



SOZO System Instructions for Use



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For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed by email at ts@impedimed.com or by phone at + 61 7 3860 3700.

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

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

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USING THIS MANUAL

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 properly functioning.

Introduction to the SOZO System

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

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 from 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.

MINIMUM REQUIREMENTS

Device Hardware

The Tablet, either a Samsung Galaxy Tablet A, or an iPad, comes with the SOZO system and communicates with the SOZO Device using *Bluetooth*^{®1} technology.

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 and the Tablet user guide.

SOZOapp

The SOZOapp for Android is pre-installed on the Tablet. For customers choosing an iPad interface, contact ImpediMed Technical Support for download instructions. Note that screenshots throughout this Instructions for Use are based on the Android SOZOapp. The iPad SOZOapp screens will look nearly identical. Please note that instructions in this User Guide are for SOZOapp and MySOZO versions 4.0 and later. Not all functionality in later versions is present in earlier ones.

Software Access

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. For internet requirements, see [MySOZO](http://MySOZO.com).

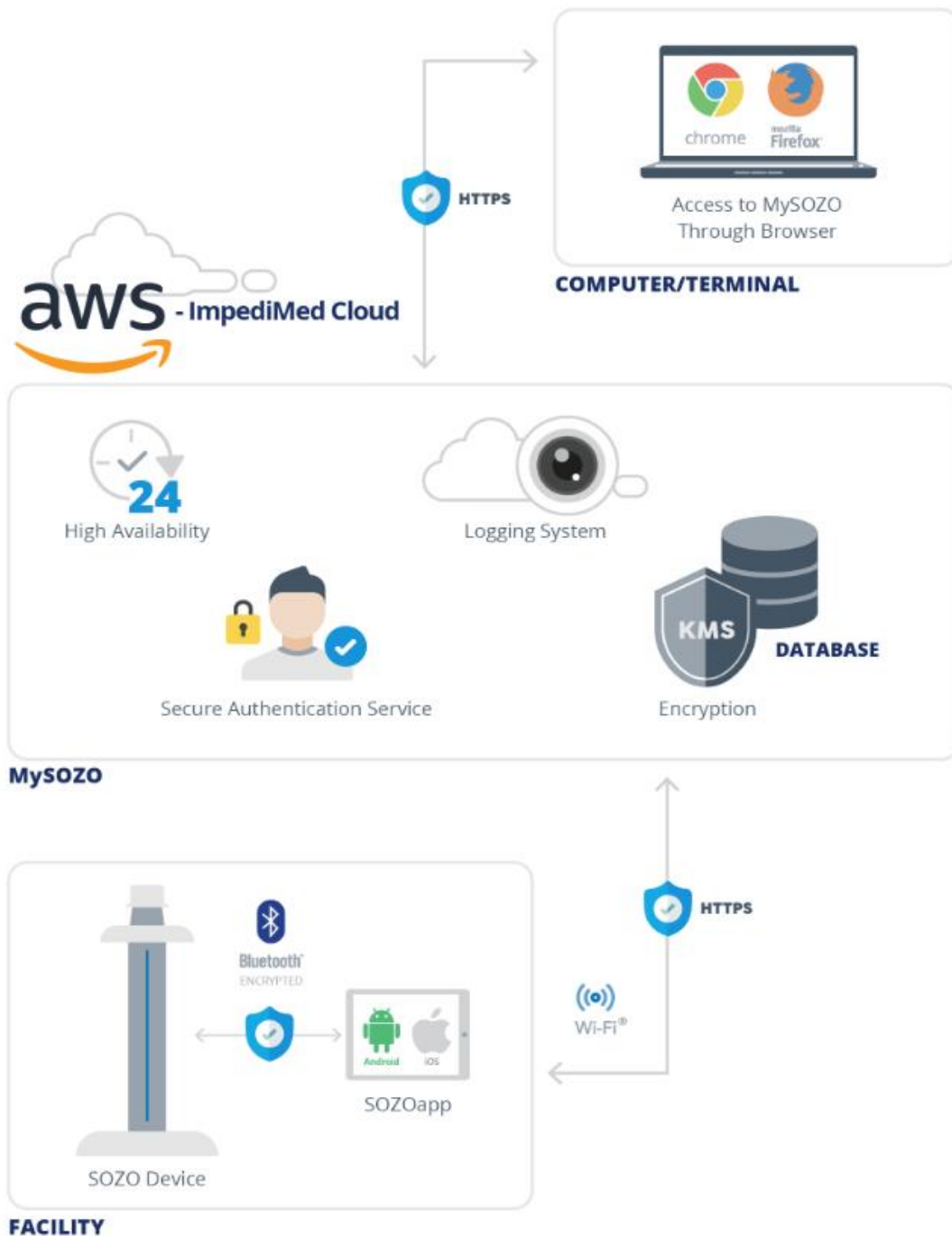
The minimum and recommended requirements for internet access are:

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 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.

SYSTEM OVERVIEW



The SOZO Device

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

The SOZO Device may assist with early detection of lymphoedema by giving an “early warning” of patient fluid status change. It may also be used to track fluid levels in patients living with heart failure. The SOZO system may be an integral part of a treatment plan for a lymphoedema and heart failure patient. Using the SOZO system, a Clinician may also track patient progress, including using the establishment of a baseline to track patient historical measurements.[1]

All other patients may also benefit from the SOZO Body Composition and Segmental 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).









Assessment Licenses

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

SAFETY

Signs and Symbols

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

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

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.

Contraindications

The SOZO Device should not be used by:



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















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.

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 nebulizer. • 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.

Storage Conditions and Use

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.

Environmental Transport and Storage Conditions








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

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

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

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.
	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.
	Using the SOZO Device on carpet may cause static electricity, which could damage the equipment. If installing the SOZO Device on carpet is unavoidable, please use the SOZOsupport Stand, or an antistatic mat.
	Various environmental factors environment may interfere with the SOZO Device performance including: the effects of lint, dust, light (including direct sunlight), as well as pets, pests, or children. Example 3: 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.

DEVICE ASSEMBLY

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.

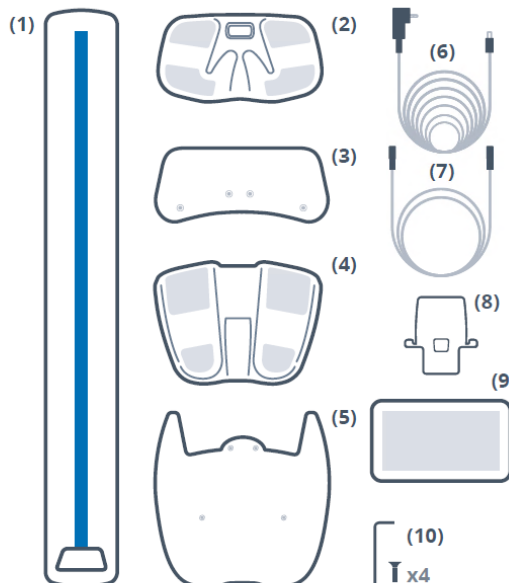
Identify SOZO Device Components

Before assembly, identify the SOZO Device components shown below.

1

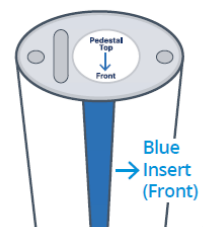
Identify components

1. SOZOsupport Stand
2. SOZotouch
3. Handplate
4. SOZOstep
5. Footplate
6. Power Adaptor
7. SOZOconnect Cable
8. SOZOcradle
9. Tablet including the SOZO application
10. Screws and hex key for stand



2

Identifying which end is the top of the pedestal

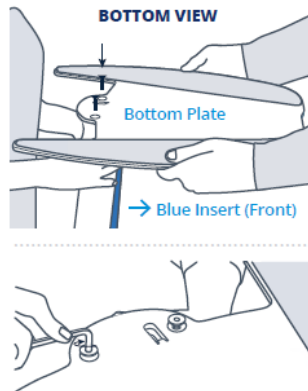


Assembling the Device

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

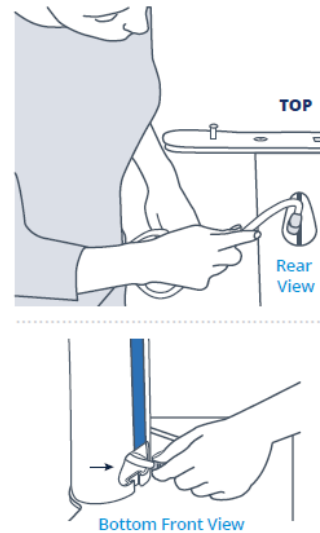
***NOTE:** It is recommended that two people take part in assembling the stand in order to make the process quicker, easier and safer.

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



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

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



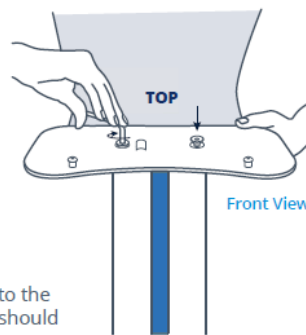
***NOTE:** The connector cable port is identical on both the hand plate and foot plate.

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

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

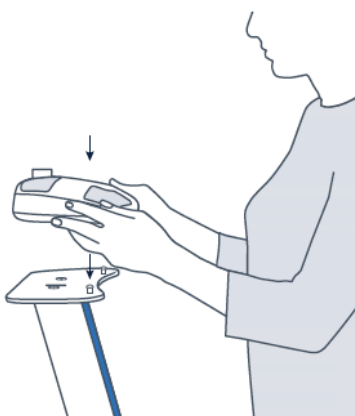
b. Using the hex key (10), attach the handplate with the remaining screws provided.

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



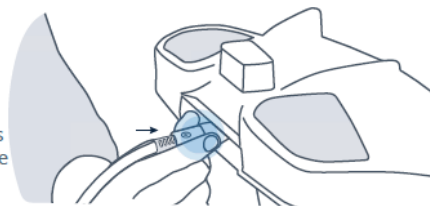
6 Attach the SOZotouch (2) to the handplate (3).

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



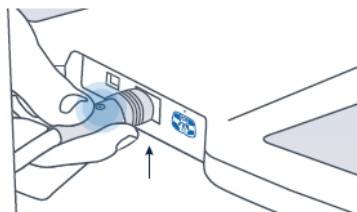
7 Attach the SOZOconnect cable (7) to the SOZotouch (2).

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



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

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

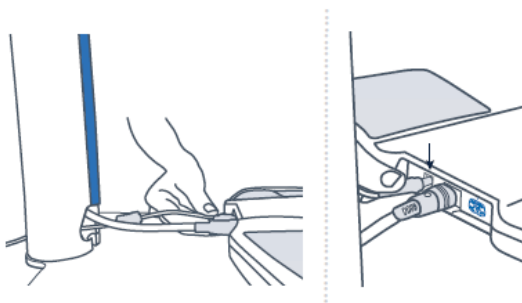


9

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

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

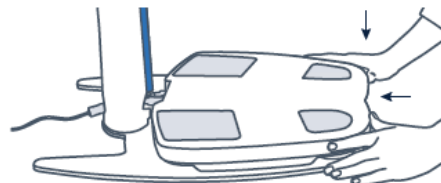
Locate the power supply port on the back of the SOZOstep. Feed the corresponding end of the power supply cable through the openings in the bottom of the stand and connect it into the port.



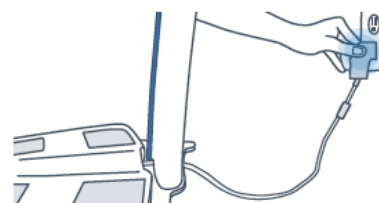
10

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

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



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

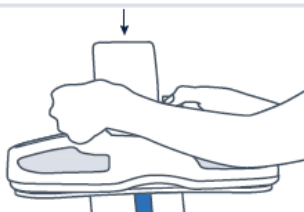


***NOTE:** Please ensure there is 4 inches or 10 centimeters between the backside of SOZOtouch and any wall.

11

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

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



12

Set-Up Complete.




NOTES:

For an easier process, have two people assemble the SOZOsupport Stand. The first person can hold the SOZOsupport Stand with the base upward while the second person holds the Footplate on the SOZOsupport Stand. The first person attaches the Footplate using the Hex Key.

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

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

Observe the following warnings while assembling the SOZO Device.

	Only use the Power Adaptor supplied with the SOZO Device. The use of any other Power Adaptor may expose the patient to the risk of electrocution.
	Ensure that the SOZOconnect Cable is plugged in to the Handplate and Foot plate before connecting the Power Cord. If the SOZO Device must be moved, ensure that the Power Cord is disconnected before moving or uninstalling the system.
	When plugging the Power Cord into the wall outlet, the SOZO system will automatically run a self-test to ensure functionality. Do not touch the stainless-steel electrodes when a self-test is running.

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

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 levelled 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.

NOTES:

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](#).

SETUP OF SOZO DEVICE COMPLETE.

Introduction to the MySOZO 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 you may begin using the SOZOapp on the Tablet or access MySOZO.com.
- After the Clinic receives and starts SOZO system setup, ImpediMed will establish the initial authorization and licenses and create the first Clinic Administrator.
- Once the initial Clinic Administrator has been created by ImpediMed, additional Administrators and Clinicians may be added by Clinic. All users, whether they are Administrators or Clinicians, are identified by their email address.

MySOZO Users (Administrators and Clinicians)

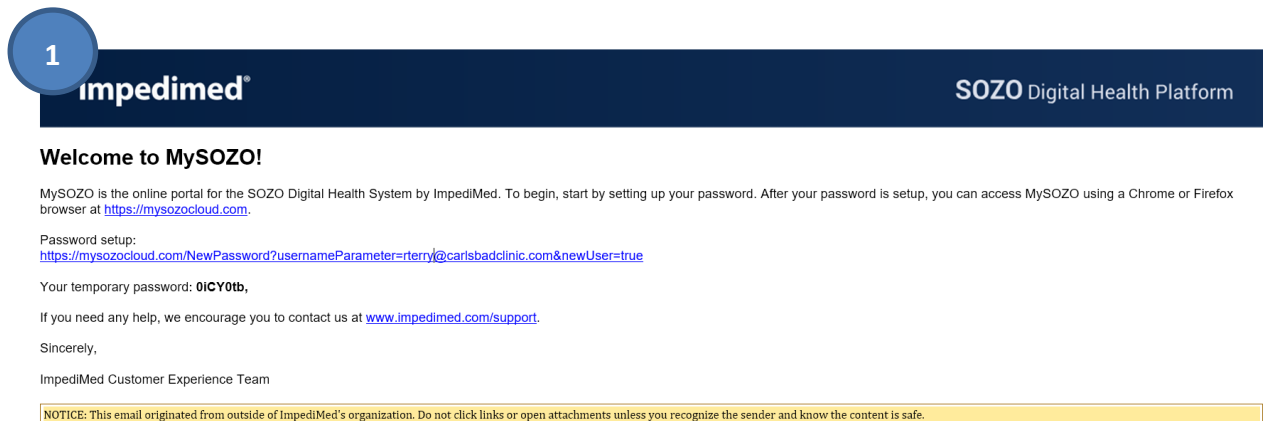
The below steps, including Login, password set-up, and reset for forgotten password or expiration, apply to all MySOZO users.

First Time Set-Up

1. New user Email
 - a. ImpediMed sends the user an email, as shown in example below, with a temporary password. In email, the user clicks Set Password.
2. Set New Password
 - a. After the user clicks the email link, the “Set New Password” screen appears. The user enters the Temporary Password that was provided in the email.
 - b. Ensure new password meets all letter and character requirements.
 - c. Set and confirm new password. Click submit.

NOTES:

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



2a

SOZO® Digital Health Platform

Set New Password

Email
rterry@carlsbadclinic.com

Temporary Password
Enter temporary password

New Password
Enter new password

Confirm New Password
Enter new password

Submit

Cancel

[Password Policy](#)

impedimed®

CE 2797

2b

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

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CE 2797

2c

SOZO® Digital Health Platform

Set New Password

Email
rterry@carlsbadclinic.com

Temporary Password

New Password

New Password

Your password has been successfully updated.

OK

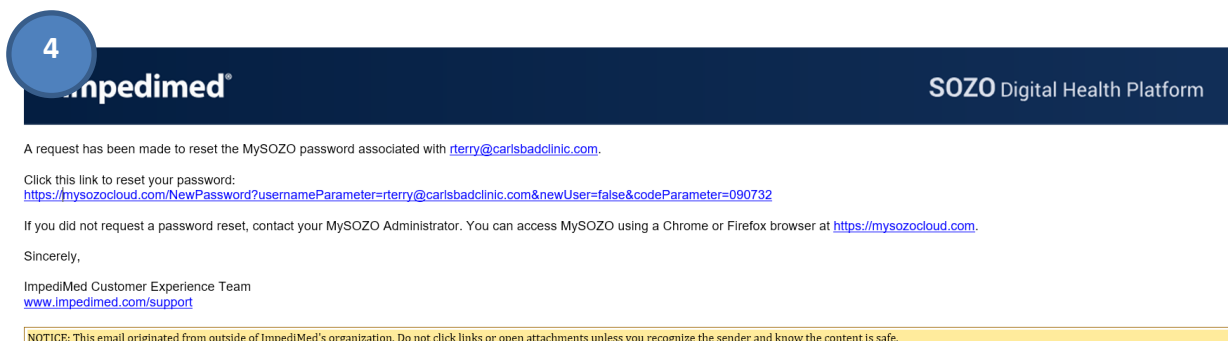
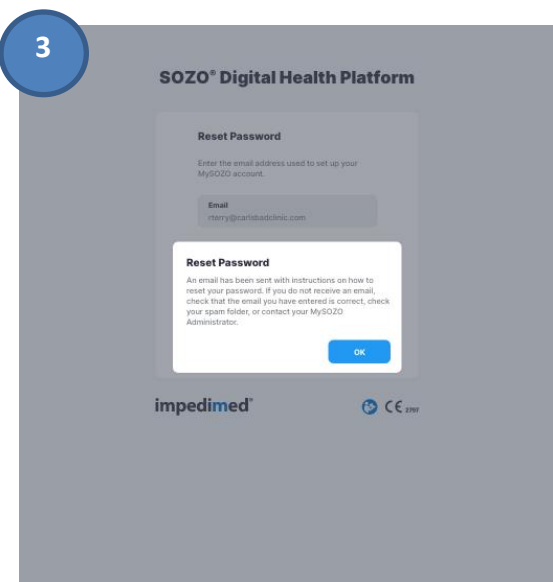
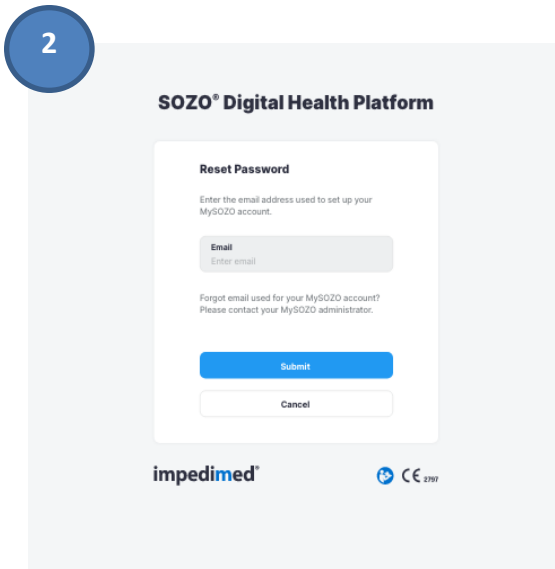
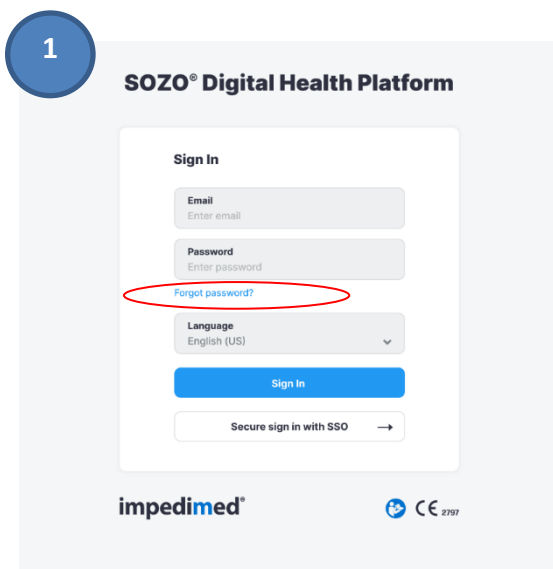
[Password Policy](#)

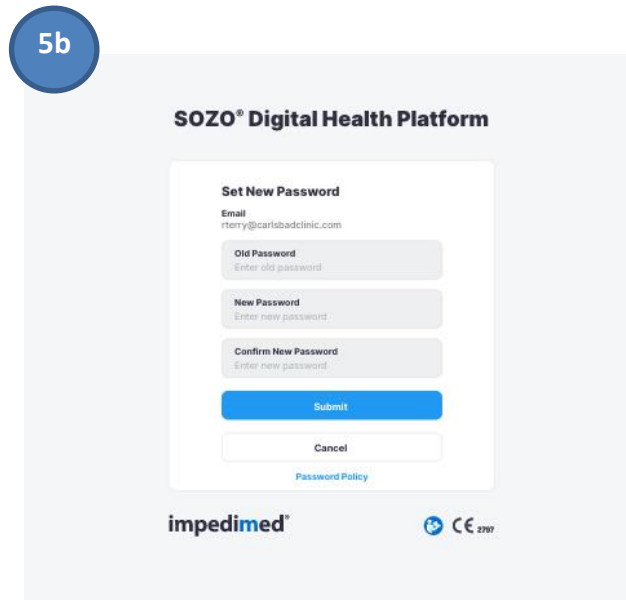
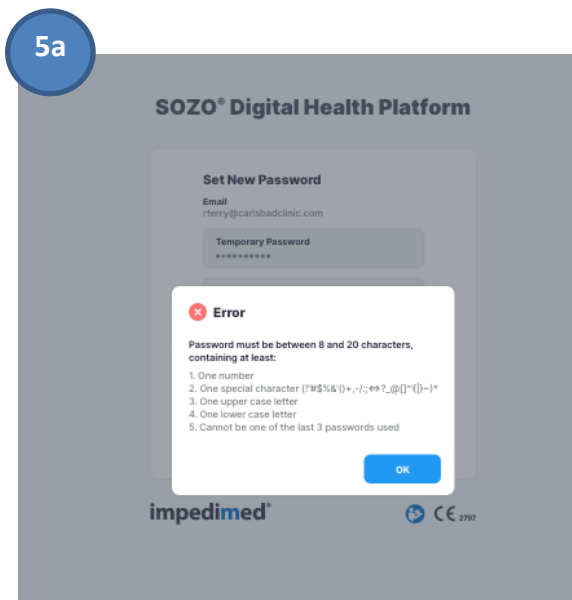
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Password Reset

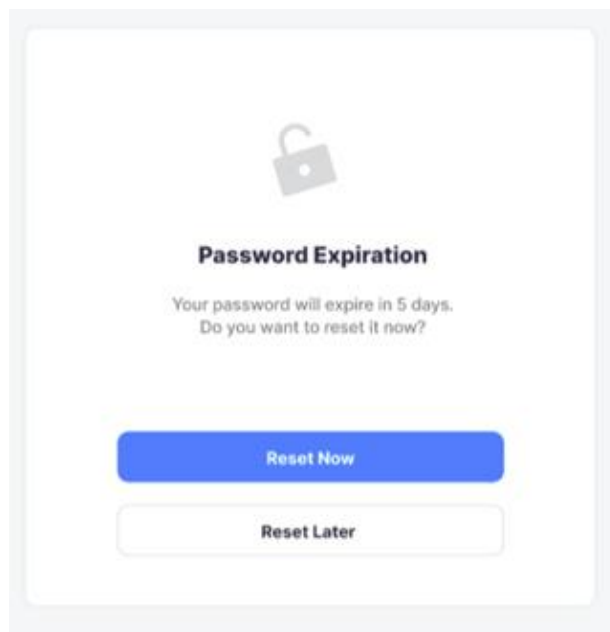
1. If the user is experiencing trouble signing in or have forgotten their password, click “forgot password”, located underneath the password box.
2. When prompted enter the user will enter an email address for the MySOZO account.
3. A pop-up notifies the user to expect a password reset email from ImpediMed.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





Password Expiration

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



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 certain SOZO system-wide 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.

Administrator Home Page

For Administrators, set a password and login 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.

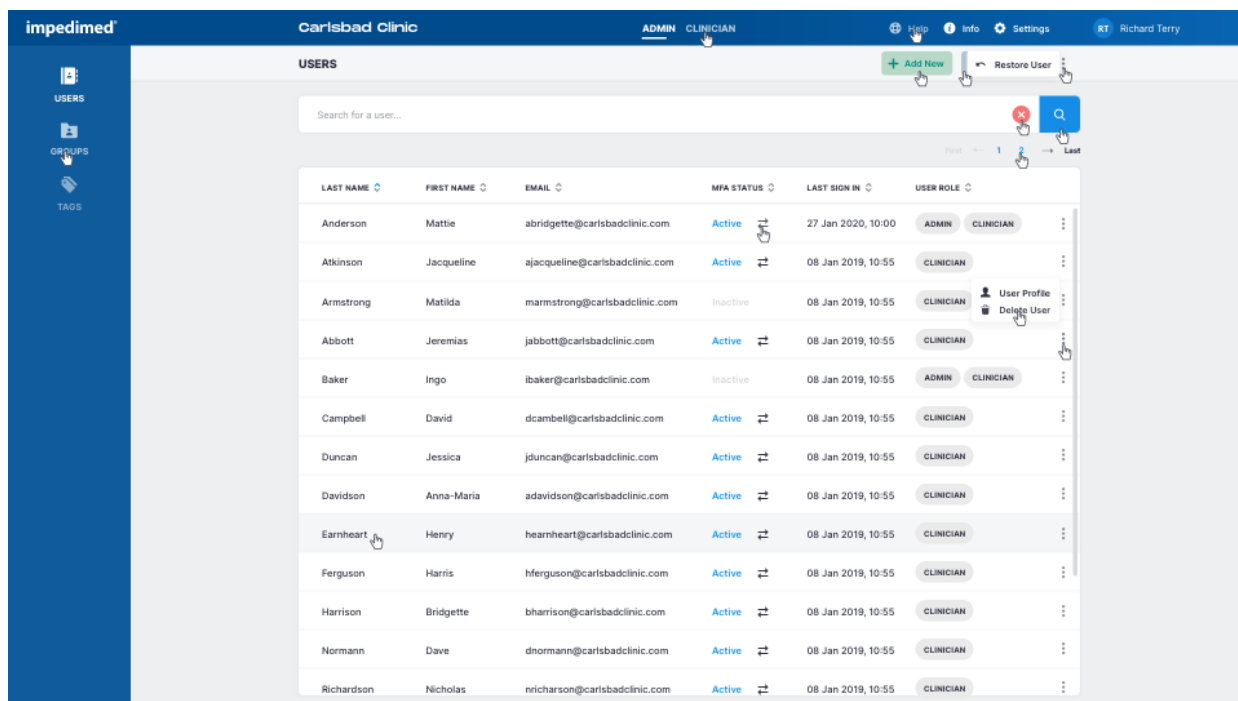
Users may be assigned both Administrator and Clinician roles, and access both functions from the same login. The Admin icon is bold if the user is logged in as an Administrator. If an Administrator also has the Clinician role, they can toggle between Administrator and Clinician screens by clicking **Admin**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

The screenshot displays the MySOZO Administrator interface for Carlsbad Clinic. The top navigation bar includes the ImpediMed logo, the clinic name, and a toggle switch for 'ADMIN' (selected) and 'CLINICIAN'. A red circle highlights this toggle. The main content area is titled 'USERS' and features a search bar and buttons for '+ Add New' and 'Export Audit Logs'. Below these is a table listing users with columns for Last Name, First Name, Email, MFA Status, Last Sign In, and User Role. The 'User Role' column shows 'ADMIN' and 'CLINICIAN' roles for some users, with 'ADMIN' being bolded for users logged in as administrators.

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
Earnheart	Henry	hearnheart@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Ferguson	Harris	hferguson@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Harrison	Bridgette	bharrison@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Normann	Dave	dnormann@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN
Richardson	Nicholas	nricharson@carlsbadclinic.com	Active	08 Jan 2019, 10:55	CLINICIAN

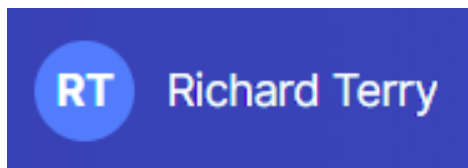
Banner and Icons

The banner icons enable common administrative functions. Roll your mouse over the icons for their description.



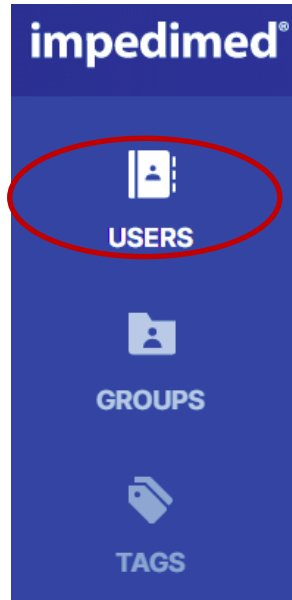
User Profile Icon

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



User List Icon

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



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.

A screenshot of the MySOZO Administrator web interface. The top navigation bar includes the 'impedimed' logo, the clinic name 'Carlsbad Clinic', and user roles 'ADMIN' and 'CLINICIAN'. A 'Help' icon (a question mark) is circled in red in the top right corner. On the left is a sidebar with 'USERS', 'GROUPS', and 'TAGS' icons. The main area displays a 'USERS' table with columns for LAST NAME, FIRST NAME, EMAIL, MFA STATUS, and LAST SIGN IN. A 'Help' modal window is open on the right, displaying technical support contact information for North America, including email addresses and phone numbers, and links to user guides and support documentation.

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

Sign Out Icon

To sign out of MySOZO at any time, click the profile icon then click the **Sign Out** icon in the lower right corner.

The screenshot displays the MySOZO interface for 'Carlsbad Clinic'. The left sidebar contains navigation icons for 'USERS', 'GROUPS', and 'TAGS'. The main area shows a 'USERS' table with columns: LAST NAME, FIRST NAME, EMAIL, MFA STATUS, LAST SIGN IN, and USER. A search bar is at the top of the table. On the right, the 'My Account' dropdown menu is open, showing fields for First Name, Middle Name, Last Name, Email, Country Code, and Phone Number. Below these fields are checkboxes for 'Admin' and 'Clinician' roles. At the bottom of the dropdown, the 'Sign Out' option is highlighted with a red arrow.

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

Administrator Functions

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**.

LAST NAME	FIRST NAME	LAST SIGN IN	USER ROLE
Anderson	Mattie	27 Jan 2020, 10:00	ADMIN, CLINICIAN
Atkinson	Jacqu	08 Jan 2019, 10:55	CLINICIAN
Armstrong	Matid	08 Jan 2019, 10:55	CLINICIAN
Abbott	Jerem	08 Jan 2019, 10:55	CLINICIAN
Baker	Ingo	08 Jan 2019, 10:55	ADMIN, CLINICIAN
Campbell	David	08 Jan 2019, 10:55	CLINICIAN
Duncan	Jessic	08 Jan 2019, 10:55	CLINICIAN
Davidson	Anna	08 Jan 2019, 10:55	CLINICIAN
Earnheart	Henry	08 Jan 2019, 10:55	CLINICIAN

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.

LAST NAME	FIRST NAME	LAST SIGN IN	USER ROLE
Anderson	Mattie	27 Jan 2020, 10:00	ADMIN, CLINICIAN
Atkinson	Jacqu	17 Apr 2019, 17:00	CLINICIAN
Armstrong	Matid	05 Jan 2020, 12:37	CLINICIAN
Abbott	Jerem	23 Dec 2017, 16:55	CLINICIAN
Baker	Ingo	27 Jan 2019, 10:30	ADMIN, CLINICIAN
Campbell	David	08 Jan 2020, 10:55	CLINICIAN
Duncan	Jessic	13 Aug 2019, 15:52	CLINICIAN

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.

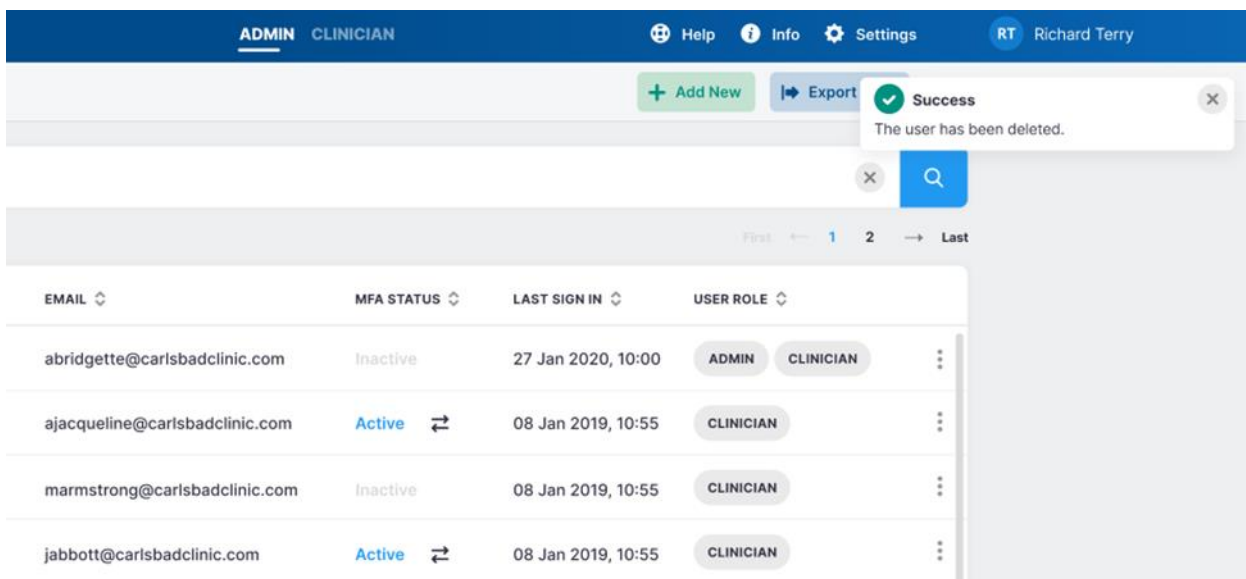
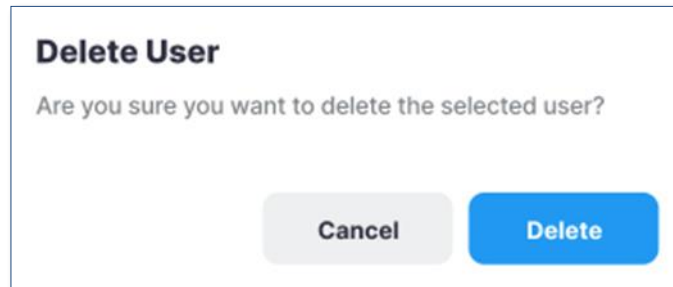
The screenshot shows the 'Carlsbad Clinic' user management interface. A modal window titled 'User Profile' is open, allowing an administrator to edit a user's details. The background shows a table of users with columns for Last Name, First Name, Last Sign In, and User Role. The modal form includes fields for First Name (Richard), Middle Name (Joseph), Last Name (Terry), Email (rterry@carlsbadclinic.com), Country Code (United States (+1)), and Phone Number (8004567789). The Role is set to Admin and Clinician. A 'Save' button is at the bottom right of the modal.

LAST NAME	FIRST NAME	LAST SIGN IN	USER ROLE
Anderson	Mattie	27 Jan 2020, 10:00	ADMIN CLINICIAN
Atkinson	Jacqu	08 Jan 2019, 10:55	CLINICIAN
Armstrong	Matild	08 Jan 2019, 10:55	CLINICIAN
Abbott	Jerem	08 Jan 2019, 10:55	CLINICIAN
Baker	Ingo	08 Jan 2019, 10:55	ADMIN CLINICIAN
Campbell	David	08 Jan 2019, 10:55	CLINICIAN
Duncan	Jessic	08 Jan 2019, 10:55	CLINICIAN
Davidson	Anna-	08 Jan 2019, 10:55	CLINICIAN
Earnheart	Henry	08 Jan 2019, 10:55	CLINICIAN

Delete User

To delete a user:

1. 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.



Restore User

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

To restore a deleted User:

1. 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 you want to restore.
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' page in the MySOZO interface. The page has a blue header with 'impedimed' and 'Carlsbad Clinic' logos, and a navigation bar with 'ADMIN' and 'CLINICIAN' tabs. A sidebar on the left contains 'USERS', 'GROUPS', and 'TAGS' links. The main content area is titled 'RESTORE USER' and features a search bar and a table of users. A red circle highlights the 'Restore' button in the user list.

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

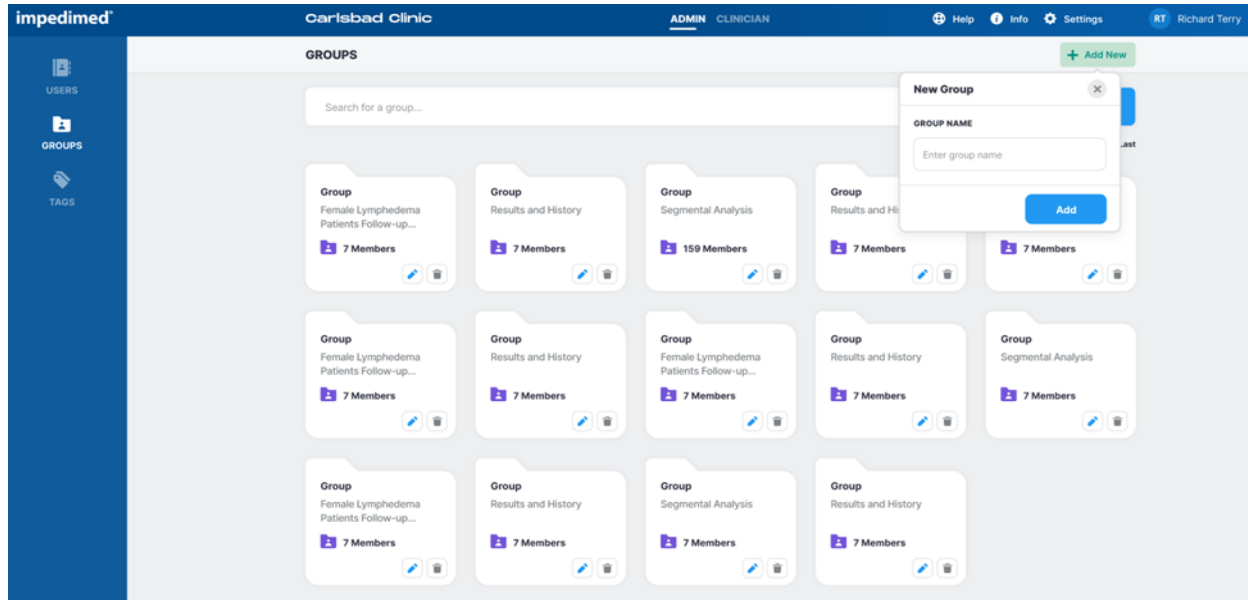
Restore User

Are you sure you want to restore the selected user?

CancelRestore

Patient Groups

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



Create a New Group

To create a new Patient Group:

1. 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.

Rename/Delete Group

To rename a Patient Group:

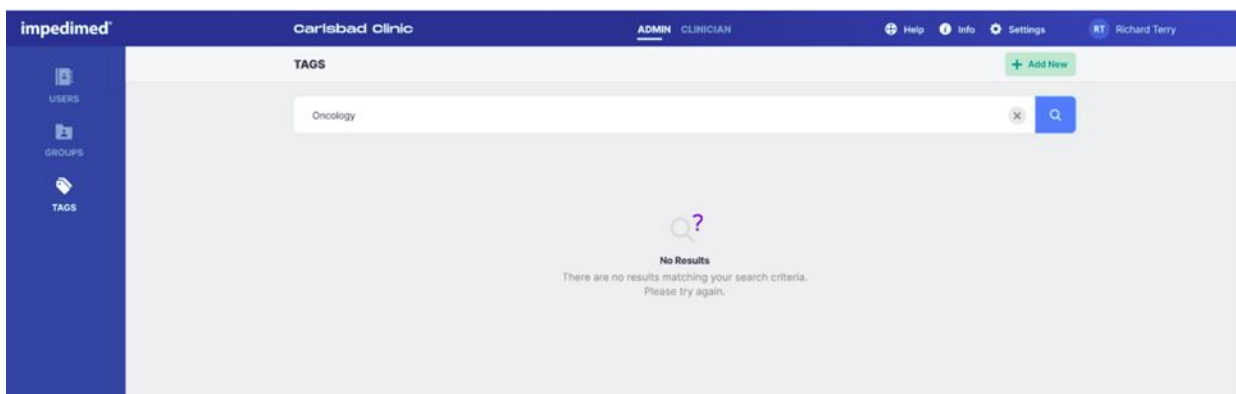
1. Click the **blue pencil** (edit icon) on the folder you wish to update.
2. Update the Patient Group name.
3. Click the **blue disk** (save icon).
4. A success confirmation will appear in the top right corner.

To delete a Patient Group:

1. Click the **grey trash can** (delete icon) on the folder you wish to delete.
2. A delete group warning will pop-up, select **delete**.
3. A success confirmation will appear in the top right corner.

Patient Tags

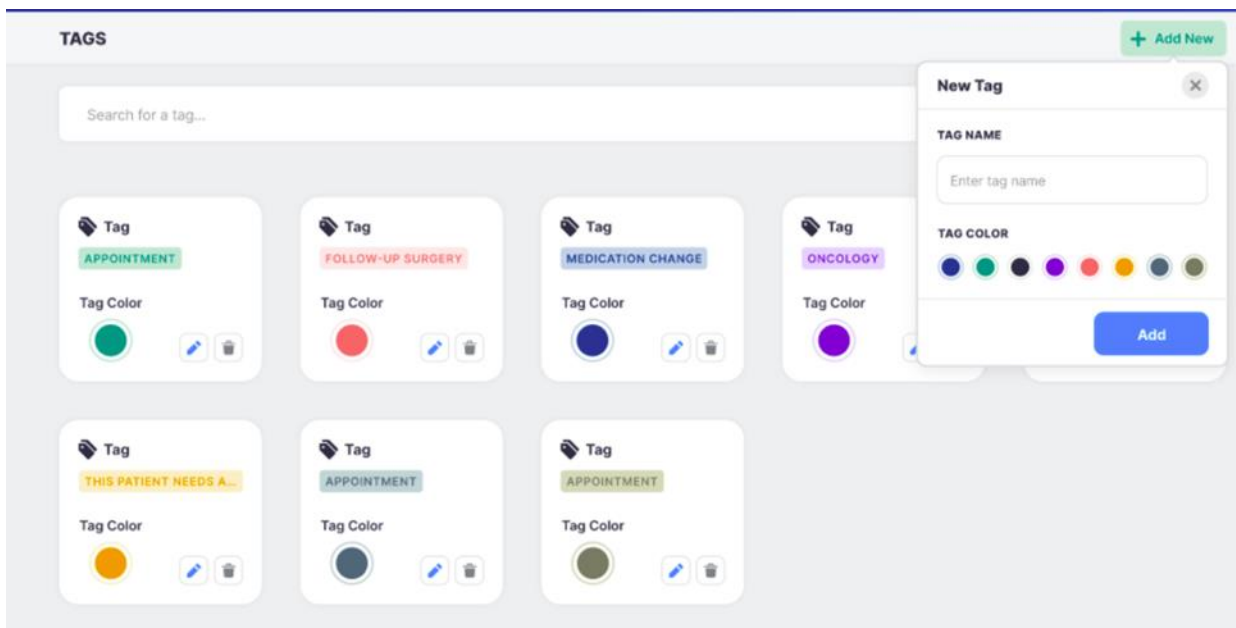
Tags are clinic-defined 48-character colour-coded objects that can be applied to a given measurement by a clinician. The tags used within a clinic can only be managed by a user with an Administrator role.



Create a New Tag

To create a new Tag:

5. Click **add new** in the top right corner.
6. Enter the tag name.
7. Click **add**.
8. The new tag folder will appear below with the other tag folders.



Rename/Delete Tag

To rename a Tag:

5. Click the **blue pencil** (edit icon) on the folder you wish to update.
6. Update the tag name.
7. Click the **blue disk** (save icon).
8. A success confirmation will appear in the top right corner.

To delete a Tag:

4. Click the **grey trash can** (delete icon) on the folder you wish to delete.
5. A delete tag warning will pop-up, select **delete**.
6. 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.

Settings

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

This includes password policies, password expiration period, time zone, logout inactivity time, and licenses. Once changes have been made, click Save. A success confirmation will appear in the top right corner.

The screenshot displays the MySOZO system interface for 'carlsbadclinic'. The top navigation bar includes 'ADMIN' and 'CLINICIAN' tabs, along with 'Help', 'Info', 'Settings', and a user profile for 'Richard Terry'. The left sidebar contains icons for 'USERS', 'GROUPS', and 'TAGS'. The main content area shows a 'USERS' table with columns for 'LAST NAME', 'FIRST NAME', 'EMAIL', 'MFA STATUS', 'LAST SIGN IN', and 'USER'. A search bar is located above the table. The 'Settings' menu is open on the right, showing 'CLINIC SETTINGS' (Security Settings, Report Logo Settings, Time Zone) and 'USER SETTINGS' (Multi-Factor Authentication).

LAST NAME	FIRST NAME	EMAIL	MFA STATUS	LAST SIGN IN	USER
Anderson	Mattie	abridgette@carlsbadclinic.com	Active	27 Jan 2020, 10:00	AD
Atkinson	Jacqueline	ajacqueline@carlsbadclinic.com	Active	17 Apr 2019, 17:00	CL
Armstrong	Matilda	marmstrong@carlsbadclinic.com	Inactive	05 Jan 2020, 12:37	CU
Abbott	Jeremias	jabbott@carlsbadclinic.com	Active	23 Dec 2017, 16:55	CU
Baker	Ingo	ibaker@carlsbadclinic.com	Inactive	27 Jan 2019, 10:30	AD
Campbell	David	dcampbell@carlsbadclinic.com	Active	08 Jun 2020, 10:55	CU
Duncan	Jessica	jduncan@carlsbadclinic.com	Active	13 Aug 2019, 15:52	CU
Davidson	Anna-Maria	adavidson@carlsbadclinic.com	Active	15 Jan 2019, 10:59	CU
Earnheart	Henry	hearnheart@carlsbadclinic.com	Active	03 Mar 2016, 20:55	CU
Ferguson	Harris	hferguson@carlsbadclinic.com	Active	08 Jan 2020, 16:17	CU
Harrison	Bridgette	bharrison@carlsbadclinic.com	Active	10 Mar 2020, 13:53	CU
Normann	Dave	dnormann@carlsbadclinic.com	Active	27 Dec 2019, 20:55	CU
Richardson	Nicholas	nrichardson@carlsbadclinic.com	Active	21 Jan 2019, 13:57	CU

Security Options

In SOZOapp default settings, users set up and maintain individually chosen passwords specific to MySOZO and SOZOapp. Per hospital policy, MySOZO allows a user with Administrator role to configure single sign-on (SSO) or multi-factor authentication as additional security measures.

If your organization is set up for **Single Sign-On (SSO)** users can rely on SSO to log in instead. You may work with ImpediMed Technical Support during MySOZO setup or contact ImpediMed Technical Support after the system has been installed, to set up SSO. Additional instructions on accessing SSO may be found at www.impedimed.com.

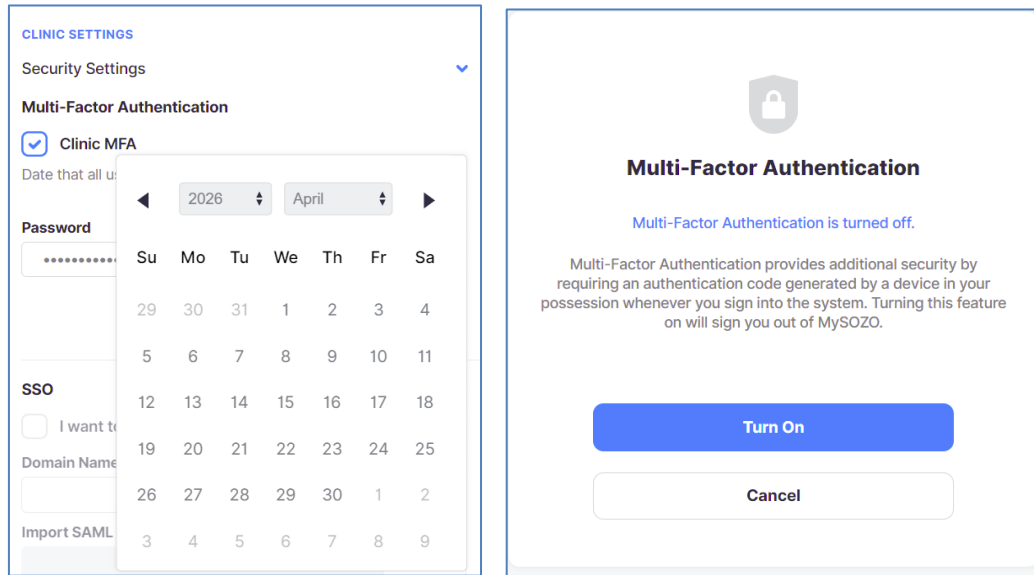
Alternately, you may elect to implement **multi-factor authentication (MFA)**. MFA access is located within the settings pop up:

The screenshot shows the ImpediMed Admin interface for Carlsbad Clinic. The main area displays a table of users with columns for Last Name, First Name, Email, MFA Status, Last Sign In, and User Role. A search bar is at the top of the table. On the right, a 'Settings' pop-up is open, showing 'CLINIC SETTINGS' and 'Security Settings'. Under 'Multi-Factor Authentication', the 'Clinic MFA' checkbox is checked, and the 'Date that all users must enable MFA by' is set to '23 Nov 2020'. A 'Password' field is also present. Below this, the 'SSO' section has an unchecked checkbox for 'I want to have SSO as an authentication server'. The 'Password Policy' section at the bottom specifies password requirements: length (8-20 characters), complexity (number, special character, upper/lower case letters), and expiration (30-1090 days).

LAST NAME	FIRST NAME	EMAIL	MFA STATUS	LAST SIGN IN	USER
Anderson	Mattie	abridgette@carlsbadclinic.com	Inactive	27 Jan 2020, 10:00	AD
Atkinson	Jacqueline	ajacqueline@carlsbadclinic.com	Inactive	17 Apr 2019, 17:00	CU
Armstrong	Matilda	marmstrong@carlsbadclinic.com	Inactive	05 Jan 2020, 12:37	CU
Abbott	Jeremias	jabbott@carlsbadclinic.com	Inactive	23 Dec 2017, 16:55	CU
Baker	Ingo	ibaker@carlsbadclinic.com	Inactive	27 Jan 2019, 10:30	AD
Campbell	David	dcampbell@carlsbadclinic.com	Inactive	08 Jun 2020, 10:55	CU
Duncan	Jessica	jduncan@carlsbadclinic.com	Inactive	13 Aug 2019, 15:52	CU
Davidson	Anna-Maria	adavidson@carlsbadclinic.com	Inactive	15 Jan 2019, 10:59	CU
Earnheart	Henry	hearnheart@carlsbadclinic.com	Inactive	03 Mar 2016, 20:55	CU
Ferguson	Harris	hferguson@carlsbadclinic.com	Inactive	08 Jan 2020, 16:17	CU
Harrison	Bridgette	bharrison@carlsbadclinic.com	Inactive	10 Mar 2020, 13:53	CU
Normann	Dave	dnormann@carlsbadclinic.com	Inactive	27 Dec 2019, 20:55	CU
Richardson	Nicholas	nricharson@carlsbadclinic.com	Inactive	21 Jan 2019, 13:57	CU

To turn MFA on, the Administrator will need to enter their password. At that point a pop-up will display a QR code that the Administrator can use to link to a third-party authenticator, and first-time entry of the MFA code. 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. A pop-up will indicate successful completion. The Administrator will be logged out of the system, and from that point on, will have to use both password and MFA code to log back in.

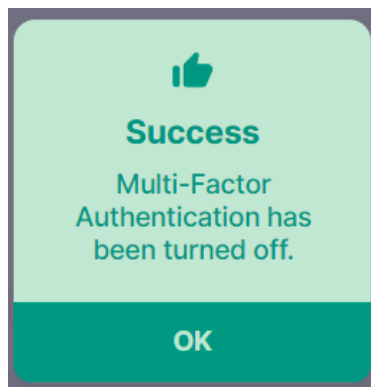
An Administrator can also require MFA for all other users within the clinic. Within settings, the Administrator will define the date by which all other users must implement MFA for their account from within settings. On that date, all users will have to implement MFA for their own account after attempting to log in.



Note:

Once an Administrator has required MFA use by the clinic, staff will not be able to log 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 current MFA code. After turning MFA off the following message will appear:



The user will then be logged out of the system and return to the log in screen.

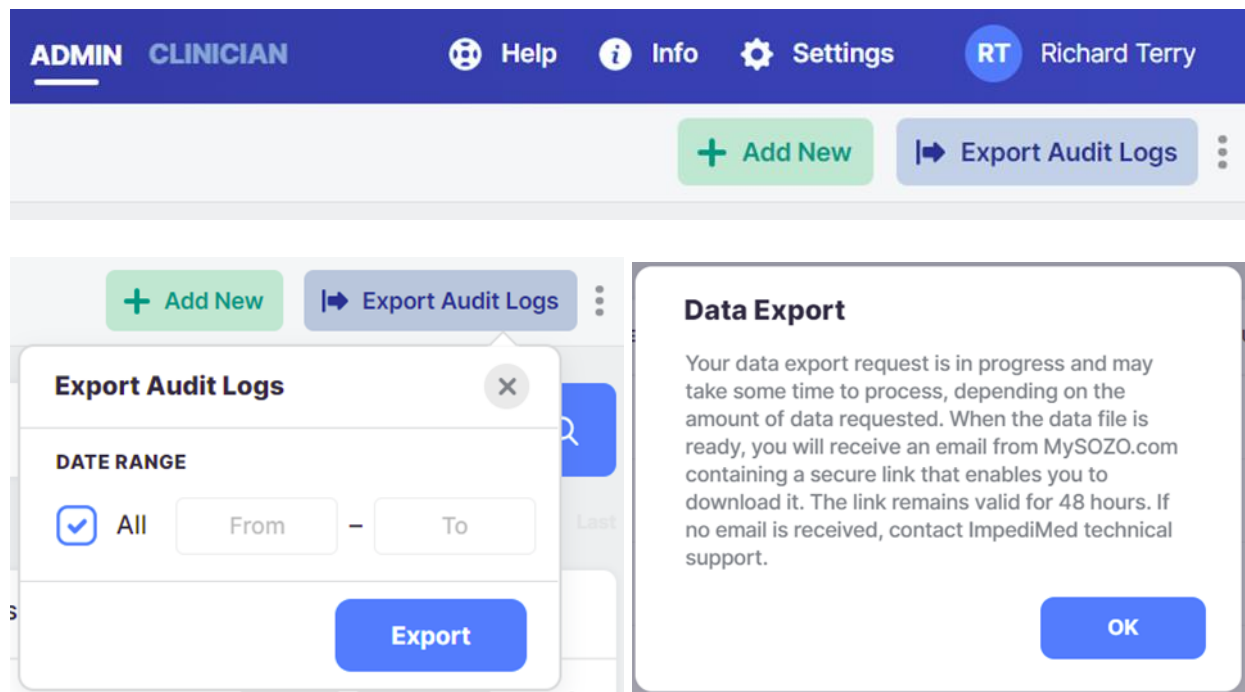
Audit Logs

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' log 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 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 your 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 your 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.

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

Clinician Home Page

Clinicians, prior to signing in for the first time, must set a password and login 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.

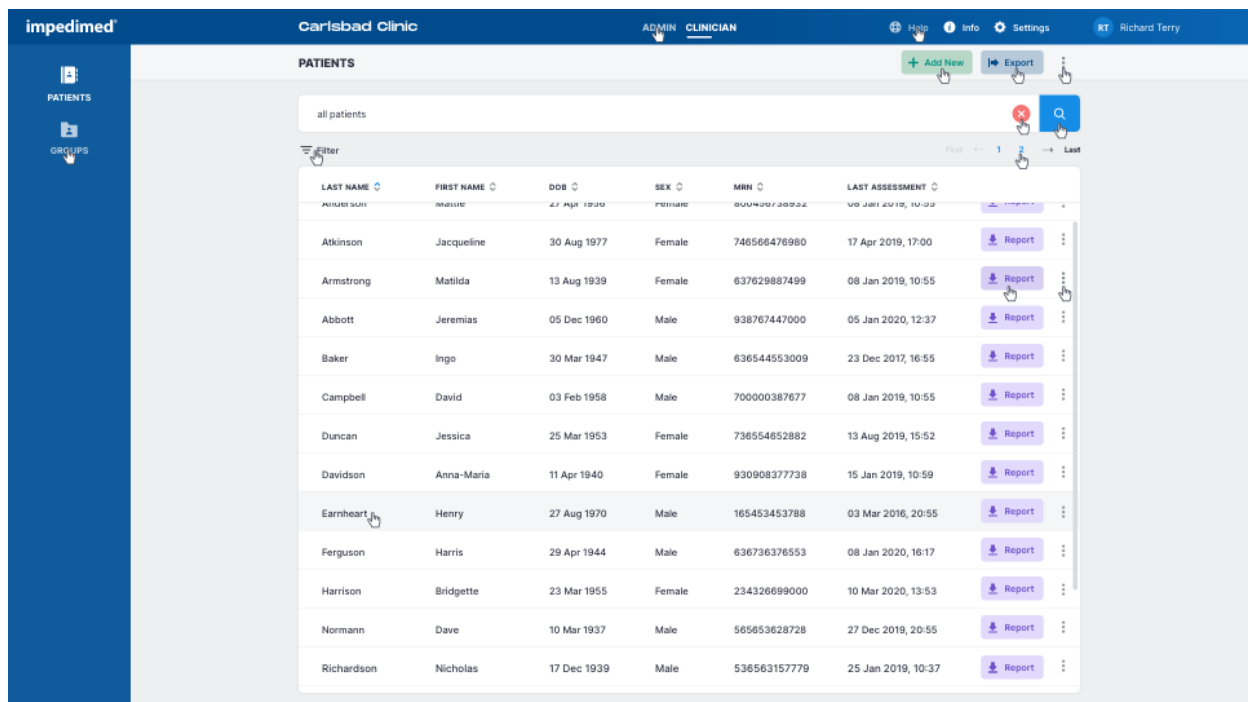
Any user may have been assigned to both Clinician and Administrator roles. Users with Clinician role will default to the Clinician role on initial login; the icon will be displayed in bold. If a Clinician also has Administrator rights, they can toggle between Clinician and Administrator screens by clicking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

The screenshot displays the MySOZO Clinician Home Page for Carlsbad Clinic. The interface includes a top navigation bar with 'ADMIN' and 'CLINICIAN' tabs, and a left sidebar with 'PATIENTS' and 'GROUPS' options. The main content area shows a 'PATIENTS' list with a search bar and a table of patient records. Each record includes fields for Last Name, First Name, DOB, Sex, MRN, and Last Assessment, along with a 'Report' button.

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

Banner and Icons

The banner icons enable common administrative functions. Roll your mouse over the icons for their description.

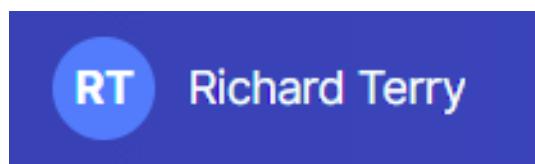


The screenshot shows the 'impedimed' banner for 'Carlsbad Clinic'. The 'ADMIN' tab is selected. The 'PATIENTS' section is active, displaying a list of patients. Above the list are buttons for '+ Add New', 'Export', and a search icon. The patient list table has columns for LAST NAME, FIRST NAME, DOB, SEX, MRN, and LAST ASSESSMENT. Each row includes a 'Report' button and a three-dot menu icon. The user 'RT Richard Terry' is logged in.

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT	Report	More
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2019, 17:00	Report	More
Armstrong	Matilda	13 Aug 1939	Female	637629887499	08 Jan 2019, 10:55	Report	More
Abbott	Jeremias	05 Dec 1960	Male	938767447000	05 Jan 2020, 12:37	Report	More
Baker	Ingo	30 Mar 1947	Male	636544553009	23 Dec 2017, 16:55	Report	More
Campbell	David	03 Feb 1958	Male	700000387677	08 Jan 2019, 10:55	Report	More
Duncan	Jessica	25 Mar 1953	Female	736554652882	13 Aug 2019, 15:52	Report	More
Davidson	Anna-Maria	11 Apr 1940	Female	930908377738	15 Jan 2019, 10:59	Report	More
Earnheart	Henry	27 Aug 1970	Male	165453453788	03 Mar 2016, 20:55	Report	More
Ferguson	Harris	29 Apr 1944	Male	636736376553	08 Jan 2020, 16:17	Report	More
Harrison	Bridgette	23 Mar 1955	Female	234326699000	10 Mar 2020, 13:53	Report	More
Normann	Dave	10 Mar 1937	Male	565653628728	27 Dec 2019, 20:55	Report	More
Richardson	Nicholas	17 Dec 1939	Male	536563157779	25 Jan 2019, 10:37	Report	More

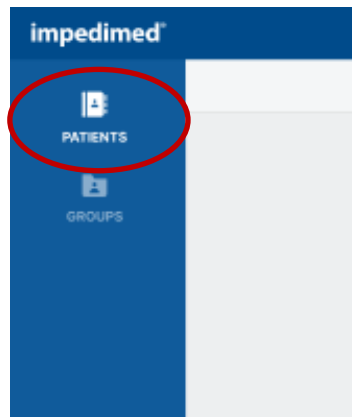
User Profile Icon

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



Patient List Icon

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



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.

PATIENTS

all patients

Filter

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT
Anderson	Mattie	27 Apr 1956	Female	800456738932	08 Jan 2019, 10:55
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2019, 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 2019, 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
Davidson	Anna-Maria	11 Apr 1940	Female	930908377738	15 Jan 2019, 10:59
Earnheart	Henry	27 Aug 1970	Male	165453453788	03 Mar 2016, 20:55
Ferguson	Harris	29 Apr 1944	Male	636736376553	08 Jan 2020, 16:17
Harrison	Bridgette	23 Mar 1955	Female	234326699000	10 Mar 2020, 13:53
Normann	Dave	10 Mar 1937	Male	565653628728	27 Dec 2019, 20:55
Richardson	Nicholas	17 Dec 1939	Male	536563157779	25 Jan 2019, 10:37

Help

Technical Support

North America

tsu@impedimed.com

USA/Canada (toll free): +1 877 247 0111 option 4
US: +1 760 585-2125

All Others

tsu@impedimed.com

+61 7 3860 3700 option 2

For Instructions for Use, please visit:
<https://www.impedimed.com/products/sozo/>

For support and additional documentation, please visit:
<https://impedimed.com/support>

Sign Out Icon

To sign out of MySOZO at any time, click the profile icon then click the **Sign Out** icon in the lower right corner.

The screenshot displays the MySOZO interface for a user named Richard Terry. The main area shows a list of patients with columns for Last Name, First Name, DOB, Sex, MRN, and Last Assessment. On the right, the 'My Account' dropdown menu is open, showing fields for First Name, Middle Name, Last Name, Email, Country Code, and Phone Number. Below these fields, the user's role is listed as 'Admin' and 'Clinician'. At the bottom of the dropdown, the 'Sign Out' option is highlighted with a red arrow.

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT
Anderson	Mattie	27 Apr 1956	Female	800456738932	08 Jan 2019, 10:55
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2019, 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 2019, 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
Davidson	Anna-Maria	11 Apr 1940	Female	930908377738	15 Jan 2019, 10:59
Earnheart	Henry	27 Aug 1970	Male	165453453788	03 Mar 2016, 20:55
Ferguson	Harris	29 Apr 1944	Male	636736376553	08 Jan 2020, 16:17
Harrison	Bridgette	23 Mar 1955	Female	234326699000	10 Mar 2020, 13:53
Normann	Dave	10 Mar 1937	Male	565653628728	27 Dec 2019, 20:55
Richardson	Nicholas	17 Dec 1939	Male	536563157779	25 Jan 2019, 10:37

Clinician Functions

The Clinician home page includes the primary MySOZO functions.

The screenshot shows the ImpediMed Clinician interface for Carlsbad Clinic. The left sidebar has 'PATIENTS' and 'GROUPS' buttons. The top navigation bar includes 'ADMIN', 'CLINICIAN', 'Help', 'Info', 'Settings', and a user profile 'RT Richard Terry'. The main area is titled 'PATIENTS' and features a search bar with 'all patients' and buttons for '+ Add New' and 'Export'. Below the search bar is a table with columns: LAST NAME, FIRST NAME, DOB, SEX, MRN, and LAST ASSESSMENT. The table lists 14 patients, each with a 'Report' button. Red arrows point to the 'PATIENTS' button, the '+ Add New' button, the 'Export' button, and the 'Report' button for the first patient.

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

Search for Patient

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

The screenshot shows the same ImpediMed Clinician interface, but with the search bar containing the text 'anna'. The table now displays only three patients whose first names start with 'Anna': Anderson, Atkinson, and Armstrong. The 'Report' button for the first patient is highlighted with a red arrow.

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT	Report
Anderson	Anna	27 Apr 1956	Female	8004567389-32	08 Jan 2019, 10:55	Report
Atkinson	Anna	30 Aug 1977	Female	8004567389-32	08 Jan 2019, 10:55	Report
Armstrong	Anna-Maria	13 Aug 1939	Female	8004567389-32	08 Jan 2019, 10:55	Report

Patient Dashboard

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

To access a specific patient's data:

1. Go to the Patient Dashboard
2. Enter the patients' name.
3. Click the **search** icon.

NOTES:

Every time the Dashboard is accessed, it will hide all patient data and appear blank. Simply clicking 'search' with a blank field will bring up the full patient list for your facility.

impediMed Carlsbad Clinic ADMIN CLINICIAN Help Info Settings Richard Terry

< Back Mattie Anderson Profile Notes

First name: Mattie Last name: Anderson Date of birth: 27 Apr 1966 Sex: Female Medical record number: 8009007799657 Last assessment: 12 Mar 2021 17:05

No Measurements
No measurements have been taken for this patient.
Take a new measurement to review results.

impediMed Carlsbad Clinic ADMIN CLINICIAN Help Info Settings Richard Terry

< Back Mattie Anderson Profile Notes

First name: Mattie Last name: Anderson Date of birth: 27 Apr 1966 Sex: Female Medical record number: 8009007799657 Last assessment: 12 Mar 2021 17:05

Filter

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

Create Patient

A Clinician creates a Patient by 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**.

The screenshot shows the 'Create Patient' form in the ImpediMed Carlsbad Clinic interface. The form is a modal window with a close button (X) in the top right. It contains the following fields and sections:

- Personal Information:**
 - Middle Name (Optional): Enter middle name
 - Last Name (Required): Enter last name
 - Email (Required): Enter email. A 'NOT PROVIDED' button is next to the field.
 - MRN (Required): Enter medical record number
 - Date of Birth (Required): Select date
 - Sex (Required): Select sex
 - Height (Required): Enter height (cm)
 - Phone Number (Optional): Enter phone number
 - Address (Optional): Enter address
 - City (Optional): Enter city
 - State (Optional): Enter state
 - Country (Optional): Select country
 - Postal Code (Optional): Enter postal code
- ASSESSMENT TYPE:**
 - ☒ L-Dex Analysis for Lymphedema
 - Assessment* (Required Fields):
 - Unilateral (Selected) / Bilateral
 - Body Element*: Arm (Selected) / Leg
 - Risk Limb*: Left (Selected) / Right
 - Limb Dominance*: Left / Right
 - HF-Dex for Heart Failure
 - Fluid Analysis for ESRD
 - Body Composition
 - Segmental Analysis
 - ☐ Info: The unilateral selection is for use with patients that have only one limb at risk of lymphedema. Both limbs will be measured and used to calculate the L-Dex score.
- GROUPS:** A list of predefined groups is shown at the bottom of the form.

The background shows a list of patients with columns for Last Name, First Name, Date of Birth, Sex, MRN, and Date of Birth. A sidebar on the left has 'PATIENTS' and 'GROUPS' tabs. The top navigation bar includes 'ADMIN', 'CLINICIAN', 'Help', 'Info', 'Settings', and 'Richard Terry'.

Notes:

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

Delete Patient

To delete a Patient:

1. Click on the **three dots** located next to the patient's information.
2. Select **Delete Patient**.
3. Click **Delete** in the delete patient warning pop-up.
4. A **success** confirmation will appear in the top right corner.

The first screenshot shows the 'PATIENTS' list in the ImpediMed Carlsbad Clinic interface. The table lists patients with columns for LAST NAME, FIRST NAME, DOB, SEX, MRN, and LAST ASSESSMENT. A 'Delete Patient' button is visible in the dropdown menu for the patient 'Atkinson, Jacqueline'.

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

The second screenshot shows the same patient list with a 'Delete Patient' dialog box overlaid. The dialog asks 'Are you sure you want to delete the selected patient?' and has 'Cancel' and 'Delete' buttons.

Notes:

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.

Restore Patient

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

To restore a deleted Patient:

1. Click the **three dots** located in the top right corner, next to the **Export** tab.
2. Select **Restore Patient**.
3. Search the Patient list for the Patient profile you want to restore.
4. Click the **blue arrow** to restore the Patient.
5. A restore patient warning will pop-up, select **Restore**.
6. A success confirmation will appear in the top right corner.

The screenshot shows the 'RESTORE PATIENT' interface in the MySOZO application. The top navigation bar includes the 'impedimed' logo, 'Carlsbad Clinic', and user information 'Richard Terry'. The left sidebar has 'PATIENTS' and 'GROUPS' options. The main content area has a search bar and a table of patients. The table has columns for 'LAST NAME', 'FIRST NAME', 'DOB', 'SEX', 'MRN', and 'LAST ASSESSMENT'. Each row has a 'Restore' button. The table is filtered to show 12 patients.

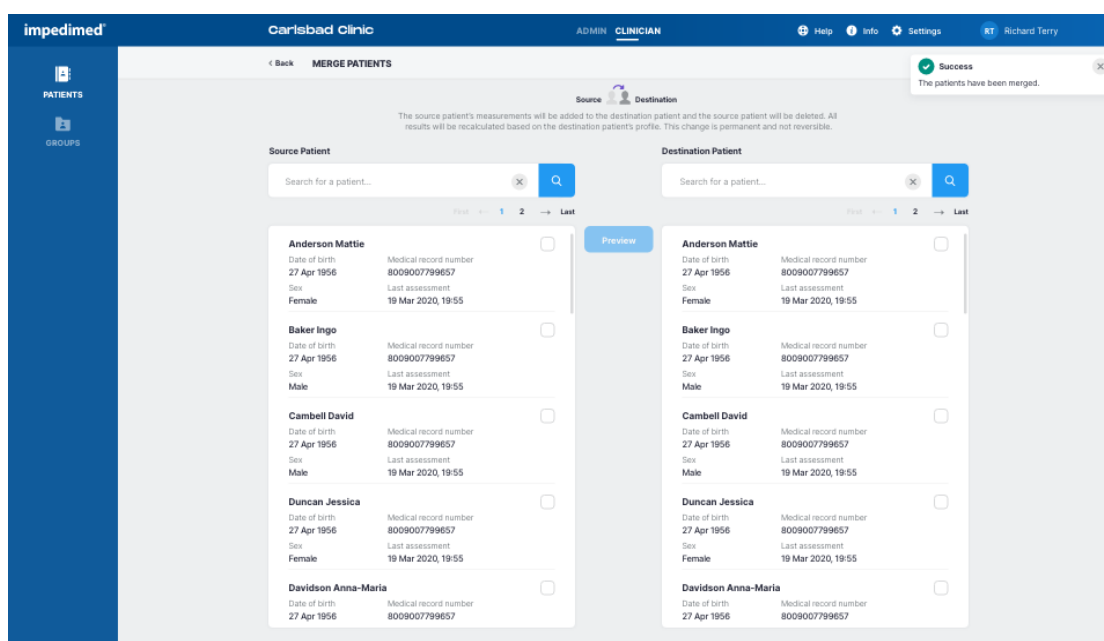
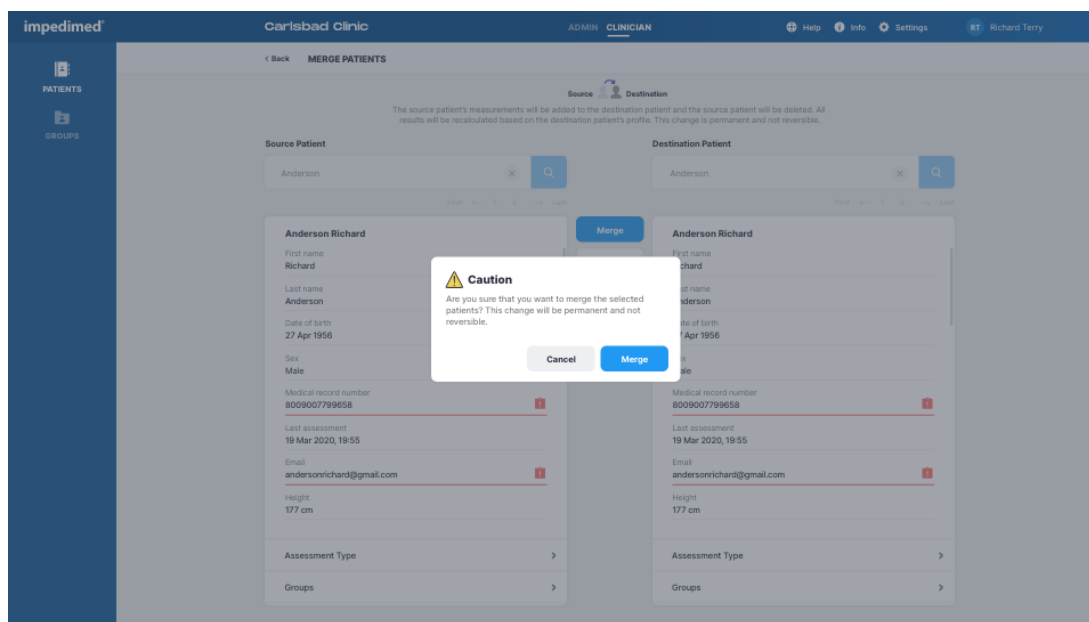
LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT	Restore
Anderson	Mattie	27 Apr 1956	Female	8004567389-32	08 Jan 2019, 10:55	Restore
Atkinson	Jacqueline	30 Aug 1977	Female	8004567389-32	08 Jan 2019, 10:55	Restore
Armstrong	Matilda	13 Aug 1939	Female	8004567389-32	08 Jan 2019, 10:55	Restore
Abbott	Jeremias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

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



Notes:

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.

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

Edit Patient Profile

To edit a patient profile:

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

Notes:

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

When to Select “Only future measurements”

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

When to Select “All measurements including historical”

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

Availability of Assessment Specific Data on Patient Profile

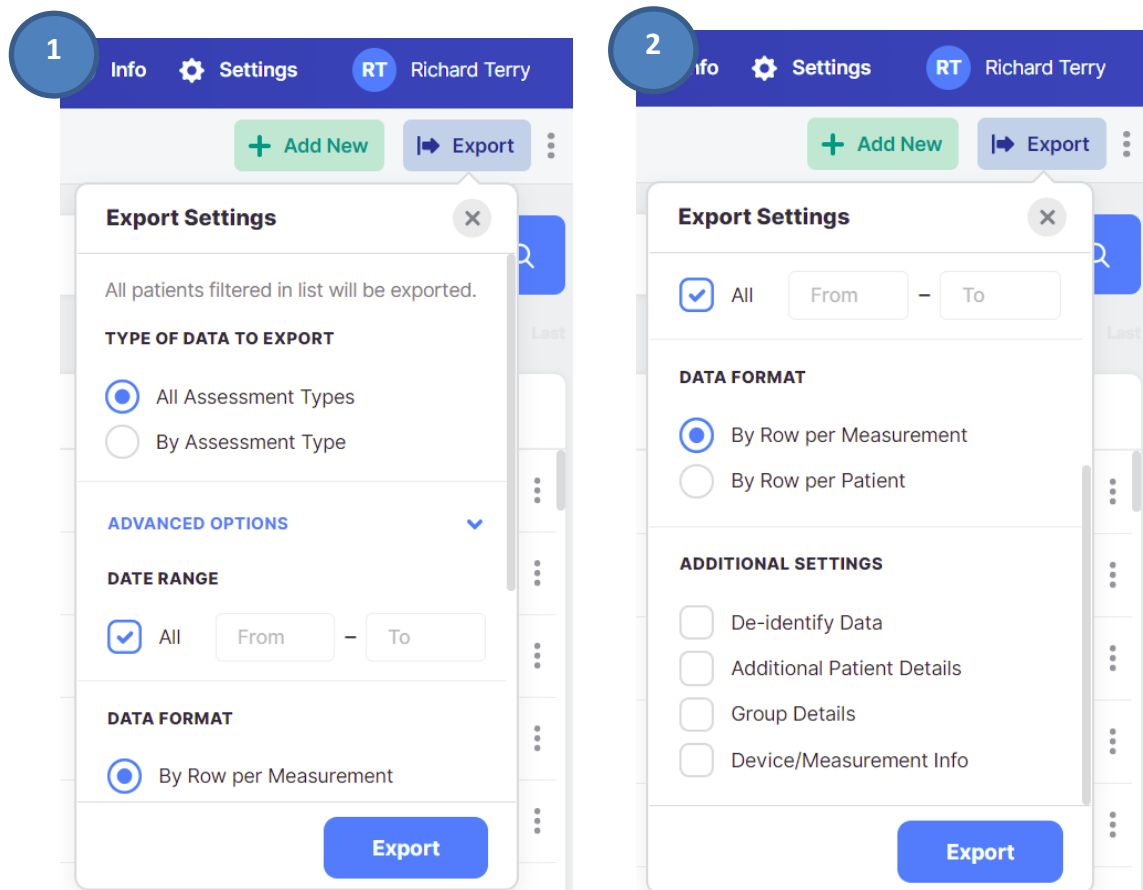
L-Dex data (at-risk limb, dominant limb) is shown in the patient profile when the L-Dex Assessment is selected. Please note that deselecting the L-Dex Assessment will gray out the patient L-Dex settings, which will not be saved.

Export Patient Data

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

Note:

Advanced settings includes a wide range of options that can be scrolled through to customize your 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.



3

Data Export

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

OK

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 clinician homepage, **search** 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.
4. Input the **date range**.
5. Click **create**.
6. The patient report will automatically download in PDF format.

The screenshot shows the 'Create Report' dialog box in the MySOZO application. The dialog is titled 'Create Report' and is overlaid on a blurred background of the patient dashboard. It contains several columns of checkboxes for selecting assessments and history charts. The 'DATE RANGE' section at the bottom has a 'All' button selected. A 'Create' button is at the bottom right.

Assessments	History Graphs
<input type="checkbox"/> L-Dex	<input type="checkbox"/> L-Dex
<input type="checkbox"/> HF-Dex	<input type="checkbox"/> HF-Dex
<input type="checkbox"/> ESRD	<input type="checkbox"/> ECF/TBW/Weight
<input type="checkbox"/> Body Composition	<input type="checkbox"/> ECF
<input type="checkbox"/> Segmental	<input type="checkbox"/> ECF %
	<input type="checkbox"/> TBW
	<input type="checkbox"/> TBW %
	<input type="checkbox"/> ECF
	<input type="checkbox"/> ECF %
	<input type="checkbox"/> TBW
	<input type="checkbox"/> TBW %
	<input type="checkbox"/> ICF
	<input type="checkbox"/> ICF %
	<input type="checkbox"/> ICF
	<input type="checkbox"/> ICF %
	<input type="checkbox"/> Hy-Dex
	<input type="checkbox"/> SMM
	<input type="checkbox"/> SMM %
	<input type="checkbox"/> FM
	<input type="checkbox"/> FM %
	<input type="checkbox"/> FFM
	<input type="checkbox"/> FFM %
	<input type="checkbox"/> Protein & Minerals
	<input type="checkbox"/> Protein & Minerals %
	<input type="checkbox"/> BMI
	<input type="checkbox"/> Phase Angle
	<input type="checkbox"/> BMR
	<input type="checkbox"/> Weight

DATE RANGE

☒ All ☐ From To

Create

Notes:

Patient reports may also be made directly from a measurement results screen.

Patient reports in PDF format cannot be created from the SOZOapp.

Settings

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

The clinician can adjust preferred units of measure (kg vs lb; cm vs ft/in; litres vs pints) and can elect to have multi-factor authentication turned on for their account even if it is not a clinic requirement. Once changes have been made, click save. A success confirmation will appear in the top right corner.

The screenshot displays the MySOZO interface for a clinician at Carlsbad Clinic. The main area shows a list of patients with columns for Last Name, First Name, DOB, Sex, MRN, and Last Assessment. A 'Settings' dropdown menu is open on the right, showing 'CLINIC SETTINGS' (Time Zone) and 'USER SETTINGS' (Measurement Units, Multi-Factor Authentication).

LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT
Anderson	Mattie	27 Apr 1956	Female	800456738932	08 Jan 2019, 10:55
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2019, 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 2019, 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
Davidson	Anna-Maria	11 Apr 1940	Female	930908377738	15 Jan 2019, 10:59
Earnheart	Henry	27 Aug 1970	Male	165453453788	03 Mar 2016, 20:55
Ferguson	Harris	29 Apr 1944	Male	636736376553	08 Jan 2020, 16:17
Harrison	Bridgette	23 Mar 1955	Female	234326699000	10 Mar 2020, 13:53
Normann	Dave	10 Mar 1937	Male	565653628728	27 Dec 2019, 20:55
Richardson	Nicholas	17 Dec 1939	Male	536563157779	25 Jan 2019, 10:37

Settings

CLINIC SETTINGS

Time Zone (UTC-07:00) Pacific Time (US and Can...)

USER SETTINGS

Measurement Units >

Multi-Factor Authentication >

Patient Dashboard

The Patient Dashboard has detailed information about each patient which includes name, date of birth, sex, medical record, last assessment date, and measurements if any. Individual patient reports can be created from the dashboard.

The information is important for the Clinician's role of viewing, recording, and evaluating historical measurements and assessment results.

To go to the Patient Dashboard:

1. Click the **patient's** icon located in the top left corner.
2. Enter the patients' name, or leave blank to bring up a list of all patients.
3. Click the **search** icon.


The screenshot shows the Patient Dashboard for Mattie Anderson. The top navigation bar includes the ImpediMed logo, Carlsbad Clinic name, and user information (Richard Terry). The left sidebar has 'PATIENTS' and 'GROUPS' icons. The main content area displays patient details: First name: Mattie, Last name: Anderson, Date of birth: 27 Apr 1966, Sex: Female, Medical record number: 8009007799657, and Last assessment: 12 Mar 2021 17:05. Below this, a message states 'No Measurements' with a question mark icon, indicating that no measurements have been taken for this patient.

The screenshot shows the Patient Dashboard for Mattie Anderson with a list of measurements. The top navigation bar and patient details are the same as in the previous screenshot. The main content area displays a table of measurements with columns for DATE, BASELINE, and TAGS. The table lists various measurements over time, including Medication Change, Physical Therapy, Radiation, Chemotherapy, and Surgery.

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

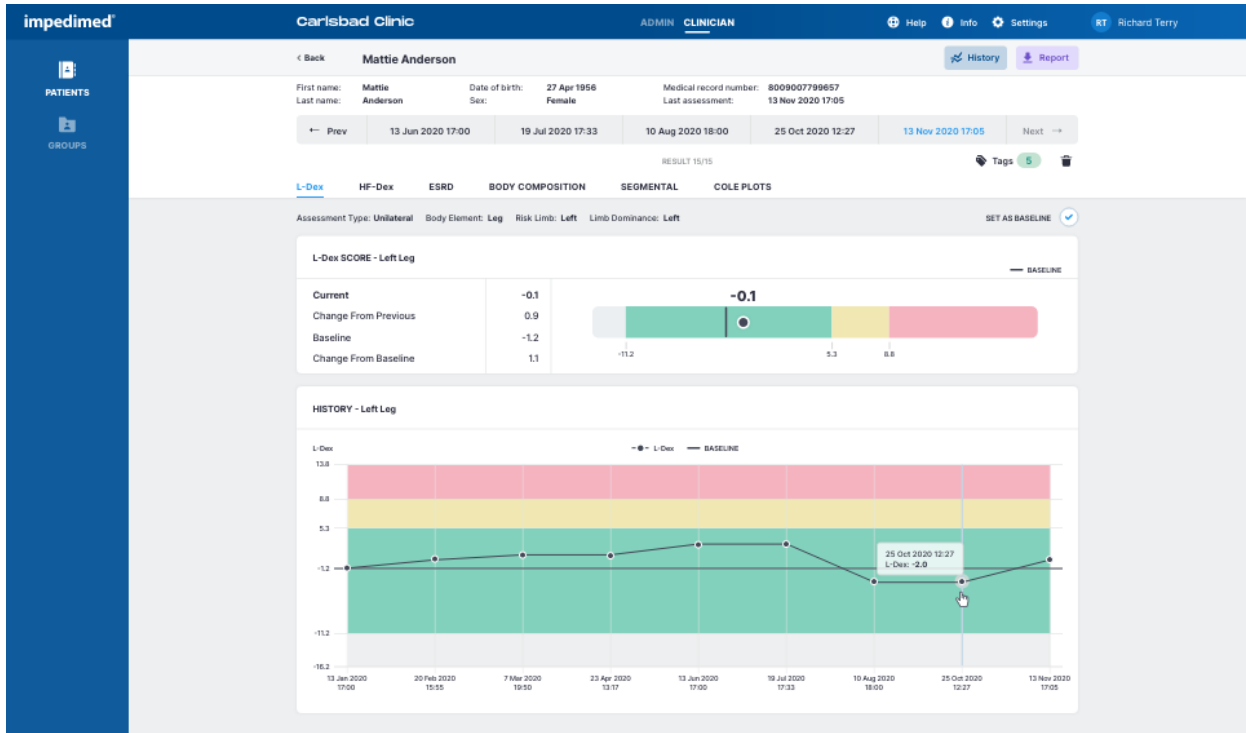
Patient Measurement History

Selecting a patient will bring up a list of all the measurements taken for the patient. If the clinic has created any tags that have been applied to a patient measurement, they will be shown in list:

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 Clinician can click on one of the listed dates to bring up the results from that measurement.

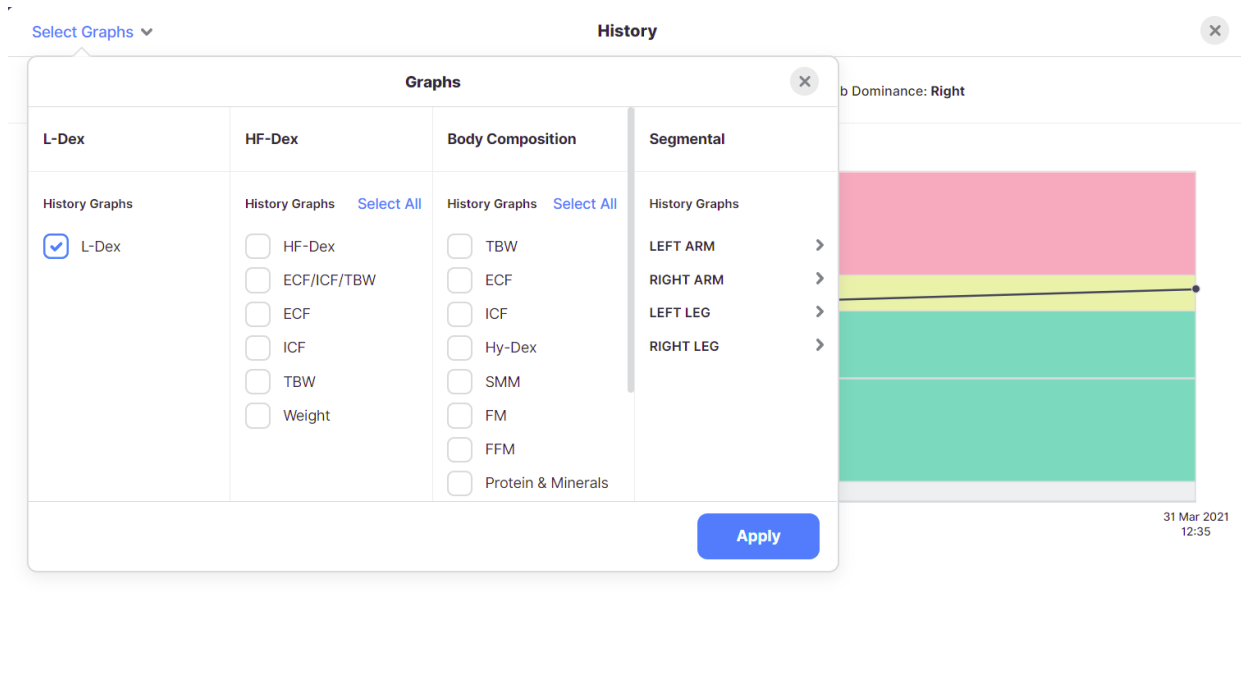
The results for one module will initially be displayed. The Clinician can click on different module types, or different measurement dates, from within the displayed record, to assess the patient's measurement results.



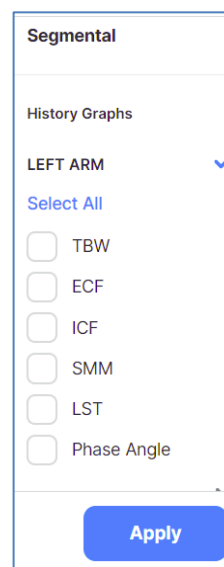
Notes:

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. Graphs will be created for each module licensed to the facility and applied to the patient profile. The popup will allow the user to select outputs to be graphed for each module, by selecting the desired outputs and clicking 'Apply':



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

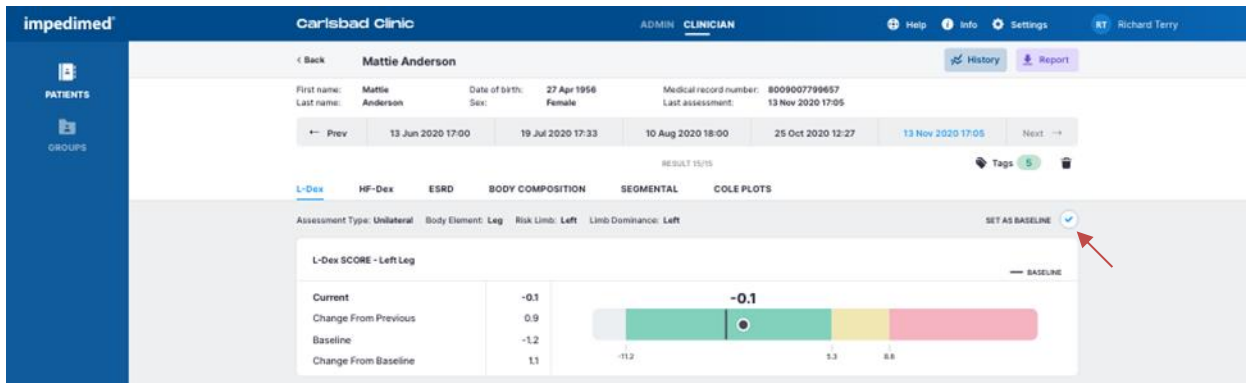


Additionally, many graphs will provide an option to switch between objective and relative units of measure (litres/pints vs. % TBW)



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.



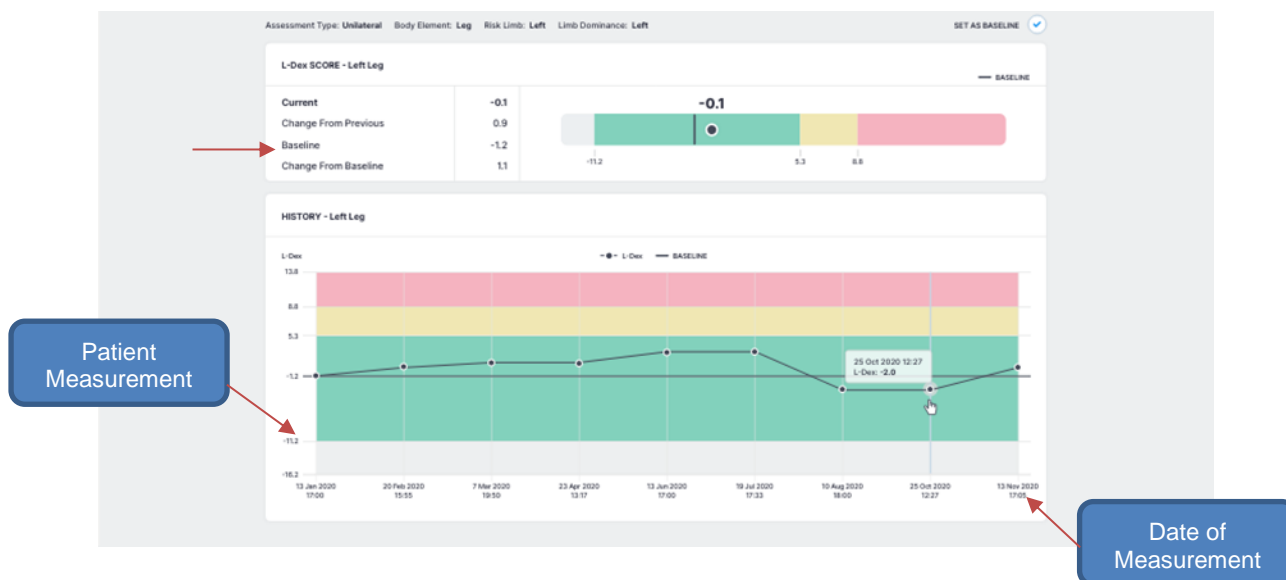
To choose the proper measurement as the baseline, the measurement should be:

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

Note that 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.

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.



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

For more about reviewing Cole plots in the SOZOapp, see section **Reviewing Cole Plots After Measurement**.



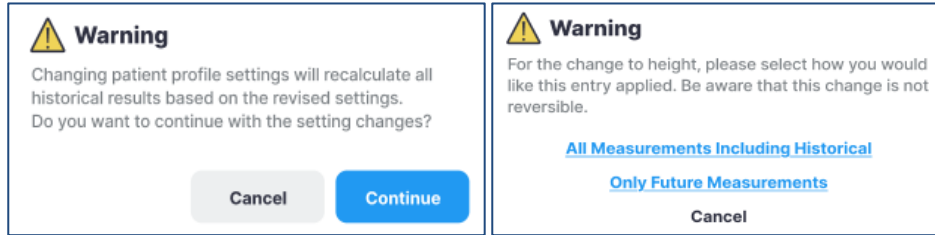
If the Right Whole Body Cole plot is low quality, measurements for the HF-Dex assessment type will not be displayed.

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.

Profile Change Warnings

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



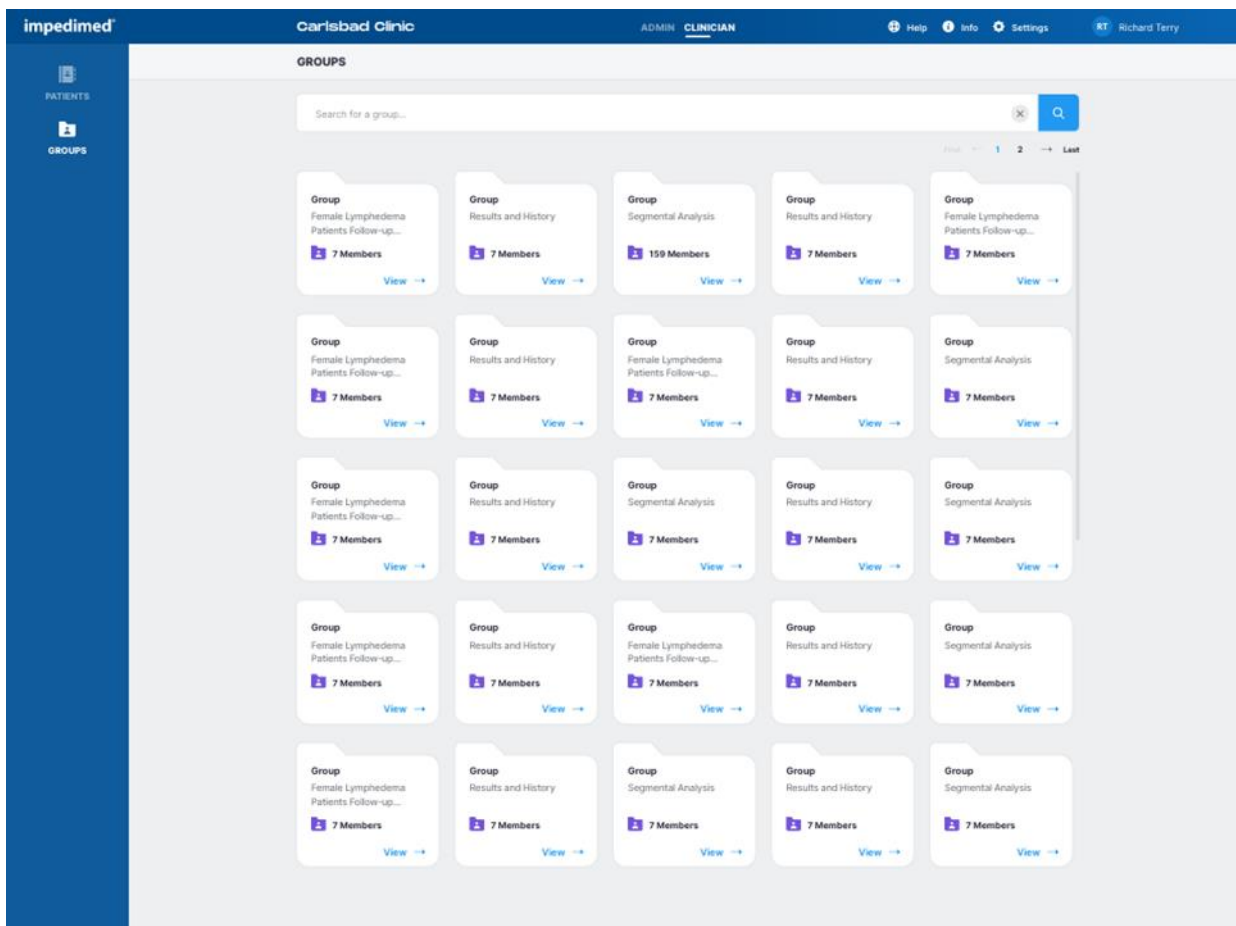
Notes:

Adding a new assessment to the patient profile may trigger a caution about the intended use of that assessment. Ensure you understand the instructions for use for: L-Dex in the L-Dex Assessment User Guide; HF-Dex in the HF-Dex User Guide. Similar warnings are presented in 4.0 software.



Patient Groups

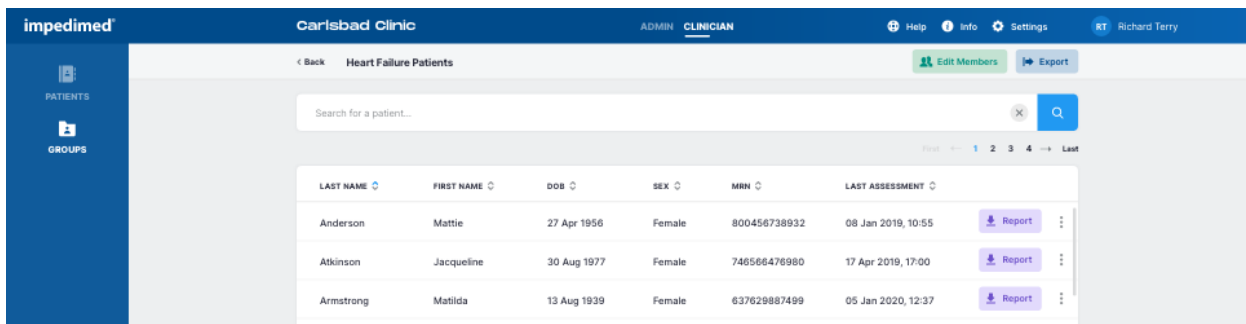
In MySOZO version 4.0 and later, patients can be assigned to predefined groups within your SOZO database. Administrator access is required to manage group creation. Clinician access is required to add or remove patients from groups.



Group Features

To access grouping features:

1. **Click** the **Patient Groups** tab located on the left side panel. This will bring up all current groups within your facility.
 - 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 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 group search for the patient's name in the right-hand column and check the box next to their profile. Selecting at least one patient will highlight the **'Remove'** button. Click the **'Remove'** button to add patients to the group.



LAST NAME	FIRST NAME	DOB	SEX	MRN	LAST ASSESSMENT	
Anderson	Mattie	27 Apr 1956	Female	800456738932	08 Jan 2019, 10:55	Report
Atkinson	Jacqueline	30 Aug 1977	Female	746566476980	17 Apr 2019, 17:00	Report
Armstrong	Matilda	13 Aug 1939	Female	637629887499	05 Jan 2020, 12:37	Report

PREPARING THE PATIENT

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 by wiping with a damp cloth.
- Remains still during the measurement with elbows away from the body.

Fluid or Tissue Analysis Measurements

If fluid and/or tissue analysis is intended, ensure the patient observes the following preparation tips to receive consistent Fluid Analysis and Tissue Analysis 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.

Measurement Accuracy

For best chances of 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.

Positioning the Patient

The SOZO system is designed to accommodate patients who are unable to stand and may exceed the maximum weight limitation (up to 375lbs if patient is standing, and up to 750 lbs if patient is sitting). [DEVICE ASSEMBLY](#) provides instructions for system configuration for standing and seated positions.

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

Measurement Results

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.

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.

Seated Position

When using the 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.

MySOZO APP

Introduction to the SOZOapp

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

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

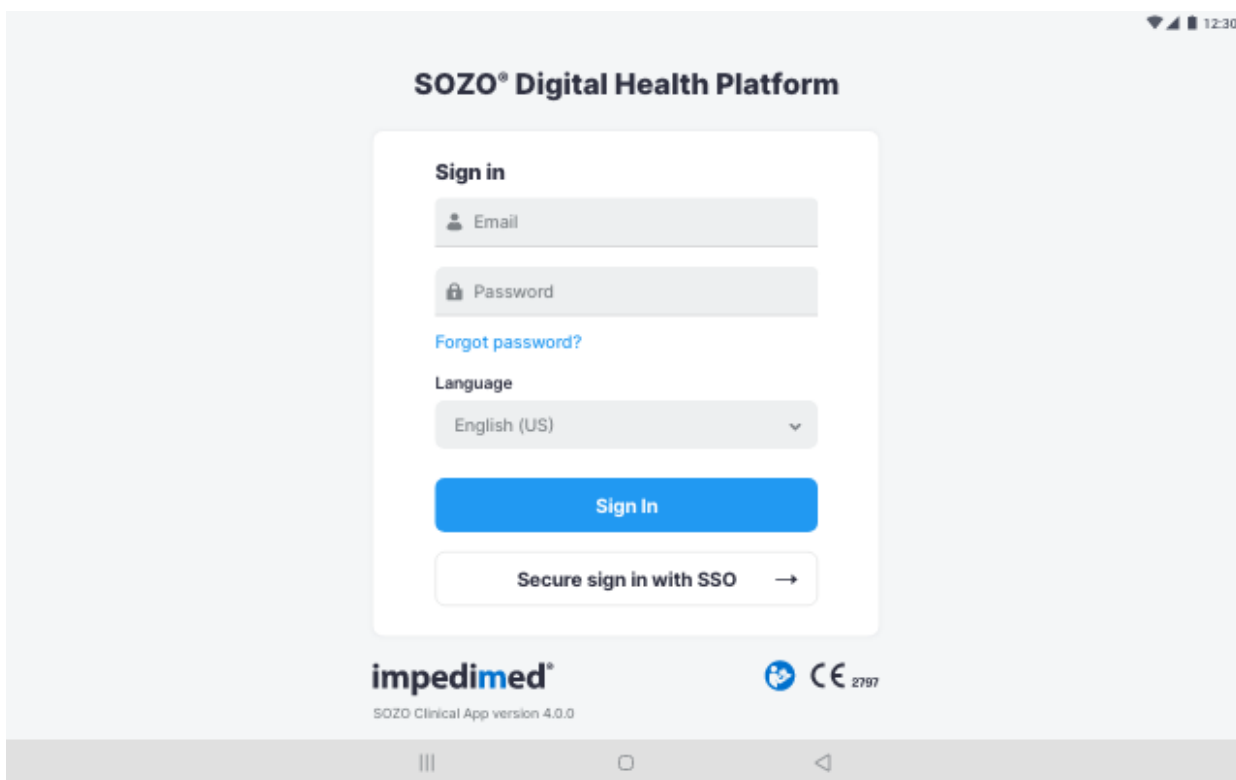
Start-Up

Sign In

For Clinicians or Administrators, set a password and login per instructions in the [First Time Set-Up](#) section of the IFU.

To log in to the SOZOapp

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



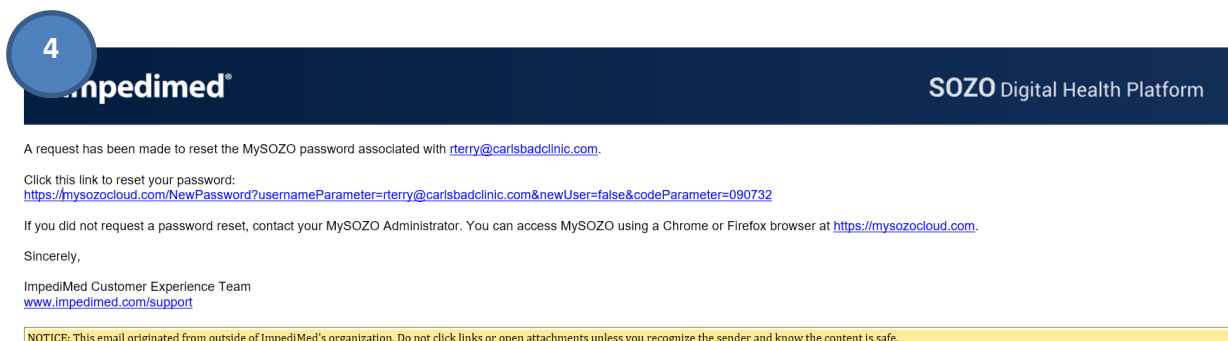
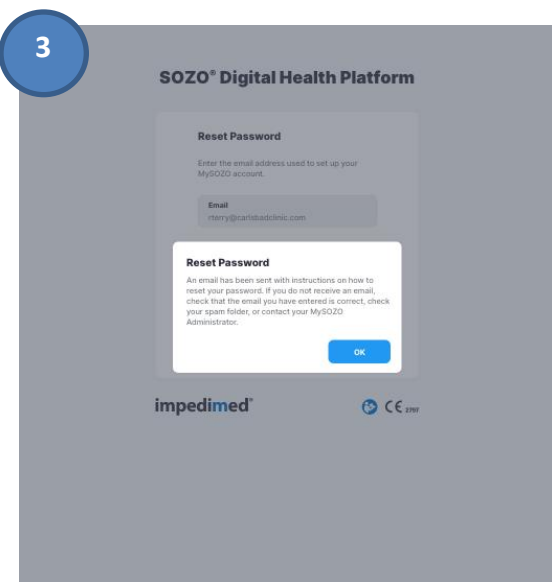
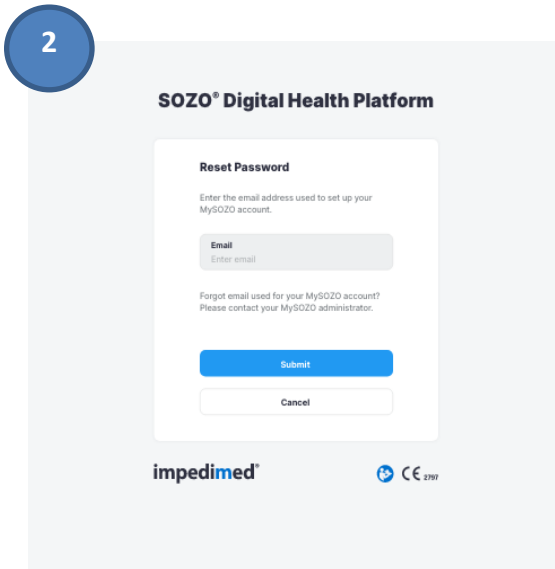
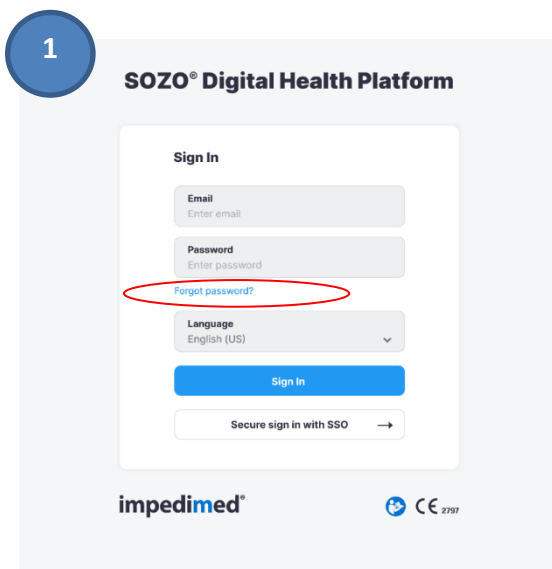
Notes:

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](#).

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

Password Reset

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



5a

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

impedimed® 

5b

SOZO® Digital Health Platform

Set New Password

Email
rterry@carlsbadclinic.com

Old Password
Enter old password


New Password
Enter new password

Confirm New Password
Enter new password

Submit

Cancel

[Password Policy](#)

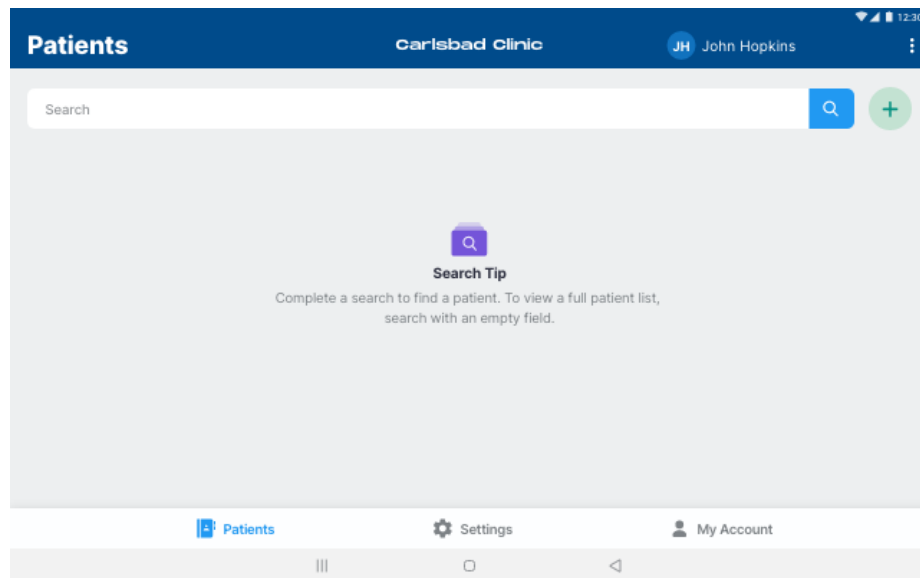
impedimed® 

SOZOapp Landing Page

Note:

Only users with a Clinician role may sign in to SOZOapp.

After successful sign in, the SOZOapp home screen with an empty “Patient List” appears.

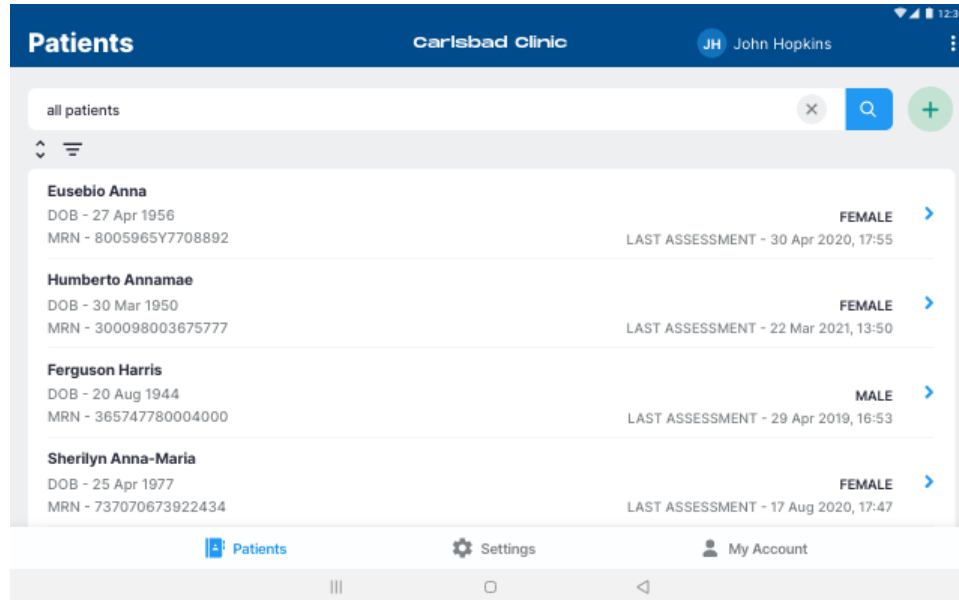


Note:

The list will always initially appear to be empty at sign in. This is to help accidental observations of patient information. Please refer to section Search for Patient.

Banner and Icons

Primary navigation in SOZOapp is managed through the three tabs at the bottom of the screen to access patient list, settings, and the Clinician account.



User Profile Icon

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



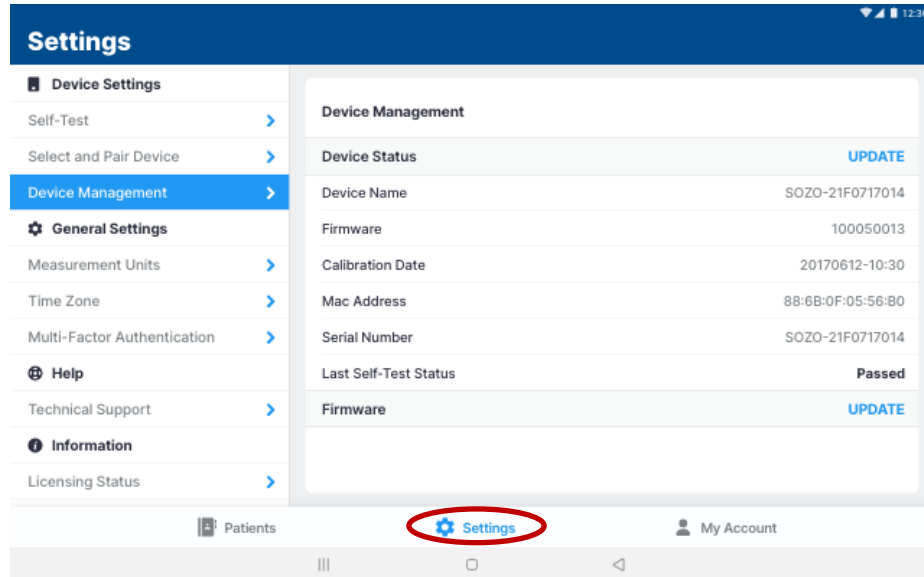
Patient List Icon

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



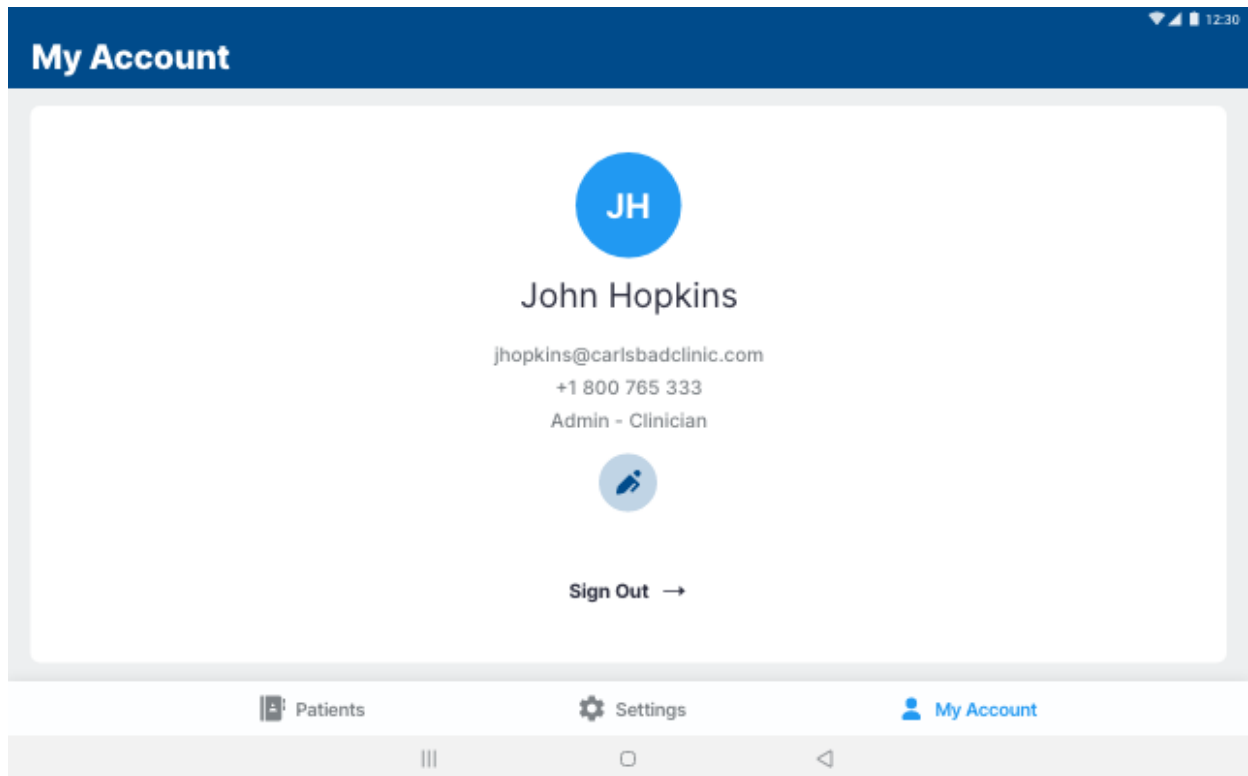
Settings Icon

The Clinician may access certain SOZOapp user settings by clicking Settings, located at the bottom centre of the home page. For more information on Clinician-accessible settings functions, see section **SOZOapp Settings**.



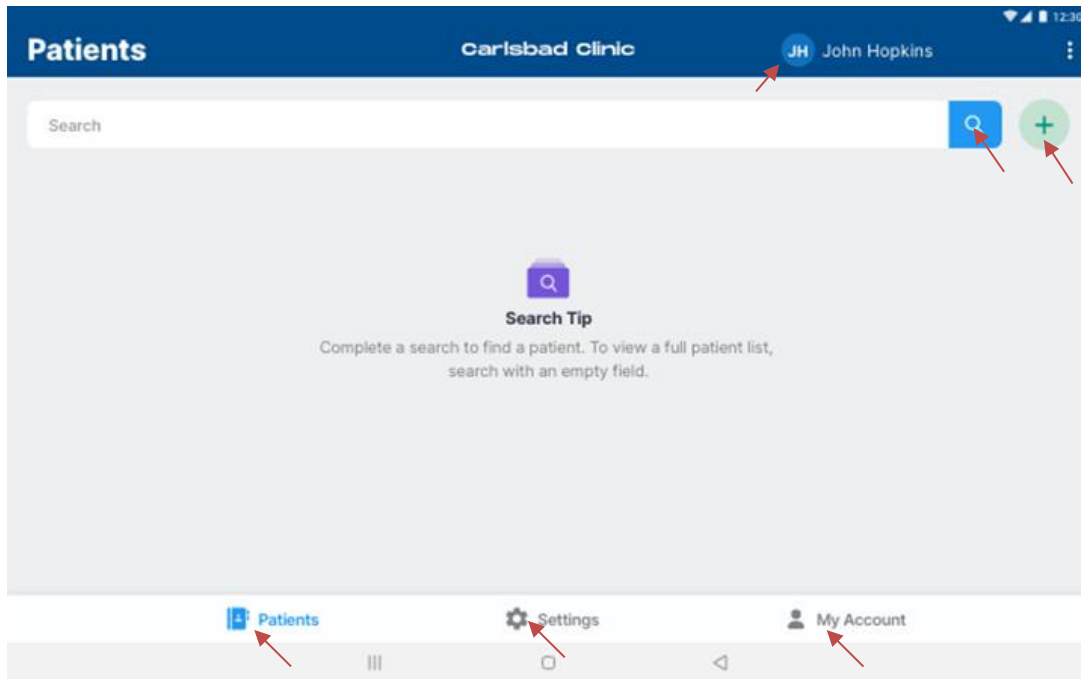
Sign Out Icon

To sign out of MySOZO at any time, click the My Account icon then click the **Sign Out**.



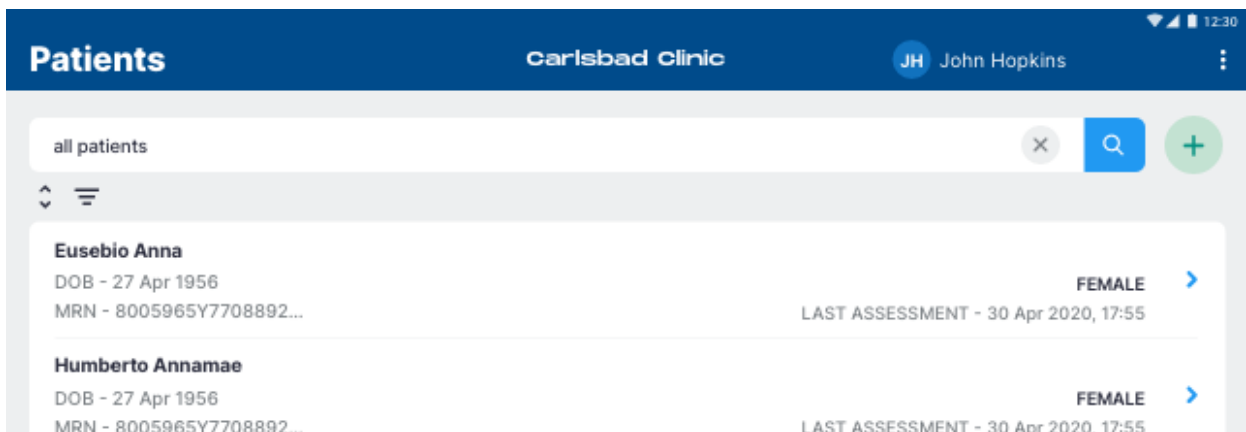
SOZOapp Navigation

The SOZOapp home page includes the primary MySOZO functions.



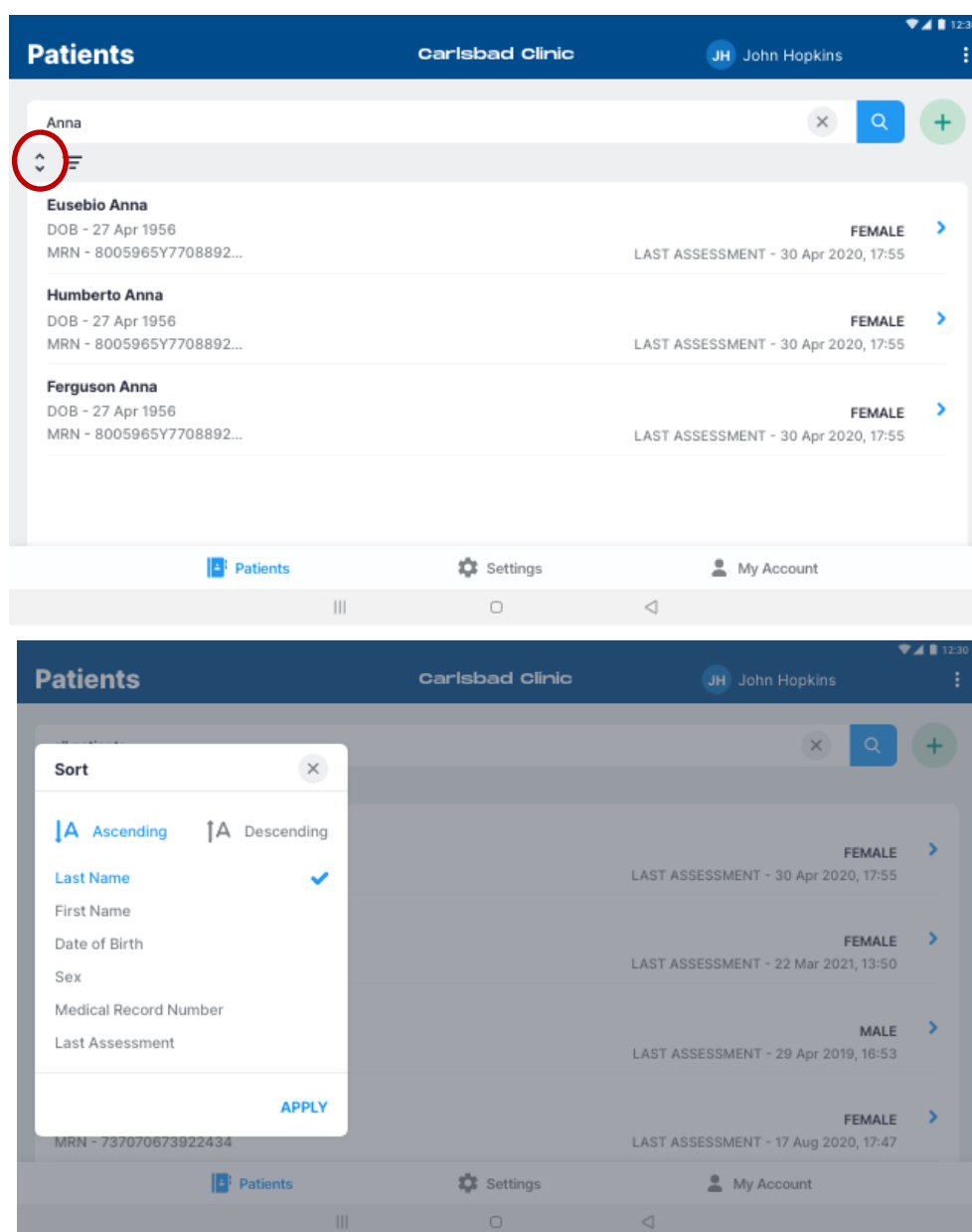
Search for Patient

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



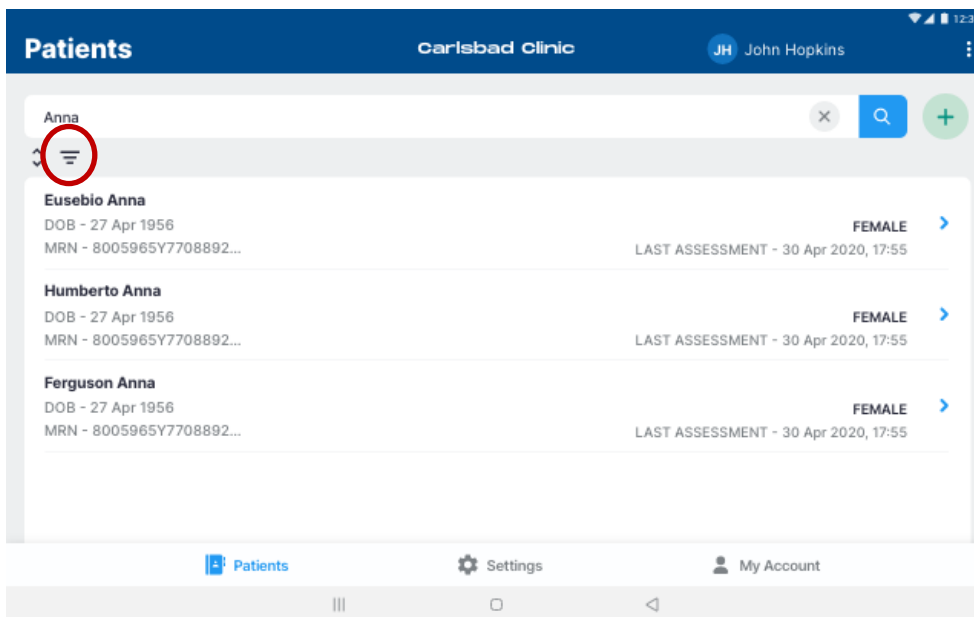
The patient list may be re-arranged using the sort feature. Tap the **Sort icon** and select criteria for sorting, which are:

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



Patient Filters

The patient list may alternatively be filtered. Click the filter button 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.

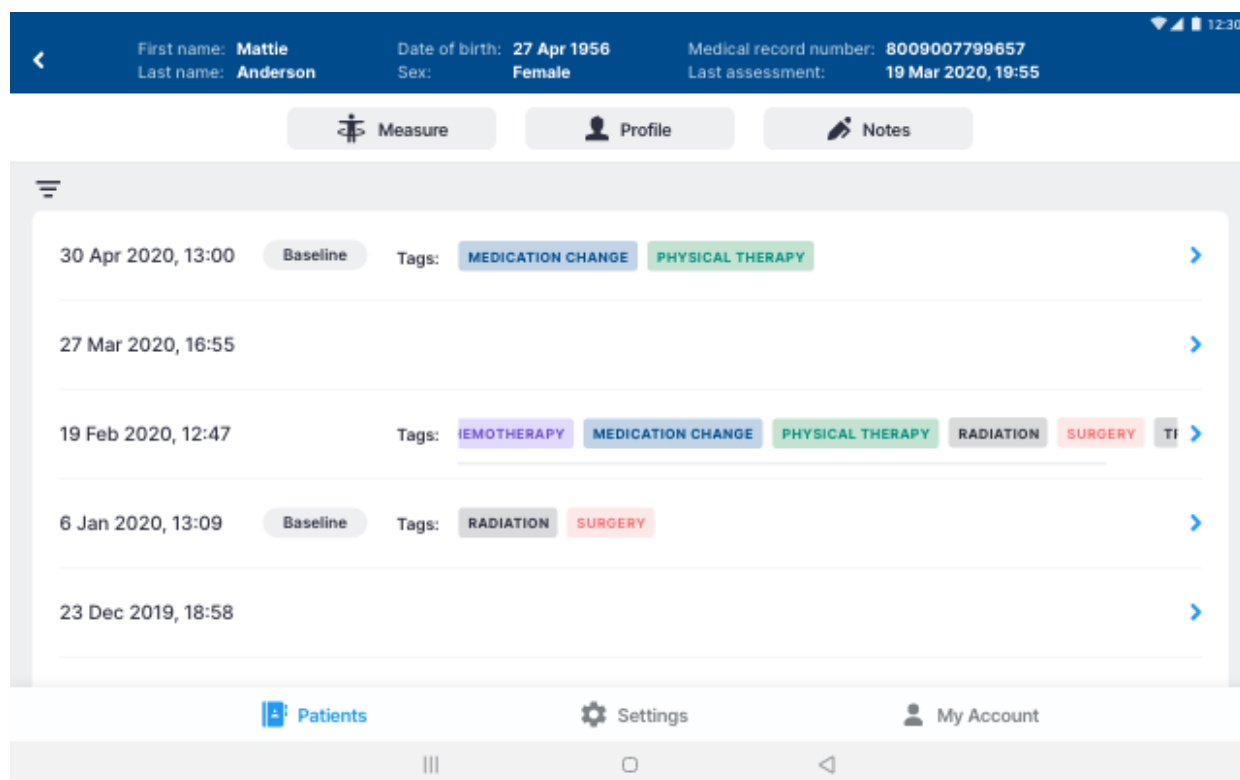


Patient Dashboard

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

To go to the Patient Dashboard:

1. Search all patients or enter the patients' name.
2. Click the **search** icon.



Create Patient

Clinicians can create a Patient by clicking the **Add icon**. 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, click the Not Provided box next to the Email Address field.
2. Select the appropriate **assessment types**.
3. When done, click **Create**.

The screenshot shows a mobile application interface for creating a new patient. The 'NEW PATIENT' modal is open, displaying a 'DEMOGRAPHICS' section. The form includes the following fields:

- First Name* (required)
- Middle Name (optional)
- Last Name* (required)
- Country Code (optional)
- Phone Number (optional)
- Address (optional)
- Email* (required)
- City (optional)

A keyboard is visible at the bottom of the screen, indicating that the user is currently editing a text field. The background shows a list of existing patients, including 'Eusebio Ann' and 'Humberto A'.

Assessment Types

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

1. Scroll down the “Create Patient” window for a list of types of assessments which apply to the patient.
2. Select the types that apply.
 - a. Note that 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
 - b. Select additional assessment options such as unilateral/bilateral, body element, risk limb, and limb dominance.

The screenshot shows a mobile application interface for creating a patient profile. The window is titled 'Patients' and has a 'CLOSE' button at the top left and a 'SAVE' button at the top right. The main section is titled 'ASSESSMENT TYPE'. Under this heading, there is a list of assessment options. The first option, 'L-Dex Analysis for Lymphedema', is selected with a blue checkmark. Below this, there are four sub-options, each with a radio button: 'Assessment*' (selected as 'Unilateral'), 'Body Element*' (selected as 'Arm'), 'Risk Limb*' (selected as 'Left'), and 'Limb Dominance*' (selected as 'Left'). To the right of these options is an 'Info' box with the text: 'The unilateral selection is for use with patients that have only one limb at risk of lymphedema. Both limbs will be measured and used to calculate the L-Dex score.' Below the sub-options, there are four more assessment options, each with a checkbox: 'Fluid Analysis for Heart Failure', 'Fluid Analysis for ESRD', 'Body Composition Analysis', and 'Segmental Body Composition Analysis'. At the bottom of the window, there is a section titled 'GROUPS' with two options: 'Female Lymphedema Patients' (selected with a blue checkmark) and 'Male Lymphedema Patients' (not selected).

Notes:

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

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.

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

Delete Patient

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

Restore Patient

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

Edit Patient Profile

To edit a patient profile:

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

PROFILE CLOSE SAVE

DEMOGRAPHICS *Required Fields

First Name*
Mattie

Middle Name

Last Name*
Anderson

Email* NOT PROVIDED

Medical Record Number*
8008744870009

Date of Birth*
29 Apr 1967

Sex*
Female

Height (cm)*
167

Country Code

Phone Number

Address

City

State

Country

Postal Code

ASSESSMENT TYPE



☒ L-Dex Analysis for Lymphedema

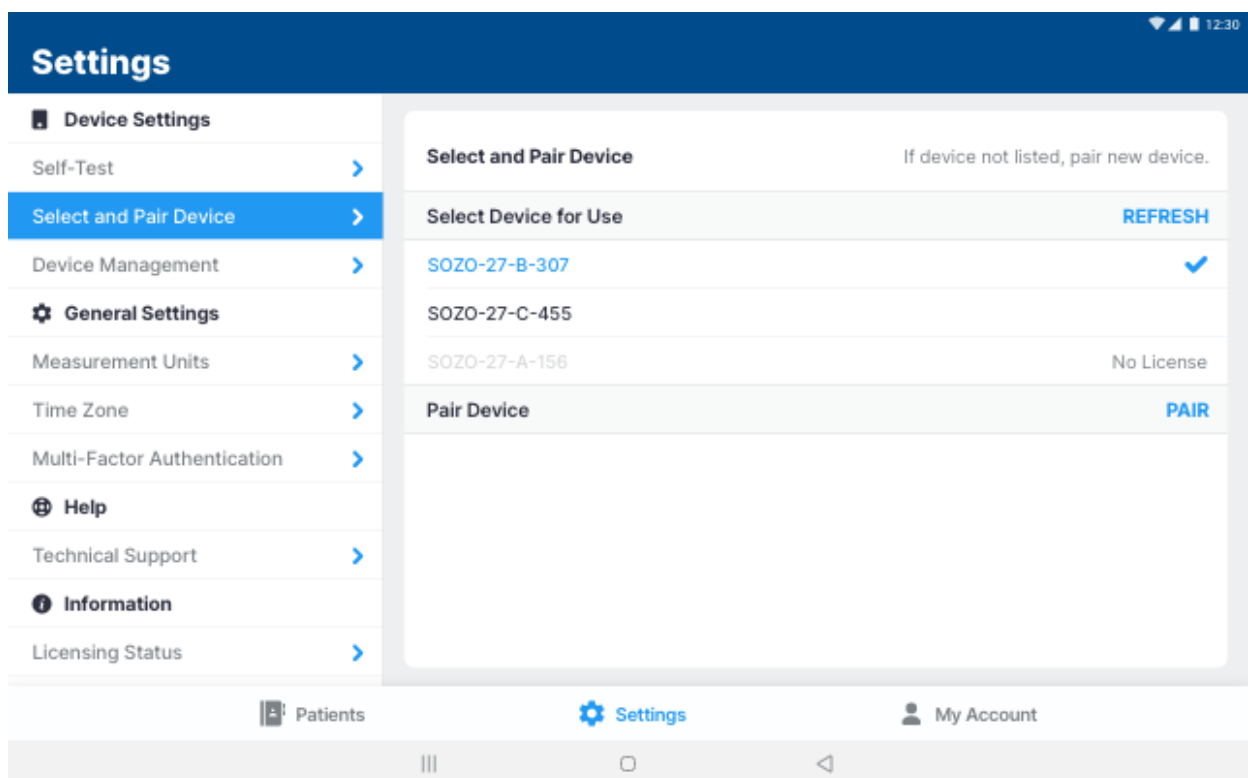
☐ L-Dex Analysis for Lymphedema

Pairing the 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:

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.
- c. Tap the **SOZO app icon**  located on the Tablet home screen.
 - i. If SOZOapp has been deleted, contact ImpediMed for re-installation.
 - ii. As newer SOZOapp versions are released, the appearance of the SOZOapp icon may change.
- d. Tap the **SOZO app icon**  located on the Tablet home screen and sign in.
 - i. If SOZOapp has been deleted, contact ImpediMed for re-installation.
 - ii. As newer SOZOapp versions are released, the appearance of the SOZOapp icon may change.
- e. Go to the Settings menu, and then 'Select and Pair Device'. A list of SOZO systems that have been paired over Bluetooth will be presented. If the paired device is not present, press **Refresh**.



Do not pair an Android device (Samsung Tablet) to a SOZO system whose serial number starts with IOS- The android SOZOapp will not be able to communicate with this SOZO Device. If this occurs, chose a SOZO Device with a identification that does not start with IOS or navigate into the Bluetooth settings menu to unpair the SOZO Device.

iOS:

- a. The SOZO Device must be paired through SOZOapp itself, not through the operating system. If the device is selected 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-).

General Pairing Instructions:

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

The SOZO Device serial number may be found on the

- SOZOtouch housing
- SOZOconnect cable
- SOZOstep housing

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

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

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 logs in. Once the SOZO Device is selected, the SOZOapp automatically pairs with the SOZO Device through *Bluetooth®*.

SOZOapp Settings

From the SOZOapp settings menu, the Clinician may change some SOZO settings in the SOZOapp, and run a self-test on the paired SOZO Device.

To make updates, select Settings, located at the bottom of the SOZOapp home screen.

Within the settings options the user can configure preferred Measurement Units, turn on personal Multi-Factor Authentication, and update Tablet software through the Software Information submenu.

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

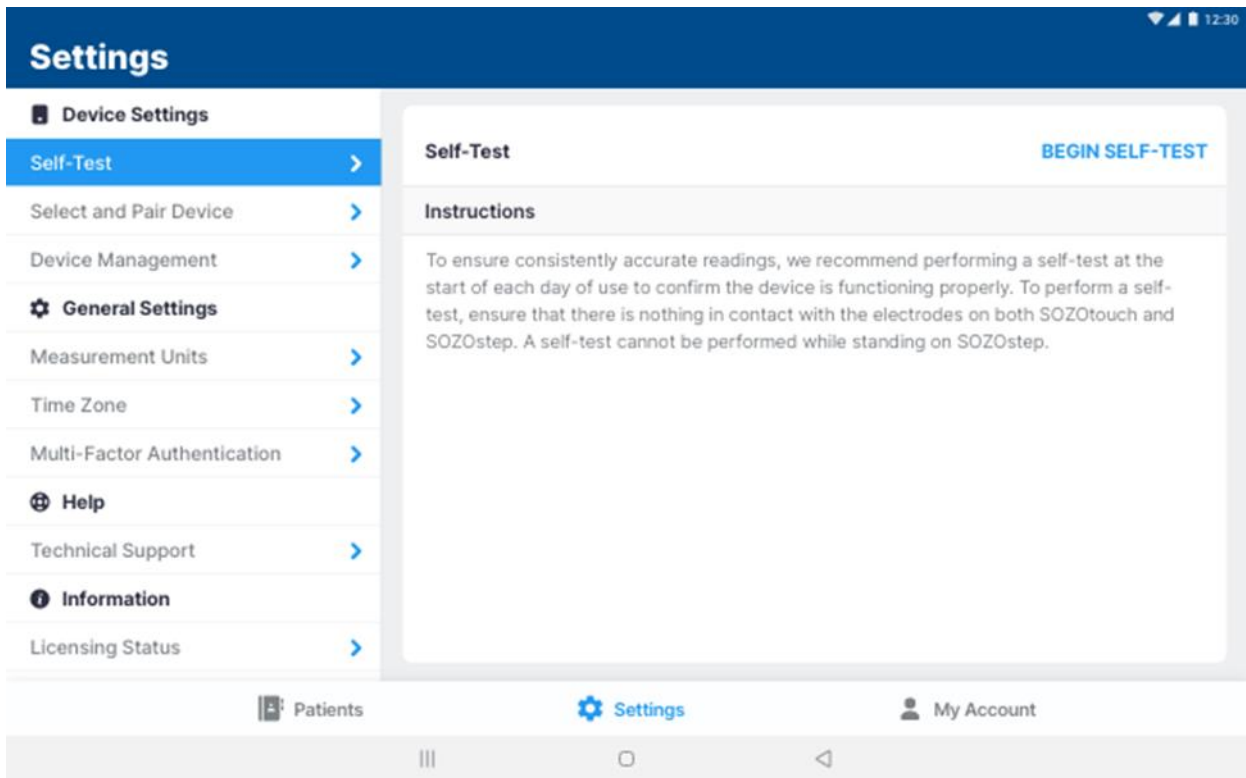
Self-Test

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
- **Mandatory Step Before Taking Measurements:** A self-test is mandatory preparation for taking measurements. It should be run daily before taking the first measurement of the day.

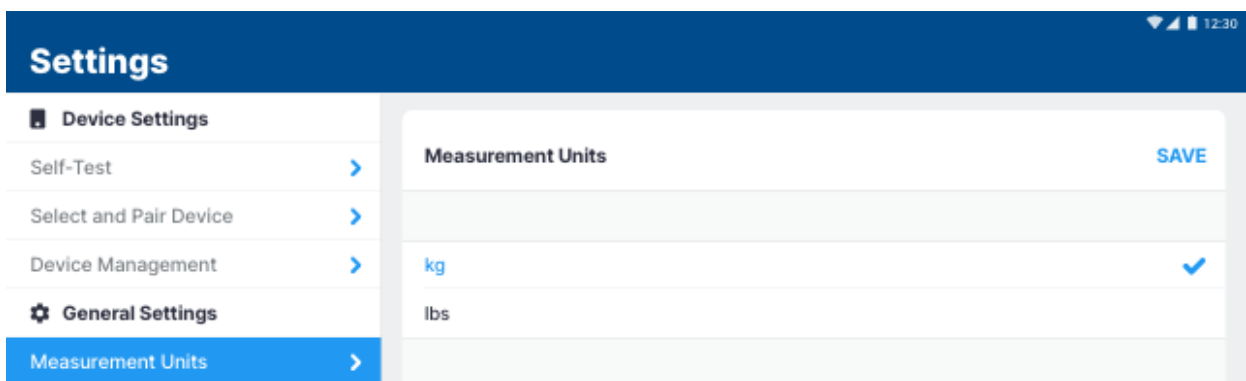
To run a self-test:

1. Select "Begin Self-Test".
2. Follow additional instructions as prompted.



Adjusting Measurement Units

Under **Settings**, the measurement standard for weight, height, and fluid volume may be converted. Kilograms may be converted to pounds, centimetres to inches and litres to pints. When updates are complete, tap **Save**.



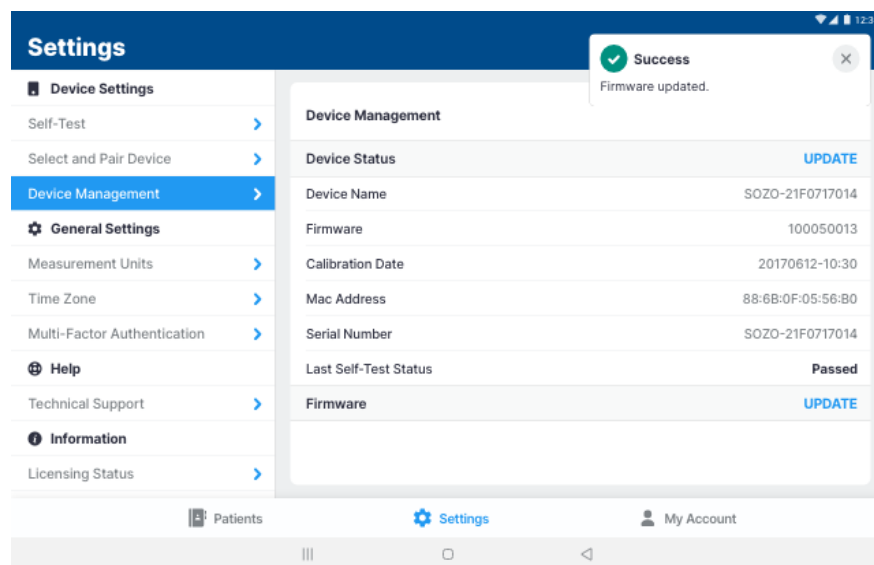
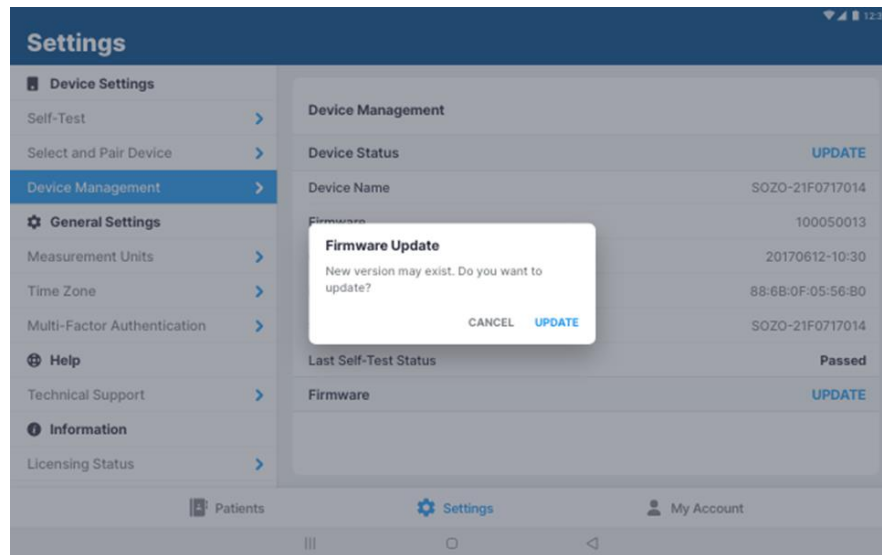
Software/Firmware Update

Under Settings, SOZOapp software, or SOZO system firmware, may be updated by **tapping update**. This process may take a 2-3 minutes. The Tablet or SOZO Device should not be turned off during this time.

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

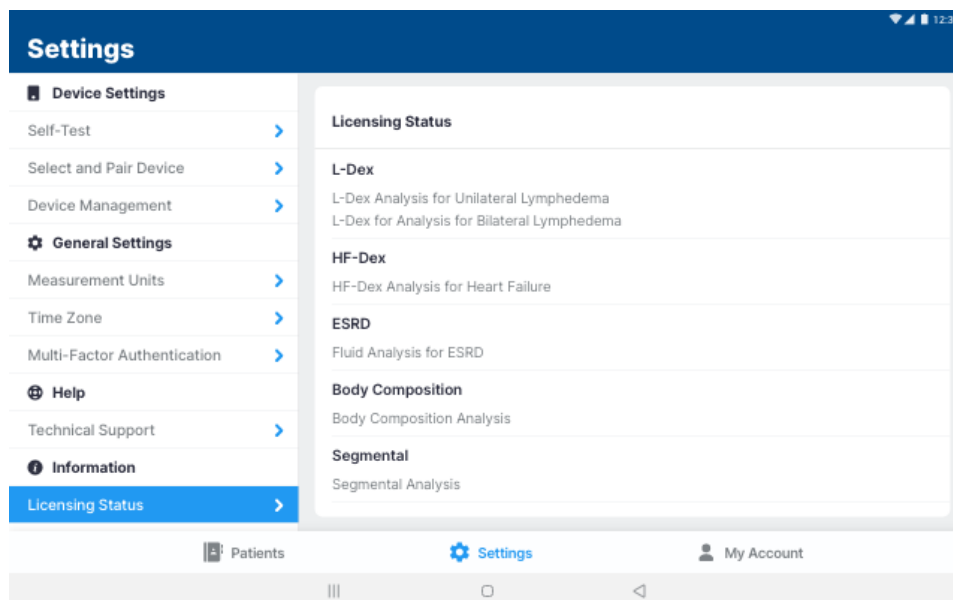
NOTE:

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



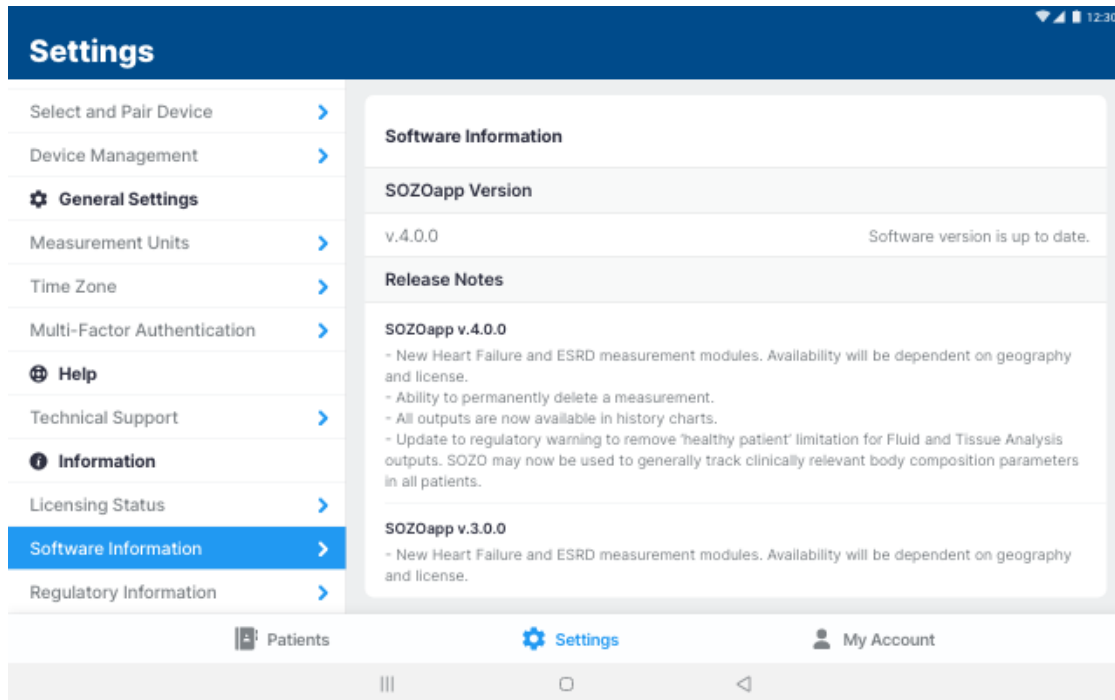
Licensing Status

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.



Software Version

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



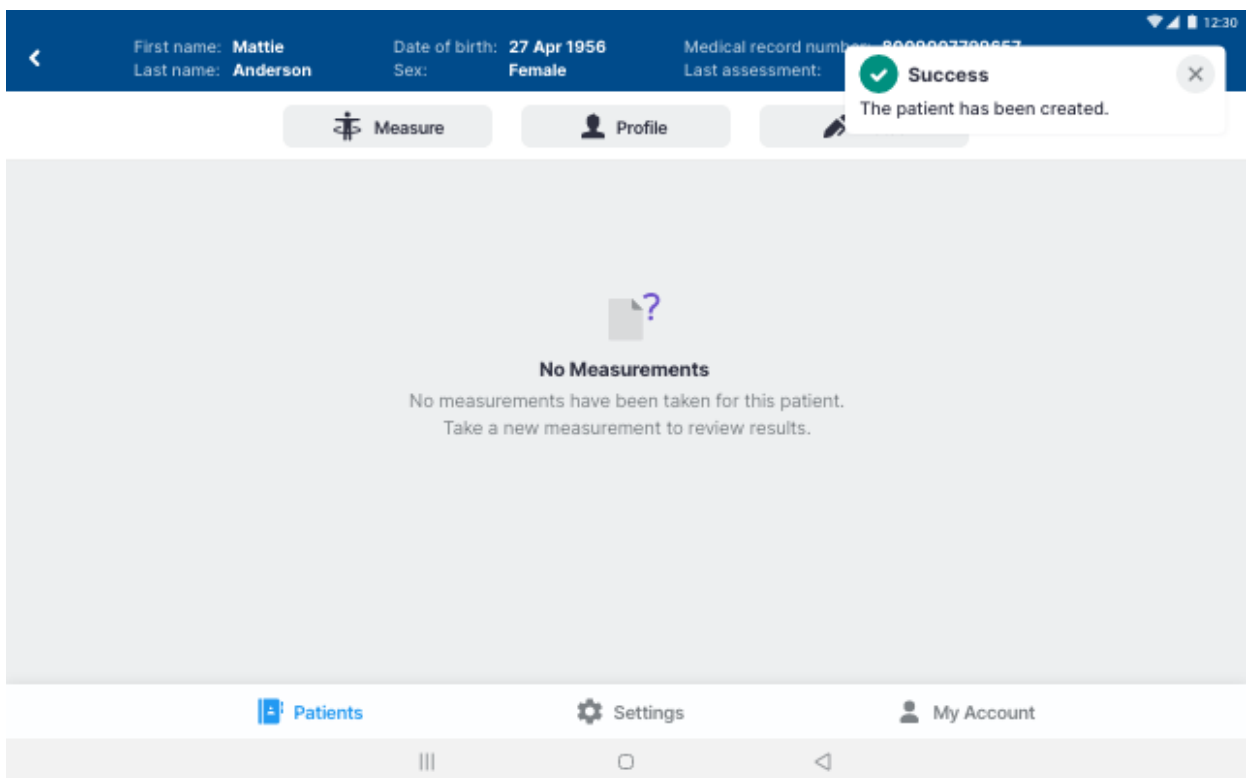
The Android SOZOapp must be the same version as MySOZO. If the Android SOZOapp version is not the most current version as MySOZO, the user will be prompted to automatically update upon login. If the automatic update process is not successful, contact your IT support or ImpediMed technical support for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

If the iOS SOZOapp version is not the most current version, the user will be notified upon login and the SOZOapp will not progress past the login screen. If this occurs, contact your IT support or ImpediMed technical support for a compatible version of the SOZOapp.

Taking Measurements

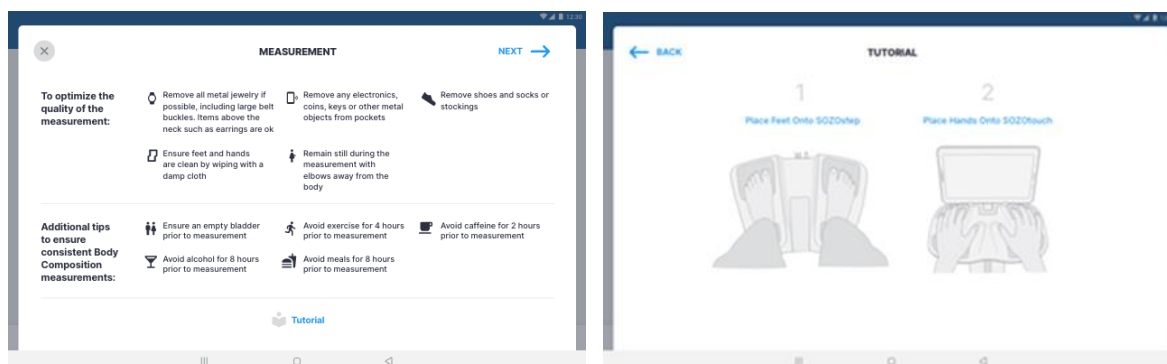
The SOZO Device supports various types of measurements for each Assessment, such as measurements for the detection of lymphoedema (L-Dex module), for monitoring of fluid in Heart Failure patients (HF-Dex), and for different body composition outputs (Body Composition and Segmental).

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



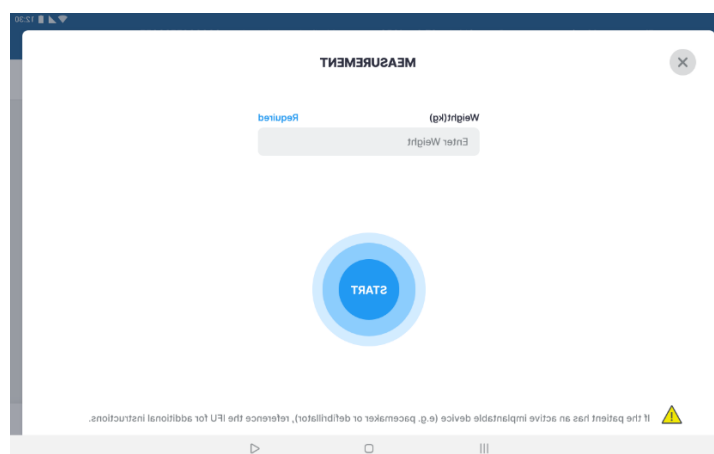
To take patient measurements:

1. Search and select the patient from the patient list.
2. From the patient dashboard, **tap the measure icon** to begin new patient measurements.
3. After tapping the measure icon, measurement instructions appear. To optimize measurement quality, ensure patient compliance with these instructions. When done, click Next.



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

4. Confirm that the SOZOstep is stationary and on a level surface.
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. Confirm that SOZOtouch is stationary and on a level surface.
7. 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.
8. **Enter Patient Weight and then Tap Start** to begin measuring the patient's weight.
 - a. This triggers a five-second countdown before the start of the measurement.
 - b. Accurate weight entry is critical to tissue and fluid 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.

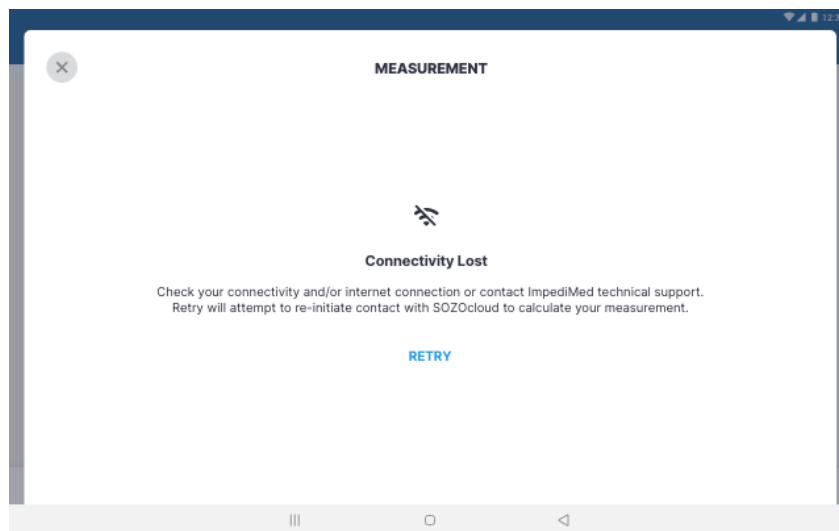
Notes:

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

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

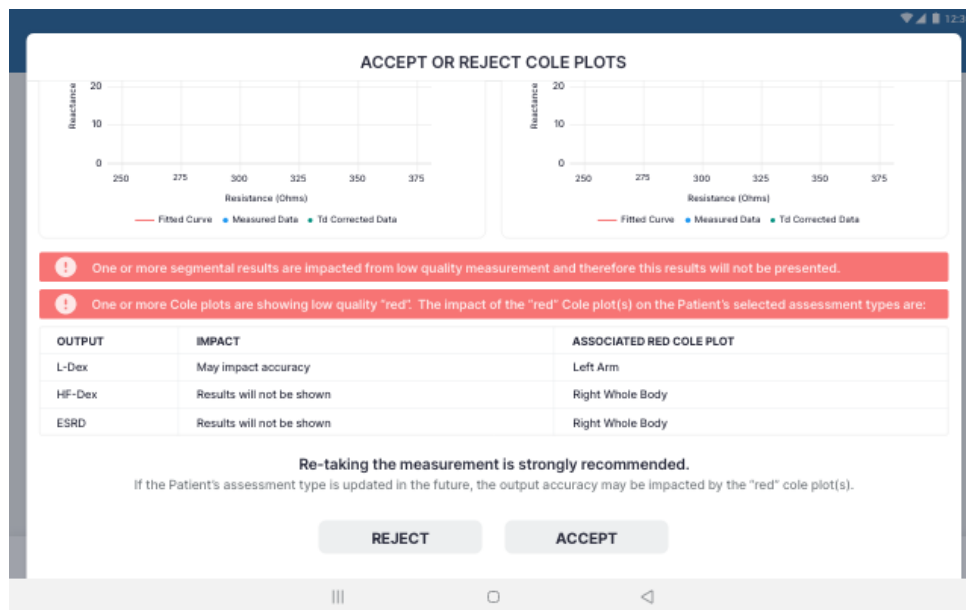
Loss of Connectivity During Measurement

If you lose connectivity while the measurement is in progress, follow troubleshooting tips in [Connectivity Error](#).



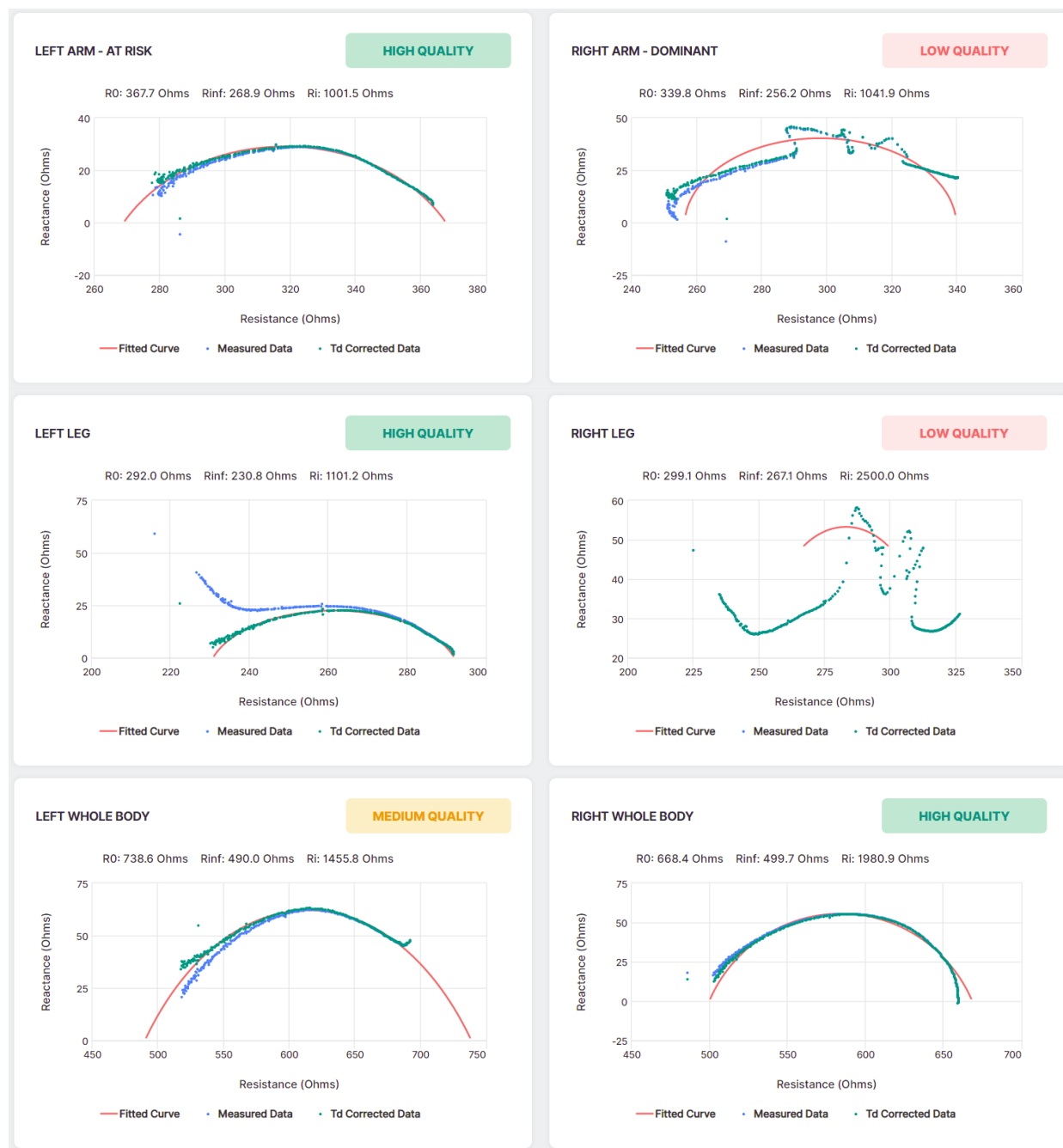
Reviewing Cole Plots After Measurement

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



Accept or Reject Measurements

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



Interpreting Cole Plots

On a Cole plot, the dark blue dots are the raw “Measured Data,” and the light blue dots are “Td Corrected Data,” representing the raw measured data after error correction has been applied. The solid red semi-circle or “Fitted Curve” represents the final curve to

which the Td corrected data was fitted. Some degree of “scatter” of Measured Data is acceptable. If Td Corrected Data is consistent with the red Fitted Curve, as shown below, the Cole plot is “High Quality.”

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

A large amount of scattered data may be due to interference from a nearby mobile phone or other piece of operating electrical equipment. Determination of the quality of a given measurement can only be made at the time of measurement, but Cole plots are also shown when reviewing historical result.

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

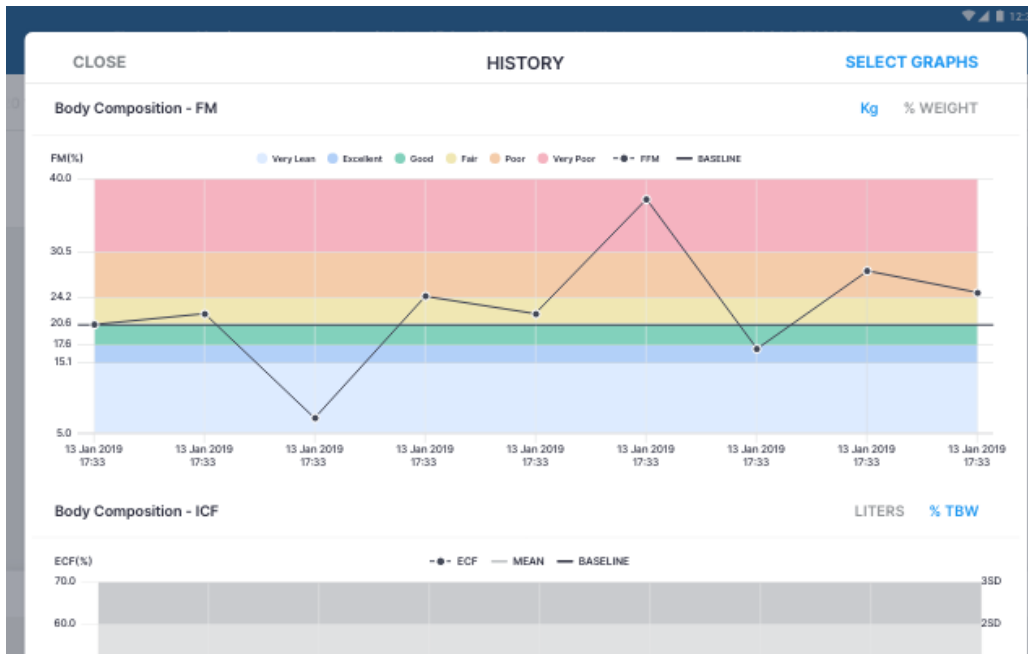
The Clinician cannot accept or reject some, but not all, Cole plots. If they tap **Accept**, all Cole plots are accepted. If **Reject** is tapped, all Cole plots are rejected.

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

Accepting Measurements

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

History



Cole plots associated with a given measurement are stored with each measurement, and may be reviewed alongside a given measurement's results.

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

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** set as baseline.

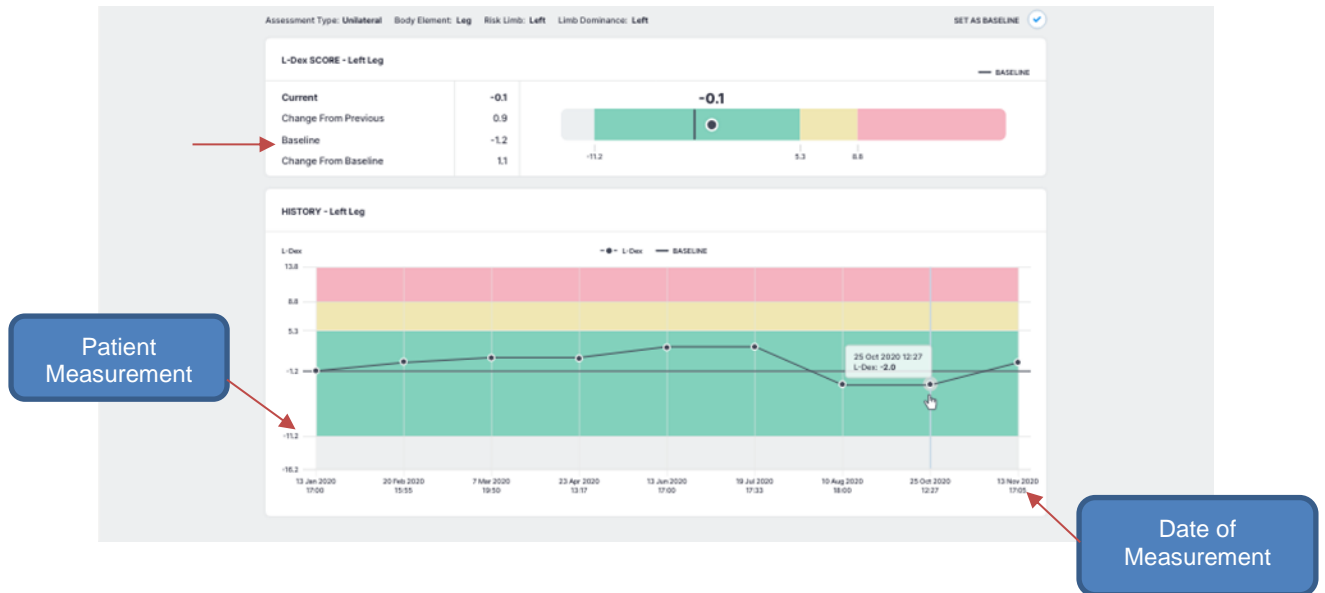
To choose the proper measurement as the baseline, the measurement should be:

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

Note that 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.

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.



Deleting Measurements

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

First name: Mattie
Last name: Anderson
Date of birth: 27 Apr 1956
Sex: Female
Medical record number: 0000007300557
Last assessment: 7 Feb 20

Success
Baseline has been updated.

History Tags 5 Delete

L-DEX HF-DEX ESRD BODY COMPOSITION SEGMENTAL COLE PLOTS

Dialysis Status: Post Dialysis SET ECF BASELINE 17.6 (L) SAVE

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

INTRACELLULAR FLUID (ICF) LITERS % TBW

WEIGHT Kg

Patients Settings My Account

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



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

Impact of Licensing Additional Assessments on Results

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

Impact of Cancellation of Assessment License on Results

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

When to Select “Only future measurements”

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

When to Select “All measurements including historical”

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

Availability of Assessment Specific Data on Patient Profile

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

Assessments

The SOZO Device supports the following Assessment Types:

- 1) L-Dex
- 2) HF-Dex
- 3) ESRD
- 4) Body Composition Analysis
- 5) Segmental Analysis

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

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

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
- Body Composition 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 displays are only available if licenced.

Assessment Specific Instructions For Use

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

L-Dex[®] for Lymphoedema

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.

Instructions for Use

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

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

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

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



Ensure that you update the patient profile correctly to fit each patient's needs, taking into consideration the relevant facts and circumstances related to measurement, as identified in this User Guide, since this will affect the validity of measurements. Incorrect measurements may impact the accuracy of the L-Dex calculations and may affect the L-Dex assessment based upon L-Dex calculations. For more information about making the correct selections, see instructions for use of the SOZOapp in [Section Error! Reference source not found.](#), and in [Section Error! Reference source not found.](#).

The Lymphoedema Index (L-Dex)

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

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

The underlying calculations for unilateral assessments using the SOZO system have not changed from any previous L-Dex devices. The impedance of the extracellular fluid space (R0) of the unaffected limb is compared with the contralateral affected limb. Clinical data has shown this to have “excellent” accuracy when used as a clinical aid to assess unilateral fluid accumulation in the limb following cancer treatment.²

² 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.



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

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

L-Dex Assessment Results

L-Dex Scores

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

L-Dex Scores ≤ -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 Scores $\Delta \geq +6.5$



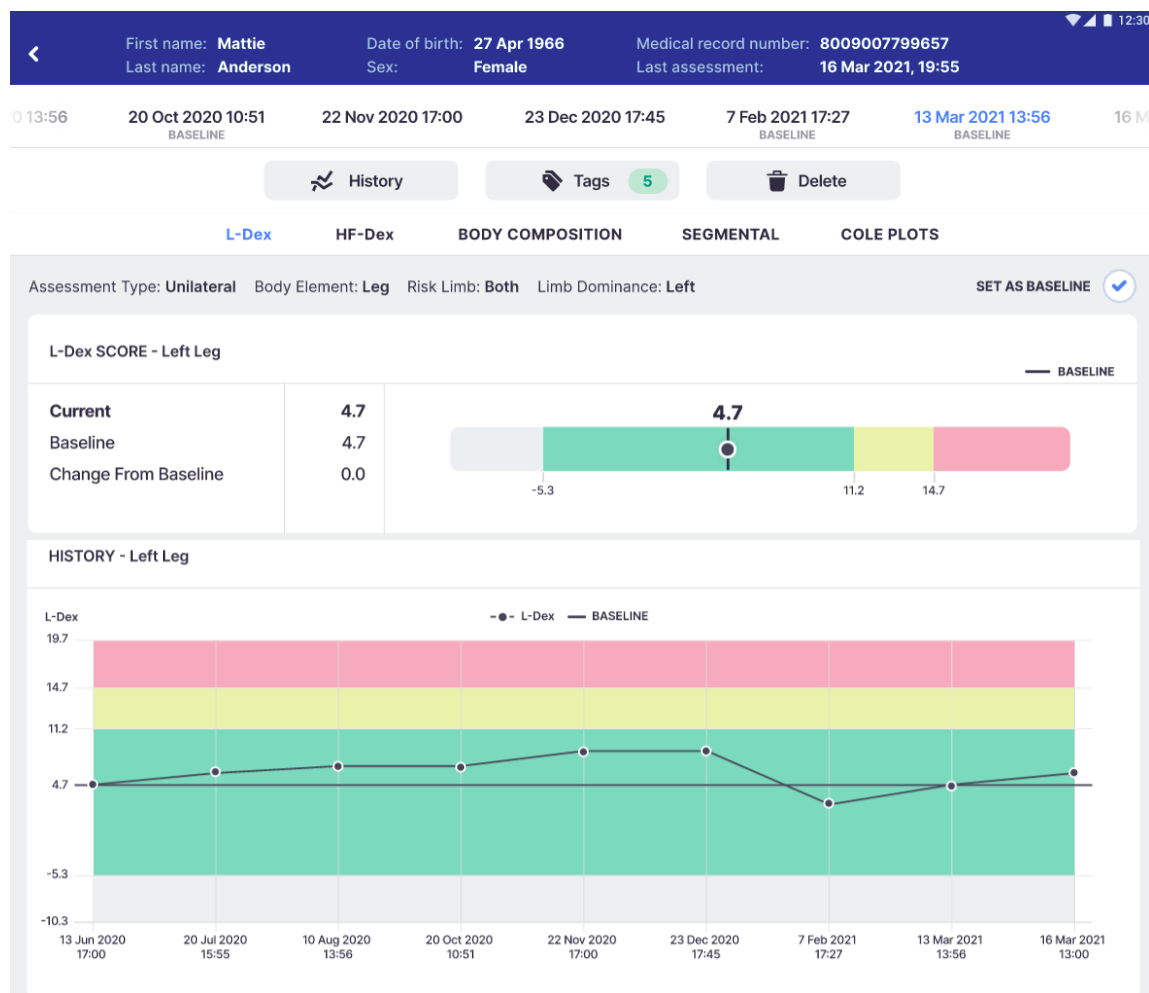
L-Dex scores that have changed +6.5 L-Dex units from the baseline may indicate early signs of lymphoedema.

Viewing L-Dex Results

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

Example of L-Dex Results and Measurement History

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 the main User Guide, "SOZO System Instructions for Use."



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*’:



Please note that if an incorrect baseline is selected, simply select the correct measurement and baseline.

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

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

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

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

For more information about setting the baseline for an L-Dex assessment, see the main User Guide, "SOZO System Instructions for Use."

All prior measurements with the L-Dex Assessment may be viewed in MySOZO as well. For more about accessing MySOZO, see the main User Guide, "SOZO System Instructions for Use."

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

HF-Dex™ Analysis

Indications for Use

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

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

Instructions for Use

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

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

In order to use the HF-Dex module, the facility will require a 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”.

HF-Dex Assessment Results

HF-Dex Scores

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

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

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

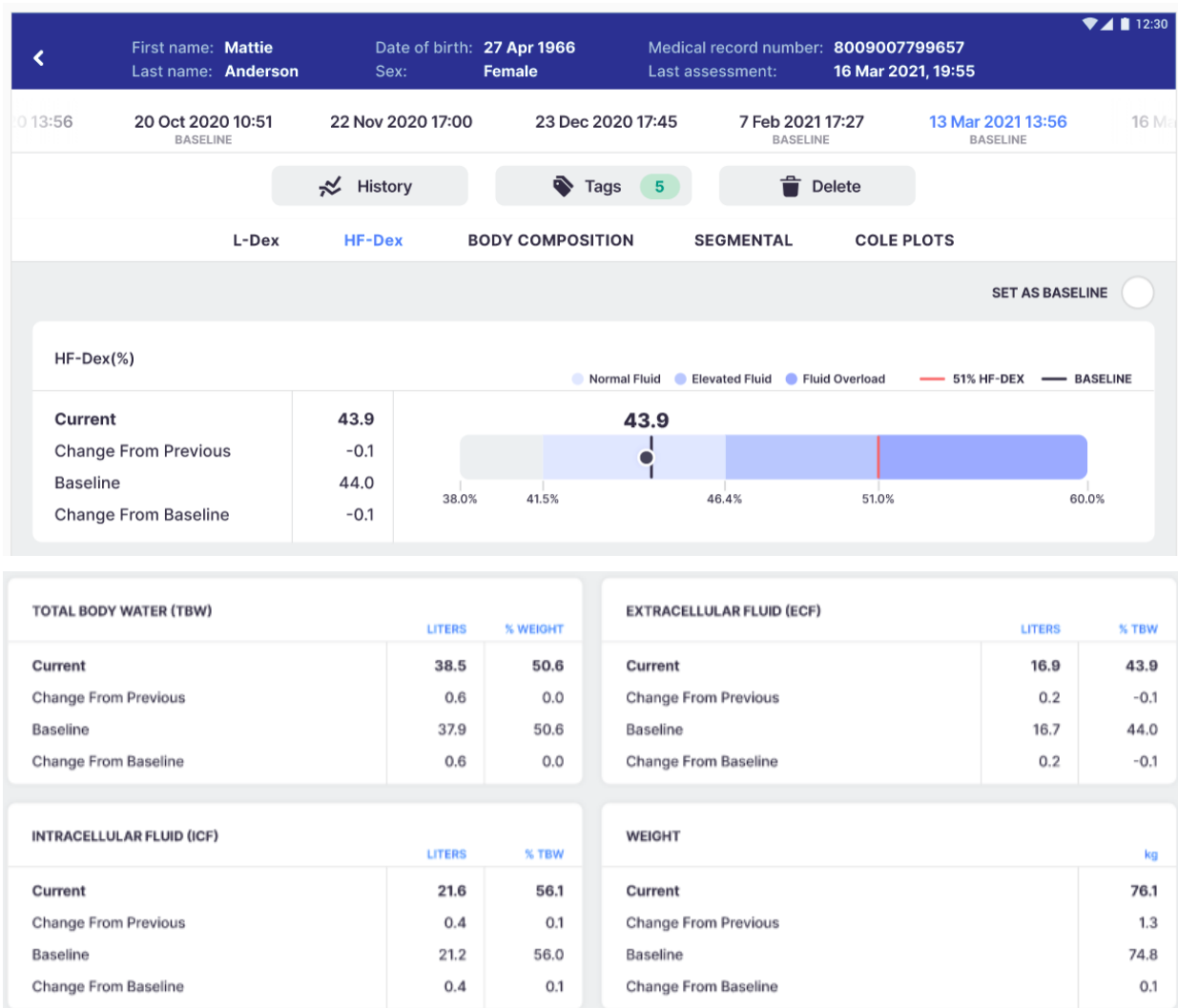
Dark Blue range: Patients whose HF-Dex score falls into the dark blue range have a higher score that compares to levels in a decompensated heart failure population. Clinical data shows that patients with elevated scores should be carefully monitored. Decisions regarding the patient’s management should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

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

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

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



At the bottom of the results screen, the patient's HF-Dex scores will be shown on a history graph as well.

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.

ESRD

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.

Instructions for Use

Ensure that you have read and understand the instructions for use in all sections of this User Guide for setup, installation and use of the SOZOapp, and also ensure that you have read and understand the instructions for use for setup, installation and use of MySOZO and the SOZOapp. 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 facility 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".

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:

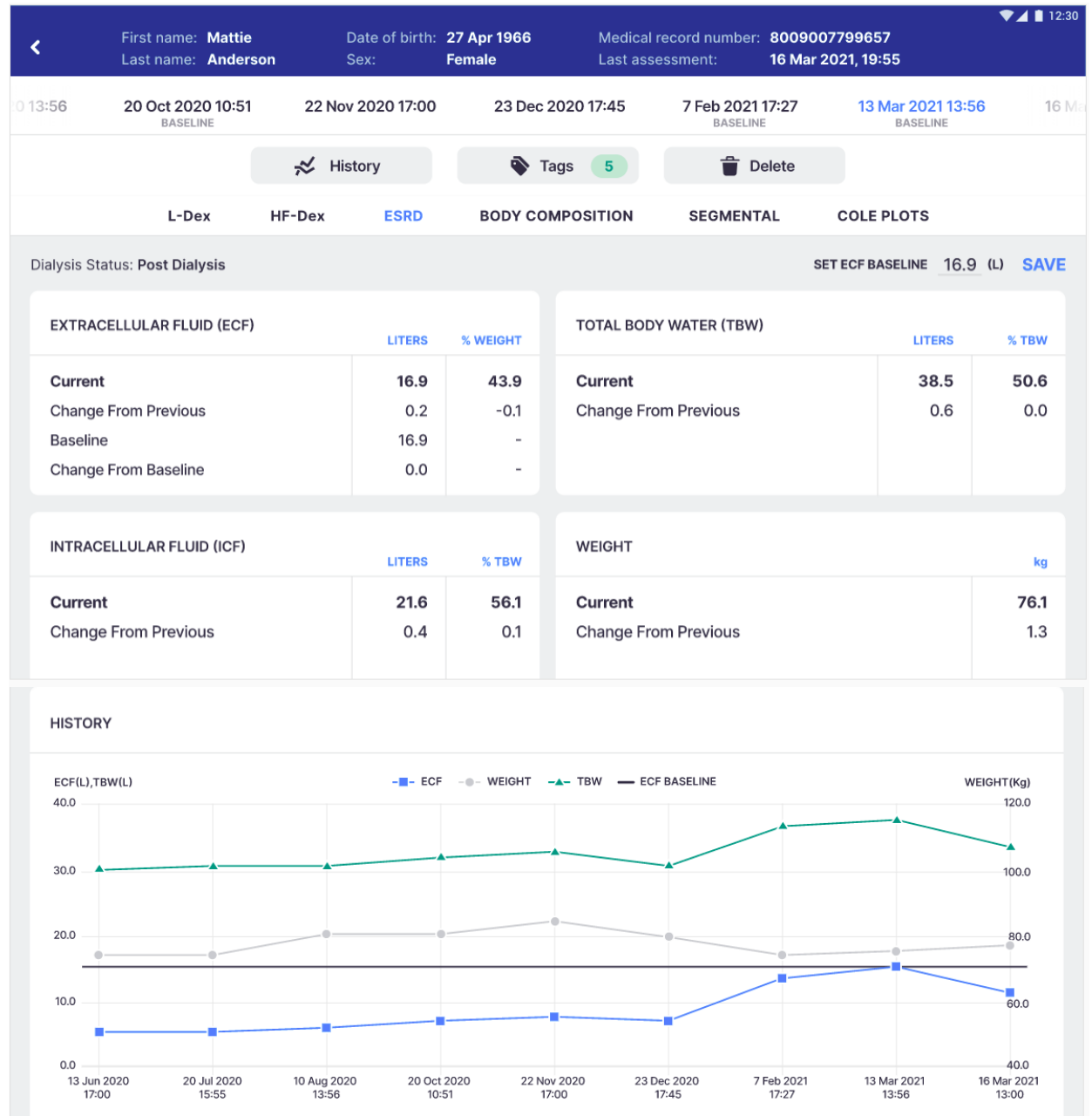
ESRD Assessment Results

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

Example of ESRD Module Results



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.

Body Composition Analysis

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 Tissue Analysis 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.

Instructions for Use

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

Body Composition Module 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.

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 Application section below.

Segmental Body Composition Module Results (Individual Limbs)

If your facility has licenced 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:

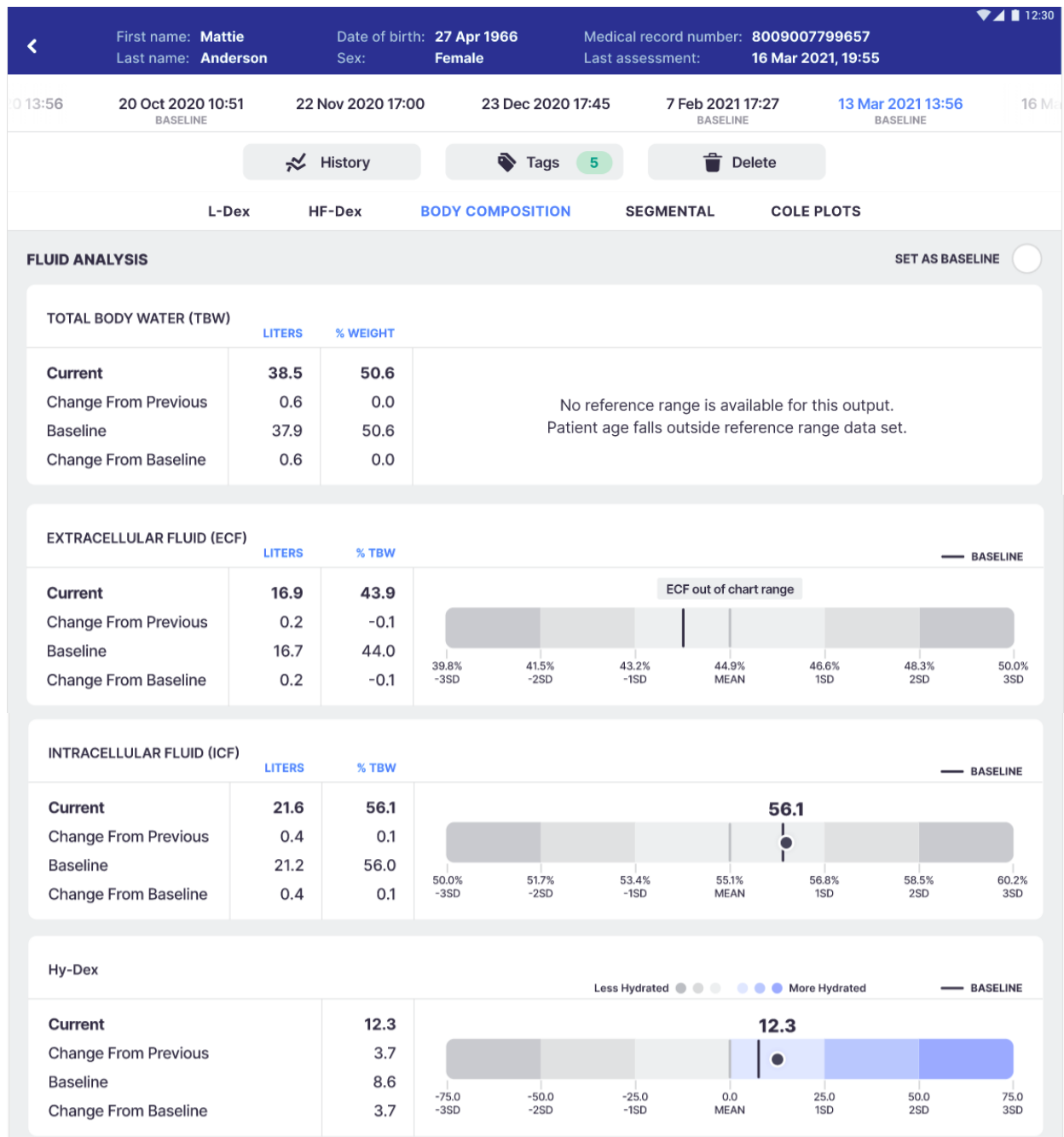
- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- ECF and ICF distribution (expressed as a percentage of total body water for the limb)
- Skeletal Muscle Mass (SMM)
- Lean Soft Tissue (a subset of Fat-Free Mass)
- Phase Angle

NOTES:

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.

Reference ranges are not available for individual body segments.

Example of Body Composition Results



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

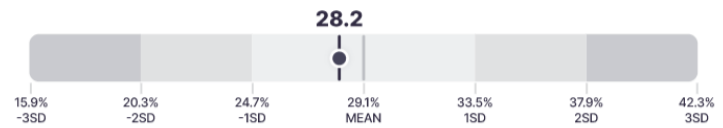
TISSUE ANALYSIS

SKELETAL MUSCLE MASS (SMM)

kg % WEIGHT

— BASELINE

Current	21.4	28.2
Change From Previous	0.3	0.0
Baseline	21.1	28.2
Change From Baseline	0.3	0.0

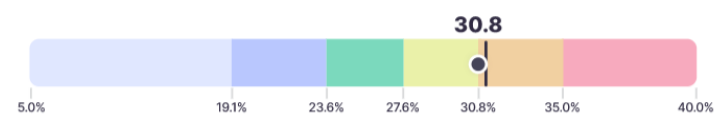


FAT MASS (FM)

kg % WEIGHT

Very Lean Lean Good Fair High Very High — BASELINE

Current	23.5	30.8
Change From Previous	0.4	-0.1
Baseline	23.1	30.9
Change From Baseline	0.4	-0.1

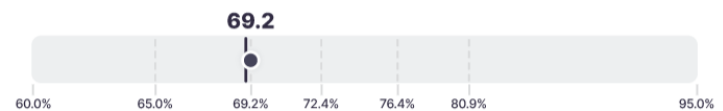


FAT FREE MASS (FFM)

kg % WEIGHT

— BASELINE

Current	52.6	69.2
Change From Previous	0.9	0.1
Baseline	51.7	69.1
Change From Baseline	0.9	0.1



PROTEIN & MINERALS

kg % WEIGHT

— BASELINE

Current	14.1	18.6
Change From Previous	0.3	0.1
Baseline	13.9	18.5
Change From Baseline	0.2	0.1



METABOLIC REPORT

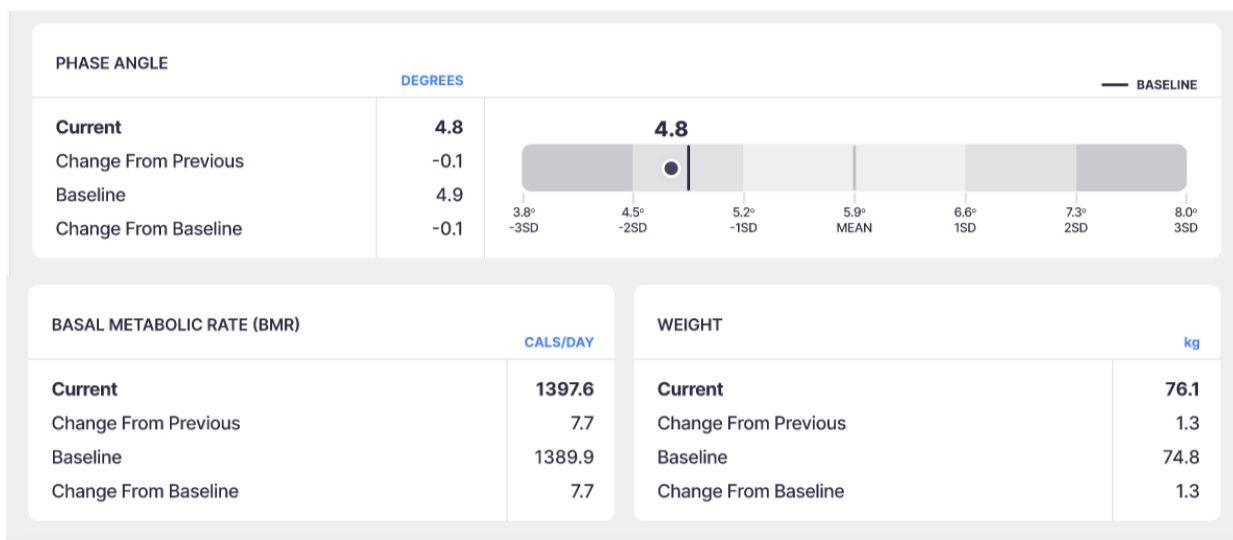
BODY MASS INDEX (BMI)

kg/m²

Underweight Healthy Overweight Obese — BASELINE

Current	26.3
Change From Previous	0.4
Baseline	25.9
Change From Baseline	0.4





⬅

First name: **Mattie**
Last name: **Anderson**

Date of birth: **27 Apr 1966**
Sex: **Female**

Medical record number: **8009007799657**
Last assessment: **16 Mar 2021, 19:55**

10:13:56
20 Oct 2020 10:51
BASILINE
22 Nov 2020 17:00
23 Dec 2020 17:45
7 Feb 2021 17:27
BASILINE
13 Mar 2021 13:56
BASILINE
16 Mar 2021 13:56

History
 Tags 5
 Delete

L-Dex
HF-Dex
BODY COMPOSITION
SEGMENTAL
COLE PLOTS

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

LEFT ARM	CURRENT	CHANGE FROM BASELINE
Total Body Water	1.7(L)	0.0(L)
Extracellular Fluid	0.8(L), 46.7(%Tbw)	0.0(L)
Intracellular Fluid	0.9(L), 53.3(%Tbw)	0.0(L)
Skeletal Muscle Mass	1.7(Kg)	0.0(kg)
Lean Soft Tissue	2.2(Kg)	0.0(kg)
Phase Angle	0.1°	0.0°

RIGHT ARM	CURRENT	CHANGE FROM BASELINE
Total Body Water	1.9(L)	0.0(L)
Extracellular Fluid	0.8(L), 44.2(%Tbw)	0.0(L)
Intracellular Fluid	1.1(L), 55.8(%Tbw)	0.0(L)
Skeletal Muscle Mass	1.7(Kg)	0.0(kg)
Lean Soft Tissue	2.4(Kg)	0.0(kg)
Phase Angle	0.1°	0.0°

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

LEFT LEG	CURRENT	CHANGE FROM BASELINE
Total Body Water	8.0(L)	0.0(L)
Extracellular Fluid	4.0(L), 49.9(%Tbw)	0.0(L)
Intracellular Fluid	4.0(L), 50.1(%Tbw)	0.0(L)
Skeletal Muscle Mass	6.2(Kg)	0.0(kg)
Lean Soft Tissue	10.4(Kg)	0.0(kg)
Phase Angle	0.1°	0.0°

RIGHT LEG	CURRENT	CHANGE FROM BASELINE
Total Body Water	7.7(L)	0.0(L)
Extracellular Fluid	3.6(L), 47.5(%Tbw)	0.0(L)
Intracellular Fluid	4.1(L), 52.5(%Tbw)	0.0(L)
Skeletal Muscle Mass	6.2(Kg)	0.0(kg)
Lean Soft Tissue	9.9(Kg)	0.0(kg)
Phase Angle	0.1°	0.0°

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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.

Please note that 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 your estimation, is in suitable good health. It may take some time to establish an appropriate baseline measurement for your patient.

Application: Body Composition Analysis

At the conclusion of a measurement, the Body Composition Analysis module will present a screen containing a wide range of body composition information in your 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 utilized to provide additional data and guidance to the clinician.

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.

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.

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.

ECF & ICF Distribution

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

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".

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 as 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 along are presented.

Protein and Minerals

The human body utilizes 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.

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). NOTE: the SOZO device does not directly measure SMM, and the SMM value calculated is based on an algorithm developed and published in Janssen (2010)³. Reference ranges for SMM were established based on data presented in Janssen (2000)⁴.

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.

Phase Angle

The resistance/reactance of a person's cell membrane at a 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)⁵.

³ Janssen I *et al*, “Estimation of skeletal muscle mass by bioelectrical impedance analysis.” *J. Appl Physiol.* 89(2):465-71

⁴ Janssen I *et al*, “Skeletal muscle mass and distribution in 468 men and women aged 18-88 yr.” *J Appl Physiol* 89:81-88.

⁵ 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.

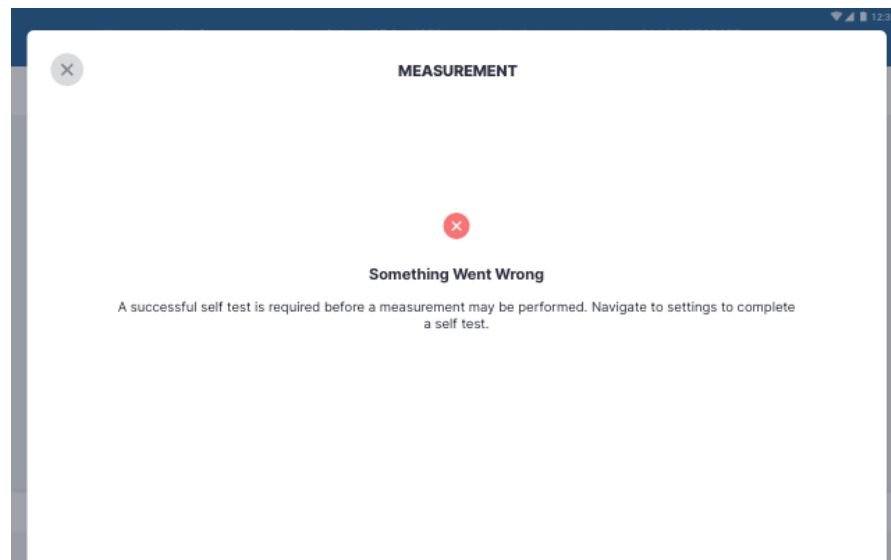
SOZOapp Troubleshooting

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

Error Messages

Self-Test Error

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



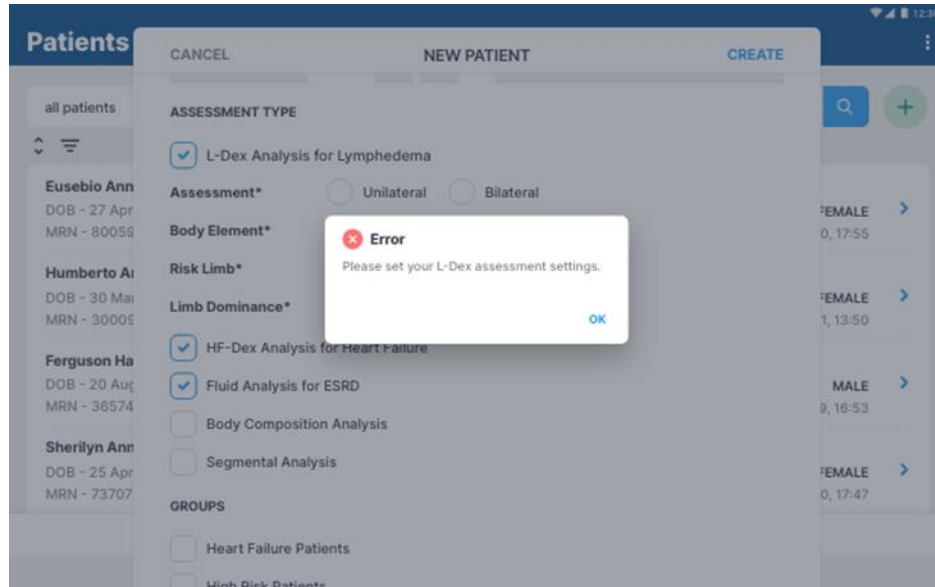
Try any one of the below actions to resolve this issue:

- Ensure nothing is touching the SOZO Device.
- Reset the Bluetooth® button on the back of SOZOtouch.
- Unplug the SOZO Device from the wall outlet and plug back in.
- Re-run the self-test function.

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.

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

Patient Dashboard Error

After starting measurement, an error message may appear on the Patient Dashboard.
“Something Went Wrong.”

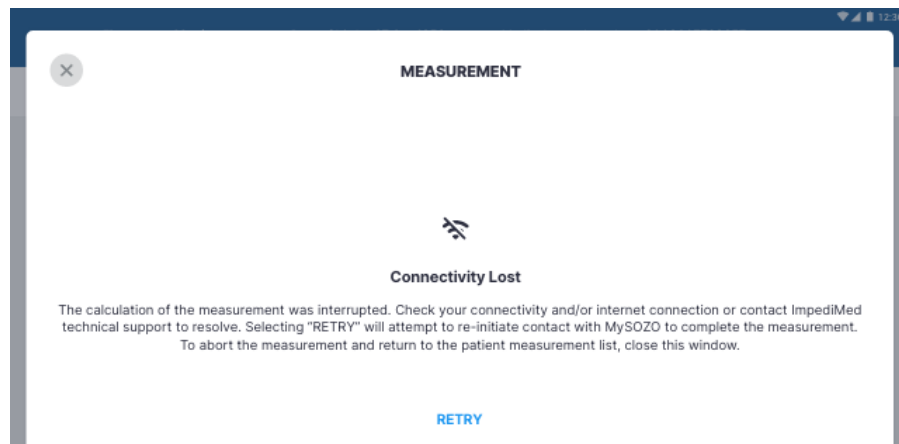


Follow the below actions to resolve this issue:

1. Ensure that the patient is standing and correctly positioned on the SOZO Device before tapping Measure.

Connectivity Error

If connectivity is lost while measurement is in progress, an error message appears.
“Connectivity Lost.”



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.
4. To restart. See [Taking Measurements](#)

General Troubleshooting Chart

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

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
Form fields have character limits and entry requirements. Various error messages can occur if these field requirements are not met.	User has completed a form field that does not meet minimum/maximum/character type requirements	Enter data in mandatory fields according to requirements described in error message.
SOZO hardware does not emit audible clicks when powering on; LED at back of unit is not emitting a blue light.	Power cord not properly connected or potential hardware failure.	Confirm power cord is properly connected. If cord is correctly inserted, contact ImpediMed technical support.
Self-test fails.	Person/object making contact with electrodes during self-test.	Ensure no extraneous objects in contact with electrodes during self-test; re-run self-test.
L-Dex; HF-Dex, Body Composition, Segmental, tab is missing from the history or results.	The assessment type is not chosen, or license is not available.	Check the assessment types chosen for the patient and adjust accordingly. Check available licenses and contact ImpediMed technical support if unable to resolve.
No SOZO devices are selectable even after device is paired via Bluetooth.	Device is not licensed.	Check license status. Contact ImpediMed technical support if license status is incorrect.

Signing in to SOZOapp / MySOZO		
Issue/Error message	Potential Cause	Resolution
"Empty fields. Please enter your username and your password to continue."	User has attempted to log 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 username and password and attempt to log in again. Continued error: change password with your IT admin.
"There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support."	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection, 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 upgraded.	Select "Yes" and follow prompts to automatically update SOZOapp to latest version.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	Potential Cause	Resolution
"There are no results matching your search criteria"	Search terms do not identify any patients or clinicians.	Revise search terms.
"Either your connection might have timed out or you need to contact the support team."	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection.	Check Tablet settings to ensure Tablet is connected to local Wi-Fi network. If Tablet is connected, contact your IT admin; otherwise call ImpediMed technical support.
"For security reasons your session has expired" or you have been logged out and see the login page.	User will be logged out automatically based on initial login. The logout time is set by the Clinic administrator.	Log back in with username and password.
"Measurement not started. Electrode check failed"	SOZO hardware verifies that electrodes are connected correctly before taking a measurement. Ensure that correct patient contact is made for all eight electrodes. If any physical damage has occurred to hardware electrode check may also fail.	Power the SOZO Device off and on, ensure correct patient contact and repeat measurement. If error persists, contact ImpediMed technical support.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	Potential Cause	Resolution
"There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support."	Error in sending data from SOZO hardware/Tablet to MySOZO.com. Potential issue with disruption of WiFi signal.	Take another measurement. Move location of SOZO Device if it is in an area with other equipment that emits electromagnetic signals. Check the WiFi signal near the Tablet and troubleshoot as appropriate. If error persists, contact ImpediMed technical support.
"Measurement wasn't valid. Please try a new measurement."	Patient is not contacting electrodes cleanly with bare hands/feet; patient preparation steps were not followed.	Ensure that all patient preparation steps have been followed and attempt another measurement. If error persists, contact ImpediMed technical support.
Use of SOZOapp/MySOZO (Clinician) (cont'd)		
Issue/Error Message	Potential Cause	Resolution
"A user with this first name, last name, and date of birth already exists"	When creating new patient, a patient already exists with this combination of first & last names, and DOB	Review existing patient to ensure unnecessary duplication of patient profiles.
"Device not found. Please check your selected device"	SOZOapp is not currently paired to a nearby SOZO Device	Verify that the device chosen is available via Bluetooth by selecting "pair device". If device is selected and error has occurred, ensure that the serial numbers match (if multiple units at your Clinic). If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. Verify SOZO hardware is powered on by pushing button and verifying blue light at back of unit is illuminated. Turn off and restart the Tablet and the SOZO Device. If error persists, contact ImpediMed technical support

"Possible device connection problem" or "There is a Bluetooth connection problem..." or "Pairing failed, Please try again"	Tablet Bluetooth has been turned off or SOZO Device Bluetooth has malfunctioned.	Confirm Tablet Bluetooth is turned on, that the proper SOZO device is selected, and that the Tablet is within range to allow a Bluetooth connection. Turn off and restart the Tablet and the SOZO Device. Press the Bluetooth reset button on the back of the SOZOtouch panel and verify blue light at back of unit is illuminated. If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. If Bluetooth is enabled on the Tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.
"Self-test unknown error"	Internal error in running self-test; potential hardware failure or firmware/software incompatibility.	Contact ImpediMed technical support
"Self-test failed"	User attempts to run self-test but either device has hardware issue or contact is made with electrodes.	Verify that nothing is touching the electrodes and repeat self-test. If error persists, contact ImpediMed technical support.
"Status retrieved. Please run a self-test and try again."	Unit has not recently run a self-test.	Run a self-test per instructions for use.
No error message, but Clinician notes that patient historical measurement data looks different compared with last review	Patient details have been changed and the measurement results have been recalculated.	Check the patient settings to ensure that they are correct. Height, age, and L-Dex settings must match historical measurement records to have same measurement results.

Administrator Interfacing with SOZO System		
Issue/Error Message	Potential Cause	Resolution
"The email entered already exists for another clinician or administrator. The email used must be unique."	When creating a new clinician, the selected username is identical to an existing username/email.	Use different username/email.
"Your passwords do not match. Please re-enter them".	During user password creation, a different password was entered in the confirmation box.	Verify and re-enter passwords.
"Firmware update unknown error"	Unknown error has occurred during SOZO firmware update.	Please contact ImpediMed technical support.
"Firmware update failed"	Update procedure failed.	Attempt to install firmware again. If failure persists, please contact ImpediMed technical support.
Password doesn't work.	Password forgotten.	Review MySOZO set up for instructions on resetting password.

PERSONAL DATA

Read our privacy policy located at

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

CARE AND MAINTENANCE

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-
www.impedimed.com/support
INTL: +61-7-3860-3700
US: 1-877-247-0111



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

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

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

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

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.

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.

Repairs

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

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

Technical Support

Australia

Phone: + 61 7 3860 3700 option 2

Fax: + 61 7 3260 1225

USA

Phone: (877) 247-0111 Option 2

Fax: (760) 804-9245

SOZO Website: www.impedimed.com

SOZO Help Email: tsu@impedimed.com

Components and Accessories

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

Description
SOZOsupport Stand
SOZOconnect Cable
Power Adaptor
Tablet
Tablet Sleeves

PRODUCT WARRANTY

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

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

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

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

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

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

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

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

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

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

REGULATORY STATEMENT


FCC ID: QQQBT121

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.

SAFETY INFORMATION

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

Guidance and Manufacturer's Declaration – Immunity			
The SOZO Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Device should assure that it is used in such an environment.			
Immunity test	4 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 50 or 60 Hz</p>	<p>30A/M 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)	(V1) = 3Vrms (V2) = 6Vrms	Portable and mobile communications equipment should be separated from the SOZO by no less than the distances calculated/listed below: $D=(3.5/V1)(\text{Sqrt } P)$ $D=(12/V2)(\text{Sqrt } P)$ $D=(12/E1)(\text{Sqrt } P)$ 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	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		

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

GLOSSARY

Administrator-MySOZO User authorized to manage Clinician and Administrator accounts and perform SOZO system-wide administrative functions. The Administrator has exclusive authority to adjust certain SOZO system-wide settings through MySOZO.

Assessment-An assessment of measurements taken of the patient, which is an output of the SOZO system. Different types of Assessments are available to the ImpediMed customer and viewable on the SOZOapp and MySOZO, including L-Dex®, Fluid Analysis and Tissue Analysis.

Assessment license-ImpediMed grants a separate license for each type of Assessment. Once an Assessment is licensed, the Clinic has access to that Assessment for all current and previous measurements. The availability of the Assessment license is viewable in MySOZO and the SOZOapp.

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

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

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 User Guide.

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

Clinician - The primary User of the SOZO system, and an authorized User of MySOZO and the SOZOapp. The Clinician uses the SOZO Device to take and record measurements of patients; view and evaluate measurements and Assessments over time; and assess patient progress.

Cole plots - The SOZO measurement data is displayed in the form of a complex impedance plot, commonly called a Cole plot. The X axis is the resistance value, and

the Y axis is the reactance value of the measurement at each of the 256 frequencies measured. Cole plots are reviewed when determining whether to accept or reject measurements. The SOZO software helps determine the quality of measurements as high, medium, or low quality.

Consumable-A hardware component of the SOZO Device which the ImpediMed customer uses recurrently, and which eventually wears out, gets used up or is discarded. For example, the Tablet sleeve is a consumable.

Contralateral limb-The limb located on the other side of the patient's body. For purposes of the L-Dex Assessment of a patient with unilateral 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.

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).

Fluid Analysis User Guide-LBL-525-2, the Fluid Analysis Assessment Instructions for Use.

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

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 lymphoedema, using certain patient measurements taken with the SOZO Device. Indications for Use and Instructions for Use of the L-Dex Assessment is in the L-Dex User Guide.

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

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

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

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

MySOZO-The central cloud-based hub for the SOZO system that computes, and stores assessments based on raw measurement data taken from the SOZO Device. Users may access MySOZO.com via the internet.

Parameter-A clinically meaningful output based upon measurements.

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

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

Phi-Phase Angle. Phase Angle is the arctangent of resistance/reactance of a person's cell membrane at a 50 kHz frequency. Phase Angle is expressed as a degree (e.g. 5.5°).

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

Rinf-Rinfinity. Rinf is the impedance measured at an infinite frequency.

R0-The impedance measured 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, provided to the ImpediMed customer as part of the SOZO system, with the SOZOapp pre-installed.

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).

Tissue Analysis User Guide-LBL-525-3, the Tissue Analysis Assessment Instructions for Use.

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.