



**SOZO® System
Instructions for Use**



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For EU Customers: All products at the end of their life may be returned to
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For patent(s) and/or patent application(s) see: <https://www.impedimed.com/patents/>

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1 SYSTEM OVERVIEW

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 Device is a medical device which uses ImpediMed's patented Bioimpedance Spectroscopy (BIS) for fast non-invasive measurement of fluid levels in human patients. ImpediMed's BIS technology provides a user-friendly platform to take quick, accurate patient measurements for assessment of patient body water volume, including extracellular fluid, intracellular fluid, and total body water.

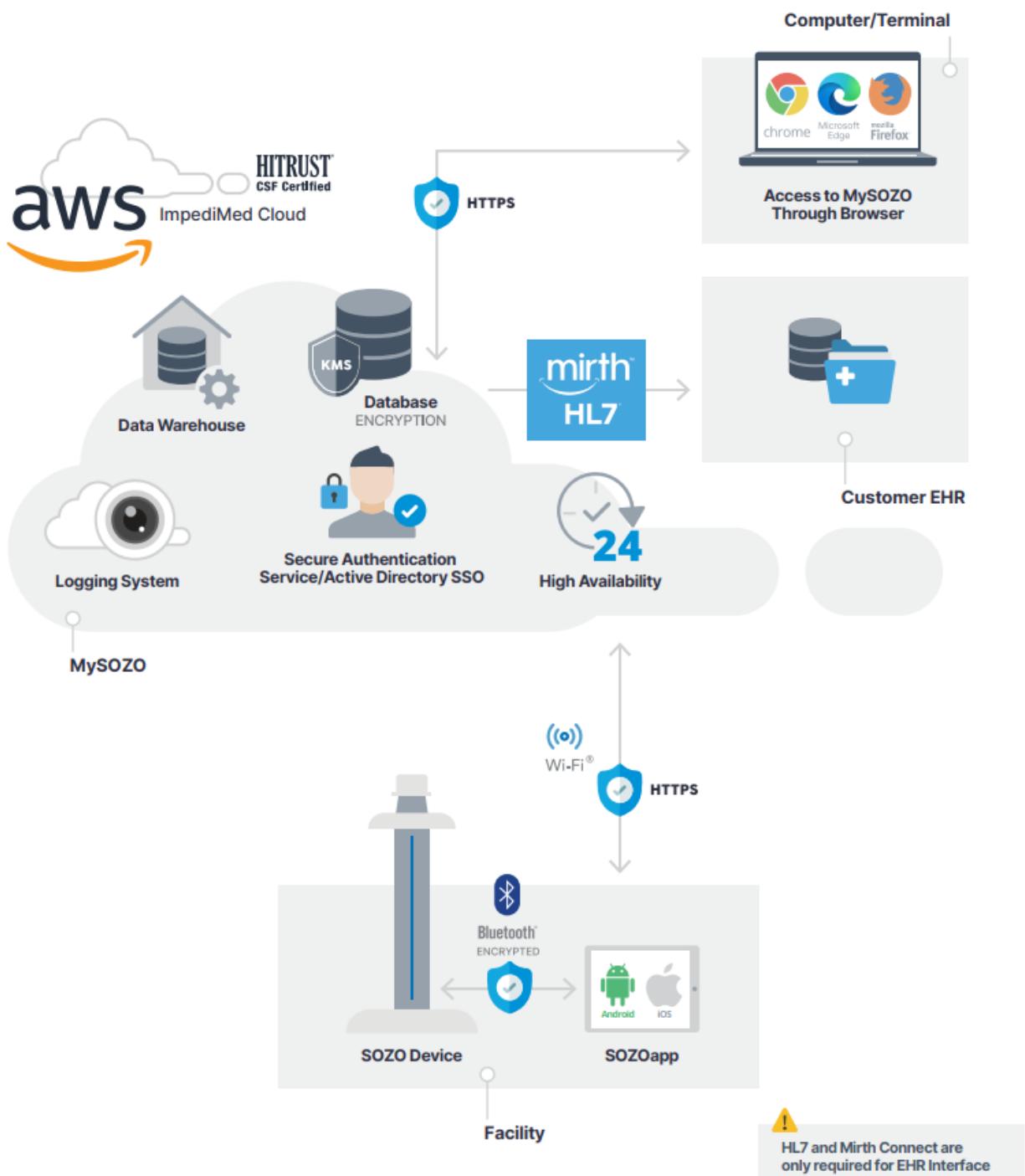
The SOZO System may assist with early detection of lymphoedema by giving an "early warning" of patient fluid status change. It may also be used to track fluid levels in patients living with heart failure or end stage kidney disease. The SOZO system may be an integral part of a treatment plan for a lymphoedema and heart failure patient. Using the SOZO system, a Clinician may also 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).

The Next Primary Vital Sign®: a SOZO scan is fast and may be performed by any member of the team. Results are available immediately on the device and online – and may be transferred automatically to your EHR.

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®¹* technology.

The SOZO system software is made up of the SOZOapp and MySOZO. The SOZOapp is a software application on the Tablet and provides the main user interface for the SOZO system.

The SOZO Device and SOZOapp are used in conjunction with MySOZO, a cloud-based system. 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,

www.lenovo.com or 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 Licences

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

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

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	Minimum: >15 Mbps download, 5 Mbps upload Recommended: >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.
	<p>A note refers to important information to which the user should pay special attention.</p> <p>Notes provide added insight and helpful information which can be useful to the operator.</p>
	For EU Customers. All products at the end of their life may be returned to ImpediMed for recycling.
	<p>This device is rated BF as per IEC60601-1.</p> <p>This device meets the standard IEC60601-1-2.</p>
	This is a Class 2 medical device.
IP21	Protected from touch by fingers and objects greater than 12 millimetres. 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

The SOZO Device should not be used by:



Patients with cardiac arrhythmias who have permanent pacemakers (PPM) or ICDs, or

Patients with any other active implanted electronic equipment (e.g., infusion pumps, neurostimulators, brain stimulators, etc.) or Patients undergoing external defibrillation.

2.4 Warnings

Pregnant patients:



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

2.5 Precautions

	Ensure that you have read and understand these entire instructions for use document before using the SOZO Device. No other specific skill or training is required to take measurements using the SOZO Device.
	Do not allow the SOZO Device to 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.
	Devices or other sources can potentially cause interference problems: <ul style="list-style-type: none">• Example 1: Heat from a radiant heater.• Example 2: Moisture from a nebuliser.• Example 3: Devices generating large electromagnetic fields such as MRI or DXA.
	Keep away from small children or animals. Strangulation due to cables may occur and small parts may be inhaled or swallowed.
	Avoid using on subjects with metal allergies. Allergic reactions may be caused by the stainless steel used in the electrodes of the SOZO Device.
	Avoid using accessories, detachable parts and materials not described in the instructions for use, interconnecting the SOZO Device with other equipment not described in the instructions for use, or modifying the SOZO Device in any way.
	The use of accessories, transducers, and cables other than those specified may result in increased Emissions or decreased Immunity of the SOZO Device

	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 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.
	SOZO impedance measurements require contact with all four (two hand and two foot) electrodes, therefore patients with partial or full limb amputation cannot have their impedance values measured with SOZO.

2.5.1 Storage Conditions and Use

2.5.1.1 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.

2.5.1.2 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.

2.5.2 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 MySOZO

3.1 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 licences and create the first Clinic Administrator.
- Once the initial Clinic Administrator has been created by ImpediMed, additional Administrators and Clinicians may be added by the Clinic Administrators. All users, whether they are Administrators or Clinicians, are identified by their email address.

3.2 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.

3.2.1 First Time Set-Up

1. New user Email

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

2. Set New Password

- 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 new password and confirmation of the new password. To view the password, click the eye icon.
- Ensure the new password meets all 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

- 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.

The temporary password expires in 24 hours.

1

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.

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.

2a**SOZO® Digital Health Platform**

Sign In

Email

Password

(eye icon)

[Forgot password?](#)

Language
 English (US) ▼

Sign In

[Secure sign in with SSO](#) →

impediMed®**2b****SOZO® Digital Health Platform****Sign In****Email**

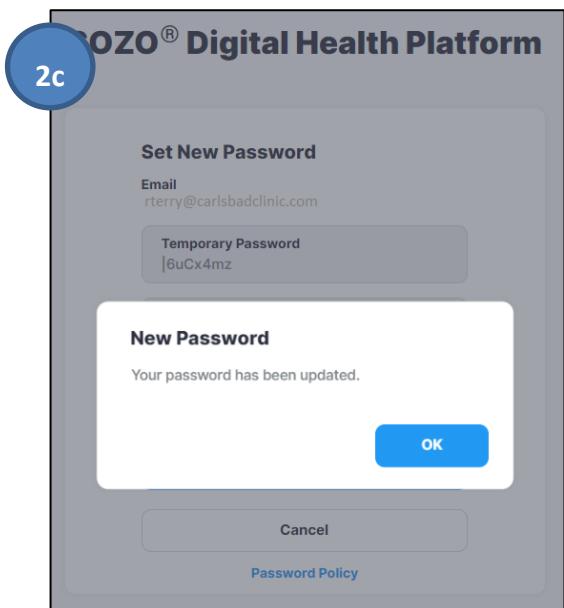
Enter email

Password

[Forgot password?](#)**Error**

Please enter both an email address and password.

OK**impediMed®**



3.2.2 Password Reset

1. If the user is experiencing trouble signing in or has 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 the new password meets all letter and character requirements.
 - b. To set and confirm the 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 →

2

SOZO® Digital Health Platform

Reset Password

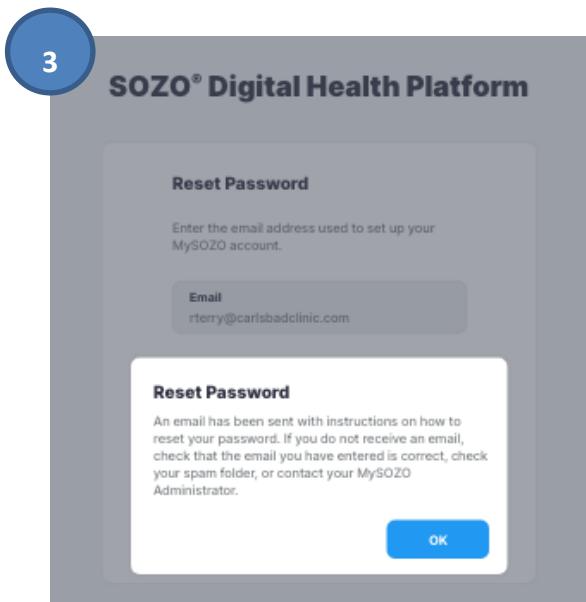
Enter the email address used to set up your MySOZO account.

Email
Enter email

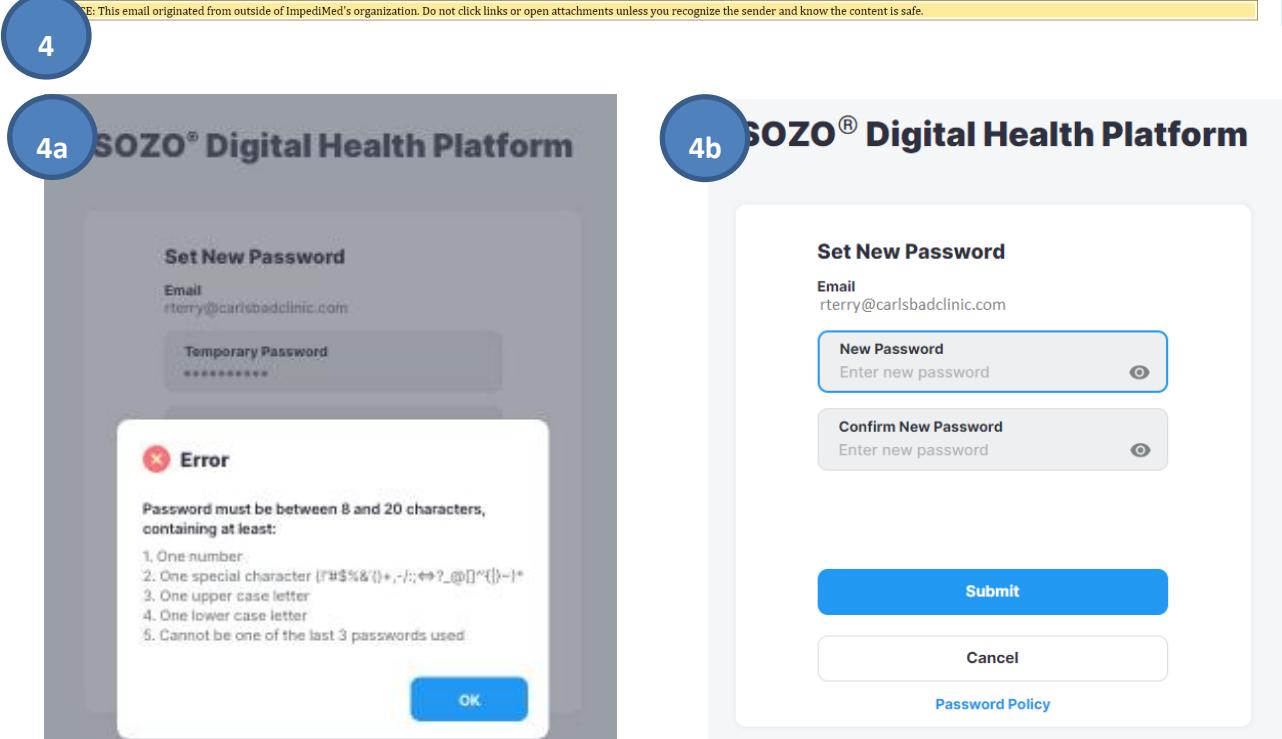
Forgot email used for your MySOZO account?
Please contact your MySOZO administrator.

Submit

Cancel

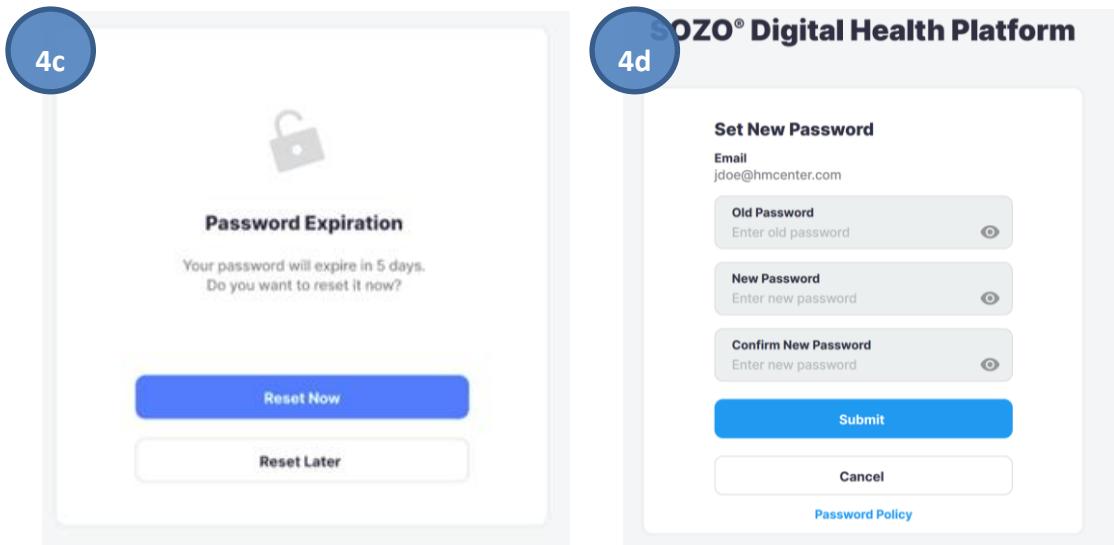


The image shows the ImpediMed logo on the left and the SOZO Digital Health Platform header on the right, both set against a dark blue background.



3.2.3 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**.



4 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.

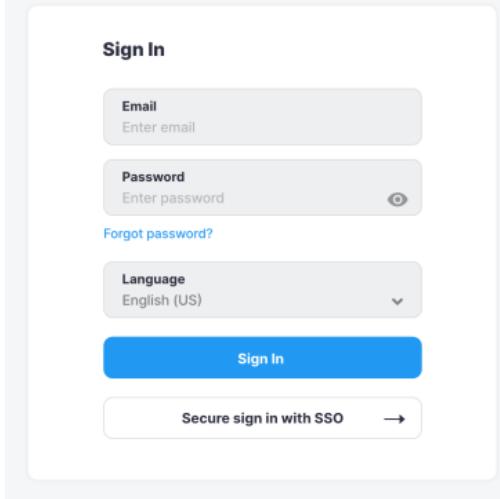
A user with a Clinician role has authority to do the following:

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

4.1 MYSOZO Quick Start Guide

- Utilize the Google Chrome, Chromium-Based Microsoft Edge, or the Mozilla Firefox web browsers to log in to www.mysozo.com.
- Enter a user email address and password

SOZO® Digital Health Platform



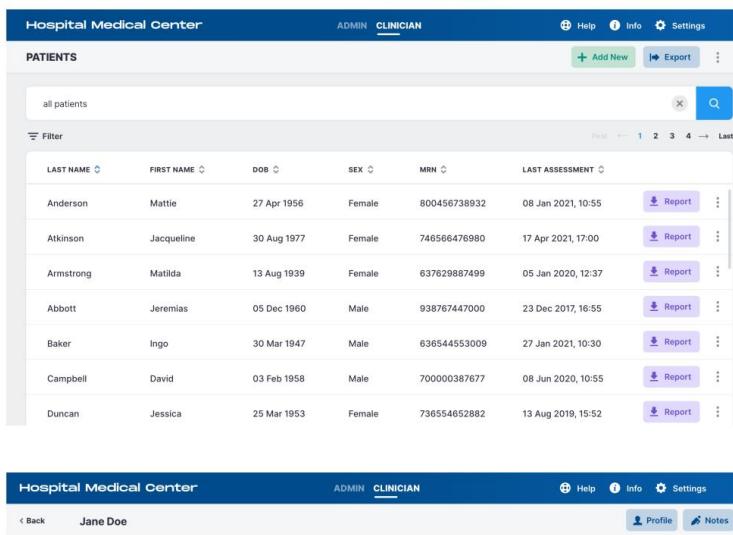
The image shows the 'Sign In' page of the SOZO Digital Health Platform. It features a light gray background with a central white sign-in box. The box has a title 'Sign In' at the top. It contains three input fields: 'Email' (placeholder 'Enter email'), 'Password' (placeholder 'Enter password' with an eye icon for visibility), and 'Language' (dropdown menu set to 'English (US)'). Below these are a blue 'Sign In' button and a 'Secure sign in with SSO' button with a right-pointing arrow. At the bottom left of the sign-in box is a 'Forgot password?' link.

Sign In

1. Using Chrome or Firefox or Edge Chromium sign into mysozo.com

Username is your email address created by your MySOZO Administrator.

- The SOZO patient list includes specific patients that can be searched by name.



The image displays two screenshots of the SOZO patient management interface. The top screenshot shows the 'PATIENTS' list page with a table of patient data. The table columns are: LAST NAME, FIRST NAME, DOB, SEX, MRN, and LAST ASSESSMENT. Each row includes a 'Report' button and a 'More' (three-dot) menu. The bottom screenshot shows a detailed view for a patient named 'Jane Doe', with tabs for 'Profile' and 'Notes'.

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT
Anderson	Matte	27 Apr 1956	Female	800456738932	08 Jan 2021, 10:55
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2021, 17:00
Armstrong	Matilda	13 Aug 1939	Female	637629887499	05 Jan 2020, 12:37
Abbott	Jeremias	05 Dec 1960	Male	938767447000	23 Dec 2017, 16:55
Baker	Ingo	30 Mar 1947	Male	636544553009	27 Jan 2021, 10:30
Campbell	David	03 Feb 1958	Male	700000387677	08 Jun 2020, 10:55
Duncan	Jessica	25 Mar 1953	Female	736554652882	13 Aug 2019, 15:52

Patient List

1. Provides access to a list of patients in your MySOZO database
2. Allows searching by Last/First name, DOB, sex, MRN and Last assessment date
3. Allows a clinician to create a patient report
4. Provides access to individual patient data, by selecting a patient in the patient list

- The Patient Dashboard includes patient details (e.g., patient name, DOB, sex, etc.) and the option to view results and make edits to the dashboard.

The screenshot shows the Patient Dashboard for a patient named Jane Doe. The dashboard lists various measurements taken over time, each with a date, a measurement type, and one or more tags. The measurements include:

- 16 Mar 2021 17:05: MEDICATION CHANGE, PHYSICAL THERAPY
- 13 Mar 2021, 13:56: RADIATION
- 7 Feb 2021, 17:27: CHEMOTHERAPY, MEDICATION CHANGE, SURGERY
- 23 Dec 2020, 17:45: (no tags)
- 22 Nov 2020, 17:00: PHYSICAL THERAPY
- 20 Oct 2020, 10:51: CHEMOTHERAPY, MEDICATION CHANGE
- 09 Aug 2020, 13:56: (no tags)

Patient Dashboard

1. Displays a list of all measurements taken for the patient along with information about the measurement such as baselines and tags
2. Provides access to patient profile
3. Allows access to view, create, or edit notes associated with the patient

- The SOZO patient profile includes specific patient information and demographics.

The screenshot shows the Patient Profile page for the same patient, Jane Doe. The profile includes the following demographic information:

- First Name: Jane
- Middle Name: (Optional)
- Last Name: Doe
- Email: jdoe@hospital.com
- MRN: 000000000001
- Date of Birth: 1 Apr 1966
- Country Code: (Optional)
- Phone Number: (Optional)
- Address: (Optional)
- City: (Optional)
- State: (Optional)
- Country: (Optional)

Profile

Patient profile will give access to:

1. Demographics
2. Assessment types available
3. Patient groups

- Notes allows a clinician to provide patient specific information related to in visit observations. Patient profiles can include up to 10 notes each.

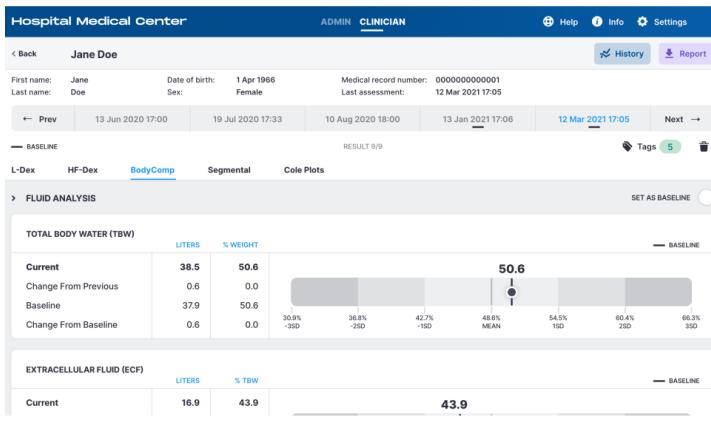
The screenshot shows the Notes page for the patient. It displays a list of notes with their titles and content:

- # NOTES 3/10
- Notes**
- Add New Note**
- Add Title**
- Add Note**
- MAR 5, 2021 at 12:52 AM**
- MS impact to L-Dex Baseline**
- This patient has noticeable atrophy in her left arm due to MS, this is why her L-Dex baseline was >15. It is not due to increased fluid levels in her right (at-risk) arm, rather it is due to depleted levels of fluid in her left (control) arm.
- Angeline Harrods**
- FEB 23, 2021 at 10:27 AM**
- Measurement Instructions**
- This patient must be measured in the seated position each time due to instability.

Notes

1. Provides access to a list of notes assigned to the selected patient
2. Ability to create new note
3. Ability to edit or delete an existing note

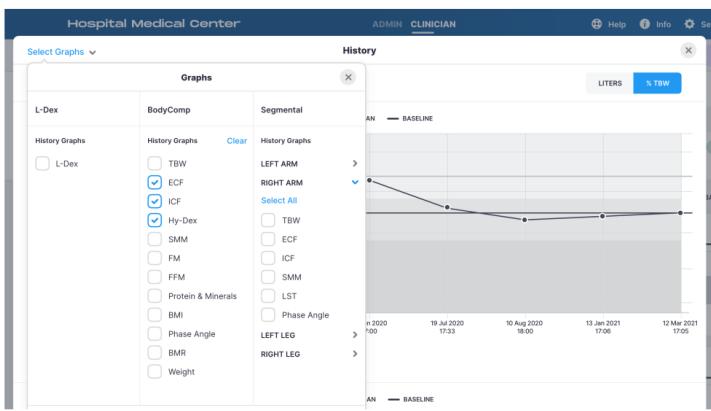
- Results displays a catalog of previous impedance measurements, each of which can be selected individually by a clinician for evaluation.



Results

1. Provides access to measurement outputs
2. Provides access to historical data
3. Ability to set baseline to customize trending results
4. Ability to assign measurement tags
5. Ability to create report

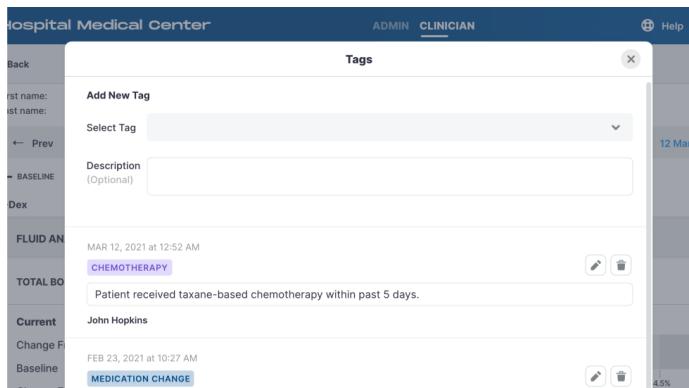
- History tracks previous measurements and other data for patient profiles.



History

1. Displays graphs of patient measurements overtime
2. Ability to select history graphs to view

- Tags allows for patients to be assigned tags that define specific measurements.



Tags

1. Provides access to a list of tags assigned to the selected measurement
2. Ability to assign new tag
3. Ability to edit or delete an existing tag

- Groups allows patients to be aggregated into defined applicable groups.

Groups

- Provides access to a list of groups created by your MySOZO Administrator
- Ability to add or remove a patient from a group

- Merge Patients allows multiple patients profiles to be merged into a single profile.

Merge Patients

- Allows patient data to be merged under one single patient profile

- Restore Patient allows deleted patient profiles to be resurrected.

Restore Patient

- Provides access to a list of deleted patients
- Ability to activate a deleted patient

- Other menu items include “Help”, “Info”, “Settings”, and “My Account” which allow clinicians to access features and other helpful account settings.

SEX	MRN	LAST ASSESSMENT	
Female	800456738932	08 Jan 2021, 10:55	Report
Female	746566476980	17 Apr 2021, 17:00	Report
Female	637629887499	05 Jan 2020, 12:37	Report
Male	938767447000	23 Dec 2017, 16:55	Report

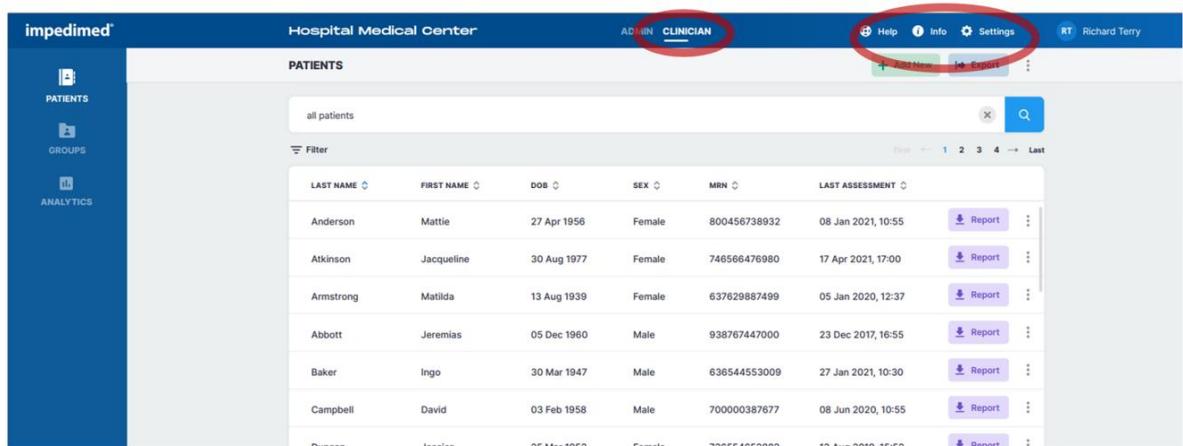
General Menu Items

1. Help
2. Info
3. Settings
4. My Account

4.2 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**.



Last Name	First Name	DOB	Sex	MRN	Last Assessment
Anderson	Mattie	27 Apr 1956	Female	800456738932	08 Jan 2021, 10:55
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2021, 17:00
Armstrong	Matilda	13 Aug 1939	Female	637629887499	05 Jan 2020, 12:37
Abbott	Jeremias	05 Dec 1960	Male	938767447000	23 Dec 2017, 16:55
Baker	Ingo	30 Mar 1947	Male	636544553009	27 Jan 2021, 10:30
Campbell	David	03 Feb 1958	Male	700000387677	08 Jun 2020, 10:55
Durran	Iacenia	25 Mar 1942	Female	734444444444	12 Jun 2019, 10:49

The banner icons enable common administrative functions.

4.2.1 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.

The screenshot shows a table of clinician data on the left and contact information on the right. The table columns are MRN and LAST ASSESSMENT. The contact information includes email and phone numbers for Technical Support, Americas, Asia Pacific, and Europe, Middle East, Africa. It also provides links for instructions for use and support documentation.

MRN	LAST ASSESSMENT
800456738932	08 Jan 2019, 10:55
746566476980	17 Apr 2019, 17:00
637629887499	05 Jan 2020, 12:37
938767447000	23 Dec 2017, 16:55
636544553009	27 Jan 2019, 10:30
700000387677	08 Jun 2020, 10:55
736554652882	13 Aug 2019, 15:52

Technical Support
Americas
✉ tsu@impedimed.com
📞 USA/Canada (toll free): +1 877-247-0111 option 4
US: +1 760-585-2125
Asia Pacific
✉ ts@impedimed.com
📞 +61 7 3860 3700 option 2
Europe, Middle East, Africa
✉ tse@impedimed.com
📞 +30 231-111-6753
For Instructions for Use, please visit:
<https://www.impedimed.com/support/ifu-documents/>
For support and additional documentation, please visit:
<https://www.impedimed.com/support>

4.2.2 Info Icon

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

The screenshot shows the Information page with sections for Licensing Status, Software Information, and Regulatory Information. The Regulatory Information section is expanded, showing the company's address in Australia and France, patent information, and a barcode.

Information

Licensing Status

Software Information

Regulatory Information

ImpediMed Limited
ABN 65 089 705 144
Unit 1, 50 Parker Court, Pinkenba
Qld. 4008, Australia

EC REP
MediMark Europe Sarl 11 rue Emile ZOLA
B.P. 2332, 38033 Grenoble Cedex 2, France

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

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

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

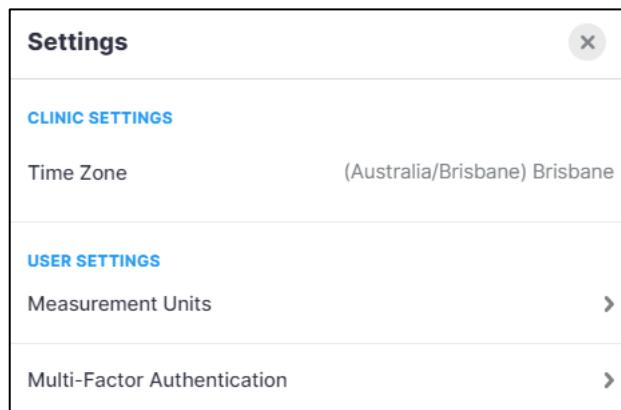
Software Information: Displays current mySOZO version and if it is up to date. Release notes for current and previous versions are listed.

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

4.2.3 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.



4.2.3.1 Time Zone Settings

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

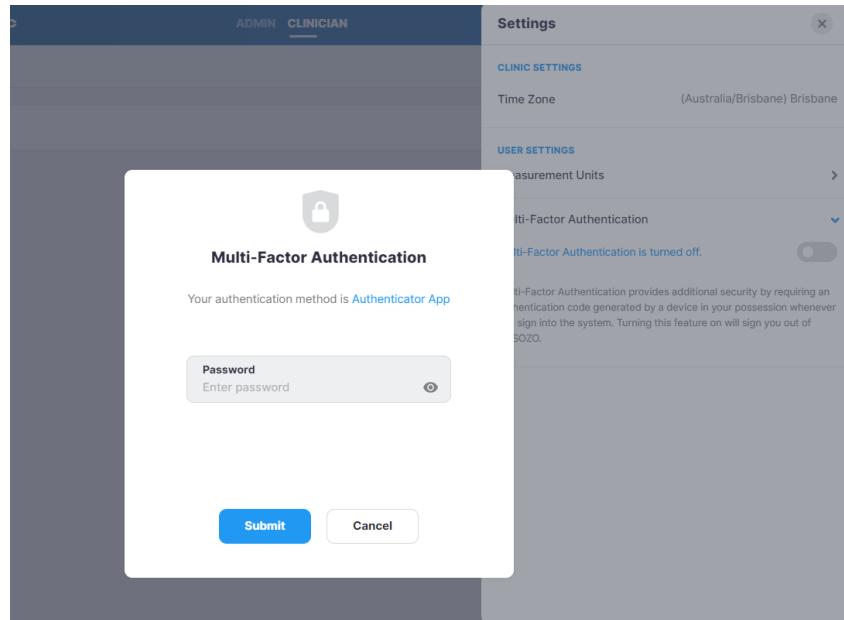
4.2.3.2 Measurement Units

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

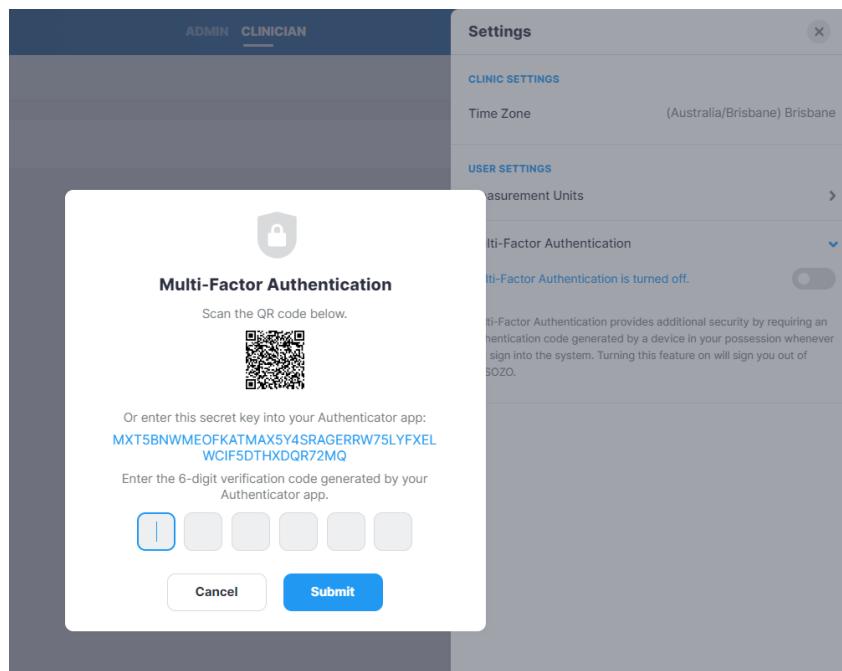
4.2.3.3 Clinician Multi-Factor Authentication

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.

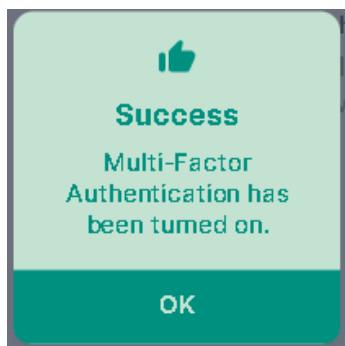
MFA will require use of a code generated by a 3rd party authenticator app (e.g. Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is set up, activate the MFA for the Clinician by using the slider under User Settings, Multi-Factor Authentication.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

4.2.4 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.

4.3 Clinician Patient List

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



4.3.1 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.

4.3.2 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.

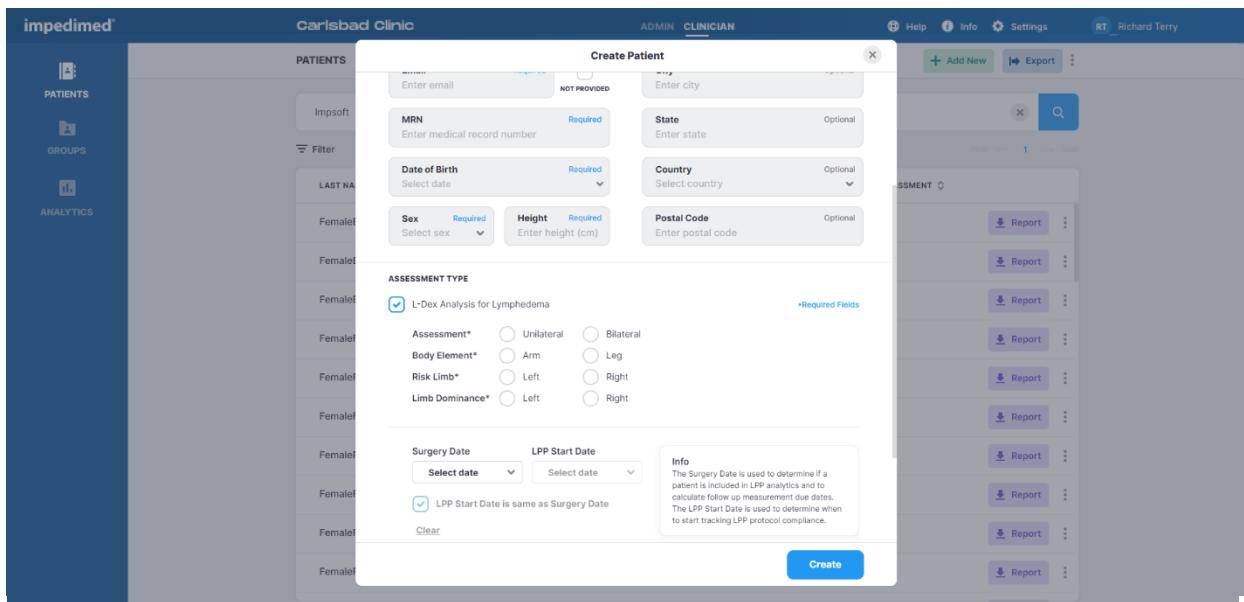
The information is important for the Clinician's role of viewing, recording, and evaluating historical measurements and assessment results. Individual patient reports can also be created from the dashboard.

4.3.3 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, 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 and HF-Dex.

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

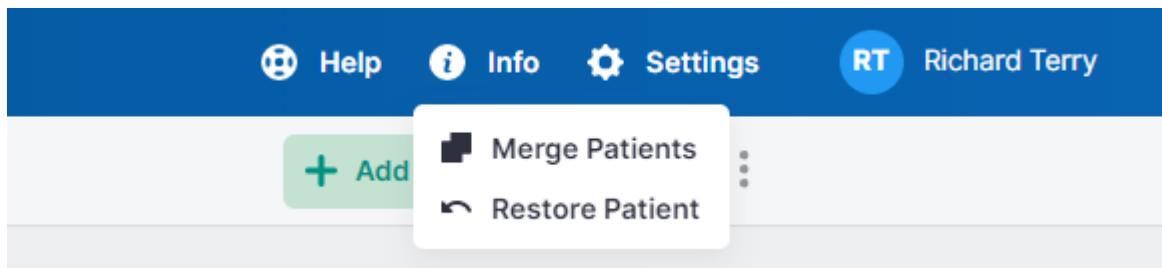
Note: the patient will remain in the MySOZO database and may be restored. To permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.

4.3.5 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 **Patient 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.

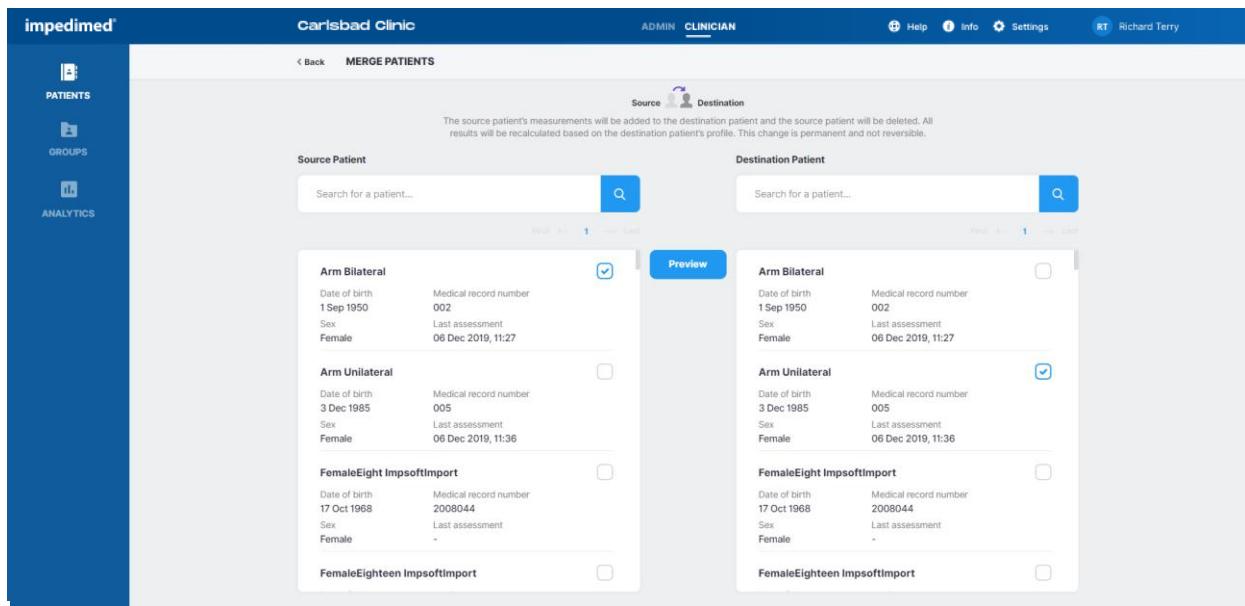


4.3.6 Merge Patient

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.



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.

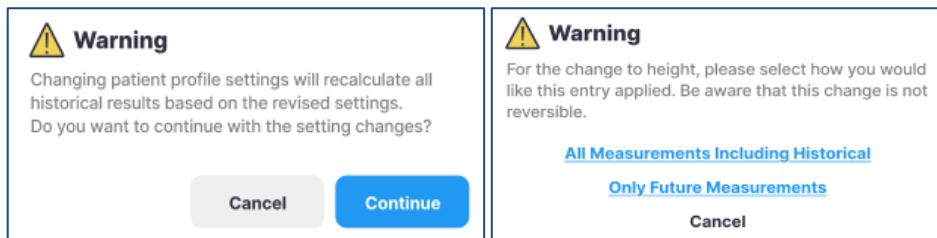
Note: if the merged patients have imported L-Dex data from a non-SOZO ImpediMed device such as the L-Dex U400, the imported measurements will not be shown if the patient L-Dex settings are different. For example, if imported U400 data assessed a patient's leg and the data is merged with a patient whose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

4.3.7 Edit Patient Profile

To edit a patient profile:

1. Navigate to the **Patient List**.
2. Search all patients by clicking magnifier icon, enter the patients' name, or MRN.
3. Click the **search** icon and select the patient.
4. From the measurement history screen, 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 the previous profile. 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.

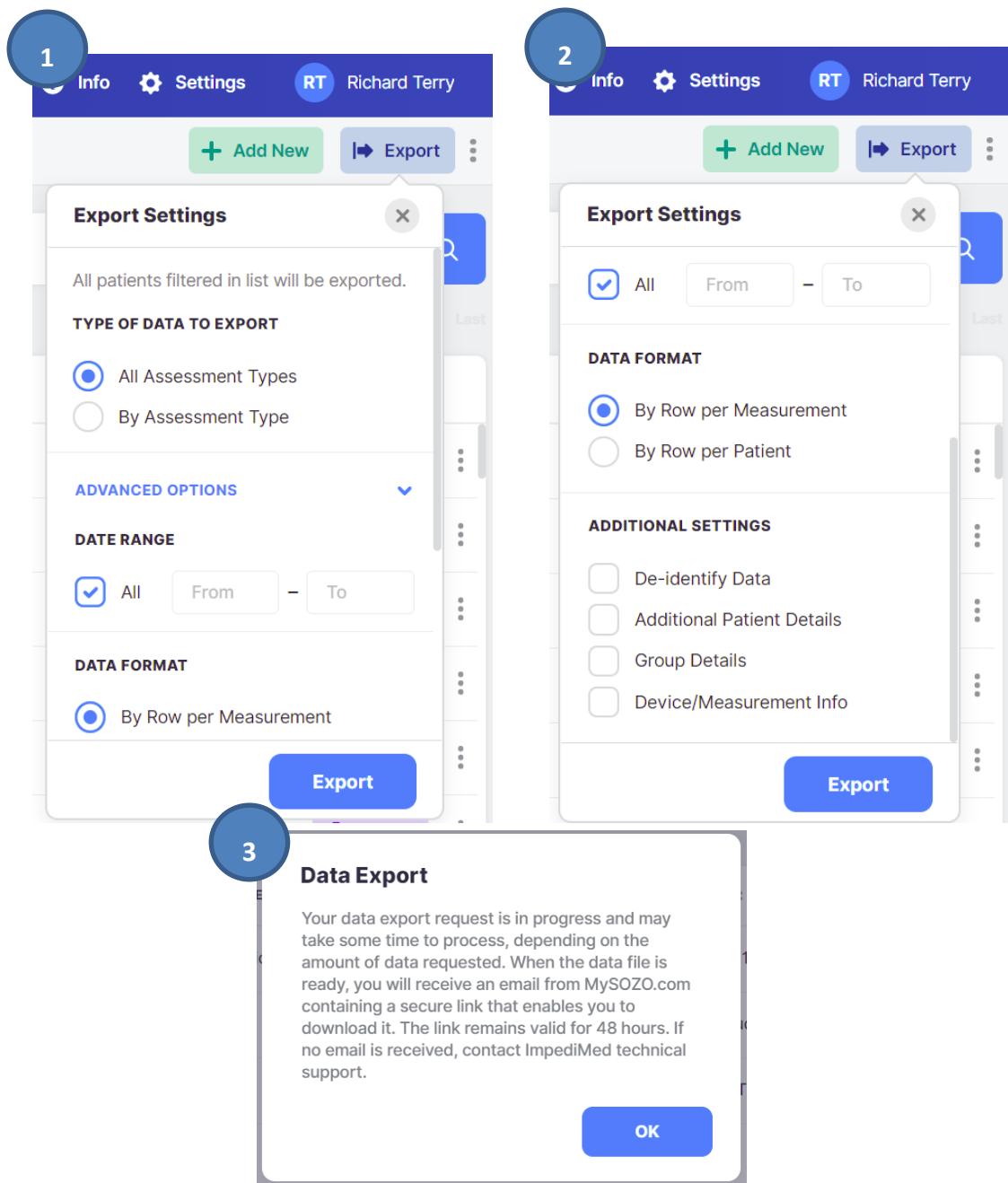
- **Availability of Assessment Specific Data on Patient Profile**

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

4.3.8 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 customise 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.



4.3.9 Report

A Clinician may create a patient report from MySOZO in the form of a PDF.

To create a patient report from the patient dashboard:

1. From the Patients List, **search** for a specific patient or all patients.
2. Click **Report**, located on the far-right side of the patient's information.
3. Select the desired assessments and history charts to be included in the report.
4. Input the **date range**.
5. Click **Create**.
6. The patient report will automatically download in PDF format.

Create Report

<input checked="" type="checkbox"/> L-Dex	<input type="checkbox"/> HF-Dex	<input type="checkbox"/> ESRD	<input checked="" type="checkbox"/> BodyComp	<input type="checkbox"/> Segmental
History Graphs	History Graphs	Select All	History Graphs	Select All
<input checked="" type="checkbox"/> L-Dex	<input type="checkbox"/> HF-Dex	<input type="checkbox"/> ECF/TBW/Weight	<input checked="" type="checkbox"/> TBW	History Graphs
		<input type="checkbox"/> ECF	<input checked="" type="checkbox"/> TBW (%Weight)	LEFT ARM >
		<input type="checkbox"/> ECF (%TBW)	<input type="checkbox"/> ECF	RIGHT ARM >
		<input type="checkbox"/> TBW	<input checked="" type="checkbox"/> ECF (%TBW)	LEFT LEG >
		<input type="checkbox"/> TBW (%Weight)	<input type="checkbox"/> ICF	RIGHT LEG >
		<input type="checkbox"/> ICF	<input type="checkbox"/> ICF (%TBW)	
		<input type="checkbox"/> ICF (%TBW)	<input type="checkbox"/> Hy-Dex	
		<input type="checkbox"/> Weight	<input type="checkbox"/> SMM	
			<input type="checkbox"/> SMM (%Weight)	
			<input type="checkbox"/> FM	
			<input type="checkbox"/> FM (%Weight)	
			<input type="checkbox"/> FFM	
			<input type="checkbox"/> FFM (%Weight)	
			<input type="checkbox"/> Protein & Minerals	
			<input type="checkbox"/> Protein & Minerals...	

DATE RANGE

All From _____ To _____

Create

Note: patient reports may also be made directly from a measurement results screen.

Note: patient reports in PDF format cannot be created from the SOZOapp.

4.4 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**.

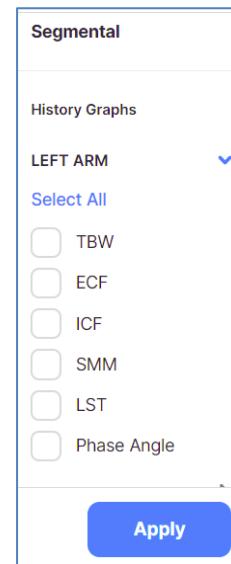
DATE	BASELINE	TAGS
15 Apr 2021, 09:13	2	RED COLE PLOT - SUSP... MEDICATION CHANGE 3 MONTH FOLLOW UP
31 Mar 2021, 12:35		MEDICATION CHANGE
31 Mar 2021, 12:33		3 MONTH FOLLOW UP
22 Mar 2021, 08:13		

The results for one assessment type will initially be displayed, e.g. L-Dex. The Clinician can click on different assessment 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:

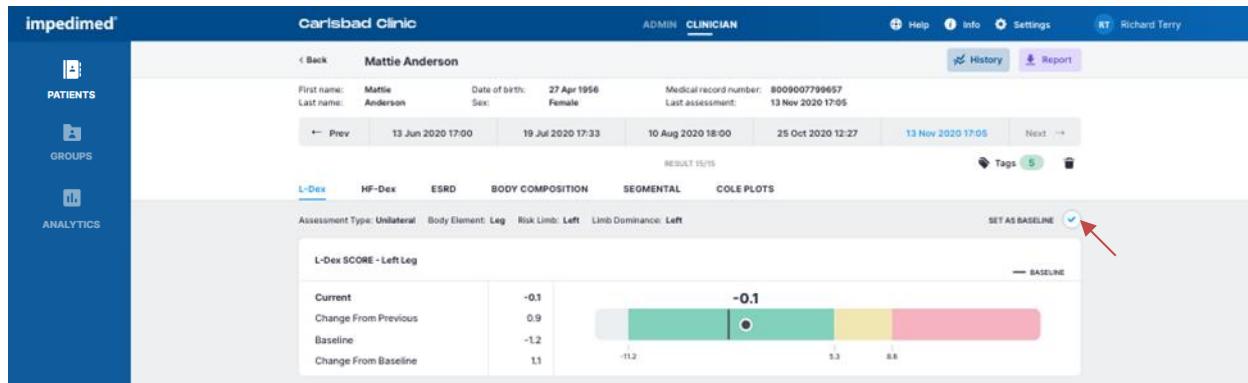


Additionally, many graphs will provide an option to switch between absolute and relative units of measure (litres/pints vs. % TBW)

LITERS % TBW

4.4.1 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”.



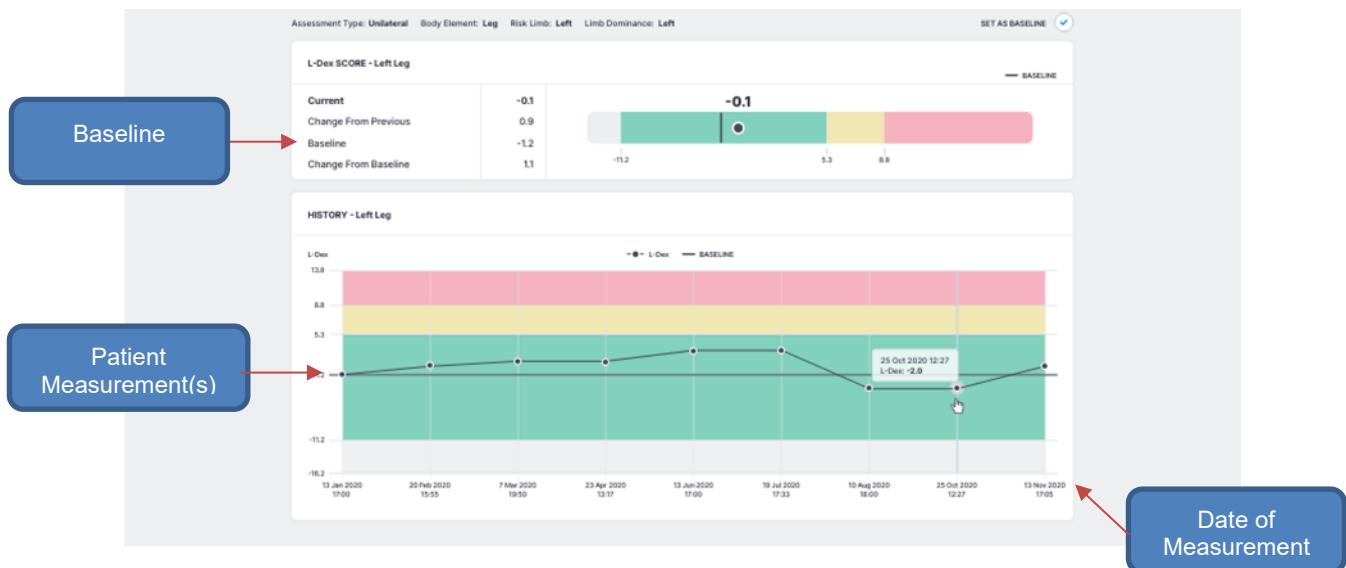
To choose the proper measurement as the baseline, the measurement should be:

- High-quality
- Taken when the patient is in a normal fluid or “euvolemic” 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.

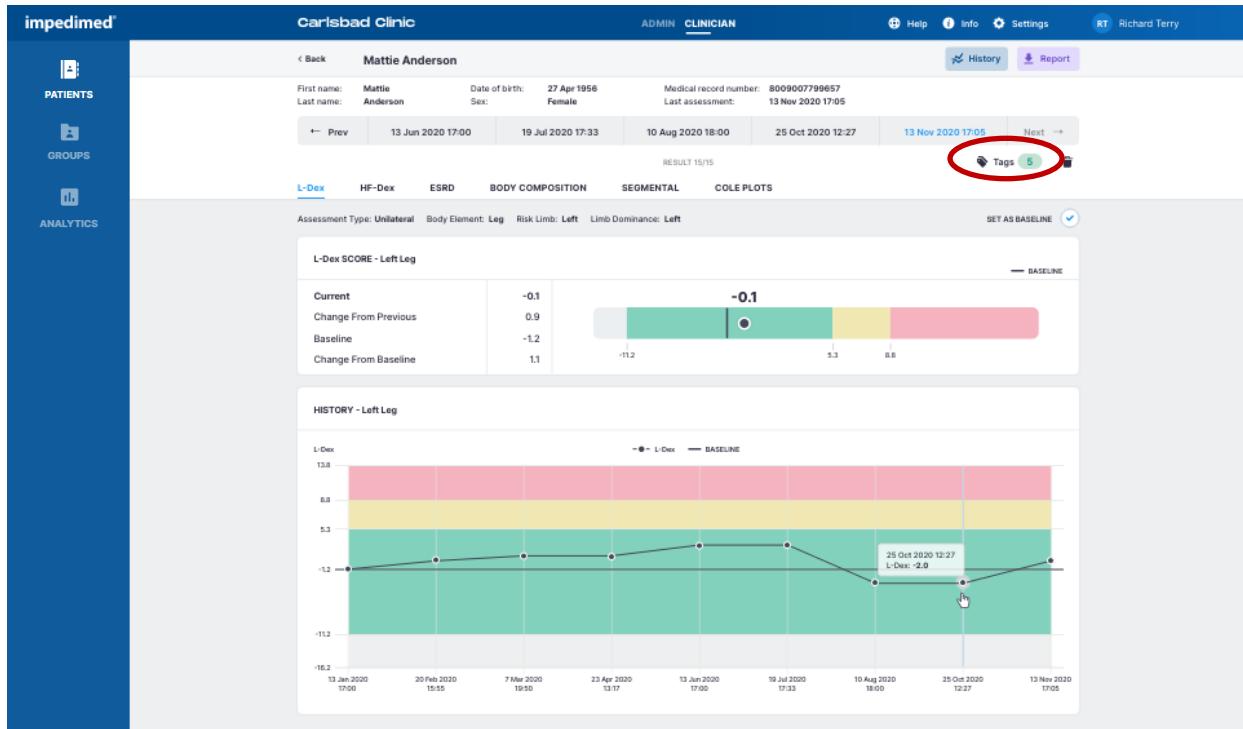
4.4.2 Evaluating Measurements Against a Baseline

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.



4.4.3 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.

4.4.4 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.

4.5 Clinician Patient Groups

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



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 **Group** 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.

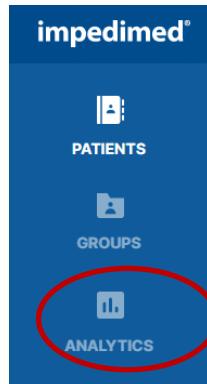
2. Select a group by clicking **View** to bring up the list of patients currently assigned to that group.
3. To **modify patients** within the group, click on **Edit Members** located in the top right corner.
 - a. To add a patient to a group search for the patient's name in the left-hand column and **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 remove patients from the group.

The screenshot shows the 'Heart Failure Patients' group in the ImpediMed software. The top navigation bar includes 'ADMIN' and 'CLINICIAN' tabs, 'Help', 'Info', 'Settings', and a user profile for 'Richard Terry'. The left sidebar has 'PATIENTS', 'GROUPS', and 'ANALYTICS' options. The main content area shows a table of patients with columns for Last Name, First Name, DOB, Sex, MRN, and Last Assessment. Each patient row has a 'Report' button. The 'Edit Members' button in the top right of the main content area is highlighted with a red circle.

The screenshot shows the SOZOapp interface with 'Patients' and 'LPP' sections. The 'Patients' section has a search bar and a table of patients with columns for Date of birth, Medical record number, Sex, and Last assessment. The 'LPP' section has a search bar and a table of patients with similar columns. The 'Edit Members' button is located in the top right corner of the 'Patients' section.

4.6 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 Lymphoedema Assessments and how well the clinic is following the Lymphoedema 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.

4.6.1 Lymphoedema Prevention Program (LPP)

This program utilizes ImpediMed's Test, Trigger, Treat® protocol for early detection and intervention of cancer-related lymphoedema. The LPP is supported by the findings of the PREVENT trial²⁻³ and McDuff et al⁴. 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 lymphoedema with improved patient outcomes compared to those monitored with tape measure. McDuff found that while the risk of lymphoedema is greatest in first 3 years it depends on therapy received with regional lymph node radiation associated with late onset lymphoedema. Therefore, they recommended regular intervals for 5 years post treatment.

² 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.

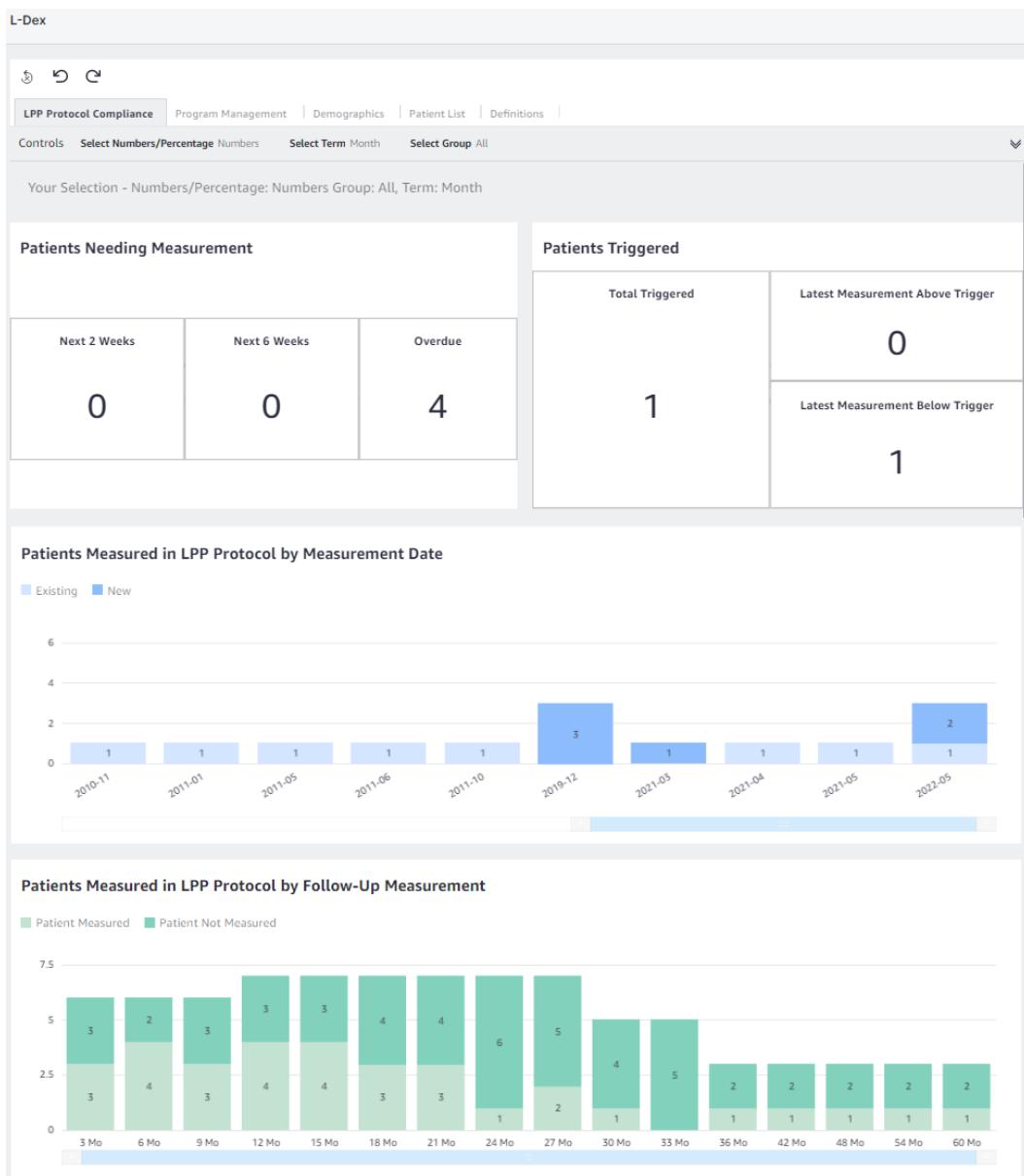
³ Ridner SH, Dietrich MS, Cowher MS, et al. A Randomized Trial Evaluating Bioimpedance Spectroscopy Versus Tape Measurement for the Prevention of Lymphedema Following Treatment for Breast Cancer: Interim Analysis. *Ann Surg Oncol* 2019.

⁴ 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.

4.6.2 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 Lymphoedema Prevention protocol as selected in the patient profile by filling out Surgery Date and LPP Start date in the patient profile.



4.6.2.1 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 surgery/treatment are included in this information.

4.6.2.2 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 surgery/treatment are included in this information.

4.6.2.3 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: all LPP patients are included in this information.

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.

4.6.2.4 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.

Note: all LPP patients are included in this information.

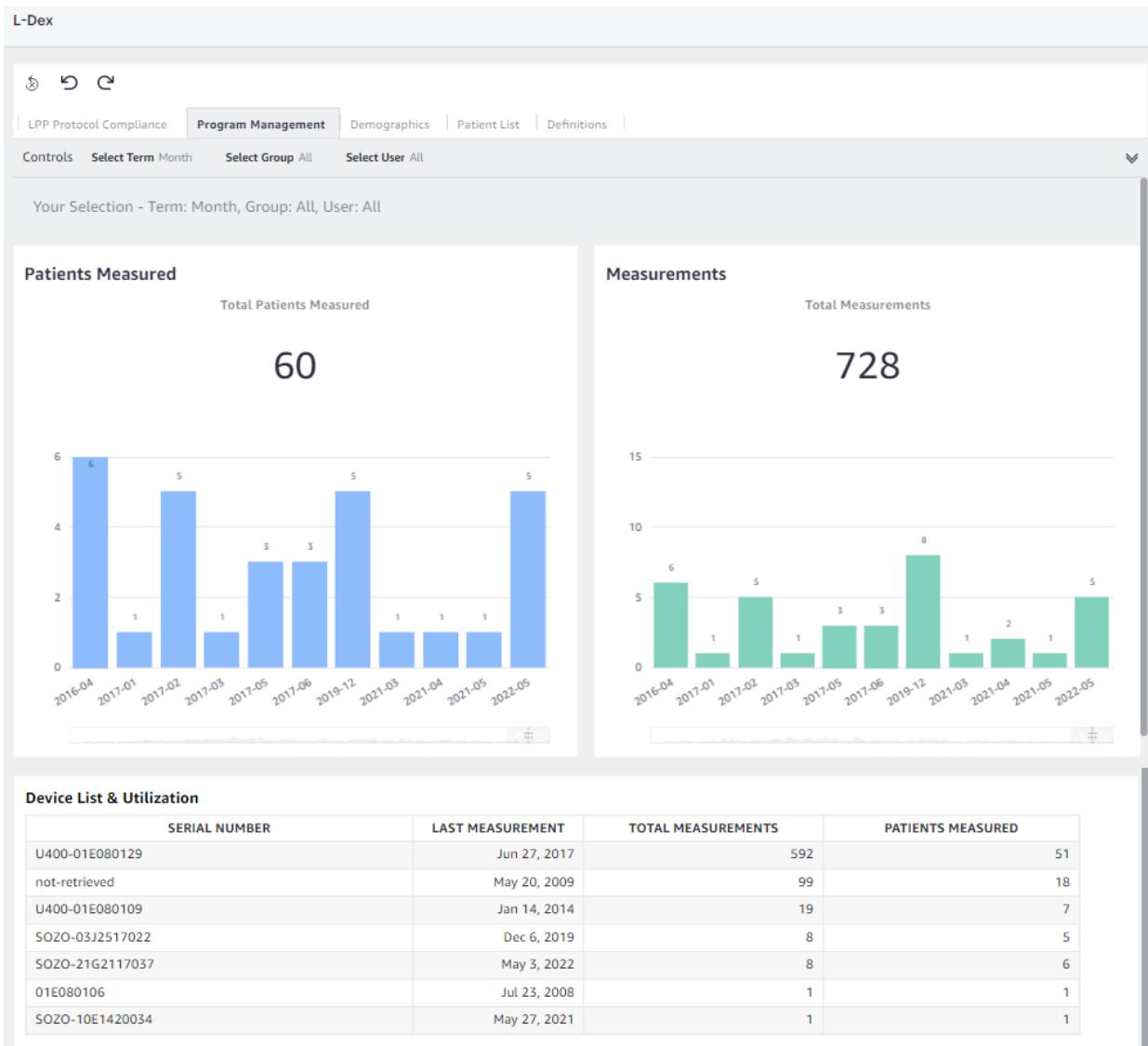
4.6.2.5 Further Definitions

- **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.

4.6.3 Program Management

This dashboard provides insight into the usage of SOZO and the L-Dex Analysis for Lymphoedema Assessment. It provides outputs based on all patients with an L-Dex measurement, regardless of if they have a baseline or surgery date set.



4.6.3.1 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.

4.6.3.2 Measurements

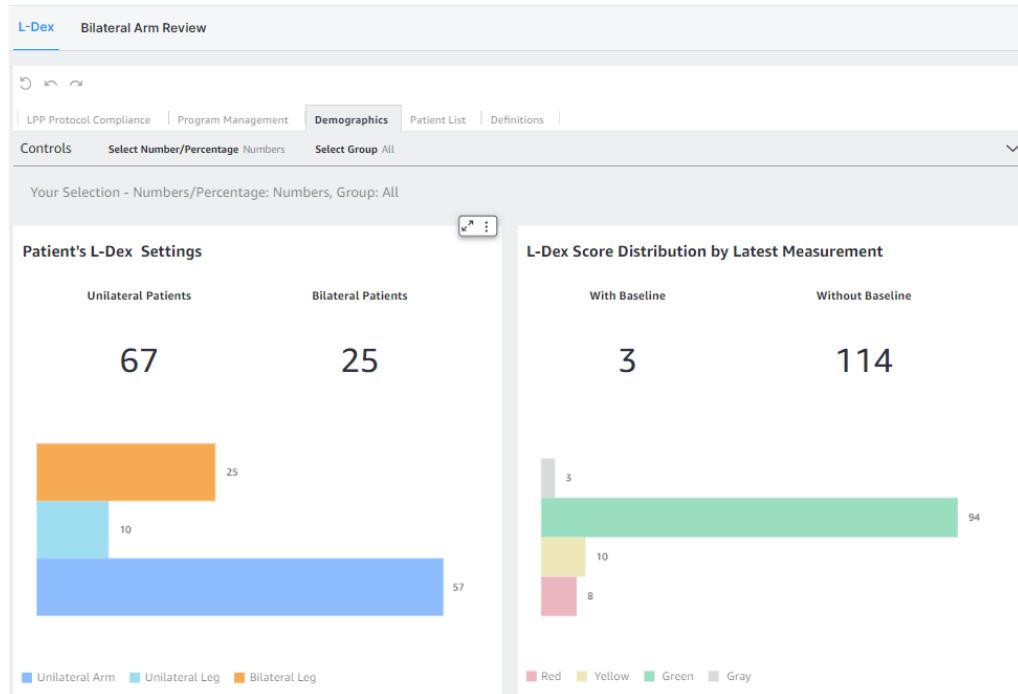
This chart provides the count of measurements taken on L-Dex patients over time, selectable by Quarter, Month, or Year from the Controls menu. The total Measurements is a count of all measurements taken on all L-Dex patients.

4.6.3.3 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.

4.6.4 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.



4.6.4.1 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 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.

4.6.4.2 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 lymphoedema measurements assessed as grey, green, yellow and red is displayed. For definitions of these categories, see 8.3.3 The Lymphoedema Index (L-Dex®).

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

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.

L-Dex Categories without a Baseline

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

L-Dex Categories with a Baseline

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

4.6.5 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.

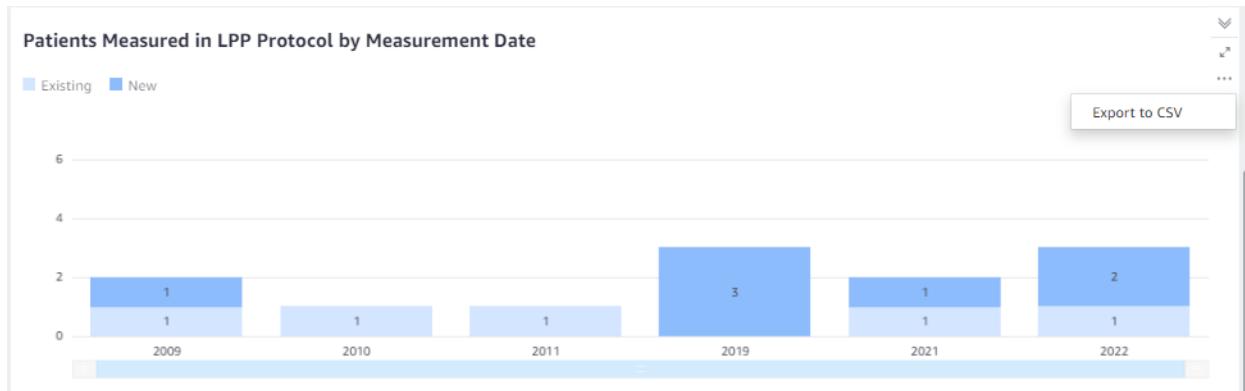
- If filtering has been applied using the Controls menu in the Protocol Compliance, Program Management or Demographics tabs then the list only contains the patient meeting the filtered criteria.
- If the clinician drills down on a graph or table element, the patient list is filtered according to the criteria of the graph.

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
1 Measurement	Example	Jan 17, 1984	Female	001	Apr 21, 2021	Apr 28, 2021
Many Measurements	Test	Jun 28, 1999	Female	002	Jun 11, 2020	Nov 30, 2022

4.6.6 Navigation

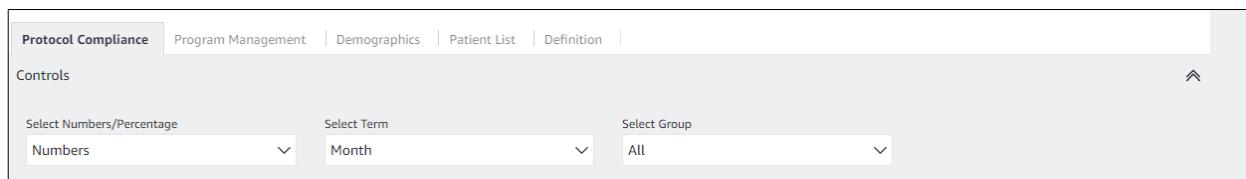
- **Exporting data:** To export the data shown for any individual chart or table on the screen, select the chart or table element. A menu on the upper right side of the chart or table will appear, select the “...” and then **“Export to CSV”**.



- **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.



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

5 MySOZO APP

5.1 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:

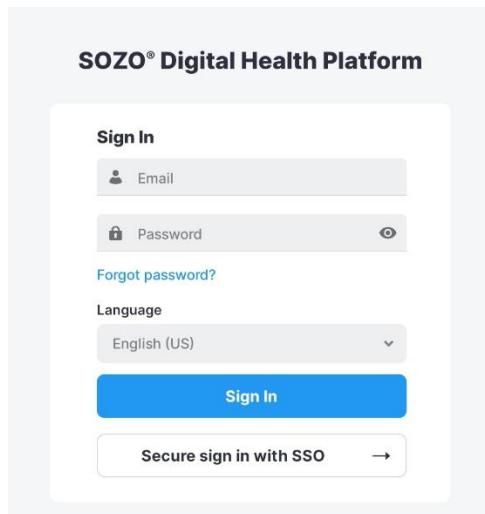
- 1) Management of patient profiles, including adding, editing, or selecting patients from a patient list.
- 2) Selecting and configuring assessments to fit the patient's diagnosis, treatment plan, and individual needs.
- 3) Taking and entering patient measurements for various assessments.
- 4) Considering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

5.1.1 Sign In

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

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](#), (refer [MySOZO Administrator section of this document](#)) As an alternative, Single Sign On (SSO) administrator instructions can also be found in MySOZO Administrator.

Note: If there is a newer version of the SOZOapp, the user will be notified upon signing in.

5.1.2 Reset Password

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 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. To set and confirm new password, click submit.

1 **OZO® Digital Health Platform**

Sign In

Email
Enter email

Password
Enter password

[Forgot password?](#) (This link is circled in red)

Language
English (US)

Sign In

Secure sign in with SSO →

2 **OZO® Digital Health Platform**

Reset Password

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

Email
Enter email

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

Submit

Cancel

3 **OZO® Digital Health Platform**

Reset Password

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

Email
rterry@carisbedclinic.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 MyOZO Administrator.

OK

A request has been made to reset the MySOZO password associated with 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

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.

4a

SOZO® Digital Health Platform

Set New Password

Email
rterry@carlsbadclinic.com

Temporary Password

Error

Password must be between 8 and 20 characters, containing at least:

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

OK

4b

SOZO® Digital Health Platform

Set New Password

Email
rterry@carlsbadclinic.com

New Password

Enter new password

Confirm New Password

Enter new password

Submit

Cancel

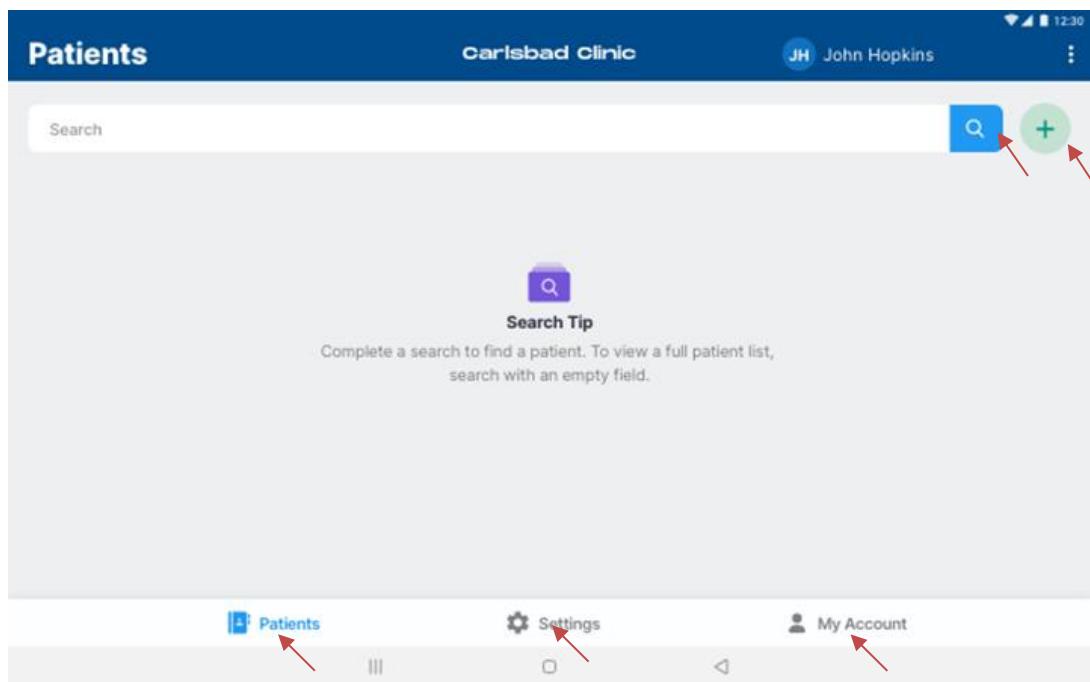
[Password Policy](#)

5.2 SOZOapp Home Screen

Note: only users with a Clinician role may sign in to SOZOapp.

After successful sign in, the SOZOapp home screen appears with an empty “Patient List”. The list will always initially appear to be empty at sign in. This is to help accidental observations of patient information.

Primary navigation in SOZOapp is managed through the three tabs at the bottom of the screen to access Patients list, Settings, and the Clinician account as well as the Search and Add New buttons at the top right.



5.3 SOZOapp Patients List

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

5.3.1 Search for Patient

To search for a patient, enter the name of the patient or MRN 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.

Eusebio Anna
DOB - 27 Apr 1956
MRN - 8005965Y7708892...
FEMALE
LAST ASSESSMENT - 30 Apr 2020, 17:55

Humberto Annamae
DOB - 27 Apr 1956
MRN - 8005965Y7708892...
FEMALE
LAST ASSESSMENT - 30 Apr 2020, 17:55

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.

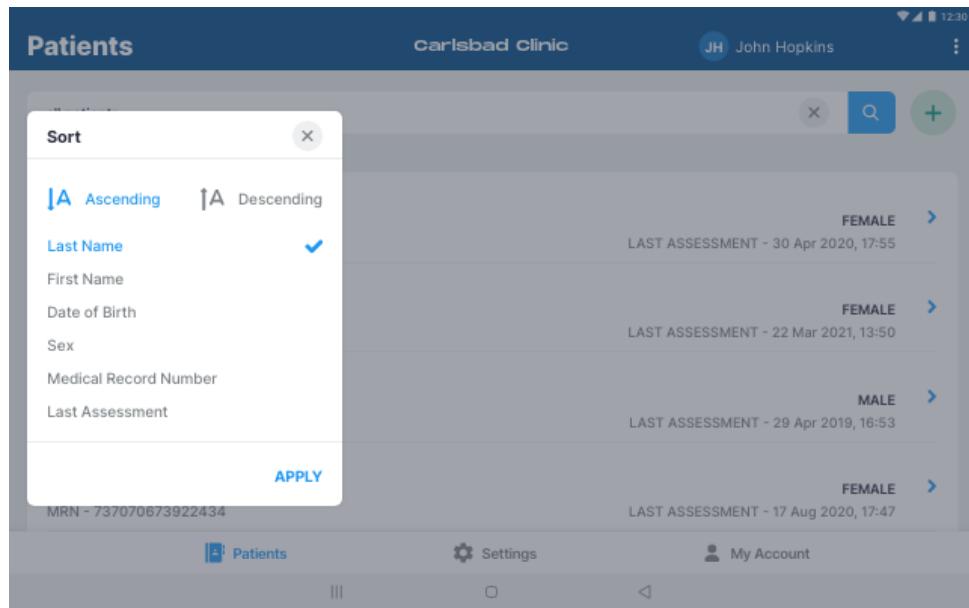
Anna

Eusebio Anna
DOB - 27 Apr 1956
MRN - 8005965Y7708892...
FEMALE
LAST ASSESSMENT - 30 Apr 2020, 17:55

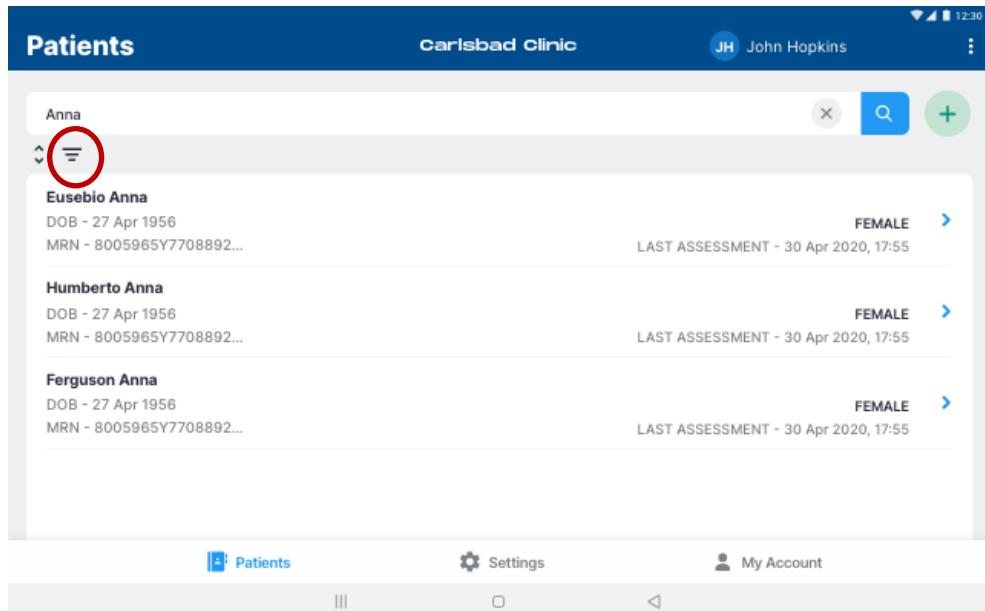
Humberto Anna
DOB - 27 Apr 1956
MRN - 8005965Y7708892...
FEMALE
LAST ASSESSMENT - 30 Apr 2020, 17:55

Ferguson Anna
DOB - 27 Apr 1956
MRN - 8005965Y7708892...
FEMALE
LAST ASSESSMENT - 30 Apr 2020, 17:55

Patients Settings My Account



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.

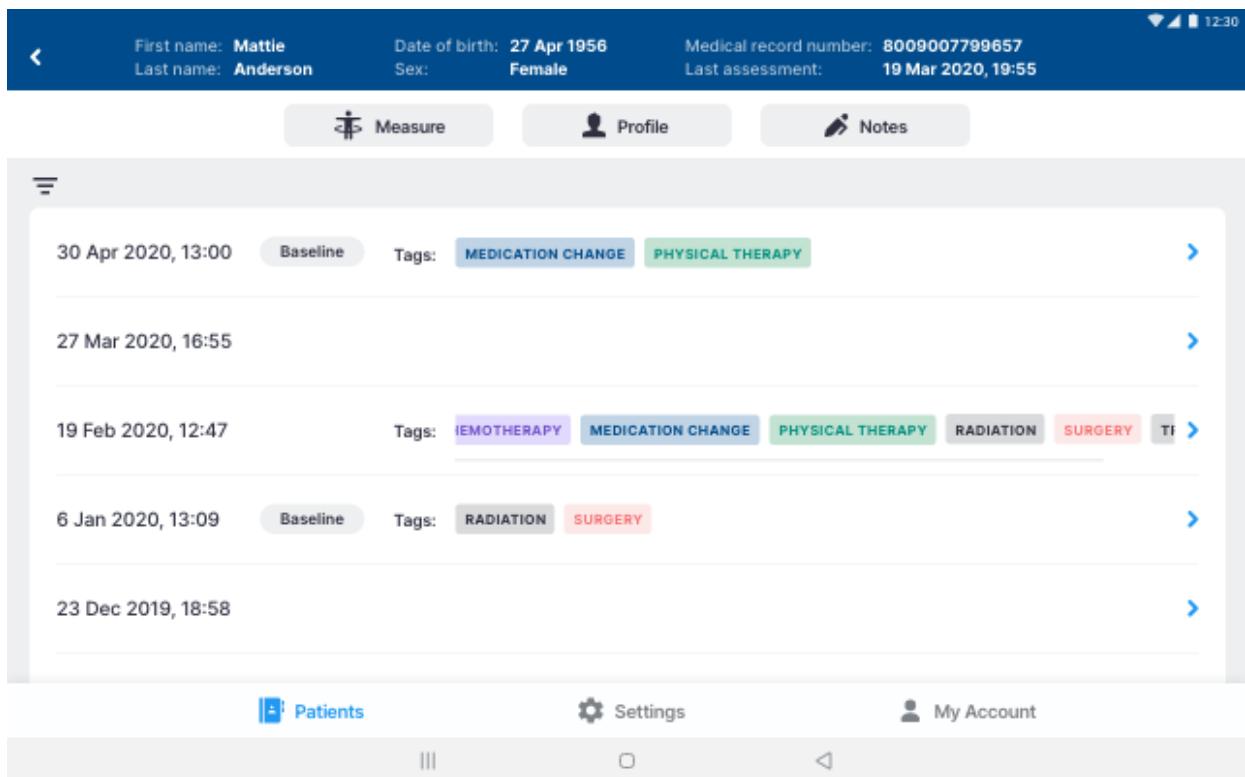


5.3.2 Patient Dashboard

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 Patients List:

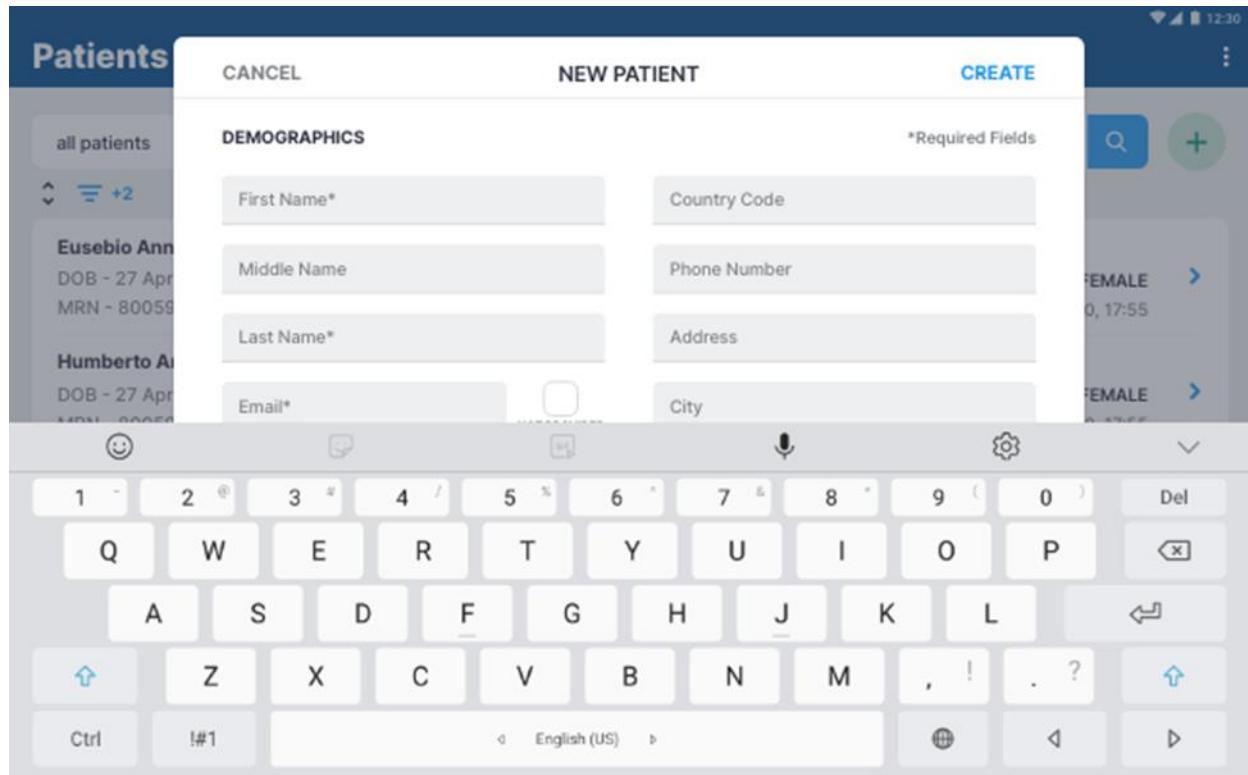
1. Search all patients or enter the patients' name.
2. Tap the **Search** icon.
3. Tap on the desired patient.



5.3.3 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**.



Note: the Clinician may optionally assign the patient to a predefined 'group'. If grouping has been set up in the clinic, 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 and HF-Dex.

5.3.3.1 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 Lymphoedema:
 - a. Select **L-Dex Analysis for Lymphoedema** and read and accept the pop-up caution.
 - b. Select additional assessment options such as unilateral/bilateral, body element, risk limb, and limb dominance. Note: bilateral assessment selection is available for patients at risk of leg lymphoedema only.
 - c. Enter the surgery date and LPP Start Date if the patient is being monitored as part of the Lymphoedema Prevention Program.

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 and HF-Dex.

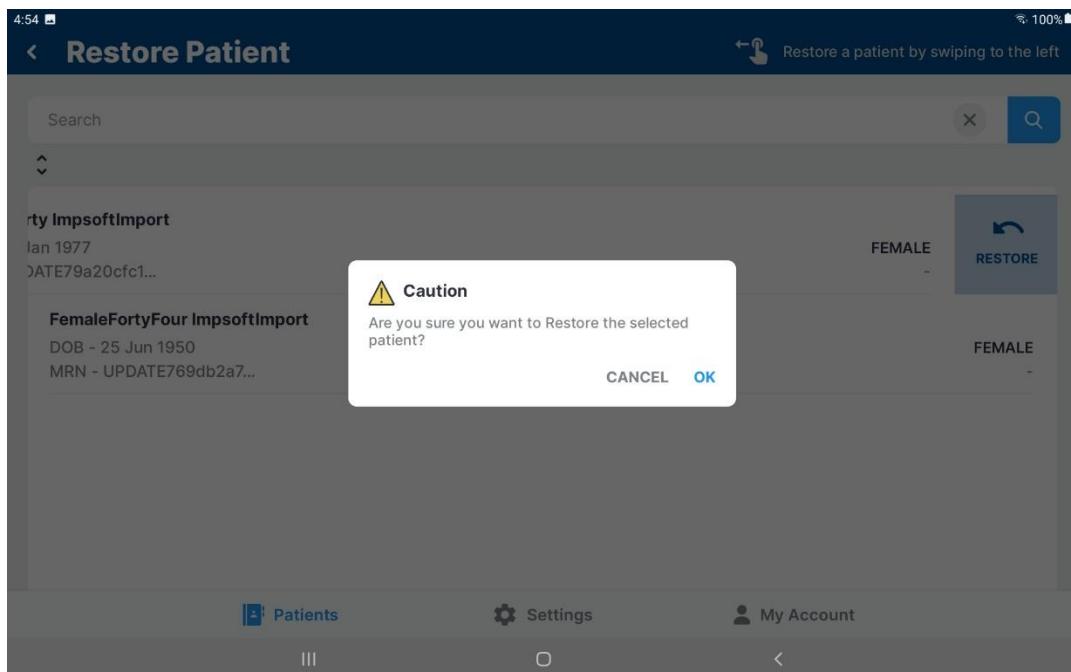
5.3.4 Delete Patient

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

5.3.5 Restore Patient

A patient may be restored by the Clinician from MySOZOapp. 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.



5.3.6 Edit Patient Profile

To edit a patient profile:

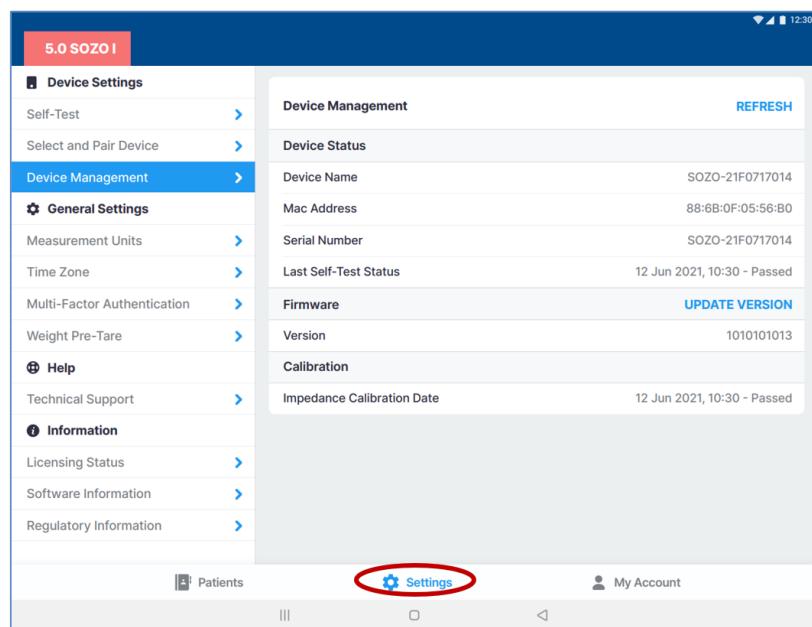
1. On the Patients List, search all patients or enter the patients' name in the search field.
2. Tap the **Search** icon and select the desired patient.
3. From the Patient Dashboard, a Clinician can tap on the **Profile** icon.
4. Make updates as needed.
5. Tap **Save**.
6. A success confirmation will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

5.4 SOZOapp Settings

The Clinician may access SOZOapp user settings by tapping Settings, located at the bottom centre 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 licences, the SOZOapp software information, and any applicable regulatory information.



5.4.1 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

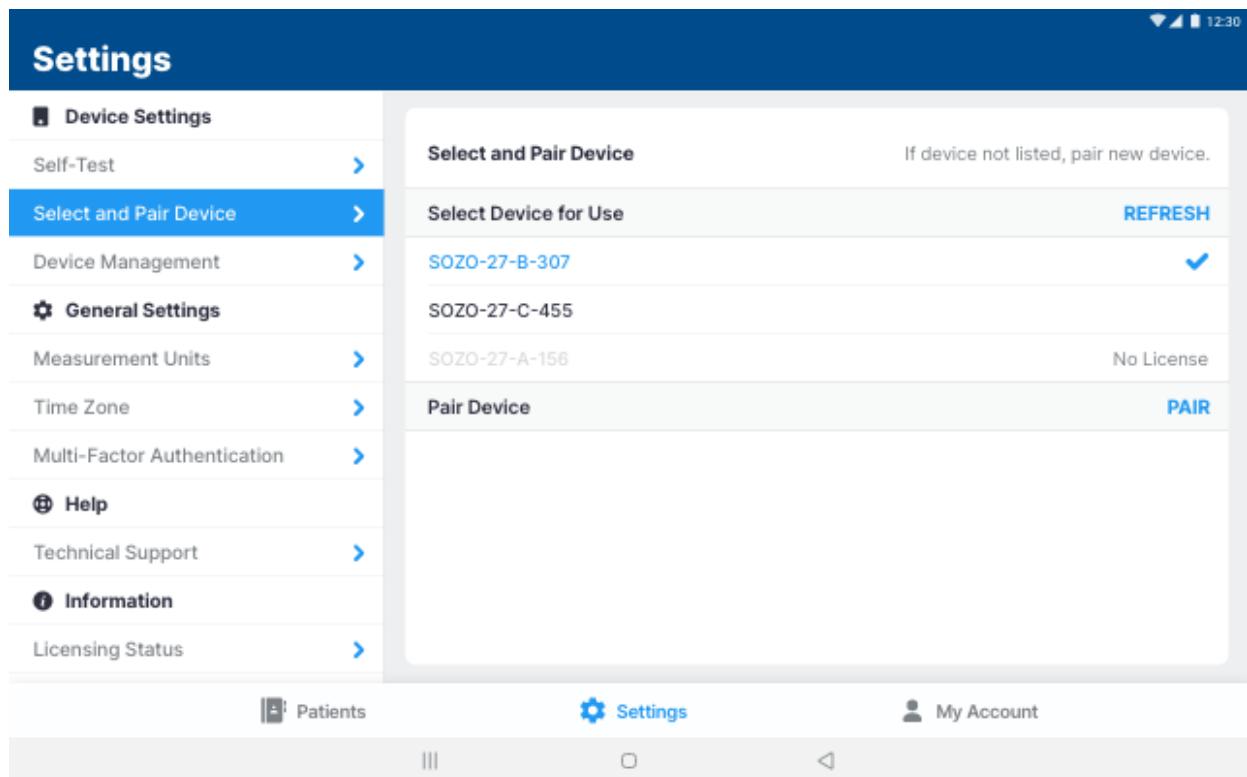
The Tablet must be paired for any new SOZO System and the pairing process must also be repeated if either the Tablet or Device are replaced. The SOZOapp may only select and work with one SOZO Device at a time.

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*®.

5.4.1.1 Android:

- a. Locate **Settings** on the Tablet and enable *Bluetooth*®.
- b. 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.
- c. Alternatively, the Tablet settings can be accessed using the **SOZOapp**. Open the **SOZOapp** and sign in.
- d. Go to the Settings page, and then '**Select and Pair Device**'.
- e. 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.
- f. Return to the SOZOapp Settings page and then 'Select and Pair Device'.
- g. A list of SOZO systems that have been previously paired over Bluetooth will be presented. If the paired device is not present, press **Refresh**.
- h. 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- as the android SOZOapp will not show that device in the Select Device for Use menu. If this occurs, choose a SOZO Device with an identification that does not start with IOS or navigate into the Bluetooth settings menu to unpair the SOZO Device.

5.4.1.2 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.

5.4.2 Self-Test

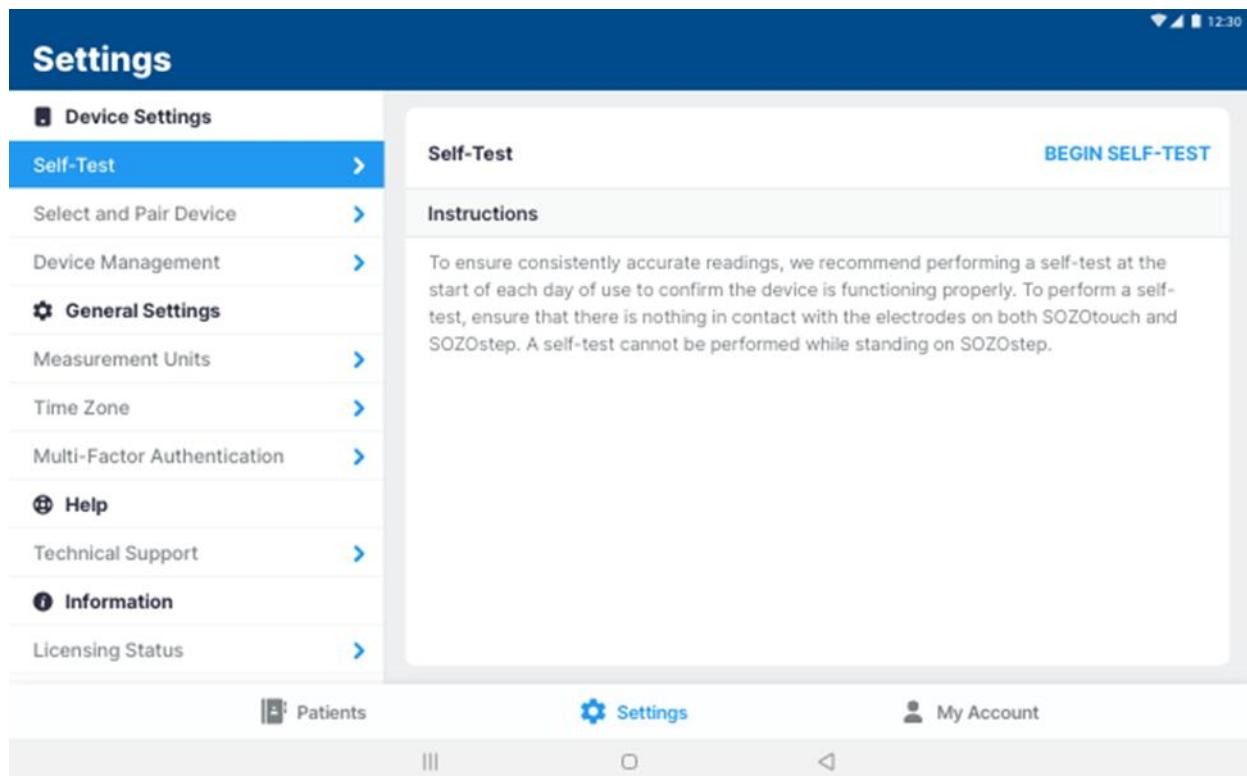
Self-tests may be run for different purposes.

- **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.



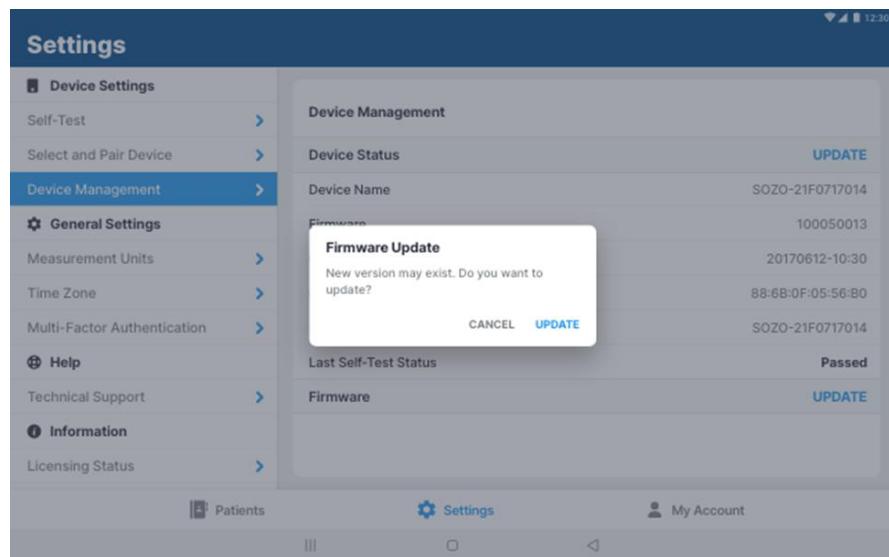
5.4.3 Device Management

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”.

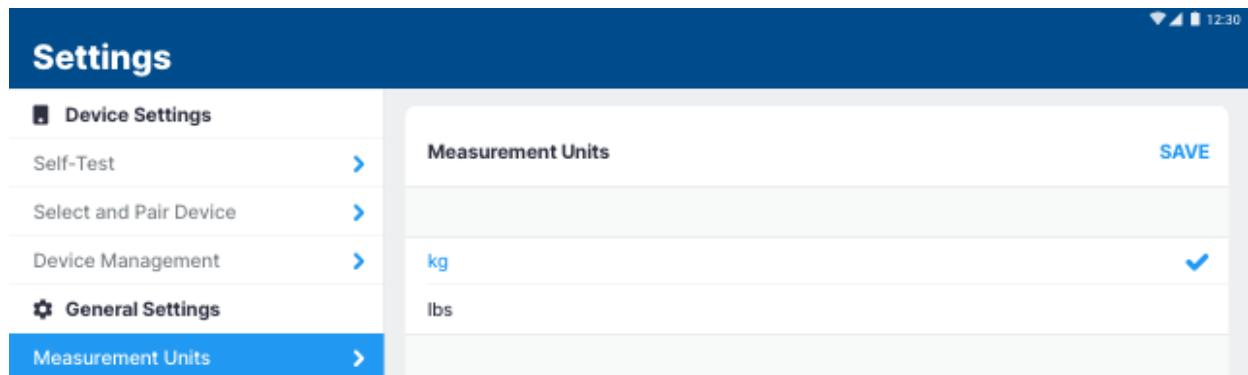
The SOZO system firmware may be updated by tapping **update** next to “Firmware”. This process may take 2-3 minutes. The Tablet or SOZO Device should not be turned off during this time.

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.



5.4.4 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, centimetres to inches and litres to pints. When updates are complete, tap **Save**.



5.4.5 Time Zone

The current Time Zone for the clinic is displayed here.

5.4.6 Multi-Factor Authentication

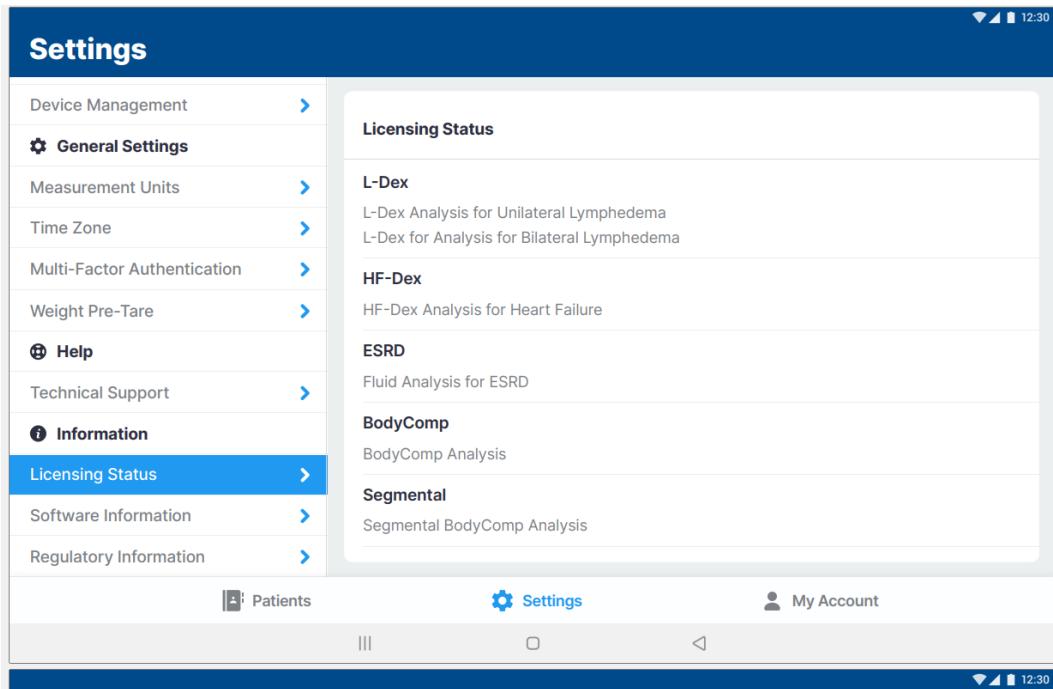
The Clinician can elect to have multi-factor authentication turned on for their account once it has been activated by the Clinic Administrator.

5.4.7 Technical Support

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

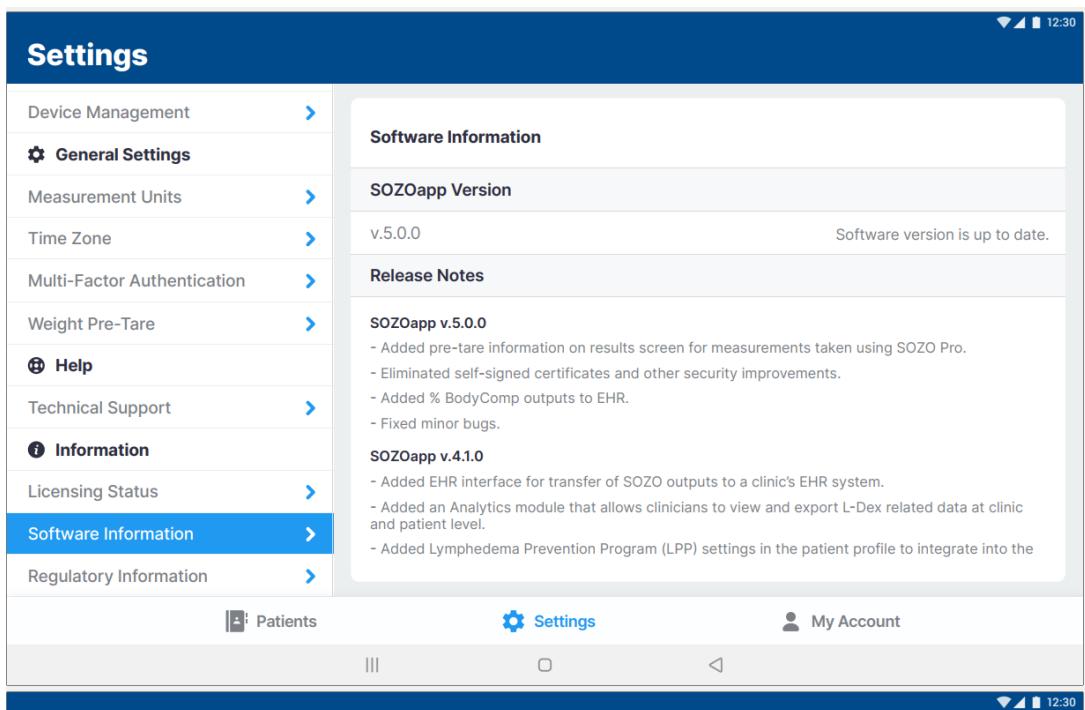
5.4.8 Licensing Status

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.



5.4.9 Software Information

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.

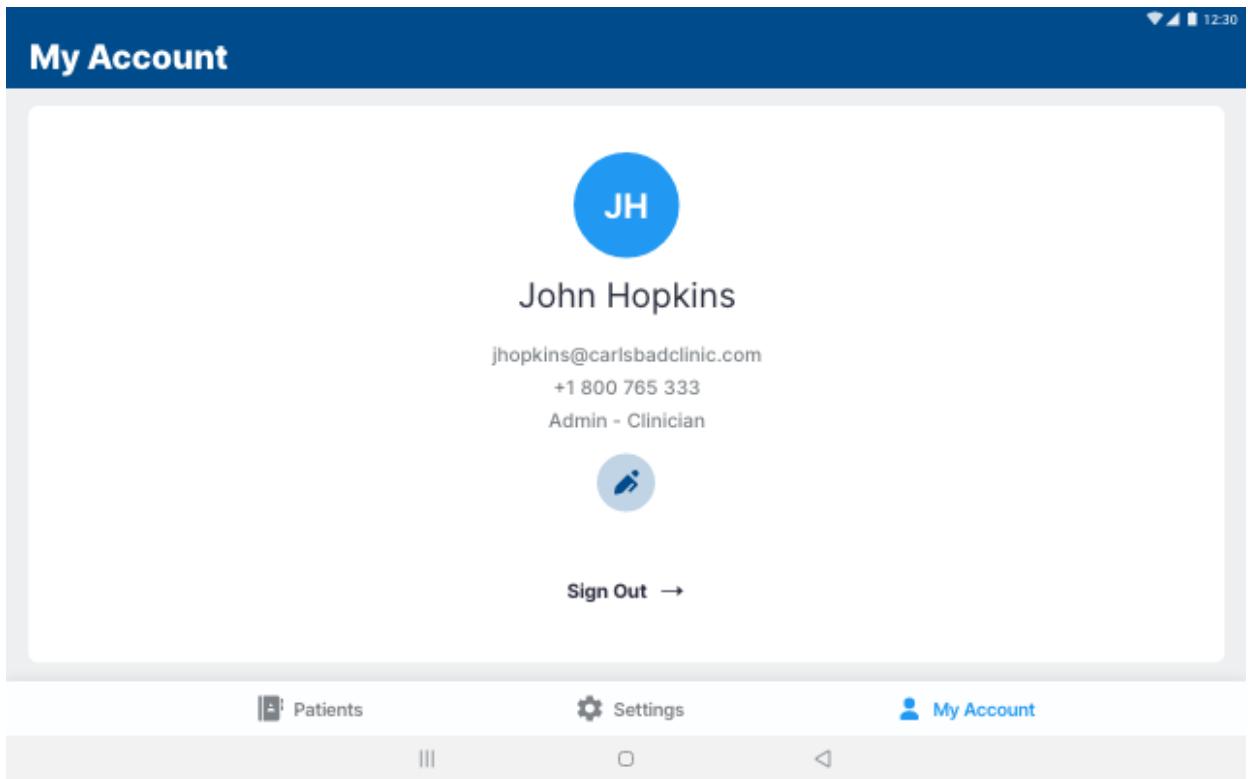
5.4.10 Regulatory Information

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

5.5 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**.



6 PREPARING THE PATIENT

6.1 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.

6.1.1 Body Composition Measurements

If body composition 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.

6.2 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.

6.2.1 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.

6.3 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 170 kg if patient is standing, and up to 340 kg 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.

6.3.1 Standing Position

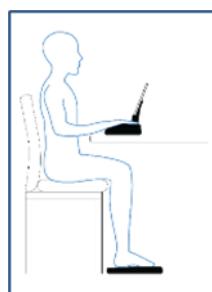
When standing on the SOZO Device, ImpediMed recommends using the SOZOsupport Stand provided with the system.

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.

6.3.2 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.

7 TAKING MEASUREMENTS

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

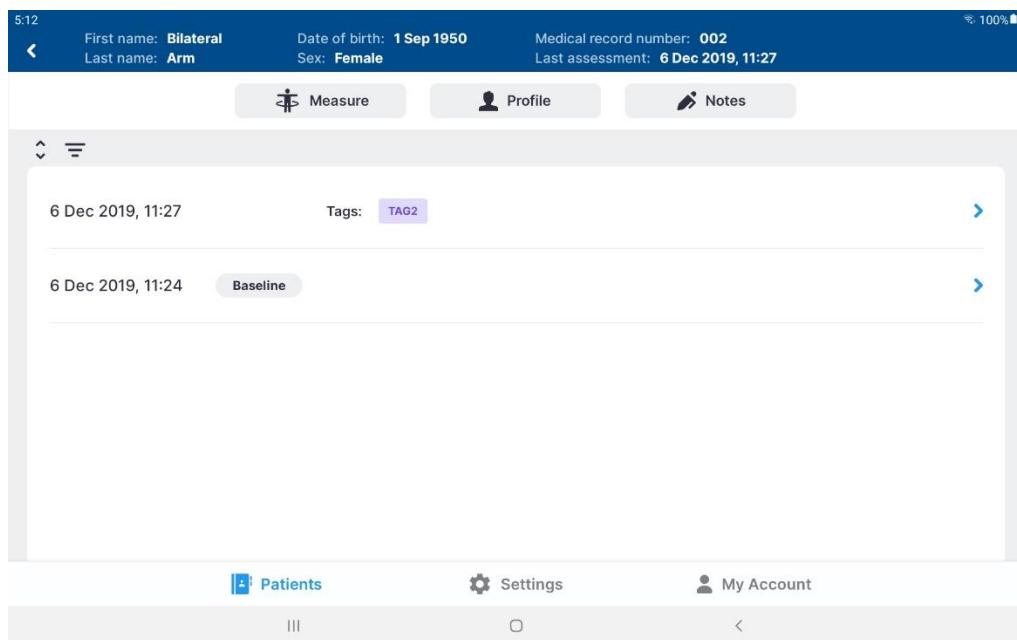
Each of the assessments along with indication-specific information and reports are discussed in greater detail below.

7.1 Starting Measurements with the SOZOapp

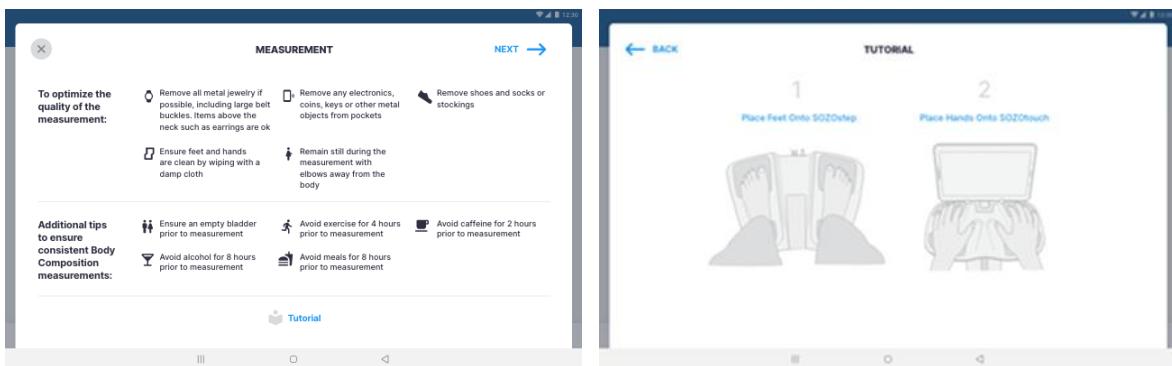
Measurements are taken using the Tablet and SOZOapp.

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 optimise 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.

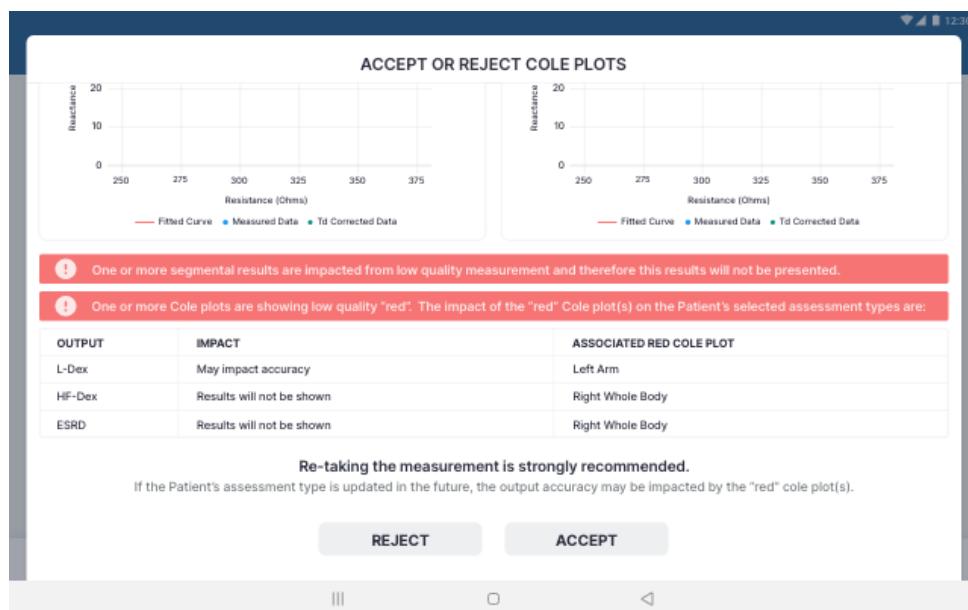
Note: surface temperature should not exceed 47° C (117° F) during normal use. Do not use SOZO Device if it is hot to the touch. Disconnect the SOZO Device by unplugging the Power Adaptor and call ImpediMed Technical Support.

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

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

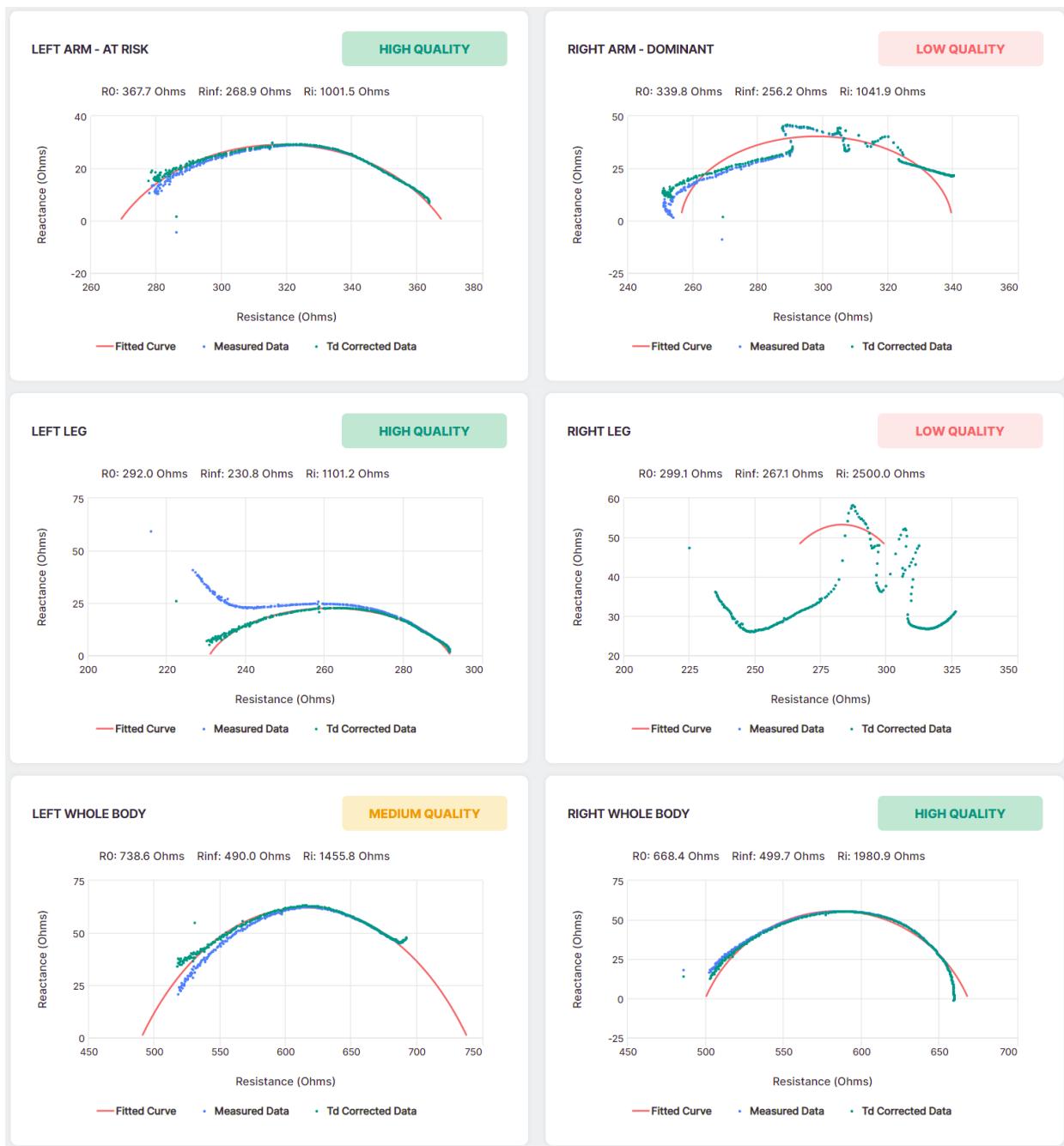
7.2 Accepting and Rejecting Cole Plots After Measurement

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.



7.3 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.

7.4 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.

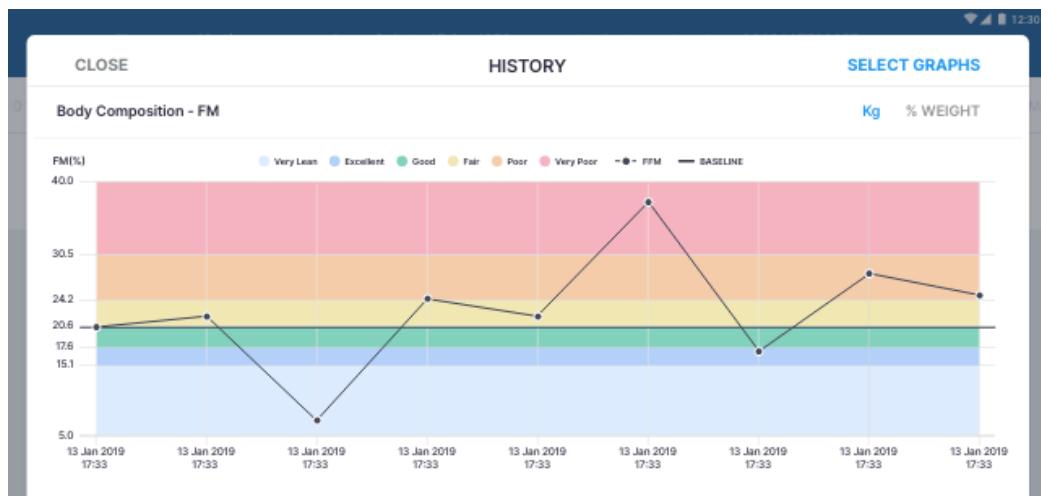
To choose the proper measurement as the baseline, the measurement should be:

- 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.

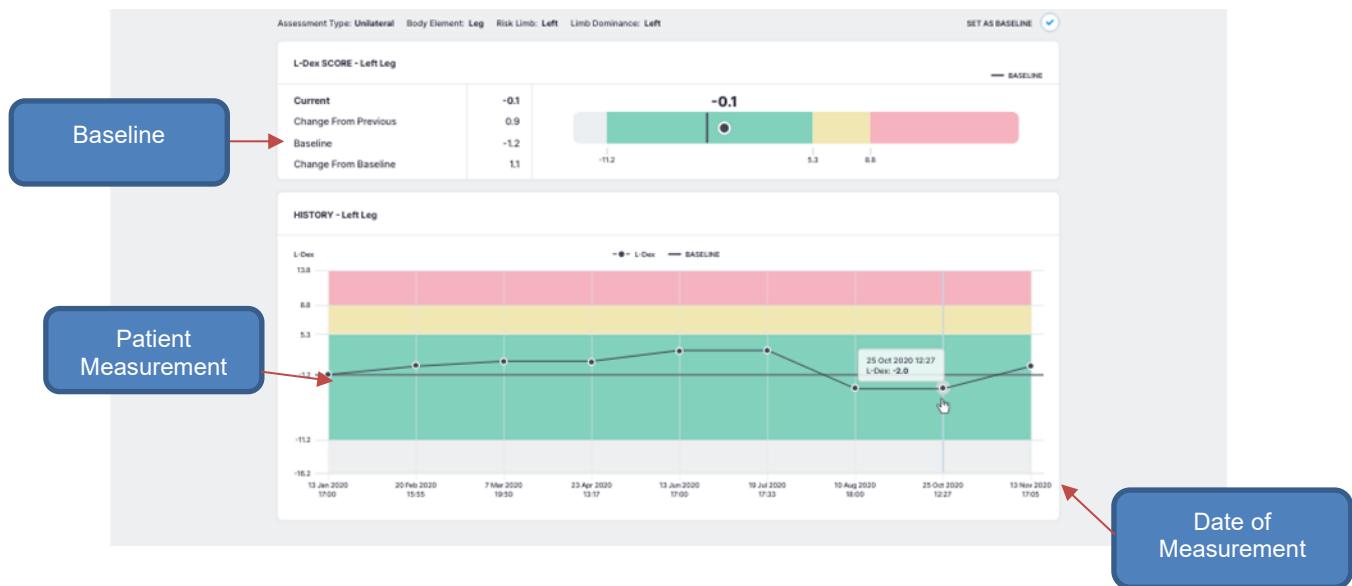
7.5 History Graphs

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



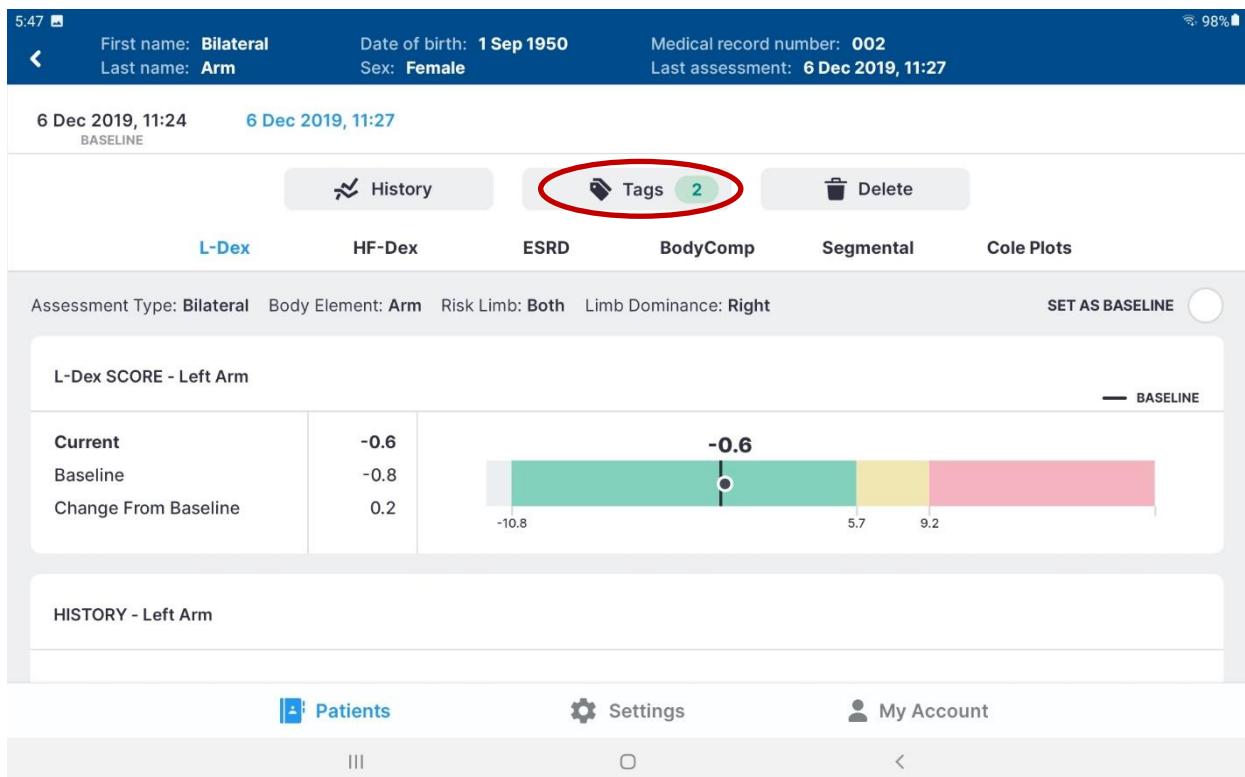
Note: only historical measurements for licensed Assessments will appear under History. Therefore, the Clinician will only be able to view licensed Assessments.

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.



7.6 Measurement Tags

A Tag can be added to a measurement to provide additional information and notes. The Tag templates 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.



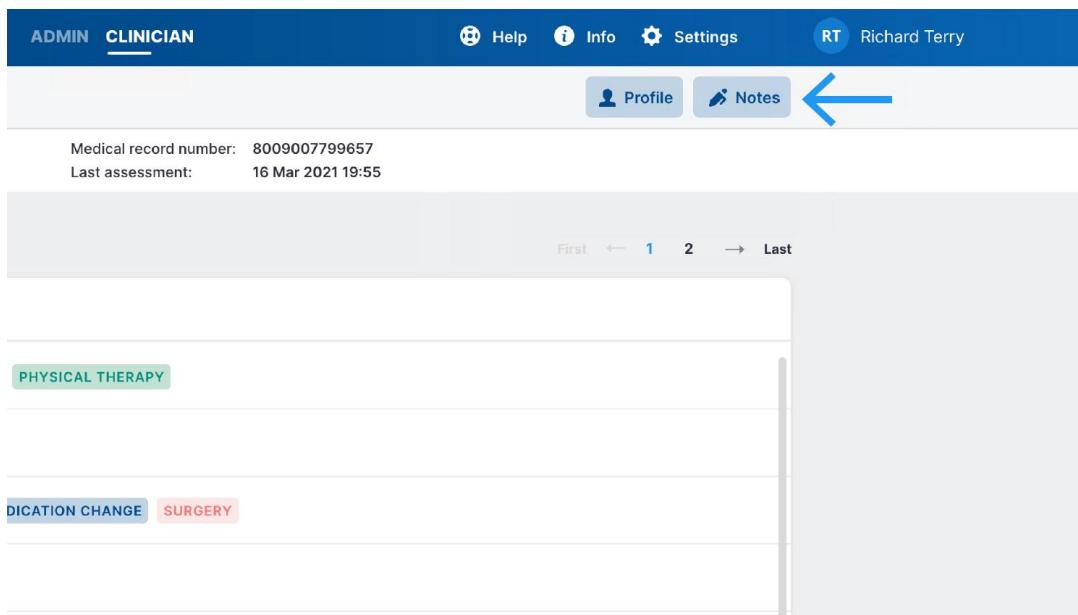
To add a Tag to a measurement, tap the “Tags” icon and tab “ADD NEW”. Select the Tag to be added from the list of available Tags and add a description if desired. Tap “SAVE” to link the Tag to the measurement.

7.7 Patient Notes

Specific patient notes can be written and updated within MySOZO and within the SOZO app. The process for accessing, creation, and update of patient notes is described below.

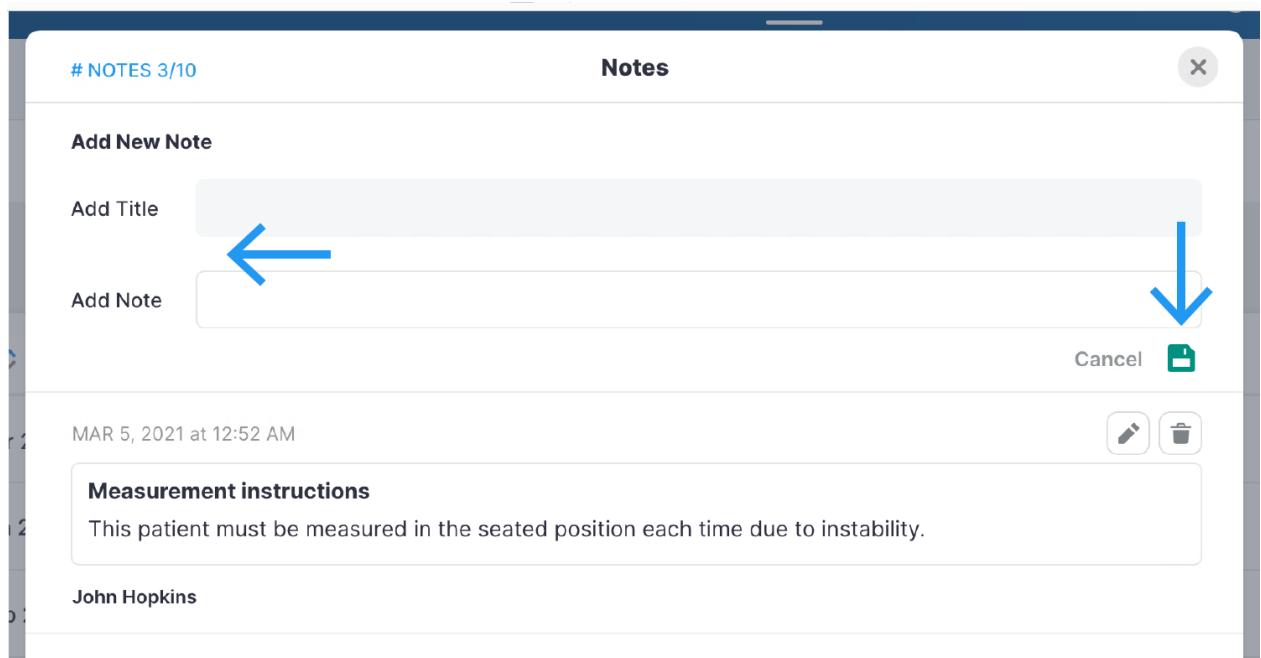
View Notes

- Sign into MySOZO as a clinician
- Find and select a patient
- Near the top of the patient dashboard, select “NOTES”.



Add New Note, Edit, or Delete Note

- Add a note title in the appropriate field.
- Add the note in the appropriate field.
- Save the note by selecting the save icon on the right of the screen.
- Notes can be edited by selecting the edit button (pencil icon) or deleted by selecting the delete button (trashcan icon). Confirm the note deletion.

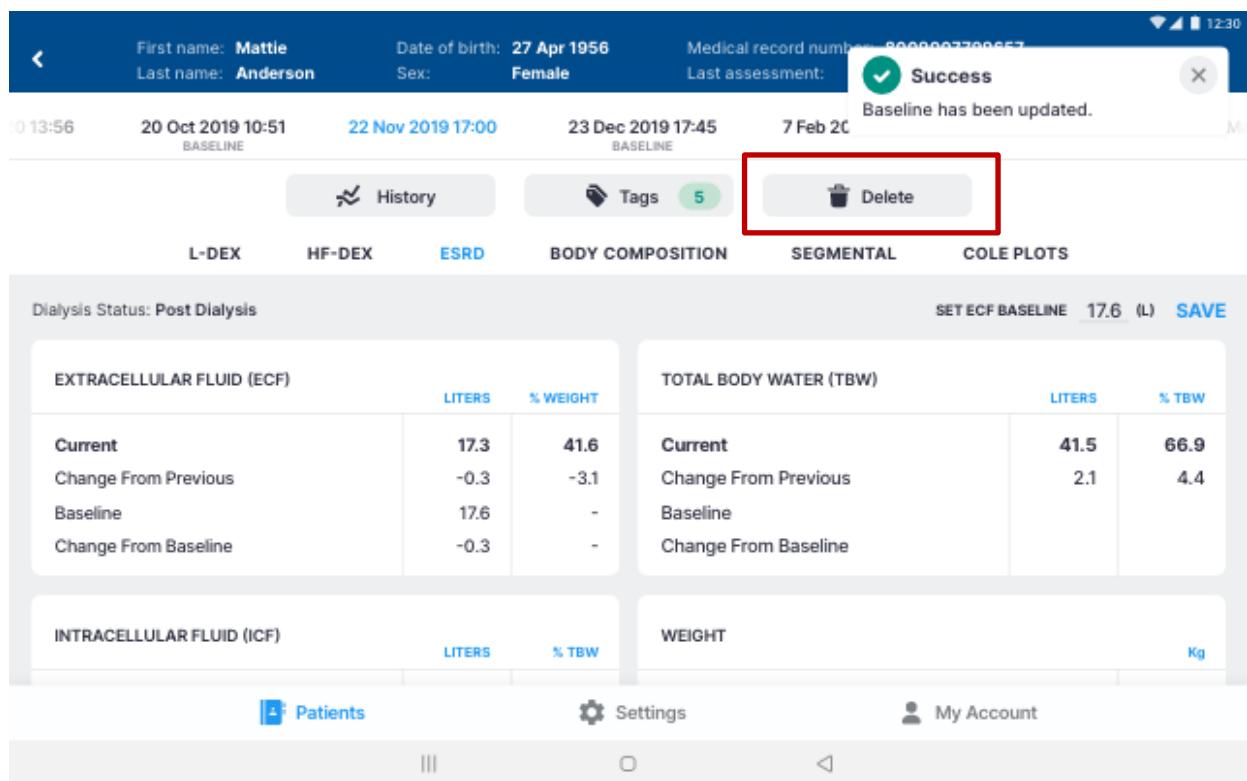


7.8 Deleting Measurements

In SOZOapp, individual measurements may be deleted, for example, if 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.



7.9 Licensing

7.9.1 Impact of Licensing Additional Assessments on Results

When the SOZO Device takes measurements, it collects and stores bioimpedance data categorised by date and time. These are independent of the type of Assessment. If the Clinic decides to purchase additional Assessment licences, 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.

7.9.2 Impact of Cancellation of Assessment Licence on Results

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

8 ASSESSMENT TYPES

The SOZO Device supports the following Assessment Types:

1. L-Dex®
2. HF-Dex™
3. ESRD
4. BodyComp™
5. Segmental BodyComp™

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

Some Assessment types may 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.

8.1 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 lymphoedema in a patient;
- HF-Dex™ aids the Clinician in monitoring fluid status in patients living with heart failure
- ESRD aids the Clinician in monitoring fluid status in patients undergoing dialysis
- BodyComp™ is used to provide fluid and tissue analysis assessments of an individual, including segmental.

Each Assessment must have a separate licence. Only Assessment types with licences 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.

8.2 Assessment Specific Instructions For Use

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

8.3 L-Dex® for Lymphoedema

8.3.1 Indications for Use

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

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

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

8.3.2 Instructions for Use

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

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

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

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



Ensure that you update the patient profile correctly to fit each patient's needs, taking into consideration the relevant facts and circumstances related to measurement, as identified in this User Guide, since this will affect the validity of measurements. Incorrect measurements may impact the accuracy of the L-Dex calculations and may affect the L-Dex assessment based upon L-Dex calculations.

8.3.3 The Lymphoedema Index (L-Dex®)

The SOZO system displays L-Dex Assessment results based upon patient measurements taken with the SOZO Device. The L-Dex Assessment produces an L-Dex score, which is based on the ratio of the impedance of the unaffected limb(s) to impedance of the at-risk limb(s). Research has established a normal range of L-

Dex scores in healthy patients. Normal L-Dex score ranges are presented in the L-Dex assessment results to assist with patient evaluation.

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

The underlying calculations for unilateral assessments using the SOZO system have not changed from any previous L-Dex devices. The impedance of the extracellular fluid space (R0) of the unaffected limb is compared with the contralateral affected limb. Clinical data has shown this to have “excellent” accuracy when used as a clinical aid to assess unilateral fluid accumulation in the limb following cancer treatment.⁵



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

For assessment of patients at risk of bilateral leg lymphoedema, where fluid accumulation could in both legs simultaneously, the comparison of contralateral limbs is not an option. SOZO uses the R0 impedance of the unaffected ipsilateral limb, instead of the unaffected contralateral limb, for bilateral assessments of fluid increases. Clinical data also has shown that arm R0, when compared to leg R0 for the assessment of fluid accumulation in bilateral leg measurements, has “very good” accuracy.¹



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

8.3.3.1 Using the L-Dex® Scale without a Baseline

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

The L-Dex scale normal range (plus or minus 3 standard deviations) measured for a healthy person without lymphoedema ranges between +10 and -10 L-Dex units. If a

⁵ SOZO's L-Dex® accuracy was determined using Receiver Operating Characteristic (ROC) curve analysis. Area under the curve (AUC) scores are established using ROC curves which compare the true positive rate (Sensitivity) against the false positive rate (100 minus Specificity) for different cut-off points of a parameter. Each point on the ROC curve represents a sensitivity/specificity pair corresponding to a particular decision threshold. The area under the ROC curve (AUC) is a measure of how well a parameter can distinguish between two groups (diseased/normal). The closer the modelled AUC comes to 1, the better it is. SOZO's L-Dex® accuracy was calculated with an area under the curve (AUC) of 0.95 for unilateral assessment and 0.80 for bilateral assessment.

baseline is not set, the normal range will centre around an L-Dex score of 0 which is the mean of the matched healthy population.

L-Dex Scores \leq -10

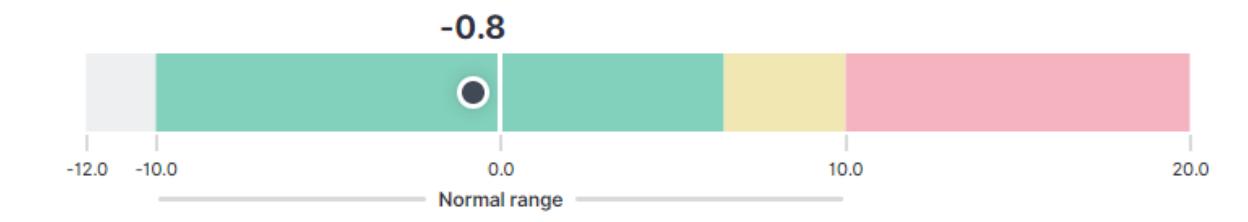


L-Dex scores equal to or less than -10 may be caused by procedural errors. A warning will be displayed stating that the measurement is out of range. Follow the instructions for use to ascertain the accuracy of the measurements in question.

L-Dex Scores > 10



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



L-Dex Categories without a Baseline

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

8.3.3.2 Using the L-Dex® Scale with a Baseline

Because each person has a different starting L-Dex score, the L-Dex scale normal range can be tailored to an individual patient by reviewing the change in L-Dex score from a Lymphoedema Assessment taken prior to treatment. This is known as a baseline measurement and the change in L-Dex score is used to categorise the measurement. In this case, an increase of 6.5 L-Dex units (two standard deviations) from the baseline may indicate early signs of lymphoedema.

When a baseline is set, the normal range will reflect a -10 to +6.5 range around the selected baseline L-Dex score. From this comparison, changes in patient fluid levels may be identified, and evaluated as changes which fall within normal or abnormal ranges.

Change in L-Dex Scores $\geq +6.5$



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



L-Dex Categories with a Baseline

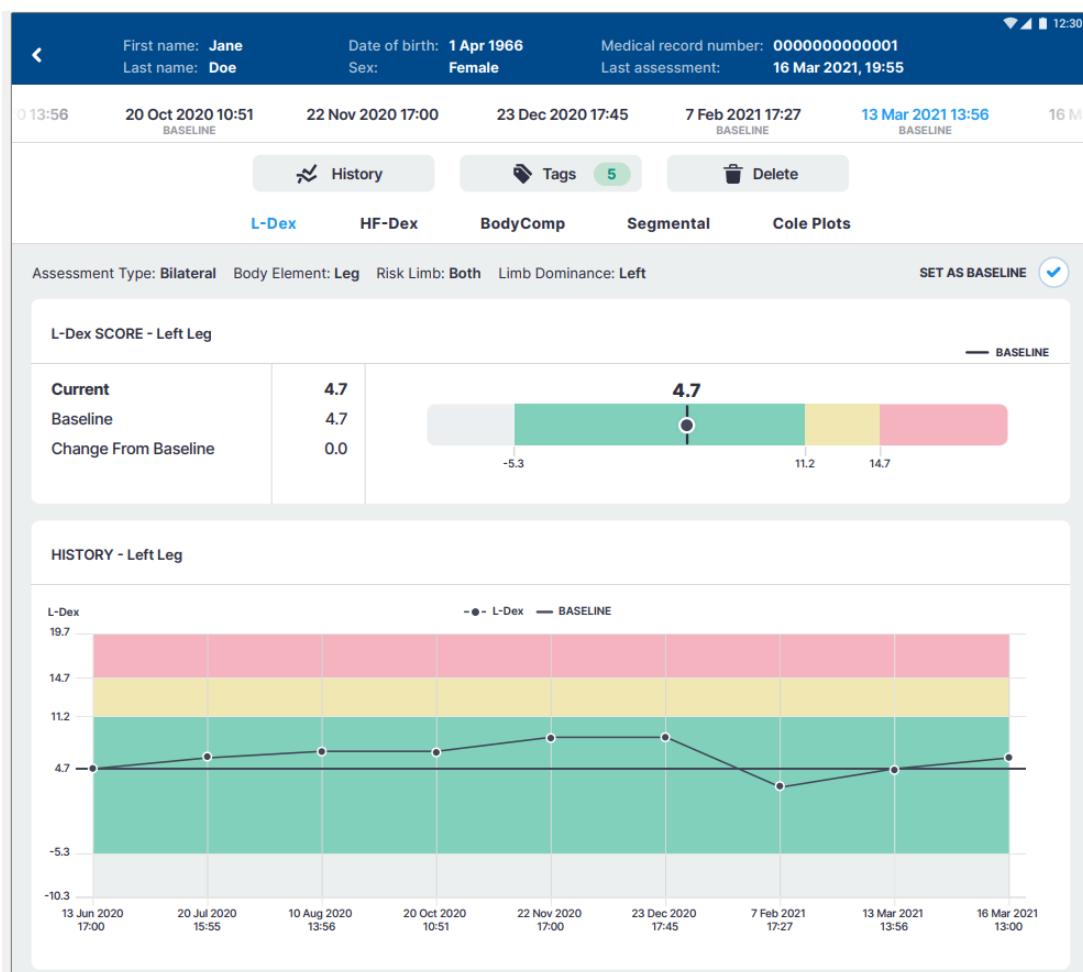
Below Normal L-Dex Change (Grey)	Change in L-Dex scores from the baseline that are greater than 3 standard deviations below the baseline (change greater than -10).
Normal L-Dex Change (Green)	Change in L-Dex scores from the baseline between 3 standard deviations less than the baseline and 2 standard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

It is recommended to use a baseline taken prior to cancer treatment whenever possible to customise the L-Dex scale for the individual. If a patient has already begun cancer treatment and there is no way to determine a healthy baseline, the clinician should use clinical judgment in conjunction with other assessments to select the most appropriate baseline measurement. If a patient has already developed lymphoedema and SOZO is being used to track their progress, do not set the baseline.

8.3.4 L-Dex® Assessment Results

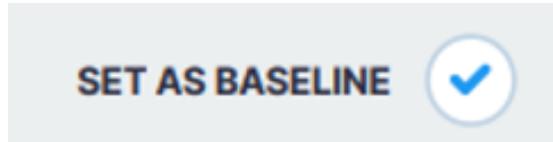
Results from a patient's L-Dex Assessment may be viewed in MySOZO or on SOZOapp.

After a successful measurement, the SOZOapp screen will display the results of an L-Dex measurement. In addition to the immediate results, a history of previous patient measurements is displayed in graph format, to allow comparison between current results and previous results. This shows increases or decreases in the L-Dex score over time. The same patient history information can be accessed from MySOZO through a web browser. For more about accessing MySOZO, see MySOZO.”



8.3.5 Setting the Baseline

Selection of a baseline – a “normal L-Dex score” for an individual patient – is the optimal way to track changes over time. To set a baseline, select the most appropriate measurement by date from the patient’s dashboard, and tap the button next to ‘set as baseline’:



If an incorrect baseline is selected, simply select the correct measurement and baseline.

For an L-Dex score, the optimal baseline is typically one of the first few measurements taken, preferably before surgery or other intervention that could impact the lymphatic system.

8.3.6 Recommended Measurement Frequency

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

- Pre-operative baseline
- Years 1-3: Every 3 months
- Years 4-5: Every 6 months
- Year 6+: Annually

8.3.7 Bilateral Arm L-Dex Assessments

ImpediMed has recently confirmed that some patients at unilateral risk of lymphoedema are incorrectly being assessed using the bilateral arm L-Dex assessment and that the bilateral arm L-Dex assessment does not have the same level of sensitivity to help detect early signs of lymphoedema as the unilateral arm L-Dex assessment.

This could result in the under-recognition of early lymphoedema. The potential health hazards associated with this issue include:

- Delay in early intervention, which could result in progression to clinical lymphoedema.
- More aggressive intervention if clinical lymphoedema develops.

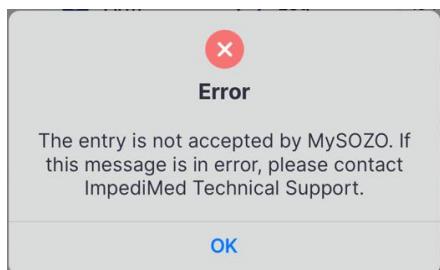
Version 4.1.0.3 and 5.0.0.1 of the MySOZO software, released in August 2023 contains an update to make unilateral L-Dex the sole assessment option for arms. L-Dex assessments for legs will not be impacted.

8.3.7.1 Impact to patient settings who had bilateral arm selections:

At the time of the software update, all patients who had bilateral arm selections chosen were modified to deselect their L-Dex related assessments. If another

assessment type was chosen, such as BodyComp, then only those assessment results will be shown. If no other assessment type was chosen for the impacted patient, no data will be shown when reviewing results.

When using MySOZO.com to edit patient lymphoedema settings, a user is not able to select both bilateral and arms as a selection. When using the SOZOapp, a user is able to select bilateral and arms as a selection, but gets the following error message when attempting to save the patient profile:



8.3.7.2 Recommended course of action for impacted patients:

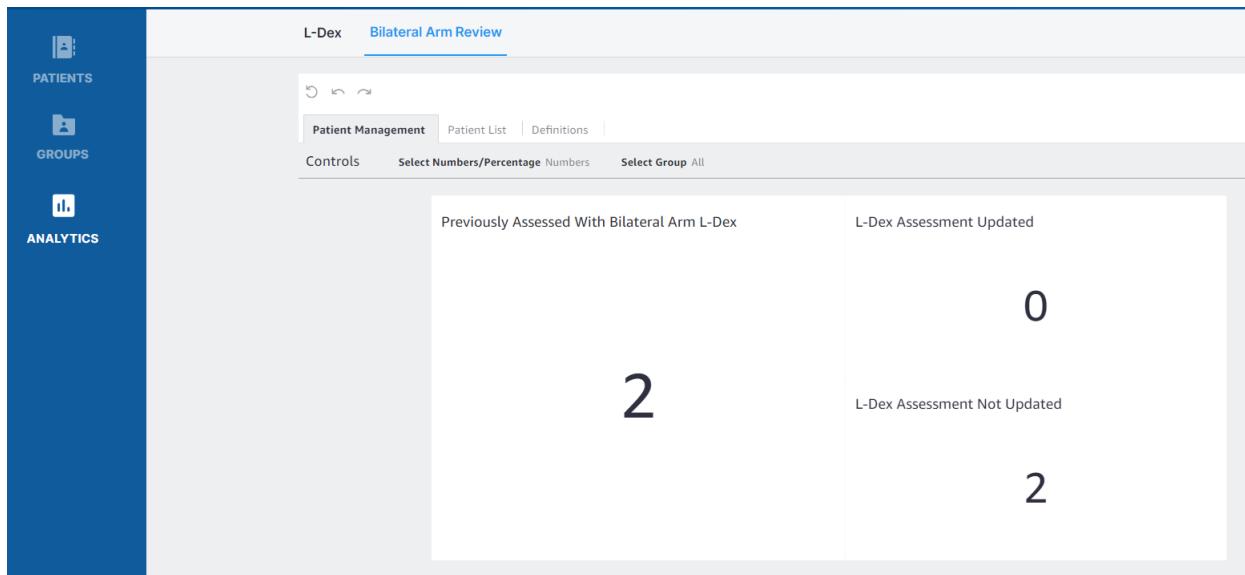
We recommend that you confirm the risk profile of the impacted patients in MySOZO and take the following actions:

- For patients at unilateral risk for lymphoedema (over 90% of breast cancer patients)⁶, confirm that the unilateral arm L-Dex assessment is selected in the patient profile and continue to screen for early signs of lymphoedema.
- For patients at bilateral risk for lymphoedema (3-10% of breast cancer patients)², guidelines suggest routine screening using clinical exam and symptom assessment.

8.3.7.3 Identification of impacted patients

To aide in the identification of impacted patients and to track follow up and patient profile settings at the time of the software update, a new tab within the analytics module has been created as shown below. The data shows the number of patients who were originally assessed with Bilateral Arm for L-Dex assessment at the time of the software update as well as those patients who have since had L-Dex assessments updated.

⁶ Heron DE, et al. Risk factors and outcomes for patients with synchronous and metachronous disease. *Cancer* 2000;88(12):2739-50.



By selecting a chart and navigating to the patient list, individual patients can be identified and their settings at the time of the software update has been saved under:

- “Previous surgery date” (if entered)
- “Previous LPP Start Date” (if entered),
- “Previous Limb Dominance Selection”

The screenshot shows the 'Patient List' screen with the following interface elements:

- Navigation icons at the top left.
- Tab navigation: Patient Management, **Patient List**, Definitions.
- Text: 'Your Selection: Group =All Patient L-Dex Status = All'.
- Table with the following data:

LAST NAME	FIRST NAME	DOB	SEX	MRN	PREVIOUS SURGERY DATE	PREVIOUS LPP START DATE	PREVIOUS LIMB DOMINANCE SELECTION	LAST ASSESSMENT DATE
Patient	Example	1990-09-30	Male	63557066			Right	2022-09-30
Patient	Example	1999-09-16	Male	1234321			Right	2022-08-10

8.4 HF-Dex™ Analysis

8.4.1 Indications for Use

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

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

8.4.2 Instructions for Use

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

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

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



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



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

8.4.3 The Heart Failure Index (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, with measurements displayed over time from oldest (left) to newest (right). The HF-Dex score is the patient's ECF/TBW%, compared to clinical data in the following manner:

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

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

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

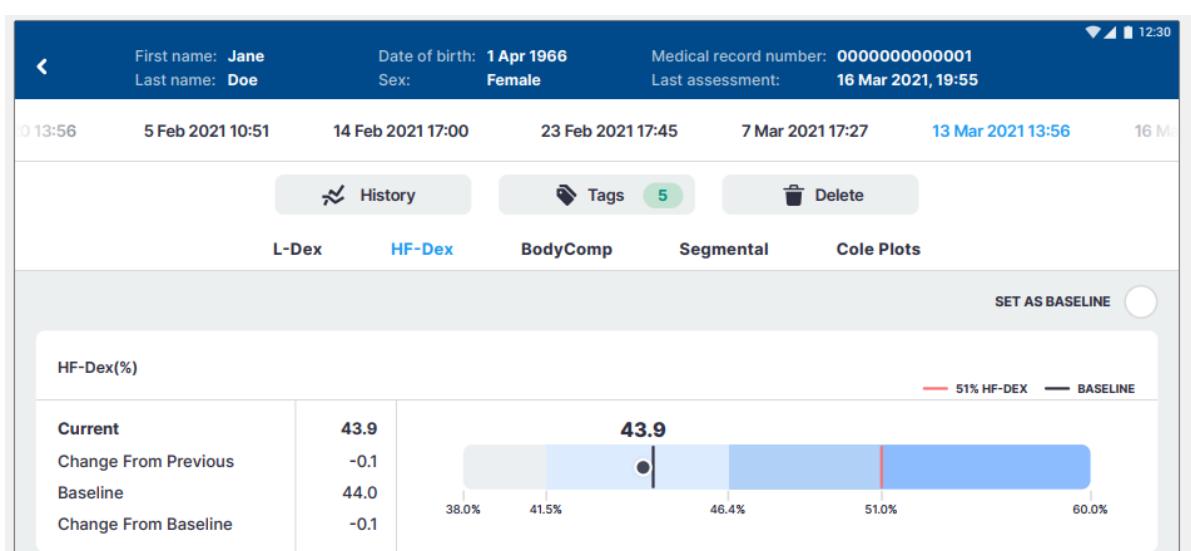
Grey range: HF-Dex values in the grey range may indicate a fluid imbalance for other causes (such as dehydration) or potential issues with measurement accuracy, and requires additional investigation.

8.4.4 HF-Dex™ Assessment Results

Information in a HF-Dex Assessment includes the patient's baseline HF-Dex score, change vs. baseline, and change from previous HF-Dex score.

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

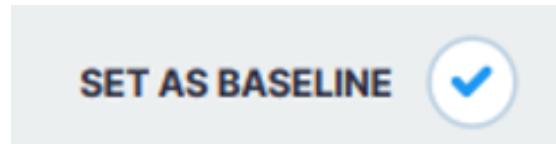
- Total Body Water (TBW)
- TBW as a % of weight
- Extracellular Fluid (ECF)
- ECF as a % of TBW
- Intracellular Fluid (ICF)
- ICF as a % of TBW
- Weight history



TOTAL BODY WATER (TBW)			EXTRACELLULAR FLUID (ECF)		
	LITERS	% TBW		LITERS	% TBW
Current	38.5	50.6	Current	16.9	43.9
Change From Previous	0.6	0.0	Change From Previous	0.2	-0.1
Baseline	37.9	50.6	Baseline	16.7	44.0
Change From Baseline	0.6	0.0	Change From Baseline	0.2	-0.1
INTRACELLULAR FLUID (ICF)			WEIGHT		
	LITERS	% TBW	CURRENT PRE-TARE: 1.0 kg		kg
Current	21.6	56.1	Current	76.1	
Change From Previous	0.4	0.1	Change From Previous	1.3	
Baseline	21.2	56.0	Baseline	74.8	
Change From Baseline	0.4	0.1	Change From Baseline	0.1	

8.4.5 Setting the Baseline

Selection of a baseline – a “normal score” for an individual patient – is the optimal way to track changes over time. To set a baseline, select the most appropriate measurement by date from the patient’s dashboard, and tap the button next to ‘set as baseline’:



If an incorrect baseline is selected, simply select the correct measurement and baseline.

For a given HF-Dex and body composition output, an optimal baseline is typically taken when the patient, in a clinician’s estimation, is in suitable good health. It may take some time to establish an appropriate baseline measurement for the patient.

8.4.6 Recommended Measurement Frequency for HF-Dex™

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

8.5 ESRD

8.5.1 Indications for Use

The ESRD Assessment is intended for patients:

- Taking diuretic medication
- Living with end-stage renal disease

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

8.5.2 Instructions for Use

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

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

In order to use the ESRD module, the clinic will require a licence for the module. The patient will additionally need to have the module selected in their profile. After doing so, ESRD module results will be presented after every measurement.



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

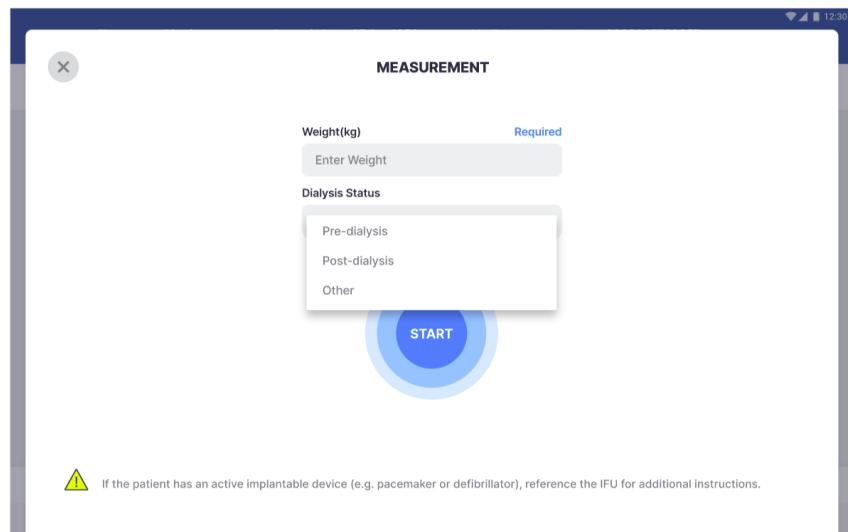


This result cannot be provided due to low measurement quality "red". For this measurement to be shown, the Right Whole Body Cole Plot (found in the Cole plot review screen after the measurement) must be medium quality "yellow" or high quality "green".

8.5.2.1 Pre- and Post-Dialysis Setting

The ESRD module incorporates a tool to allow the user to track whether a given measurement was taken immediately prior to or immediately after a dialysis treatment. If the SOZO assessment is taken independent of a dialysis treatment session, 'other' may be selected.

The choice of dialysis status must be made prior to starting a measurement, in a screen similar to the following:

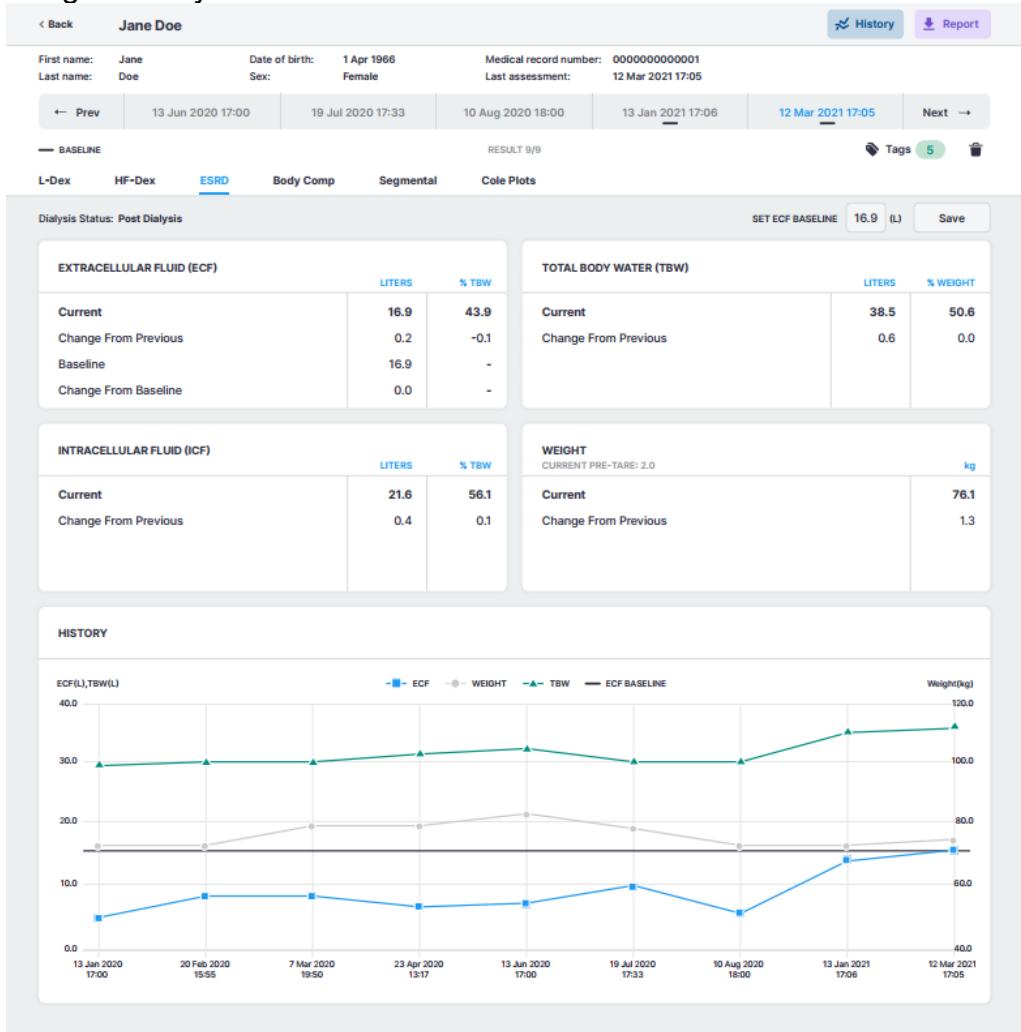


8.5.3 ESRD Assessment Results

The ESRD module is a tool to assist in the clinical assessment of fluid status in a patient living with end stage renal disease, by a medical provider. The results screen will display the following outputs:

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

- Weight history



8.5.4 Setting the Baseline

Selection of a baseline – a “normal score” for an individual patient – is the optimal way to track changes over time. To set a baseline, enter the target ECF and tap Save.

SET ECF BASELINE **ECF** (L) Save

If an incorrect baseline is saved, simply clear the text box and tap Save again.

For a given ESRD output, an optimal baseline is typically taken when the patient, in a clinician’s estimation, is in suitable good health. It may take some time to establish an appropriate baseline measurement for the patient.

8.5.5 Recommended Measurement Frequency for ESRD

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

8.6 Body Composition Analysis

8.6.1 Indications for Use

When using the SOZO Device's Tissue and Fluid Analysis assessment modules for body composition measurements, the following indications for use applies:

The SOZO system may be used to estimate the following body composition parameters in humans to track clinically relevant body composition parameters over time:

- Fat Mass (FM)
- Fat-free Mass (FFM)
- Total Body Water (TBW)
- Intracellular Fluid (ICF)
- Skeletal Muscle Mass (SMM)

The following outputs are also presented:

- Active Tissue Mass (ATM)
- Extracellular Mass (ECM)
- Body Mass Index (BMI)
- Basal Metabolic Rate (BMR; based on Mifflin – St. Jeor's algorithm) displayed in calories per day
- Protein and mineral (also known as 'dry lean mass') represents the content of a body that is not fat or fluid; calculated by subtracting total body water weight from fat-free mass weight.
- The BodyComp module will also present scores for a patient's Hydration Index (Hy-Dex[®]) Analysis, an estimation of the patient's hydration level compared to normal population data, as an indicator of hydration level. The Hy-Dex Analysis is only intended for use with healthy individuals and should not be used to monitor or treat any disease.

8.6.2 Instructions for Use

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

8.6.3 BodyCompTM Assessment Results (Whole Body)

At the conclusion of a measurement, the SOZOapp will present a screen with analysis of the fluid and tissue status of the patient using preferred units of measure and presented for the following outputs:

Fluid Analysis

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)

- TBW as a percentage of weight
- ECF and ICF distribution (expressed as a percentage of total body water)

Tissue Analysis

- Fat-Free Mass (FFM)
- Fat Mass (FM)
- Active Tissue Mass (ATM)
- Extracellular Mass (ECM)
- Skeletal Muscle Mass (SMM)
- Protein & Minerals
- Weight

Other

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

Hy-Dex® Analysis

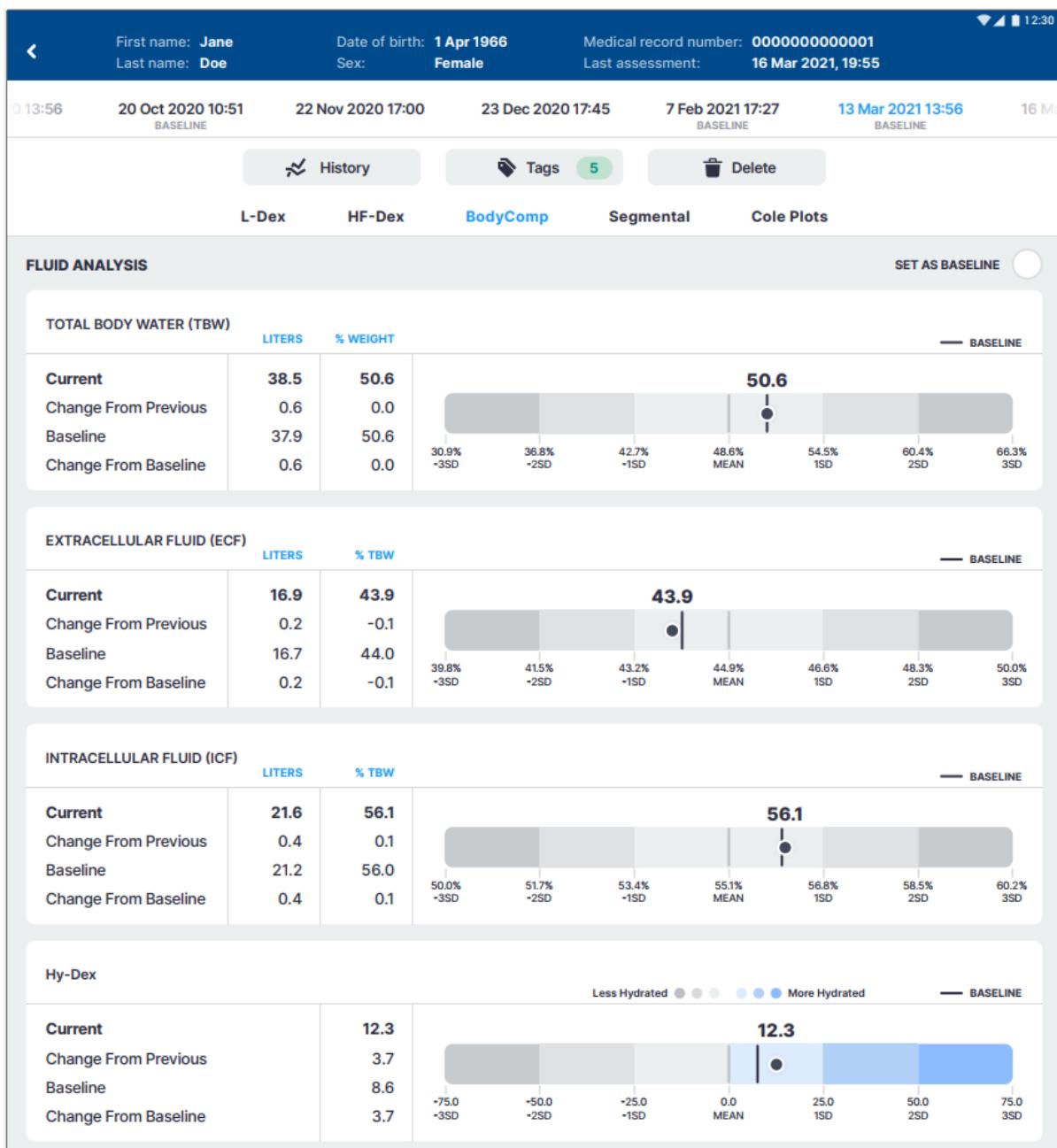
Note: all SOZO volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results are small, minor differences between absolute numbers and percentages may be observed.

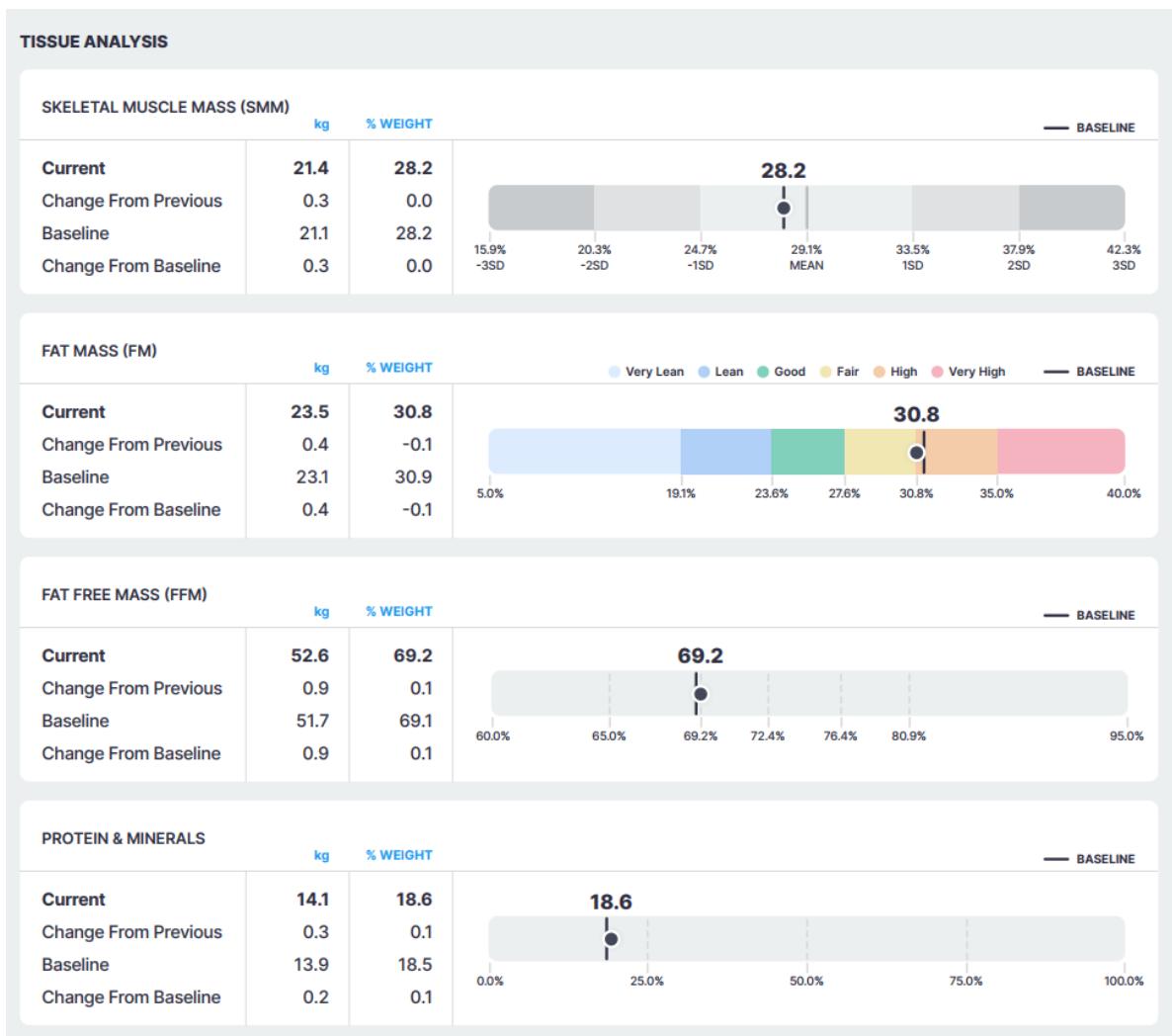
8.6.4 Reference Ranges

When reviewing patient data, the following measurement outputs provide additional reference information against which the current results can be compared:

- Total Body Water, expressed as a %
- Extracellular Fluid, expressed as a %
- Intracellular Fluid, expressed as a %
- Fat Mass, expressed as a %
- Hy-Dex
- Skeletal Muscle Mass
- BMI
- Phase Angle

For more information on how the reference ranges are derived, please see 8.6.7 Body Composition Parameters.





8.6.5 BodyComp™ Assessment Results (Segmental)

If the clinic has licensed the SOZO segmental body composition analysis module, and the patient has been selected to have segmental results presented, a subset of SOZO Body Composition outputs can also be tracked for individual limbs in the same patient.

The following body composition outputs are presented for segmental analysis:

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- ECF and ICF distribution (expressed as a percentage of total body water for the limb)
- Skeletal Muscle Mass (SMM)
- Lean Soft Tissue (a subset of Fat-Free Mass)
- Phase Angle

Note: all SOZO volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results are small, minor differences between absolute numbers and percentages may be observed.

Note: Reference ranges are not available for individual body segments.

[◀ Back](#) **Jane Doe** [History](#) [Report](#)

First name: Jane Date of birth: 1 Apr 1966 Medical record number: 000000000001
 Last name: Doe Sex: Female Last assessment: 12 Mar 2021 17:05

← Prev 13 Jun 2020 17:00 19 Jul 2020 17:33 10 Aug 2020 18:00 13 Jan 2021 17:06 12 Mar 2021 17:05 Next →

— BASELINE RESULT 9/9 [Tags](#) 5 [Delete](#)

L-Dex HF-Dex BodyComp **Segmental** Cole Plots

SET AS BASELINE (LEFT ARM) SET AS BASELINE (RIGHT ARM)

LEFT ARM			RIGHT ARM		
	CURRENT	CHANGE FROM BASELINE		CURRENT	CHANGE FROM BASELINE
Total Body Water	2.2(L)	0.0(L)	Total Body Water	2.3(L)	0.0(L)
Extracellular Fluid	1.0(L), 43.7(%TBW)	0.0(L)	Extracellular Fluid	1.0(L), 43.2(%TBW)	0.0(L)
Intracellular Fluid	1.2(L), 56.3(%TBW)	0.0(L)	Intracellular Fluid	1.3(L), 56.8(%TBW)	0.0(L)
Skeletal Muscle Mass	1.6(kg)	0.0(kg)	Skeletal Muscle Mass	1.6(kg)	0.0(kg)
Lean Soft Tissue	2.8(kg)	0.0(kg)	Lean Soft Tissue	3.0(kg)	0.0(kg)
Phase Angle	6.3°	0.0°	Phase Angle	6.3°	0.0°

SET AS BASELINE (LEFT LEG) SET AS BASELINE (RIGHT LEG)

LEFT LEG			RIGHT LEG		
	CURRENT	CHANGE FROM BASELINE		CURRENT	CHANGE FROM BASELINE
Total Body Water	7.6L	0.0(L)	Total Body Water	8.0(L)	0.0(L)
Extracellular Fluid	3.3(L), 44.0(%TBW)	0.0(L)	Extracellular Fluid	3.3(L), 41.8(%TBW)	0.0(L)
Intracellular Fluid	4.3(L), 56.0(%TBW)	0.0(L)	Intracellular Fluid	4.7(L), 58.2(%TBW)	0.0(L)
Skeletal Muscle Mass	5.8(kg)	0.0(Kg)	Skeletal Muscle Mass	6.0(kg)	0.0(kg)
Lean Soft Tissue	9.9(kg)	0.0(Kg)	Lean Soft Tissue	10.4(kg)	0.0(kg)
Phase Angle	7.6°	0.0°	Phase Angle	8.0°	0.0°

The same results and historical measurements for the patient's body composition results, including segmental results, may also be viewed in MySOZO.

8.6.6 Setting a Baseline

Selection of a baseline – a “normal score” for an individual patient – is the optimal way to track changes over time. To set a baseline, select the most appropriate measurement by date from the patient’s dashboard, and tap the button next to ‘set as baseline’:



For segmental measurements, each limb may have its own baseline set.

If an incorrect baseline is selected, simply select the correct measurement and baseline. For segmental measurements, separate baselines can be made for each limb.

For a given body composition output, an optimal baseline is typically taken when the patient, in a clinician's estimation, is in suitable good health. It may take some time to establish an appropriate baseline measurement for the patient.

8.6.7 Body Composition Parameters

At the conclusion of a measurement, the BodyComp Analysis module will present a screen containing a wide range of body composition information in the preferred units of measure (defined in the SOZOapp settings section). For patients who are being assessed for other clinical conditions, the body composition measurements may be utilised to provide additional data and guidance to the clinician.

8.6.7.1 Extracellular Fluid (ECF)

All the fluid that is not contained within the cells. ECF is usually expressed as a volume (litres or pints) and as a percentage of TBW. Reference ranges for ECF are based on internal ImpediMed data.

8.6.7.2 Intracellular Fluid (ICF)

All the fluid that is contained within the cell membranes of the body. ICF is usually expressed as a volume (litres or pints) and as a percentage of TBW. Reference ranges for ICF are based on internal ImpediMed data.

8.6.7.3 Total Body Water (TBW)

All the water within a person's body, including both intracellular and extracellular fluid. This is expressed as a volume (litres or pints) or a percentage of total mass (e.g. 60% of mass is TBW). Reference ranges for TBW are based on internal ImpediMed data.

8.6.7.4 ECF & ICF Distribution

The ratio of ECF and ICF, expressed as a percentage each of TBW (e.g. ICF 60% and ECF 40%). Changes in the ratio, particularly increases in ECF compared to previous ECF & ICF ratios, can be indicative of disease, malnutrition, inflammation, etc.

8.6.7.5 Fat Mass (FM)

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). Reference ranges for FM are based on modified ranges established by the American College of Sports Medicine 2017 "ACSM's Health-Related Physical Fitness Assessment".

8.6.7.6 Fat-Free Mass (FFM)

The amount of mass a person has that contains no fat. FFM includes bone, organs, body water, and the lean soft tissue elements of muscle and connective tissue. FFM is typically measured in mass (kg or lb) or expressed as a percentage of total mass (e.g. 60% fat free mass). In the segmental measurement assessment, the lean soft tissue elements alone are presented.

8.6.7.7 Protein and Minerals

The human body utilises proteins and minerals as “building blocks”. Protein and minerals can be thought of as Fat-Free Mass minus total body water, or “dry-lean mass.” This is expressed as a weight (kg or lb) and a percentage of total mass.

Note: This estimate may not factor in 1-2% of an individual’s total body weight, comprised of carbohydrates.

8.6.7.8 Skeletal Muscle Mass (SMM)

This 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). Reference ranges for SMM were established based on data presented in Janssen (2000)⁷.

8.6.7.9 Basal Metabolic Rate (BMR)

Amount of energy used by a person’s body when at rest. ImpediMed uses the Mifflin-St. Jeor equation to calculate BMR. Expressed in calories per day.

8.6.7.10 Phase Angle

The arctangent of reactance divided by resistance at 50 kHz frequency. Plotted as a vector, and is presented on a scale from 0-10 and is expressed as a degree. (e.g. 8.5°). Reference ranges for Phase Angle were established based on data presented in Bosy-Westphal (2006)⁸.

⁷ Janssen I et al, “Skeletal muscle mass and distribution in 468 men and women aged 18-88 yr.” J Appl Physiol 89:81-88.

⁸ Bosy-Westphal A et al, “Patterns of bioelectrical impedance vector distribution by body mass index and age: implications for body-composition analysis” Am J Clin Nutr 2005;82:1358.

9 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.

9.1 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.

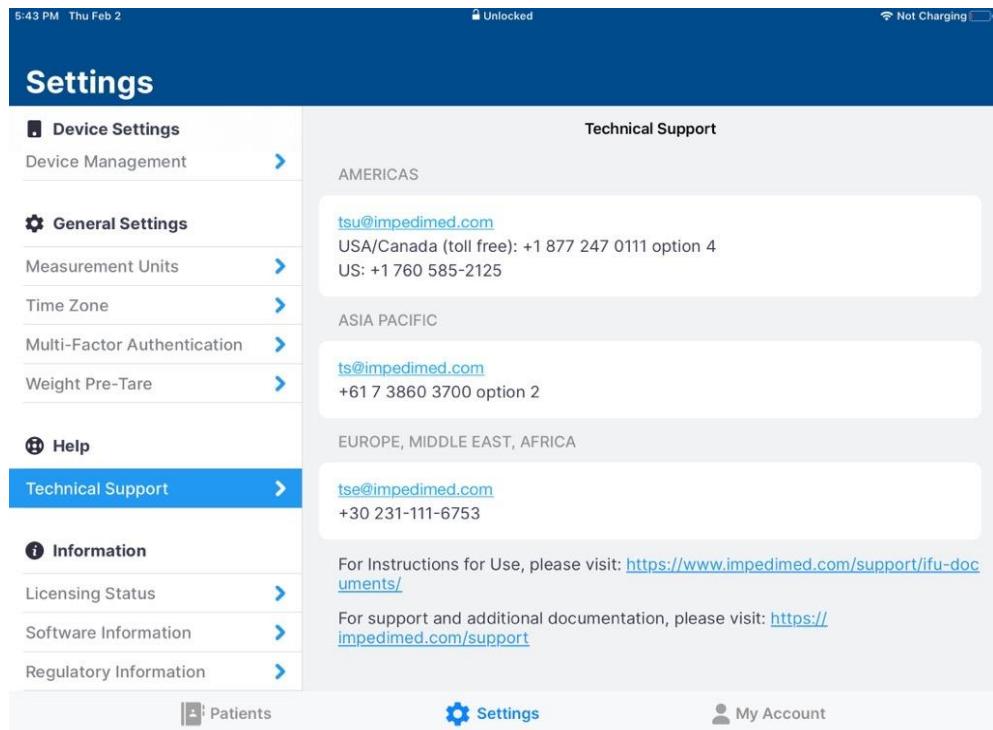
Users may be assigned both Administrator and Clinician roles, and access both functions from the same sign in. The Admin icon is bold and underlined if the user is signed in as an Administrator. If an Administrator also has the Clinician role, they can toggle between Administrator and Clinician screens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

The banner icons enable common administrative functions.

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	jbabbott@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Baker	Ingo	ibaker@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	ADMIN CLINICIAN
Campbell	David	dcampbell@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

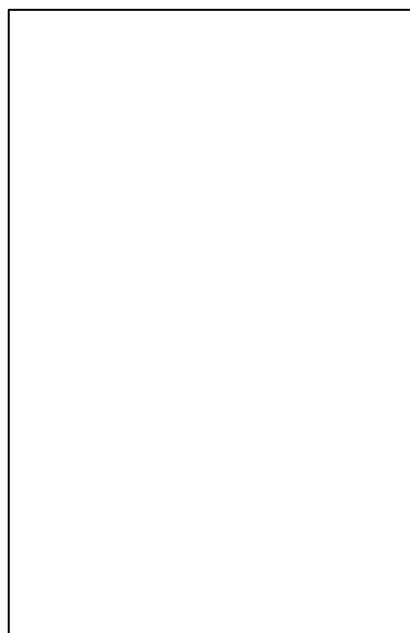
9.1.1 Help Icon

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



9.1.2 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”.

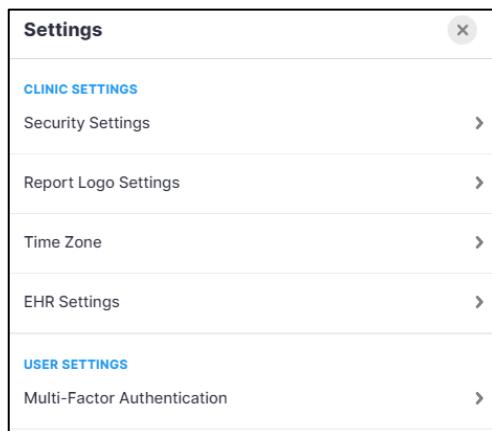
Software Information: Displays current mySOZO version and if it is up to date. There is also an option to Update if required. The administrator password will be required to Update. Release notes for current and previous versions are also listed.

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

9.1.3 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.

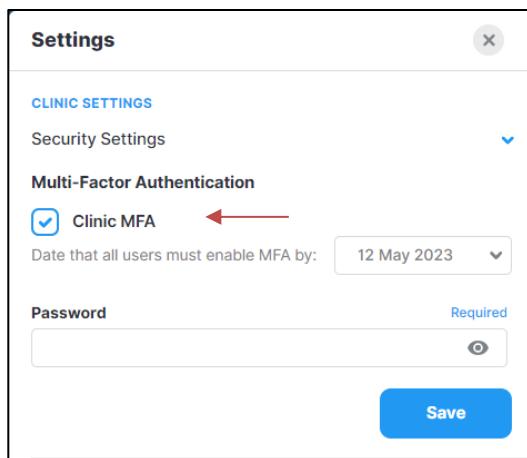


9.1.3.1 Security Settings

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 the Administrator role to configure Single Sign-On (SSO) or Multi-Factor Authentication (MFA) as additional security measures.

9.1.3.1.1 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.



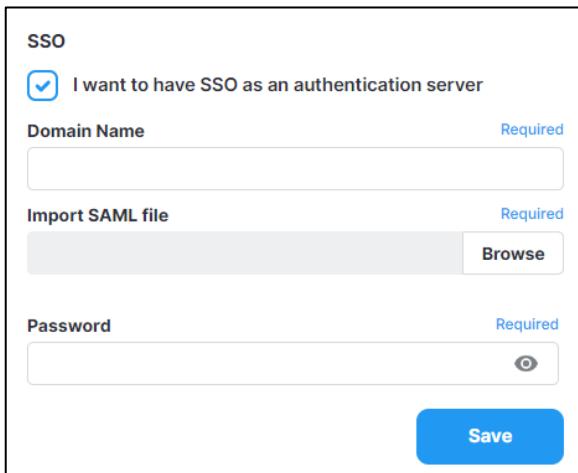
To turn MFA on, the Administrator will need to check Clinic MFA under Security Settings, enter an enable by date, their password and click Save.

Once enabled, MFA will require use of a code generated by a 3rd 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).

9.1.3.1.2 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.



The form is titled 'SSO' and contains the following fields:

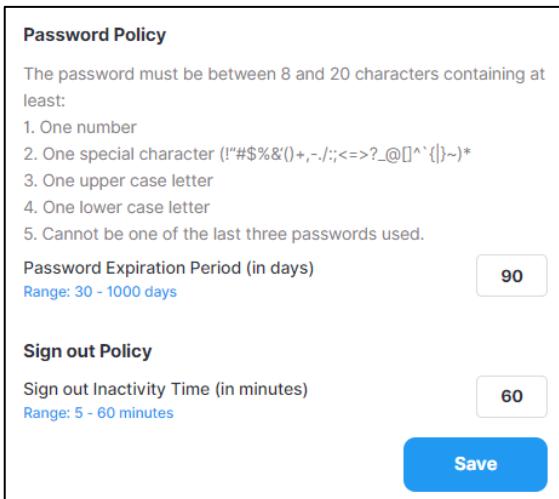
- A checked checkbox labeled 'I want to have SSO as an authentication server'.
- A 'Domain Name' input field with the label 'Required' to its right.
- An 'Import SAML file' input field with a 'Browse' button to its right and the label 'Required' to its right.
- A 'Password' input field with an 'eye' icon to its right and the label 'Required' to its right.

A blue 'Save' button is located at the bottom right of the form.

9.1.3.1.3 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.



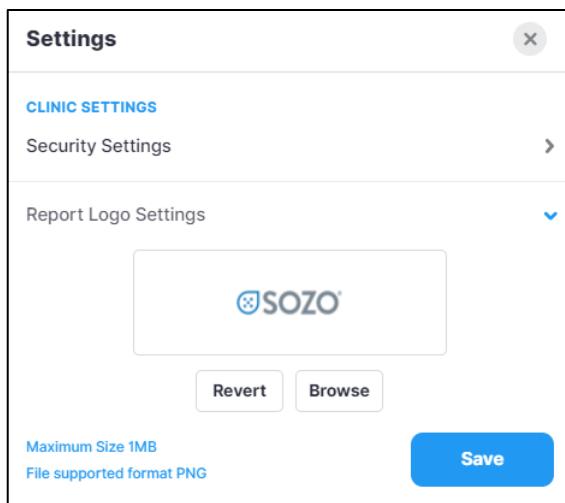
The form contains two main sections:

- Password Policy:** Describes the password requirements: must be between 8 and 20 characters containing at least one number, one special character, one upper case letter, one lower case letter, and cannot be one of the last three passwords used. It also includes a 'Password Expiration Period (in days)' input field set to 90, with a range of 30 - 1000 days.
- Sign out Policy:** Describes the sign out inactivity time: must be between 5 and 60 minutes. It includes a 'Sign out Inactivity Time (in minutes)' input field set to 60, with a range of 5 - 60 minutes.

A blue 'Save' button is located at the bottom right of the form.

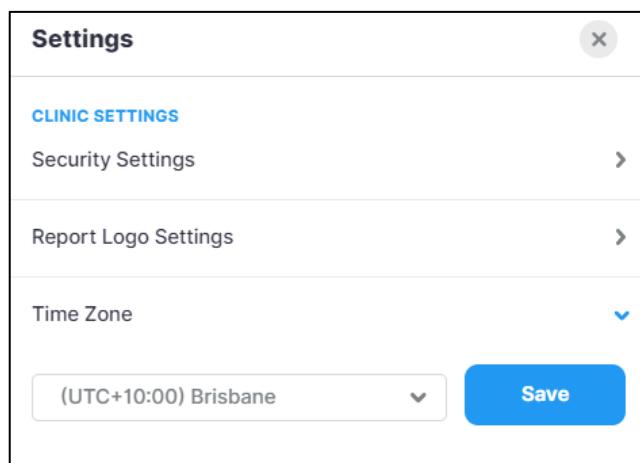
9.1.3.2 Report Logo Settings

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.



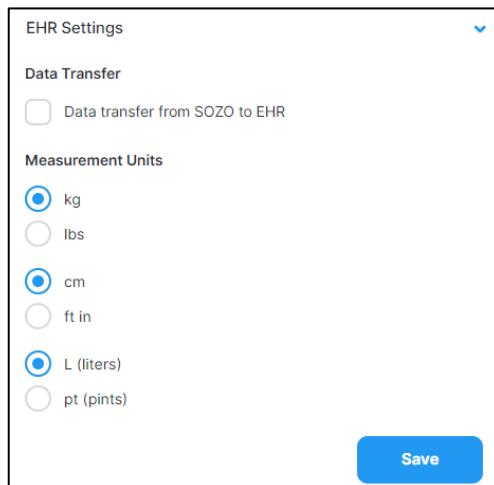
9.1.3.3 Time Zone

The Clinic Administrator can select the correct time zone here.



9.1.3.4 EHR Settings

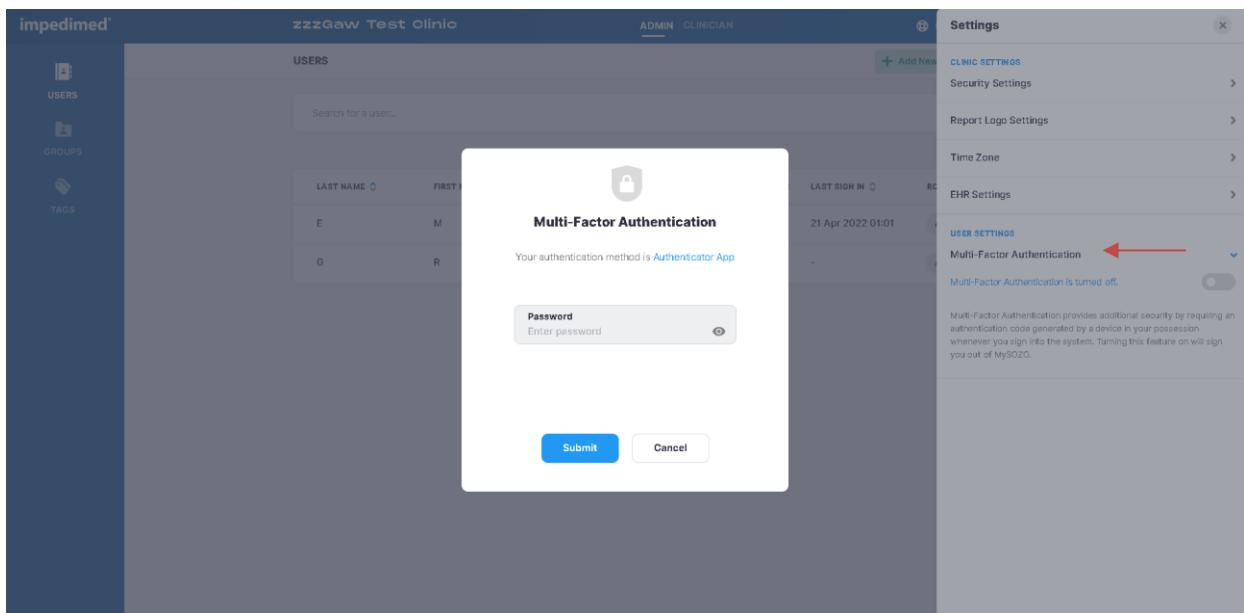
The Clinic Administrator can work with ImpediMed Technical Support during MySOZO setup or contact ImpediMed Technical Support after the system has been installed, to set up the EHR Interface Settings. Full EHR interface configuration will require additional set-up outside of MySOZO to complete.



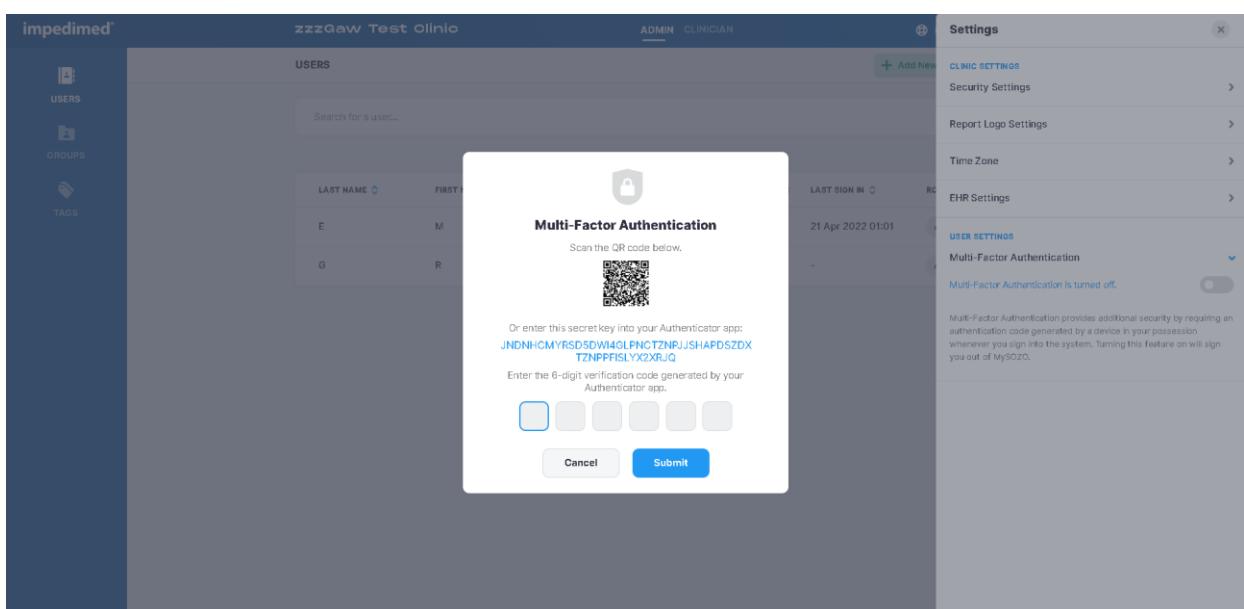
After the EHR interface has been established, the Clinic Administrator can start data transfer to an electronic health record by checking the data transfer box and select the measurement units for the transfer. Contact ImpediMed Technical Support for further details.

9.1.3.5 User Multi-Factor Authentication

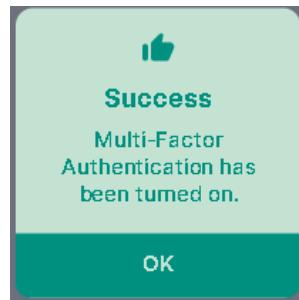
Once enabled by a Clinic Administrator (see Administrator Multi-Factor Authentication), MFA will require use of a code generated by a 3rd party authenticator app (e.g. Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is set up, activate 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.

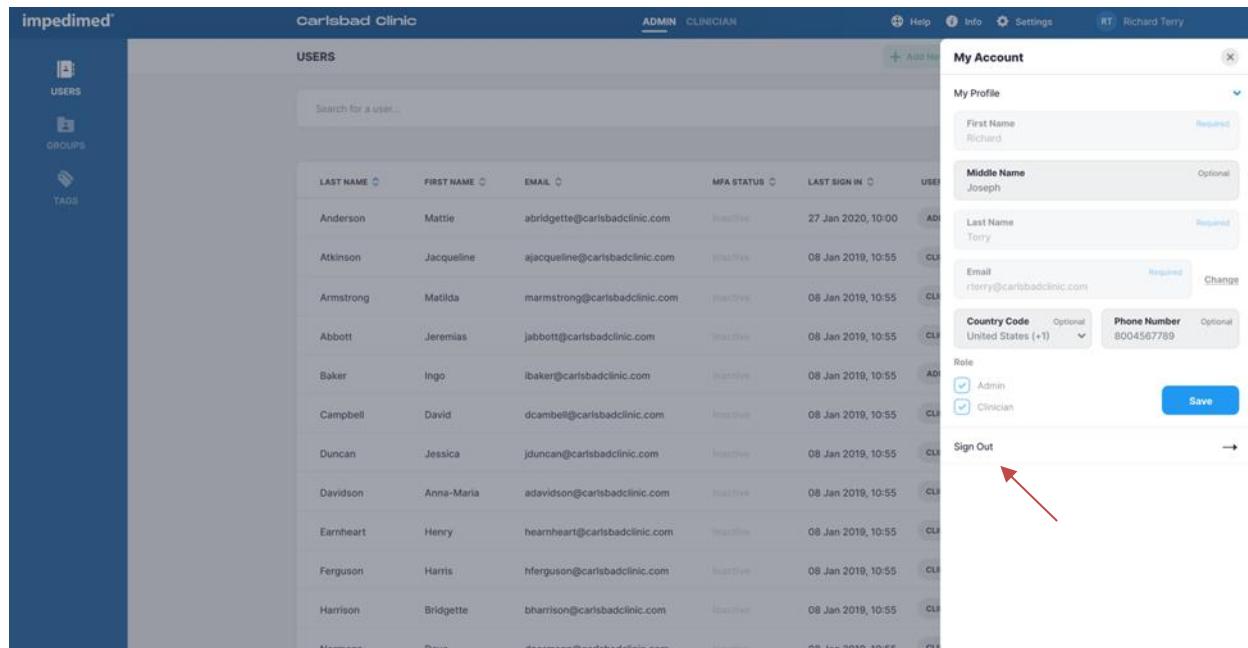
9.1.4 Administrator User Profile Icon

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



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

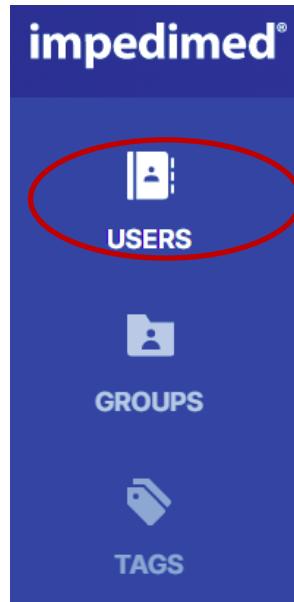
To sign out of MySOZO at any time, click the User Profile icon then click the **Sign Out** option in the menu.



The screenshot shows the 'Users' page for the 'Carlsbad Clinic' organization. The left sidebar has 'impedimed' at the top, followed by 'USERS' (selected), 'GROUPS', and 'TAGS'. The main content area shows a table of users with columns: LAST NAME, FIRST NAME, EMAIL, MFA STATUS, LAST SIGN IN, and USER. The table lists 14 users. The right sidebar is titled 'My Account' and contains the user profile for 'Richard Terry'. It includes fields for First Name (Richard), Middle Name (Joseph), Last Name (Terry), Email (rterry@carlsbadclinic.com), Country Code (United States (+1)), Phone Number (8004567789), and Role (Admin, Clinician). A 'Save' button is at the bottom. A red arrow points to the 'Sign Out' button at the bottom of the sidebar.

9.2 Administrator User List

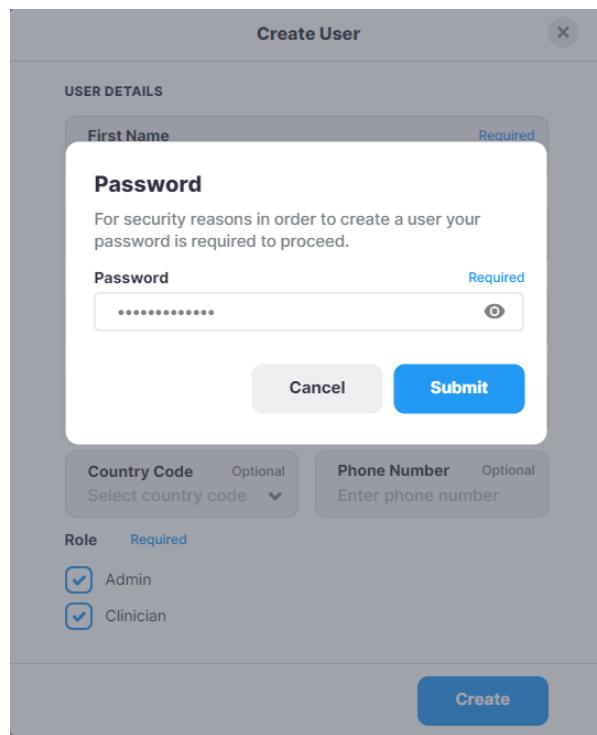
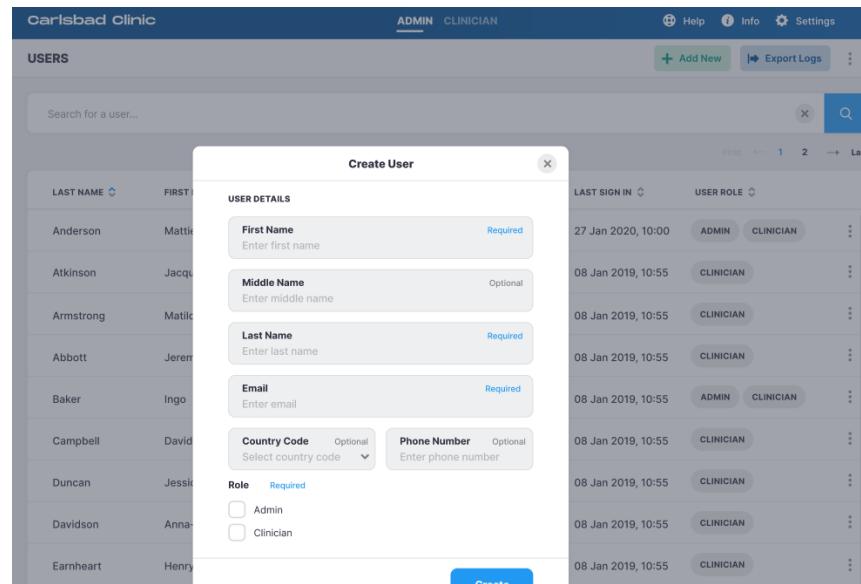
Click **USERS** at any time to return to the User List on the MySOZO Administrator home page.



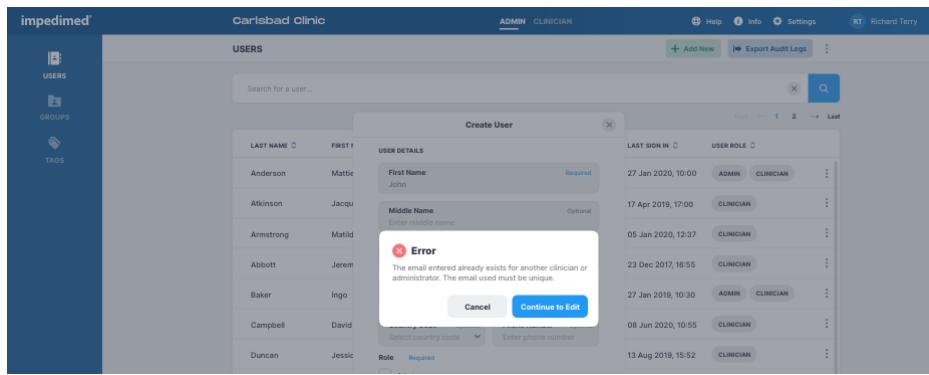
9.2.1 Create New User

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.



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.



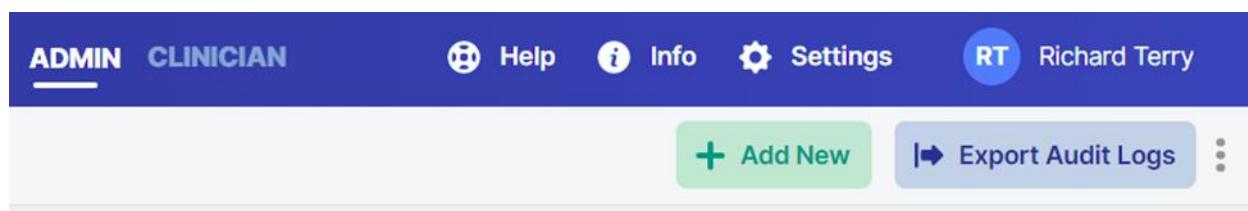
9.2.2 Audit Logs

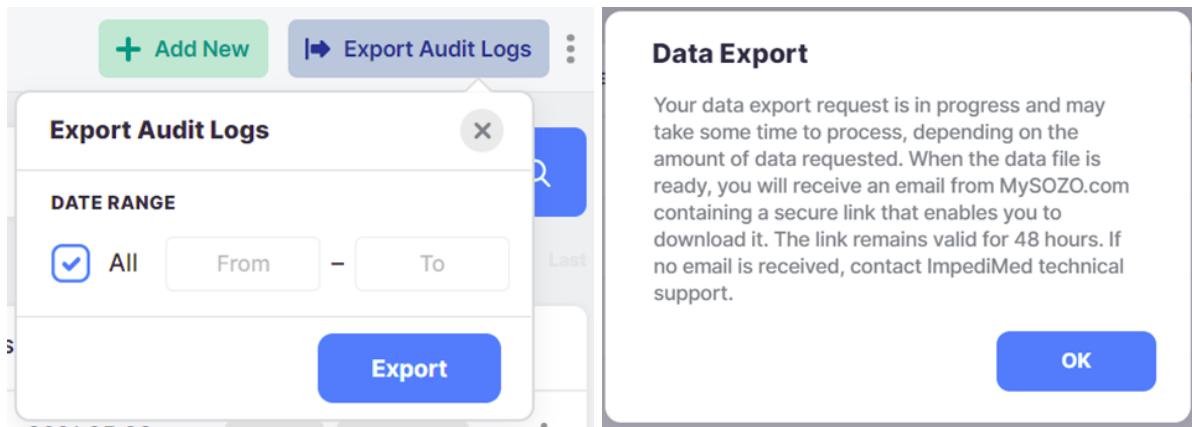
A user with Administrator role may access audit logs of all system access and events, to assist in any audit or investigation. Audit logs may be exported directly from MySOZO.

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.

9.2.3 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.

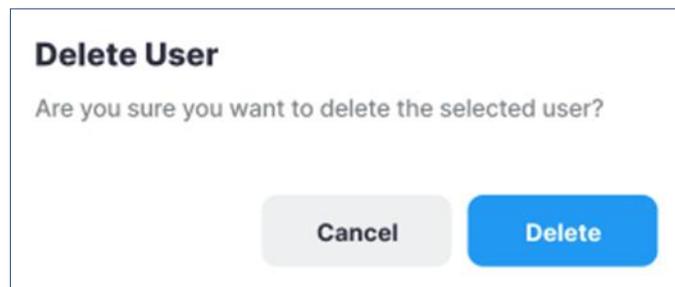
Note: only an Administrator may edit a user's email address. A Clinician may edit their own email address but does not have authority to change another user's email address.

The screenshot shows the Carlsbad Clinic software interface. At the top, there are tabs for 'ADMIN' and 'CLINICIAN'. On the right, there are links for 'Help', 'Info', 'Settings', and a 'RT' button. Below the tabs, there is a 'USERS' section with a search bar and buttons for 'Add New' and 'Export Logs'. The main area displays a table of users with columns for 'LAST NAME' and 'FIRST NAME'. A modal window titled 'User Profile' is open, showing 'USER DETAILS' for a user named Richard. The modal includes fields for 'First Name' (Required), 'Middle Name' (Optional), 'Last Name' (Required), 'Email' (Required, with a value of rterry@carlsbadclinic.com), 'Country Code' (Optional, set to United States (+1)), 'Phone Number' (Optional, with a value of 8004567789), and a 'Role' section with checkboxes for 'Admin' (checked) and 'Clinician' (checked). A 'Save' button is at the bottom of the modal. To the right of the modal, there is a table showing 'LAST SIGN IN' and 'USER ROLE' for various users, with a page navigation bar at the top right of the table.

9.2.4 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.

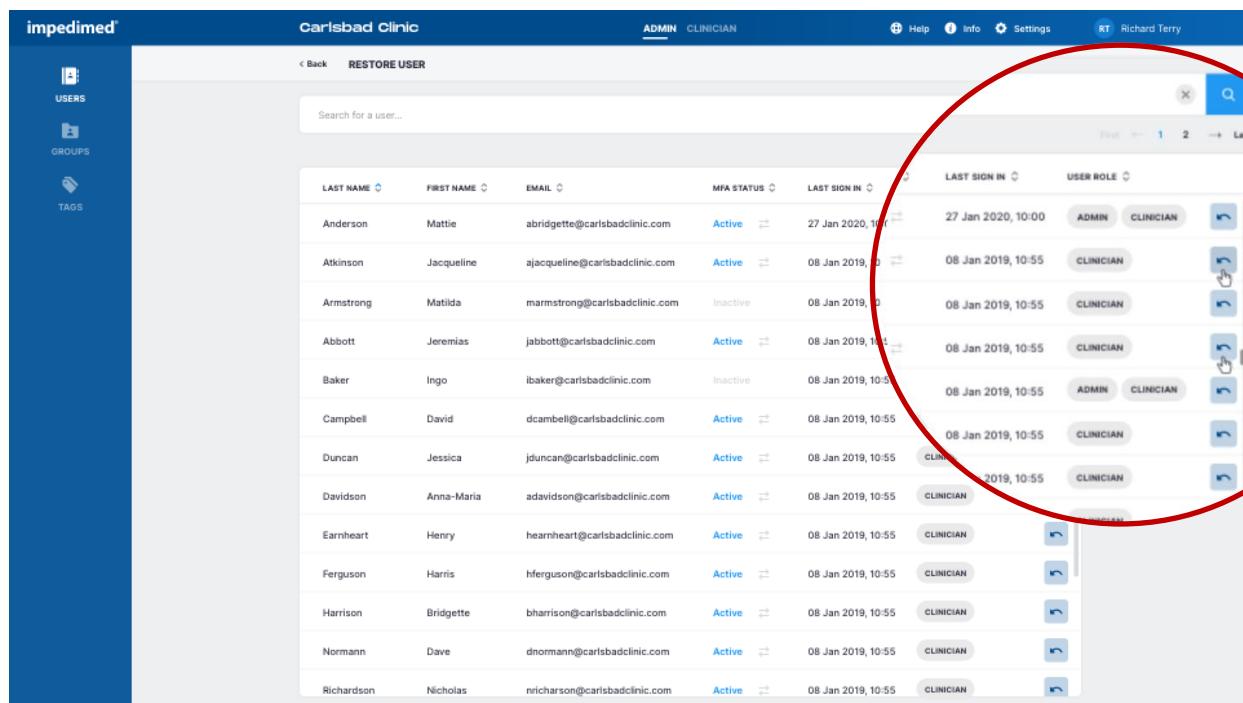


9.2.5 Restore User

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.

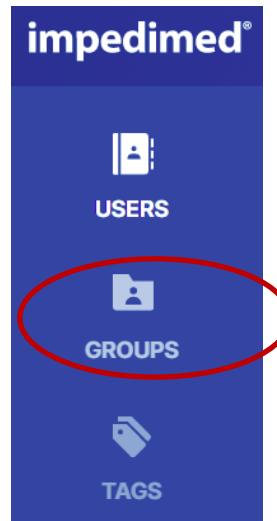


The screenshot shows the 'RESTORE USER' screen within the 'Carlsbad Clinic' application. The left sidebar has 'USERS' selected. The main area displays a table of users with columns: LAST NAME, FIRST NAME, EMAIL, MFA STATUS, LAST SIGN IN, and USER ROLE. A user named 'Richard Terry' is listed with a 'Restore' button in the last column. A red circle highlights this button. The table also shows other users like Anderson, Atkinson, Armstrong, Abbott, Baker, Campbell, Duncan, Davidson, Eamheart, Ferguson, Harrison, Normann, and Richardson, each with their respective details and role assignments.

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	ibaker@carlsbadclinic.com	Inactive	08 Jan 2019, 10:55	ADMIN CLINICIAN
Campbell	David	dcampbell@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
Eamheart	Henry	heamheart@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

9.3 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:

A screenshot of the 'Groups' list screen. The top navigation bar shows 'Carlsbad Clinic', 'ADMIN' (selected), 'CLINICIAN', 'Help', 'Info', 'Settings', and a user profile 'Richard Terry'. On the left is a sidebar with 'USERS', 'GROUPS' (selected and highlighted in blue), and 'TAGS'. The main area is titled 'GROUPS' and shows a list of groups. A search bar at the top says 'Search for a group...'. Below the search bar are 12 group cards arranged in a 3x4 grid. Each card has a 'Group' icon, a name, a member count (e.g., '7 Members'), and edit/delete icons. In the top right corner of the main area, a 'New Group' dialog box is open. It has a 'GROUP NAME' field with 'Enter group name' placeholder text and a blue 'Add' button.

9.3.1 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.

9.3.2 Rename/Delete Group

To rename a Patient Group:

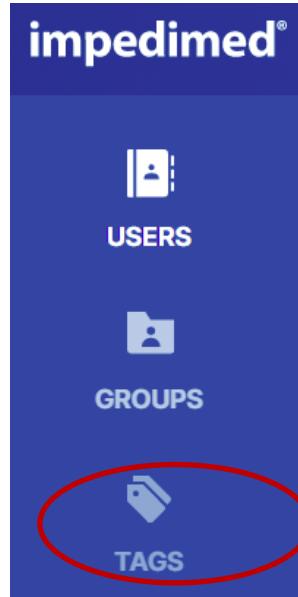
1. On the Groups List, click the **blue pencil** (edit icon) on the folder to be updated.
2. Update the Patient Group name.
3. Click the **blue disk** (save icon).
4. A success confirmation will appear in the top right corner.

To delete a Patient Group:

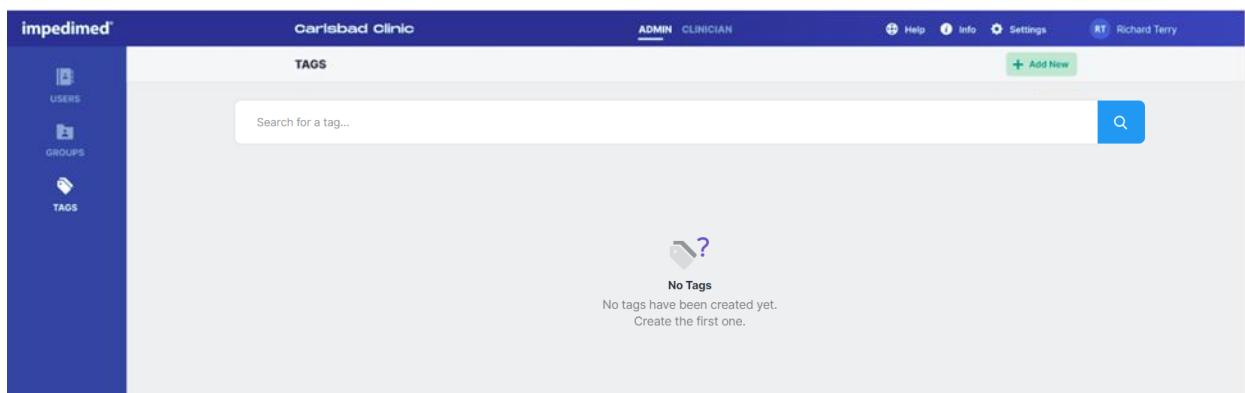
1. On the Groups List, click the **grey trash can** (delete icon) on the folder to be deleted.
2. A delete group warning will pop-up, select **Delete**.
3. A success confirmation will appear in the top right corner.

9.4 Administrator Patient Tags

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



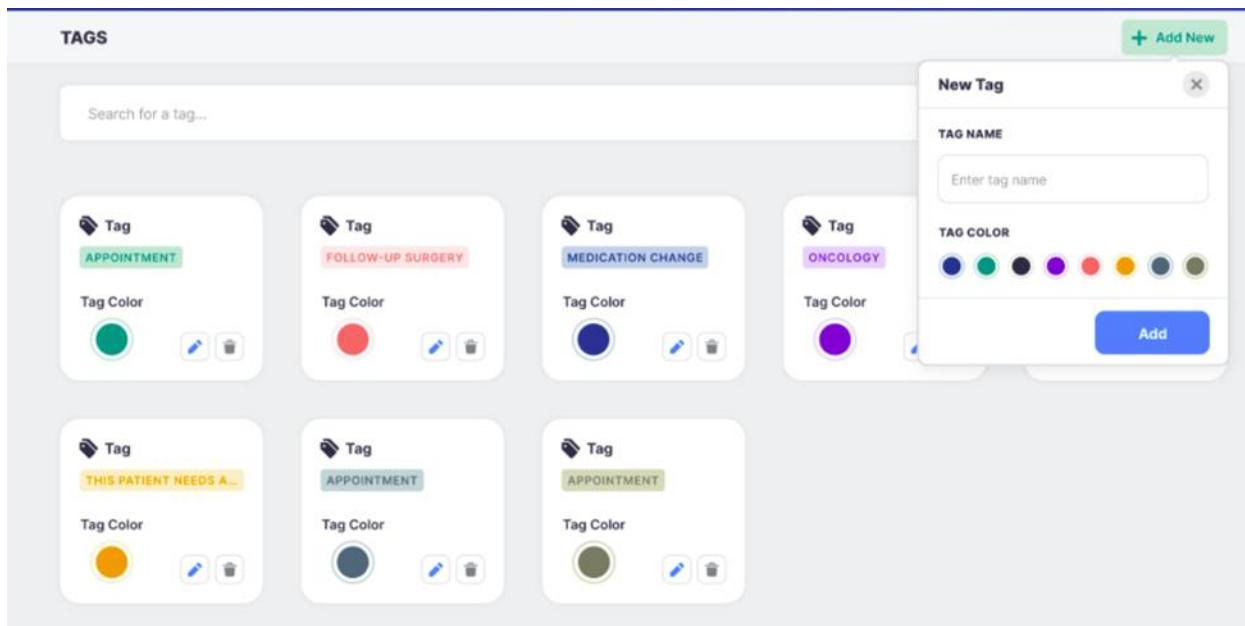
Tags are clinic-defined 48-character colour-coded objects that can be attached to a given measurement by a clinician. They allow additional information or notes to be linked to the measurement. The tags used within a clinic can only be managed by a user with an Administrator role from the Tags tab.



9.4.1 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 will appear below with the other tag folders.



9.4.2 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:

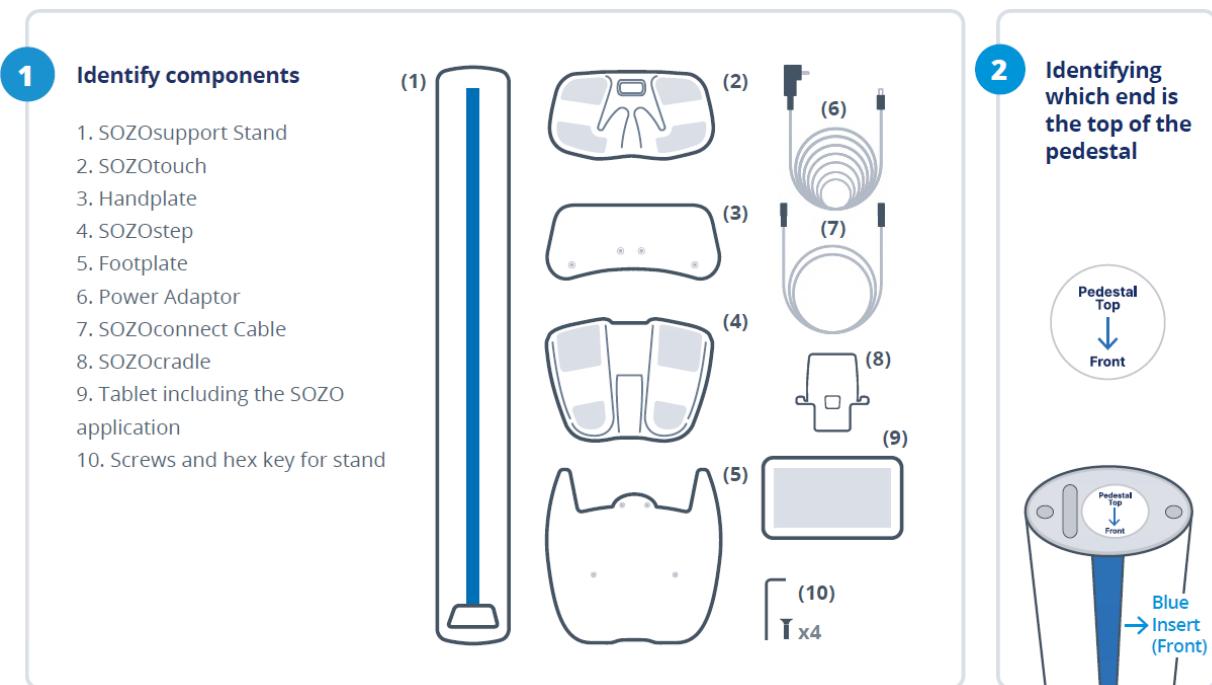
1. On the Tags List, click the **grey trash can** (delete icon) on the tag to be deleted.
2. A delete tag warning will pop-up, select **Delete**.
3. A success confirmation will appear in the top right corner.

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.

10 DEVICE ASSEMBLY

10.1 Identify SOZO® Device Components

Before assembly, identify the SOZO Device components shown below.



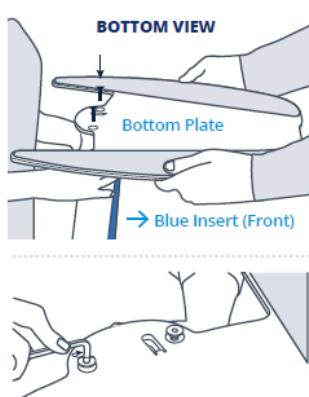
10.2 Assembling the SOZO® Device with SOZOsupport Stand

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).

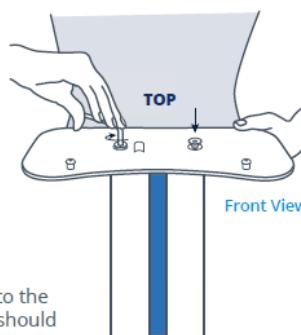


4 Screw the handplate (3) into the top of the SOZOsupport Stand (1).

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

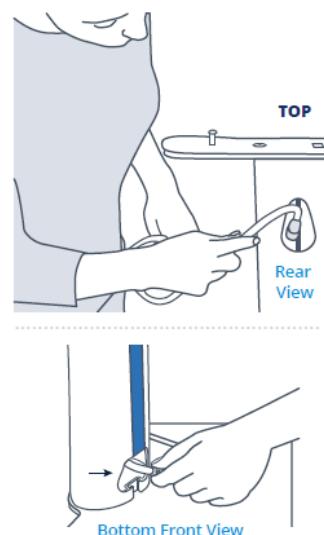
b. Using the hex key (10), attach the handplate with the remaining screws provided.

***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.



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

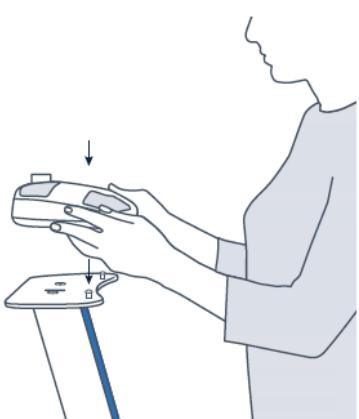
Feed the SOZOconnect cable through the droplet hole on the back of the stand and out the front hole at the base of the stand.



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

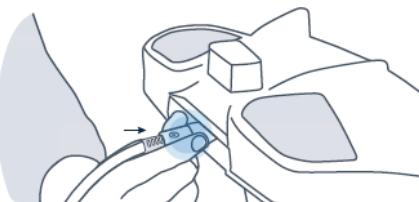
6 Attach the SOZOTouch (2) to the handplate (3).

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



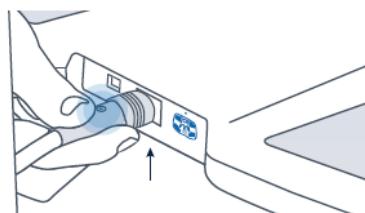
7 Attach the SOZOconnect cable (7) to the SOZOTouch (2).

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).

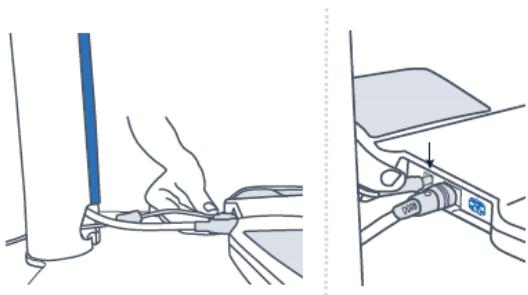
Ensure the screw on the connector cable is facing upwards before attaching it to the SOZOstep.



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

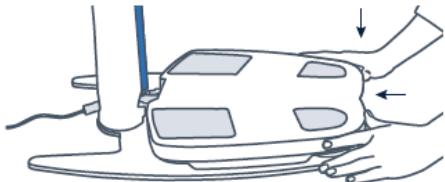
*NOTE: Ensure the SOZOconnect cable is plugged into both the SOZOtouch and SOZOstep before connecting the power cord to the SOZOstep.

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.

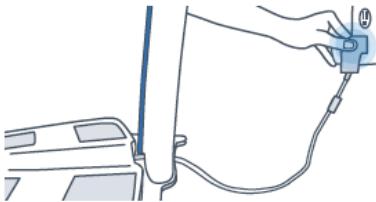


10 Attach the SOZOstep (4) to the footplate (5).

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



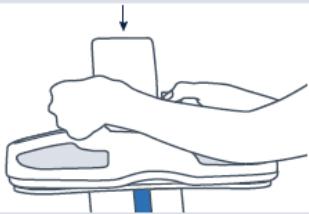
b. Once the SOZOstep is in place, plug the power cord into the wall.



*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.

NOTE:

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](#) 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 or contact ImpediMed [technical support](#).

10.3 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.

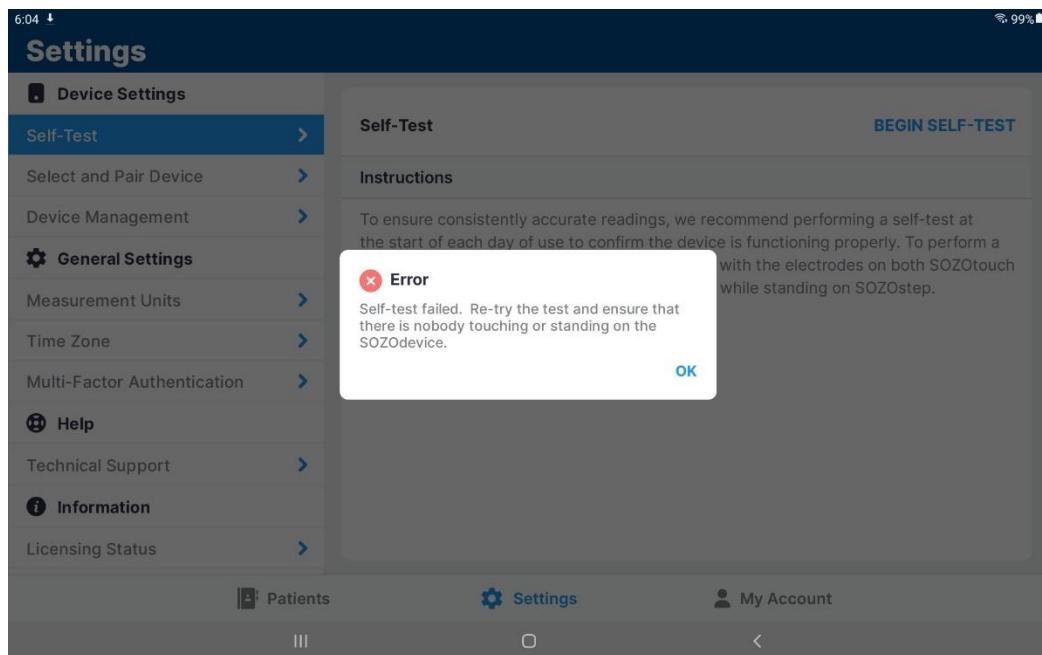
For more information on setting up the SOZO system without the SOZOsupport Stand, visit www.impedimed.com or contact ImpediMed [technical support](#).

11SOZOapp 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 11.6 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.



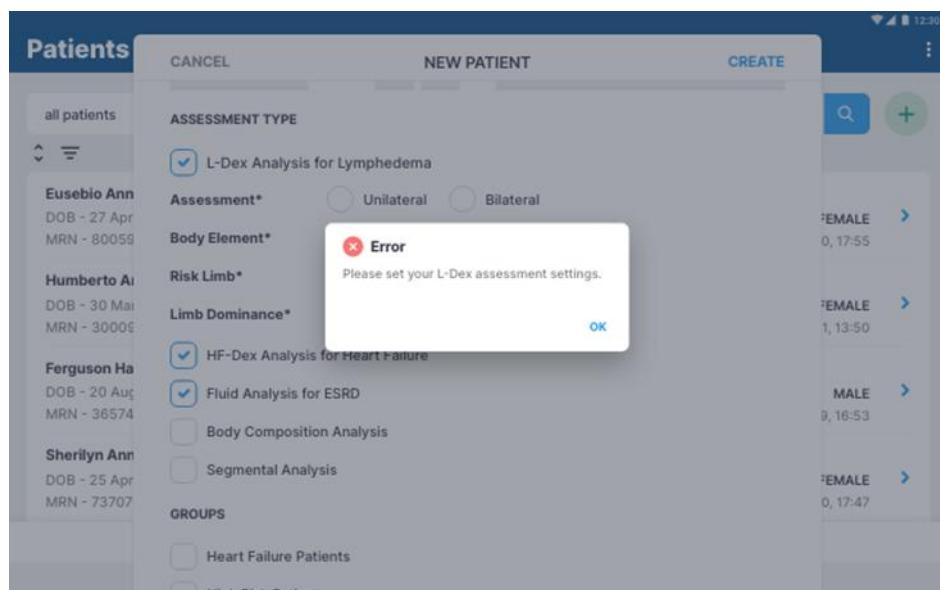
Try the below actions to resolve this issue:

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 Lymphoedema Settings Error

Editing Lymphoedema 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:

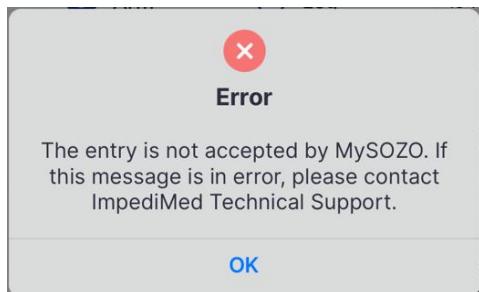
1. Under Lymphoedema Settings select Body Element, Risk Limb, and Limb Dominance.
2. Select save.
3. A success confirmation will appear in the top right corner.

Note: if Bilateral is selected as the Assessment Type, Left and Right are both automatically selected as the Risk Limb.

11.3 Bilateral arm selection

Version 4.1.0.3 and 5.0.0.1 of the MySOZO software, released in August 2023 contains an update to make unilateral L-Dex the sole assessment option for arms. L-Dex assessments for legs will not be impacted. When using MySOZO.com to edit patient lymphoedema settings, a user will not be able to select both bilateral and arms as a selection.

When using the SOZOapp, a user will be allowed to select bilateral and arms as a selection, but will get the following error message when attempting to save the patient profile:



Follow the below actions to resolve this issue. Confirm the risk profile of the impacted patients in MySOZO and:

- For patients at unilateral risk for lymphoedema (over 90% of breast cancer patients)⁹, confirm that the unilateral arm L-Dex assessment is selected in the patient profile and continue to screen for early signs of lymphoedema.
- For patients at bilateral risk for lymphoedema (3-10% of breast cancer patients)¹, guidelines suggest routine screening using clinical exam and symptom assessment.

⁹ Heron DE, et al. Risk factors and outcomes for patients with synchronous and metachronous disease. *Cancer* 2000;88(12):2739-50.

11.4 Patient Dashboard Error

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

- Go to the Settings icon.
- Select “Self-Test”. Run the Self-Test

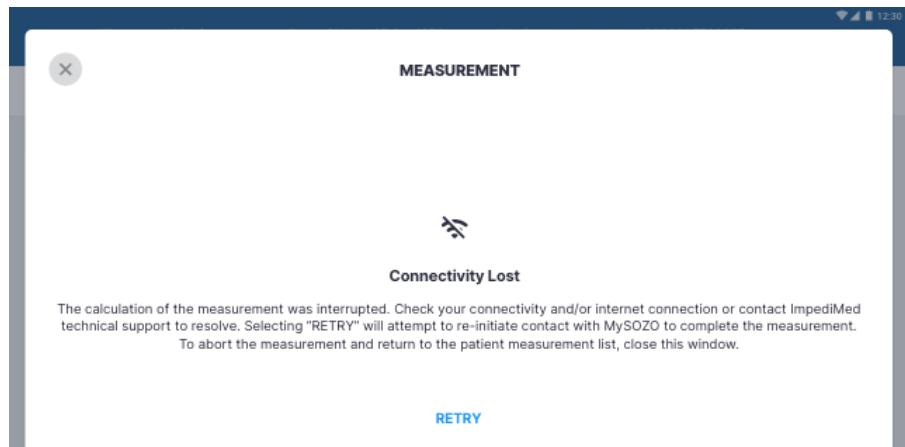


If the Self-Test fails, the actions below may resolve device issues:

- 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.

11.5 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.

11.6 General Troubleshooting Chart

The General Troubleshooting chart provides guidance for common issues and error messages. In the event that you need additional help, call +61 7 3860 3700 option 2, ImpediMed technical support, or you may email ImpediMed at ts@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 licence is not available.	Check the assessment types chosen for the patient and adjust accordingly. Check available licences and contact ImpediMed technical support if unable to resolve.
No SOZO Devices are selectable even after device is paired via Bluetooth.	Device is not licensed.	Check licence status. Contact ImpediMed technical support if licence 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 Forgot password link at mysozo.com . Enter the email address and an email will be sent to reset the 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.	On tablet select "Yes" and follow prompts to automatically update SOZOapp to latest version. If updates are blocked due to a mobile device manager or other software, contact ImpediMed Technical support for the latest version of the SOZOapp.

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 signed 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 SOZO Device chosen is available via Bluetooth by going to Settings > Select and 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.	<p>Check the patient settings to ensure that they are correct.</p> <p>Height, age, and L-Dex settings must match historical measurement records to have the same measurement results.</p>
"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 minimise 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.	<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>
When attempting to save the patient profile while in the SOZOapp, the following error message is shown: "The entry is not accepted by MySOZO. If this message is in error, please contact ImpediMed Technical Support"	Bilateral arms are selected as L-Dex Assessment type.	De-select Bilateral and/or arms. Section XX for further explanation.

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 email address is identical to an existing username/email.	Check the deleted users to see if the email was already used and restore the user. If no deleted user is found, use a different email. If a different email is not possible, contact ImpediMed technical support to determine where that email may already be in use.
“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 update firmware. 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

Read our privacy policy located at

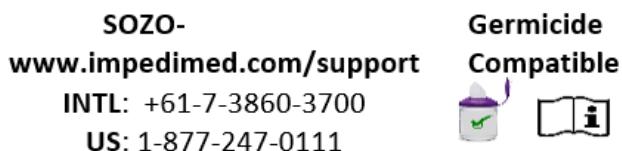
<https://www.impedimed.com/privacy-policy/>

13 CARE AND MAINTENANCE

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 Sporicidal Disinfectant and Cleaner for devices that do not display the following label 'Germicide Compatible.'



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

- Cavicide Liquid
- Cavicide 1 Liquid
- Cavicide 3 Liquid
- Caviwipes 1, Caviwipes XL
- Caviwipes 3, Caviwipes XL
- Clinell Universal Spray,
- Clinell Universal Wipes
- Sani-Cloth Prime
- Super Sani Cloth
- Super Sani Cloth Prime Wipes
- Sani Prime Liquid
- Medizar Wipes

SOZO Devices with the 'Germicide Compatible' label located on the right side of SOZOtouch may also be used with Electrode Spray :

- Signa Spray

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 authorised agent for repair.</p>
	<p>Do not attempt to sterilise 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 authorised 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/>

Asia Pacific Technical Support
+61 7 3860 3700, option 2
ts@impedimed.com

Europe, Middle East and Africa
+30 231-111-6753
tse@impedimed.com

Americas Technical Support
877-247-0111, option 4
760-585-2125
tsu@impedimed.com

13.7 Components and Accessories

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

Description
SOZOsupport Stand
SOZOconnect Cable
Power Adaptor
Tablet

14 PRODUCT WARRANTY

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

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

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

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

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

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

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

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

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

Consumables are excluded from the device warranty.

15REGULATORY STATEMENT

FCC ID: QOQBT121

This device complies with Part 15 of the FCC Rules

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

This device complies with the R&TTE Directive.

PRODUCT SPECIFICATIONS

Drive AC current	200 micro Amps RMS at a variable frequency of 3 kHz to 1000 kHz.
Frequency Scan	3 to 1000 kHz (256 frequencies) Scan speed: ~30 seconds to complete a full scan (Android), ~45 seconds (iOS).
Power Supply	24V DC, 1.0A
Dimensions	Hand Plate L=330mm, W=180mm, D=170mm Foot Plate L=450mm, W=320mm, D=40mm
Effective Radiated Power (BT Module)	-18 dBW
Weight	SOZO Device: 10.0 lb/4.5 kg SOZOsupport Stand: 25.5 lb/11.6 kg
Data Displayed	Cole resistance-reactance plot, other outputs dependent on measurement module.
Environmental transport, and storage conditions	- 25 °C without relative humidity control; and + 70 °C at a relative humidity up to 93%, non-condensing;
Environmental operating conditions	a temperature range of + 5 °C to + 40 °C a relative humidity range of 15% to 93%, non-condensing; and an atmospheric pressure range of 700 hpa to 1060 hpa.
Device (IEC 60601-1) electrical classification	Type BF 
Electromagnetic Compatibility	Meets the requirements of IEC 60601-1-2 and 60601-1-11.
Minimum service life of device and accessories	Minimum service life and associated warranty of parts and accessories is one year.

16SAFETY INFORMATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The SOZO Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SOZO Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	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.
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 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	4 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Voltage Dips/Dropout IEC 61000-4-11	<p>>95% Dip for 0.5 Cycle</p> <p>60% Dip for 5 Cycles</p> <p>30% Dip for 25 Cycles</p> <p>>95% Dip for 5 Seconds</p> <p>-----</p> <p>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>>95% Dip for 0.5 Cycle</p> <p>60% Dip for 5 Cycles</p> <p>30% Dip for 25 Cycles</p> <p>>95% Dip for 5 Seconds</p> <p>-----</p> <p>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 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms (Outside ISM) 6Vrms (In ISM and amature Bands) 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	(V1) = 3Vrms (V2) = 6Vrms	Portable and mobile communications equipment should be separated from the «Model» by no less than the distances calculated/listed below: $D=(3.5/V1)(\text{Sqrt } P)$ $D=(12/V2)(\text{Sqrt } P)$ $D=(12/E1)(\text{Sqrt } P)$ 80 to 800 MHz $D=(23/E1)(\text{Sqrt } P)$ 800 MHz to 2.7 GHz where P is the max power in watts and D is the recommended separation distance in metres. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Radiated RF IEC 61000-4-3			

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

5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5500						
5785						

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

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

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz Non-ISM $D=(3.5/V1)(\sqrt{P})$	Separation (m) 150kHz to 80MHz ISM $D=(12/V2)(\sqrt{P})$	Separation (m) 80 to 800MHz $D=(12/E1)(\sqrt{P})$	Separation (m) 800MHz to 2.7GHz $D=(23/E1)(\sqrt{P})$
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

17GLOSSARY

Administrator-MySOZO User authorised 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®, HF-Dex™, ESRD, BodyComp and Segmental BodyComp Analysis.

Assessment licence-ImpediMed grants a separate licence 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 licence is viewable in MySOZO and the SOZOapp.

At-risk limb-The limb at risk of developing lymphoedema.

Bilateral-A type of L-Dex Assessment for a patient who has both legs at risk of lymphoedema. The SOZO system compares each leg with each arm.

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.

Body Composition 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 Section.

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 authorised 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 lymphoedema, if the right arm is at-risk of lymphoedema, 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 (litres 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.

ESRD – End Stage Renal Disease.

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.

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 (litres 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 lymphoedema, SOZO compares R0 impedance of the at-risk limbs with the R0 impedance of the unaffected ipsilateral limbs. For example, if the patient has bilateral lymphoedema in both legs, the left

arm is the unaffected ipsilateral limb to the at-risk left leg, and the right arm is the unaffected ipsilateral limb to the at-risk right leg.

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

L-Dex®-The Lymphoedema 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 Section.

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

Licensed Assessments-Assessments for which a Clinic has purchased a licence.

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).

R_{inf}-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, Lenovo 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 (litres 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 lymphoedema.

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.