triggered are included in this calculation.
- **Latest Measurement Below Trigger:** This output shows patients who had previously triggered, but whose latest L-Dex values have fallen to less than 6.5 above their baseline.

#### 6.5.3 Program Management

This dashboard provides insight into the usage of SOZO and the L-Dex Analysis for Lymphedema Assessment. It provides outputs based on all Lymphedema Patients, Measurements, and Device used within the clinic.



### 6.5.3.1 Patients Measured

This chart provides the total count of L-Dex patients who have had at least one measurement in the defined time period, selectable by Month, Quarter, or Year from the Controls menu.

**Note:** a patient with multiple measurements within a time period will be counted only once. The Total Patients Measured is a count of all unique L-Dex patients who have had at least one measurement.

### 6.5.3.2 Measurements

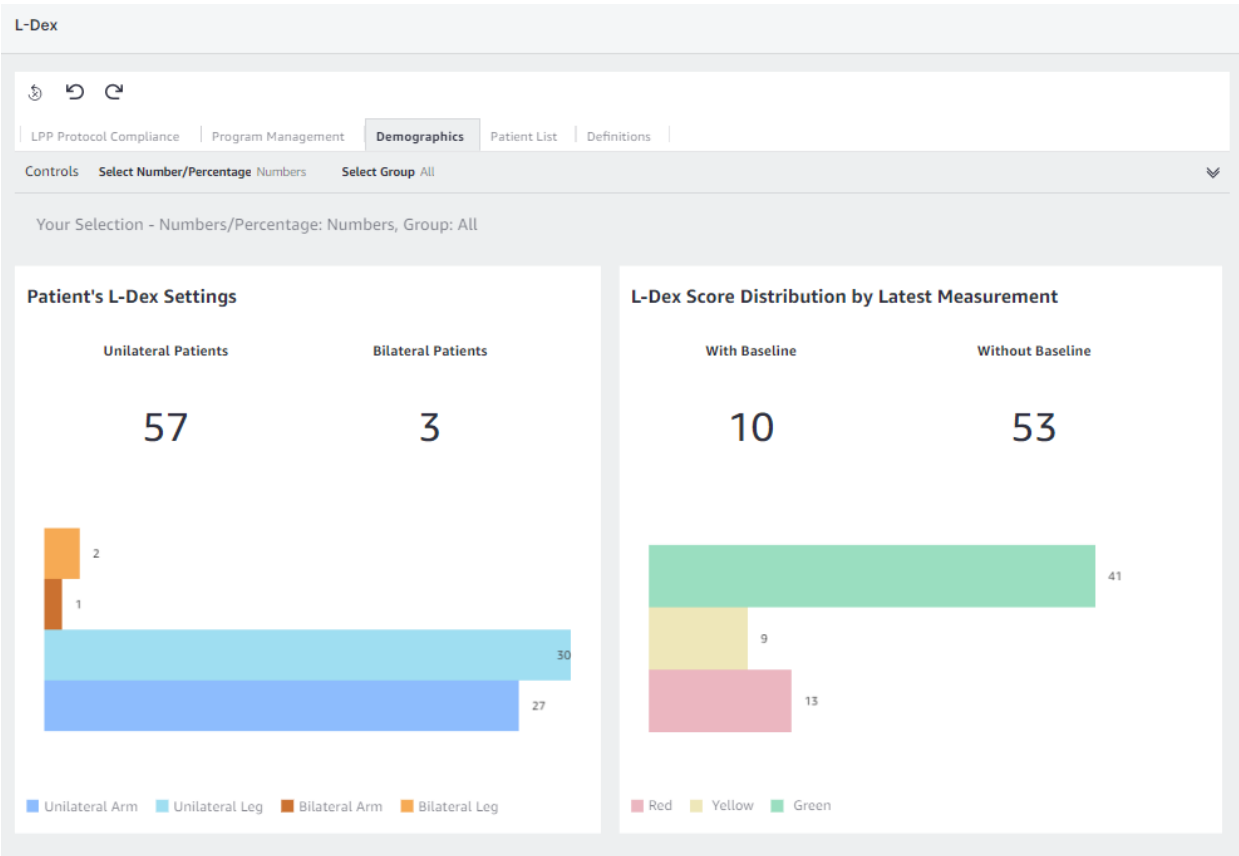
This chart provides the count of measurements taken on L-Dex patients over time, selectable by Quarter, Month, or Year from the controls menu. The total Measurements is a count of all measurements taken on all L-Dex patients.

6.5.3.3 Device List & Utilization

This table provides the total number of Patients Measured and Measurements, as defined above, by SOZO serial number. Selecting a device by clicking on it will filter the Patients Measured and Measurements to this device.

6.5.4 Demographics

This dashboard provides a summary of all L-Dex patients by their at-risk limb/s (demographics) and L-Dex Output. Only patients who have the L-Dex assessment type are included.



6.5.4.1 Patient's L-Dex® Settings

This chart provides a count of patients who have selected Unilateral or Bilateral L-Dex Assessment settings. It can be displayed as the number or as a percentage.

The distribution of the number of Bilateral Arm, Bilateral Leg, Unilateral Arm and Unilateral Leg patients is shown in bar graphs.

**Note: total L-Dex patients in the clinic is equal to sum of unilateral patients and sum of bilateral patients.**

#### 6.5.4.2 L-Dex® Score Distribution by Latest Measurement

This chart provides a count of the latest L-Dex measurement values and if there is a baseline associated with each reading. It can be displayed as the number or as a percentage.

The distribution of the number of latest lymphedema measurements categorized as gray, green, yellow and red is displayed.

**Note: these categories have a different meaning depending on whether or not a baseline has been set.**

##### L-Dex Categories without a Baseline

<b>Gray (Below Normal L-Dex)</b>	L-Dex scores below 3 standard deviations less than the population mean (below -10).
<b>Green (Normal L-Dex)</b>	L-Dex scores between 3 standard deviations less than the population mean and 2 standard deviations greater than the population mean (-10 to 6.5).
<b>Yellow (Normal L-Dex)</b>	L-Dex scores between 2 and 3 standard deviations greater than the population mean (6.5 to 10).
<b>Red (Above Normal L-Dex)</b>	L-Dex scores above 3 standard deviations greater than the population mean (above 10).

##### L-Dex Categories with a Baseline

<b>Gray (Below Normal L-Dex Change)</b>	Change in L-Dex scores from the baseline that are greater than 3 standard deviations below the baseline (change greater than -10).
<b>Green (Normal L-Dex Change)</b>	Change in L-Dex scores from the baseline between 3 standard deviations less than the baseline and 2 standard deviations greater than the baseline (change between -10 and +6.5).
<b>Yellow (Elevated Normal L-Dex Change)</b>	Change in L-Dex scores from the baseline between 2 and 3 standard deviations greater than the baseline (change between +6.5 and +10).
<b>Red (Above Normal L-Dex Change)</b>	Change in L-Dex scores from the baseline that are greater than 3 standard deviations above the baseline (change greater than +10).



**Note:** patients with no measurements will not have a baseline and will not be included in the bar graph output. Bilateral patients will include two measurements, one for each at risk limb.

**Note:** total L-Dex patients in the clinic are equal to sum of unilateral patients and sum of bilateral patients. The total # of measurements will be equal to the sum of unilateral patients and two times the sum of bilateral patients.

## 6.5.5 Patient List

The Patient list displays a list of the first name, last name, date of birth, sex, MRN, surgery date and last assessment.

- By default, this is the full list of L-Dex patients contained in the database. Each column can be sorted by ascending or descending order.
- If filtering has been applied using the Controls menu in the Protocol Compliance, Program Management or Demographics tabs then the list only contains the patient meeting the filtered criteria.
- If the clinician drills down on a graph the patient list is filtered according to the criteria of the graph.

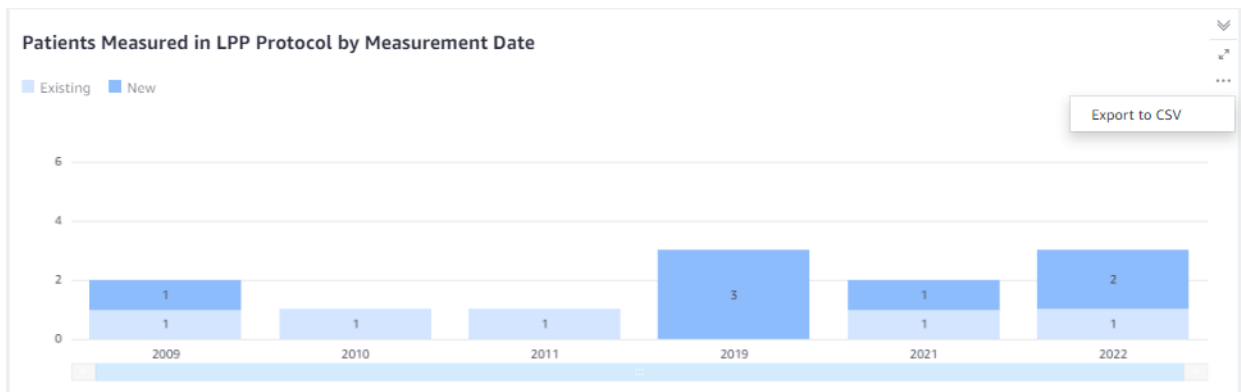
LPP Protocol Compliance	Program Management	Demographics	<b>Patient List</b>	Definitions
-------------------------	--------------------	--------------	---------------------	-------------

**Your Selections:**  
Groups = All, Clinician = All, Due = Overdue, Distribution Range = All, Limb Settings = All, Patient Triggered = All, Patient Above Trigger = All, Patient Below Trigger = All

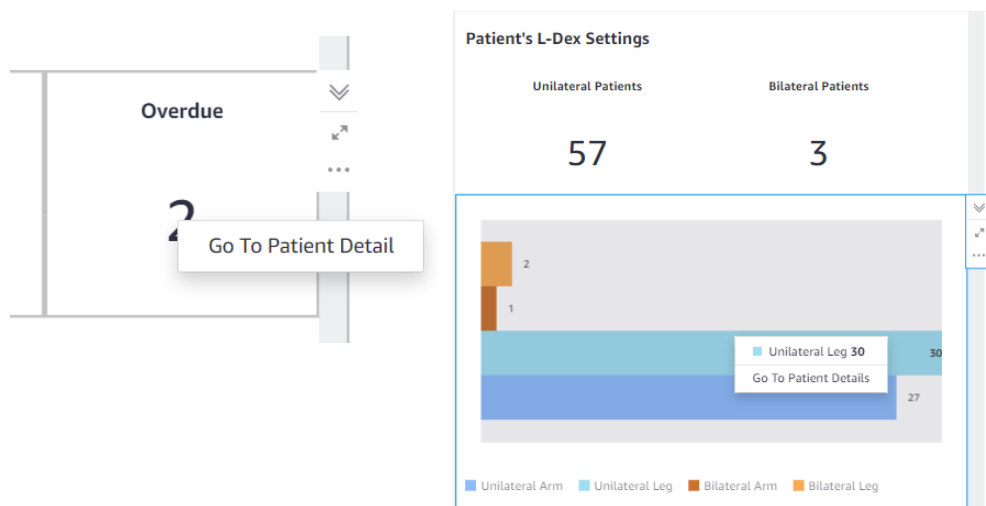
LAST NAME	FIRST NAME	DOB	SEX	MRN	SURGERY DATE	LAST ASSESSMENT
Arm	Bilateral	Sep 1, 1950	Female	002	May 21, 2019	Dec 6, 2019
Subject	Test	Dec 1, 1982	Female	001	Aug 3, 2019	Dec 6, 2019

## 6.5.6 Navigation

- **Exporting data:** To export the data shown for any individual chart or table on the screen, select the chart or table element. A menu on the upper right side of the chart or table will appear, select the “...” and then “**Export to CSV**”.



- Accessing Patient List:** By default, all patients with an L-Dex Assessment are included in the patient list. To get patient data associated with a particular chart or table element, select the data element (e.g. Overdue patients, Patients Measured in Time Period, Serial Number, Bilateral Leg Patients etc) and right click. Select “Go to Patient Details”. This will open the Patient List tab to see the patients associated with that data element.



- Customizing and/or Filtering Outputs:** To filter all outputs on a tab, the following selections can be modified through the Controls menu at the top of each page:
  - Show output in % vs. Numbers (if applicable).
  - Modify time periods displayed (Month, Quarter, Year).
  - Filter by Groups.
  - Filter by the user (clinician) who took the measurement.


Protocol Compliance | Program Management | Demographics | Patient List | Definition |

Controls ⤴

Select Numbers/Percentage: Numbers ▼

Select Term: Month ▼

Select Group: All ▼

- **Undoing Filters:** Select the 'Reset' control  located on the top left of the page to remove all filters chosen.

# 7 MySOZO APP

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## 7.1 Introduction to the SOZOapp

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

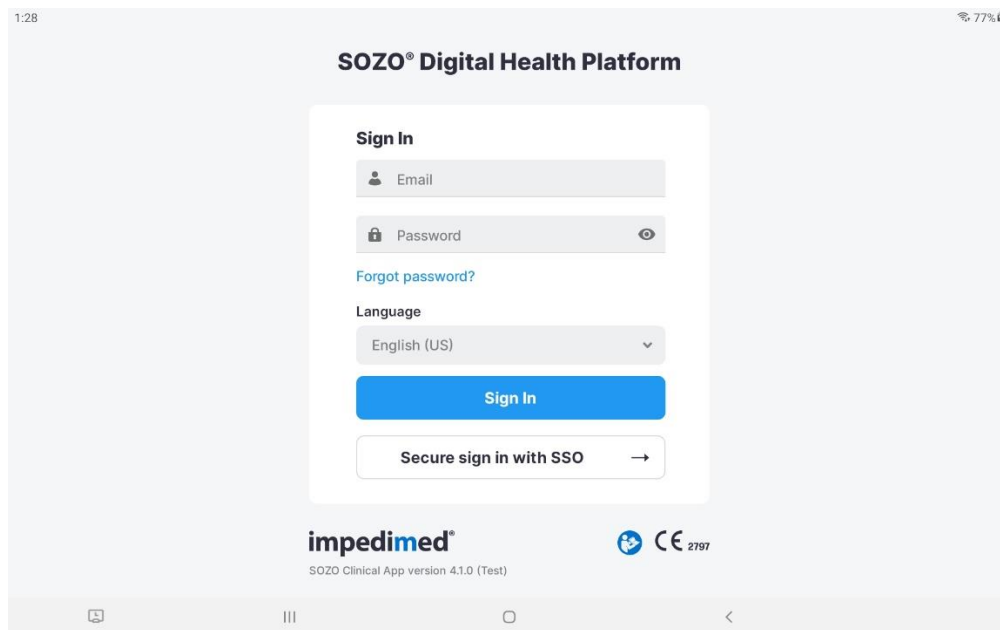
- 1) Management of patient profiles, including adding, editing, or selecting patients from a patient list.
- 2) Selecting and configuring assessments to fit the patient's diagnosis, treatment plan, and individual needs.
- 3) Taking and entering patient measurements for various assessments.
- 4) Considering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

### 7.1.1 Sign In

Clinicians must set a password and sign in per instructions in the [First Time Set-Up](#) section of the IFU.

To sign in to the SOZOapp

1. Enter email address.
2. Enter password.
3. Select preferred language if desired.



**Note:** user accounts may not be created in SOZOapp. Only Administrators may create or edit user accounts through MySOZO. For more information, see [Create New User](#).

**Note:** if there is a newer version of the SOZOapp, the user will be notified.

### 7.1.2 Password Reset

1. If the user is experiencing trouble signing in or has forgotten their password, tap “Forgot Password?”, located underneath the password box on the sign in screen.
2. When prompted, the user will enter their email address for the MySOZO account.
3. A pop-up notifies the user that a password reset email will be sent from ImpediMed if a valid email has been entered.
4. After the user has received the email with password reset instructions, click Reset Password link in the email. A new browser window opens and the “Set New Password” screen appears.
  - a. Ensure new password meets all letter and character requirements.
  - b. Set and confirm new password. Click submit.

1

## SOZO® Digital Health Platform

### Sign In

Email  
Enter email

Password  
Enter password


Forgot password?

Language  
English (US)

Sign In

Secure sign in with SSO →

impedimed®

 CE 2797

2

## SOZO® Digital Health Platform

### Reset Password

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


Email  
Enter email

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

Submit

Cancel

impedimed®

 CE 2797

3

## SOZO® Digital Health Platform

### Reset Password

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


Email  
rterry@carlsbadclinic.com

### Reset Password

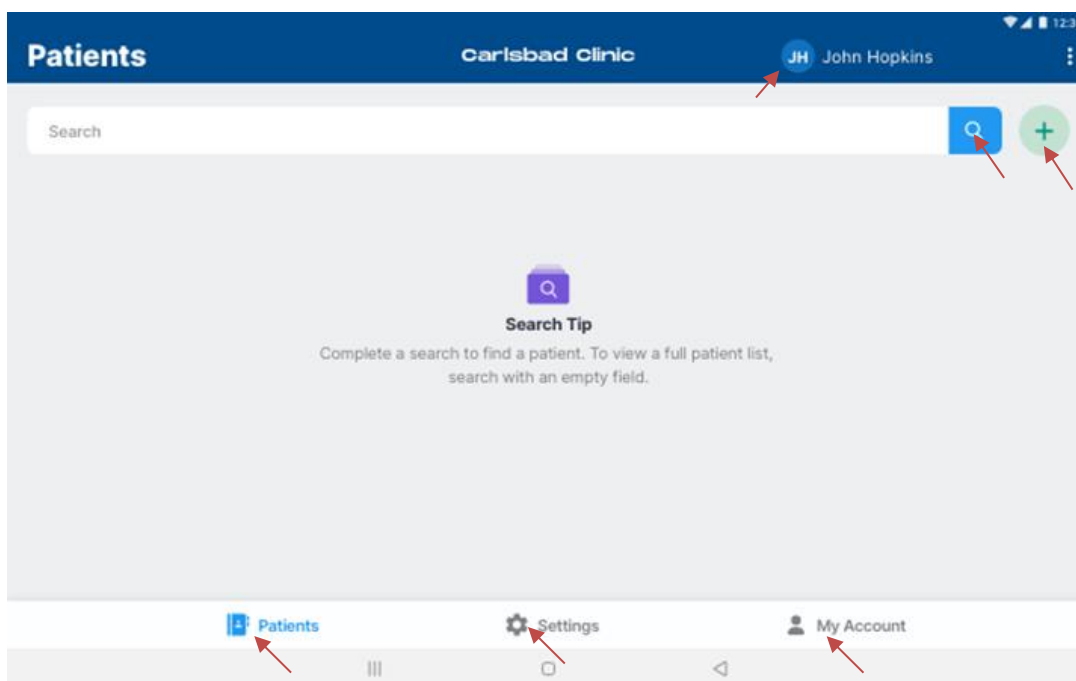
An email has been sent with instructions on how to reset your password. If you do not receive an email, check that the email you have entered is correct, check your spam folder, or contact your MySOZO Administrator.

OK

impedimed®

 CE 2797



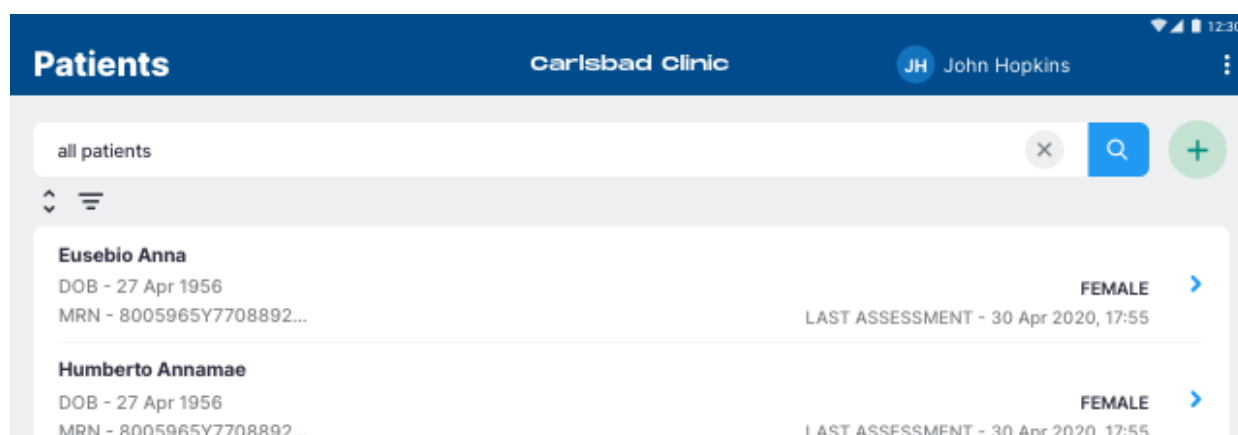


## 7.3 SOZOapp Patients List

Tap **Patients** at any time to return to the Patients List on the SOZOapp home page.

### 7.3.1 Search for Patient

To search for a patient, enter the name of the patient in the **Search** field and tap the **Search** icon. If a complete patient list is desired, simply leave the field blank and tap the **Search** icon. All patients will be displayed.

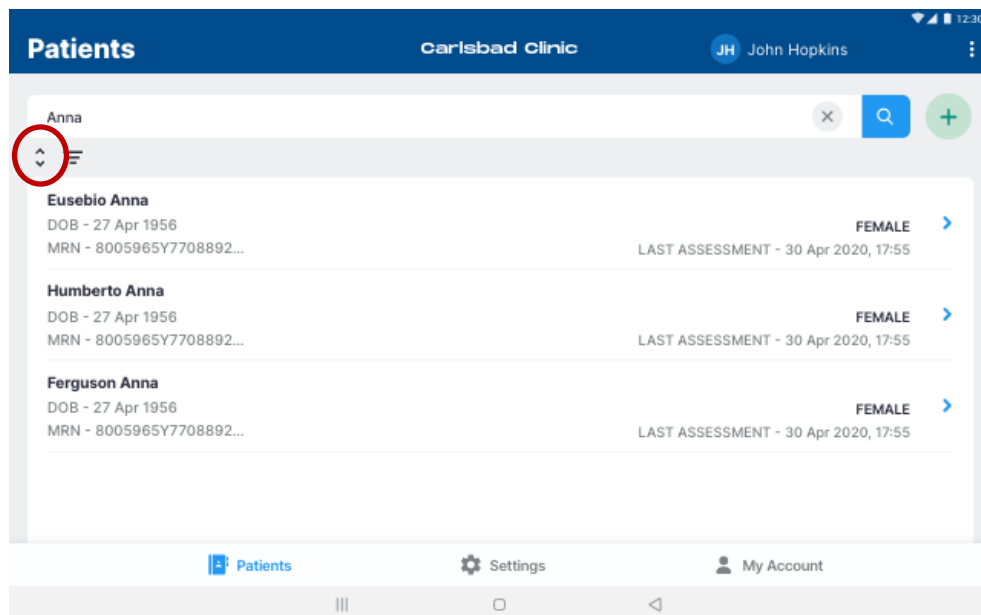


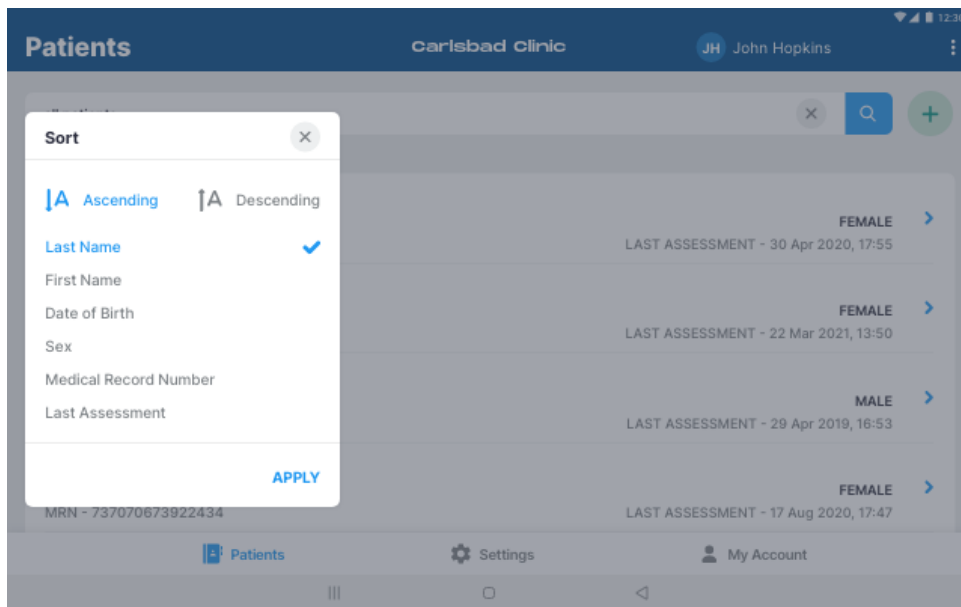


The patient list may be re-arranged using the sort feature. Tap the **Sort** icon and select criteria for sorting, which are:

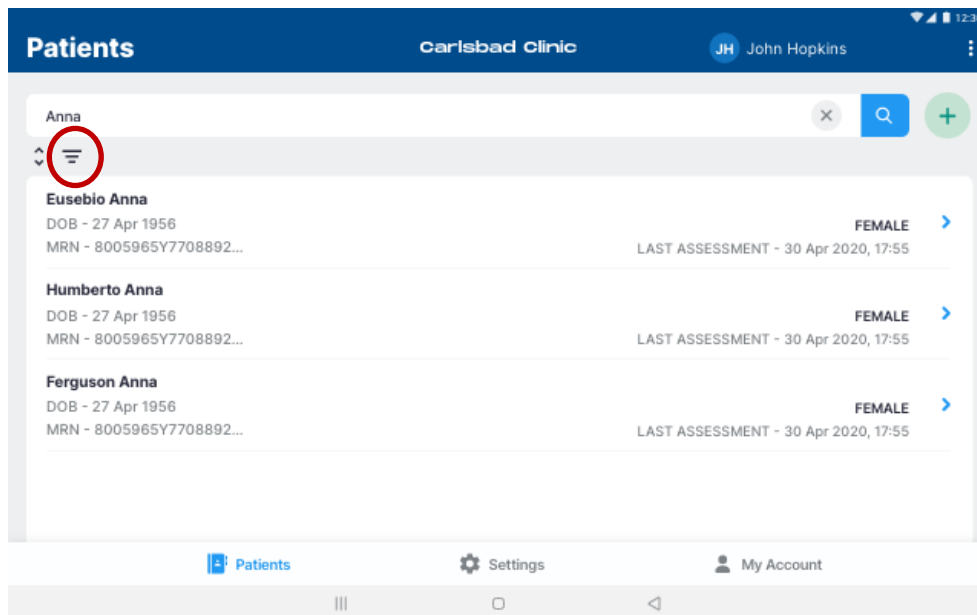
- Ascending or descending order
- First or Last Name
- Date of Birth
- Sex
- Medical Record Number
- Last SOZO Assessment

Tap **Apply** to sort the list.





After searching, the patient list may alternatively be filtered. Tap the **Filter** icon to bring up a pop-up that allows the Clinician to create a shorter patient list based on a selection of some or all Patient Groups.

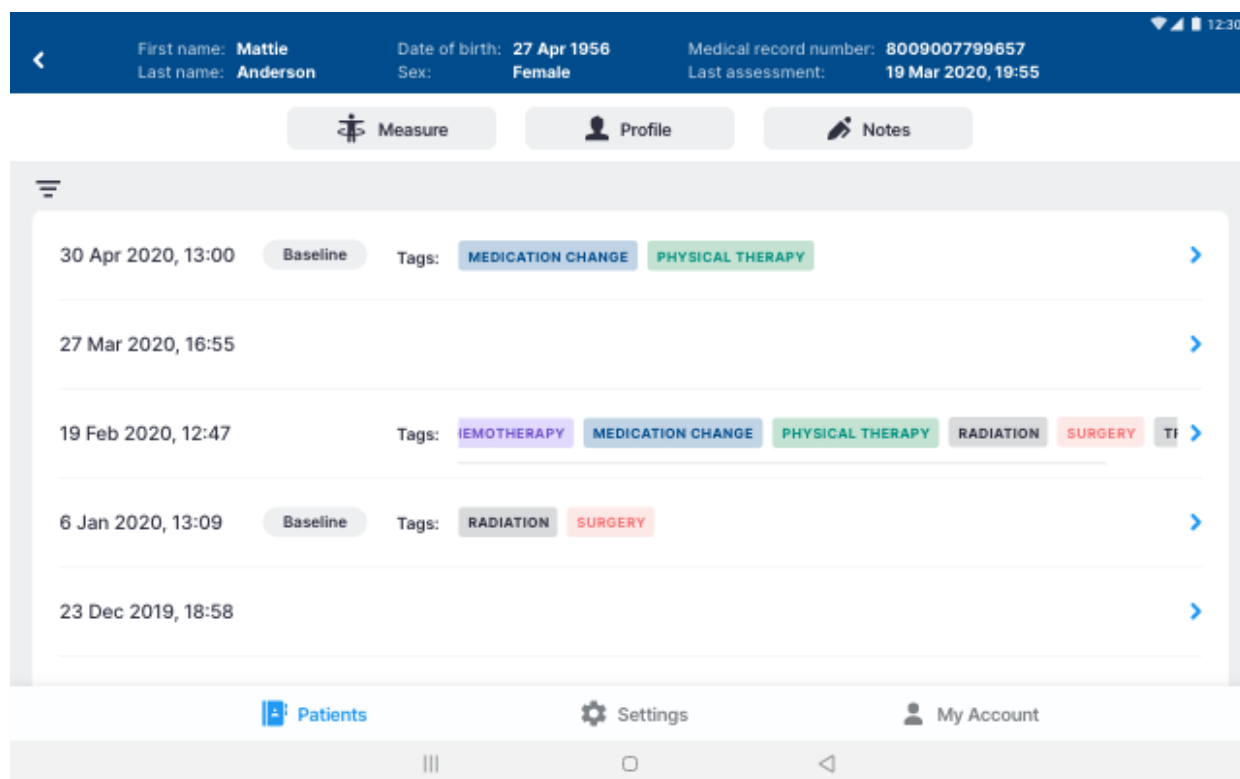


### 7.3.2 Patient Dashboard

The Patient Dashboard has detailed information about each patient which includes name, date of birth, sex, medical record number, last assessment date, and measurements if any.

To go to the Patient Dashboard from the Patient List:

1. Search all patients or enter the patients' name.
2. Tap the **Search** icon.
3. Tap on the desired patient.



### 7.3.3 Create Patient

Clinicians can create a Patient by tapping the **Add** icon from the Patients List. There is no limit to the number of patients that can be created.

1. On the **New Patient** screen, enter the Patient's first name, last name, medical record number (MRN), date of birth, sex, and height.
  - a. The remaining fields, including email address, middle name, country code, and phone number, are optional.
  - b. To leave the patient's email address blank, tap the Not Provided box next to the Email Address field.
2. Select the appropriate **Assessment Types** for the patient.
3. When done, tap **Create**.

The screenshot shows a mobile application interface for creating a new patient. The form is titled "NEW PATIENT" and has "CANCEL" and "CREATE" buttons. It contains a "DEMOGRAPHICS" section with the following fields:

- First Name\*
- Middle Name
- Last Name\*
- Country Code
- Phone Number
- Address
- Email\*
- City

A keyboard is visible at the bottom of the screen, indicating that the form is being filled out on a mobile device.

**Note:** the Clinician may optionally assign the patient to a predefined 'group'. If grouping has been set up in your clinic (only available with SOZOapp v3.1 or later), a list of available groups will appear at the bottom of the create user window. Check the box for each group the patient is to be assigned to.

**Note:** 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.

**Note:** Adding a new Assessment to the patient profile triggers a Caution about the intended use of that Assessment. Ensure 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.

### 7.3.3.1 Assessment Types

Clinicians have the option of including multiple assessments when creating a patient profile.

1. Scroll down the **New Patient** window for a list of types of assessments which apply to the patient.
2. Select the types that apply by tapping the check box next to the assessment.
  - a. Not all assessments are available in all geographic regions where SOZO is sold and may not be available for licensing.
3. For patients at risk of Lymphedema:
  - a. Select **L-Dex Analysis for Lymphedema** and read and accept the pop-up caution.
  - b. Select additional assessment options such as unilateral/bilateral, body element, risk limb, and limb dominance.
  - c. Enter the surgery date and LPP Start Date if the patient is being monitored as part of the Lymphedema Prevention Program.

The screenshot shows a mobile application interface for a patient profile. The top bar is dark blue with a back arrow, a patient name (First name, Last name), and a 'SAVE' button. Below the bar is a 'CLOSE' button and a 'PROFILE' title. The main content area is white and contains the following sections:

- Assessment Selection:** A checkbox labeled 'L-Dex Analysis for Lymphedema' is checked.
- Assessment Options:** Four rows of radio button options:
  - Assessment\*:** Unilateral (unchecked) and Bilateral (checked).
  - Body Element\*:** Arm (checked) and Leg (unchecked).
  - Risk Limb\*:** Left (checked) and Right (checked).
  - Limb Dominance\*:** Left (unchecked) and Right (checked).
- Info Box:** A white box with a blue border containing the text: 'The bilateral selection is for use with patients when both arms or both legs are at risk of lymphedema. All limbs will be measured and used to calculate the L-Dex score.'
- Surgery Date and LPP Start Date:** Two date pickers, both showing '21 May 2019'.
- LPP Start Date is same as Surgery Date:** A checkbox is checked.
- Buttons:** A 'CLEAR' button and a 'SAVE' button (partially visible on the right).
- Bottom Section:** A checkbox labeled 'HF-Dex Analysis for Heart Failure' is checked.

**Note:** adding a new Assessment to the patient profile triggers a Caution about the intended use of that Assessment. Ensure 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.

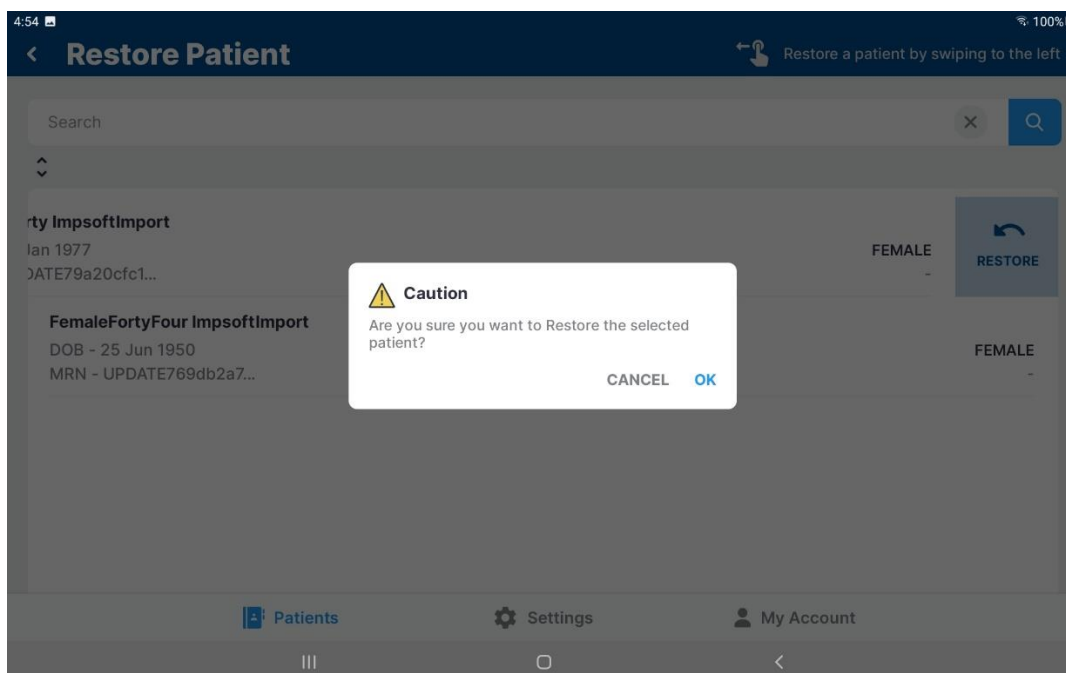
### 7.3.4 Delete Patient

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

### 7.3.5 Restore Patient

A patient may be restored by the Clinician from SOZOapp. From the Patients List, tap the three dots in the top right corner and select **Restore Patient**. A list of deleted patients will be displayed. If the desired patient is not in the visible list, conduct a search.

To restore the desired patient, swipe the patient left. Confirmation to restore the selected patient is required. To return to the Patients List, tap the Back arrow in the top left corner.



### 7.3.6 Edit Patient Profile

To edit a patient profile:

1. On the Patients List, search all patients or enter the patients' name in the search field.
2. Tap the **Search** icon and select the desired patient.
3. From the Patient Dashboard, a Clinician can tap on the **Profile** icon.
4. Make updates as needed.
5. Tap **Save**.
6. A success confirmation will appear in the top right corner.

The screenshot displays the 'PROFILE' form in the SOZOapp. The form is titled 'PROFILE' and has 'CLOSE' and 'SAVE' buttons at the top. It is divided into two main sections: 'DEMOGRAPHICS' and 'ASSESSMENT TYPE'. The 'DEMOGRAPHICS' section contains various input fields for personal information, with some fields marked as required (\*). The 'ASSESSMENT TYPE' section has two radio button options.

DEMOGRAPHICS		*Required Fields
First Name*	Mattie	Country Code
Middle Name		Phone Number
Last Name*	Anderson	Address
Email*	NOT PROVIDED	City
Medical Record Number*	8008744870009	State
Date of Birth*	29 Apr 1967	Country
Sex*	Female	Postal Code
Height (cm)*	167	

**ASSESSMENT TYPE**

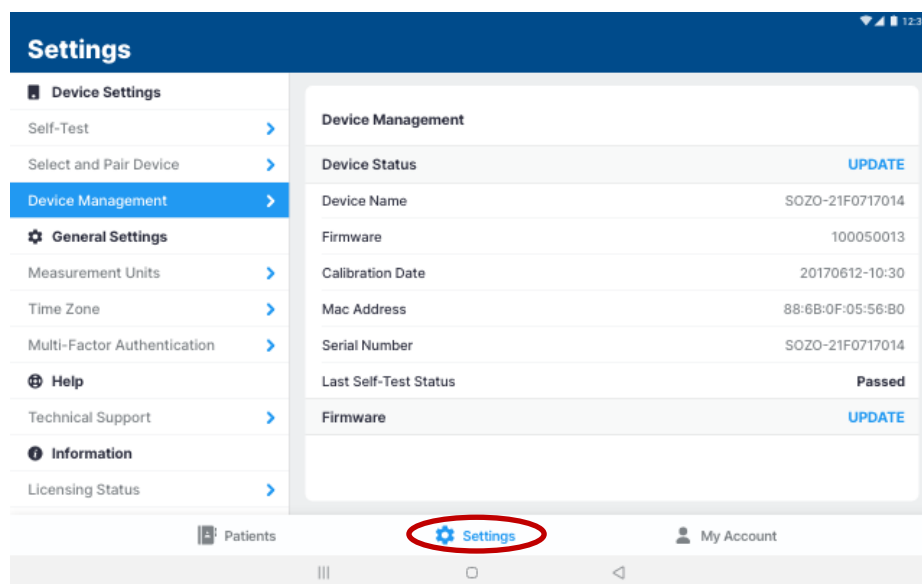
- ☐ L-Dex Analysis for Lymphedema
- ☐ L-Dex Analysis for Heart Failure

## 7.4 SOZOapp Settings

The Clinician may access SOZOapp user settings by tapping Settings, located at the bottom center of the home page.

From the SOZOapp settings menu, the Clinician can configure preferred Measurement Units, turn on personal Multi-Factor Authentication, and update Tablet software through the Software Information submenu, as well as pair and run a self-test on the paired SOZO Device.

The user may also view, but not change, selected Time Zone, Technical Support information, as well as the clinic's available SOZO licenses, the SOZOapp software information, and any applicable regulatory information.



### 7.4.1 Select and Pair Device

The Tablet must be paired with the SOZO Device in order to take measurements. Please note that Android and iOS Tablets have different pairing approaches.

Whether pairing to Android or iOS Tablets, the SOZO Device is identified by a serial number. When pairing with an iOS iPad, only devices that have identification starting with IOS will be available for connection.

The SOZO Device serial number may be found on the

- SOZOtouch housing
- SOZOconnect cable
- SOZOstep housing

The Tablet must be paired for any new SOZO Devices and the pairing process must also be repeated if either the Tablet or system are replaced. The SOZOapp may only select and work with one SOZO Device at a time.

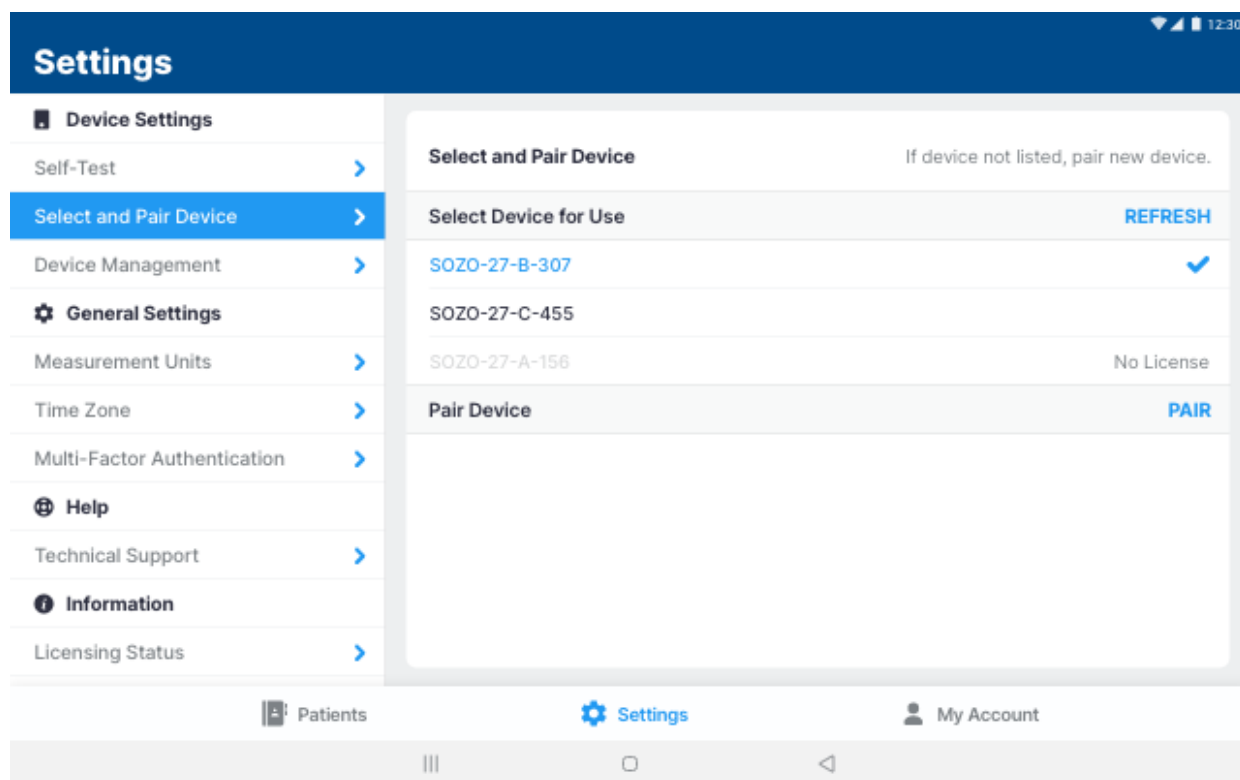
ImpediMed recommends keeping the SOZO Device together with its paired Tablet. The Tablet may pair with other devices but will only control measurements from the SOZO Device identified under “Device Name.”

SOZOapp remembers the last SOZO Device used and will automatically point to that SOZO Device, even after signing out. If using the iOS SOZOapp, the SOZO Device will only be remembered if the SOZO Device is also powered on when the user signs in. Once the SOZO Device is selected, the SOZOapp automatically pairs with the SOZO Device through *Bluetooth®*.



#### 7.4.1.1 Android:

- Locate **Settings** on the Tablet and enable *Bluetooth®*.
- Once *Bluetooth®* is enabled, the Tablet scans for connection to the SOZO Device and a device may be paired by selecting the device serial number in the tablet settings.
- Alternatively, the Tablet settings can be accessed using the **SOZOapp**. To do this, open the **SOZOapp** and sign in.
- Go to the Settings page, and then 'Select and Pair Device'.
- To pair a new device, select 'Pair Device'. This will open the Tablet settings and the device serial number should be listed under available devices. Tap on the serial number to pair.
- Return to the SOZOapp Settings page and then 'Select and Pair Device'.
- A list of SOZO systems that have been previously paired over Bluetooth will be presented. If the paired device is not present, press **Refresh**.
- Select the paired device and ensure it is highlighted blue with a tick mark next to it.



**Note: do not pair an Android device (Samsung Tablet) to a SOZO system whose serial number starts with IOS- The android SOZOapp will not be able to communicate with this 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.**

#### 7.4.1.2 iOS:

- a. The SOZO Device must be paired through **SOZOapp** itself, not through the operating system. If the device is paired through the iOS Tablet settings, the SOZOapp will be unable to communicate with the SOZO Device.
- b. Go directly to SOZOapp and sign in. From the settings menu, tap on 'Select and Pair Device', and select the appropriate iOS-compatible SOZO Device (a serial number starting with IOS-).
- c. The selected SOZO Device serial number will turn blue.

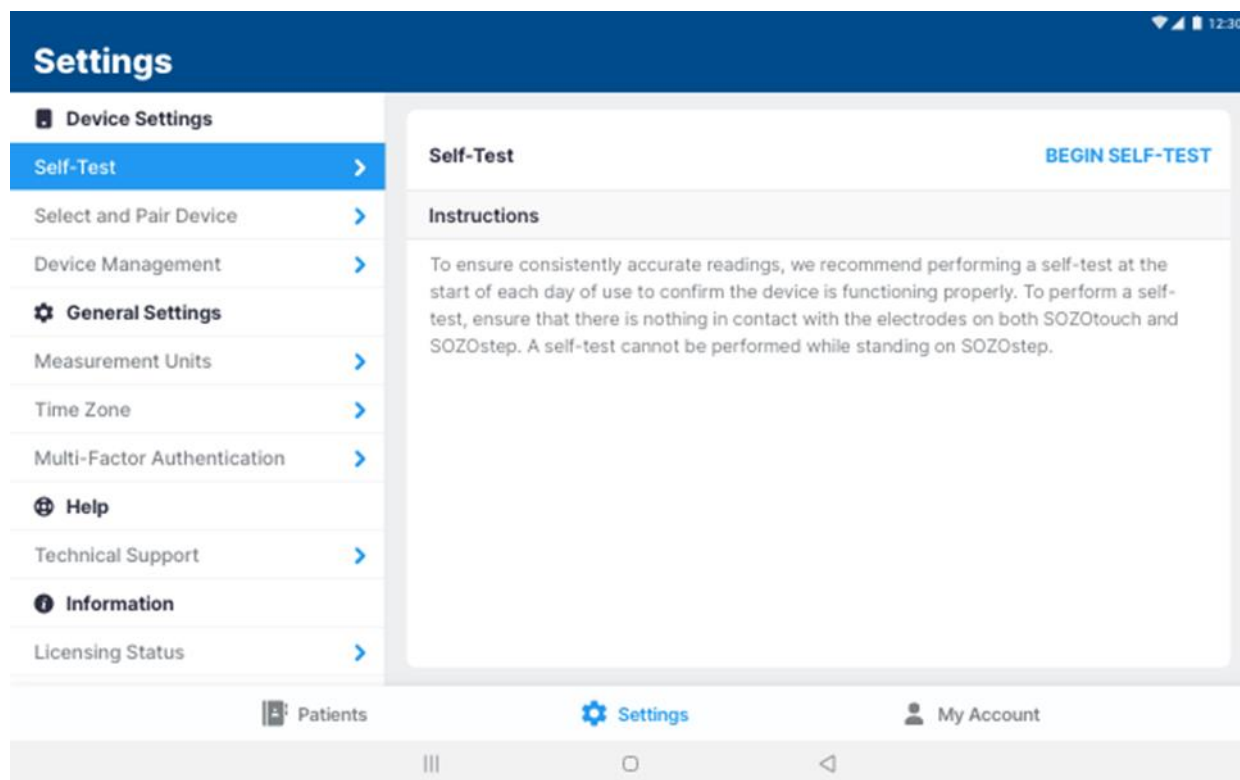
#### 7.4.2 Self-Test

Self-tests may be run for different purposes.

- **Device Status Confirmation:** A Self-test is optional to confirm connection to the correct SOZO Device during initial set-up.
- **Recommended Step Before Taking Measurements:** A self-test is recommended preparation for taking measurements. It should be run daily before taking the first measurement of the day.

To run a self-test:

1. From the Device Settings menu, select "Self Test", then "Begin Self-Test".
2. Follow additional instructions as prompted. A confirmation pop up of success or failure will be shown in the right top corner.



### 7.4.3 Device Management

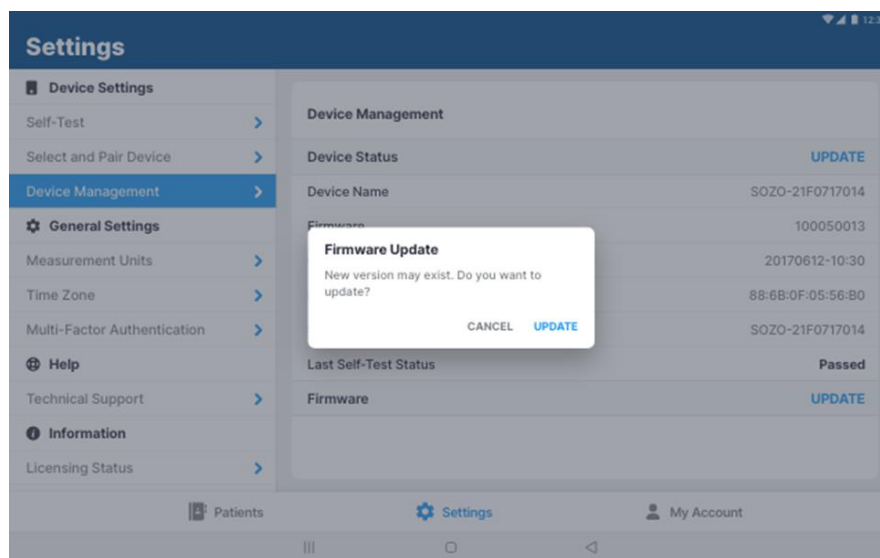
From the Device Settings menu, select “Device Management”.

Once the tablet is paired to a device, information about the device can be obtained by tapping **update** next to “Device Status”.

The SOZO system firmware may be updated by tapping **Update** next to ‘Firmware’. This process may take a 2-3 minutes. The Tablet or SOZO Device should not be turned off during this time.

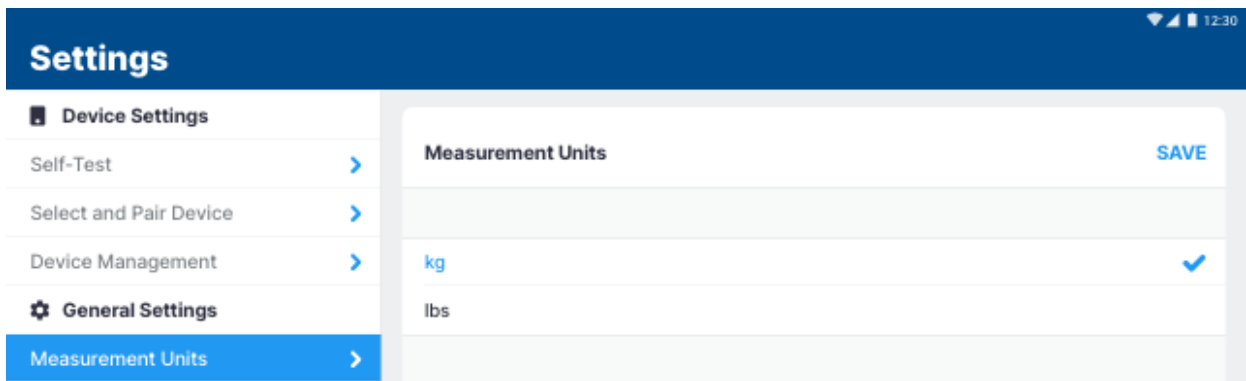
After completion of the firmware update, the firmware version should be checked by updating the device status to show the desired firmware version. The firmware functionality may be updated through the Android SOZOapp.

**Note: iOS SOZO system firmware may not be updated through SOZOapp at this time.**



### 7.4.4 Measurement Units

Under **General Settings**, the display units for weight, height, and fluid volume in the SOZOapp may be selected. Kilograms may be converted to pounds, centimeters to inches and liters to pints. When updates are complete, tap **Save**.



### 7.4.5 Time Zone

The current Time Zone for the clinic is displayed here.

### 7.4.6 Multi-Factor Authentication

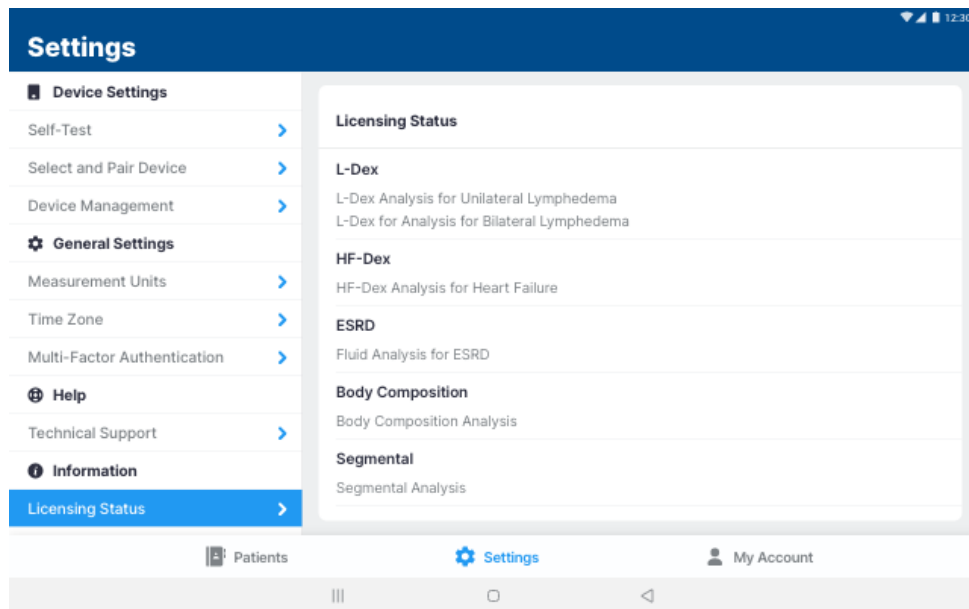
The Clinician can elect to have multi-factor authentication turned on for their account once it has been activated by the Clinic Administrator.

### 7.4.7 Technical Support

For assistance with use of SOZO, the Technical Support page includes contact information for ImpediMed technical support.

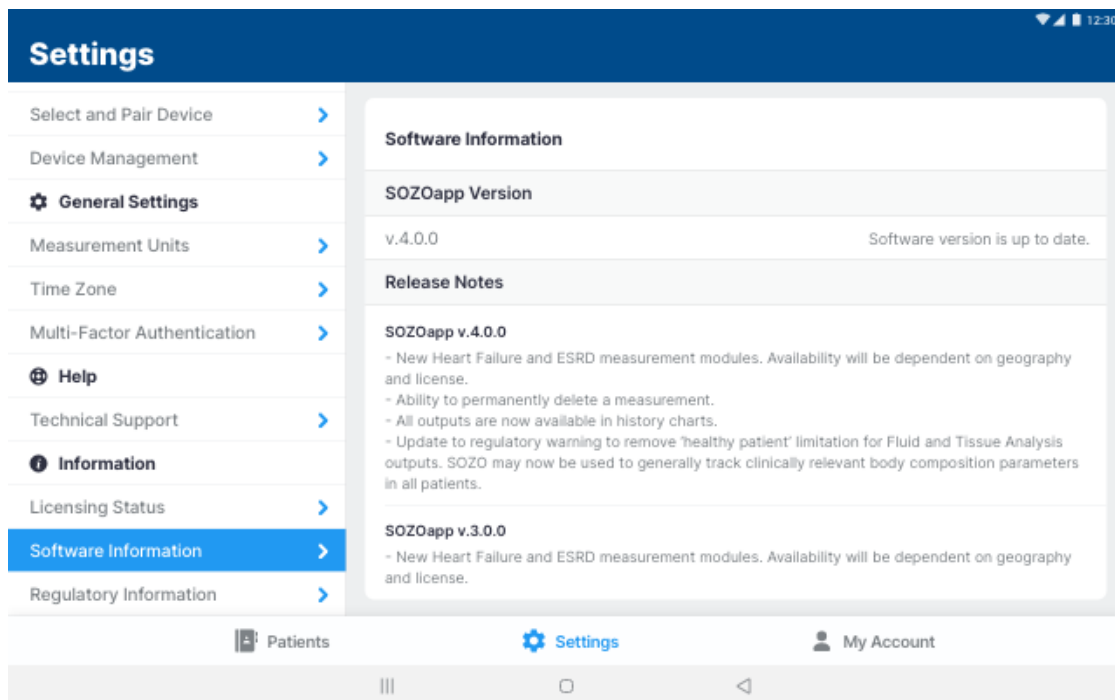
### 7.4.8 Licensing Status

Under Settings, users can view the Clinic's licensing status for various Assessments offered to ImpediMed customers. The licensing status can only be changed by ImpediMed. If desired modules are not available, please reach out to ImpediMed to discuss licensing additional modules for your use.



## 7.4.9 Software Version

The user will be notified at sign-in if a newer SOZOapp version is available. The user may confirm their SOZOapp version under **Software Information** in the **Settings** menu. In addition, the user may want to see major changes in this version and the previous released versions by reviewing the **Release Notes**.



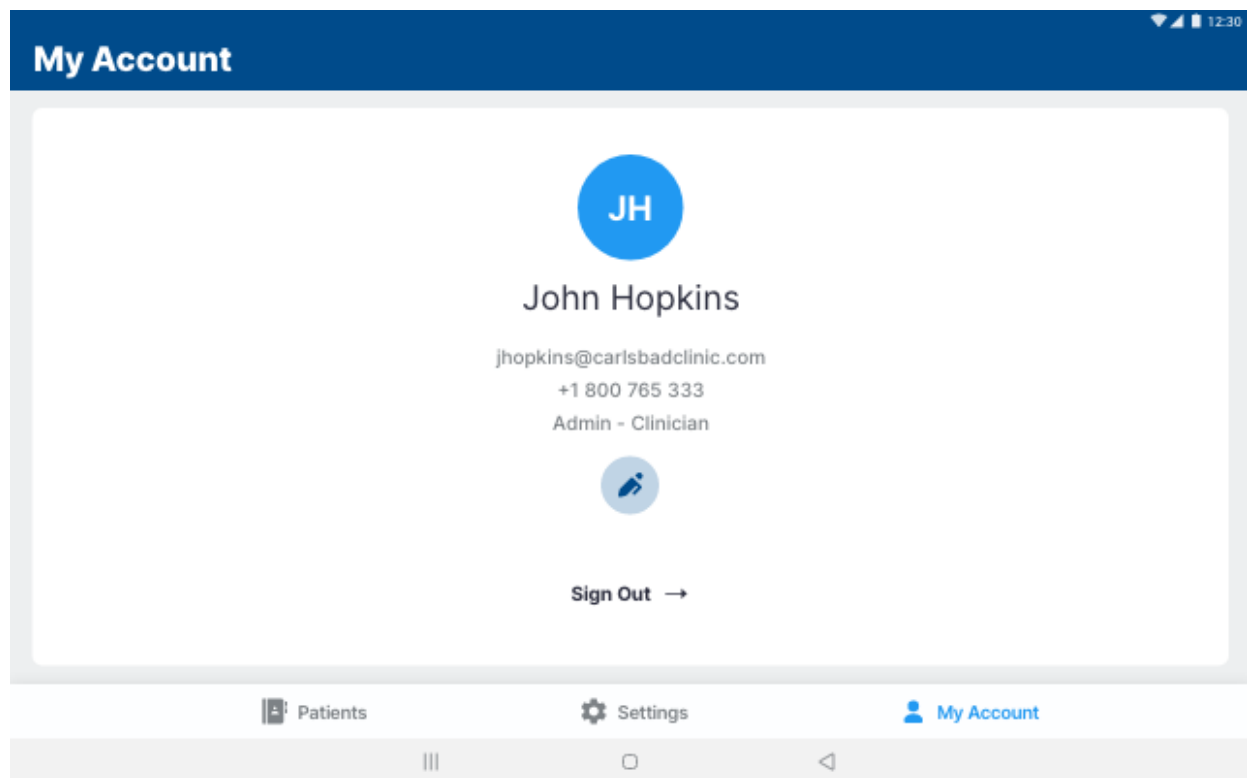
The SOZOapp must be the same version as MySOZO. If the SOZOapp version is not the most current version as MySOZO, the user will be prompted to automatically update upon sign in. If the automatic update process is not successful, contact your IT support or ImpediMed technical support for a compatible version of the SOZOapp.

#### 7.4.10 Regulatory Information

The user is provided with information regarding the manufacturer, notified body and other important information.

### 7.5 SOZOapp My Account Page

To edit the Clinician Account, navigate to the My Account tab and select the **Edit** icon..  
To sign out of MySOZO at any time, tap the My Account icon then tap **Sign Out**.



# 8 PREPARING THE PATIENT

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## 8.1 Preparing for all Measurements

The Clinician taking measurements on a SOZO Device must ensure the patient:

- Removes all metal jewellery. For example, ring and belt buckles. Items above the neck such as earrings are okay.
- Removes any electronics, coins, keys, or other metal objects from pockets.
- Removes shoes, sock, and stockings.
- Dampen hands and feet or SOZO electrodes by wiping with a damp cloth.
- Remains still during the measurement with elbows away from the body.

### 8.1.1 Body Composition Measurements

If fluid and/or tissue analysis is intended, ensure the patient observes the following preparation tips to receive consistent BodyComp Assessments:

- Empty bladder prior to measurement.
- Avoid exercise for 4 hours prior to measurement.
- Avoid caffeine 2 hours prior to measurement.
- Avoid alcohol for 8 hours prior to measurement.
- Avoid meals for 8 hours prior to measurement.

## 8.2 Measurement Accuracy

For best measurement accuracy clinicians 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.

### 8.2.1 Weight Modifications

Weight is important for measurement accuracy and must be entered correctly by the Clinician at the time of measurement. This weight is valid for that measurement only. After measurement, a patient's weight may not be modified.

## 8.3 Positioning the Patient

The SOZO system is designed in a Standing Position for patients who can stand and in a Seated Position to accommodate patients who are unable to stand and may exceed the maximum weight limit (up to 375lbs if patient is standing, and up to 750 lbs if patient

is sitting). [DEVICE ASSEMBLY](#) provides instructions for system configuration for standing and seated positions.

**Note: clinicians should always take patients measurement in the same position each time. This ensures a more accurate comparison of fluid levels.**

For best results, when taking a reading from a standing position the patient should stand at rest for 2-3 minutes prior to taking a measurement. Similarly, when taking a reading from a seated position, the patient should be seated for 2-3 minutes prior to taking a measurement.

### 8.3.1 Standing Position

When standing on the SOZO Device, ImpediMed 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 sides. The patient's hands must have contact with the electrodes.

### 8.3.2 Seated Position

When using seated, ImpediMed recommends NOT using 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.



## 9 TAKING MEASUREMENTS

The SOZO Device supports various types of measurements for each Assessment, such as measurements for the detection of lymphedema (L-Dex module), for monitoring of fluid in Heart Failure patients (HF-Dex), and for different body composition outputs (BodyCom and Segmental BodyComp).

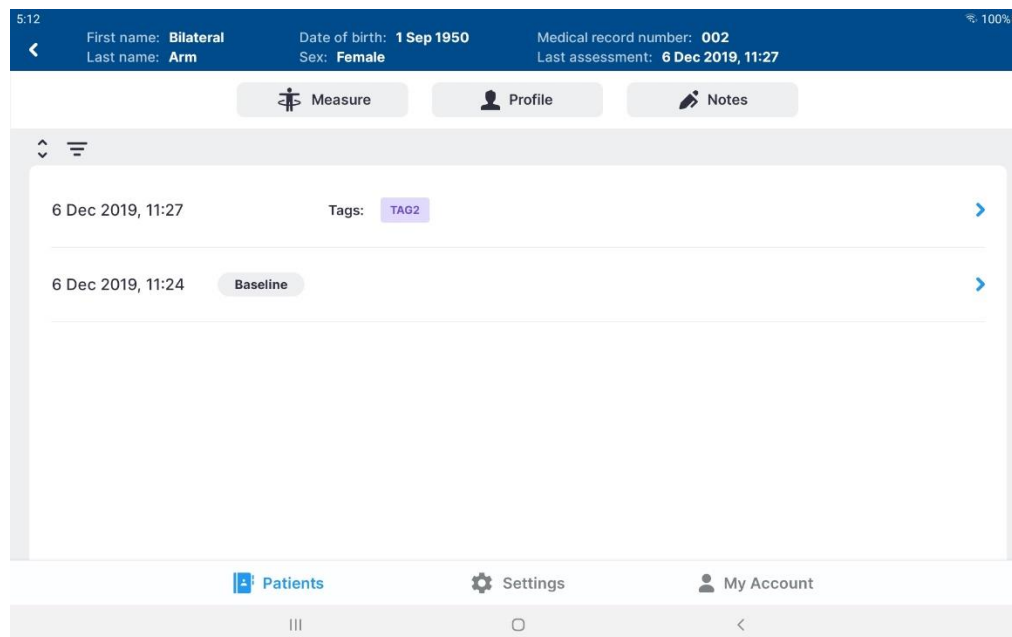
Each of the assessments along with indication-specific information and reports are discussed in greater detail in the specific Assessment User Guides, including the L-Dex, HF-Dex and BodyComp User Guides.

### 9.1 Starting Measurements with the SOZOapp

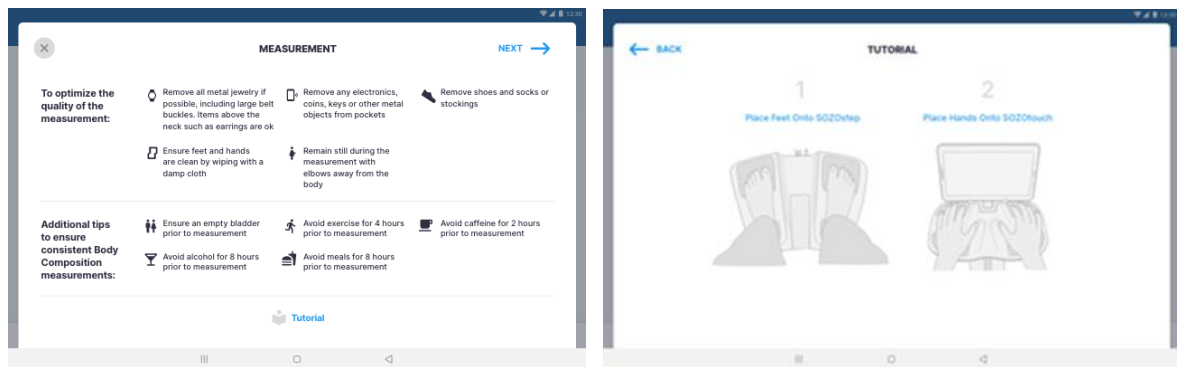
Measurements are taken using the Tablet and SOZOapp.

To take patient measurements:

1. Create a patient profile if required.
2. Search and select the patient from the patient list to open the Patient Dashboard.
3. From the Patient dashboard, tap the **Measure** icon to begin new patient measurements.

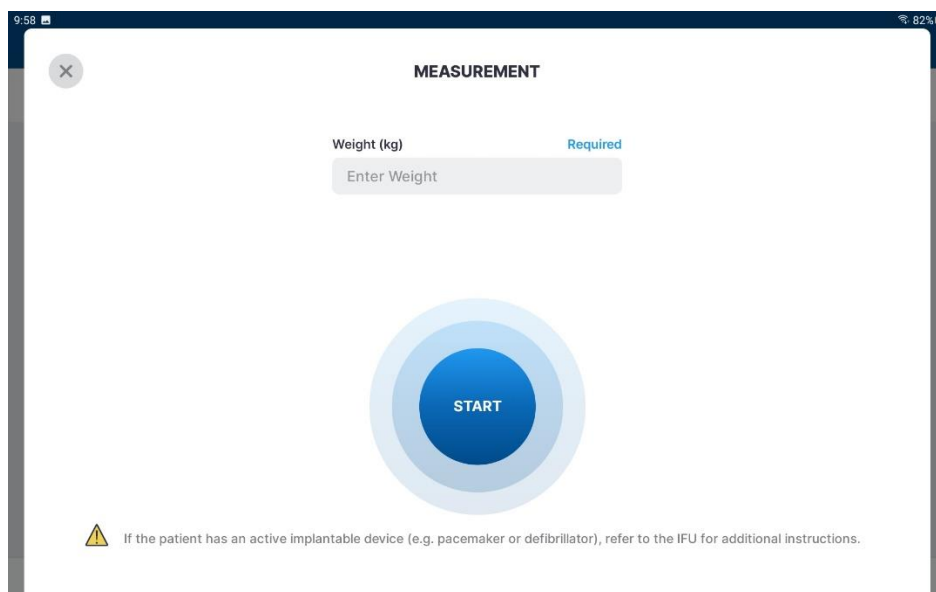


4. After tapping the **Measure** icon, measurement instructions appear. To optimize measurement quality, ensure patient compliance with these instructions. When done, tap **Next**.



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

5. Instruct the patient to place their feet onto the SOZOstep. Locate their heel recesses and ensure each foot is flat and in full contact with each electrode plate.
  - a. There are two electrode plates for the left foot, and two electrode plates for the right foot.
6. Instruct the patient to 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.
  - a. There are two electrode plates for the left hand, and two electrode plates for the right hand.
7. Enter Patient Weight and then tap **Start** to begin measuring the patient.
  - a. This triggers a five-second countdown before the start of the measurement.
  - b. Accurate weight entry is critical to body composition analysis. The patient should be weighed immediately prior to the SOZO measurement.



Once started, the SOZO Device measurement will take approximately 30 seconds. The measurement in progress window remains until the measurement is complete.

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.

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

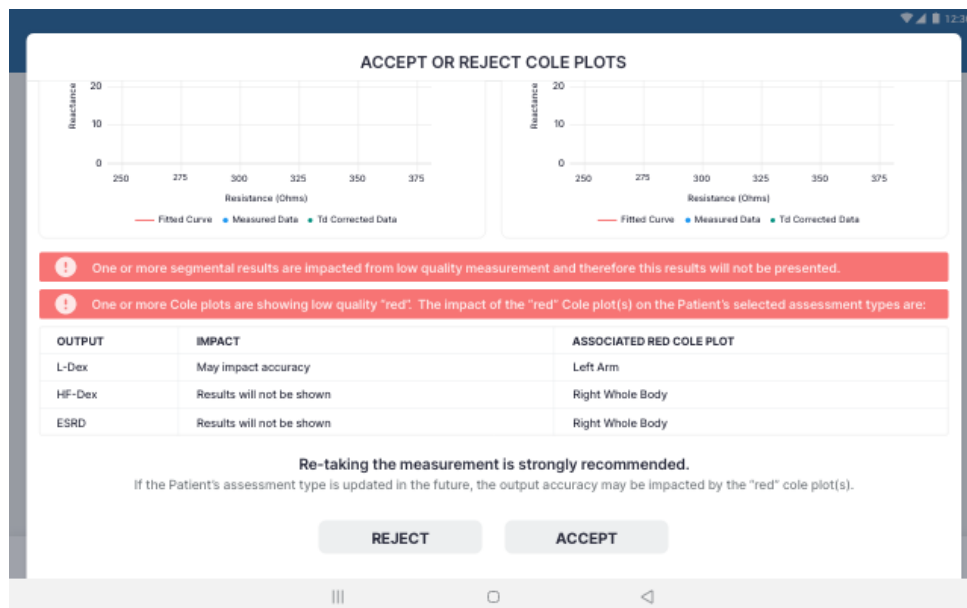
**Note: surface temperature should not exceed 47° C (117° F) during normal use. Do not use SOZO Device if it is hot to the touch. Disconnect the SOZO Device by unplugging the Power Adaptor and call ImpediMed Technical Support.**

**Note: read Intended Use and Precautions before taking measurements with the SOZO Device.**

**Note: ensure the SOZOstep is stationary and on a level surface.**

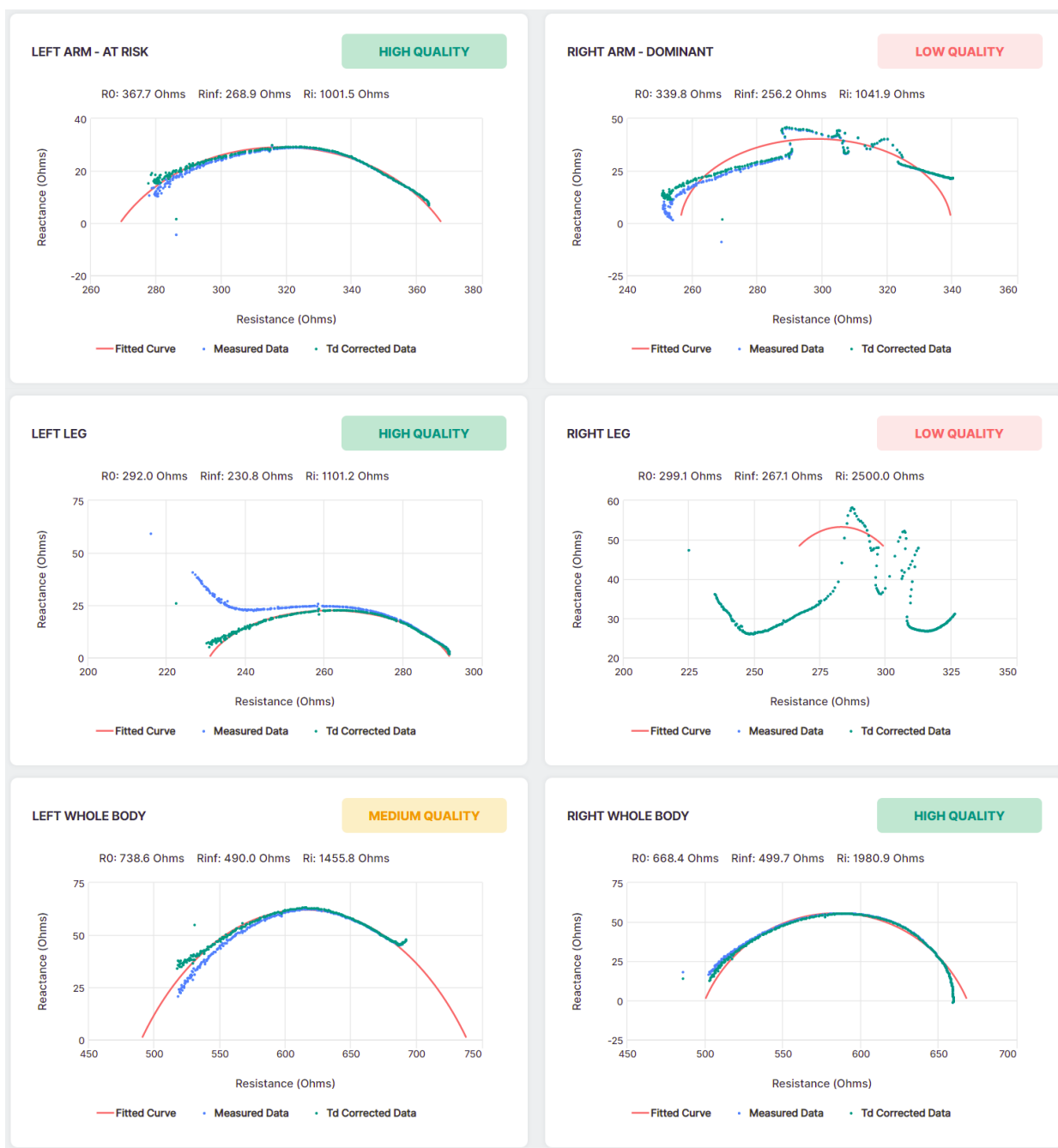
## 9.2 Accepting and Rejecting Cole Plots After Measurement

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 and not displayed prior to the results, however can be viewed with the measurement. 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 quality of the 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.

Cole plots associated with a given measurement are stored with each measurement and may be reviewed alongside a given measurement’s results on the “Cole Plots” tab.



## 9.3 Interpreting Cole Plots

On a Cole plot, the blue dots are the raw “Measured Data,” and the green dots are “Td Corrected Data,” representing the raw measured data after time delay 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 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 result.

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

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

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

If a measurement is accepted, Assessment results are displayed. Only licensed Assessments are available for viewing in the SOZOapp.

If a measurement is rejected, the user is taken back to the Patient Dashboard.

## 9.4 Setting a Baseline

As in MySOZO, a Clinician may set or remove a measurement baseline for each Assessment type in SOZOapp, and for most outputs. To adjust the baseline **check** the tickbox next to “SET AS BASELINE” in the top right corner of the desired measurement or output.

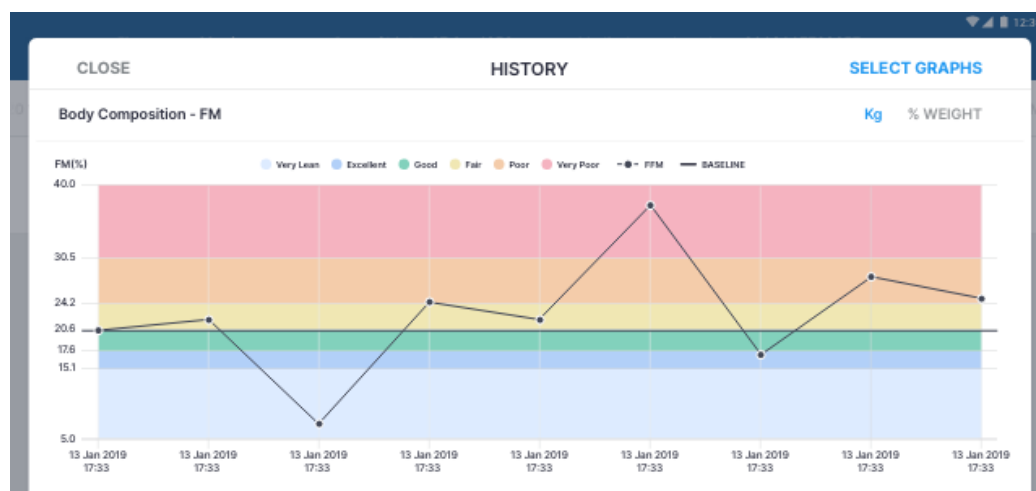
To choose the proper measurement as the baseline, the measurement should be:

- High-quality
- Taken when the patient is in a normal fluid or “euvolemic” state.
  - This is often before treatment has occurred.

**Note: if an incorrect baseline measurement is selected, either de-select the baseline for that measurement, or navigate to the correct measurement and select it as the baseline.**

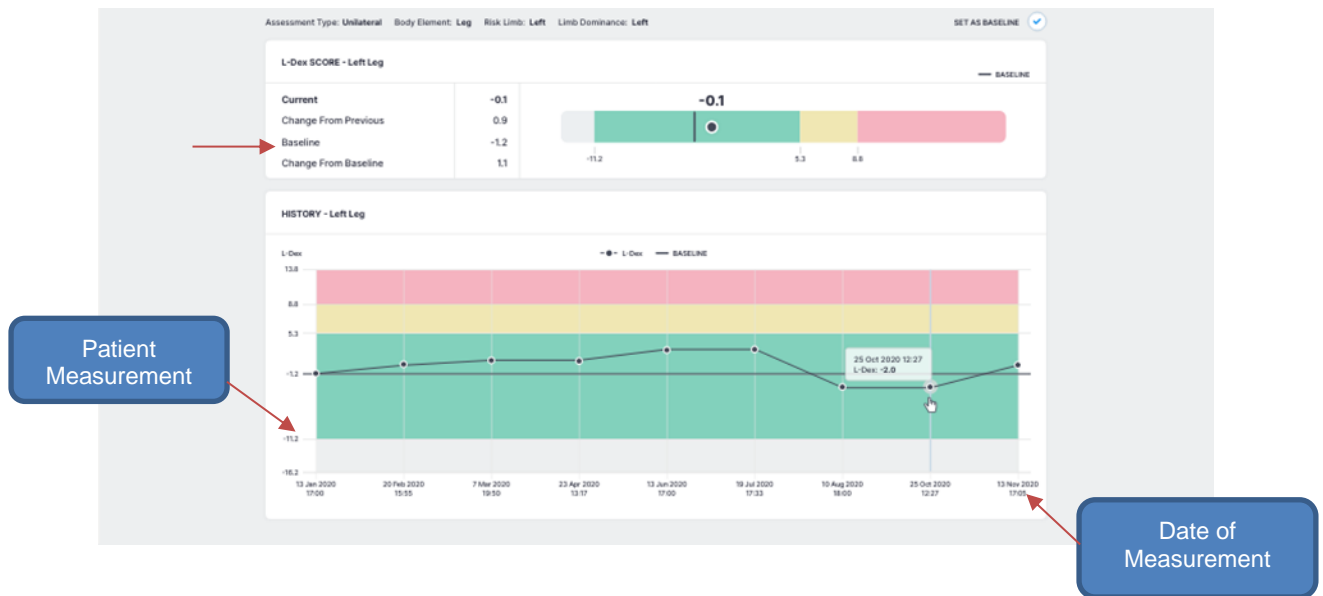
## 9.5 History Graphs

The Clinician can view longitudinal measurements of the outputs over time by tapping on “History”.



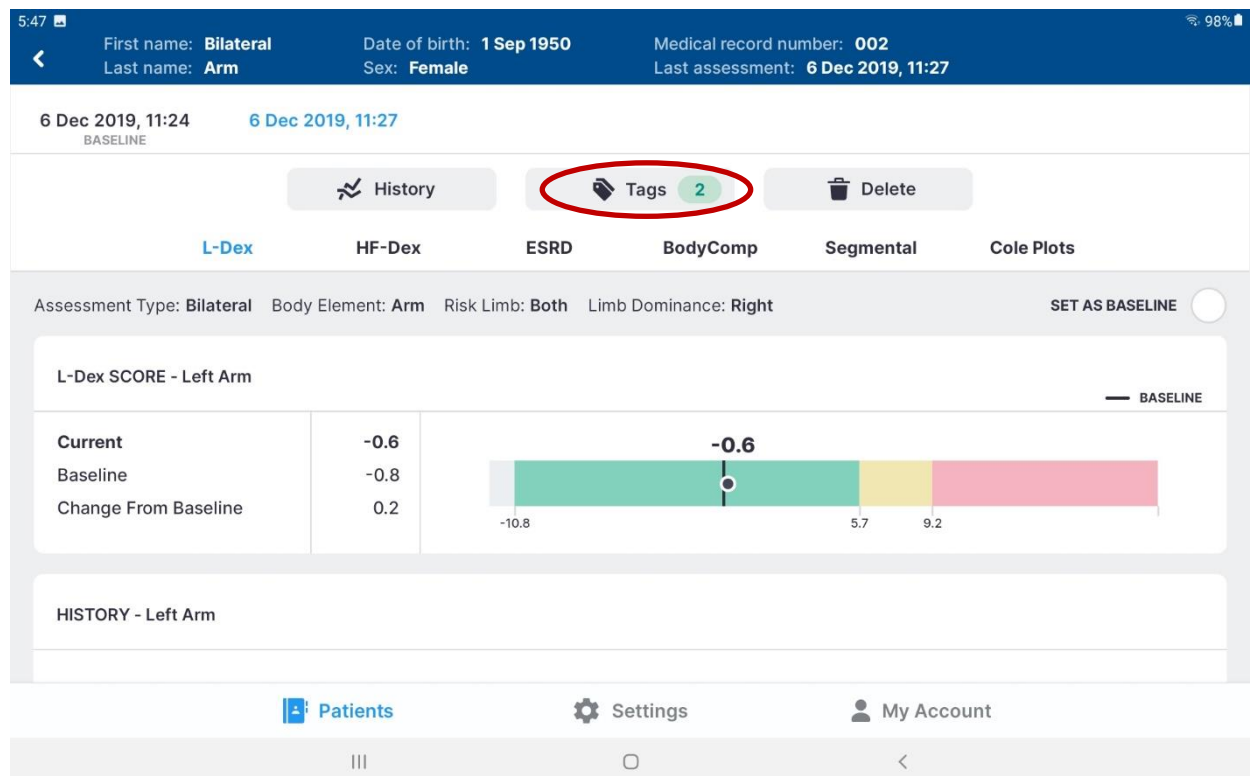
**Note: only historical measurements for licensed Assessments will appear under History. Therefore, the Clinician will only be able to view licensed Assessments.**

For any measurement outputs that can have a baseline selected, 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.



## 9.6 Measurement Tags

A Tag can be added to a measurement to provide additional information and notes. These must be created by a Clinic Administrator in MySOZO. The number of Tags linked to a measurement is listed in the Tags icon. Multiple Tags can be added to the same measurement.



To add a Tag to a measurement, tap the “Tags” icon and tab “ADD NEW”. Select the Tag to be added from the list of available Tags and add a description if desired. Tap “SAVE” to link the Tag to the measurement.

## 9.7 Deleting Measurements

In SOZOapp, individual measurements may be deleted. If, for example, low quality Cole plots were accepted and the Clinician desires to remove the measurement. First navigate to the result screen of the measurement to be deleted and tap the “Delete” icon.

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



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

The screenshot shows the patient profile for Mattie Anderson, born 27 Apr 1956, Female. A success message states 'Baseline has been updated.' The 'Delete' button is highlighted with a red box. Below the navigation bar, the 'COLE PLOTS' tab is selected, showing dialysis status and fluid measurements.

EXTRACELLULAR FLUID (ECF)			TOTAL BODY WATER (TBW)		
	LITERS	% WEIGHT		LITERS	% TBW
Current	17.3	41.6	Current	41.5	66.9
Change From Previous	-0.3	-3.1	Change From Previous	2.1	4.4
Baseline	17.6	-	Baseline		
Change From Baseline	-0.3	-	Change From Baseline		

Below the fluid measurements, there are sections for INTRACELLULAR FLUID (ICF) and WEIGHT.



## **9.8 Licensing**

### **9.8.1 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 Assessment may be added to a patient's profile, taking into consideration their intended use. Historical results will then be recalculated based on previously collected Measurement data and the new Assessment outputs will be shown in the applicable history and measurement screens.

### **9.8.2 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.

# 10 ASSESSMENT TYPES

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The SOZO Device supports the following Assessment Types:

- 1) L-Dex®
- 2) HF-Dex™
- 3) BodyComp™
- 4) Segmental BodyComp™

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. 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.

## 10.1 Choosing the Proper Assessments for the Patient

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

- L-Dex® aids the Clinician in the assessment of lymphedema in a patient;
- HF-Dex™ aids the Clinician in monitoring fluid status in patients living with heart failure
- BodyComp™ is used to provide fluid and tissue analysis assessments of an individual, including segmental.

Each Assessment must have a separate license. Only Assessment types with licenses are available to the user. The available Assessment types for a given user is displayed in the SOZOapp and MySOZO. Assessment and associated results are only available if licensed.

## 10.2 Assessment Specific Instructions For Use

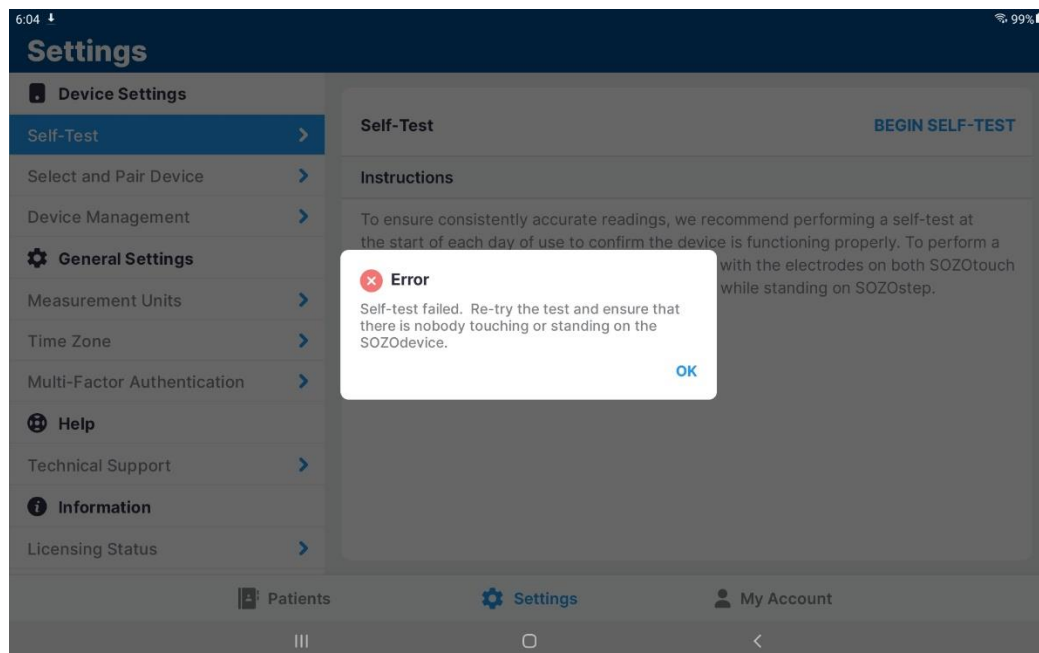
Go to [www.impedimed.com](http://www.impedimed.com) to download the Assessment-specific instructions for use, including the L-Dex Assessment User Guide (LBL-525-1), the HF-Dex User Guide (LBL-525-2), or the Body Composition and Segmental Analysis User Guide (LBL-525-3), or contact ImpediMed technical support for a printed copy.

# 11 SOZOapp TROUBLESHOOTING

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 11.5 General Troubleshooting Chart.

## 11.1 Self-Test Error

The “**Self-test failed.**” Error message may appear after running a self-test or patient measurement from the SOZOapp.



Try the below actions to resolve this issue:

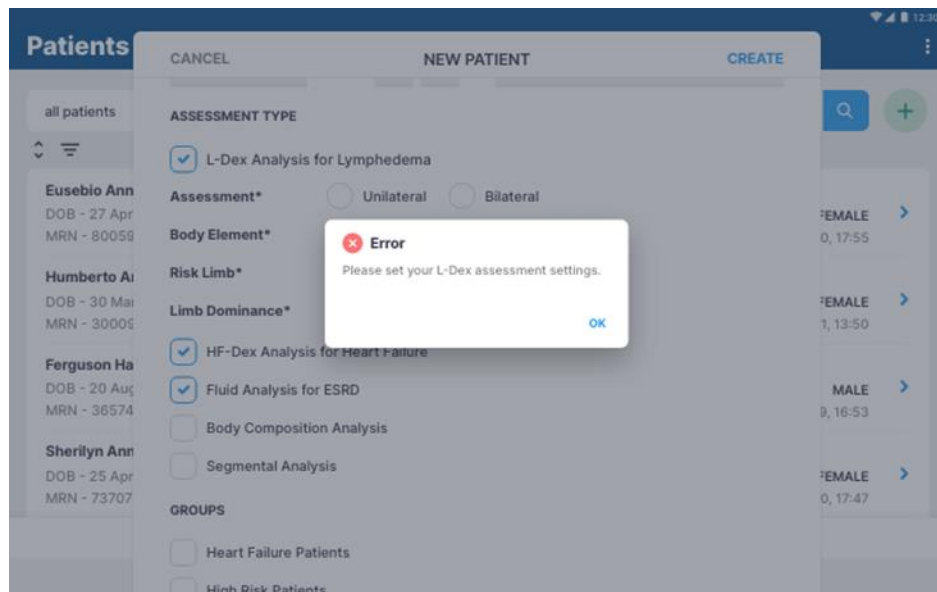
1. Ensure nothing is touching the SOZO Device during the Self-Test.
2. Reset the Bluetooth® button on the back of SOZOtouch by pressing in for 3 seconds.
3. Unplug the SOZO Device from the wall outlet for 10 seconds and plug back in.

Re-run the self-test function.

## 11.2 Lymphedema Settings Error

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

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



Follow the below actions to resolve this issue:

1. Under Lymphedema Settings select Body Element, Risk Limb, and Limb Dominance.
2. Select save.
3. A success confirmation will appear in the top right corner.

**Note:** 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 the **Risk Limb**.

### 11.3 Patient Dashboard Error

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

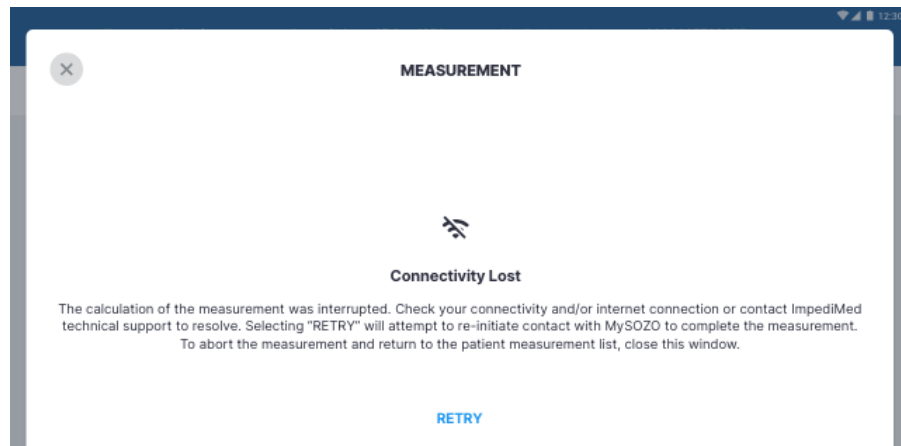


Follow the below actions to resolve this issue:

- Ensure nothing is touching the SOZO Device.
- Press the Bluetooth® button on the back of SOZOtouch.
- Unplug the SOZO Device from the wall outlet and plug back in.
- Re-run the self-test function.
- Ensure that the patient is standing and correctly positioned on the SOZO Device before tapping Measure.

## 11.4 Connectivity Error

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



Follow the below actions to resolve this issue:

1. Ensure there is a stable WiFi connection and that there is no other high EMI emitting device near the Tablet.
2. To reconnect, tap Retry
3. If this does not establish connectivity, tap Back to dashboard to end the measurement.

## 11.5 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 option 4, ImpediMed technical support, or you may email ImpediMed at [tsu@impedimed.com](mailto:tsu@impedimed.com) or visit <https://www.impedimed.com>.

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
Form fields have character limits and entry requirements. Various error messages can occur if these field requirements are not met.	User has completed a form field that does not meet minimum/maximum/character type requirements	Enter data in mandatory fields according to requirements described in error message.
SOZO hardware does not emit audible clicks when powering on; LED at back of unit is not emitting a blue light.	Power cord not properly connected or potential hardware failure.	Confirm power cord is properly connected. If cord is correctly inserted, contact ImpediMed technical support.
Self-test fails.	Person/object making contact with electrodes during self-test.	Ensure no extraneous objects in contact with electrodes during self-test; re-run self-test.
L-Dex; HF-Dex, Body Composition, Segmental, 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.
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.

Signing 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 sign in leaving either username or password blank.	Verify username and password are entered properly.
"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
"Incorrect credential combination. Please check your information and try again."	Incorrect or forgotten username/password.	Verify credentials. If error continues, change password using the Forget password link at mysozo.com. Enter the email address. An email will be sent to reset password.
"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, there may be poor WiFi coverage in the area.	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".	Signing in to SOZOapp with previous app version after MySOZO has been updated.	Select "Yes" and follow prompts to automatically update SOZOapp to latest version.

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 signed out automatically based on initial sign in. The sign out time is set by the Clinic administrator.	Sign 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.
"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.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	Potential Cause	Resolution
"Device not found. Please check your selected device"	SOZOapp is not currently paired to a nearby SOZO Device	<p>Verify that the device chosen is available via Bluetooth by selecting "pair device".</p> <p>If device is selected and error has occurred, ensure that the serial numbers match (if multiple units at your Clinic).</p> <p>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.</p> <p>Verify SOZO Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue.</p> <p>Turn off and restart the Tablet and the SOZO Device.</p> <p>If error persists, contact ImpediMed technical support</p>
"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.	<p>Confirm Tablet Bluetooth is turned on, that the proper SOZO Device is selected, and that the Tablet is within range to allow a Bluetooth connection.</p> <p>Turn off and restart the Tablet and the SOZO Device. Verify SOZO Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue.</p> <p>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.</p> <p>If Bluetooth is enabled on the Tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.</p>
"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.



Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	Potential Cause	Resolution
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.
"Something Went Wrong. The tablet encountered an error in communication with the SOZO Device. Please check that the correct SOZO Device has been paired and selected in the settings, the SOZO Device is powered on and is located near the tablet, and minimize any potential interference from other wireless devices. If the issue persists, try again and contact ImpediMed technical support."	The tablet has lost Bluetooth connection with the SOZO Device.	Confirm Tablet Bluetooth is turned on, that the proper SOZO Device is selected, and that the Tablet is within range to allow a Bluetooth connection.  Turn off and restart the Tablet and the SOZO Device. Verify SOZO Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue.  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.

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 email.
"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.

# 12 PERSONAL DATA

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Read our privacy policy located at

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

# 13 CARE AND MAINTENANCE

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## 13.1 SOZO Device Care

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

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



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



SOZO Devices with the 'Germicide Compatible' label located on the side of SOZOtouch may also be cleaned with the following:

- Cavicide Liquid
- Cavicide 1 Liquid
- Caviwipes 1, Caviwipes XL
- Clinell Liquid, Clinell Wipes
- Sani-Cloth Prime
- Super Sani Cloth
- Super Sani Cloth Prime Wipes
- Sani Prime Liquid

The Tablet may require cleaning and disinfection as well. For the Tablet provided with the 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.

	<p>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.</p> <p>Contact ImpediMed or an authorized agent for repair.</p>
	<p>Do not attempt to sterilize any component or accessory of the SOZO Device.</p>

## 13.2 SOZO Device 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.

## 13.3 Self-Test

To ensure that the SOZO system is operating correctly, run a self-test from the SOZOapp settings menu. ImpediMed recommends that the self-test be performed at the start of the day on which measurements of the patient will be taken.

## 13.4 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.

## 13.5 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

## 13.6 Technical Support

Website: <https://www.impedimed.com/support/>

Americas Technical Support  
877-247-0111, option 4  
760-585-2125

[tsu@impedimed.com](mailto:tsu@impedimed.com)

Asia Pacific Technical Support  
+61 7 3860 3700, option 2  
[ts@impedimed.com](mailto:ts@impedimed.com)

Europe, Middle East and Africa  
+30 231-111-6753  
[tse@impedimed.com](mailto:tse@impedimed.com)

### 13.7 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 Adaptor
Tablet

# 14 PRODUCT WARRANTY

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## 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.**



# 15REGULATORY STATEMENT

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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.

# 16PRODUCT SPECIFICATIONS

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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.

# 17 SAFETY 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.  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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The SOZO Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Device should assure that it is used in such an environment.			
Immunity test	4 <sup>th</sup> Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential	±1kV Differential	Mains power quality should be that of a typical

	±2kV Common	±2kV Common	commercial or hospital environment.
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Immunity test	4 <sup>th</sup> Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Voltage Dips/Dropout IEC 61000-4-11	<p>&gt;95% Dip for 0.5 Cycle</p> <p>60% Dip for 5 Cycles</p> <p>30% Dip for 25 Cycles</p> <p>&gt;95% Dip for 5----- 0% Ur for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.</p> <p>0% Ur for 1 cycle</p>	<p>&gt;95% Dip for 0.5 Cycle</p> <p>60% Dip for 5 Cycles</p> <p>30% Dip for 25 Cycles</p> <p>&gt;95% Dip for 5----- 0% Ur for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.</p> <p>0% Ur for 1 cycle</p>	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	<p>30A/M</p> <p>50 or 60 Hz</p>	<p>30A/M</p> <p>50/60 Hz</p>	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE Ur is the AC mains voltage prior to application of the test level.			

## Guidance and Manufacturer's Declaration – Immunity

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

Immunity test	4 <sup>th</sup> Edition Test Levels	Compliance level	Electromagnetic environment – guidance
<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 amature 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 «Model» by no less than the distances calculated/listed below:</p> <p><math>D=(3.5/V1)(\text{Sqrt } P)</math>  <math>D=(12/V2)(\text{Sqrt } P)</math></p> <p><math>D=(12/E1)(\text{Sqrt } P)</math>  80 to 800 MHz</p> <p><math>D=(23/E1)(\text{Sqrt } P)</math>  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 $\pm 5$ kHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
870						
930						
1 720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1 845						
1 970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID	Pulse Modulation 217 Hz	2	0.3	28

		2450, LTE Band 7				
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 $D=(3.5/\sqrt{P})(\sqrt{P})$	Separation (m) 150kHz to 80MHz ISM $D=(12/\sqrt{P})(\sqrt{P})$	Separation (m) 80 to 800MHz $D=(12/\sqrt{P})(\sqrt{P})$	Separation (m) 800MHz to 2.7GHz $D=(23/\sqrt{P})(\sqrt{P})$
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

# 18 GLOSSARY

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**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.

**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.

**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.

**At-risk limb**-The limb at risk of developing lymphedema.

**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.

**Bioimpedance**-The measure of impedance of the human body to an alternating electric current.

**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.

**BIS**-Bioimpedance Spectroscopy.

**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.

**BodyComp Assessment**-The Assessment, also referred to as "Fluid and 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), Extracellular Fluid (ECF), Intracellular Fluid (ICF), 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 are in the Body Composition User Guide.

**Clinic**-A customer of ImpediMed, such as a hospital or medical clinic, which uses the SOZO system.

**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.



**Cole plots** - The SOZO measurement data is displayed in the form of a complex impedance plot, commonly called a Cole plot. The X axis is the resistance value, and the Y axis is the reactance value of the measurement at each of the 256 frequencies measured. Cole plots are reviewed when determining whether to accept or reject measurements. The SOZO software helps determine the quality of measurements as high, medium, or low quality.

**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.

**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.

**Dominant limb**-The limb which the patient uses the most. For example, for a right-handed patient, the right arm is the dominant limb.

**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).

**Electrode Plates**-See "Electrodes."

**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.

**Fluid and Tissue Analysis User Guide** – LBL-525-3, the Fluid and Tissue Analysis Assessment Instruction for Use.

**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).

**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).

**Hex Key**-A tool which comes with the SOZO system for assembling the SOZOsupport Stand.

**HF-Dex™** - Heart Failure Index, a numeric value used in HF

**HF-Dex™ Assessment**– also referred to as 'HF-Dex'. 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, as well as other fluid analysis outputs. The HF-Dex score is the patient's ECF/TBW %, compared to clinical data in the following manner.

**HF-Dex™ User Guide** - LBL-525-2, the HF-Dex Assessment Instructions for Use.

**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.

**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).

**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.

**Impedance**-The measure of the total opposition of a circuit or part of a circuit to an electrical current.

**L-Dex®**-The Lymphedema Index, a numeric value used in L-Dex Assessment

**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.

**L-Dex® score**-The measurement parameter for the L-Dex Assessment.

**L-Dex® User Guide**- LBL-525-1, the L-Dex Assessment Instructions for Use.

**Licensed Assessments**-Assessments for which a Clinic has purchased a license.

**Measurements**-Measurement data taken by the Clinician of the patient using the SOZO Device. Measurements are the inputs in the SOZO assessment process.

**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.com via the internet.

**Parameter**-A clinically meaningful output based upon measurements.

**Product**-The SOZO Device, including all hardware components of the SOZO Device, except for any hardware component which is a “Consumable.”

**Patient**-The individual who is being measured with the SOZO Device.

**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°).

**R**-Resistance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).

**Rinf**-Rinfinity. Rinf is the impedance determined at an infinite frequency.

**R0**-The impedance determined at a frequency of 0 kHz.

**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).

**SOZOapp**-The app pre-installed on the Tablet which provides the User with access to the SOZO system.

**SOZOconnect Cable**-The hardware component of the SOZO Device used to connect the SOZOtouch with the SOZOstep.

**SOZOcradle**-The hardware component of the SOZO Device which holds the Tablet in place.

**SOZO Device**-The commercially available medical device manufactured by ImpediMed, which uses Bioimpedance Spectroscopy to perform different types of Assessments of patient fluid levels.

**SOZOsupport Stand**-The hardware component of the SOZO Device upon which the patient stands for the taking of SOZO measurements.

**SOZOstep**-A hardware component of the SOZO Device upon which the patient stands (places their feet) for connection to the SOZO Device.

**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.

**SOZOtouch**-A hardware component of the SOZO Device upon which the patient places their hands for connection to the SOZO Device.

**Tablet**- Samsung Tablet or Apple iPad, provided to the ImpediMed customer as part of the SOZO system.

**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).

**Unilateral**-A type of L-Dex Assessment for a patient with one arm or one leg at risk for lymphedema.

**User Device**-A device, including a PC, laptop or mobile device, used by the user to access MySOZO.

**Xc**-Reactance, used by the SOZO Device to perform measurements, calculated from current, voltage and phase angle (Phi).

**Z**-Impedance, which is the measure of the total opposition to an electric current. See and compare with bioimpedance.