SOZO® System Instructions for Use version 6.1

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For assistance with product set up please review the help videos at https://www.impedimed.com.

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

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

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1 SYSTEM OVERVIEW

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

1.1 Bioimpedance Spectroscopy (BIS) Technology

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

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

1.2 Introduction to the SOZO® System

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

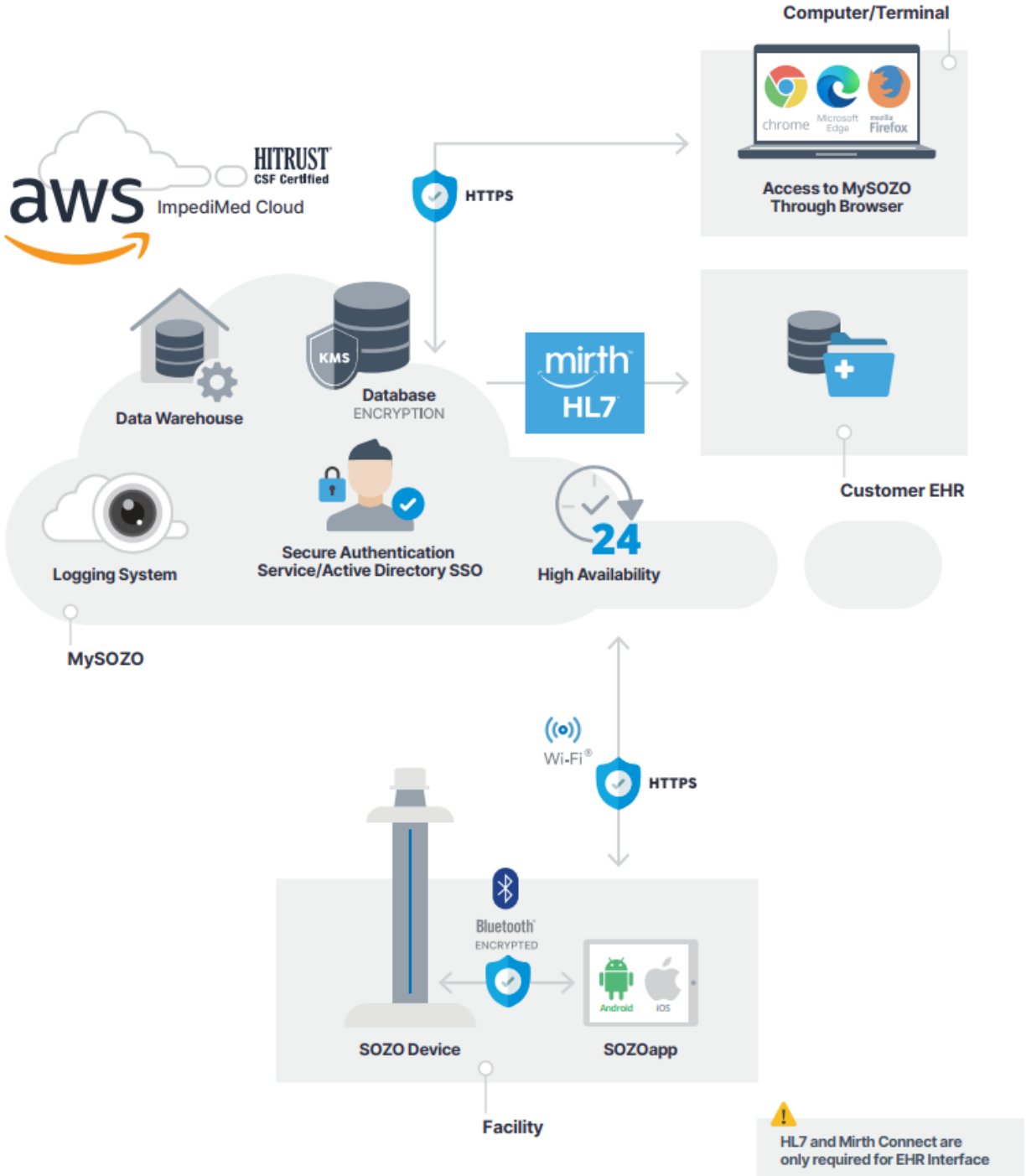
The SOZO System may assist with early detection of lymphoedema by giving an "early warning" of patient fluid status change. It may also be used to track fluid levels in patients living with heart failure or end stage kidney disease. The SOZO system may be an integral part of a treatment plan for a lymphoedema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

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

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

1.3 The SOZO® System Architecture

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



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

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

The SOZO Device and SOZOapp are used in conjunction with MySOZO, a cloud-based system. Users may access and use the SOZO system through the SOZOapp on the Tablet, or access SOZO patient records online at MySOZO.com.

1.3.1 Tablet Function

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

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

iOS: Contact ImpediMed Technical Support for download instructions.

Note: screenshots throughout this Instructions for Use are based on the Android SOZOapp and Chrome browser. The iOS SOZOapp screens will look nearly identical. Please note that instructions in this User Guide are for SOZOapp and MySOZO versions 6.1 and later. Not all functionality in later versions is present in earlier ones.

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

1.4 Assessment Licences

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

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

1.5 Minimum Internet Requirements

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

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

Minimum and Recommended Requirements

Component	Requirements
Internet Speed	**Minimum:** >15 Mbps download, 5 Mbps upload **Recommended:** >25Mbps download, 5 Mbps upload
Web Browser	Google Chrome, Mozilla Firefox, Chromium Based Edge
Minimum Screen Resolution (Tablet or PC)	≥ 1024 pixels for horizontal screen resolution
Minimum Tablet Specifications	The following tablets have been verified to function with the SOZO App and use of some tablets may be disabled within the app: o All iOS iPad Tablets (except iPad Mini 1st Gen) o Android Tablets – Lenovo TB125FU and Samsung Model SM-T580, SM-T500, SM-T510, X210, and Lenovo M-10
Recommended Tablet Specifications	• Android devices must run Android OS version 10 or later, to ensure continued support through official security updates. • iPad devices must run iPad iOS version 13 or later, to ensure continued support through official security updates.

1.6 Websites to Whitelist

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

MySOZO.com

To be able to access all functionality of MySOZO.com from a PC, the following additional websites require access:

- ***.Quicksight.aws.amazon.com – Wildcard whitelist entry used for the Analytics Module of MySOZO.com. (Workstation Browser)**
- **The following endpoints are utilised for reports in the Analytics Module of MySOZO.com, please note that each endpoint corresponds with the tenant region:**
  - **d758cqe2bs24d.cloudfront.net (US)**
  - **d39m61wgn4vuk2.cloudfront.net (APAC)**
  - **d3oh9w26wrjsck.cloudfront.net (EU)**

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

2 SAFETY

2.1 Signs and Symbols

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

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

2.2 Intended Use

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

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

2.3 Contraindications

The SOZO Device should not be used by:

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

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

Electronic implantable Devices that are allowed / not allowed for SOZO	
Allowed	**Not Allowed**
Stents	Pacemakers
Orthopedic plates, screws, pins	ICDs (implantable cardioverter defibrillators)
Joint replacements	Infusion pumps or other implantable medication pumps
Continuous glucose monitor	Neurostimulators (deep brain, spinal cord, vagal nerve, sacral nerve, etc.)
Cochlear implant	Implantable cardiac loop recorder
CardioMEMS	LVADs (while interference with LVADs are unlikely, ImpediMed does not have clinical data to verify this use)

Note: The list above is not all inclusive; it is a representative list of devices commonly asked about. Contact the physician or ImpediMed if you have questions about any device not listed.

2.4 Warnings

Pregnant patients:

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

2.5 Precautions

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

Do not allow the SOZO Device to encounter any liquids.

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

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

Devices or other sources can potentially cause interference problems:

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

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

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

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

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

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

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

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

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

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

SOZO impedance measurements require contact with all four (two hand and two foot) electrodes, therefore patients with partial or full limb amputation cannot have their impedance values measured with SOZO.

2.5.1 Storage Conditions and Use

2.5.1.1 Environmental Operating Conditions

The SOZO Device must be operated in the following conditions:

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

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

2.5.1.2 Environmental Transport and Storage Conditions

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

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

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

2.5.2 Location for Use

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

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

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

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

Various environmental factors may interfere with the SOZO Device performance including: the effects of lint, dust, light (including direct sunlight), as well as pets, pests, or children. Example: Devices generating large electromagnetic fields such as MRI or DXA.

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

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

3 MySOZO and SOZOapp

3.1 Introduction to the MySOZO System

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

3.2 MySOZO Users (Administrators and Clinicians)

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

3.2.1 First Time Set-Up

1. New user Email
    a. ImpediMed sends the user an email from no-reply@impedimed.com with a temporary password, as shown in the example below. The user clicks the Password setup link provided in the email.
2. Set New Password
    a. After the user clicks the email link, a new browser window opens and the “Set New Password” screen appears. The user enters the Temporary Password that was provided in the email followed by the new password and confirmation of the new password. To view the password, click the eye icon.

b. Ensure the new password meets all character requirements.

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

1. One number
2. One special character: !“#$%&”()*+,-./:;<=>?_@[]^`{|}~
3. One upper case letter
4. One lower case letter
5. You cannot use your last 3 passwords

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

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

The temporary password expires in 24 hours.

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impedimed® SOZO Digital Health Platform

Welcome to MySOZO!

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

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

Your temporary password: **0iCY0tb,**

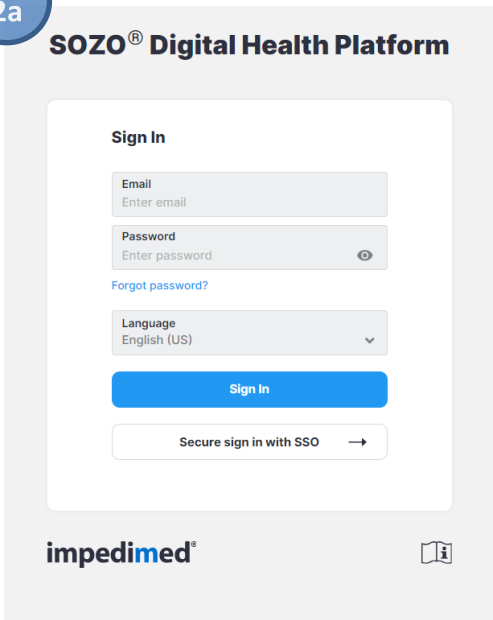
If you need any help, we encourage you to contact us at www.impedimed.com/support.

Sincerely,

ImpediMed Customer Experience Team

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

2a



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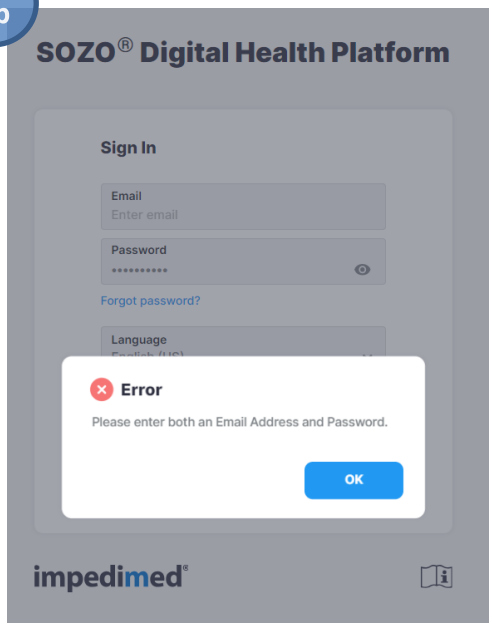

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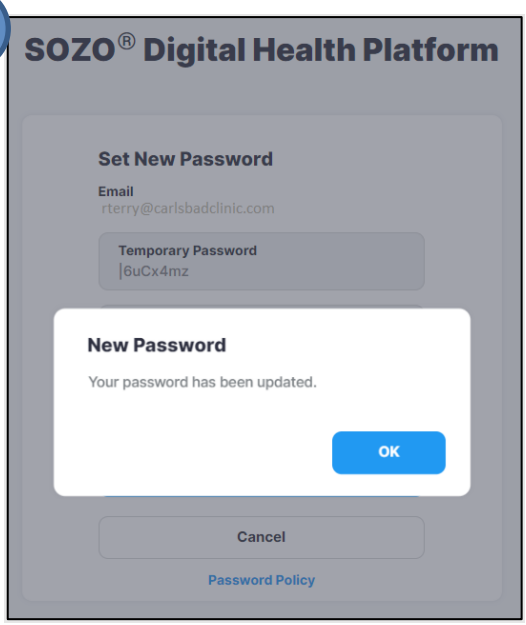
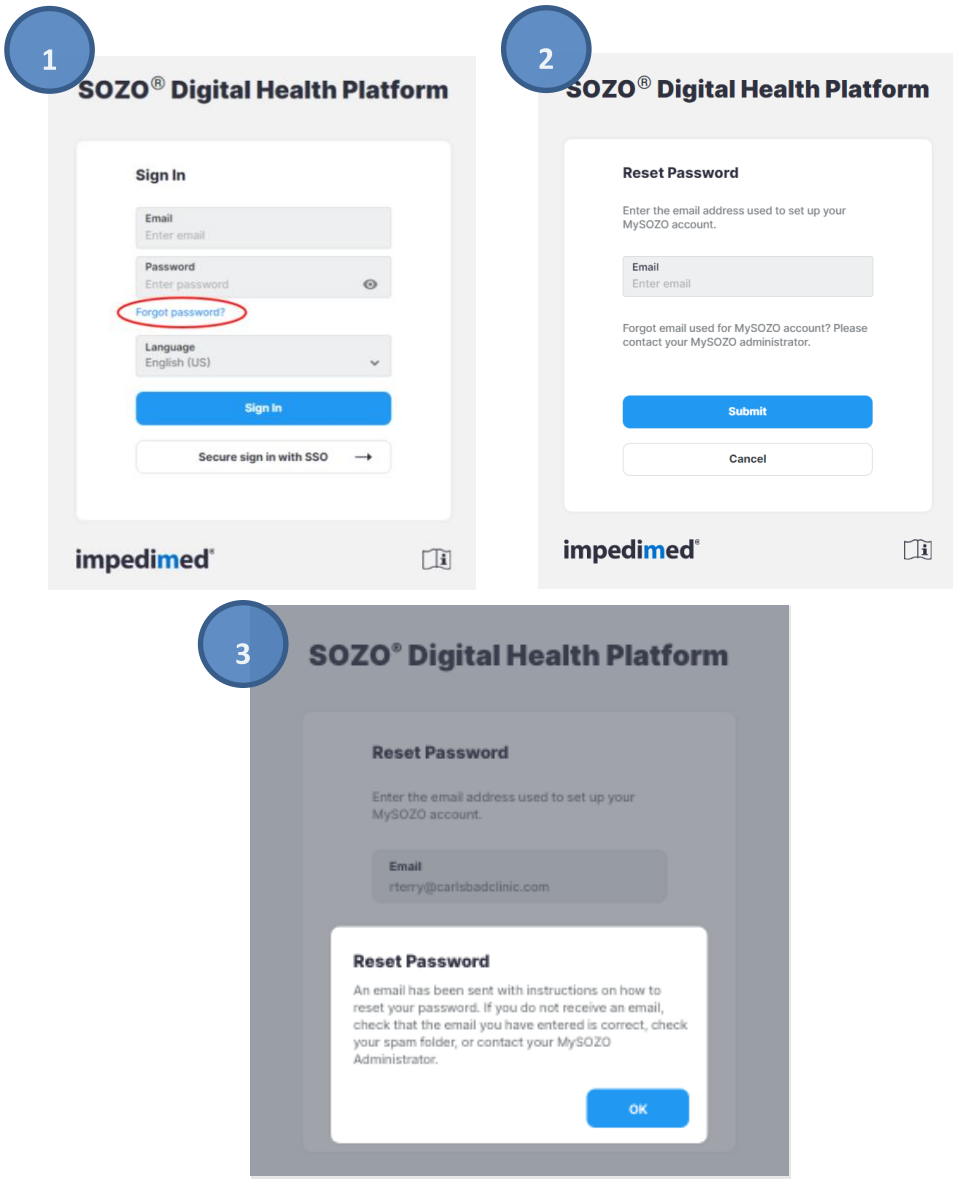


3.2.2 Password Reset

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



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impedimed® SOZO Digital Health Platform

A request has been made to reset the MySOZO password associated with rterry@carlsbadclinic.com.

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

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

Sincerely,

ImpediMed Customer Experience Team
www.impedimed.com/support

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

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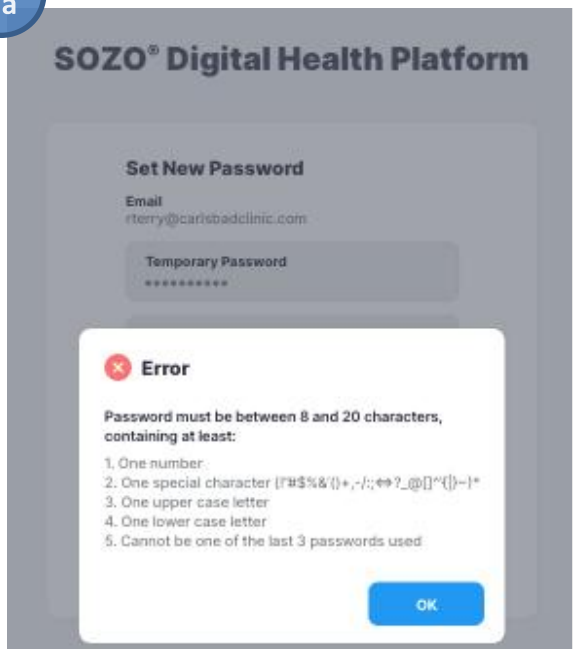

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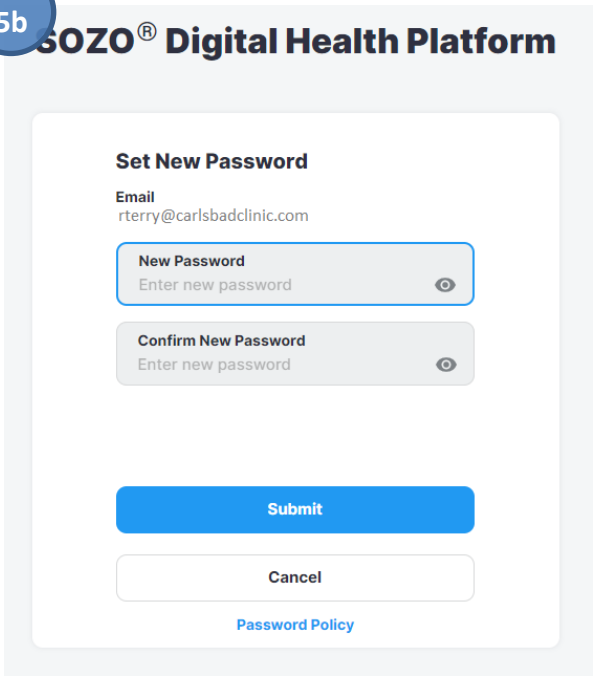

3.2.3 Password Expiration

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

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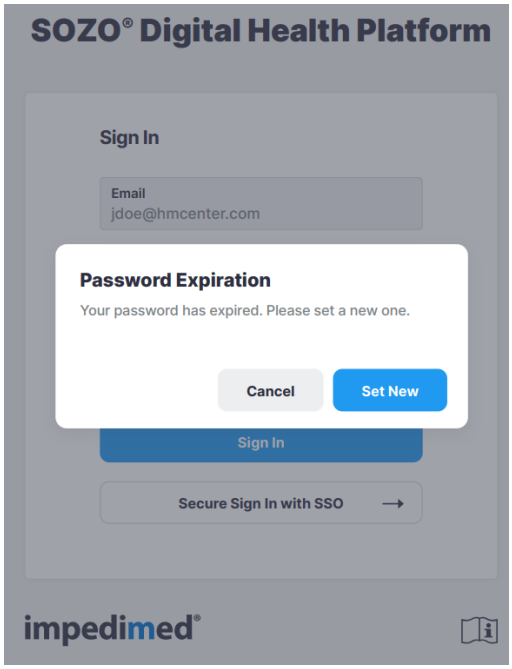

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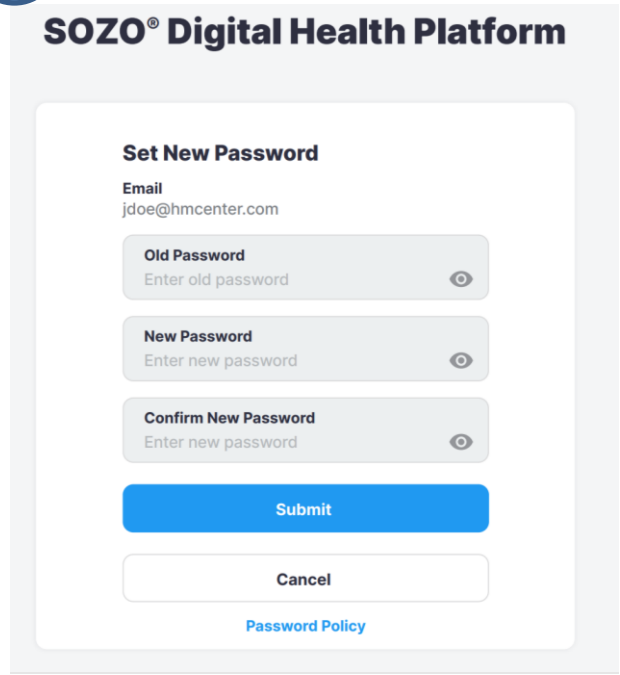
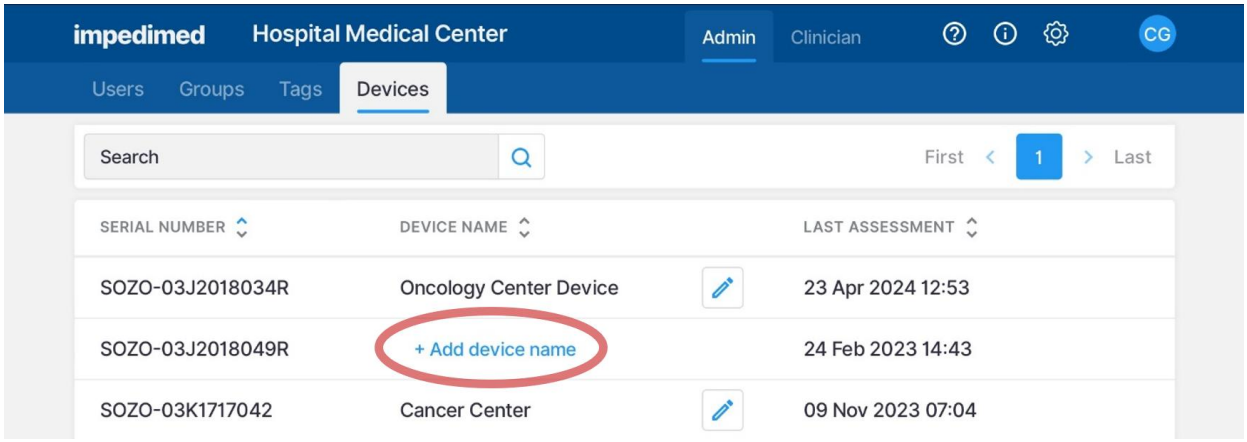
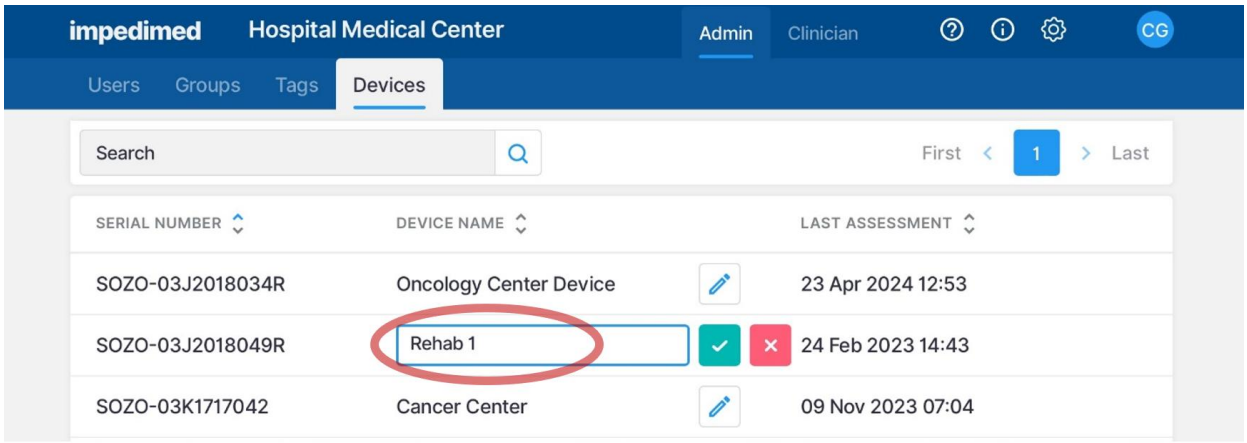


3.2.4 Naming A SOZO Device

When setting up a new SOZO device in a system where multiple devices are in use, naming each device may be helpful. To name a device, navigate to the “Admin” module and the Devices tab, select “+ Add device name” for the desired SOZO device.



Add the device name then select the green check box, to confirm the device name.



4 MySOZO AND SOZOapp CLINICIAN

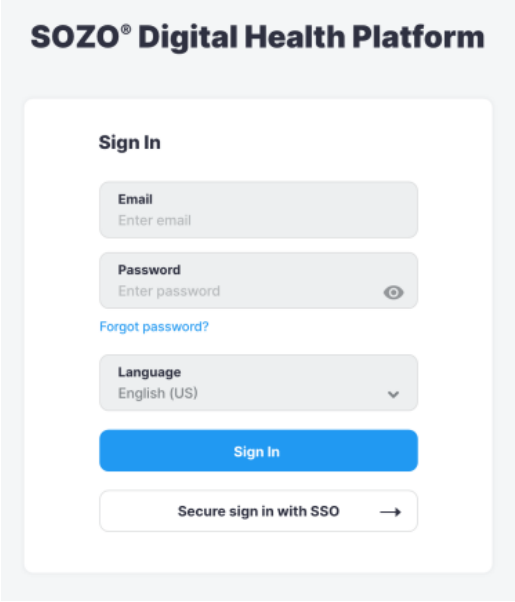
In the ImpediMed SOZO software version 6.1, the MySOZO web site and the SOZOapp, the tablet application, are designed to share a nearly identical user interface. As a result, MySOZO and SOZOapp share many of the same features and capabilities. Clinicians may use MySOZO, for patient record review and assessment but can complete several of the functions that were exclusive to the SOZOapp in previous software versions. Although many of the features and functionality are available in both MySOZO and the SOZOapp. MySOZO cannot be used to take a measurement; this is managed solely by the Clinician directly from the SOZOapp.

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

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

4.1 MYSOZO and SOZOapp Quick Start Guide

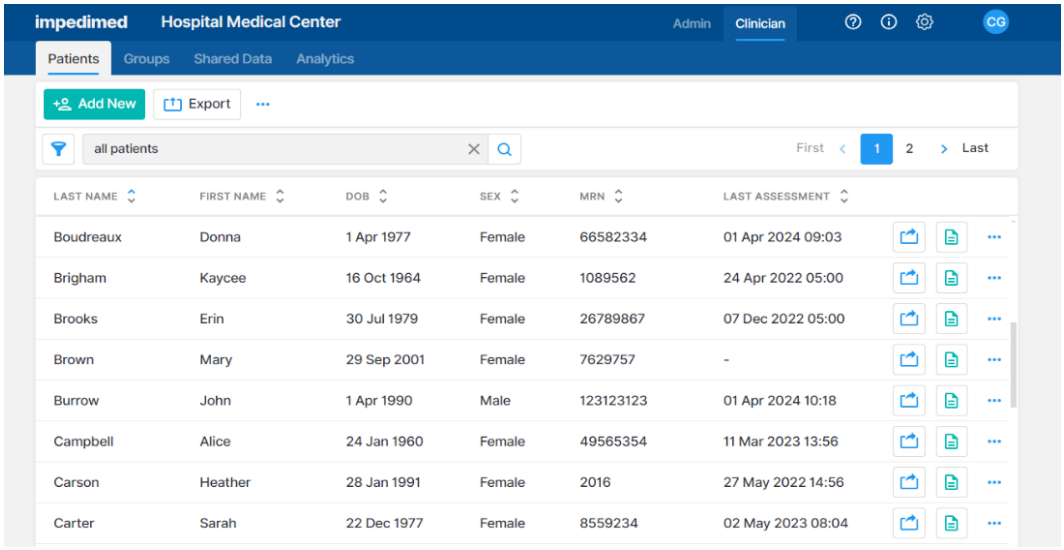
- Utilise the Google Chrome, Chromium-Based Microsoft Edge, or the Mozilla Firefox web browsers to log in to www.mysozo.com.
- Enter a user email address and password.



Use Chrome, Firefox, or Chromium browser to log into mysozo.com.

The sign-in / user email was assigned by the MySOZO Administrator.

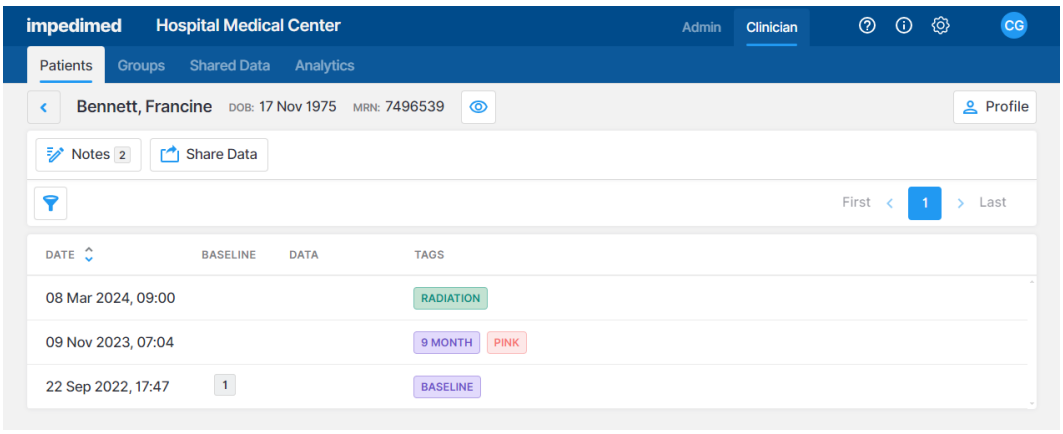
- The SOZO patient list includes specific patients that can be searched by name.



Patient List

- Allows access to list of patients in MySOZO database.
- Patient List sorts by Last/First name, DOB, sex, MRN #, and last assessment date.
- Access each patient's data by selecting a patient from the patient list.

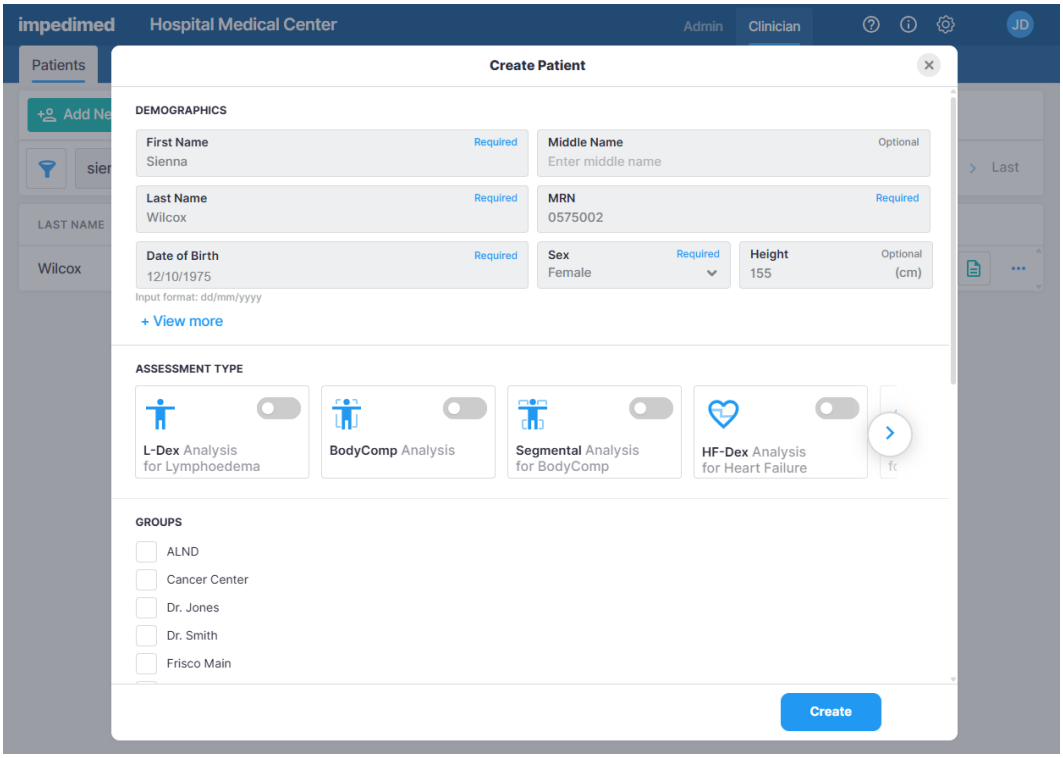
- The Patient Dashboard includes patient details (e.g., patient name, DOB, sex, etc.) and the option to view results and make edits to the dashboard.



Patient Dashboard

- Displays a list of all measurements taken for each patient and customizations such as baselines and tags.
- Provides access to patient profile.
- Allows access to view, create, or edit notes attributed to the patient.

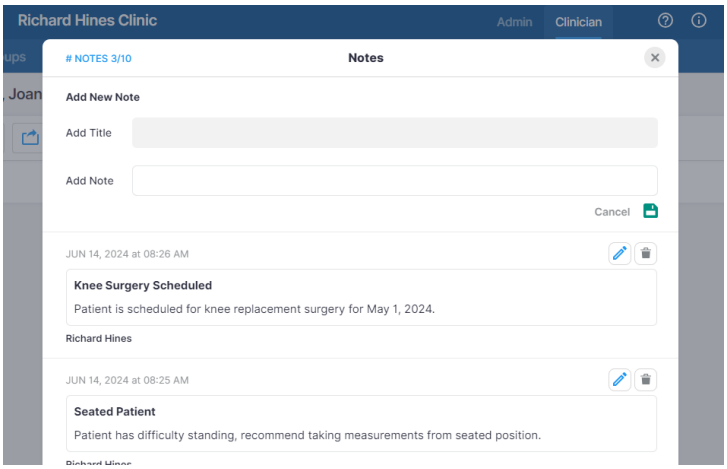
- The SOZO patient profile includes specific patient information and demographics.



Profile

- Demographics
- Assessment types available
- Patient Groups

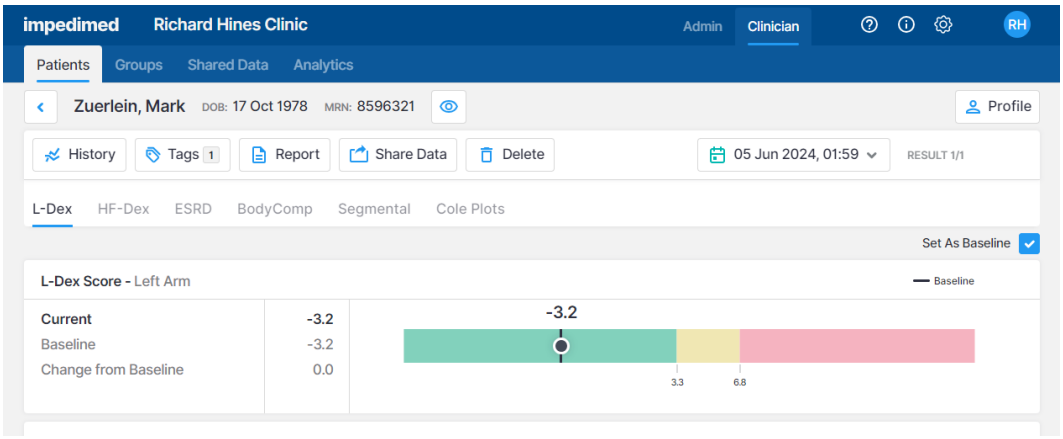
- Notes allows a clinician to provide patient specific information related to in visit observations. Patient profiles can include up to 10 notes each.



Patient Notes

- Provides access to notes assigned to the selected patient.
- Create new notes for each patient, as needed (maximum 10 notes per patient).
- Ability to edit or delete an existing note.

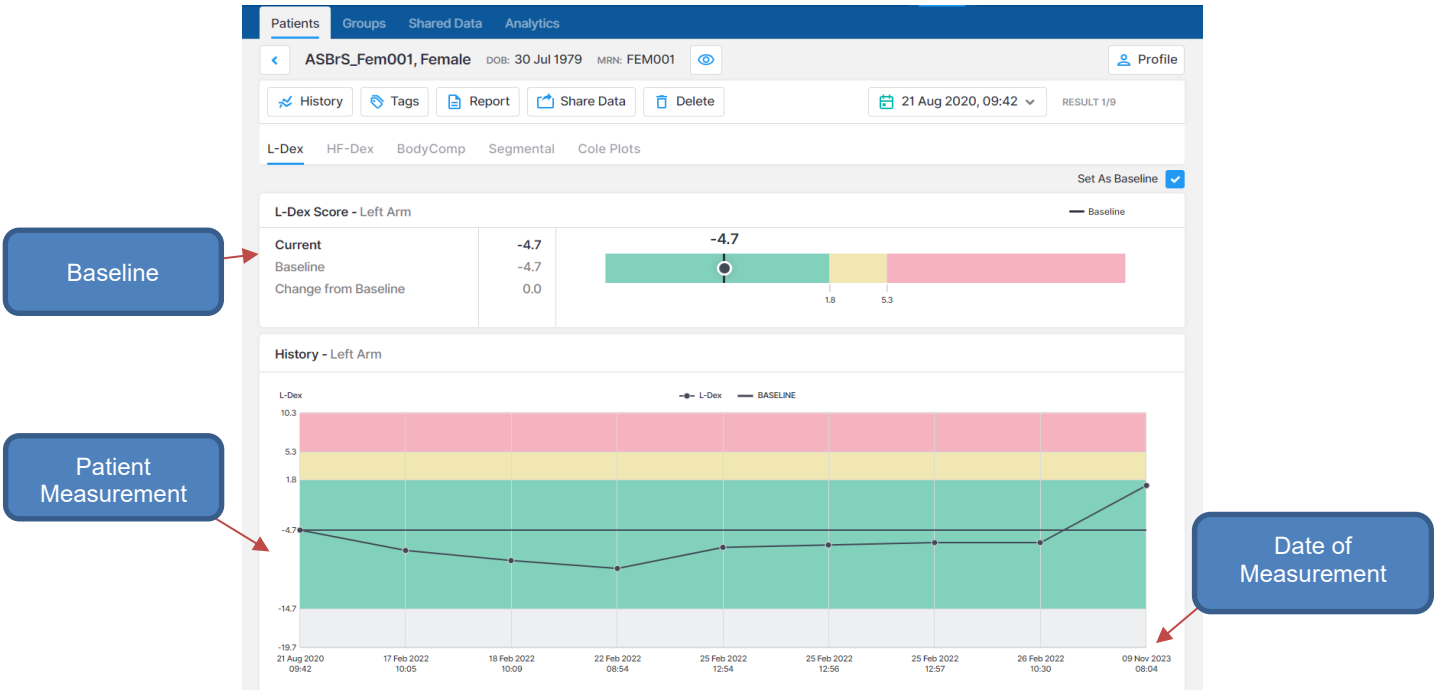
- Results displays a catalog of previous impedance measurements, each of which can be selected individually by a clinician for evaluation.



Patient Impedance Results

- Provides access to current and historic measurement outputs.
- Ability to set a baseline to accurately track patient condition.
- Ability to assign measurement tags and create customized reports.

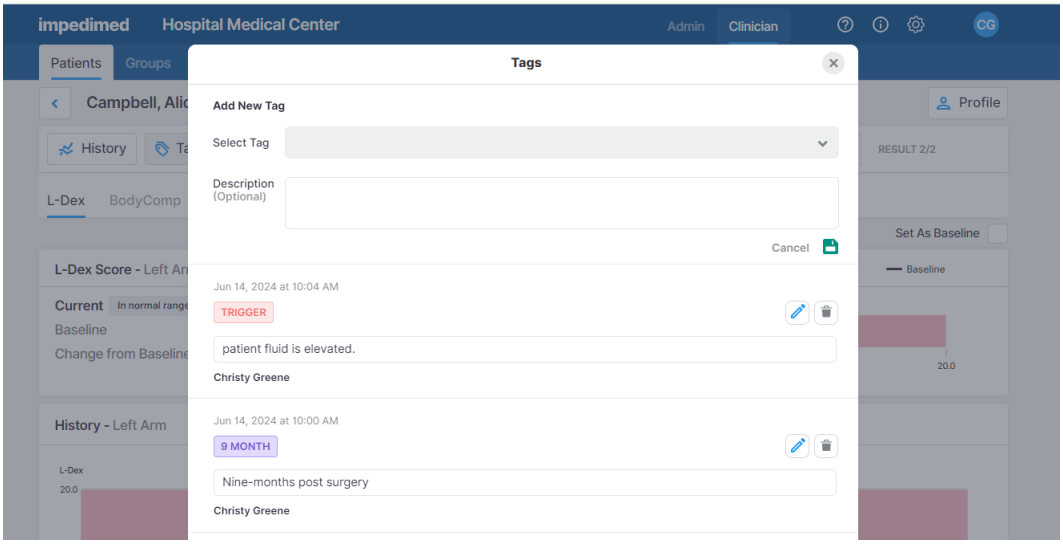
- History tracks previous measurements and other data for patient profiles.



History

- Display trending of patient measurements over time.
- Ability to select specific historic graphs to compare current patient conditions.

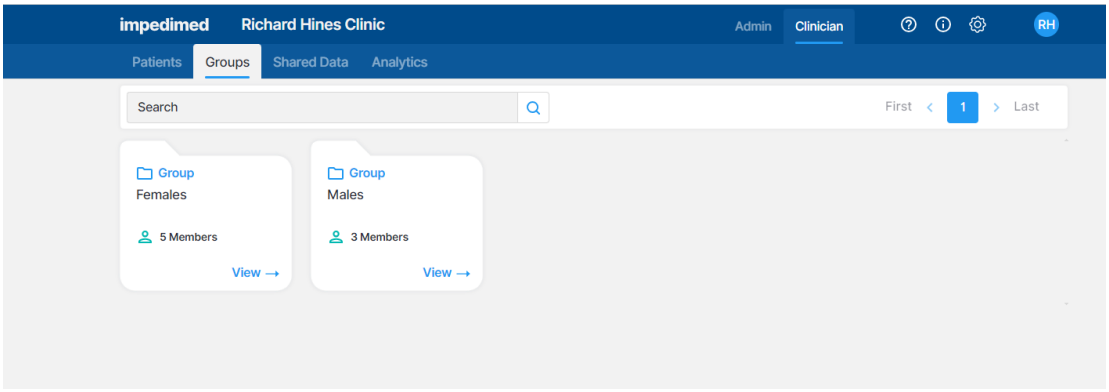
- Tags allows for patients to be assigned tags that define specific measurements.



Tags

- Create a list of tags assigned to specific measurements.
- Assign, edit, or delete tags.

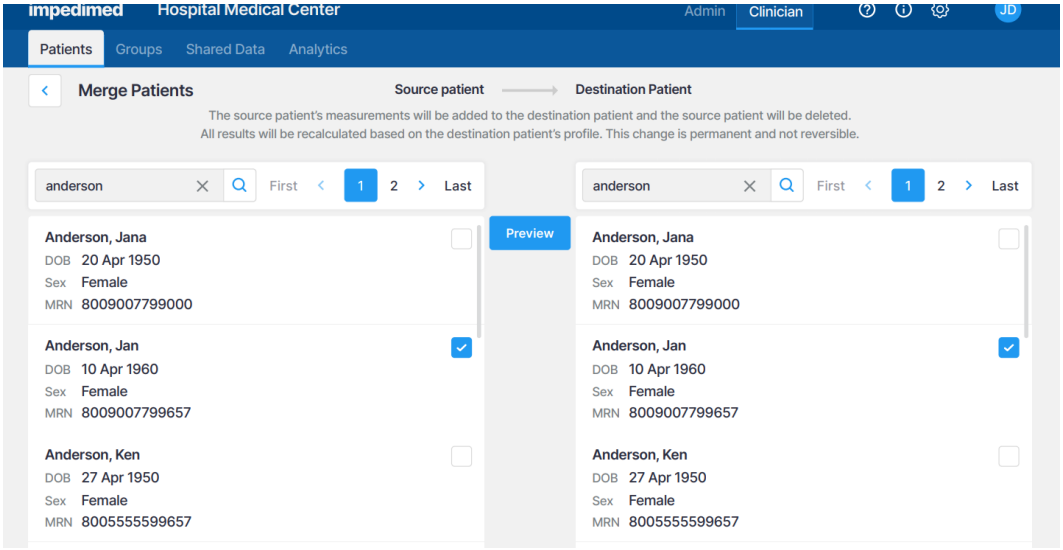
- Groups allows patients to be aggregated into defined applicable groups.



Groups

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

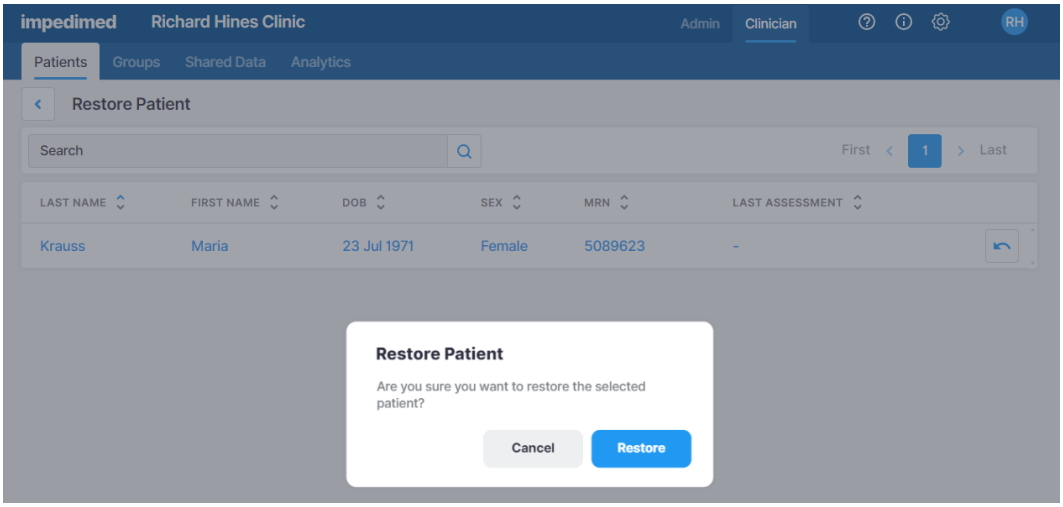
- Merge Patients allows multiple patient profiles to be merged into a single profile.



Merge Patient Profiles

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

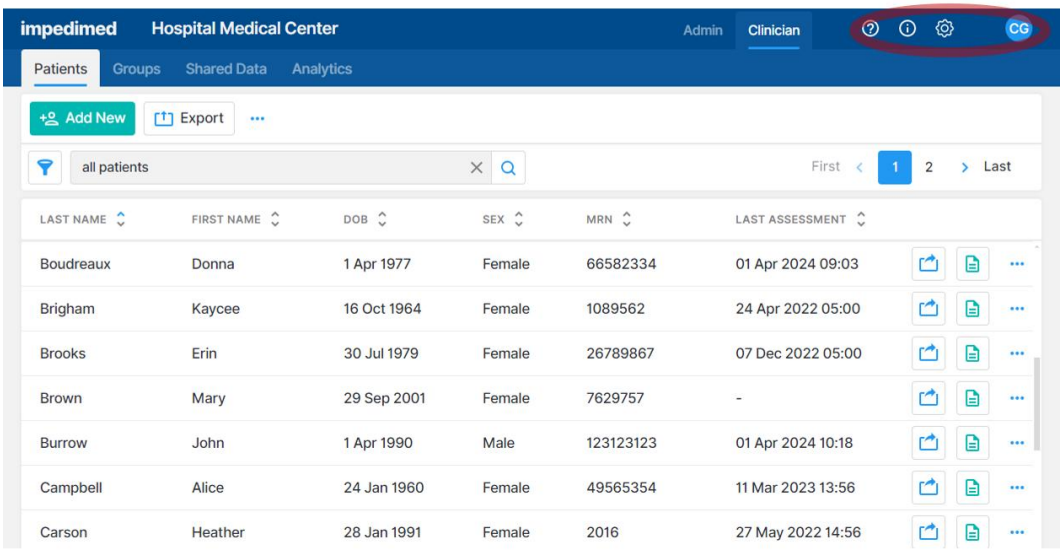
- Restore Patient allows deleted patient profiles to be resurrected.



Restore Patient

- Access to list of deleted patients.
- Ability to activate deleted patient profiles.

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



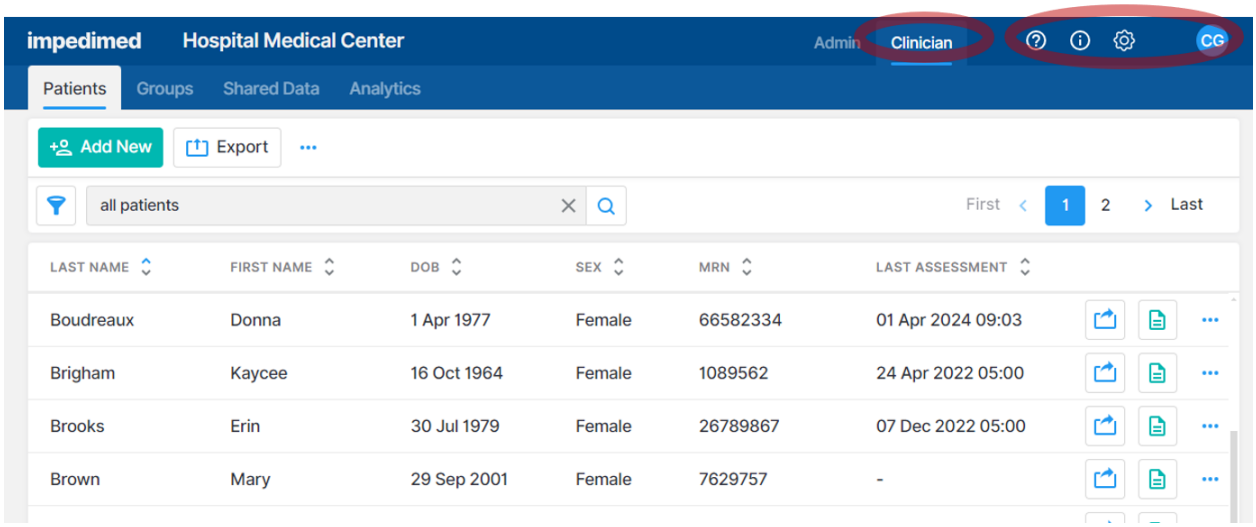
General Menu Items

- Help
- Info
- Settings
- My Account

4.2 Clinician Home Page

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

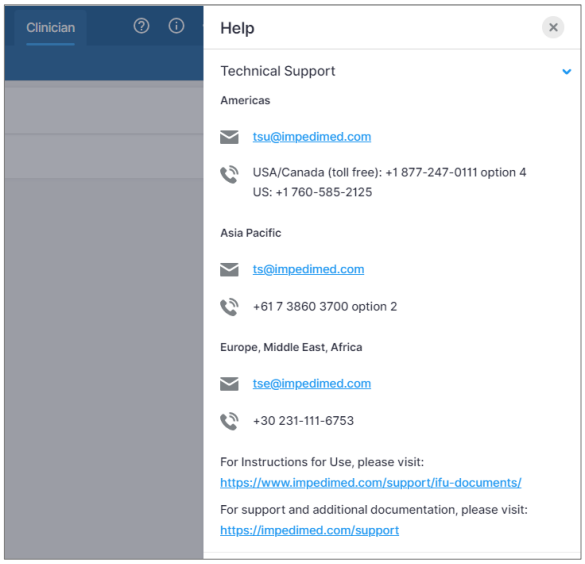
Any user may be assigned to both Clinician and Administrator roles. Users assigned a Clinician role will default to the Clinician role on initial sign in; the icon will be displayed in bold and underlined. If a Clinician also has Administrator rights, they can toggle between Clinician and Administrator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



The banner icons enable common administrative functions.

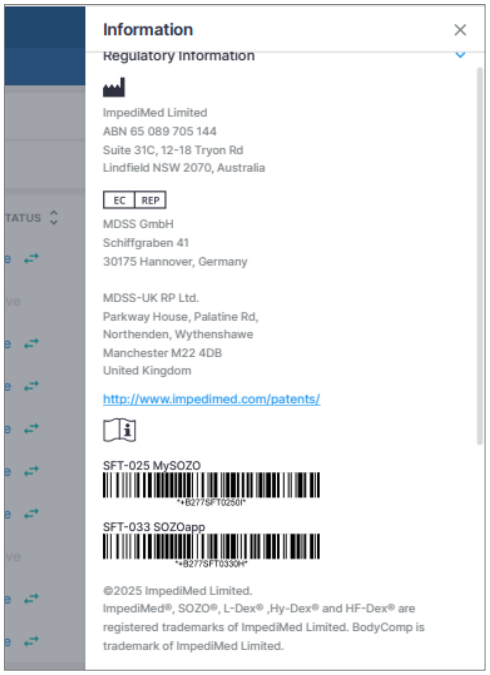
4.2.1 Help Icon

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



4.2.2 Info Icon

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



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

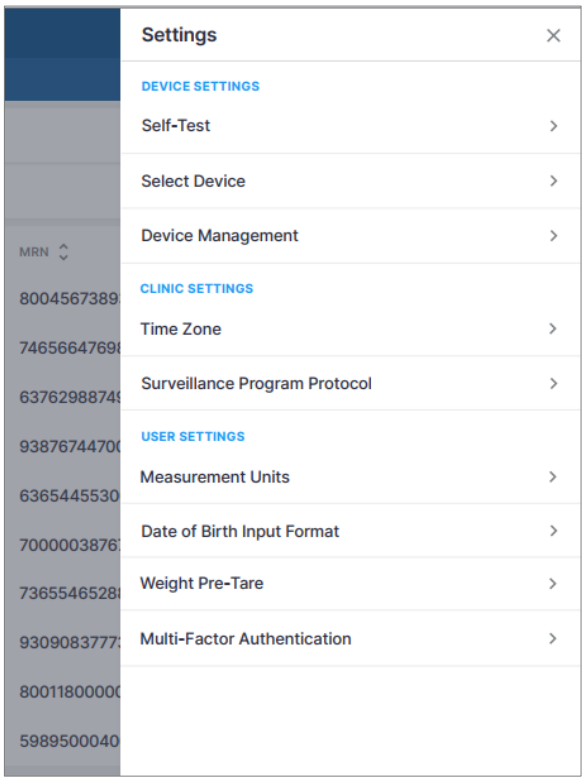
Software Information: Displays current MySOZO version and if it is up to date. Release notes for current and previous versions are listed.

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

4.2.3 Clinician Settings Icon

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

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



4.2.3.1 Time Zone Settings

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

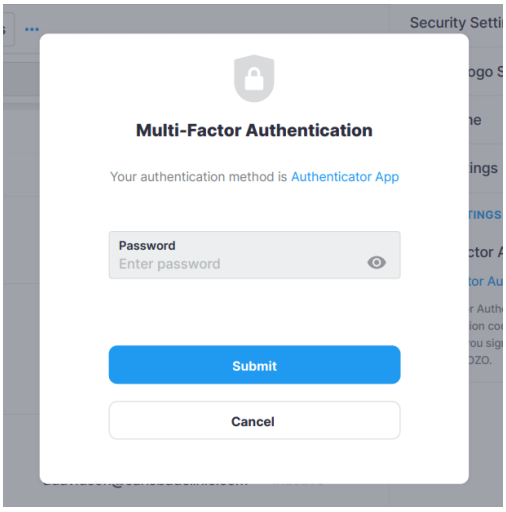
4.2.3.2 Measurement Units

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

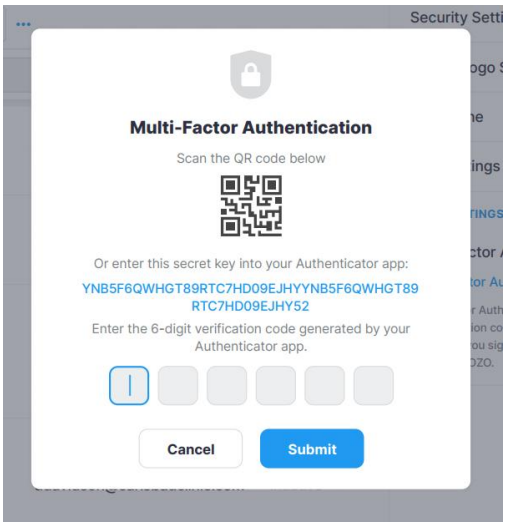
4.2.3.3 Clinician Multi-Factor Authentication

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

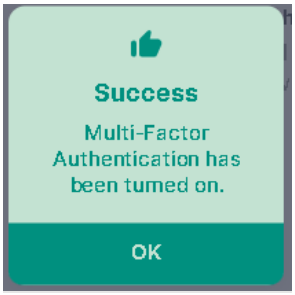
MFA will require use of a code generated by a 3rd party authenticator app (e.g., Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is is set up, activate the MFA for the Clinician by using the slider under User Settings, Multi-Factor Authentication.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



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



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

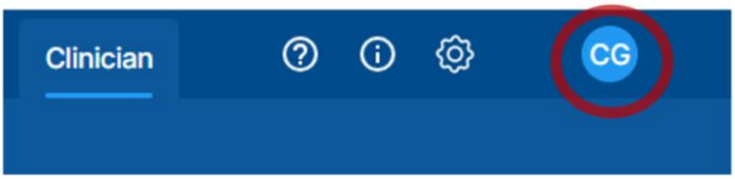


The Clinician will be signed out of the system, and from that point on, will have to use both a password and an MFA code to sign back in.

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

4.2.4 Clinician User Profile Icon

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



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

4.3 Clinician Patient List

Select the **Patients** tab at any time to return to the Patient List on the MySOZO Clinician home page.

4.3.1 Search for Patient

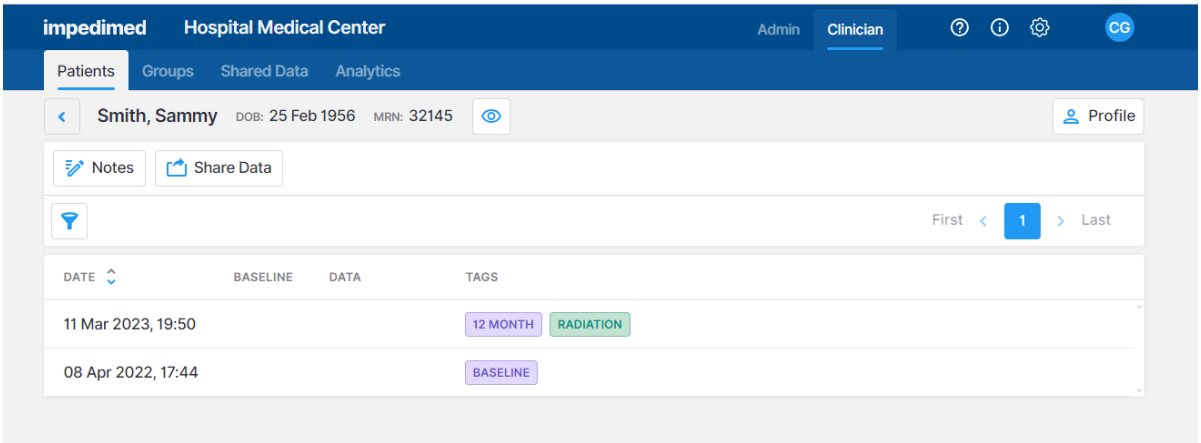
To search for a specific patient, enter the name or medical record number (MRN) of the patient in the **Search Patient** field and click the **Search** icon. This will bring up a list of patients matching the search criteria.

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

4.3.2 Patient Dashboard

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

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



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

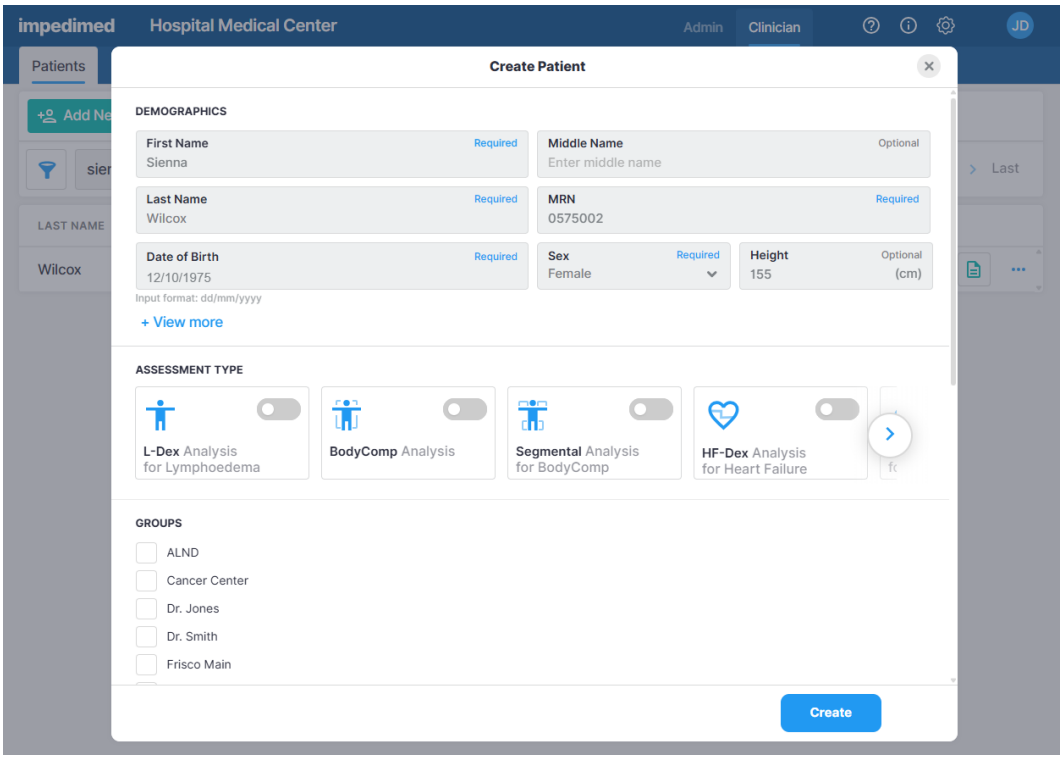
4.3.3 Create Patient

Note: There is no limit to the number of patients that can be created. Patients are created by clinician users.

To create a Patient:

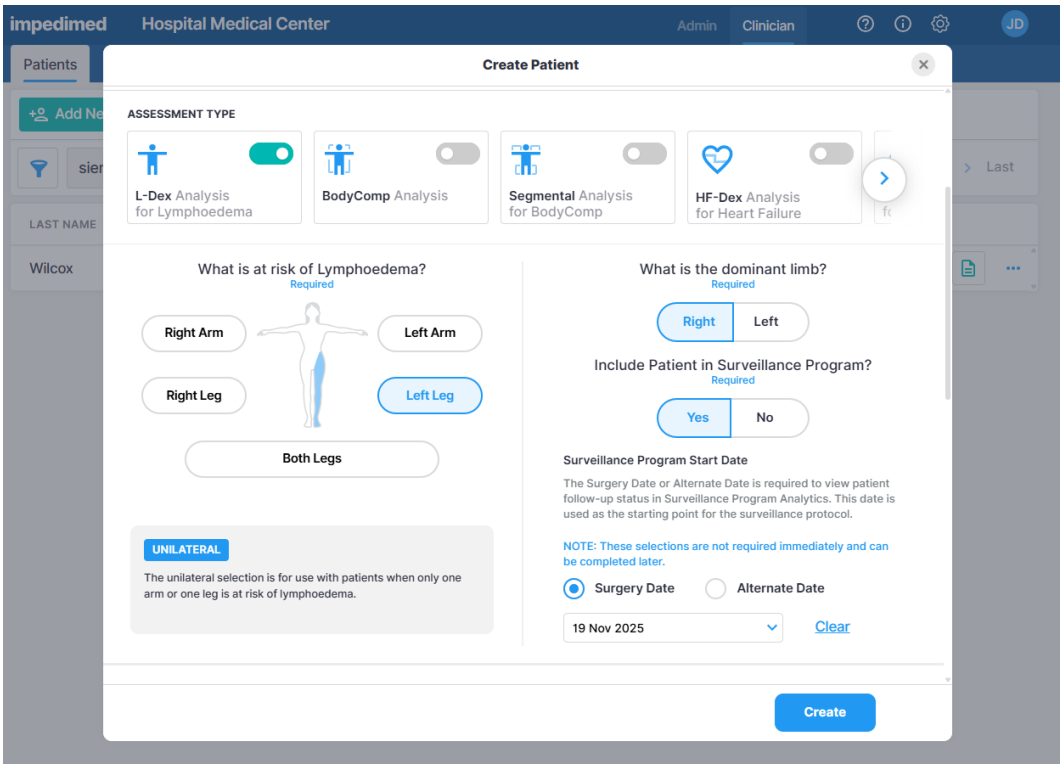
1. Navigate to the **Patients List** and select **Add New**.
2. On the **Create Patient** screen, enter the Patient's first name, last name, medical record number (MRN), date of birth, sex, and height. Note that height is not required at the time of patient creation but will be required before a measurement can be taken.
3. To view more fields, select + View More. These fields, including email address, middle name, country code, and phone number, are optional.
4. Select the appropriate **Assessment types** using the toggle switches next to the icons (L-Dex, BodyComp, Segmental, HF-Dex, etc.). Depending on your selection, a warning may appear as a reminder of the intended use of the selected assessment type. When L-Dex is selected, more options for selecting required information appear.

   In the example screen image below, a profile has been started for female patient Sienna Wilcox. The next step will show that L-Dex assessment type has been selected for Sienna Wilcox.



5. If you select L-Dex Analysis Assessment Type, select all required L-Dex assessment information. Note that Surgery Date and Alternate Date are not required at the time of patient creation and can be added later.
6. If the patient is being monitored as part of the Lymphoedema Surveillance Program, select Yes for “Include Patient in Surveillance Program”.

   In the example screen image below, patient Sienna Wilcox is at risk of Lymphoedema in her left leg (only one leg is at risk; therefore, this will indicate a Unilateral measurement), her dominant limb is on her right side, and her surgery date of November 19, 2025, has been entered. Additionally, this patient will be included in the Surveillance Program (for information on the surveillance program, see 4.6 Clinician Analytics).



7. When you have finished filling in all required information, select Create. A success confirmation pop-up will appear.

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

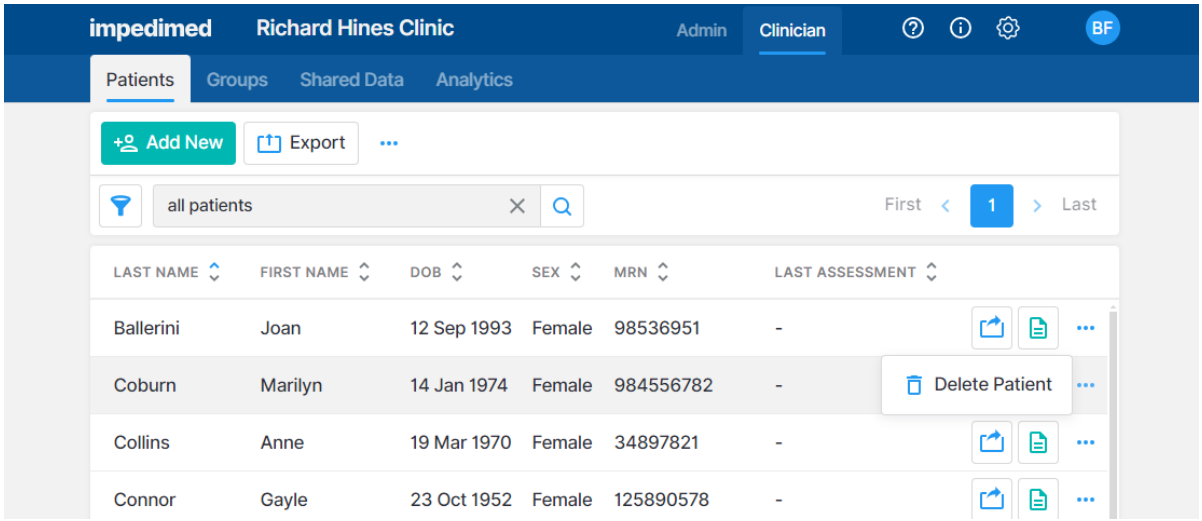
Note: adding a new assessment to the patient profile my trigger a caution about the intended use of that assessment. Ensure that you understand the instructions for use for L-Dex and HF-Dex.

4.3.4 Delete Patient

To delete a Patient:

1. Complete a search for the patient to be deleted from the **Patients List**.
2. Click on the **ellipsis (three dots)** located next to the patient’s information.

3. Select **Delete Patient**.
4. Click **Delete** in the delete patient warning pop-up. A **success** confirmation will appear in the top right corner.



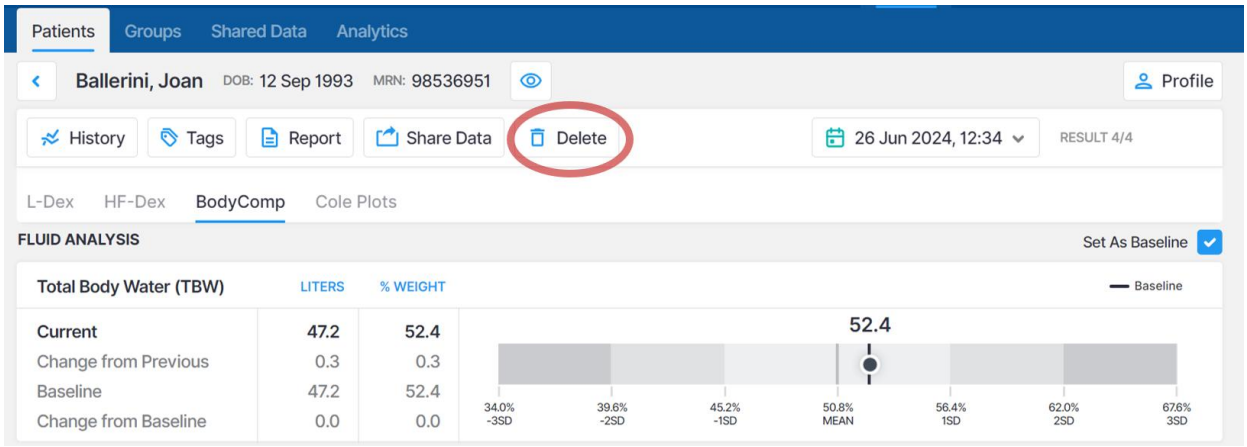
Note: the patient will remain in the MySOZO database and may be restored. To permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.

4.3.5 Delete Measurement

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

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

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



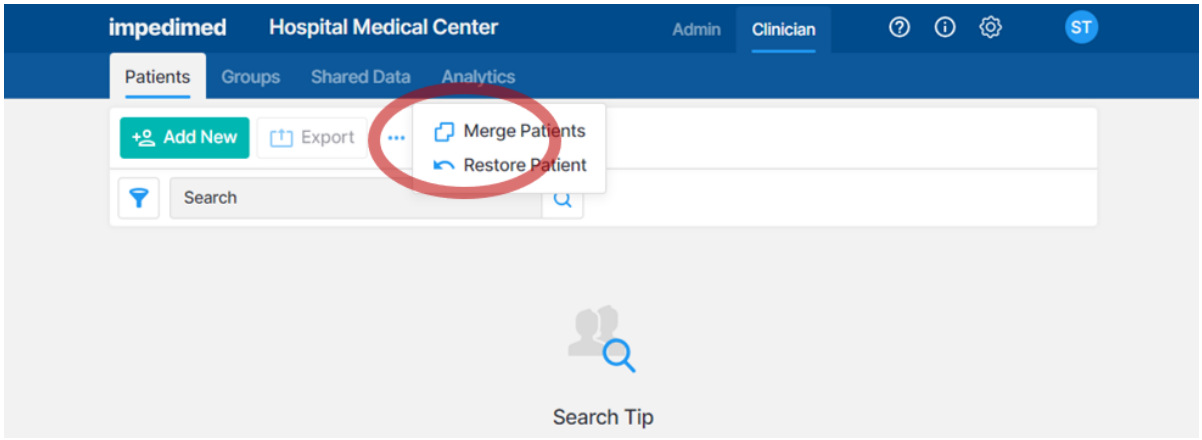
Note: the patient will remain in the MySOZO database and may be restored. To permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.

4.3.6 Restore Patient

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

To restore a deleted Patient:

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



4.3.7 Merge Patient Profiles

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

To merge two patient profiles:

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

Note: after clicking merge, the source patient will be deleted. All their measurement data will be integrated with the destination patient. The additional data will be recalculated based on the destination patient profile.

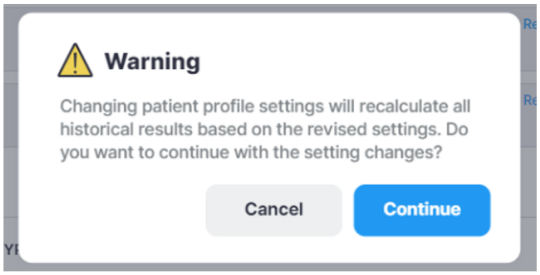
Note: if the merged patients have imported L-Dex data from a non-SOZO ImpediMed device such as the L-Dex U400, the imported measurements will not be shown if the patient L-Dex settings are different. For example, if imported U400 data assessed a patient's leg and the data is merged with a patient whose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

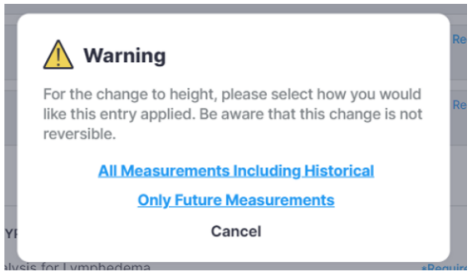
4.3.8 Edit Patient Profile

To edit a patient profile:

1. Navigate to the **Patient List**.
2. Search all patients by clicking magnifier icon, enter the patients' name, or MRN.
3. Click the **search** icon and select the patient.
4. Click on the Profile icon.
5. Make updates as needed.
6. Click **Save**. A success confirmation will appear in the top right corner.

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





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

- **When to Select "Only future measurements"**

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

- **When to Select "All measurements including historical"**

  Tap ***All measurements including historical*** to recalculate all prior Assessments according to the new height. This is appropriate when the patient's height has been entered incorrectly and measurements have already been taken.

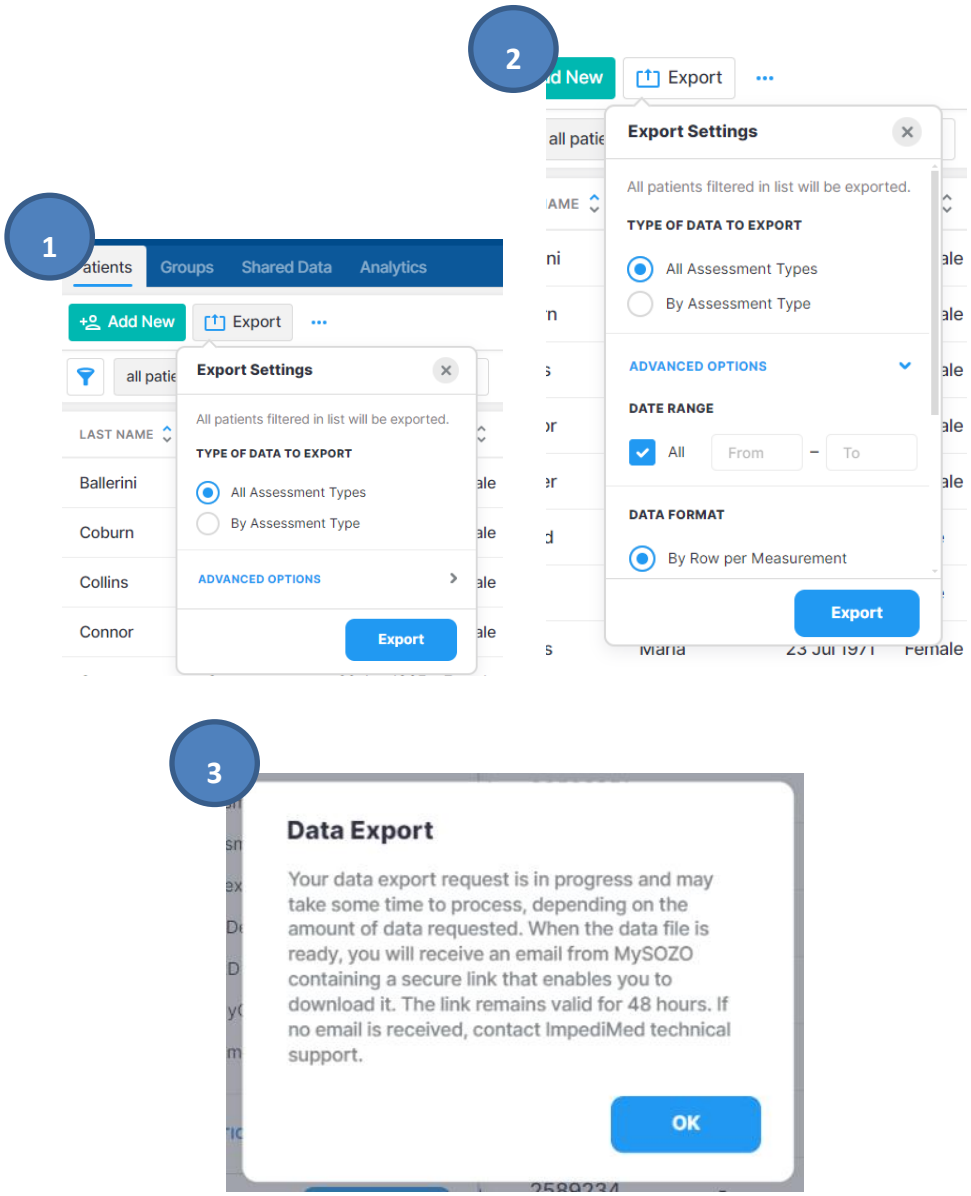
- **Availability of Assessment Specific Data on Patient Profile**

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

4.3.9 Export Patient Data

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

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



4.3.10 Shared Data

Shared data allows for sharing of patient data between clinics that are not on the same database to enable a continuous view of patient trending data across care teams.

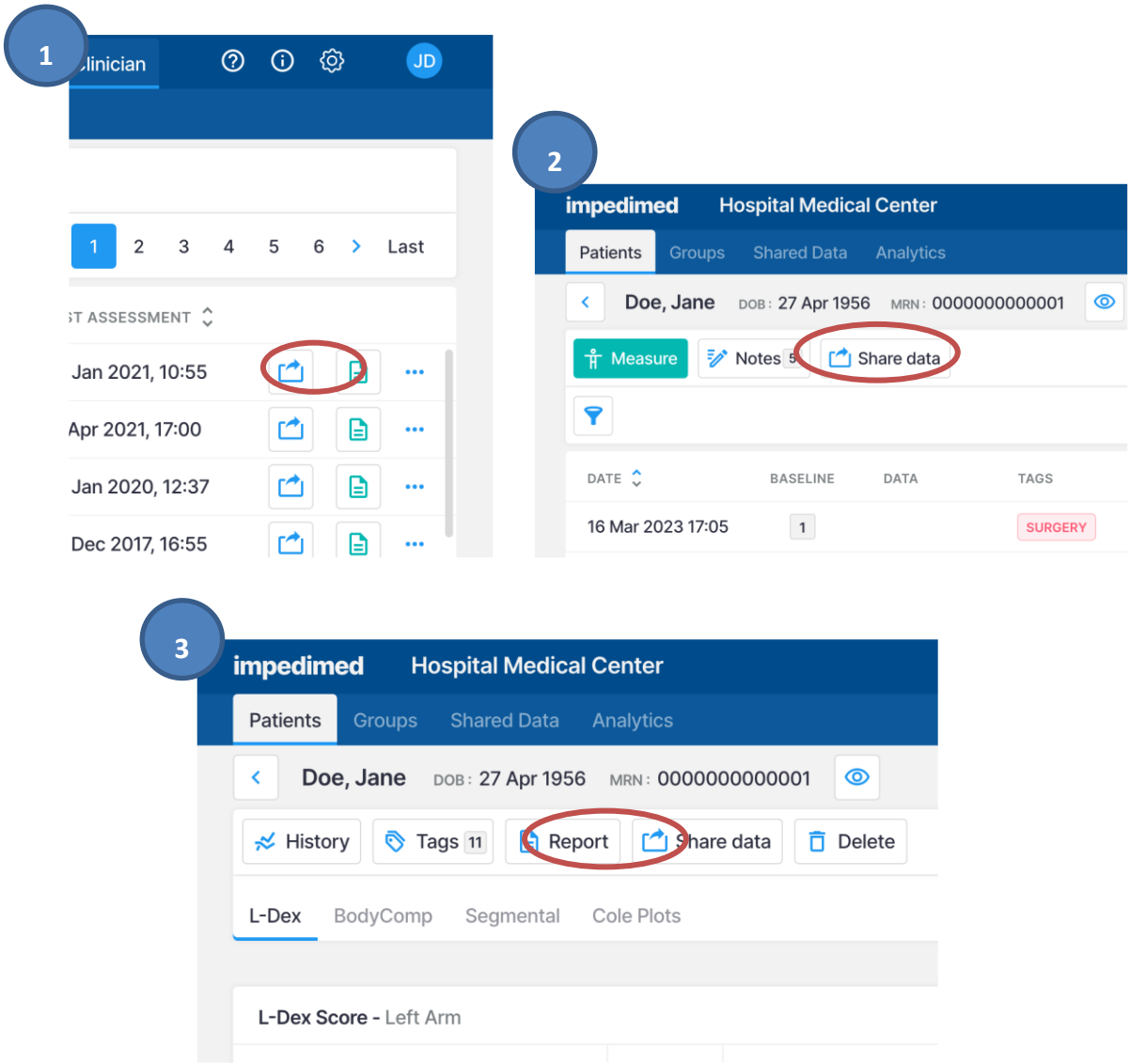
NOTE: To share data, both the sender and receiver must be on SOZO software version 6.1.

NOTE: Customers may reach out to ImpediMed customer service if they would prefer that their clinic name not appear within the "Share Data" SOZO software module.

4.3.10.1 Sharing Data

Data can be shared from 3 locations:

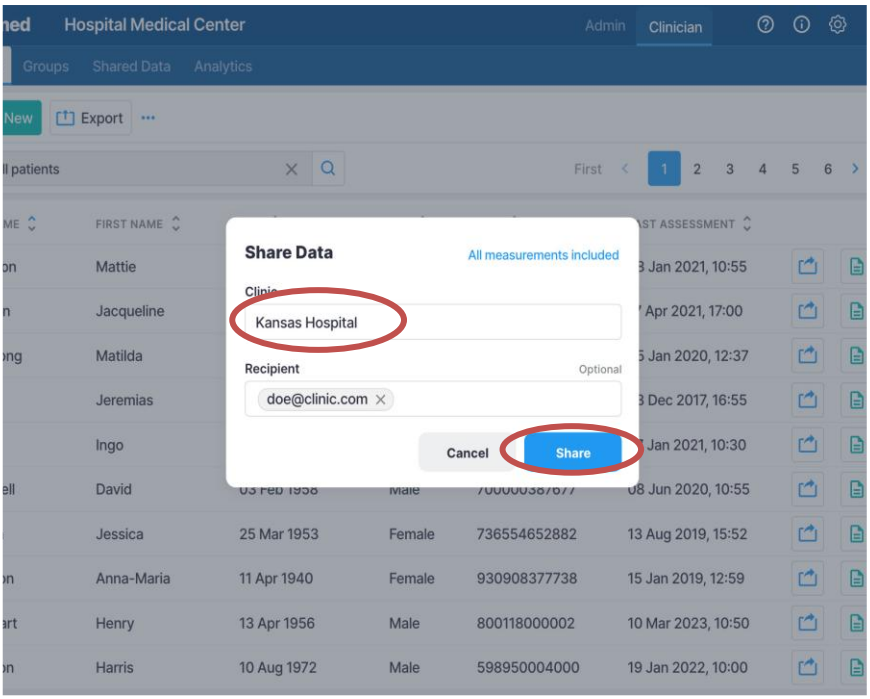
1. Patient list (All measurements will be shared).
2. Patient Dashboard (All measurements will be shared).
3. Results (Choice between sharing all measurements or the current measurement).



Select **Share Data** for one of the three locations listed above. Type and select the clinic you want to share data with and select **Share**.

- If the clinic name is greyed out and says “version not compatible” that means the clinic is not on software version 6.1 and can’t receive shared data.

- Note: An email address for a particular SOZO user can be included to receive email notification that they have received shared data.



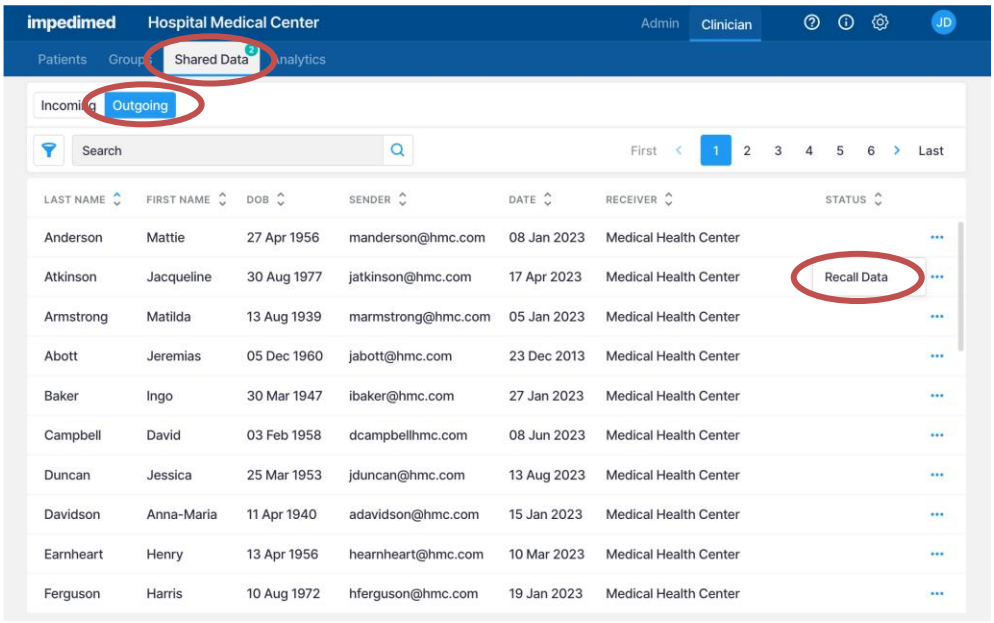
4.3.10.2 View Outgoing Data

To view data that you have shared, first select the Shared Data tab, then select Outgoing. From there, you can view a list of patients where data has been shared and filter and sort the list using any of the arrows listed above the columns.

4.3.10.2.1 Recalling Shared Data

To recall data that has been shared, first select the **Shared Data** tab, then select **Outgoing.** Click the 3 dots next to the record to be recalled and select **Recall**.

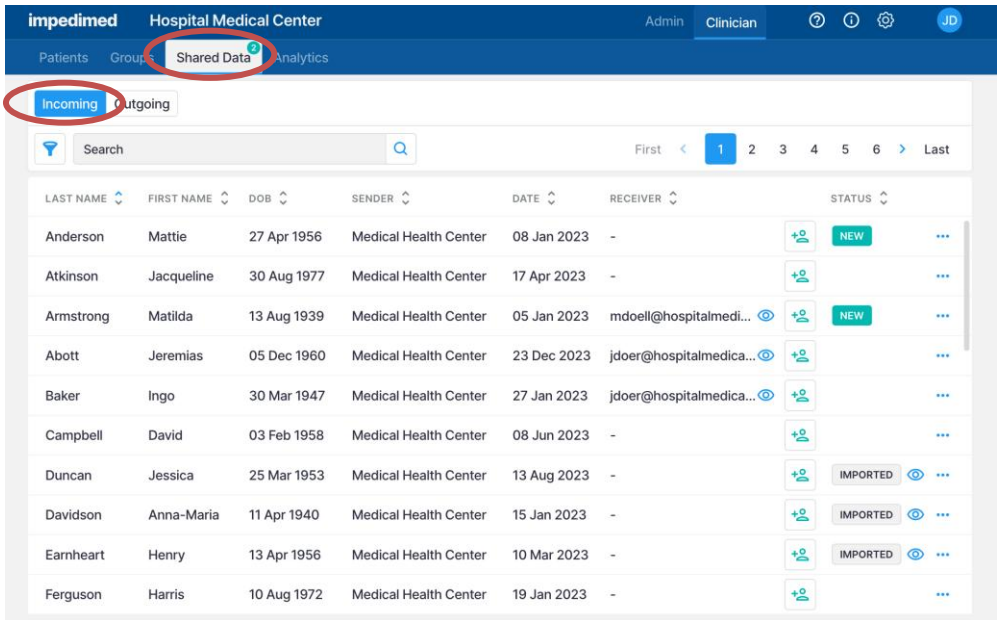
- Select the eye icon to view recall details.
- Note: if the receiving clinic has already imported the shared data, it can't be recalled.



4.3.10.3 View Incoming Data

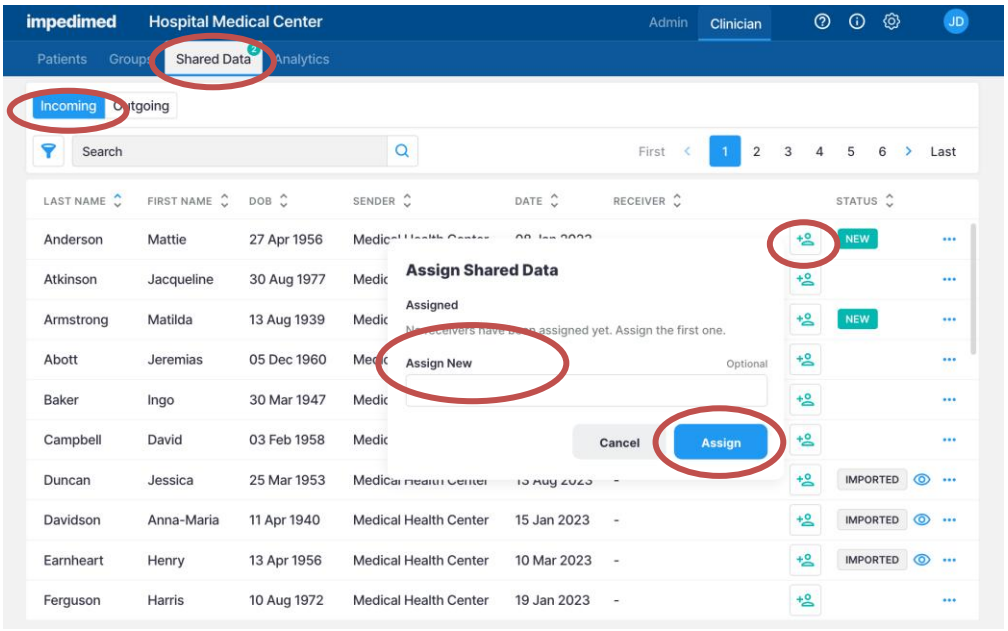
To view data that has been shared with you, first select the **Shared Data** tab, then select **Incoming.** From there, you can view a list of patients where data has been shared and filter and sort the list using any of the arrows listed above the columns.

- The eye icon next to the Status will provide import details



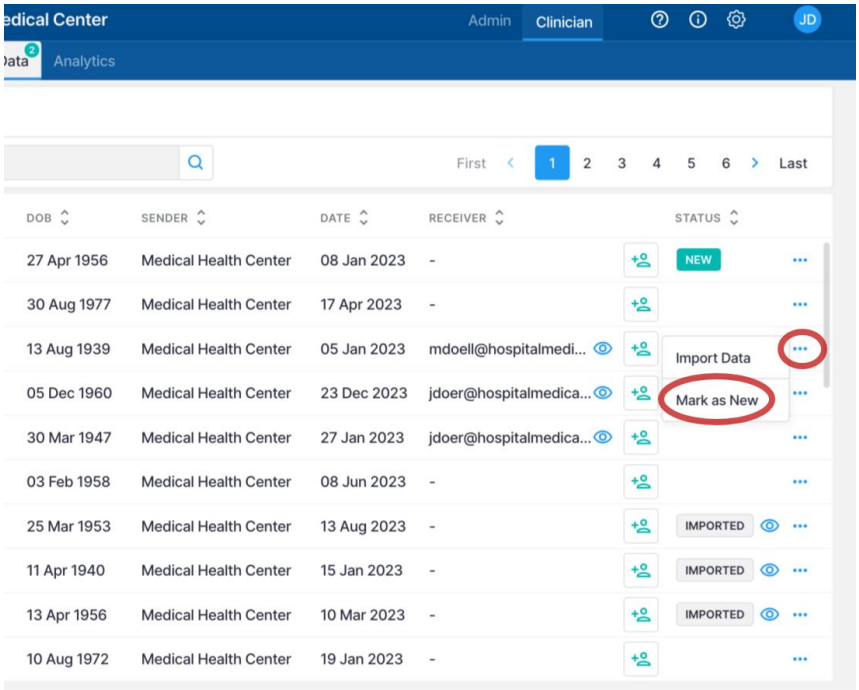
4.3.10.3.1 Add other Receivers to Incoming Data

To add other receivers to incoming data, first select **Incoming**, then select **Receiver.** Start typing the email(s) of the clinician user(s) in your clinic that you would like to add, then select the user from the populated list and select **Assign**. The clinician user(s) will receive an email notification.



4.3.10.3.2 Mark as New

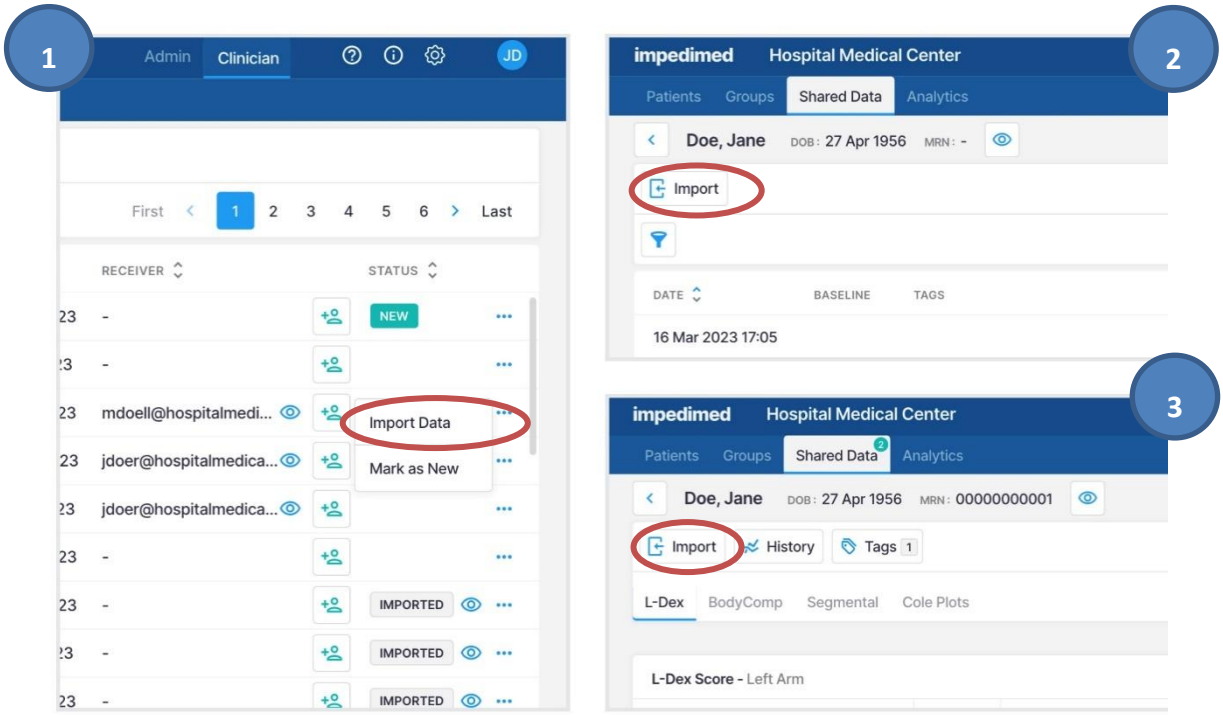
To mark incoming data as new, first select incoming, then click the ellipsis (three dots) next to the record and select **Mark as New**.



4.3.10.3.3 Import Incoming Data

Data can be imported from 3 locations:

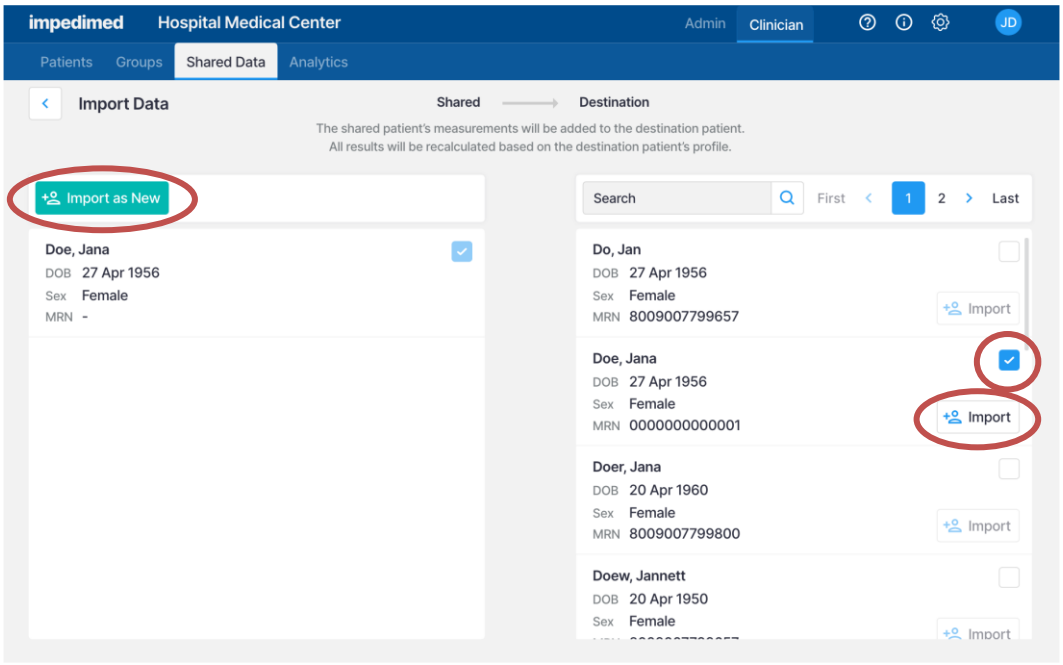
1. Shared data list
   - Click the ellipsis (three dots) next to the record to import and select **Import Data**
2. Shared data patient dashboard
   - Select the record to view and select **Import**
3. Shared data patient result
   - Select the record to view then select the measurement date to view and select **Import**.



Once you have selected Import, you can either import as new to create a new patient or select the patient in your database to merge.

1. To create a new patient, click Import as New, confirm the patient information, enter the MRN for your clinic and finalize by clicking Create.
2. To add shared data to an existing patient, select the patient from the list, select Import, Confirm the patient information is the same as in your existing patient profile, then click Confirm and Import.

Note: All imported data will be indicated on the patient dashboard.

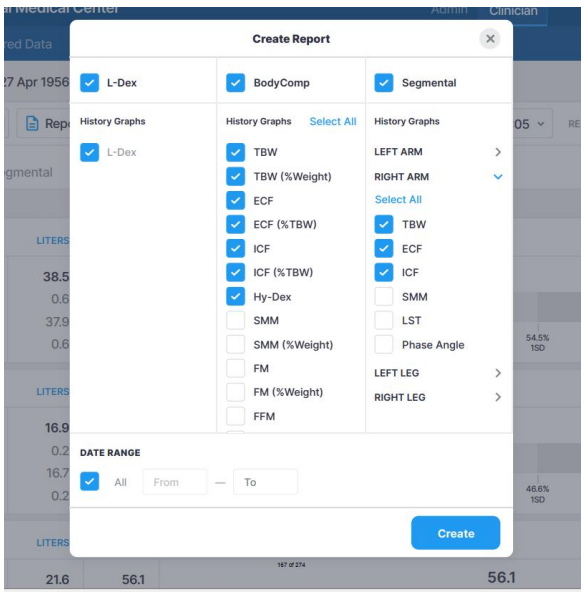


4.3.11 Report

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

To create a patient report from the patient dashboard:

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

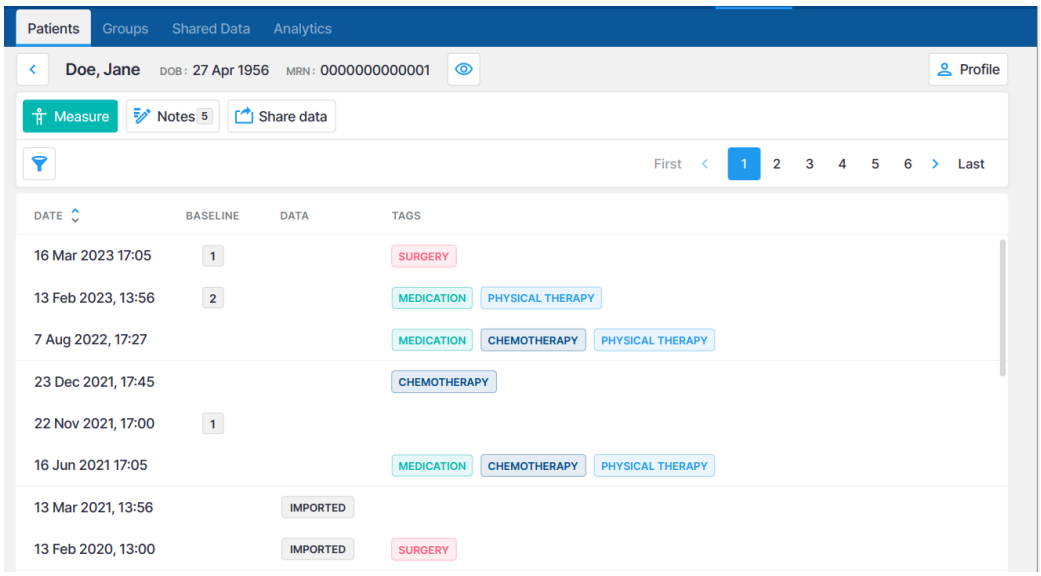


Note: patient reports may also be made directly from a measurement results screen.

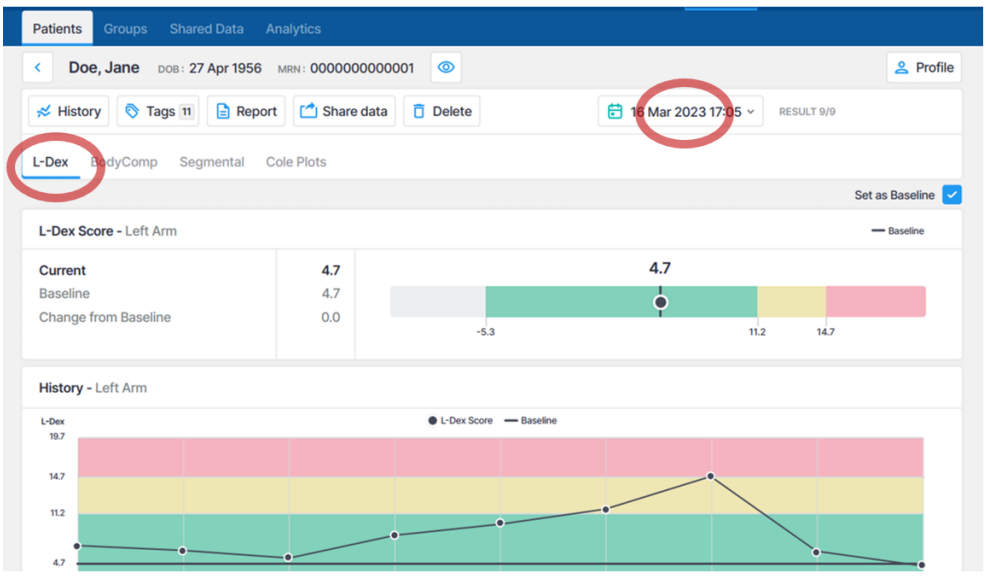
Note: patient reports in PDF format cannot be created from the SOZOapp.

4.4 Measurement Dashboard

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

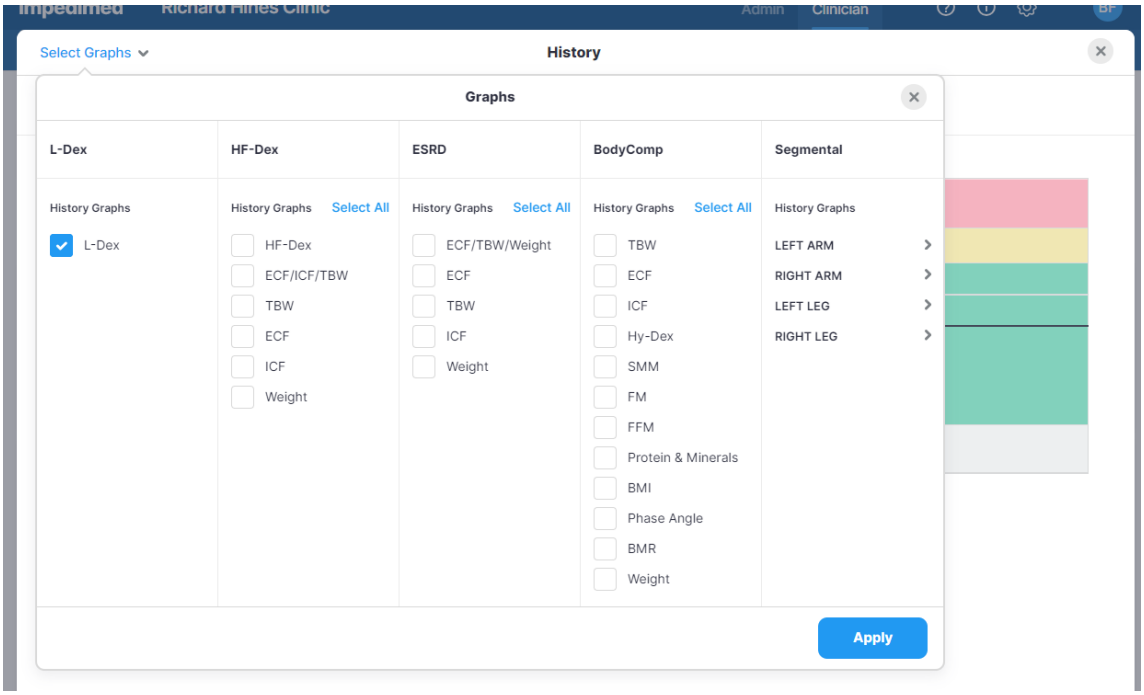


The results for one assessment type will initially be displayed, e.g., L-Dex. The Clinician can click on different assessment types, or different measurement dates, from within the displayed record. The selected assessment type is underlined in blue (e.g., L-Dex) and measurement date is listed next to the green calendar icon.

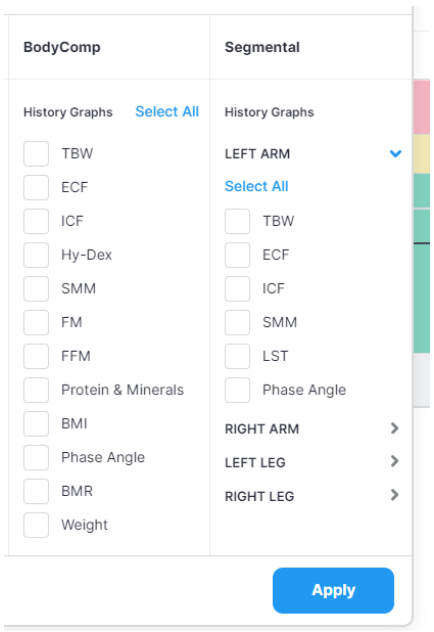


Note: only the measurement history of licenced Assessments that have been selected in the patient profile appears in History.

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



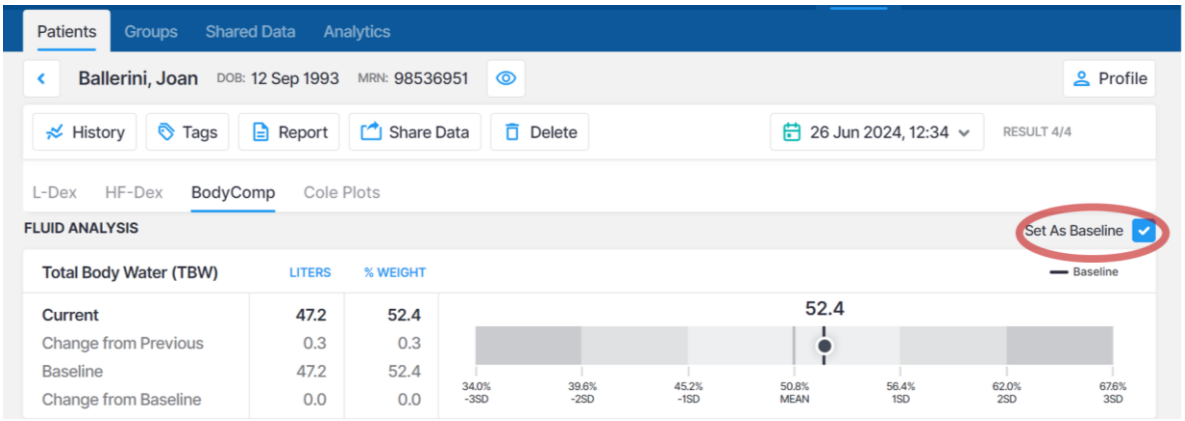
Sub-menus are available for each limb’s segmental measurements:



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

4.4.1 Setting a Baseline

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



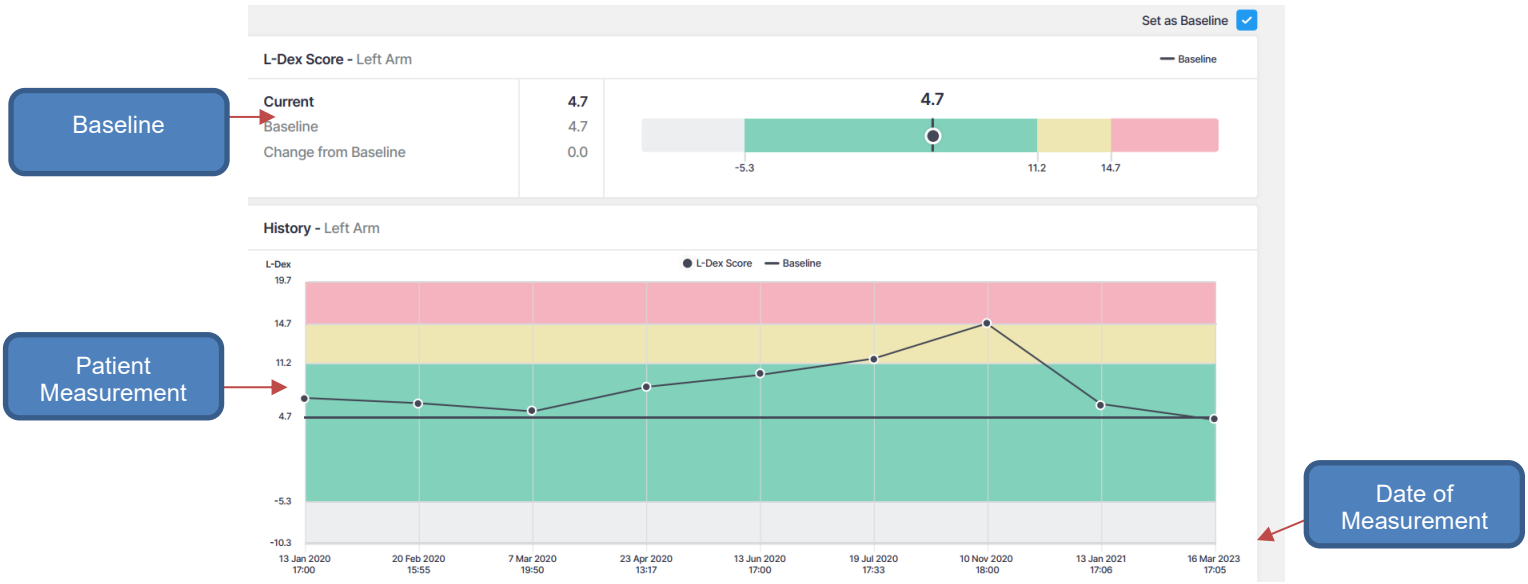
To choose the proper measurement as the baseline, the measurement should be:

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

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

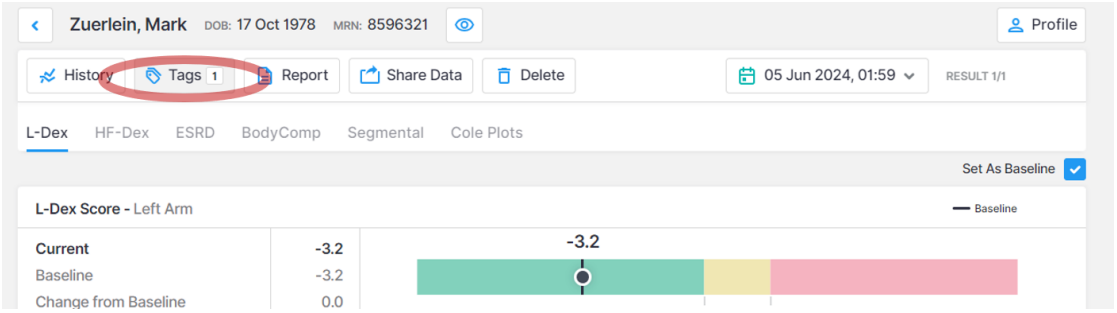
4.4.2 Evaluating Measurements Against a Baseline

For any measurement outputs that can have a baseline selected, the Clinician may compare patient measurements taken over time against the baseline. From this comparison, the Clinician may identify changes in patient fluid levels, and see if these changes fall within normal or abnormal ranges.

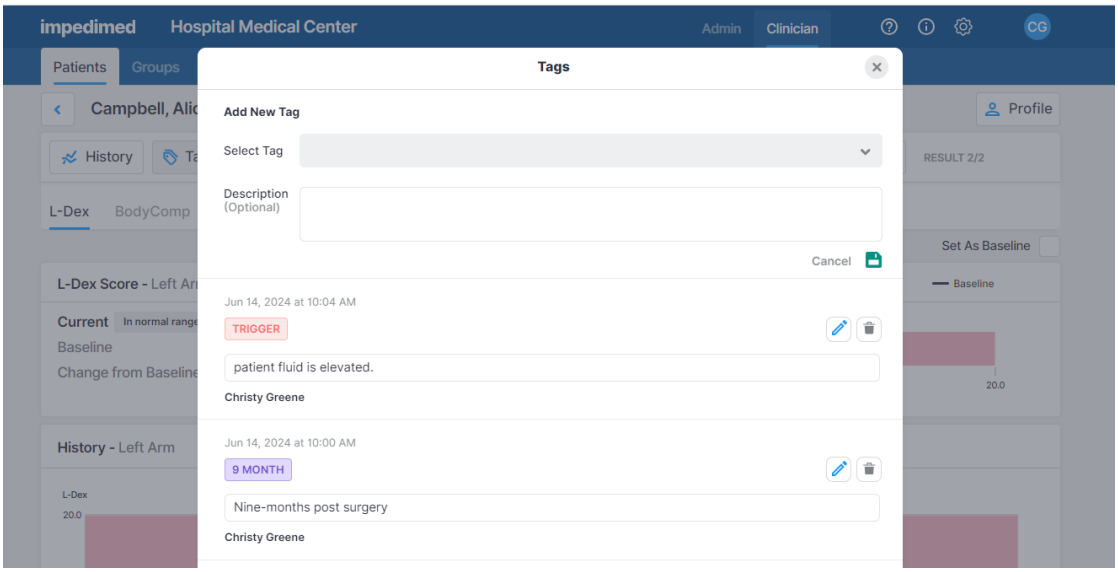


4.4.3 Adding a Measurement Tag

A Tag can be added to a measurement to provide additional information and notes. These must be created by a Clinic Administrator. The number of Tags linked to a measurement is listed in the top left corner, below the patient's name. Multiple Tags can be added to the same measurement and saved using the green save icon.



The number of tags (red circle above) is listed in the "Tags" icon on the measurement page.



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

4.4.4 Cole Plots

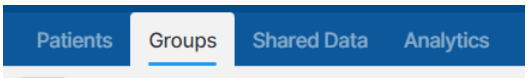
The SOZO software helps determine the quality of the Cole Plots by the following:

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

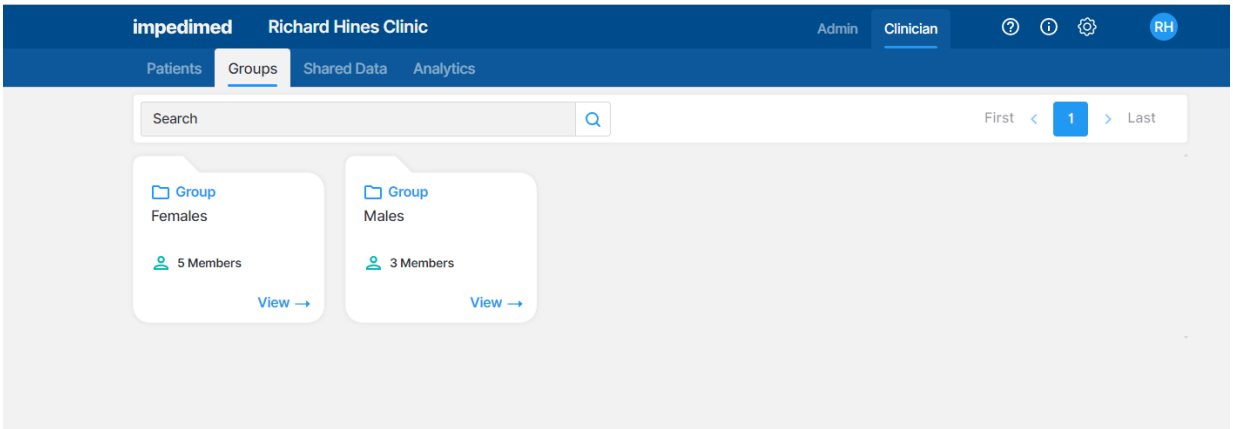
If the Right Whole-Body Cole plot is low quality, measurements for the HF-Dex assessment type will not be displayed.

4.5 Clinician Patient Groups

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

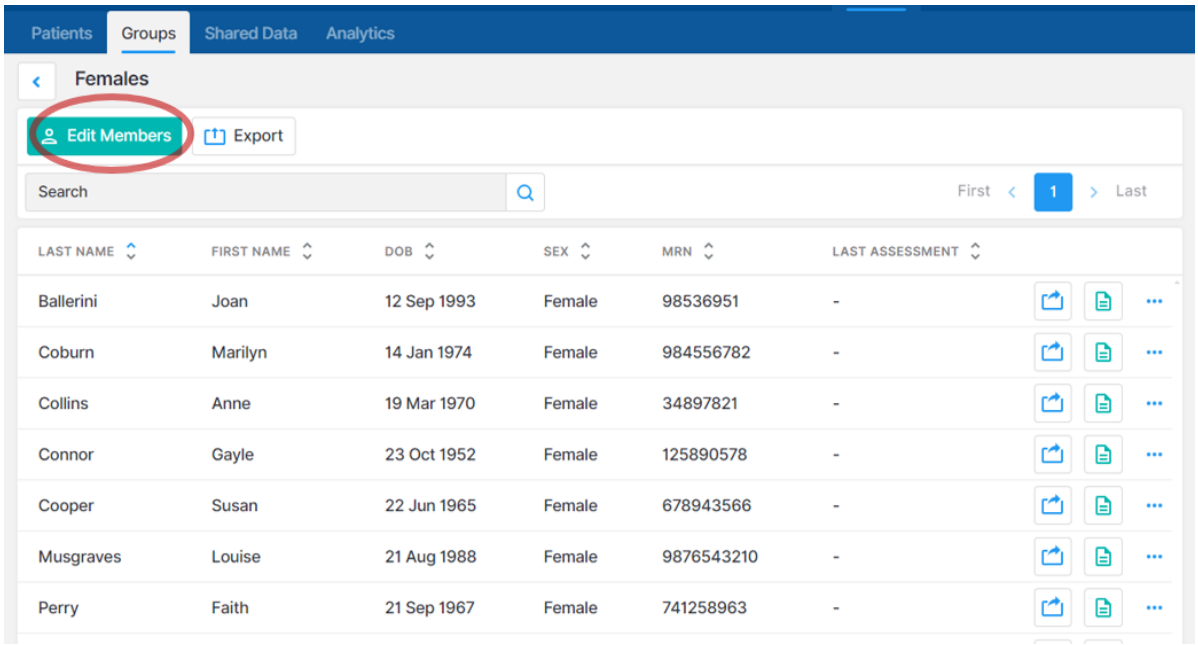


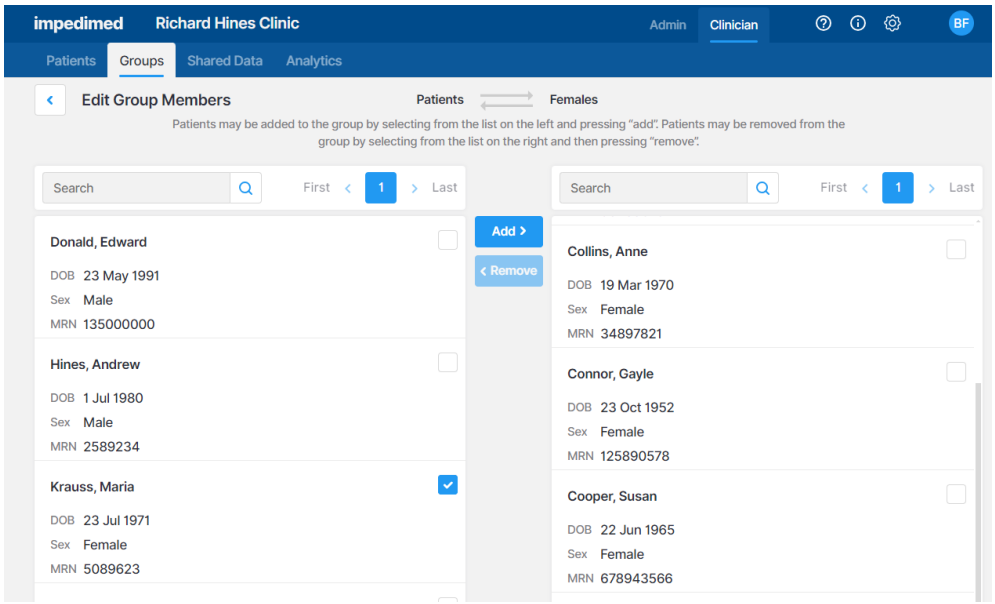
Patients can be assigned to predefined groups within the SOZO database. Administrator access is required to manage group creation. Clinician access is required to add or remove patients from groups.



To access **Group** features:

1. **Click** the **Groups** tab located along the top of the panel, between **Patients** and **Shared Data** This will bring up all current groups within the clinic.
    a. If the Patient Groups tab is empty, only individuals with Administrator permissions can create or name them.
2. Select a group by clicking **View** to bring up the list of patients currently assigned to that group.
3. To **modify patients** within the group, click on **Edit Members** located in the top right corner.
    a. To add a patient to a group search for the patient's name in the left-hand column and **check** the box next to their profile. Selecting at least one patient will highlight the **Add** button. **Click** the **Add** button to add patients to the group.
    b. To remove a patient from a group, search for the patient's name in the right-hand column and check the box next to their profile. Selecting at least one patient will highlight the **Remove** button. Click the **Remove** button to remove patients from the group.


Patients
Groups
Shared Data
Analytics
Females
Edit Members
Export
Search
First
1
Last
LAST NAME
FIRST NAME
DOB
SEX
MRN
LAST ASSESSMENT
Ballerini Joan 12 Sep 1993 Female 98536951 -
Coburn Marilyn 14 Jan 1974 Female 984556782 -
Collins Anne 19 Mar 1970 Female 34897821 -
Connor Gayle 23 Oct 1952 Female 125890578 -
Cooper Susan 22 Jun 1965 Female 678943566 -
Musgraves Louise 21 Aug 1988 Female 9876543210 -
Perry Faith 21 Sep 1967 Female 741258963 -


impedimed
Richard Hines Clinic
Admin
Clinician
BF
Patients
Groups
Shared Data
Analytics
Edit Group Members
Patients
Females
Patients may be added to the group by selecting from the list on the left and pressing "add". Patients may be removed from the group by selecting from the list on the right and then pressing "remove".
Search
First
1
Last
Donald, Edward
DOB 23 May 1991
Sex Male
MRN 135000000
Hines, Andrew
DOB 1 Jul 1980
Sex Male
MRN 2589234
Krauss, Maria
DOB 23 Jul 1971
Sex Female
MRN 5089623
Add >
< Remove
Collins, Anne
DOB 19 Mar 1970
Sex Female
MRN 34897821
Connor, Gayle
DOB 23 Oct 1952
Sex Female
MRN 125890578
Cooper, Susan
DOB 22 Jun 1965
Sex Female
MRN 678943566

4.6 Clinician Analytics

Selects the **Analytics** tab (red circle below) from the tabs across the top at any time to return to the Analytics page on the MySOZO Clinician home page.

The Clinician Analytics dashboard provides tools to track both Lymphoedema Assessments and how well the clinic is following the Lymphoedema Surveillance Program. Information on protocol compliance and patients in the Surveillance Program who have triggered is provided as well as data for Patient & Measurement Overview and Patient Distribution. The information in the Analytics dashboard is updated hourly.

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

4.6.1 Lymphoedema Surveillance Program

This program utilises ImpediMed's Test, Trigger, Treat® protocol for early detection and intervention of cancer-related lymphoedema. The evidence-based protocol option for the lymphoedema surveillance program is supported by the findings of the PREVENT trial[2-3] and McDuff et al[4]. The PREVENT trial followed patients at 3–6-month intervals for 3 years. The study showed that a prospective surveillance program using BIS was able to identify and treat patients for subclinical lymphoedema with improved patient outcomes compared to those monitored with tape measure. McDuff found that while the risk of lymphoedema is greatest in the first 3 years, the lymphoedema risk is directly impacted by therapy received with regional lymph node radiation which correlated to late onset lymphoedema. Therefore, the experts in the study recommended regular intervals for 5 years post treatment.

4.6.2 Surveillance Program Tab

The Surveillance Program tab displays the program overview, the number of patient measurements that are upcoming or are overdue, the number of patients triggered, and compliance to the surveillance protocol.

---

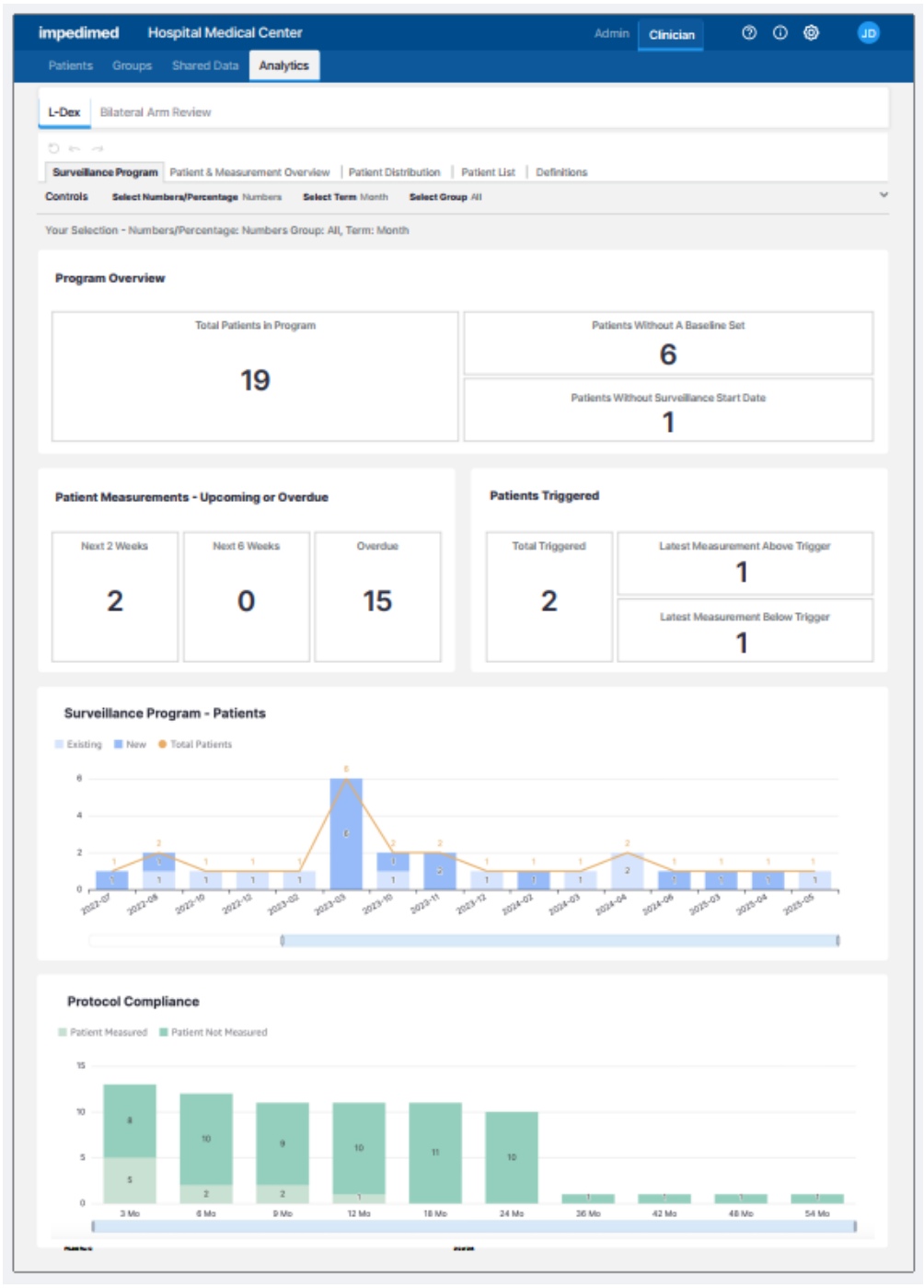
[2] Ridner SH, Dietrich MS, Boyages J, et al. A Comparison of Bioimpedance Spectroscopy or Tape Measure Triggered Compression Intervention in Chronic Breast Cancer Lymphedema Prevention. *Lymphatic Research and Biology* 2022.

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

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

Note: this dashboard only includes patients who have a baseline measurement selected and are included in the Lymphoedema surveillance program as selected in the patient profile (Surgery Date or Alternate Date are entered in the patient profile). The *Surgery Date or Alternate Date entered in the profile is used as the starting date for the surveillance protocol (see 4.6.2.5, Further Definitions)*.

The Program Overview in the Analytics Surveillance tab is shown below. The total number of patients in the program, the number of patients without a baseline set, and the number of patients without a surveillance start date are displayed. Additionally, the number of patient measurements that are upcoming or are overdue and the number of patients triggered are displayed.



Directly beneath the graphs in the Patients view and Protocol Compliance view is a blue horizontal bar that allows you to change the range. Slide the end of the bar right or left and the display adjusts automatically.

4.6.2.1 Patients Measurements – Upcoming or Overdue

This displays the total number of patients in the surveillance program who are due for their measurement in the next 2 weeks, 6 weeks, and the patients who are overdue. The due date for a patient is calculated based on the surveillance start date and the defined frequency within the surveillance program protocol. Measurement status is determined by the surveillance program start date and protocol intervals selected.

Example: For every 6-month protocols, a patient is counted as having a measurement if a measurement occurs within 3 months on either side of the due date.

4.6.2.2 Patients Triggered

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

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

4.6.2.3 Surveillance Program - Patients

This provides the number of patients in the surveillance program who were measured during the selected time period.

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

4.6.2.4 Protocol Compliance

This provides the total number of surveillance program patients who took a measurement within the target protocol time period vs. those patients who did not take a measurement for each measurement target date. The surveillance program target dates are defined below and calculated for each patient based on the Surveillance Start Date of the patient and the surveillance program protocol selected for the clinic. Patients will be considered measured if they have had a measurement halfway between the protocol timepoints. For example, if the protocol interval is

every 6 months, the patient will be counted as measured if they had a measurement within 3 months on either side of the due date.

4.6.2.5 Further Definitions

- **Surveillance Program Start Date**: The Surgery/Alternate Date should be the first treatment date that had an impact on the Lymphatic system. This date will be used to track when measurements should be started and when the follow-up measurements should be taken based on the Surveillance Program Protocol. The Surgery/Alternate date is an optional field that is specified in the patient profile for individual patients but is required for a patient to be included in the Surveillance Program Dashboard in Analytics.
- **Testing Frequency**: The surveillance program protocol, either evidence-based or custom, should be determined by the SOZO administrator and will be utilised clinic-wide
  - Evidence-Based Protocol
    - Years 1-3: Every 3 months
    - Years 4-5: Every 6 months
    - Year 6: Every 12 months
  - Custom Protocol
    - Duration up to 6 years
    - Testing frequency:
      - Years 1-2: Every 3, 4 or 6 months
      - Years 3-6: Every 3, 4, 6 or 12 months

4.6.3 Patient & Measurement Overview

This dashboard provides insight into the usage of SOZO and the L-Dex Analysis for Lymphoedema Assessment. It provides outputs based on all Lymphoedema patients, Total Measurements, and Devices used within the clinic.

SERIAL NUMBER	DEVICE NAME	LAST MEASUREMENT	PATIENTS	TOTAL MEASUREMENTS
SOZO-03K1118015	null	null	3	27
SOZO-03K1717042	Cancer Center	Nov 09, 2023	6	26
SOZO-03L0717126	null	Nov 13, 2023	5	21
SOZO-19F2621058	Rehab Department	Mar 13, 2023	13	20
SOZO-21E0817034	Christy's Device	May 13, 2025	9	19
SOZO-03L0717124	Medical Oncology	Jun 03, 2022	2	15
NO SERIAL NUMBER	null	null	3	12
SOZO-03K1918074R	null	Mar 13, 2023	7	11
SOZO-03L0118036R	null	Oct 26, 2023	7	9
SOZO-03L0717143	null	Nov 09, 2023	2	9
SOZO-03J2018049	null	Nov 23, 2023	2	8
SOZO-07C0920062	Katie's Device	Apr 10, 2025	2	8
SOZO-07C0920067	null	Dec 10, 2023	4	7
SOZO-20J5022004	null	May 05, 2025	1	7
SOZO-21F0717014	null	Dec 15, 2023	3	7
SOZO-21G2117041	Test naming MS 7:47 AM PT	Feb 21, 2023	1	7

4.6.3.1 Patients Measured

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

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

4.6.3.2 Measurements

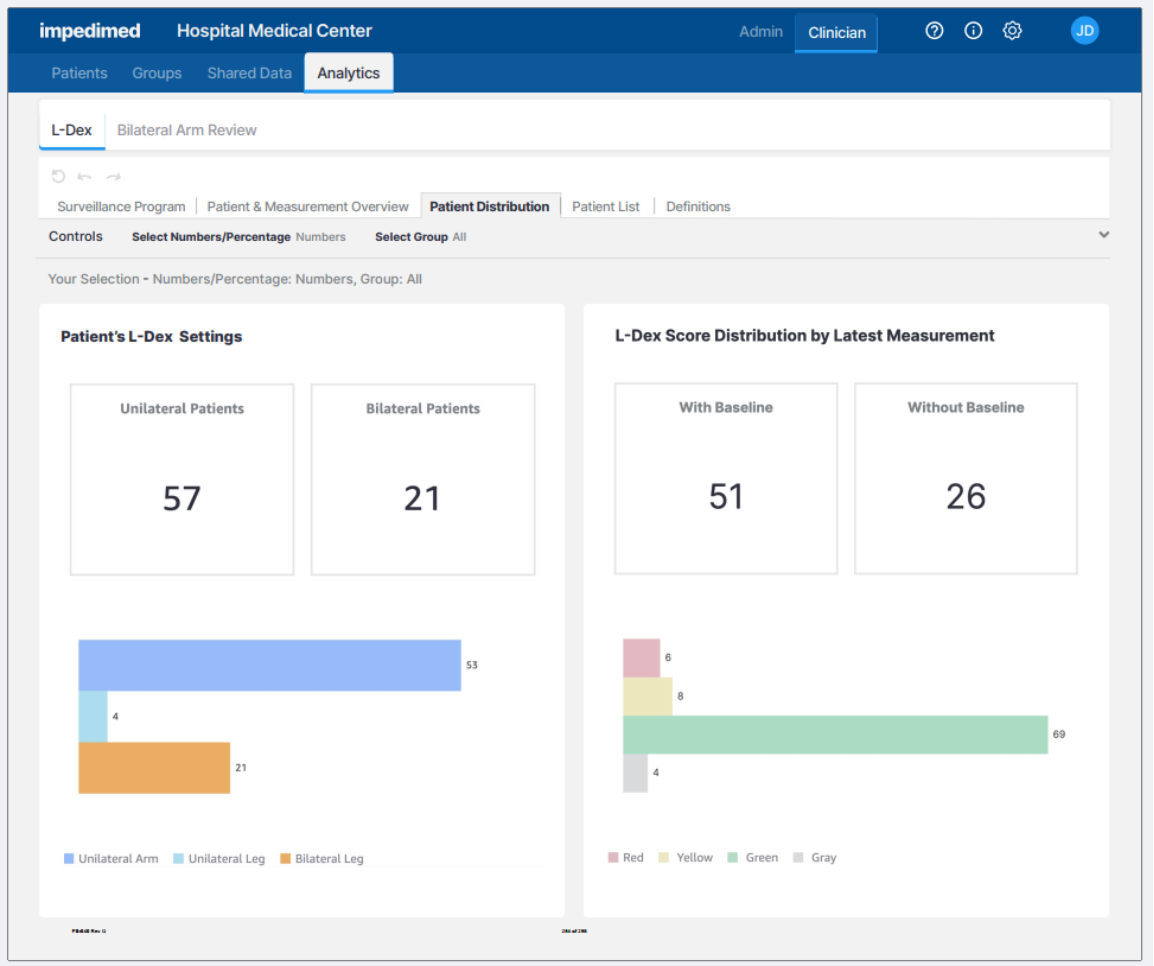
This chart provides the count of measurements taken on L-Dex patients over time, selectable by Month, Quarter or Year from the Controls menu. The total Measurements is a count of all measurements taken on all L-Dex patients.

4.6.3.3 **Device List & Utilisation**

This table provides the total number of Patients and Measurements, as defined above, by SOZO serial number.

4.6.4 Patient Distribution

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



4.6.4.1 Patient's L-Dex® Settings

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

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

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

4.6.4.2 L-Dex® Score Distribution by Latest Measurement

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

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

Note: these categories have a different meaning depending on whether a baseline has been set.

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

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

L-Dex Categories without a Baseline

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

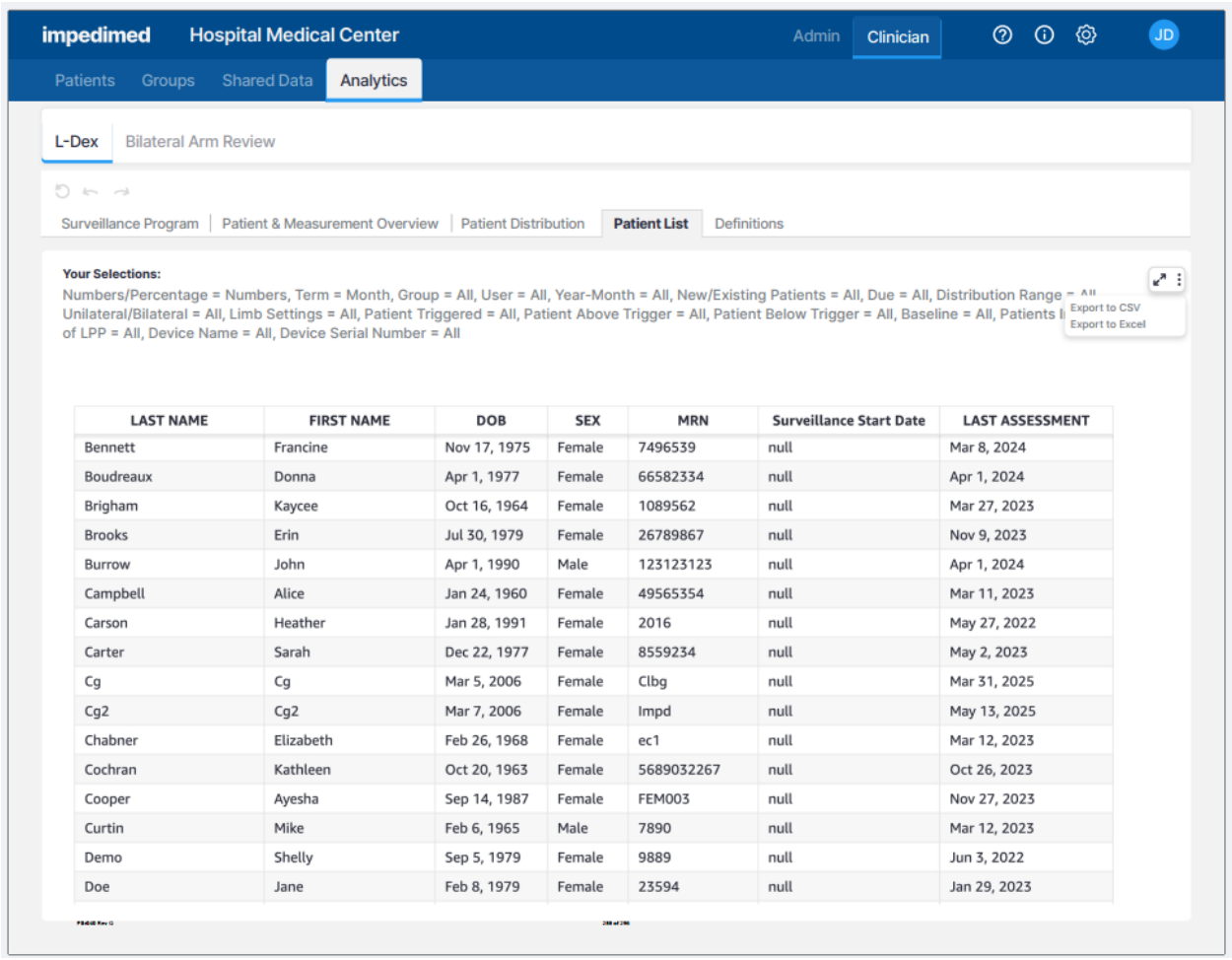
L-Dex Categories with a Baseline

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

4.6.5 Patient List

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

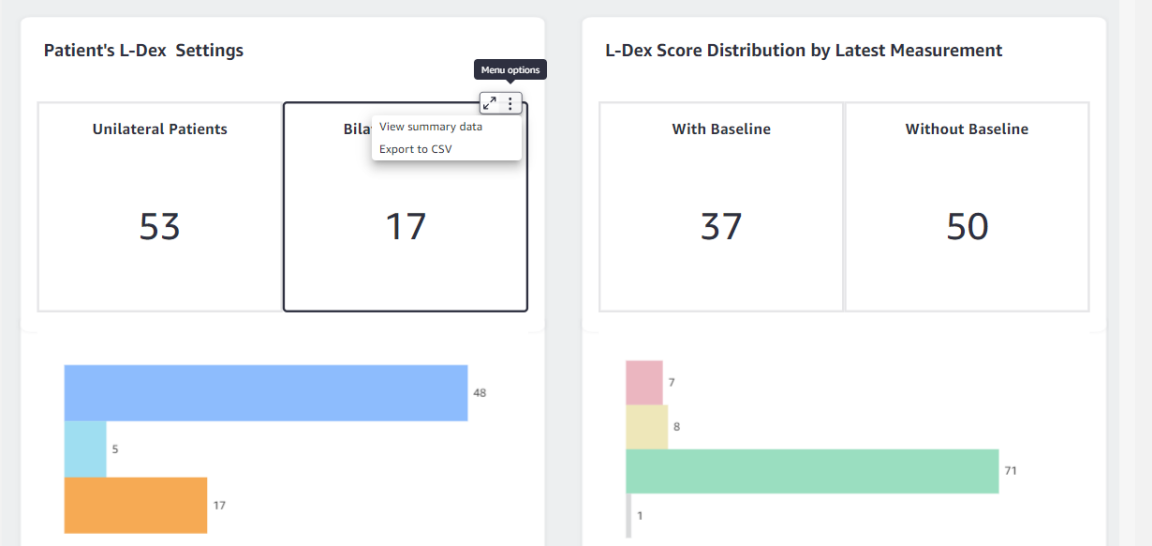
- By default, this is the full list of L-Dex patients contained in the database. Each column can be sorted by ascending or descending order.
- If the clinician drills down on a graph or table element, the patient list is filtered according to the criteria of the graph.



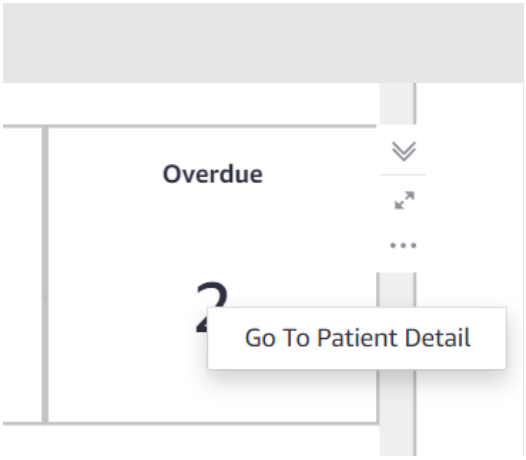
LAST NAME	FIRST NAME	DOB	SEX	MRN	Surveillance Start Date	LAST ASSESSMENT
Bennett	Francine	Nov 17, 1975	Female	7496539	null	Mar 8, 2024
Boudreaux	Donna	Apr 1, 1977	Female	66582334	null	Apr 1, 2024
Brigham	Kaycee	Oct 16, 1964	Female	1089562	null	Mar 27, 2023
Brooks	Erin	Jul 30, 1979	Female	26789867	null	Nov 9, 2023
Burrow	John	Apr 1, 1990	Male	123123123	null	Apr 1, 2024
Campbell	Alice	Jan 24, 1960	Female	49565354	null	Mar 11, 2023
Carson	Heather	Jan 28, 1991	Female	2016	null	May 27, 2022
Carter	Sarah	Dec 22, 1977	Female	8559234	null	May 2, 2023
Cg	Cg	Mar 5, 2006	Female	Clbg	null	Mar 31, 2025
Cg2	Cg2	Mar 7, 2006	Female	Impd	null	May 13, 2025
Chabner	Elizabeth	Feb 26, 1968	Female	ec1	null	Mar 12, 2023
Cochran	Kathleen	Oct 20, 1963	Female	5689032267	null	Oct 26, 2023
Cooper	Ayesha	Sep 14, 1987	Female	FEM003	null	Nov 27, 2023
Curtin	Mike	Feb 6, 1965	Male	7890	null	Mar 12, 2023
Demo	Shelly	Sep 5, 1979	Female	9889	null	Jun 3, 2022
Doe	Jane	Feb 8, 1979	Female	23594	null	Jan 29, 2023

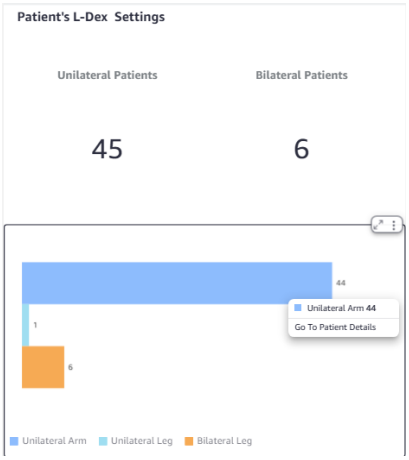
4.6.6 Navigation

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

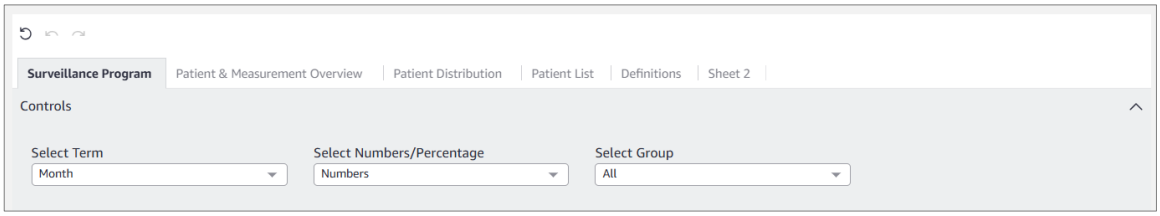


- **Accessing Patient List:** By default, all patients with an L-Dex Assessment are included in the patient list. To get patient data associated with a particular chart or table element, select the data element (e.g., Overdue patients, Patients Measured in Time Period, Serial Number, Bilateral Leg Patients,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





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



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

5 SOZOapp

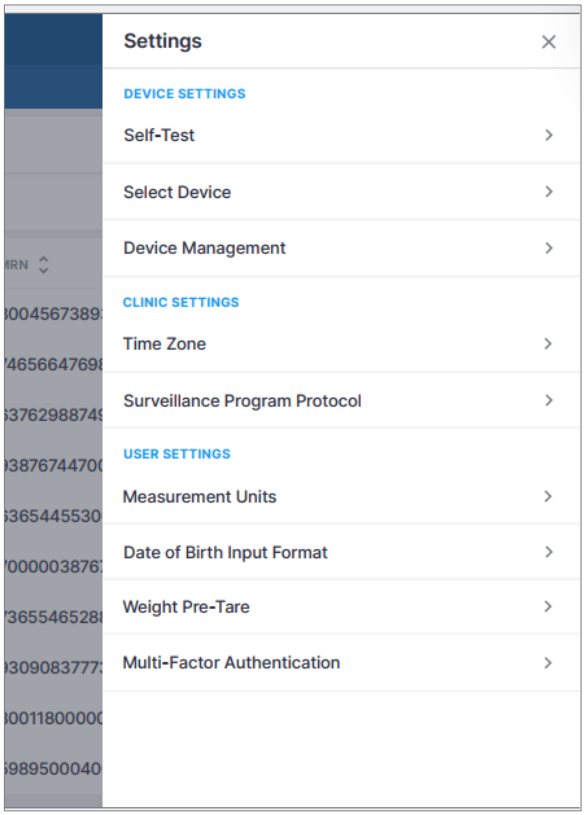
5.1 SOZOapp Settings

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

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

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

Note: The user can view and change Pre-Tare Weight only when a SOZO Pro device is connected.



5.1.1 Select and Pair Device

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

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

The SOZO Device serial number may be found on the

- SOZOtouch housing
- SOZOconnect cable
- SOZOstep housing

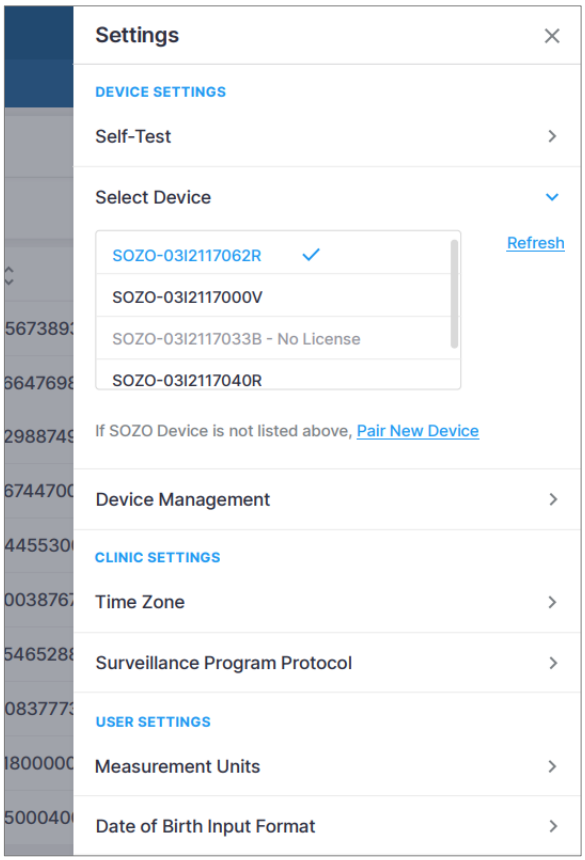
The Tablet must be paired for any new SOZO Devices, and the pairing process must also be repeated if either the Tablet or system is replaced. The SOZOapp may only select and work with one SOZO Device at a time.

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

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

5.1.1.1 Android:

a. To use a SOZO device with an Android tablet for the first time, it first must be paired through the Android operating system.
    i. Locate **Settings** on the Tablet and enable *Bluetooth*®.
    ii. Once *Bluetooth*® is enabled, the Tablet scans for connection to the SOZO Device. Select the option to **Pair new device** and select the SOZO Device serial number.
    iii. Alternatively, the Tablet settings can be accessed using the **SOZOapp** and navigating to the **Settings** page and clicking **Select Device**. Select the option to **Pair New Device** to open the tablet Bluetooth settings.
    Note: If a SOZO device has been previously paired with the tablet, it will not be listed when adding a new device.
b. After pairing the SOZO device it must then be selected within the **Select Device** menu of the SOZOapp **Settings**.
    i. A list of SOZO Devices that have been previously paired over Bluetooth will be presented. If the paired device is not present, press **Refresh**.
    ii. Select the desired device and ensure it is highlighted blue with a tick mark next to it.



Note: do not pair an Android device (Samsung Tablet) to a SOZO system whose serial number starts with IOS- as the android SOZOapp will not show that device in the Select Device for Use menu. If this occurs, choose a SOZO Device with an identification that does not start with IOS or navigate into the Bluetooth settings menu to unpair the SOZO Device.

5.1.1.2 iOS:

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

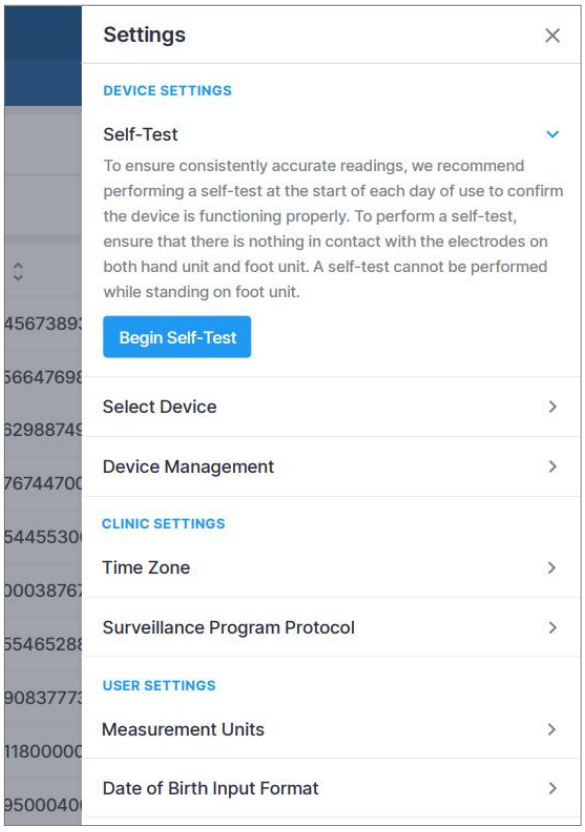
5.1.2 Self-Test

Self-tests may be run for different purposes.

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

To run a self-test:

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



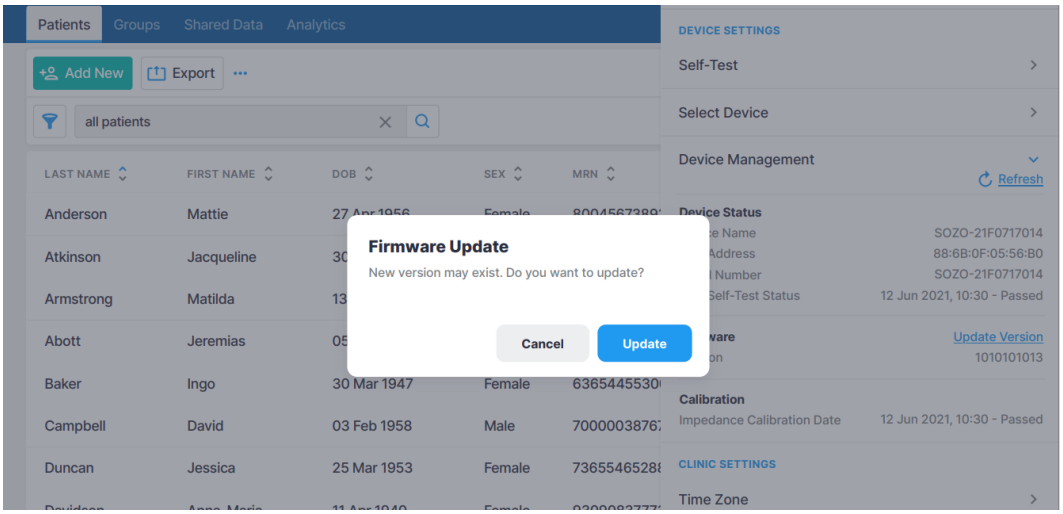
5.1.3 Device Management

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

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

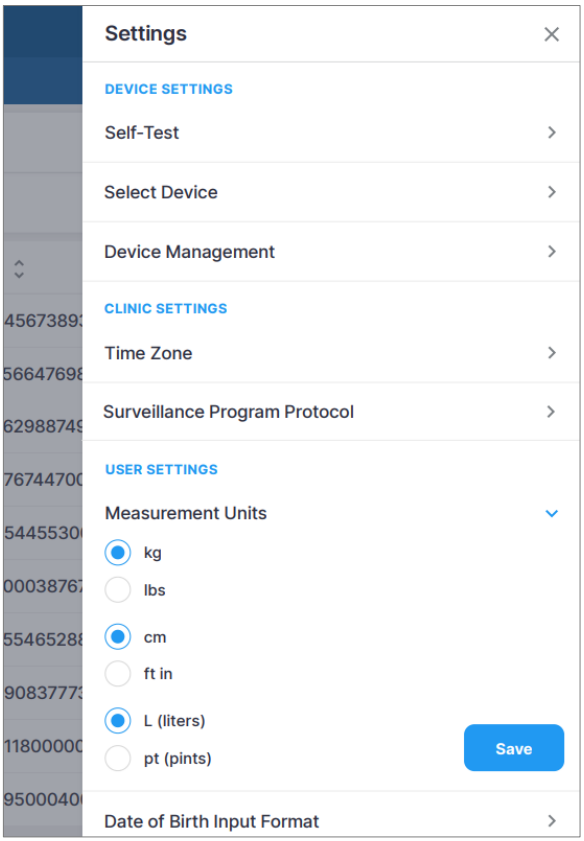
The SOZO system firmware may be updated by tapping **update** next to “Firmware”. This process may take 2-3 minutes. The Tablet or SOZO Device should not be turned off during this time.

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



5.1.4 Measurement Units

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



5.1.5 Time Zone

The current Time Zone for the clinic is displayed here.

5.1.6 Multi-Factor Authentication

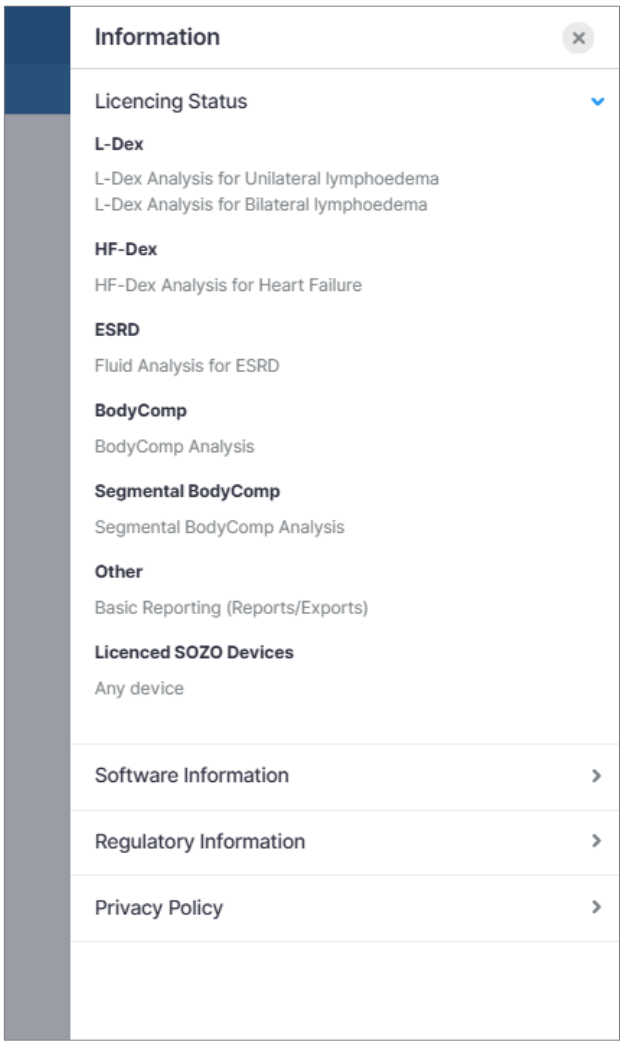
The Clinician can elect to have multi-factor authentication turned on for their account once it has been activated by the Clinic Administrator.

5.1.7 Technical Support

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

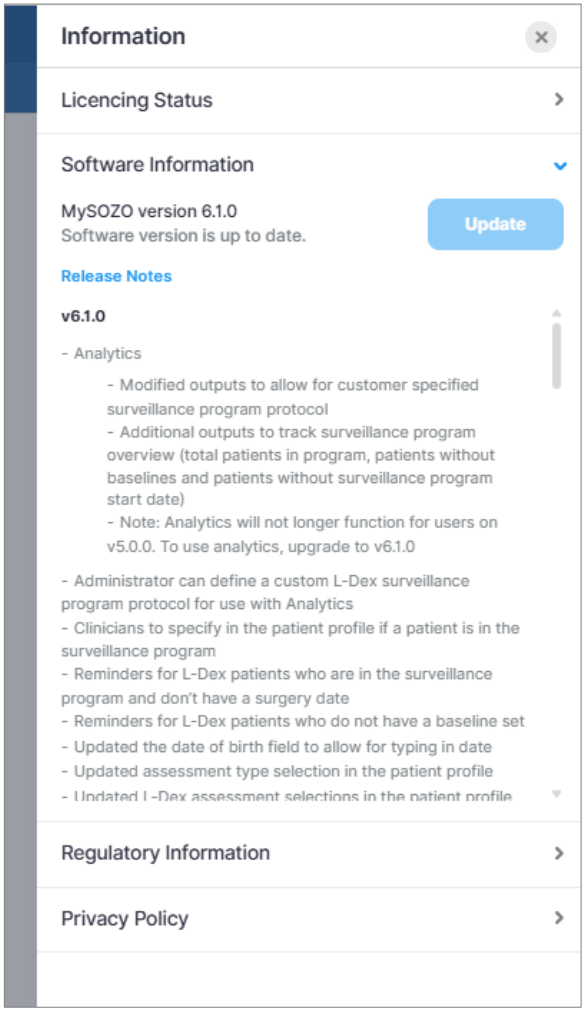
5.1.8 Licencing Status

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



5.1.9 Software Information

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



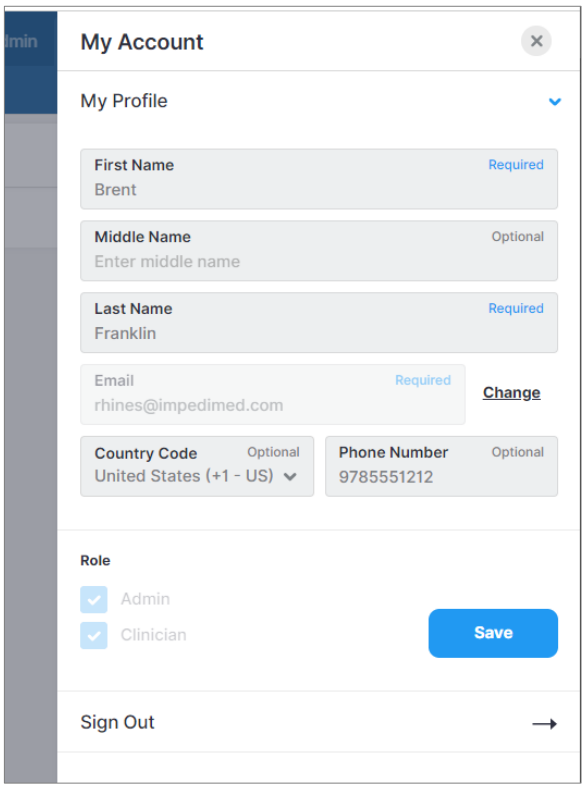
5.1.10 Regulatory Information

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

5.2 SOZOapp My Account Page

To edit the Clinician Account, navigate to the user initials in the blue circle (upper right) and select My Profile. Select **Save** once changes have been made.

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



6 PREPARING THE PATIENT

6.1 Preparing for all Measurements

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

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

6.1.1 Factors Affecting Measurement

NOTE: Measurement results can be impacted by several factors

- Placing a mobile phone in close proximity (less than 2 metres) to the device during operation
- Metal implants, clips or other types of artificial limbs or implants in the patient
- Patients touching a metal surface during the measurement process
- Using the device when the patient is connected to other medical devices (increasing the risk of electrical interference)

6.1.2 Body Composition Measurements

If body composition analysis is intended, ensure the patient observes the following preparation tips to receive consistent BodyComp Assessments:

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

6.2 Measurement Accuracy

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

6.2.1 Weight Modifications

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

6.3 Positioning the Patient

The SOZO system is designed in a Standing Position for patients who can stand and in a Seated Position to accommodate patients who are unable to stand and may exceed the maximum weight limit (up to 170 kg if patient is standing, and up to 340 kg if patient is sitting). DEVICE ASSEMBLY provides instructions for system configuration for standing and seated positions.

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

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

6.3.1 Standing Position

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

The patient should:

- Distribute body weight evenly on both feet.
- Keep arms relaxed with elbows at their sides, abducted slightly such that they are not in contact with the torso. The patient's hands must have contact with the electrodes.

6.3.2 Seated Position

When using seated, ImpediMed recommends NOT using a metal chair or table.

The patient should:

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

7 TAKING MEASUREMENTS

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

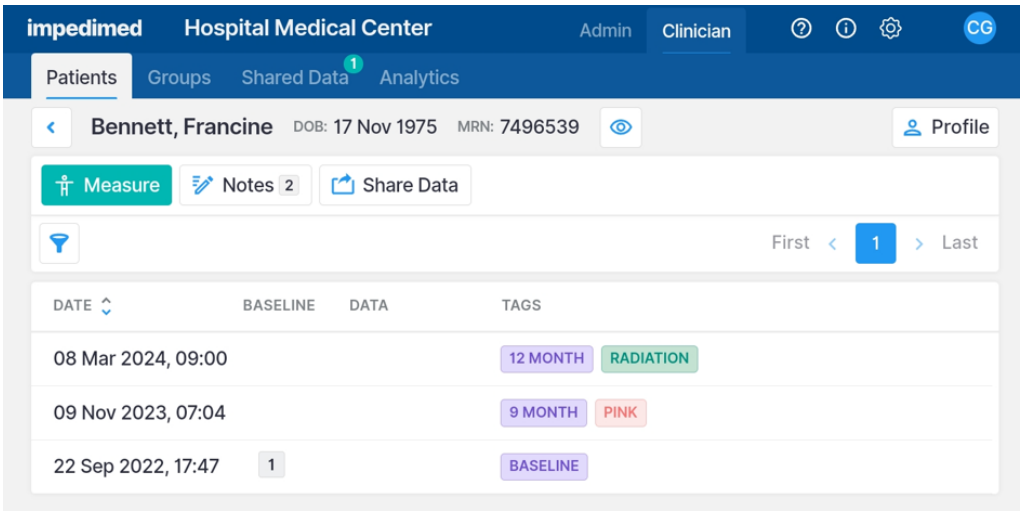
Each of the assessments along with indication-specific information and reports are discussed in greater detail below.

7.1 Starting Measurements with the SOZOapp

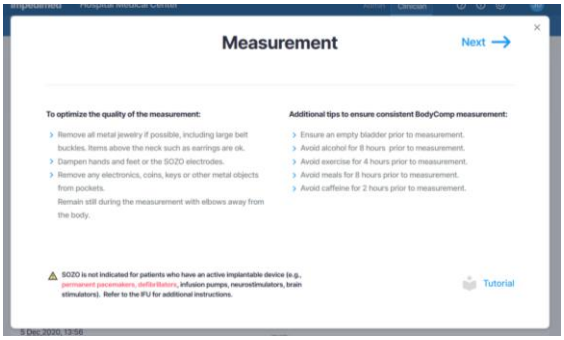
Measurements are taken using the Tablet and SOZOapp.

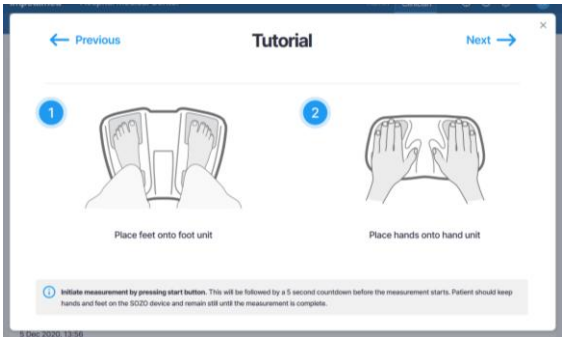
To take patient measurements:

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



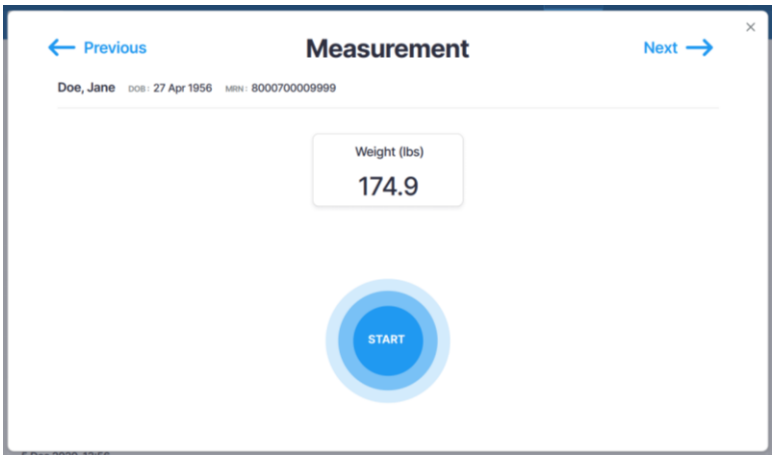
4. After tapping the **Measure** icon, measurement instructions appear. To optimise measurement quality, ensure patient compliance with these instructions. When done, tap **Next**.





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

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



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

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

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

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

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

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

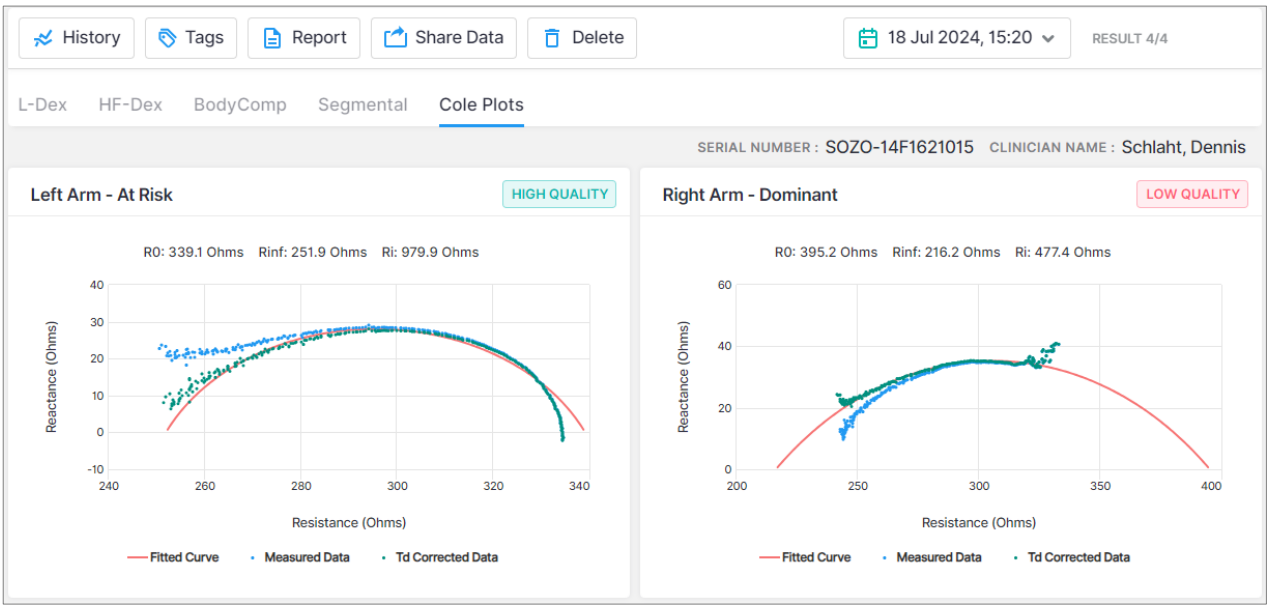
7.2 Accepting and Rejecting Cole Plots After Measurement

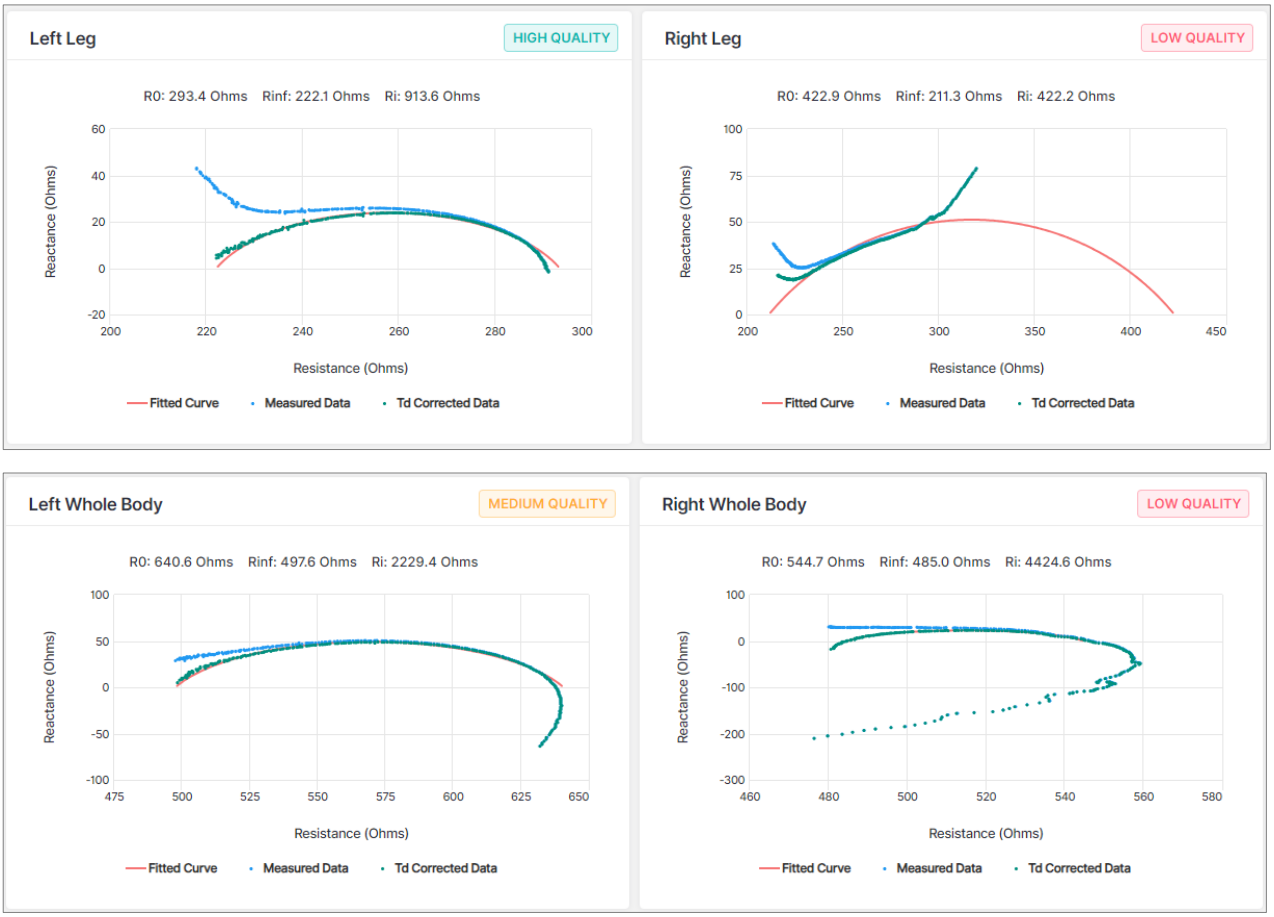
After the measurement process is complete, the system calculates and assesses the Cole plots. If all 6 Cole plots are assessed as high quality, the Cole plots will be

automatically accepted and not displayed prior to the results, however, can be viewed with the measurement. If any of the 6 Cole plots are assessed as medium or low quality, the next step is to view the Cole plots results, in order to evaluate the quality of the measurements.

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

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





7.3 Interpreting Cole Plots

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

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

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

If all the Cole plots are high quality, the measurements are automatically accepted. If, however, one or more of the Cole plots are medium quality or low quality, ***Accept*** and ***Reject*** buttons appear at the bottom of the Cole Plots

screen. When this occurs, the Clinician must decide to accept or reject the measurements.

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

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

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

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

7.4 Setting a Baseline

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

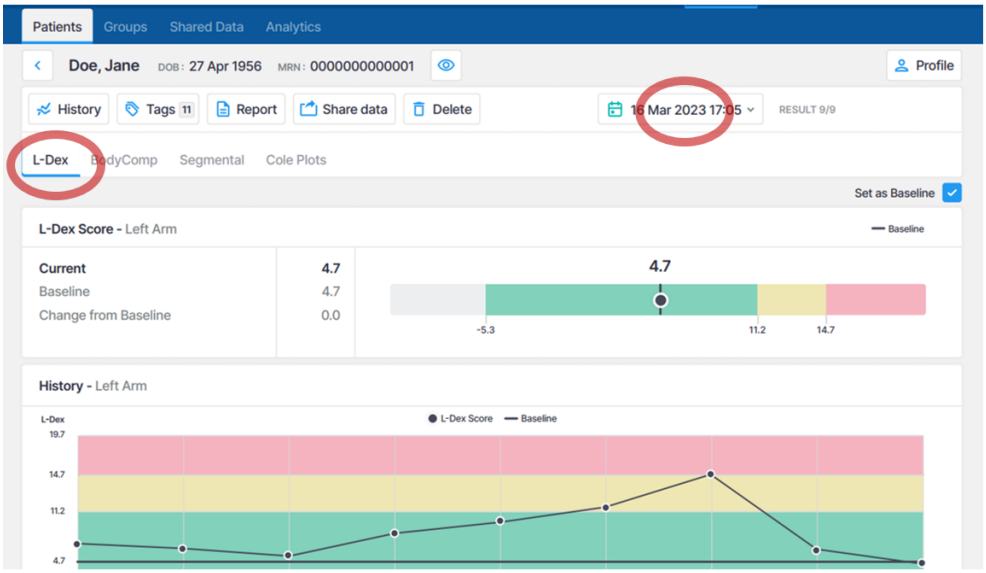
To choose the proper measurement as the baseline, the measurement should be:

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

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

7.5 History Graphs

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

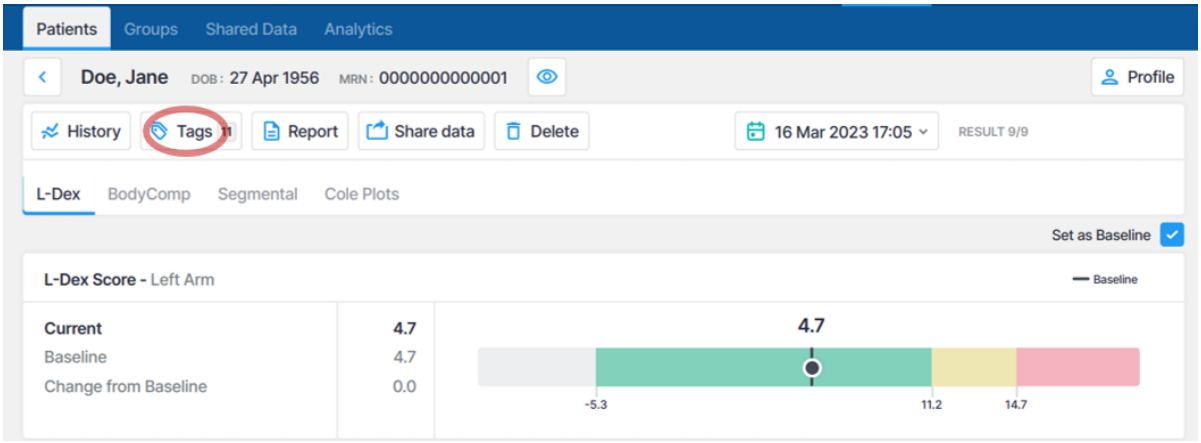


Note: only historical measurements for licenced Assessments will appear under History. Therefore, the Clinician will only be able to view licenced Assessments.

For any measurement outputs that can have a baseline selected, the Clinician may compare patient measurements taken over time against the baseline. From this comparison, the Clinician may identify changes in patient fluid levels, and see if these changes fall within normal or abnormal ranges.

7.6 Measurement Tags

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



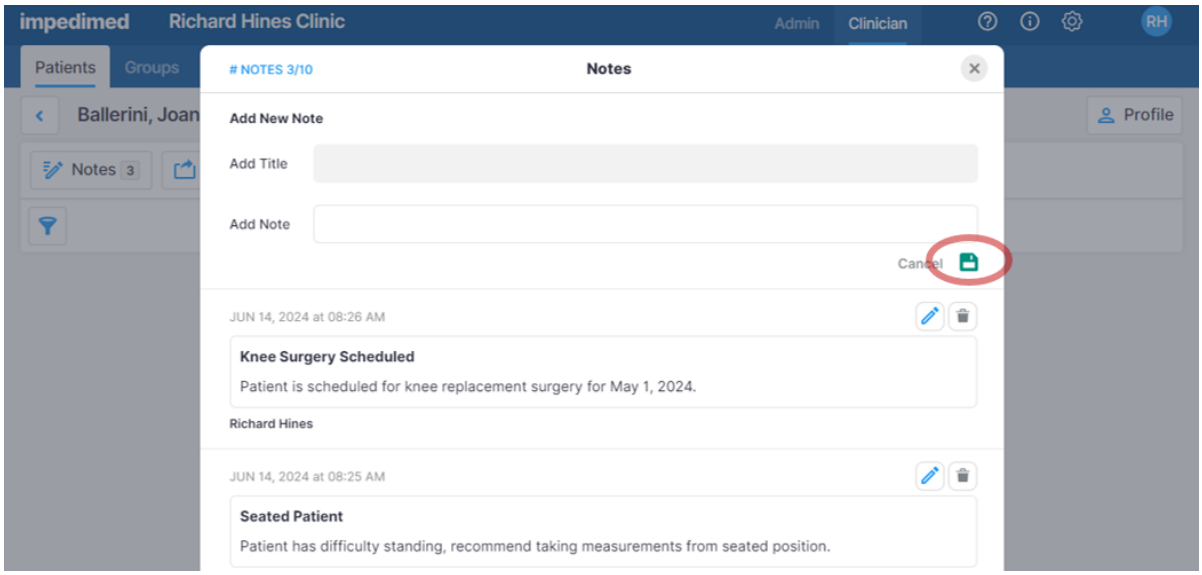
To add a Tag to a measurement, tap the “Tags” icon and tab “ADD NEW”. Select the Tag to be added from the list of available Tags and add a description if desired. Tap “SAVE” to link the Tag to the measurement.

7.7 Patient Notes

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

View Notes

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



Add New Note, Edit, or Delete Note

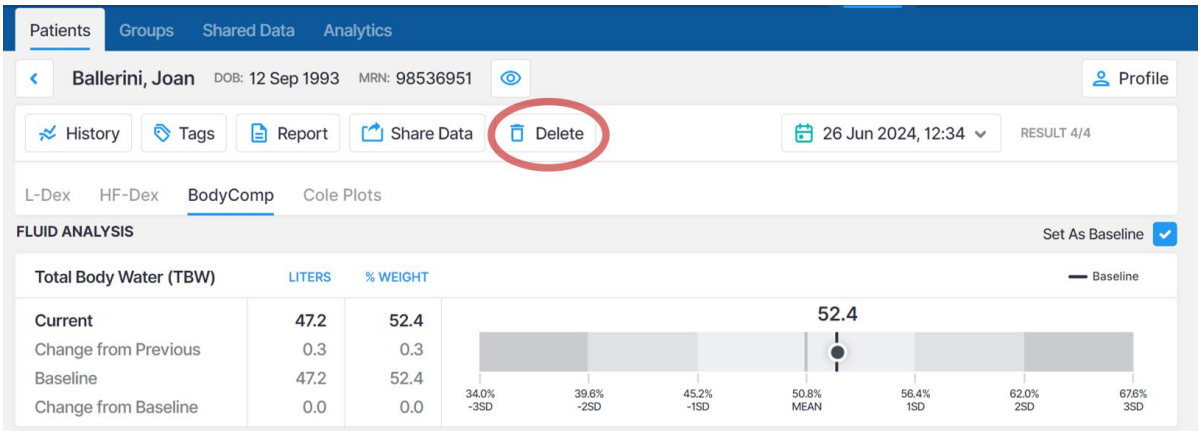
- Add a note title in the appropriate field.
- Add the note in the appropriate field.
- Save the note by selecting the save (green floppy disk) icon on the right of the screen.
- Notes can be edited by selecting the edit button (pencil icon) or deleted by selecting the delete button (trashcan icon).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

7.8 Deleting Measurements

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

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

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



7.9 Licencing

7.9.1 Impact of Licencing Additional Assessments on Results

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

7.9.2 Impact of Cancellation of Assessment Licence on Results

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

8 ASSESSMENT TYPES

The SOZO Device supports the following Assessment Types:

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

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

Some Assessment types may not be available in certain geographic regions. Contact ImpediMed sales or technical support with any inquiries. Each Assessment has its own instructions for use providing information on how to use the Assessment and outputs, and Assessment-specific precautions, warnings, and contraindications.

8.1 Choosing the Proper Assessments for the Patient

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

- L-Dex® aids the Clinician in the assessment of lymphoedema in a patient who has or is at risk of lymphoedema.
- HF-Dex® aids the Clinician in monitoring fluid status in patients living with heart failure.
- ESRD aids the Clinician in monitoring fluid status in patients undergoing dialysis.
- BodyComp™ is used to provide fluid and tissue analysis assessments of an individual, including segmental.

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

8.2 Assessment Specific Instructions for Use

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

8.3 L-Dex® for Lymphoedema

8.3.1 Indications for Use

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

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

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

8.3.2 Instructions for Use

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

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

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

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

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

8.3.3 The Lymphoedema Index (L-Dex®)

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

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

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

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

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

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

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

8.3.3.1 Using the L-Dex® Scale without a Baseline

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

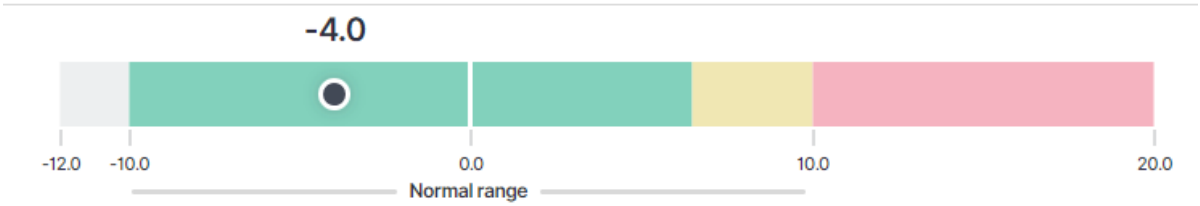
The L-Dex scale normal range (plus or minus 3 standard deviations) measured for a healthy person without lymphoedema ranges between +10 and -10 L-Dex units. If a baseline is not set, the normal range will centre around an L-Dex score of 0 which is the mean of the matched healthy population.

L-Dex Scores ≤ -10

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

L-Dex Scores >10

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



L-Dex Categories without a Baseline

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

8.3.3.2 Using the L-Dex® Scale with a Baseline

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

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

Change in L-Dex Scores ≥+6.5

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

L-Dex Categories with a Baseline

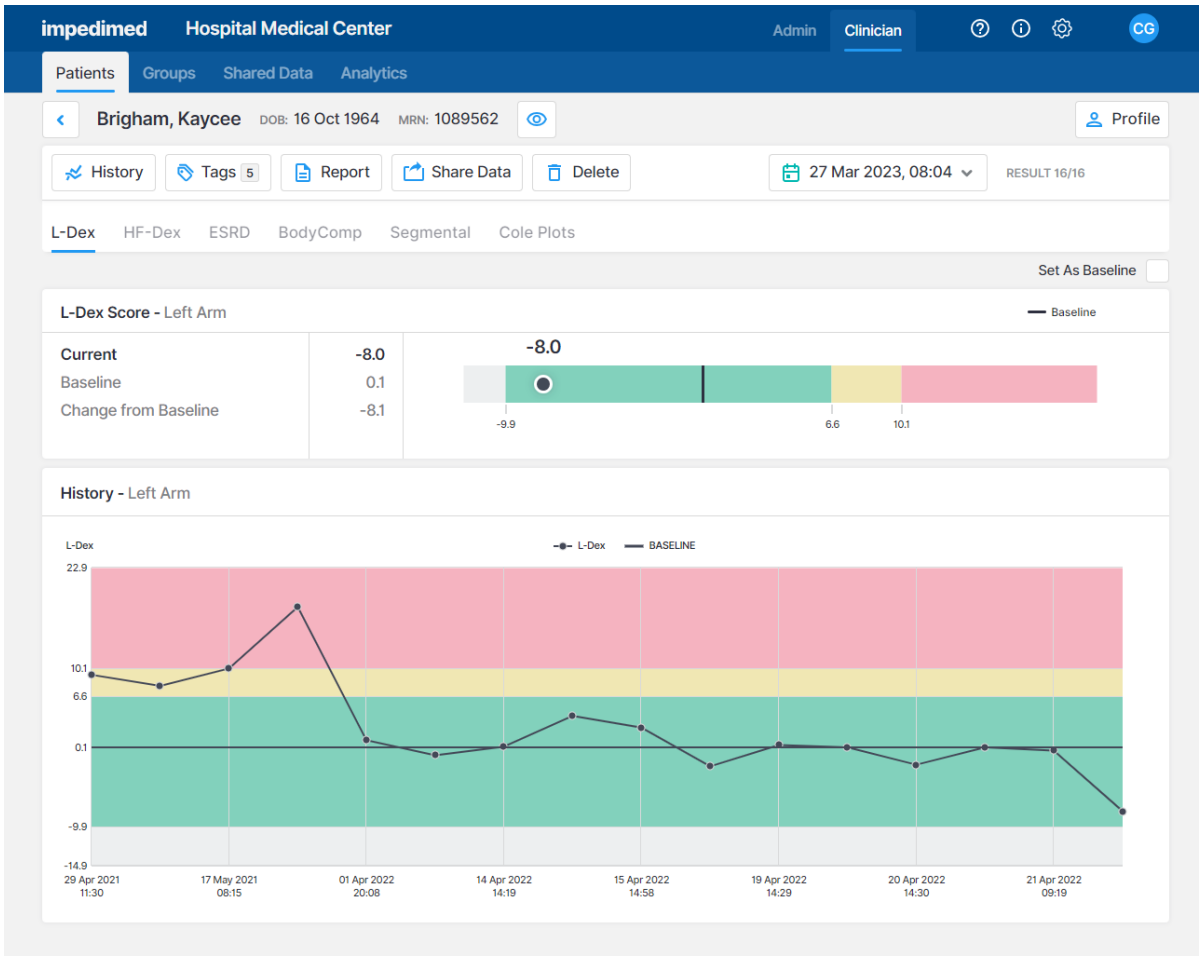
Below Normal L-Dex Change (Grey)	Change in L-Dex scores from the baseline that are greater than 3 standard deviations below the baseline (change greater than -10).
Normal L-Dex Change (Green)	Change in L-Dex scores from the baseline between 3 standard deviations less than the baseline and 2 standard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

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

8.3.4 L-Dex® Assessment Results

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

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



8.3.5 Setting the Baseline

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

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

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

8.3.6 Recommended Measurement Frequency

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

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

8.3.6.1 Recommended course of action for impacted patients:

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

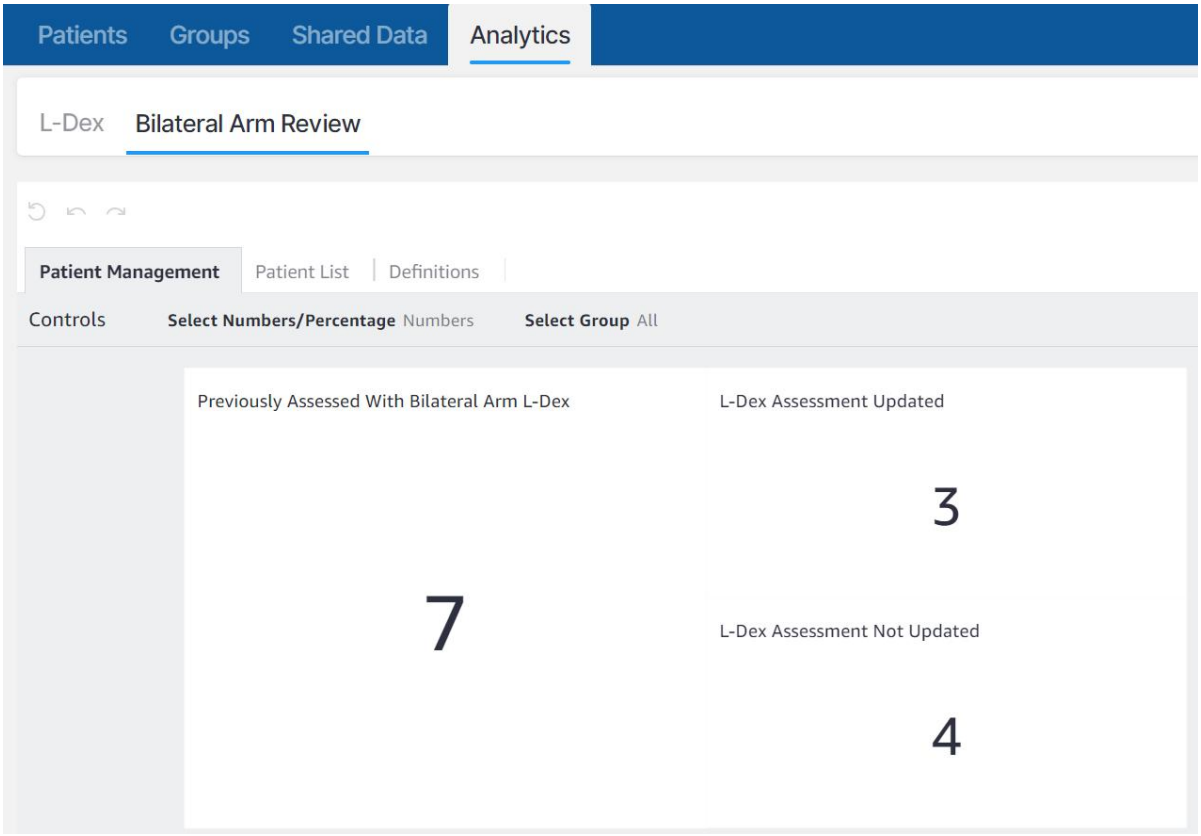
- For patients at unilateral risk for lymphoedema (over 90% of breast cancer patients)[6], confirm that the unilateral arm L-Dex assessment is selected in the patient profile and continue to screen for early signs of lymphoedema.

- For patients at bilateral risk for lymphoedema (3-10% of breast cancer patients)[2], guidelines suggest routine screening using clinical exam and symptom assessment.

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

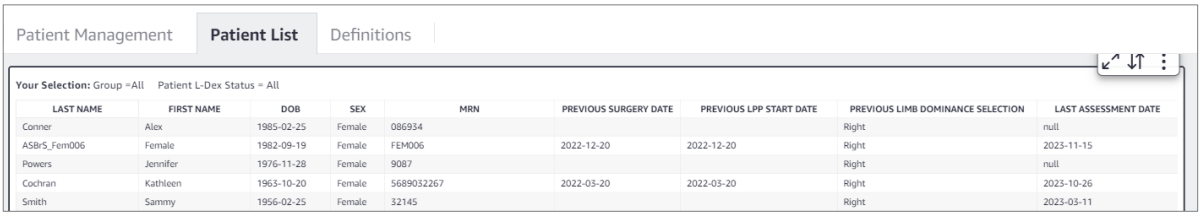
8.3.6.2 Identification of impacted patients

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



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

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



8.4 HF-Dex® Analysis

8.4.1 Indications for Use

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

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

8.4.2 Instructions for Use

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

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

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

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

8.4.3 The Heart Failure Index (HF-Dex®)

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

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

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

Dark Blue range: Patients whose HF-Dex score falls into the dark blue range have an even higher score that indicate higher fluid levels. 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.

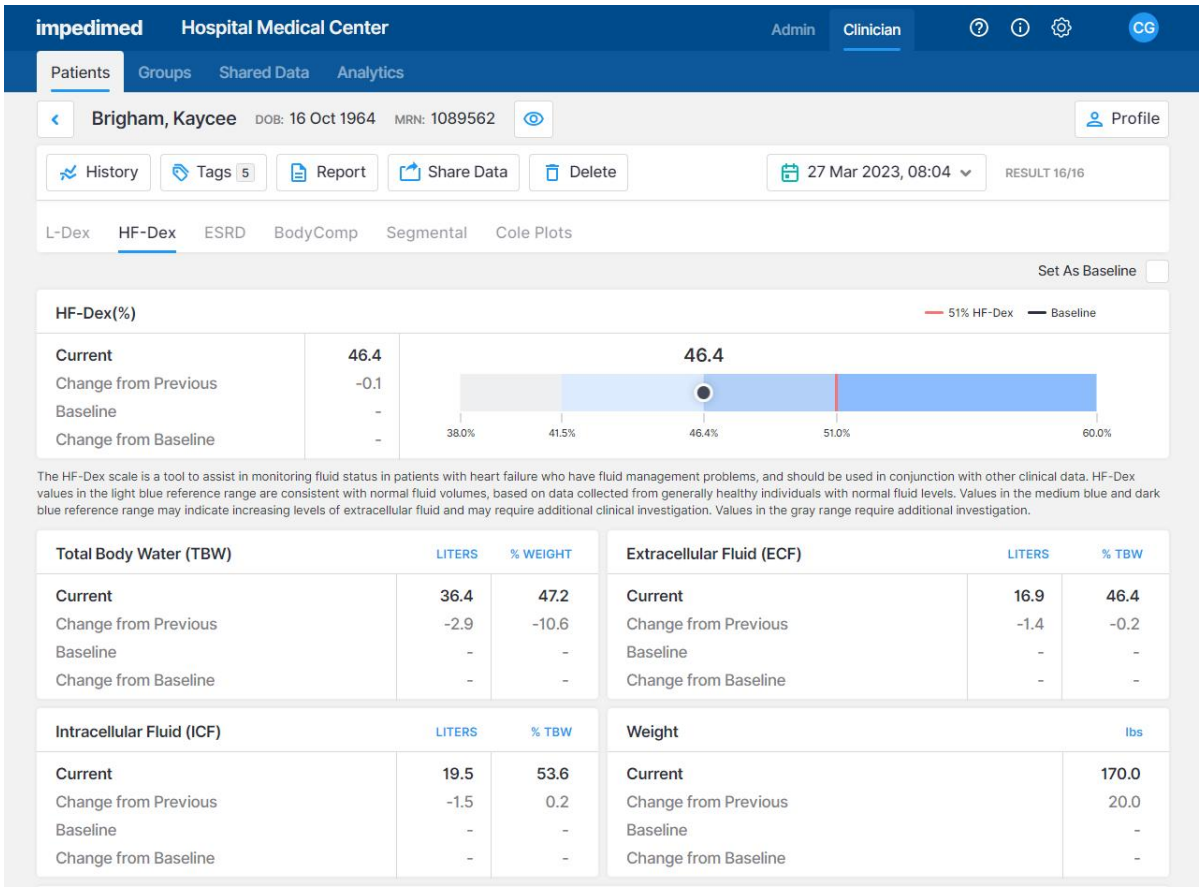
Grey range: HF-Dex values in the grey range may indicate a fluid imbalance for other causes or potential issues with measurement accuracy and requires additional investigation.

8.4.4 HF-Dex® Assessment Results

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

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

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



8.4.5 Setting the Baseline

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

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

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

8.4.6 Recommended Measurement Frequency for HF-Dex®

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

8.5 ESRD

8.5.1 Indications for Use

The ESRD Assessment is intended for patients:

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

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

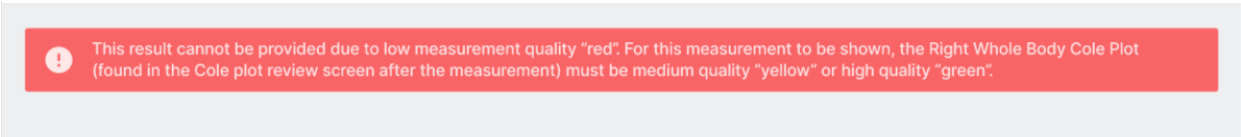
8.5.2 Instructions for Use

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

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

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

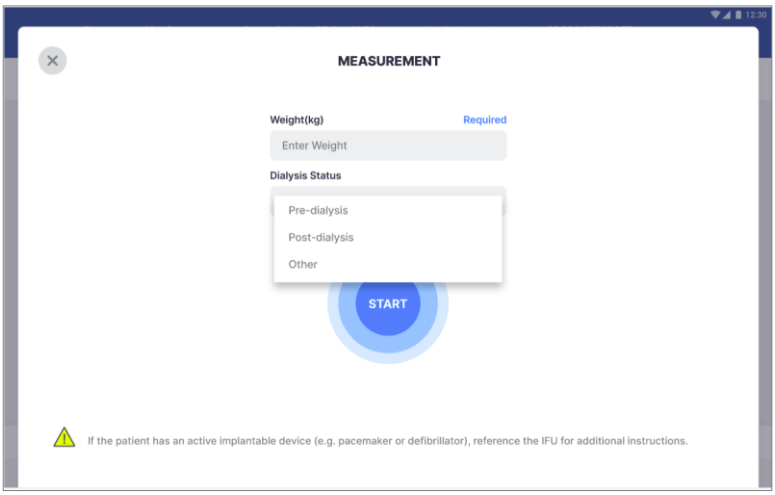
Measurement quality is important. Specifically, the patient's Right Whole-Body measurement will need to be of a medium or high quality. If a patient's Right Whole-Body Cole plot was assessed to be low quality ("red"), the measurement should be retaken. If a low-quality measurement is accepted, ESRD outputs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



8.5.2.1 Pre- and Post-Dialysis Setting

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

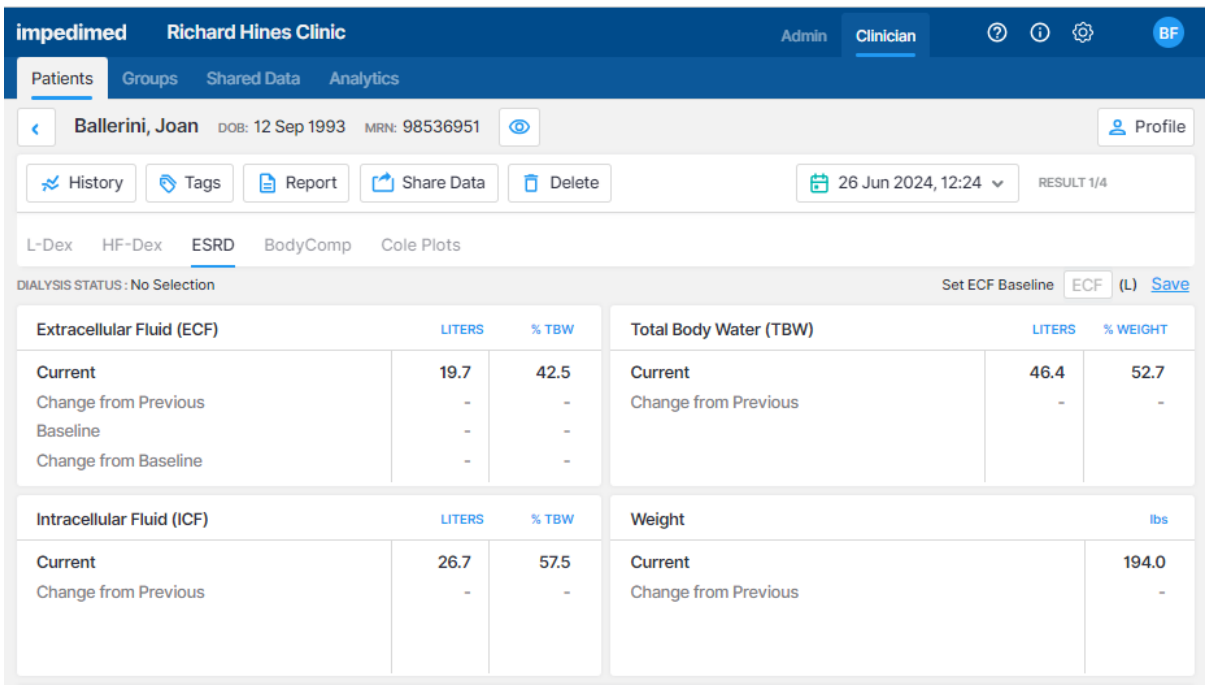
The choice of dialysis status must be made prior to starting a measurement, in a screen similar to the following:

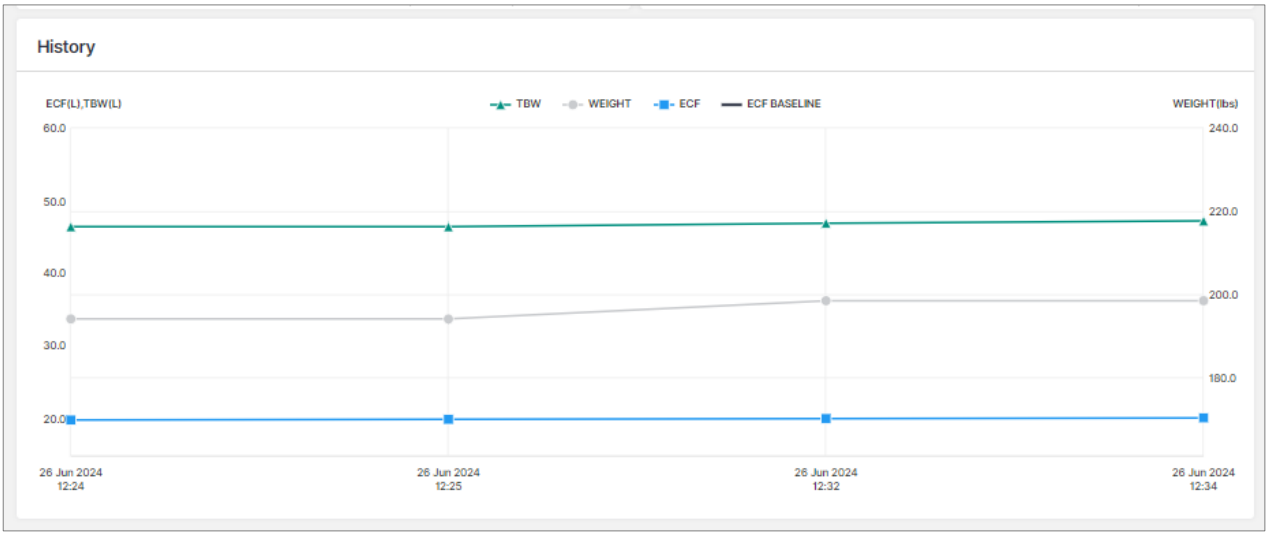


8.5.3 ESRD Assessment Results

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

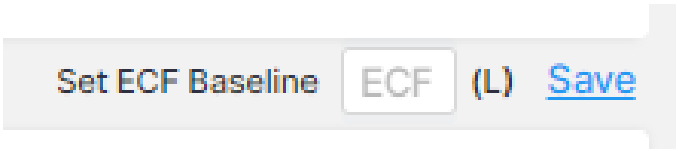
- Total Body Water (TBW)
- TBW as a % of weight
- Extracellular Fluid (ECF)
- ECF as a % of TBW
- Intracellular Fluid (ICF)
- ICF as a % of TBW
- Weight history





8.5.4 Setting the Baseline

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



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

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

8.5.5 Recommended Measurement Frequency for ESRD

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

8.6 Body Composition Analysis

8.6.1 Indications for Use

When using the SOZO Device’s BodyComp Analysis assessment modules for body composition measurements, the following indications for use applies:

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

- Fat Mass (FM)
- Fat-free Mass (FFM)
- Total Body Water (TBW)

- Intracellular Fluid (ICF)
- Skeletal Muscle Mass (SMM)

The following outputs are also presented:

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

8.6.2 Instructions for Use

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

8.6.3 BodyComp™ Assessment Results (Whole Body)

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

Fluid Analysis

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- TBW as a percentage of weight
- ECF and ICF distribution (expressed as a percentage of total body water)

Tissue Analysis

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

Other

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

Hy-Dex® Analysis

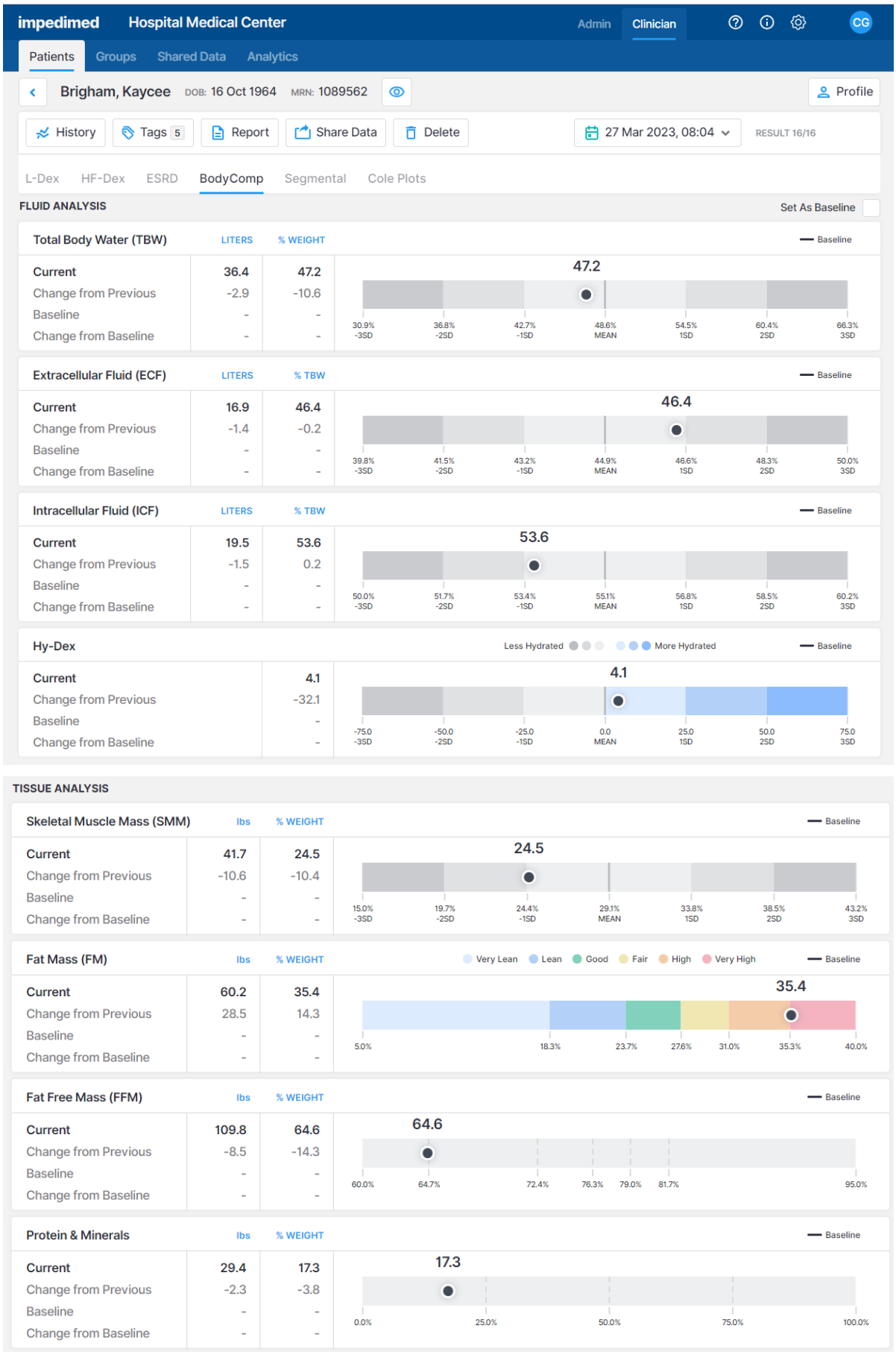
Note: all SOZO volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results are small, minor differences between absolute numbers and percentages may be observed.

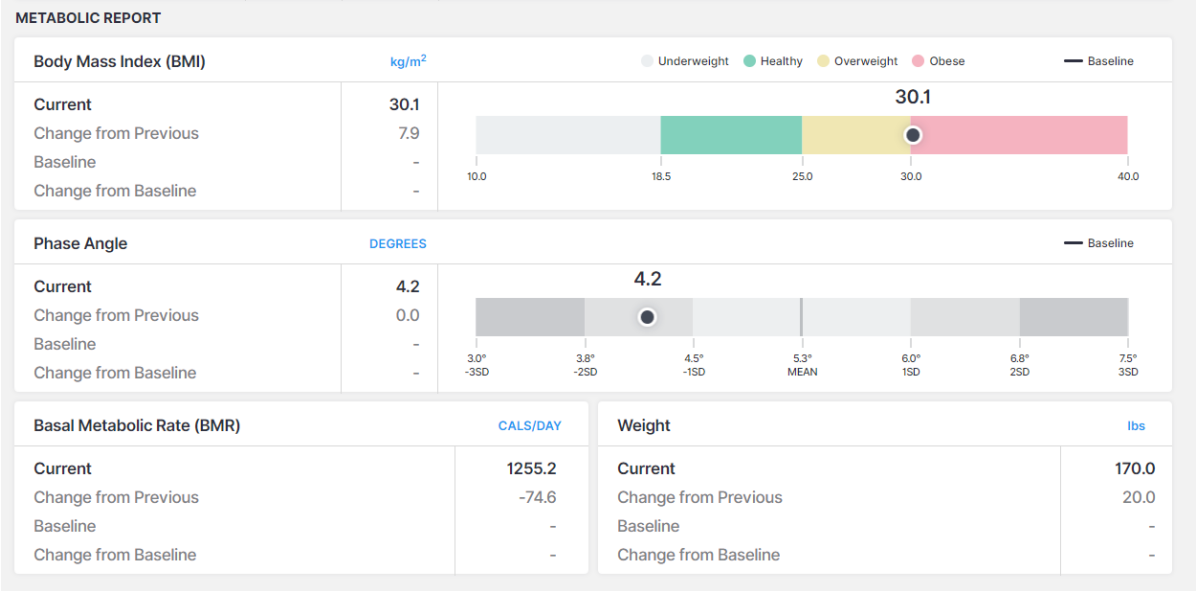
8.6.4 Reference Ranges

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

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

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


impedimed
Hospital Medical Center
Admin
Clinician
CG
Patients
Groups
Shared Data
Analytics
Brigham, Kaycee
DOB: 16 Oct 1964
MRN: 1089562
Profile
History
Tags 5
Report
Share Data
Delete
27 Mar 2023, 08:04
RESULT 16/16
L-Dex
HF-Dex
ESRD
BodyComp
Segmental
Cole Plots
FLUID ANALYSIS
Set As Baseline
Total Body Water (TBW)
LITERS
% WEIGHT
Baseline
Current 36.4 47.2
Change from Previous -2.9 -10.6
Baseline - -
Change from Baseline - -
47.2
30.9% -3SD
36.8% -2SD
42.7% -1SD
48.6% MEAN
54.5% 1SD
60.4% 2SD
66.3% 3SD
Extracellular Fluid (ECF)
LITERS
% TBW
Current 16.9 46.4
Change from Previous -1.4 -0.2
Baseline - -
Change from Baseline - -
46.4
39.8% -3SD
41.5% -2SD
43.2% -1SD
44.9% MEAN
46.6% 1SD
48.3% 2SD
50.0% 3SD
Intracellular Fluid (ICF)
LITERS
% TBW
Current 19.5 53.6
Change from Previous -1.5 0.2
Baseline - -
Change from Baseline - -
53.6
50.0% -3SD
51.7% -2SD
53.4% -1SD
55.1% MEAN
56.8% 1SD
58.5% 2SD
60.2% 3SD
Hy-Dex
Less Hydrated
More Hydrated
Current 4.1
Change from Previous -32.1
Baseline -
Change from Baseline -
4.1
-75.0 -3SD
-50.0 -2SD
-25.0 -1SD
0.0 MEAN
25.0 1SD
50.0 2SD
75.0 3SD
TISSUE ANALYSIS
Skeletal Muscle Mass (SMM)
lbs
% WEIGHT
Current 41.7 24.5
Change from Previous -10.6 -10.4
Baseline - -
Change from Baseline - -
24.5
15.0% -3SD
19.7% -2SD
24.4% -1SD
29.1% MEAN
33.8% 1SD
38.5% 2SD
43.2% 3SD
Fat Mass (FM)
lbs
% WEIGHT
Very Lean
Lean
Good
Fair
High
Very High
Current 60.2 35.4
Change from Previous 28.5 14.3
Baseline - -
Change from Baseline - -
35.4
5.0%
18.3%
23.7%
27.6%
31.0%
35.3%
40.0%
Fat Free Mass (FFM)
lbs
% WEIGHT
Current 109.8 64.6
Change from Previous -8.5 -14.3
Baseline - -
Change from Baseline - -
64.6
60.0%
64.7%
72.4%
76.3%
79.0%
81.7%
95.0%
Protein & Minerals
lbs
% WEIGHT
Current 29.4 17.3
Change from Previous -2.3 -3.8
Baseline - -
Change from Baseline - -
17.3
0.0%
25.0%
50.0%
75.0%
100.0%



8.6.5 BodyComp™ Assessment Results (Segmental)

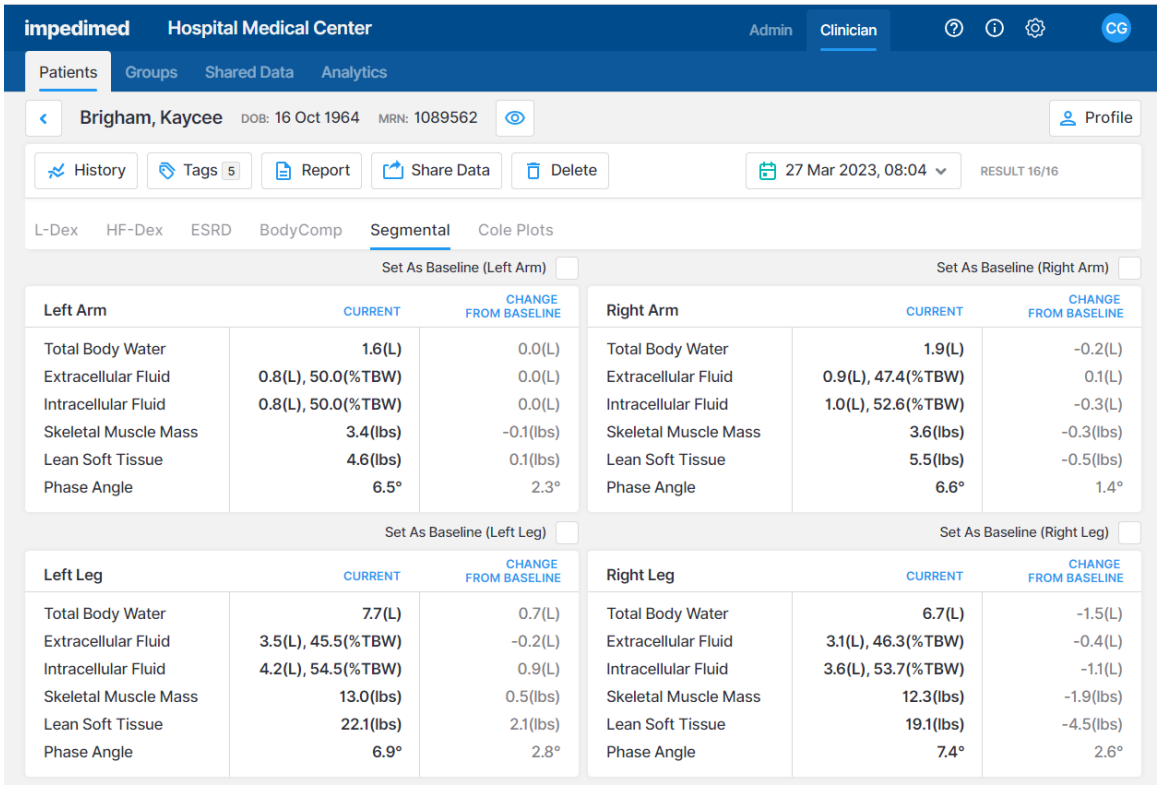
If the clinic has licenced the SOZO segmental body composition analysis module, and the patient has been selected to have segmental results presented, a subset of SOZO Body Composition outputs can also be tracked for individual limbs in the same patient.

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

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

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



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

8.6.6 Setting a Baseline

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

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

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

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

8.6.7 Body Composition Parameters

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

8.6.7.1 Extracellular Fluid (ECF)

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

8.6.7.2 Intracellular Fluid (ICF)

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

8.6.7.3 Total Body Water (TBW)

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

8.6.7.4 ECF & ICF Distribution

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

8.6.7.5 Fat Mass (FM)

The amount of mass a person has that is made up of fat. FM is typically measured in kilograms (kg) or pounds (lb) and is also expressed as a percentage of total mass (e.g., 24% body fat). Reference ranges for FM are based on modified ranges established by the American College of Sports Medicine 2017 "ACSM's Health-Related Physical Fitness Assessment".

8.6.7.6 Fat-Free Mass (FFM)

The amount of mass a person has that contains no fat. FFM includes bone, organs, body water, and the lean soft tissue elements of 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 alone are presented.

8.6.7.7 Protein and Minerals

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

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

8.6.7.8 Skeletal Muscle Mass (SMM)

This includes all muscle mass that mechanically acts on bones to create movement. It does not include cardiac or smooth muscle. Expressed as mass (kg or lb). Reference ranges for SMM were established based on data presented in Janssen (2000)[7].

8.6.7.9 Basal Metabolic Rate (BMR)

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

8.6.7.10 Phase Angle

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

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

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

9 MySOZO ADMINISTRATOR

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

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

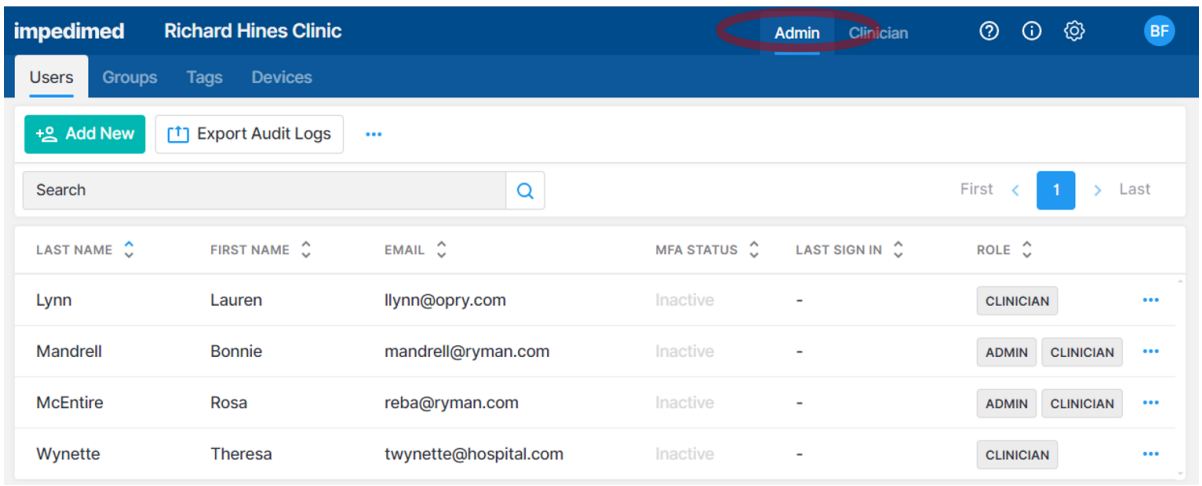
A user with an Administrator role can be created or added by another existing user with an Administrator role. Users are identified by their email address.

9.1 Administrator Home Page

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

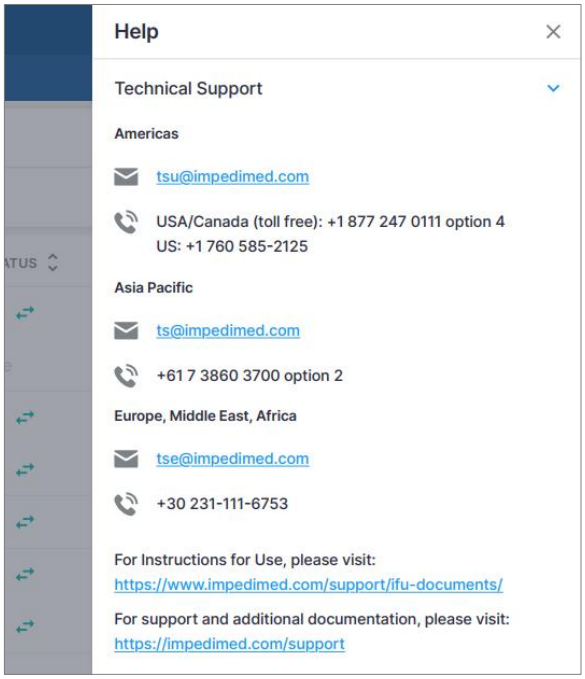
Users may be assigned both Administrator and Clinician roles, and access both functions from the same sign in. The Admin tab is bold and underlined if the user is signed in as an Administrator. If an Administrator also has the Clinician role, they can toggle between Administrator and Clinician screens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

The banner icons enable common administrative functions.



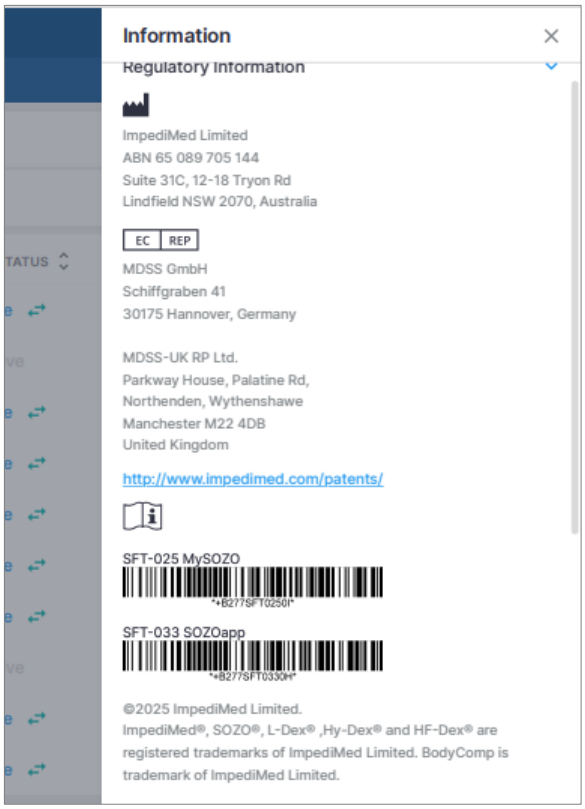
9.1.1 Help Icon

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



9.1.2 Info Icon

For information about MySOZO, click the **Info** icon.



The Information page includes Licencing Status, Software Information and Regulatory Information.

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

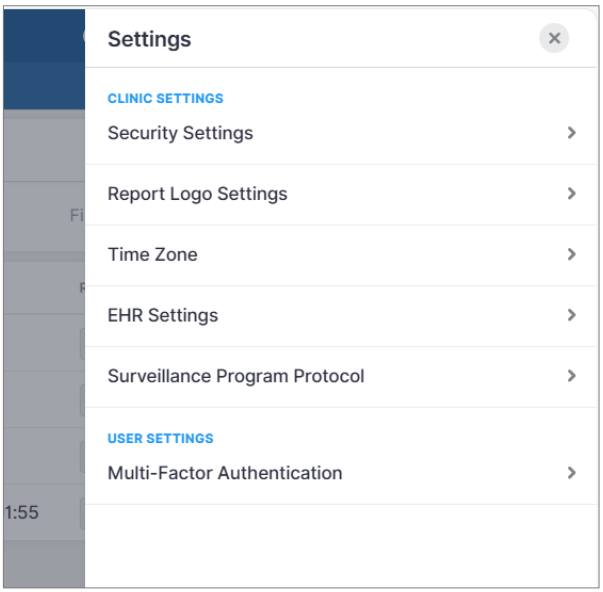
Software Information: Displays current mySOZO version and if it is up to date. There is also an option to Update if required. The administrator password will be required to Update. Release notes for current and previous versions are also listed.

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

9.1.3 Administrator Settings Icon

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

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

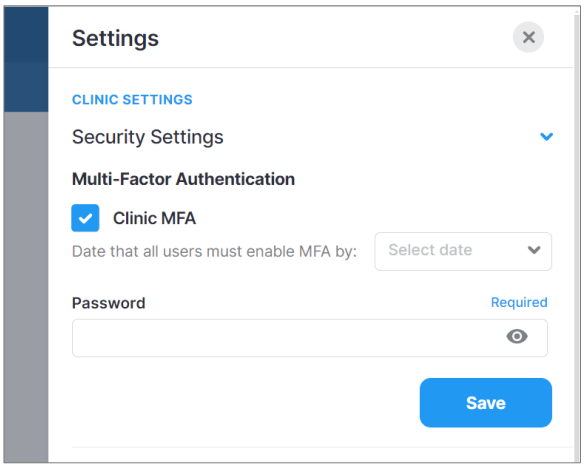


9.1.3.1 Security Settings

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

9.1.3.1.1 Administrator Multi-Factor Authentication

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

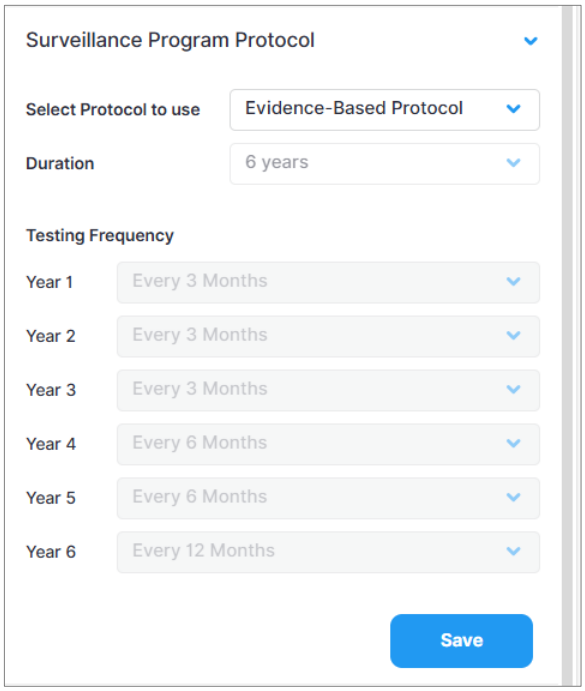


To turn MFA on, the Administrator will need to check Clinic MFA under Security Settings, enter an enable by date, their password and click Save.

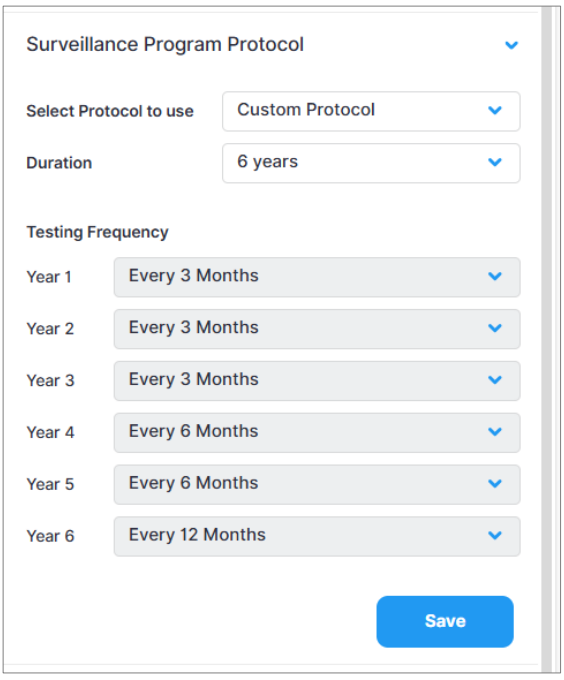
9.1.3.2 Once enabled, MFA will require use of a code generated by a 3rd party authenticator app (e.g., Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is is set up, activate the MFA for the Clinic Administrator account using the slider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

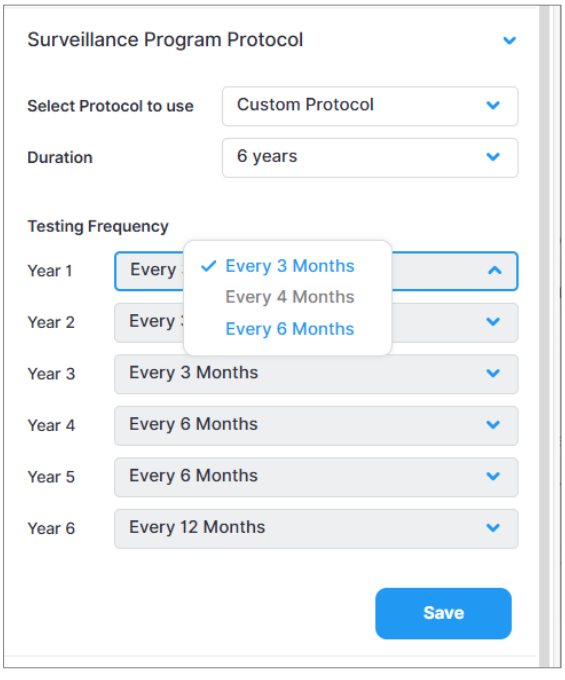
Surveillance Program Protocol

The Clinic Administrator can set the surveillance protocol to be used, Evidence-Based or Custom.



If Custom Protocol is selected, the Administrator can change the default Duration and then set the Testing Frequency for each year in the selected Duration years.

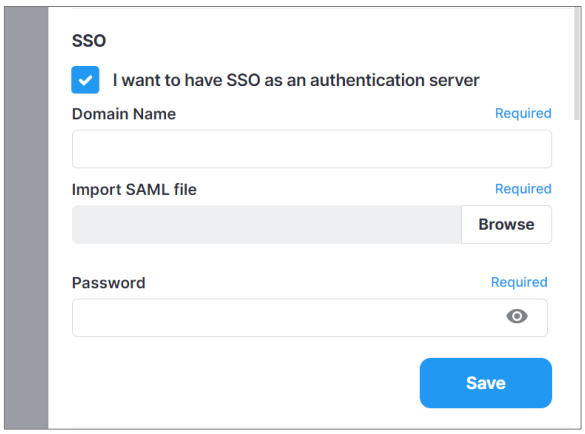




User Multi-Factor Authentication).

9.1.3.2.1 Single Sign-On

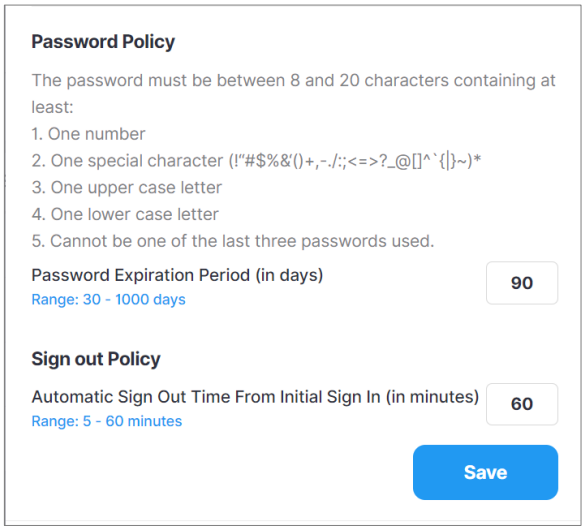
If your organization is set up for **Single Sign-On (SSO)** users can rely on SSO to sign in instead. Users can work with ImpediMed Technical Support to set up SSO.



9.1.3.2.2 Password and Sign Out Policy

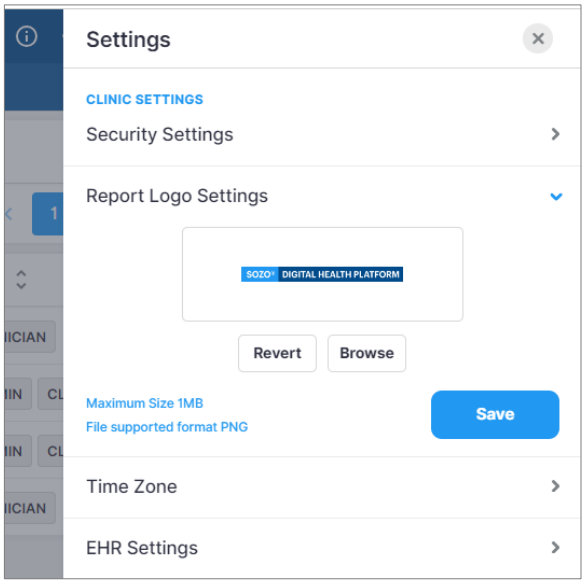
The Clinic Administrator can set the Password Expiration Period here. This defines the length of time which a user's password is valid. After this time period, the user is required to change their password. It can range from 30 to 1000 days.

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



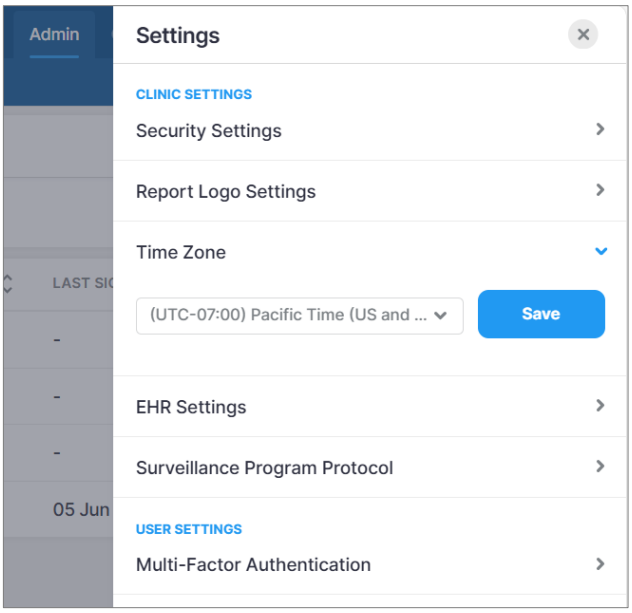
9.1.3.3 Report Logo Settings

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



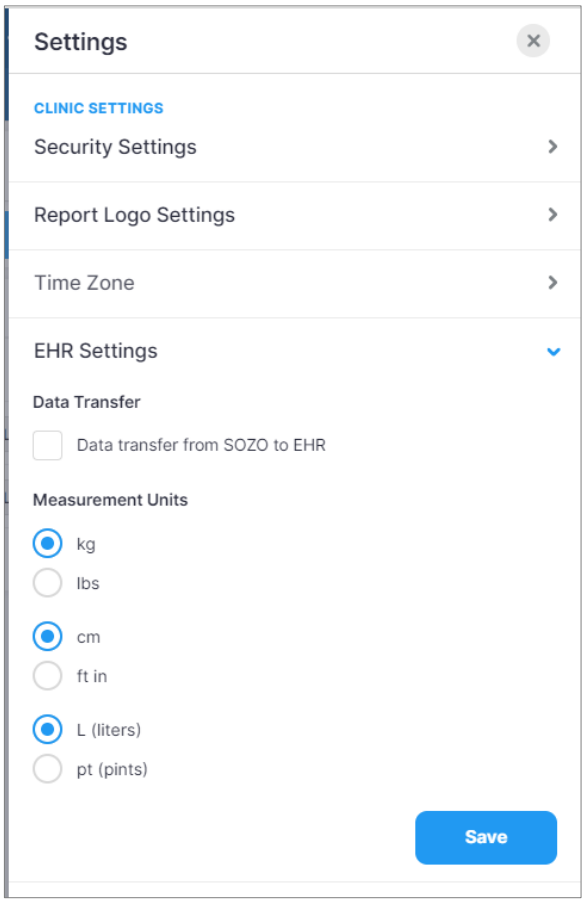
9.1.3.3.1 Time Zone

The Clinic Administrator can select the correct time zone here.



9.1.3.4 EHR Settings

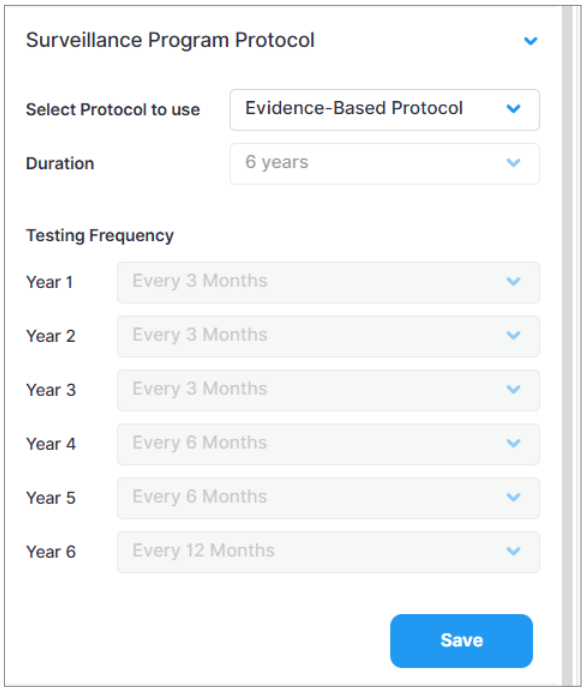
The Clinic Administrator can work with ImpediMed Technical Support during MySOZO setup or contact ImpediMed Technical Support after the system has been installed, to set up the EHR Interface Settings. Full EHR interface configuration will require additional set-up outside of MySOZO to complete.



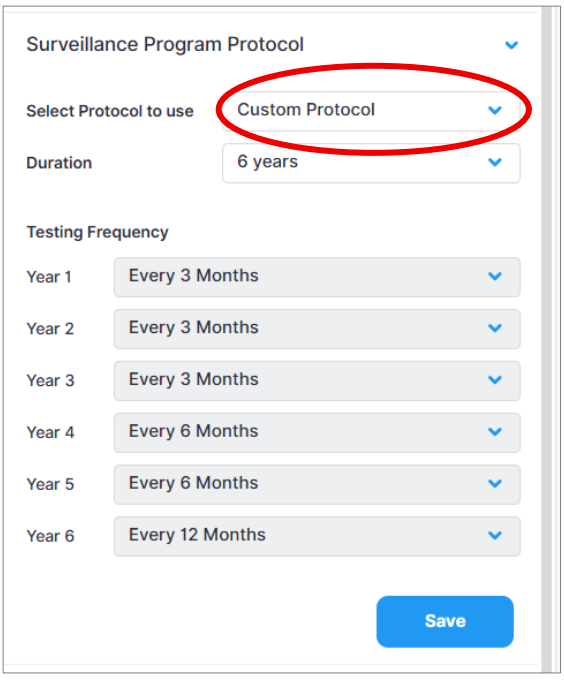
After the EHR interface has been established, the Clinic Administrator can start data transfer to an electronic health record by checking the data transfer box and select the measurement units for the transfer. Contact ImpediMed Technical Support for further details.

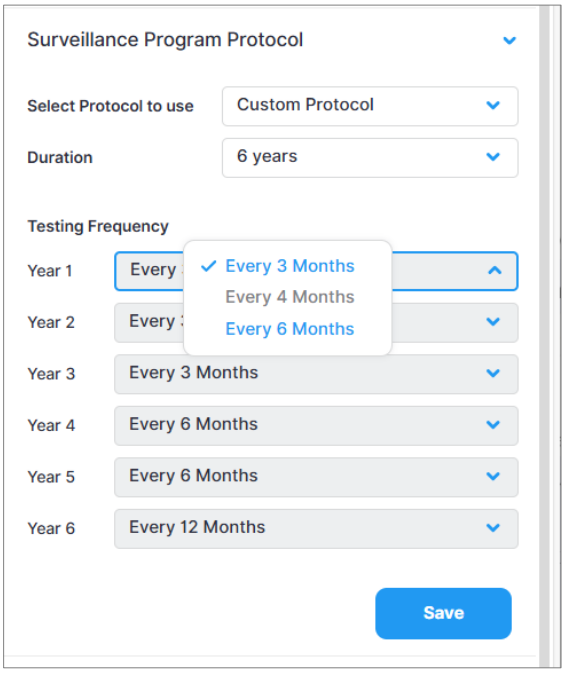
9.1.3.5 Surveillance Program Protocol

The Clinic Administrator can set the surveillance protocol to be used, Evidence-Based or Custom.



If Custom Protocol is selected, the Administrator can change the default Duration and then set the Testing Frequency for each year in the selected Duration years.

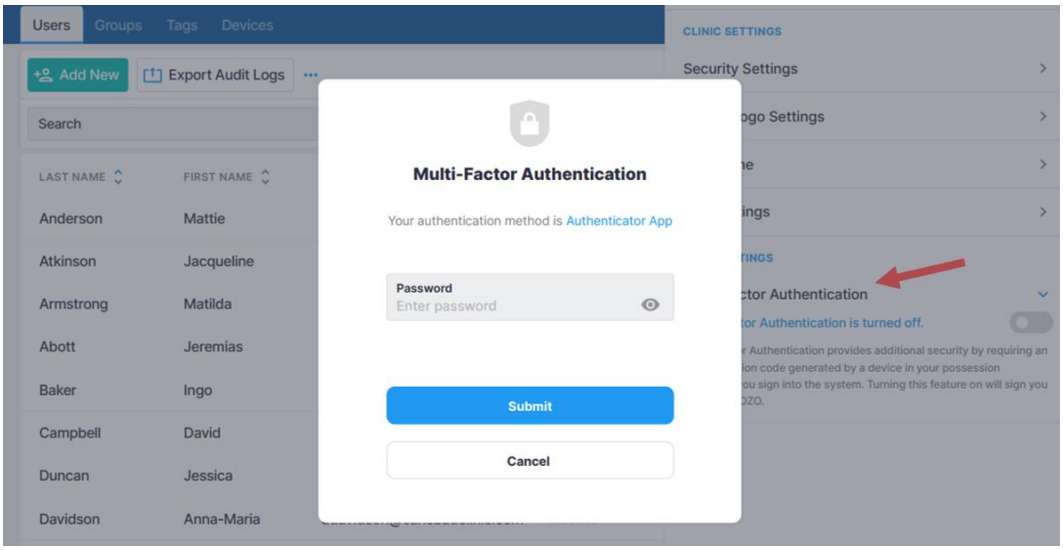




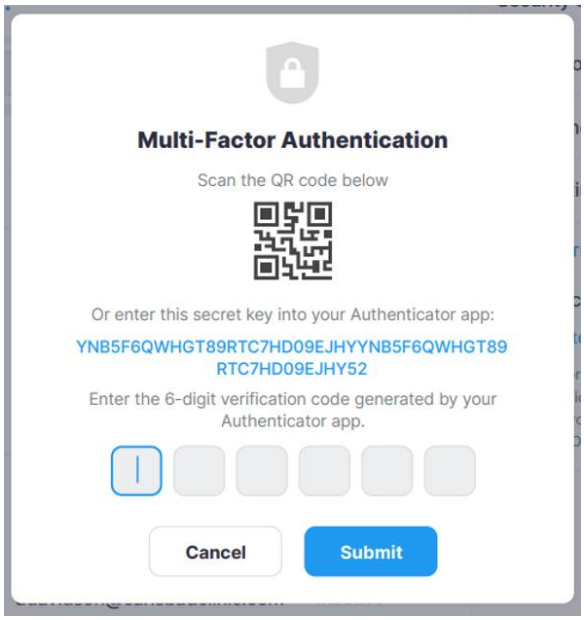
9.1.3.6 User Multi-Factor Authentication

Once enabled by a Clinic Administrator (see Administrator Multi-Factor Authentication), MFA will require use of a code generated by a 3rd party

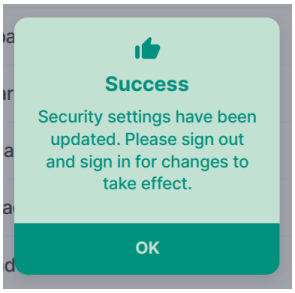
authenticator app (e.g., Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is is set up, activate the MFA for the Clinic Administrator by using the slider under User Settings, Multi-Factor Authentication. At this, point a pop-up will display and the Administrator password is required to be entered.



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



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



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

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

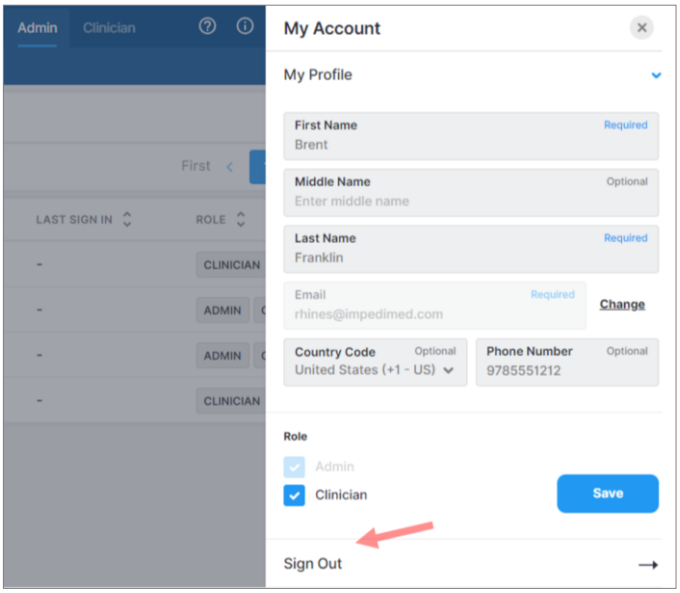
An Administrator may elect to turn MFA off for all users. This can be performed from within MySOZO settings, and requires entry of both the user password and an MFA code. After turning MFA off a success message will appear. The user will then be signed out of the system and return to the sign in screen.

9.1.4 Administrator User Profile Icon

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

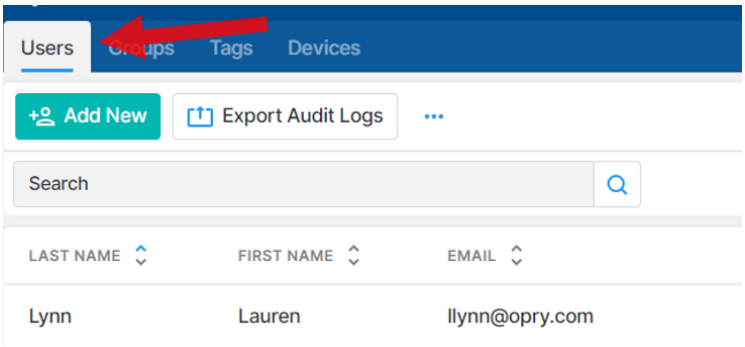
To review or edit the User profile, click the User Profile icon and then select **My Profile**.

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



9.2 Administrator User List

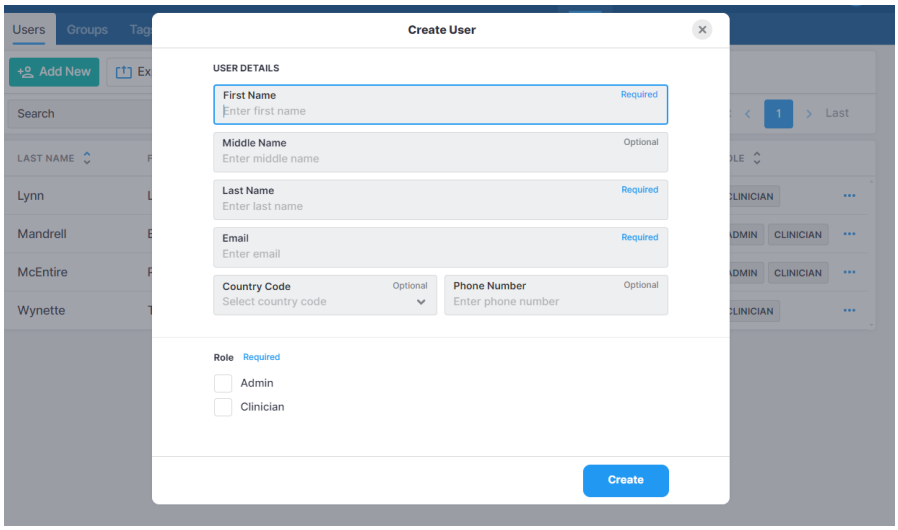
Click **USERS** at any time to return to the User List on the MySOZO Administrator home page.

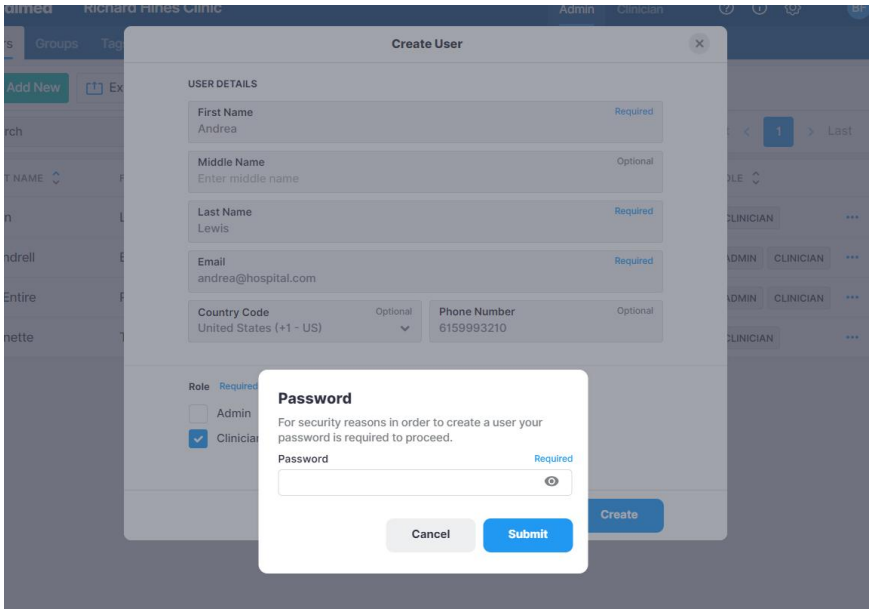


9.2.1 Create New User

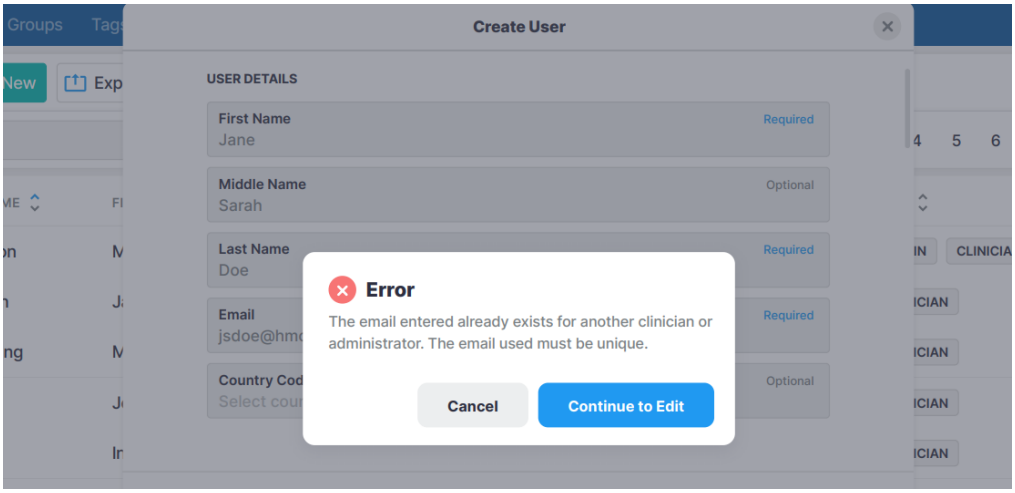
An Administrator creates a user by clicking **Add New**. The user may be assigned as an Administrator and/or Clinician. There is no limit to the number of users that can be created.

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





Every user must have their own email address. If the email is already assigned, a Caution will state that the user already exists. The same email address may not be assigned to more than one user, even when the user is acting as both the Administrator and the Clinician.



9.2.2 Audit Logs

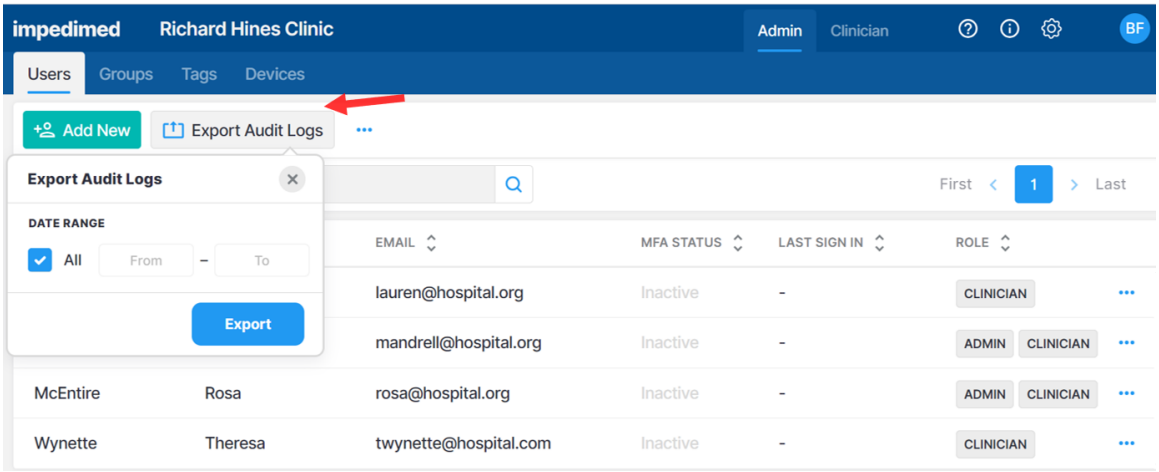
A user with Administrator role may access audit logs of all system access and events, to assist in any audit or investigation. Audit logs may be exported directly from MySOZO.

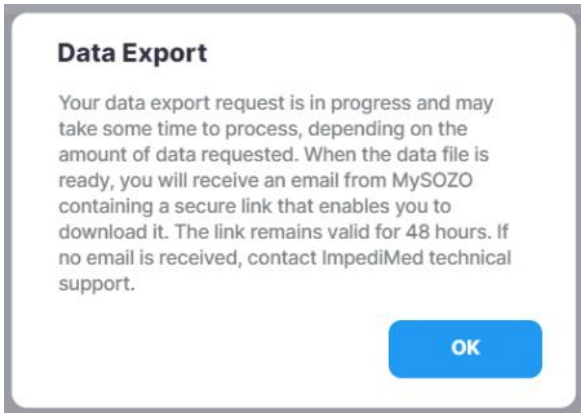
Audit logs include identity of users who have viewed certain MySOZO pages or information, identity of users who have retrieved data, users' sign in and log out dates and times, date and time of measurements, edits to patient or user profiles.

To export audit logs:

1. Click **Export Audit Logs** in the top right corner.
2. Check **all** to view all audit logs.
    a. Enter dates in the "To" and "From" box to view audit logs from a specific date range. The default is set to 'all dates'.

3. Click **Apply** to export logs. A pop-up will appear, stating that the data export request is in progress.
4. ImpediMed will send the user an email containing a secure link to download the Audit Logs. The link is valid for 48 hours.





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

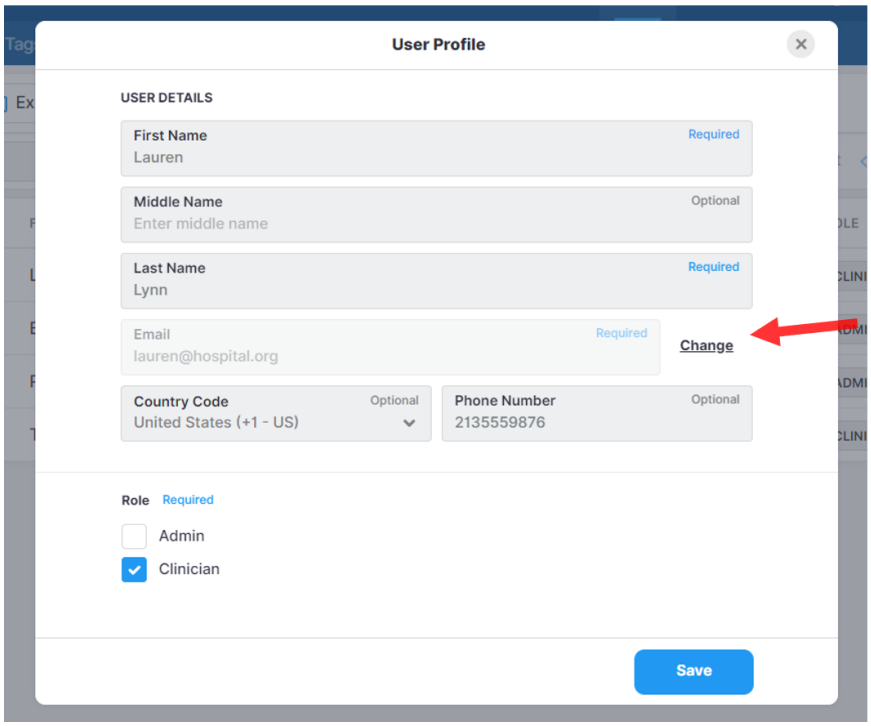
9.2.3 Edit User

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

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

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

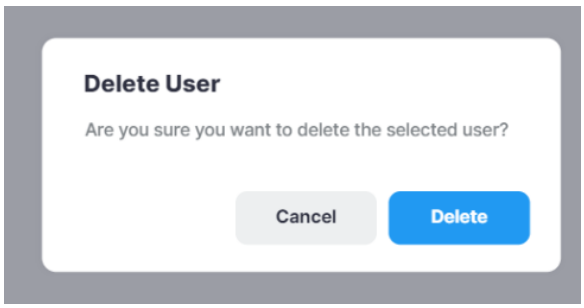
Note: only an Administrator may edit a user's email address. A Clinician may edit their own email address but does not have authority to change another user's email address.



9.2.4 Delete User

To delete a user:

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



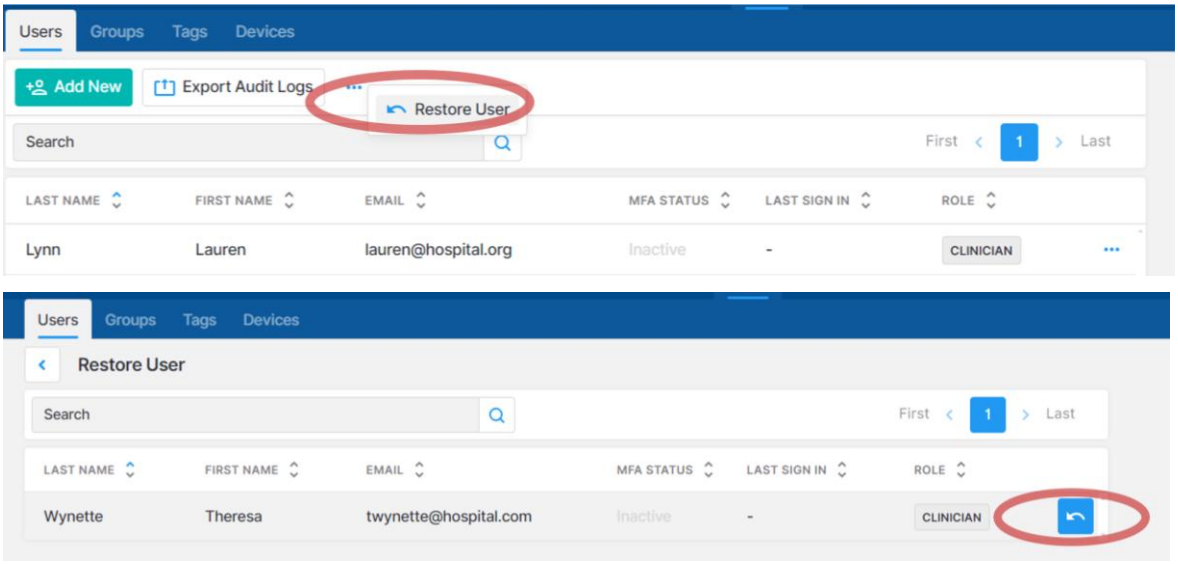
9.2.5 Restore User

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

To restore a deleted User:

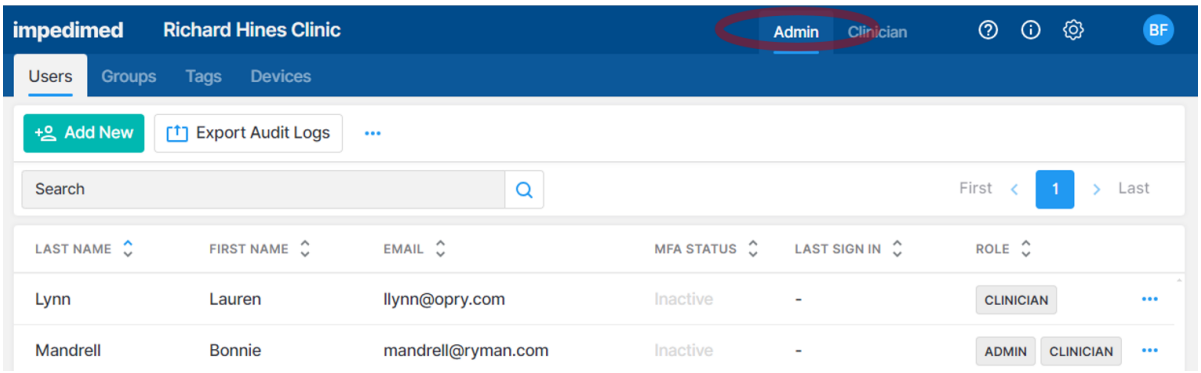
1. On the Users List, click the **three dots** located in the top right corner, next to the **Export Audit Logs** tab.
2. Select **Restore** user.
3. Search the user list for the user profile to be restored.
4. Click the **blue arrow** to restore the user.

5. In the restore user warning pop-up, select **Restore**. A **success** confirmation will appear in the top right corner.

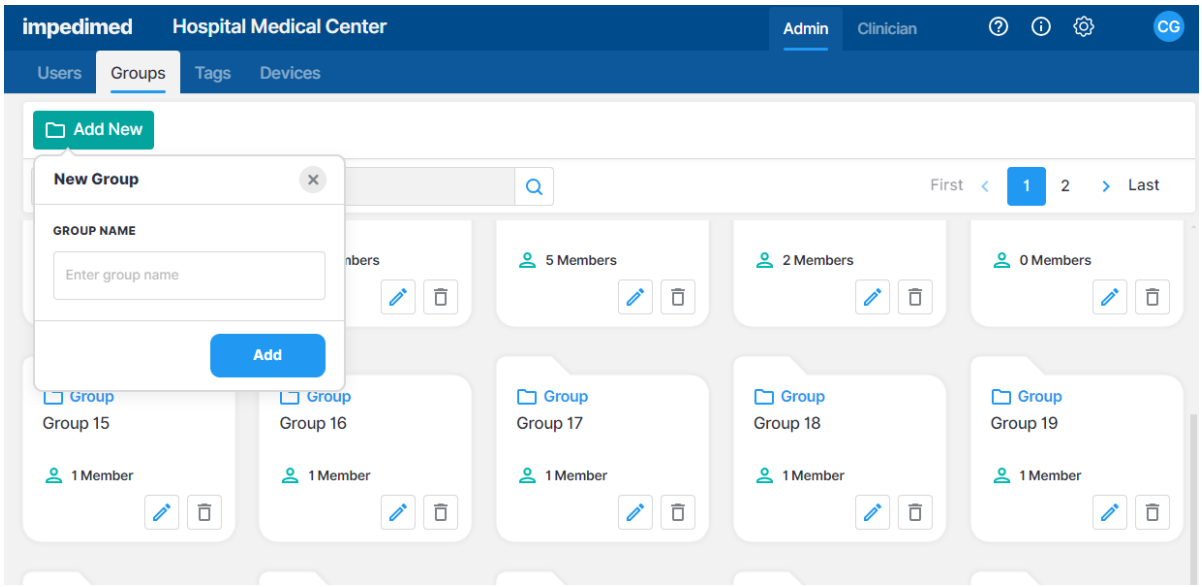


9.3 Administrator Patient Groups

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



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



9.3.1 Create a New Group

To create a new Patient Group:

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

9.3.2 Rename/Delete Group

To rename a Patient Group:

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

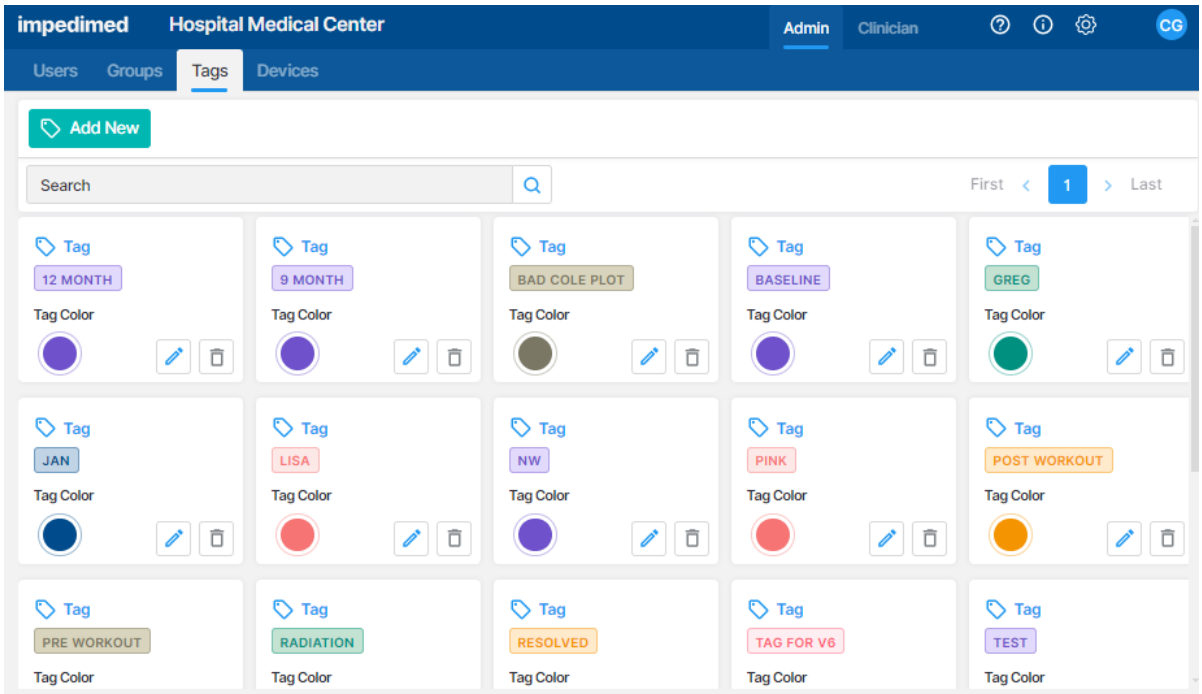
To delete a Patient Group:

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

9.4 Administrator Patient Tags

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

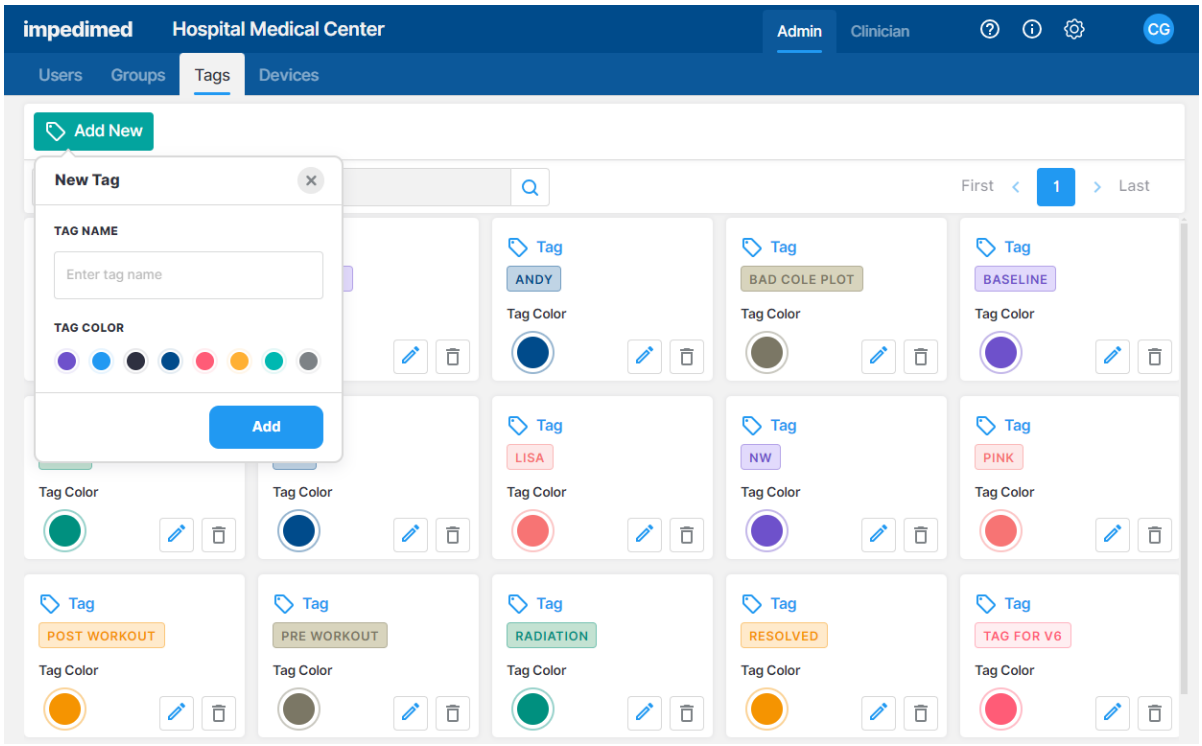
Tags are clinic-defined 48-character colour-coded objects that can be attached to a given measurement by a clinician. They allow additional information or notes to be linked to the measurement. The tags used within a clinic can only be managed by a user with an Administrator role.



9.4.1 Create a New Tag

To create a new Tag:

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



9.4.2 Rename/Delete Tag

To rename a Tag:

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

To delete a Tag:

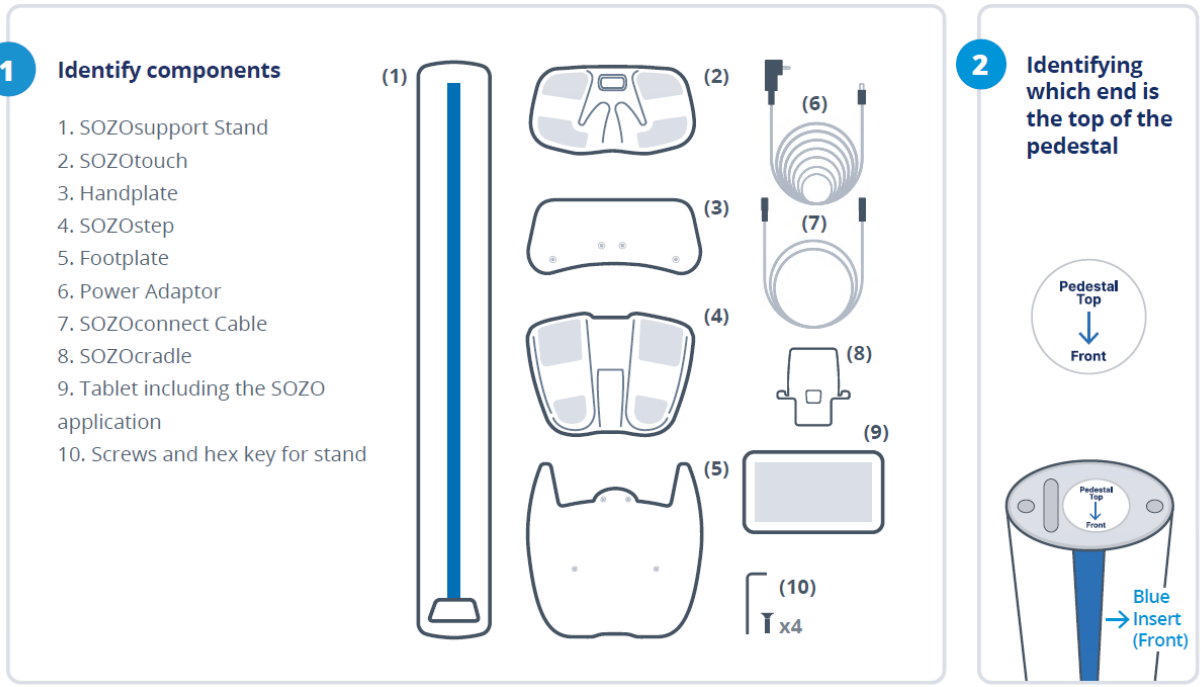
1. On the Tags List, click the **grey trash can** (delete icon) on the tag to be deleted.
2. A delete tag warning will pop up, select **Delete**. A success confirmation will appear in the top right corner.

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

10 DEVICE ASSEMBLY

10.1 Identify SOZO® Device Components

Before assembly, identify the SOZO Device components shown below.



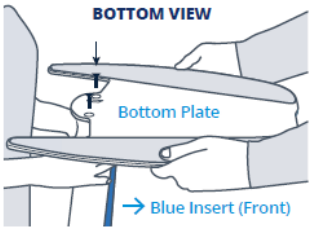
10.2 Assembling the SOZO® Device with SOZOsupport Stand

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

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

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

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

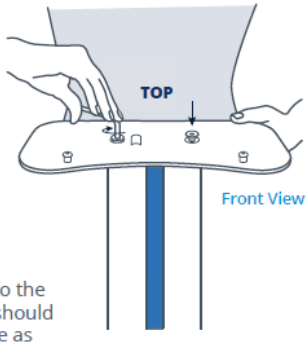


4 **Screw the handplate (3) into the top of the SOZOsupport Stand (1).**

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

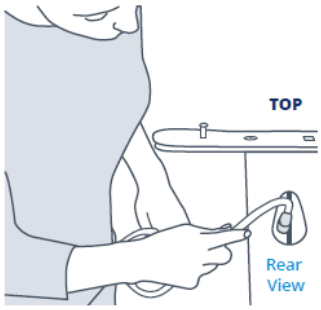
b. Using the hex key (10), attach the handplate with the remaining screws provided.

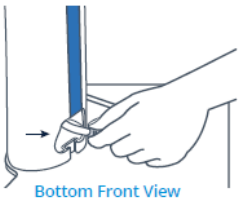
***NOTE:** Once both plates are connected to the SOZOsupport Stand, the large drop hole should be near the top opposite of the blue stripe as shown in top graphic of step 4.



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

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

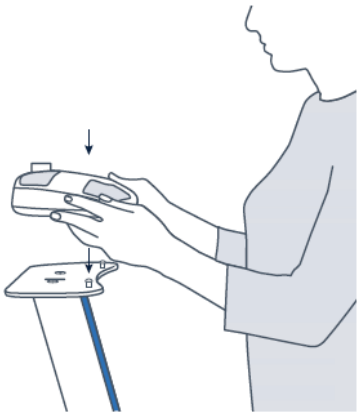




***NOTE:** The connector cable port is identical on both the hand plate and foot plate.

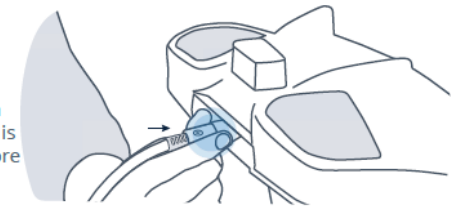
6 **Attach the SOZOtouch (2) to the handplate (3).**

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



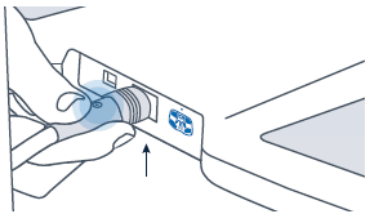
7 **Attach the SOZOconnect cable (7) to the SOZOtouch (2).**

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



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

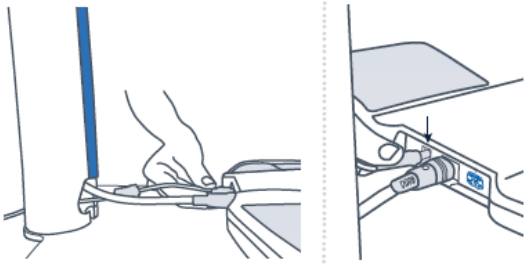
Ensure the screw on the connector cable is facing upwards before attaching it to the SOZOstep.



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

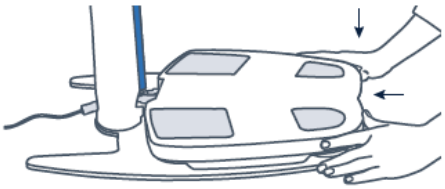
***NOTE:** Ensure the SOZOconnect cable is plugged into both the SOZOtouch and SOZOstep before connecting the power cord to the SOZOstep.

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

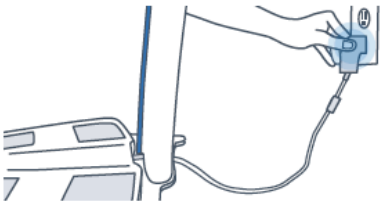


10 **Attach the SOZOstep (4) to the footplate (5).**

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



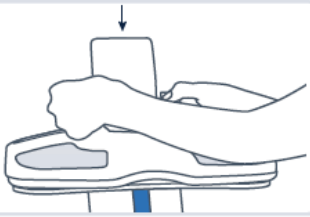
b. Once the SOZOstep is in place, plug the power cord into the wall.



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

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

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



12 **Set-Up Complete.**

NOTE:

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

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

Before using the SOZO Device for the first time, make sure to follow all steps for start-up of MySOZO and the SOZOapp.

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

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

10.3 Assembling the SOZO® Device without the SOZOsupport Stand.

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

1. Place the SOZOtouch on a level surface at a comfortable height, such as a table or desk, so the patient may place their hands on the SOZOtouch while they are sitting down.
2. Place the SOZOstep on a level surface beneath and in alignment with the SOZOtouch. Ensure that the SOZOstep is positioned in such a way that the power supply can be easily connected and disconnected.
3. Confirm that the SOZOtouch is stationary and on a level surface. Place the SOZOcradle onto the SOZOtouch with the ledge of the holder facing the SOZOtouch stainless steel electrodes.
4. Locate the power supply port on the back of the SOZOstep and plug the corresponding end of the Power Cord into that port.
5. Take the remaining end of the power supply cable and plug it into the nearest wall outlet. The SOZO Device may be safely turned off by unplugging the Power Adaptor.

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

To use the SOZO Device while the patient is sitting, follow the instructions for use.

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

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

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

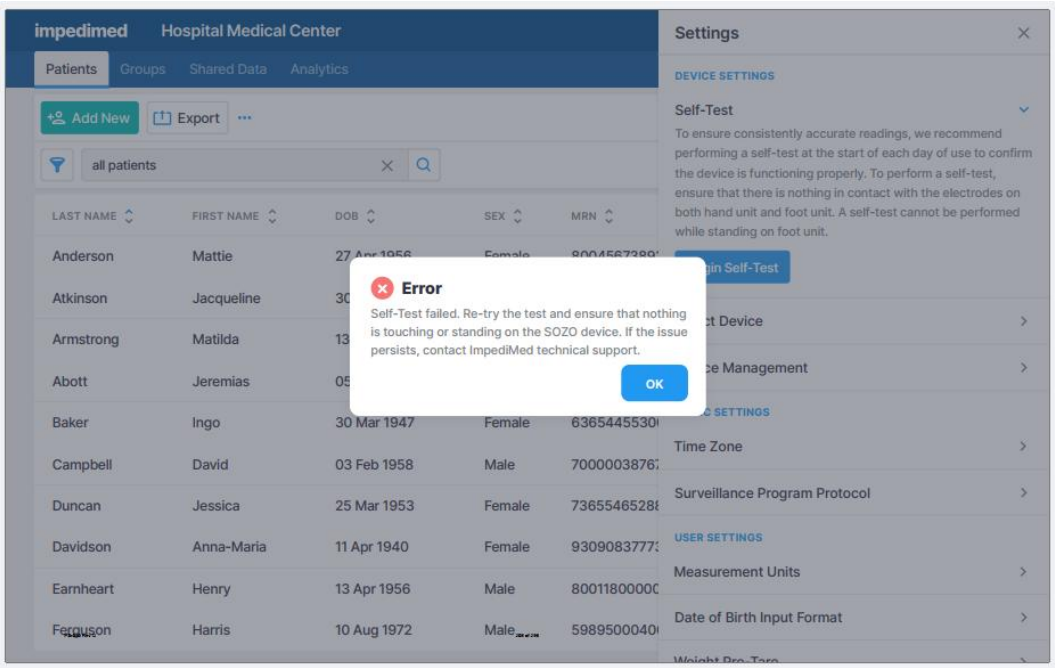
For more information on setting up the SOZO system without the SOZOsupport Stand, visit www.impedimed.com or contact ImpediMed technical support.

11 TROUBLESHOOTING

Below are troubleshooting tips for error messages which may appear in MySOZO or the SOZOapp. This is not a complete list of all possible error messages. For a detailed list of troubleshooting issues in the SOZOapp and MySOZO, see 11.5 General Troubleshooting Chart.

11.1 Self-Test Error

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



Try the below actions to resolve this issue:

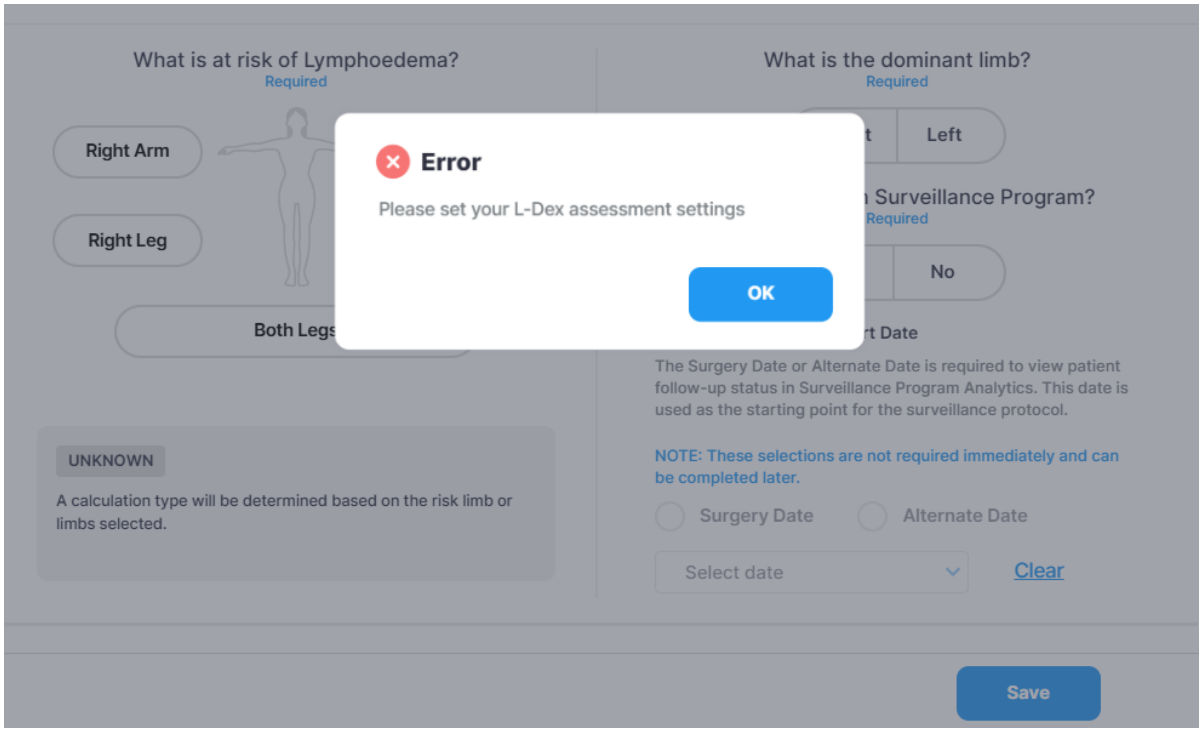
1. Ensure that nothing is touching the SOZO Device during the Self-Test.
2. Reset the Bluetooth® button on the back of SOZOtouch by pressing it for 3 seconds.
3. Unplug the SOZO Device from the wall outlet for 10 seconds and plug it back in.

Re-run the self-test function.

11.2 Lymphoedema Settings Error

Editing Lymphoedema Settings on the patient profile in either MySOZO or the SOZOapp may trigger an error message similar to the message below.

"*Please set your L-Dex settings.*"



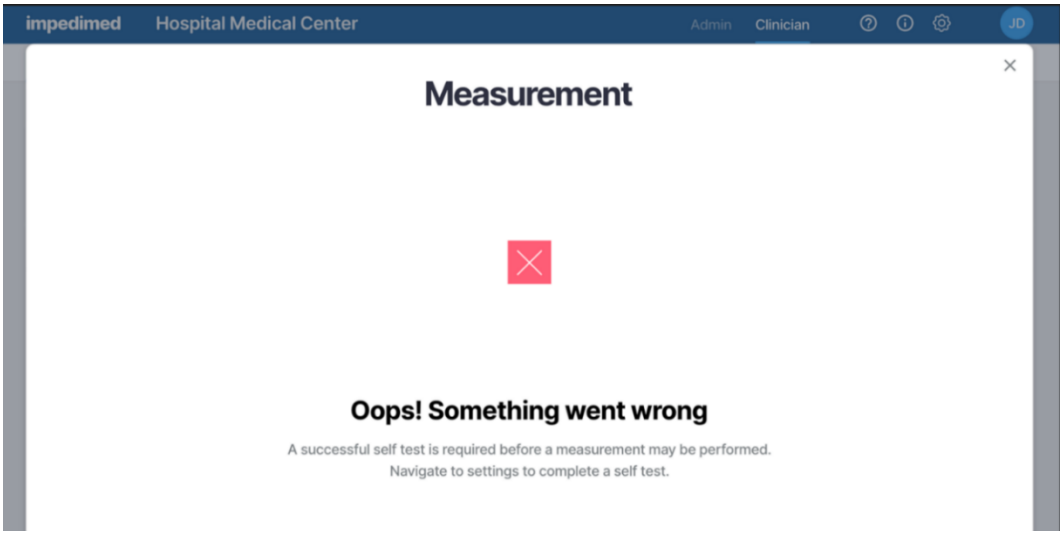
Follow the below actions to resolve this issue:

1. Under "What is at risk of Lymphoedema?", select the option that applies: Right Arm, Left Arm, Right Leg, Left Leg, Both Legs.
2. Under "What is the dominant limb?", select Right or Left.
3. Under "Include Patient in Surveillance Program?", select Yes or No.
4. Select Save. A success confirmation will appear in the top right corner.

11.3 Patient Dashboard Error

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

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

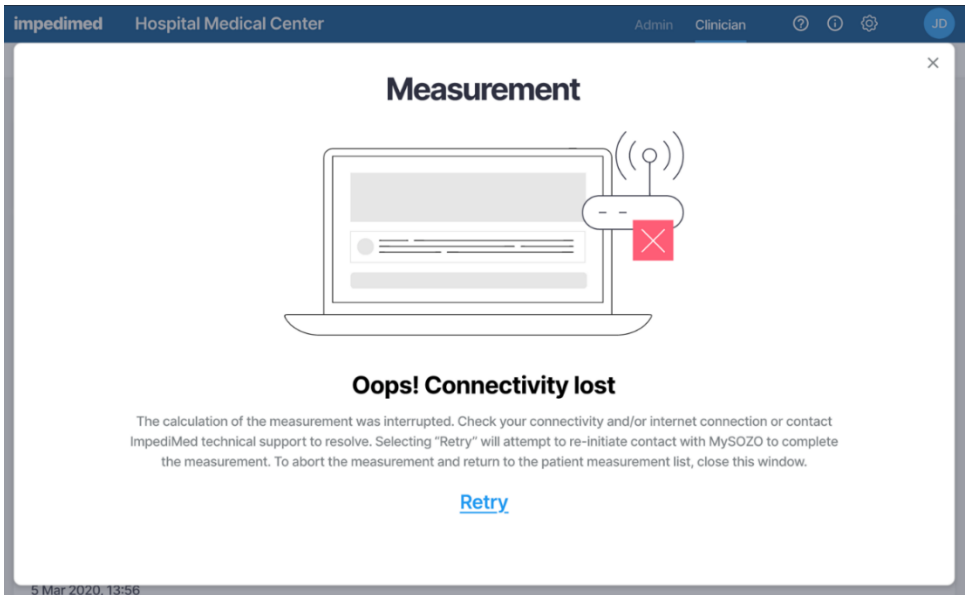


If the Self-Test fails, the actions below may resolve device issues:

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

11.4 Connectivity Error

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



Follow the below actions to resolve this issue:

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

11.5 General Troubleshooting Chart

The General Troubleshooting chart provides guidance for common issues and error messages. In the event that you need additional help, call +61 7 3860 3700 option 2, ImpediMed technical support, or you may email ImpediMed at ts@impedimed.com or visit https://www.impedimed.com.

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

Signing in to SOZOapp / MySOZO		
Issue/Error message	Potential Cause	Resolution
"Empty fields. Please enter your username and your password to continue."	User has attempted to sign in leaving either username or password blank.	Verify username and password are entered properly.
"Password must be between 8 and 20 characters containing at least: 1. One number 2. One special character !“#$%&”()*+,-./:;<=>?_@[]^`{|}~ 3. One upper case letter 4. One lower case letter” 5. You cannot use your last 3 passwords.”	Password does not meet requirements.	Create password using the listed requirements
“Incorrect credential combination. Please check your information and try again.”	Incorrect or forgotten username/password.	Verify credentials. If error continues, change password using the Forgot password link at mysozo.com. Enter the email address and an email will be sent to reset the password.
“There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support.”	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection, there may be poor Wi-Fi coverage in the area.	Check Tablet settings to ensure Tablet is connected to local Wi-Fi network. Otherwise call ImpediMed technical support.
“There is a new version of SOZOapp available. You are required to download and update it to continue using MySOZO. To continue, press Yes”.	Signing in to SOZOapp with previous app version after MySOZO has been updated.	On tablet select “Yes” and follow prompts to automatically update SOZOapp to latest version. If updates are blocked due to a mobile device manager or other software, contact ImpediMed Technical support for the latest version of the SOZOapp.
Use of SOZOapp / MySOZO (Clinician)		

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

“Device not found. Please check your selected device”	SOZOapp is not currently paired to a nearby SOZO Device	Verify that the SOZO Device chosen is available via Bluetooth by going to Settings > Select and 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 Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue. 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. Verify SOZO Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue. If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. If Bluetooth is enabled on the Tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.
“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 the 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 the same measurement results.

“Something Went Wrong. The tablet encountered an error in communication with the SOZO Device. Please check that the correct SOZO Device has been paired and selected in the settings, the SOZO Device is powered on and is located near the tablet, and minimise any potential interference from other wireless devices. If the issue persists, try again and contact ImpediMed technical support.”	The tablet has lost Bluetooth connection with the SOZO Device.	Remove the cable from the power supply and plug it in again. Make sure the cable is securely connected to the device. Confirm Tablet Bluetooth is turned on, that the proper SOZO Device is selected, and that the Tablet is within range to allow a Bluetooth connection. Turn off and restart the Tablet and the SOZO Device. Verify SOZO Device is powered on by pushing the clear Bluetooth® button on the back of SOZOtouch for 3 seconds, it should illuminate blue. If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. If Bluetooth is enabled on the Tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.
When attempting to save the patient profile while in the SOZOapp, the following error message is shown: “The entry is not accepted by MySOZO. If this message is in error, please contact ImpediMed Technical Support”	Bilateral arms are selected as L-Dex Assessment type.	De-select Bilateral and/or arms. Section 11.3 for further explanation.

Administrator Interfacing with SOZO System		
Issue/Error Message	Potential Cause	Resolution
“The email entered already exists for another clinician or administrator. The email used must be unique.”	When creating a new clinician, the selected email address is identical to an existing username/email.	Check the deleted users to see if the email was already used and restore the user. If no deleted user is found, use a different email. If a different email is not possible, contact ImpediMed technical support to determine where that email may already be in use.
“Your passwords do not match. Please re-enter them”.	During user password creation, a different password was entered in the confirmation box.	Verify and re-enter passwords.
“Firmware update unknown error”	Unknown error has occurred during SOZO firmware update.	Please contact ImpediMed technical support.
“Firmware update failed”	Update procedure failed.	Attempt to update firmware. If failure persists, please contact ImpediMed technical support.
Password doesn’t work.	Password forgotten.	Review MySOZO set up for instructions on resetting password.

12 PERSONAL DATA

Read our privacy policy located at

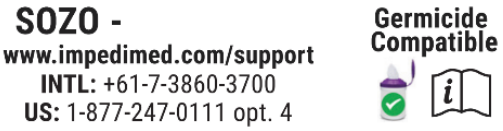
https://www.impedimed.com/privacy-policy/

13 CARE AND MAINTENANCE

13.1 SOZO Device Care

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

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



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

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

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

- Signa Spray

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

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

13.2 SOZO Device Maintenance

The SOZO Device does not require any periodic or preventive maintenance other than cleaning and/or disinfecting, in accordance with Section 13.1 above. The SOZO Device does not require any periodic calibration.

13.3 Self-Test

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

13.4 Repairs

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

13.5 Tablet Maintenance

The Tablet is shipped partially charged. Please follow the manufacturer's instructions for use supplied with the Tablet for the longevity of the Tablet.

13.6 Technical Support

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

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

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

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

13.7 Components and Accessories

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

Description
SOZOsupport Stand
SOZOconnect Cable
Power Adaptor
Tablet

14 PRODUCT WARRANTY

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

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

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

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

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

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

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

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

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

Consumables are excluded from the device warranty.

15 REGULATORY STATEMENT

FCC ID: QOQBT121

This device complies with Part 15 of the FCC Rules

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

This device complies with the R&TTE Directive.

16 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.

17 SAFETY INFORMATION

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

Guidance and Manufacturer's Declaration – Immunity			
The SOZO Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Device should assure that it is used in such an environment.			
Immunity test	4th 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	4th Edition Test Levels	**Compliance level**	**Electromagnetic environment – guidance**
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds ---------- 0% Ur for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% Ur for 1 cycle	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds ---------- 0% Ur for 0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees. 0% Ur for 1 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SOZO Device requires continued operation during power mains interruptions, it is recommended that the SOZO Device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/M 50 or 60 Hz	30A/M 50/60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE Ur is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration – Immunity			
The SOZO Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Device should assure that it is used in such an environment.			
Immunity test	4th Edition Test Levels	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms (Outside ISM) 6Vrms (In ISM and amature Bands) 150 kHz to 80 MHz 10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	(V1) = 3Vrms (V2) = 6Vrms	Portable and mobile communications equipment should be separated from the «Model» by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) D=(12/V2)(Sqrt P) D=(12/E1)(Sqrt P) 80 to 800 MHz D=(23/E1)(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.

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

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

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

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

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

18 GLOSSARY

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

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

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

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

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

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

Bioimpedance Spectroscopy-The technology used by the SOZO Device to accurately measure body water volumes of the patient, based upon bioimpedance parameters over a frequency range of 3 - 1000 kHz using 256 frequencies.

BIS-Bioimpedance Spectroscopy.

BMR-Basal Metabolic Rate. Basal Metabolic Rate is the amount of energy used by a person's body when at rest. ImpediMed uses the Mifflin-St. Jeor equation to calculate BMR. BMR is expressed in calories per day.

Body Composition Assessment-The Assessment, also referred to as "Fluid and Tissue Analysis," performed by the SOZO Device of the body composition of the patient, designed to estimate various body composition parameters, including Total Body Water (TBW), Extracellular Fluid (ECF), Intracellular Fluid (ICF), Fat-free Mass (FFM) or Fat Mass (FM), Basal Metabolic Rate (BMR), Skeletal Muscle Mass (SMM), Phase Angle (Phi), Body Mass index (BMI), and the Hydration Index (Hy-Dex®) analysis. Indications for Use are in the Body Composition Section.

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

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

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

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

Contralateral limb-The limb located on the other side of the patient's body. For purposes of the L-Dex Assessment of a patient with unilateral lymphoedema, if the right arm is at-risk of lymphoedema, then the left arm is the contralateral limb.

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

ECF-Extracellular fluid. Extracellular fluid is all the fluid that is not contained within the cells. ECF is usually expressed as a volume (litres or pints).

Electrode Plates-See "Electrodes."

Electrodes-Stainless steel plate components of the SOZOtouch (where the patient places their hands), and of the SOZOstep (where the patient places their feet), which drive and sense electrical current for the performance of Bioimpedance Spectroscopy.

ESRD – End Stage Renal Disease.

FM-Fat Mass. Fat mass is the amount of mass a person has that is made up of fat. FM is typically measured in kilograms (kg) or pounds (lb) and is also expressed as a percentage of total mass (e.g., 24% body fat).

FFM- Fat-Free Mass. Fat Free Mass is the amount of mass a person has that contains no fat. FFM includes bone, muscle, connective tissue, organs, and body water. FFM is typically measured in mass (kg or lb) or expressed as a percentage of total mass (e.g., 60% fat free mass).

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

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

HF-Dex® Assessment– also referred to as 'HF-Dex'. The HF-Dex score is a tool to assist in the clinical assessment of fluid status on a patient with heart failure by a medical provider. The results screen will display the patient's HF-Dex score on a scale, as well as other fluid analysis outputs. The HF-Dex score is the patient's ECF/TBW %, compared to clinical data in the following manner.

Hy-Dex®- Hydration Index. A bi-directional "open-ended" scale that displays a person's fluid status as compared to a dataset from an average population. Can be used as a tool to assist a Clinician or user in assessing their fluid status or hydration.

ICF-Intracellular fluid. Intracellular fluid is all the fluid that is contained within the cell membranes of the body. ICF is usually expressed as a volume (litres or pints).

Ipsilateral limb-The limb on the same side of the patient's body. For purposes of L-Dex Assessment of a patient with bilateral lymphoedema, SOZO compares R0 impedance of the at-risk limbs with the R0 impedance of the unaffected ipsilateral limbs. For example, if the patient has bilateral lymphoedema in both legs, the left arm is the unaffected ipsilateral limb to the at-risk left leg, and the right arm is the unaffected ipsilateral limb to the at-risk right leg.

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

L-Dex®-The Lymphoedema Index, a numeric value used in L-Dex Assessment.

L-Dex Assessment- also referred to as "L-Dex," based upon L-Dex values, derived from the ratio of impedance for the unaffected limb and the at-risk limb, of the body fluid levels of patients at risk of 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 Section.

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

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

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

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

Parameter-A clinically meaningful output based upon measurements.

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

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

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

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

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

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

SMM-Skeletal Muscle Mass. Skeletal Muscle Mass includes all muscle mass that mechanically acts on bones to create movement. It does not include cardiac or smooth muscle. Expressed as mass (kg or lb).

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

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

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

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

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

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

SOZO system-The commercially available medical device system manufactured by ImpediMed, also referred to as the SOZO Digital Health Platform in the SOZOapp, which uses Bioimpedance Spectroscopy to perform various Assessments of patient fluid levels. The SOZO system is comprised of hardware-the SOZO Device and the Tablet, and software - MySOZO and the SOZOapp.

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

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

TBW-Total Body Water. Total Body Water is the total water within a person's body, including both intracellular and extracellular fluid. This is expressed as a volume (litres or pints) or a percentage of total mass (e.g., 60% of mass is TBW).

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

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

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

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