SOZO® Pro Hardware
SOZO® Pro Software Version 6.2.0.1

Instructions for Use

ImpediMed Limited
ABN 65 089 705 144
Suite 31C
12-18 Tryon Rd.
Lindfield NSW 2070
Australia

Phone : + 61 7 3860 3700

Fax : + 61 7 3260 1225

Email : enquiries@impedimed.com

Website : http://www.impedimed.com

Distributed in the United States by:

ImpediMed Inc
5900 Pasteur Court, Suite 125
Carlsbad, CA 92008
(877) 247-0111
tsu@impedimed.com

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

For other assistance, or to report product issues, please contact ImpediMed U.S. by email at tsu@impedimed.com or by phone at: 877 247 0111 option 4

EC	REP

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

UKRP
MDSS-UK RP Ltd.
Parkway House, Palatine Rd, Northenden, Wythenshawe
Manchester M22 4DB
United Kingdom

CE 2797

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/

TABLE OF CONTENTS

1 SYSTEM OVERVIEW 8

1.1 Bioimpedance Spectroscopy (BIS) Technology 8

1.2 Introduction to the SOZO® Pro System 8

1.3 The SOZO® Pro System Architecture 9

1.3.1 Tablet Function 11

1.4 Cybersecurity Information 11

1.4.1 Cybersecurity Overview and Shared Responsibility 11

1.4.2 Security Specifications and Controls 12

1.4.3 Network Ports and Data Flows 13

1.4.4 Supporting Infrastructure and Deployment Requirements 13

1.4.5 Software Bill of Materials (SBOM) 14

1.4.6 Software and Firmware Updates 14

1.4.7 Detection of and Response to Anomalous Conditions 14

1.4.8 Features that Protect Critical Functionality 15

1.4.9 Backup, Restore, and Configuration Recovery 15

1.4.10 Secure Configuration of Shipped Devices 16

1.4.11 Security Logging and Forensic Information 17

1.4.12 End of Support and End of Life 17

1.4.13 Decommissioning and Data Sanitization 17

1.5 Radio Frequency Wireless Specifications 18

1.6 Assessment Licenses 19

1.7 Minimum Internet Requirements 19

1.8 Websites to Whitelist 21

2 SAFETY 22

2.1 Signs and Symbols 22

2.2 Intended Use 23

2.3 Indication for Use 23

2.4 Contraindications 24

2.5 Warnings 24

2.6 Precautions 24

2.6.1 Prescription Use Only 26

2.6.2 Storage Conditions and Use 26

2.6.3 Location for Use 26
3 PERSONAL DATA 28
4 DEVICE ASSEMBLY 29
4.1 Identify SOZO Pro Device Components 29
4.2 Assembling the SOZO Pro Device with SOZO Pro Stand 31
4.3 Using the SOZO® Pro Device for Seated Measurements 35
5 MySOZO 37
5.1 Introduction to the MySOZO System 37
5.2 MySOZO Users (Administrators and Clinicians) 37
5.2.1 First Time Set-Up 37
5.2.2 Password Reset 40
5.2.3 Password Expiration 42
6 MYSOZO ADMINISTRATOR 43
6.1 Administrator Home Page 43
6.1.1 Help Icon 44
6.1.2 Info Icon 45
6.1.3 Administrator Settings Icon 46
6.1.4 Administrator User Profile Icon 52
6.2 Administrator User List 52
6.2.1 Create New User 53
6.2.2 Edit User 54
6.2.3 Delete User 55
6.2.4 Restore User 56
6.2.5 Audit Logs 56
6.3 Administrator Patient Groups 57
6.3.1 Create a New Group 58
6.3.2 Rename/Delete Group 58
6.4 Administrator Patient Tags 58
6.4.1 Create a New Tag 59
6.4.2 Rename/Delete Tag 60
6.5 Naming a SOZO Pro Device 61
7 MYSOZO AND SOZOapp CLINICIAN 62
7.1 Clinician Home Page 62

7.1.1 Help Icon 63
7.1.2 Info Icon 63
7.1.3 Clinician Settings Icon 64
7.1.4 Clinician My Account Page 76
7.2 Clinician Patient List 76
7.2.1 Search for Patient 76
7.2.2 Patient Dashboard 77
7.2.3 Create Patient 78
7.2.4 Delete Patient 80
7.2.5 Delete Measurement 81
7.2.6 Restore Patient 81
7.2.7 Merge Patient Profiles 82
7.2.8 Edit Patient Profile 83
7.2.9 Export Patient Data 84
7.2.10 Shared Data 85
7.2.11 Report 91
7.3 Measurement Dashboard 94
7.3.1 Setting a Baseline 96
7.3.2 Evaluating Measurements Against a Baseline 96
7.3.3 Adding a Measurement Tag 96
7.3.4 Cole Plots 97
7.4 Clinician Patient Groups 98
7.5 Clinician L-Dex Analytics 100
7.5.1 Lymphedema Surveillance Program 100
7.5.2 Surveillance Program Tab 100
7.5.3 Patient & Measurement Overview 103
7.5.4 Patient Distribution 105
7.5.5 Patient List 108
7.5.6 Navigation 109
8 PREPARING THE PATIENT 111
8.1 Preparing for all Measurements 111
8.1.1 Factors Affecting Measurement 111
8.1.2 Body Composition Measurements 111
8.2 Measurement Accuracy 112
8.2.1 Weight 112

8.3 Positioning the Patient....112
8.3.1 Standing Position....112
8.3.2 Seated Position....113
9 TAKING MEASUREMENTS....114
9.1 Starting Measurements with the SOZOapp....114
9.2 Accepting and Rejecting Cole Plots After Measurement....117
9.3 Interpreting Cole Plots....121
9.4 Licensing....122
9.4.1 Impact of Licensing Additional Assessments on Results....122
9.4.2 Impact of Cancellation of Assessment License on Results....122
10 ASSESSMENT TYPES....123
10.1 Choosing the Proper Assessments for the Patient....123
10.2 L-Dex® for Lymphedema Instructions for Use....124
10.2.1 Indications for Use....124
10.2.2 The Lymphedema Index (L-Dex®)....124
10.2.3 Recommended Measurement Frequency....129
10.2.4 L-Dex® Assessments....129
10.2.5 Setting the Baseline....132
10.3 HF-Dex® for Heart Failure Instructions for Use....133
10.3.1 Indications for Use....134
10.3.2 HF-Dex® Assessments....134
10.3.3 HF-Dex® Measurement Results....135
10.3.4 Setting the Baseline....137
10.3.5 Historical Results....137
10.4 BodyComp™ Analysis Instructions for Use....138
10.4.1 Indications for Use....138
10.4.2 BodyComp™ Assessment Results (Whole Body)....138
10.4.3 Setting the Baseline....142
10.5 Segmental BodyComp™ Assessment Parameters (Limbs)....143
10.5.1 Example of Segmental BodyComp™ Results....143
10.5.2 Setting a Baseline....144
11 TROUBLESHOOTING....145
11.1 Device Errors....145

11.2 Self-Test Error 145
11.3 Lymphedema Settings Error 147
11.4 Patient Dashboard Error 148
11.5 Connectivity Error 149
11.6 General Troubleshooting Chart 150
12 CARE AND MAINTENANCE 158
12.1 SOZO Pro Device Care 158
12.2 SOZO Pro Device Maintenance 159
12.3 Self-Test 159
12.4 Repairs 159
12.5 Tablet Maintenance 159
12.6 Weight Scale Maintenance and Calibration 159
12.7 Technical Support 160
12.8 Components and Accessories 160
13 PRODUCT WARRANTY 161
14 REGULATORY STATEMENT 164
15 PRODUCT SPECIFICATIONS 165
16 SAFETY INFORMATION 167
17 GLOSSARY 172

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 the quality of measurements in the form of a Cole plot.

The SOZO Pro 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® Pro System

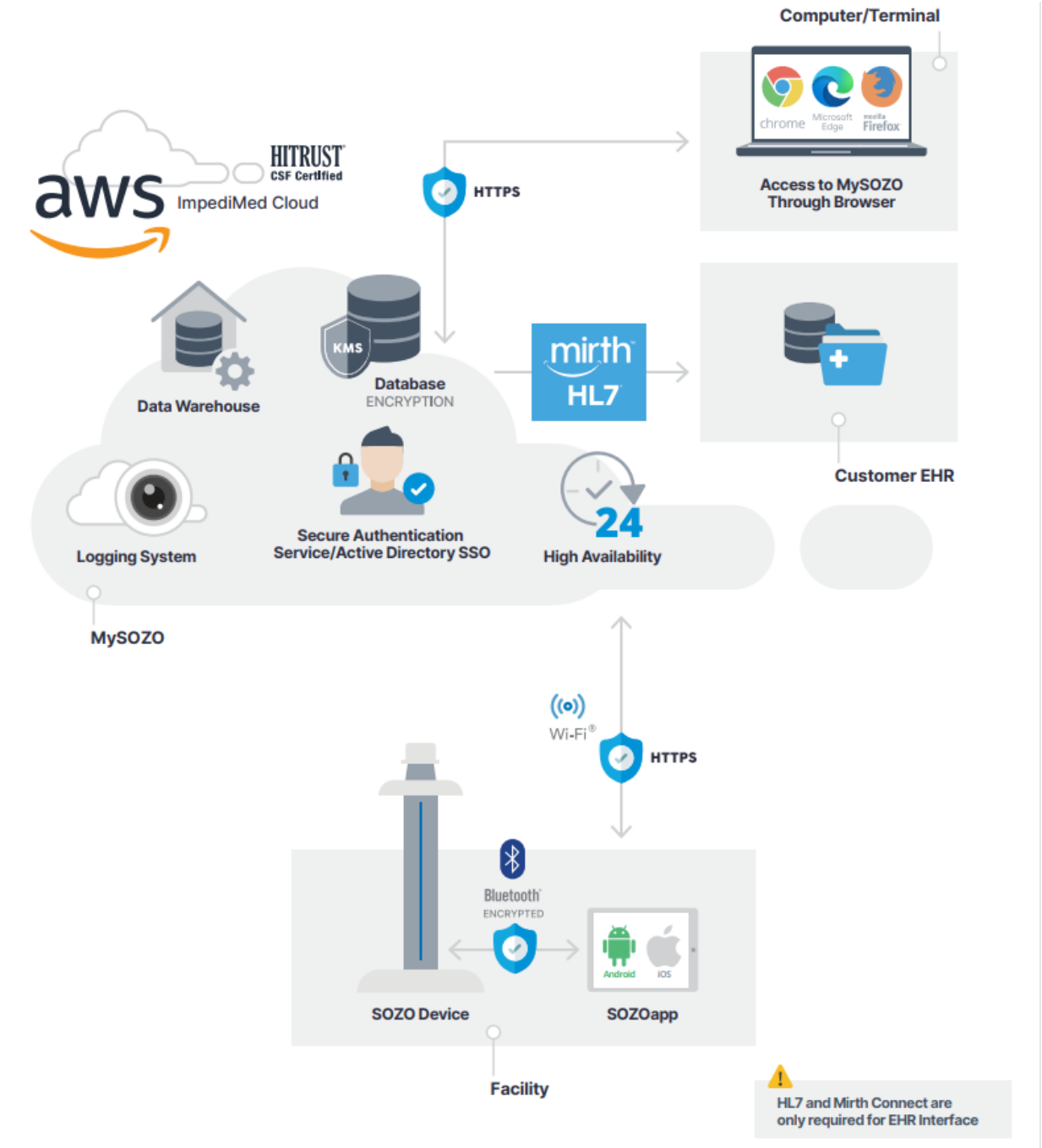
The SOZO Pro System is a medical device which uses ImpediMed's patented Bioimpedance Spectroscopy (BIS) for fast non-invasive measurement of fluid levels in human patients. ImpediMed's BIS technology provides a user-friendly platform to take quick, accurate patient measurements for assessment of patient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

The SOZO Pro System may assist with early detection of lymphedema by giving an "early warning" of patient fluid status change. The SOZO Pro System may be an integral part of a treatment plan for a lymphedema or heart failure patient. Using the SOZO Pro 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 Pro BodyComp™ and Segmental BodyComp modules, to monitor and track relevant parameters of their body composition, such as fat mass (FM), fat-free mass (FFM) and skeletal muscle mass (SMM).

1.3 The SOZO® Pro System Architecture

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



SOZO Pro System Architecture

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

The SOZO Pro 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 Pro System.

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

Security Controls

In the SOZO System Architecture diagram above, security controls are identified by a blue shield. In the table below, security controls are further described.

System Element	What It Is	Security Control Applied
SOZO Pro Device to Tablet	Local link carrying raw measurement data	Encrypted Bluetooth (Security Mode 4, Secure Simple Pairing). No patient identifiers traverse this link.
SOZOapp to MySOZO	App-to-cloud transmission of demographic and measurement data	TLS 1.2 over port 443
Browser to MySOZO	Clinician and Administrator web portal access	TLS 1.2 over port 443
Browser/Tablet to SSO.MySOZO.com	Single Sign-On, where the tenant is SSO-enabled	TLS 1.2 over port 443; SAML 2.0 authentication
MySOZO to Customer EHR	HL7 interface via Mirth, EHR-enabled tenants only	TLS 1.2 over port 443 (inbound to customer)
Data at rest in MySOZO	Patient demographic, measurement, and result data	AES-256 encryption at the database and storage-media level; keys managed by AWS KMS
Access to MySOZO	User authentication and authorization	Secure Authentication Service, role-based access, optional MFA, account lockout, and session timeout
Activity across MySOZO	Security and audit events	Logging system; logs cannot be modified by end users or ImpediMed staff

[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.*

1.3.1 Tablet Function

The Tablet is the primary user interface for the SOZO Pro Device. Clinicians use the Tablet for all SOZO Pro 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.

NOTE: Instructions in this IFU are for SOZOapp and MySOZO version 6.2. 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 13, Product Warranty.

1.4 Cybersecurity Information

1.4.1 Cybersecurity Overview and Shared Responsibility

The SOZO Pro device is a connected medical device system. This chapter describes the cybersecurity features built into the SOZO Pro, the supporting environment the system needs to operate securely, and the responsibilities shared between ImpediMed and the customer.

The SOZO Pro System is made up of the SOZO Pro Device, the SOZOapp on an Android or iOS Tablet, and MySOZO, a cloud application hosted and managed by ImpediMed on Amazon Web Services. The SOZO Pro Device and SOZOapp do not store patient data. Patient demographic data and raw measurement data are transmitted from the SOZOapp to the customer's logically separated MySOZO database, where all patient data resides.

The diagrams in Section 1.3 (SOZO System Architecture) and the data flow described in Section 5 illustrate how the components communicate and where the cybersecurity controls described in this chapter are applied: an encrypted Bluetooth link between the SOZO Device and the Tablet, an encrypted TLS 1.2 connection over port 443 between the SOZOapp and MySOZO, and encryption of data at rest within MySOZO.

Shared responsibility:

ImpediMed is responsible for the security of MySOZO and its AWS hosting environment, for the integrity of the SOZOapp and SOZO Device firmware it distributes, and for monitoring and responding to vulnerabilities across the SOZO ecosystem.

The customer (the healthcare organization) is responsible for the security of its own network and Tablets, including enabling Tablet encryption, applying mobile device

management, managing user accounts and credentials within MySOZO, and ensuring its network meets the requirements listed in the Supporting Infrastructure and Deployment Requirements section below.

1.4.2 Security Specifications and Controls

Authentication and Passwords

- MySOZO passwords must be 8 to 20 characters and include at least one uppercase letter, one lowercase letter, one number, and one special character. The previous three passwords cannot be reused.
- After five failed login attempts, the account is locked for 30 minutes to protect against brute-force and dictionary attacks.
- Sessions require re-authentication after a period of inactivity (60 minutes by default, configurable by an Administrator).
- Password expiration defaults to three months and is configurable by an Administrator.
- Administrators may enable Multi-Factor Authentication (MFA) for all users. Users may use a Time-based One Time Password (TOTP) authenticator application of their choice.
- Where the customer integrates an identity provider using SAML 2.0, password policy, password history, and MFA are managed in the customer's directory.

Encryption

- SOZO Pro Device to Tablet: encrypted Bluetooth (Security Mode 4, Secure Simple Pairing). No patient identifiers are carried over this link.
- SOZOapp to MySOZO and web browser to MySOZO: TLS 1.2 over HTTPS port 443.
- Tablet data at rest: the Tablet supports native encryption (AES-128 with CBC and ESSIV:SHA256). ImpediMed recommends that customers enable Tablet encryption.
- MySOZO data at rest: AES-256 encryption at both the database level and the storage media level; credentials are additionally salted.

Anti-Malware and Firewall

The SOZO Pro Device firmware is a closed embedded system and does not run user-installable software, so anti-malware on the SOZO Device is neither applicable nor required. For the Tablet, ImpediMed recommends that customers manage anti-malware, OS patching, and firewall posture through their mobile device management solution; the Tablet supports most MDM applications. Network firewall configuration at the customer site is described in the Supporting Infrastructure and Deployment Requirements section below (the SOZOapp requires outbound access to the endpoints listed there over port 443).

1.4.3 Network Ports and Data Flows

The SOZO Pro System uses a small, fixed set of network connections. All connections that carry patient data use TLS 1.2 over port 443.

Connection	Port	Direction	Purpose
SOZO Pro Device ↔ Tablet	n/a (Bluetooth)	Local	Encrypted Bluetooth link carrying raw measurement data. No network port; no patient identifiers.
SOZOapp → MySOZO.com	443	Outbound	TLS 1.2. Patient demographic data, raw measurement data, and results.
Browser → MySOZO.com	443	Outbound	TLS 1.2. Clinician/Administrator access to the web portal.
Browser/Tablet → SSO.MySOZO.com	443	Outbound	TLS 1.2. Single Sign-On, where the tenant is SSO-enabled.
Browser → *.quicksight.aws.amazon.com and regional CloudFront endpoints	443	Outbound	TLS 1.2. Analytics module reporting (workstation browser only).
MySOZO → Customer EHR (Mirth, 44.205.49.238)	443	Inbound to customer	TLS 1.2. Only required where EHR integration is implemented.

No inbound ports need to be opened on the customer network for routine SOZO Pro operation. The EHR connection above is the only inbound flow, and it applies only to customers who implement EHR integration.

1.4.4 Supporting Infrastructure and Deployment Requirements

To operate the SOZO Pro securely, the customer environment must meet the following requirements. Internet speed, browser, screen resolution, and supported Tablet requirements are listed in the Minimum Internet Requirements Section; the endpoints that must be reachable are listed in the Websites to Whitelist Section.

- Wi-Fi: the Tablet requires an encrypted Wi-Fi connection. WPA2-PSK and WPA2-Enterprise with 802.1x authentication are supported. The Tablet supports 802.11 a/b/g/n/ac.
- Supported encryption interfaces: TLS 1.2 for all connections to MySOZO over port 443; encrypted Bluetooth between the SOZO Pro Device and Tablet.
- Outbound access: the customer network and any web proxy or firewall must allow outbound HTTPS (port 443) to the endpoints listed in the Websites to Whitelist Section.

- Tablet management: ImpediMed recommends enrolling Tablets in a mobile device management solution to enforce device encryption, OS updates, and access controls.

ImpediMed Technical Support can assist with secure network deployment and SSO or EHR configuration on request.

1.4.5 Software Bill of Materials (SBOM)

ImpediMed maintains a Software Bill of Materials (SBOM) for the SOZO Pro System software, identifying the third-party and open-source software components, their versions, their support status, and known vulnerabilities. The SBOM is maintained as part of configuration management and is updated to reflect changes in marketed software.

Customers may request a current, machine-readable SBOM for their deployed SOZO Pro software version by contacting ImpediMed Technical Support at tsu@impedimed.com. ImpediMed will provide or make the SBOM available on a continuing basis.

1.4.6 Software and Firmware Updates

ImpediMed distributes only version-identifiable, ImpediMed-authorized software and firmware. The SOZO Pro System is not updated from public app stores.

- Android: the SOZOapp is pre-installed on the Tablet. Updates are distributed by ImpediMed through Managed Google Play.
- iOS: the SOZOapp is distributed through Apple Business Manager. Contact ImpediMed Technical Support for download instructions.
- SOZO Device firmware updates, when required, are delivered and applied through ImpediMed-authorized channels.

How users know an update is available: MySOZO and the SOZOapp display the running software version. ImpediMed notifies customers when a new authorized version is released and, where distribution is managed (Managed Google Play, Apple Business Manager), authorized updates are made available to enrolled Tablets. Available updates also appear as a notification within the MySOZO portal. Users should only install SOZO Pro software obtained through these ImpediMed-authorized channels.

1.4.7 Detection of and Response to Anomalous Conditions

The SOZO Pro System is designed to detect and respond to anomalous and security-relevant conditions. Security events such as failed and successful login attempts, account lockouts, and creation, modification, or deletion of users and records are logged in MySOZO with the user and a timestamp. After five failed login attempts an account is automatically locked for 30 minutes, and inactive sessions are automatically ended and require re-authentication.

MySOZO is hosted on AWS infrastructure protected by network firewalls with intrusion prevention, and back-end application errors and operational anomalies are monitored centrally. Administrators can review security logs and audit reports in MySOZO to identify suspicious activity. If a user suspects a cybersecurity incident, they should contact ImpediMed Technical Support tsu@impedimed.com.

1.4.7.1 Responding to a Suspected Cybersecurity Vulnerability or Incident

- Stop using the affected Tablet or account if you believe it is compromised, and do not attempt to investigate by altering device configuration.
- Have an Administrator review the MySOZO security and audit logs and, where appropriate, reset credentials or disable affected accounts.
- Report the suspected vulnerability or incident to ImpediMed Technical Support at tsu@impedimed.com or by phone. ImpediMed will investigate, perform a security risk analysis, and coordinate remediation and any required notifications.

1.4.8 Features that Protect Critical Functionality

The SOZO System is designed so that a security event does not compromise the integrity of stored patient data or the safety of a measurement.

- The SOZO Pro Device and SOZOapp hold no patient data at rest; results are calculated server-side in MySOZO and only held in volatile memory on the Tablet during use. Loss or theft of a Tablet therefore does not expose stored patient records.
- Each customer's data is held in a logically separated MySOZO database, limiting the impact of any single account compromise to that tenant.
- Account lockout, automatic session timeout, and role-based access limit the ability of a compromised credential to act.
- If network connectivity to MySOZO is unavailable, the SOZOapp cannot transmit or retrieve patient data; it does not fall back to an insecure local store. Connectivity troubleshooting is described in Section 11.

1.4.9 Backup, Restore, and Configuration Recovery

Patient data and configuration reside in MySOZO, not on the SOZO Pro Device or Tablet, so backup and recovery are managed centrally by ImpediMed.

- ImpediMed backs up the MySOZO databases as part of its managed hosting on AWS, supporting restoration of patient data and tenant configuration.
- Tenant configuration (users, roles, password and MFA policy, patient groups and tags, device naming) is stored in MySOZO and is recoverable by ImpediMed as part of a tenant restore.

- Authorized, authenticated Administrators retain and recover their own configuration through the MySOZO Administrator settings, where they can re-create or restore users, reset credentials, and reapply settings.
- Because the Tablet holds no patient data, replacing a Tablet does not require a data restore; the replacement Tablet is enrolled and the SOZOapp is provisioned through the customer's managed distribution, then signs in to the existing MySOZO tenant.

1.4.10 Secure Configuration of Shipped Devices

SOZO Pro tablets are shipped as "out-of-the-box" and are not configured/managed by ImpediMed. The SOZO Pro Device firmware is shipped in a fixed, hardened configuration that is not user-modifiable.

User-configurable settings and their security implications:

Setting	Recommended secure configuration	Risk if weakened
Tablet encryption	Enable native Tablet encryption.	Data on a lost Tablet could be accessible (note: no patient records are stored at rest).
Mobile device management	Enroll Tablet in MDM; enforce OS patching, anti-malware, and lock policy.	Unmanaged Tablets may run outdated or unauthorized software.
MFA	Enable MFA for all users.	Credential theft alone could grant access.
Password expiration / inactivity timeout	Retain defaults or apply organizational policy.	Long-lived sessions or passwords increase exposure.
Multi-Role accounts	Provision only where required.	Over-broad privileges increase impact of a compromise.
Network endpoint allow-list	Allow only the Section 1.6 endpoints over port 443.	Overly open egress increases attack surface.

Credential reset for any user can be performed by an Administrator in MySOZO. Anti-malware and firewall posture for the Tablet are managed by the customer through MDM and the customer network.

1.4.11 Security Logging and Forensic Information

MySOZO records security-relevant events to support detection, investigation, and forensic review. These logs cannot be modified by end users or by ImpediMed staff.

What is logged:

- Login events: successful and failed logins, the user account, and timestamp.
- Data and patient records: creation, modification, and deletion, including the targeted record, the user, and timestamp.
- Administrative functions: creation, access, modification, deletion, and export of data, users, and settings, including the user and timestamp.

How logs are stored and consumed:

Logs are generated and stored within the MySOZO environment on AWS, separately from the SOZO Pro Device and Tablet, so that forensic evidence is retained even if a Tablet is lost. Administrators can view and run audit and security reports through the MySOZO web portal which can be exported in .CVS format and uploaded into the customer SIEM. Application and infrastructure events are additionally monitored centrally by ImpediMed. Customers who operate a SIEM and require log feeds for their own monitoring can implement Single Sign-On to integrate access logs.

1.4.12 End of Support and End of Life

ImpediMed maintains the SOZO Pro System software, including security updates, while a software version is supported. ImpediMed communicates end-of-support and end-of-life information for SOZO software versions and components to customers in advance.

At end of support, ImpediMed may no longer be able to provide security patches or software updates for that version. If a device or software version remains in use after end of support, cybersecurity risk can be expected to increase over time, and that risk transfers to the operating organization. Customers should plan to move to a supported version before end of support and should contact ImpediMed Technical Support for the current support status of their SOZO software and Tablet operating system.

Tablet operating system support is governed by the Tablet manufacturer. The recommended minimum operating system versions in the Minimum Internet Requirements section are intended to keep Tablets within their manufacturer security-update window.

1.4.13 Decommissioning and Data Sanitization

When a SOZO System or component is retired, the following steps ensure that confidential, sensitive, and proprietary data and software are removed.

1. Tablet: remove the Tablet from the customer's MySOZO tenant and from MDM, then perform a factory reset to erase the SOZOapp and all local data. Because the SOZOapp stores no patient records at rest, a factory reset removes any residual application data.

2. SOZO Pro Device: the SOZO Pro Device does not store patient data or operational data; only firmware is present. Disconnect and return or recycle the Device per the instructions below.
3. MySOZO tenant: when a customer ends services, the customer receives a copy of their data, verifies receipt, and ImpediMed securely destroys the tenant database using a purge and re-write method and provides a certificate of destruction.

1.5 Radio Frequency Wireless Specifications

Radio Frequency Wireless Technology Requirements	
Radio Frequency / Wireless Characteristics	**Description**
Technology Description	The radio frequency device system utilizes Bluetooth™ Low Energy Peripheral.
Operating characteristics	The operating characteristics met the Bluetooth Low Energy standard requirements and passed radiated emissions testing performed by a third party. Emissions requirements are documented and passed via design control verification and validation testing. The RF power amplifier is limited by the Laird module to within the allowable limits for Bluetooth™ devices.
Quality of Service	QoS is not applicable to Bluetooth Low Energy as the device has no control over the prioritization of Bluetooth Low Energy traffic.
Recommended wireless security measures	The device uses Bluetooth Low Energy pairing and bonding to encrypt connections; however, there is no attempt made to authenticate the tablet or ImpediMed device during the initiation of the connection. No PII is transmitted across the connection and the ImpediMed device is only able to connect to a single central device (tablet) at a time, so it is immediately evident to the operator if the ImpediMed device is not connected to the tablet that the operator is using. Therefore, risk is extremely low that an attacker could either extract sensitive information or inject clinically relevant false information into the connection.
Wireless connection and troubleshooting	ImpediMed device selection, pairing, and pairing tools are included in the "Select and Pair Device" section of the IFU.
Wireless coexistence issues / mitigations	Bluetooth Low Energy is highly robust and insensitive to other wireless protocols while also emitting at such low power that it does not meaningfully interfere with most other wireless protocols even in the same 2.5GHz frequency band.
EMC and telecommunication compliance	EMC testing compliance is documented in Section 15, Product Specifications.
RF Wireless Communication Information	ImpediMed devices comply with Part 15 of the FCC Rules. For further discussion, see the Regulatory Statement section of the IFU.

RF Source Warnings	RF emissions are discussed in the Safety Information section of the IFU.
RF Reference Standards Information	RF reference standard application and descriptions are included in Safety Information section of the IFU.

1.6 Assessment Licenses

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

1.7 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.

Component	Requirements
	• iPad devices must run iPad iOS version 13 or later, to ensure continued support through official security updates.

1.8 Websites to Whitelist

To be able to take measurements, operate, 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 utilized for reports in the Analytics Module of MySOZO.com,

  NOTE: 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.
	Refer to the 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.

Symbol	Definition
IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.
Rx only	Prescription use only medical device.

2.2 Intended Use

Ensure that you have read and understand this entire Instructions for Use (IFU) before using the SOZO Pro Device. No other specific skill or training is required to take measurements using the SOZO Pro Device.

The SOZO Pro Device is a medical device intended for clinical use by operators who have read this IFU. The SOZO Pro 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 Indication for Use

The SOZO Pro Body Fluid Analyzer has the following uses:

For adult human patients at risk of lymphedema:

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

The use of the device to obtain an L-Dex score is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, either removed, damaged or irradiated.

The SOZO Pro Body Fluid Analyzer 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.

The SOZO Pro system may be used as an adjunct to existing methods by aiding clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of protein-calorie malnutrition (PCM).

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

- Fat mass
- Fat-free mass
- Total body water
- Intracellular fluid
- Extracellular fluid
- Skeletal muscle mass
- The following outputs are also presented:
- 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 SOZO Pro Device measures current (I), voltage (V) and phase angle (Phi), and from these values calculates resistance (R), reactance (Xc), and impedance (Z), which are used to estimate the above body composition parameters. The device/ software will also display the Cole plot, subject height, weight, age and sex.

2.4 Contraindications

The SOZO Pro Device should not be used for:

- Patients with any active implantable electronic equipment (e.g., infusion pumps, neurostimulators, brain stimulators, etc.), except for permanent pacemakers (PPMs) or implantable cardioverter-defibrillators (ICDs), for which SOZO Pro is not contraindicated, or
- Patients undergoing external defibrillation.

2.5 Warnings

Pregnant patients:

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

2.6 Precautions

	Ensure that you have read and understand these entire instructions for use document before using the SOZO Pro Device. No other specific skill or training is required to take measurements using the SOZO Pro Device.
	Do not allow the SOZO Pro Device to encounter any liquids.

	Only use the Power Adaptor supplied with the SOZO Pro Device. The use of any other Power Adaptor may expose the patient to the risk of electrocution.
	Do not use or operate the SOZO Pro 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 nebulizer. • Example 3: Devices generating large electromagnetic fields such as MRI or DXA.
	Keep away from small children or animals. Strangulation due to cables may occur and small parts may be inhaled or swallowed.
	Avoid using on subjects with metal allergies. Allergic reactions may be caused by the stainless steel used in the electrodes of the SOZO Pro Device.
	Avoid using accessories, detachable parts and materials not described in the instructions for use, interconnecting the SOZO Pro Device with other equipment not described in the instructions for use, or modifying the SOZO Pro 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 Pro 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 Pro 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 Pro Device is assessed under supervision of a physician when managing a chronic disease.
	The SOZO Pro Device has a maximum weight capacity of 220 kg (485 lbs). Do not use the SOZO Pro Device in a standing position if patient weight exceeds 200 kg (485 lbs).
	The SOZO Pro Device is intended for indoor use only. Do not use outdoors.
	SOZO Pro 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.

2.6.1 Prescription Use Only

The SOZO Pro device, MySOZO and the SOZOapp are for prescription use only.

2.6.2 Storage Conditions and Use

2.6.2.1 Environmental Operating Conditions

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

2.6.2.2 Environmental Transport and Storage Conditions

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

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

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

2.6.3 Location for Use

When used with the Stand accessory, the SOZO Pro 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 the Hand Unit on a non-metal desk that allows comfortable access from a seated position to the Foot Unit and Hand Unit components. For seated use, a non-metal chair should be used.

Do not place the SOZO Pro Device, other than the SOZO Pro stand, on any object or material made of metal.

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

Using the SOZO Pro Device on carpet may cause static electricity, which could damage the equipment. If installing the SOZO Pro

Device on carpet is unavoidable, please use the Stand or an antistatic mat.

Various environmental factors may interfere with the SOZO Pro 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 anesthetic gases or in an oxygen-rich environment.

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

Prior to use, ensure that SOZO Pro is positioned on a level surface by using the Foot Unit’s level indicator.

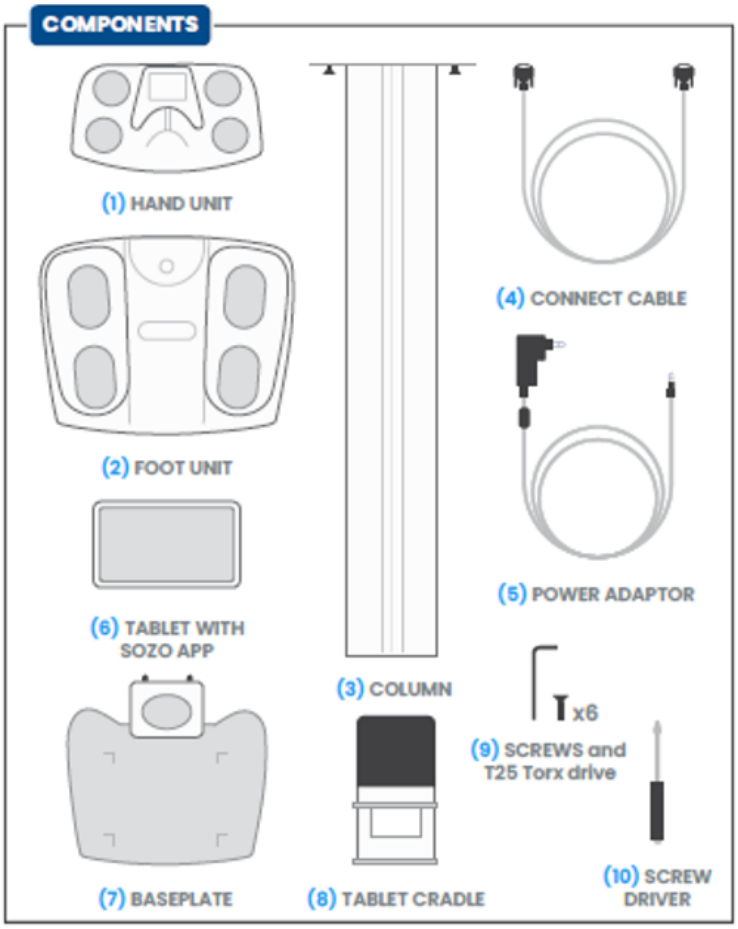
3 PERSONAL DATA

Read our privacy policy located at https://www.impedimed.com/privacy-policy/

4 DEVICE ASSEMBLY

4.1 Identify SOZO Pro Device Components

Before assembly, identify the device components shown below, which are specific to SOZO Pro.



(1) **Hand Unit** - A hardware component of the SOZO Pro Device upon which the patient places their hands for impedance measurement, includes a graphical display.

(2) **Foot Unit** - A hardware component of the SOZO Pro Device upon which the patient stands (places their feet) for impedance and weight measurement. The leveling of the foot unit is critical to weight scale accuracy.

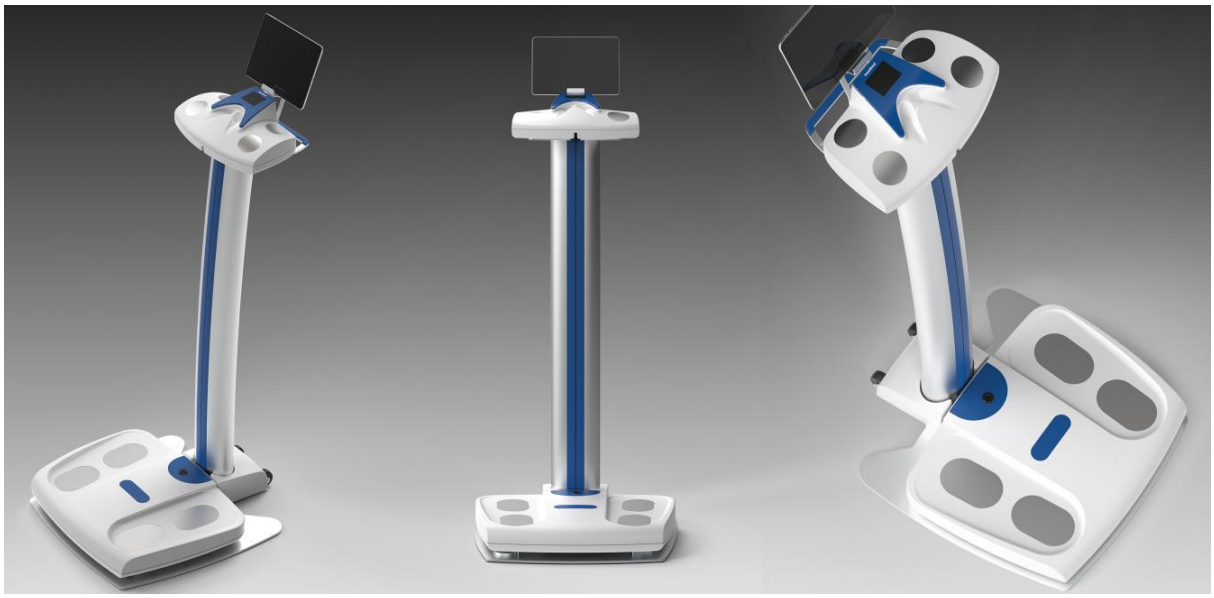
(3), (7), (8) **Stand** - The Stand secures the SOZO Pro unit in a suitable position for standing measurements. The stand is composed of the **Column**, **Baseplate**, and **Tablet Cradle**.

(4) **Connect Cable** - The hardware component of the SOZO Pro Device used to connect the Hand Unit with the Foot Unit.

(5) **Power Adaptor** - Medical grade universal power adaptor 24 VDC.

(8) **Tablet Cradle** - The hardware component of the SOZO Pro Device which holds the Tablet in place.

Tablet (not shown) - iOS or Android Tablets will function with a SOZO Pro system.



SOZO Pro

SOZO Pro Unit with Display

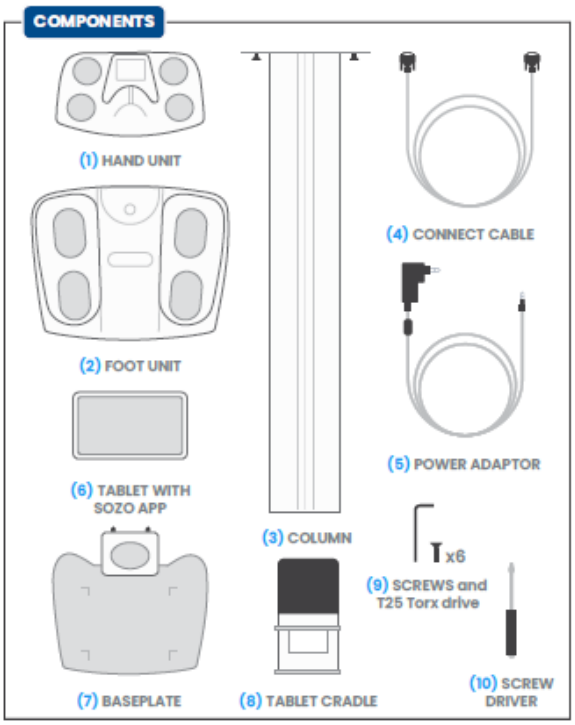
Below are SOZO Pro Hand Unit display examples (patient weight, impedance measurement in progress, and completed impedance measurement)

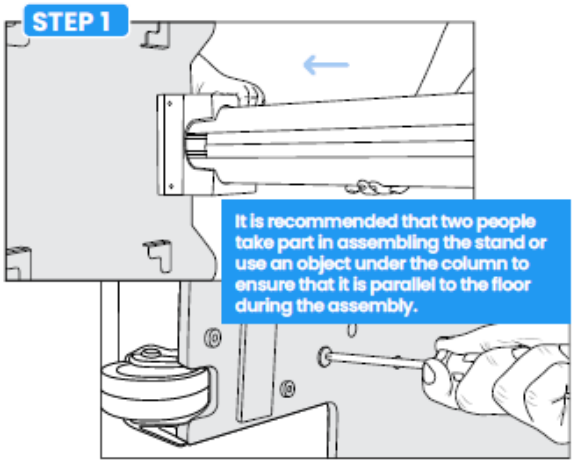
4.2 Assembling the SOZO Pro Device with SOZO Pro Stand

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

NOTES:

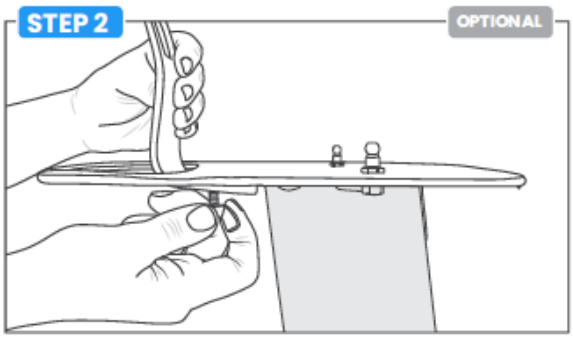
For an easier process, have two people assemble the SOZO Stand. The first person can lay the column on its side, while the second person holds the baseplate parallel to and aligned with the column. The first person attaches the baseplate to the column using the 6 screws and T25 torx drive.





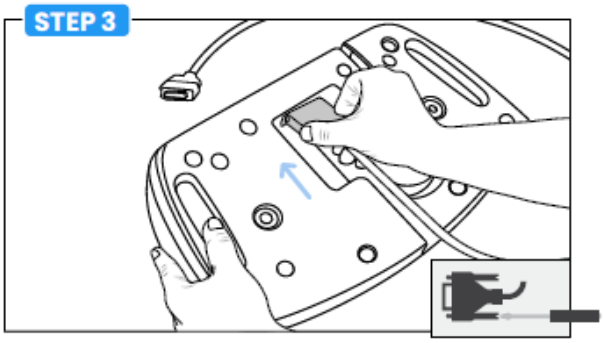
Screw the base of the column(3) into the baseplate(7).

Lay the column on its side and hold the baseplate, perpendicular to the column. Then, slide the base of the column into the baseplate, with the handle towards the wheels and the blue stripe facing towards the front. Attach the column to the baseplate using the 6 screws and the T25 torx drive. For best alignment, attach screws loosely and then tighten once all 6 are in place.



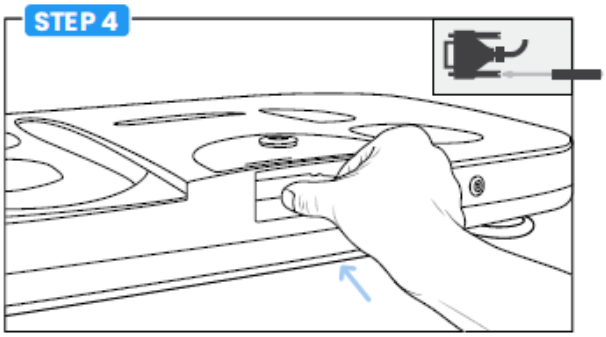
Attach the tablet cradle(8) to the top of the column(3).

Then use the two wing nuts to screw the cradle in securely.



Attach the connect cable(4) to the hand unit(1).

Feed the connect cable into the underside of the hand unit and secure it under the cable clamp, then insert it into the port ensuring the connectors are fully seated. Use the screw driver provided to tighten the two screws.

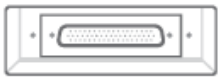


Attach the connect cable(4) to the foot unit(2).

Insert the connect cable into the port ensuring the connectors are fully seated, then use a small screwdriver to tighten the two screws.

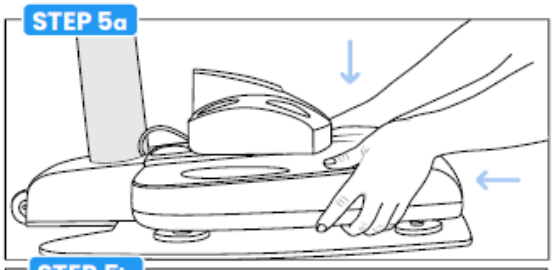
NOTE: For steps 3+4 ensure correct alignment between the connect cable and the port.

CONNECT CABLE (FRONT VIEW)

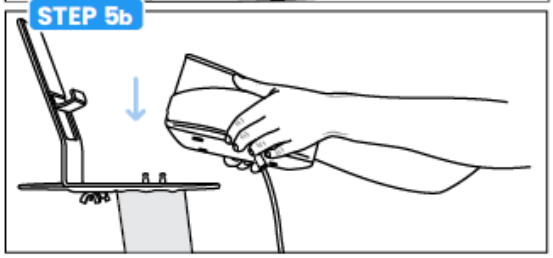


FOOT / HAND UNIT PORT (FRONT VIEW)

STEP 5a



STEP 5b



Attach the foot unit(2) and hand unit(1) to the column(3).

Place the foot unit on the baseplate, then place the hand unit on to the top of the column, so that it clicks onto the top 2 posts.

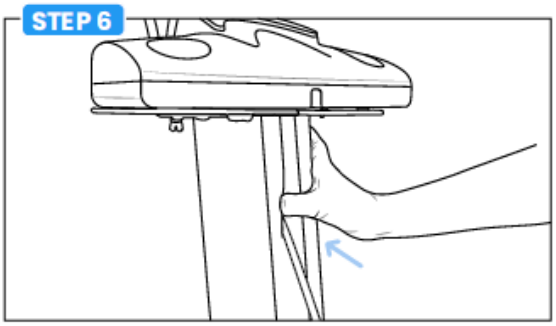
The foot unit will require leveling prior to use. When it is removed from the shipping container, remove the tape and confirm that the leveling feet are threaded all the way in.

To level the scale, raise or lower the foot unit feet by gently turning them clockwise or counterclockwise until the scale is level. The foot unit will be level when the bubble in the level indicator is in the center and the foot unit is stable, and does not rock back and forth.

CAUTION
The leveling feet should never be turned to their fully extended position. If this must be done it is recommended to move the SOZO Pro to a flat and level place and start the leveling process over.

Slide the foot unit forward into place.

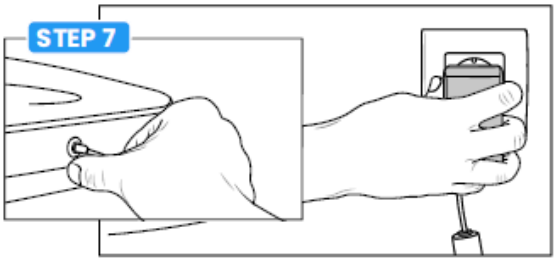
STEP 6



Feed connect cable(4) into the column(3).

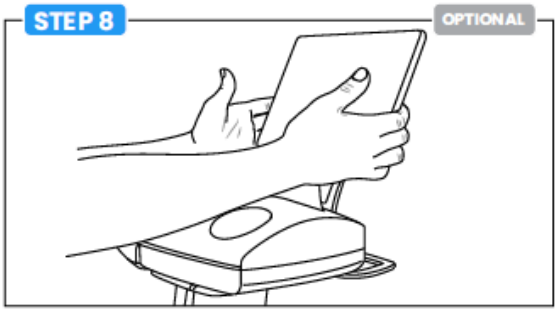
Press the connect cable down the middle of the blue rubber stripe on the front of the column. Ensure the connect cable exits below the end of the blue stripe.

STEP 7



Plug the power adaptor(5) into the foot unit(2), then into the wall.

STEP 8 OPTIONAL



Place the tablet(6) into the tablet cradle(8).

NOTE: Optionally, at the user's discretion, a metal plate with adhesive backing can be placed on the back of the tablet or tablet case, so that it is aligned to the area where the magnet is located on the tablet holder.

Weight scale calibration recommended annually after assembly. Refer to LBL-567 for details.

NOTE: The SOZO Pro scale will require leveling prior to use. To level the scale, raise or lower the SOZO Pro Foot Unit feet by gently turning them clockwise or counterclockwise until the scale is level on the flat surface where the device is in use. The scale will be level when the bubble in the level indicator on the Foot Unit is in the center and the Foot Unit is stable and does not rock back and forth.

Observe the following warnings while assembling the SOZO Pro Device.

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

Ensure that the SOZO Pro Connect Cable is plugged in to the Hand and Foot units before connecting the Power Cord. If the SOZO Pro Device must be moved, ensure that the Power Cord is disconnected before moving or uninstalling the system.

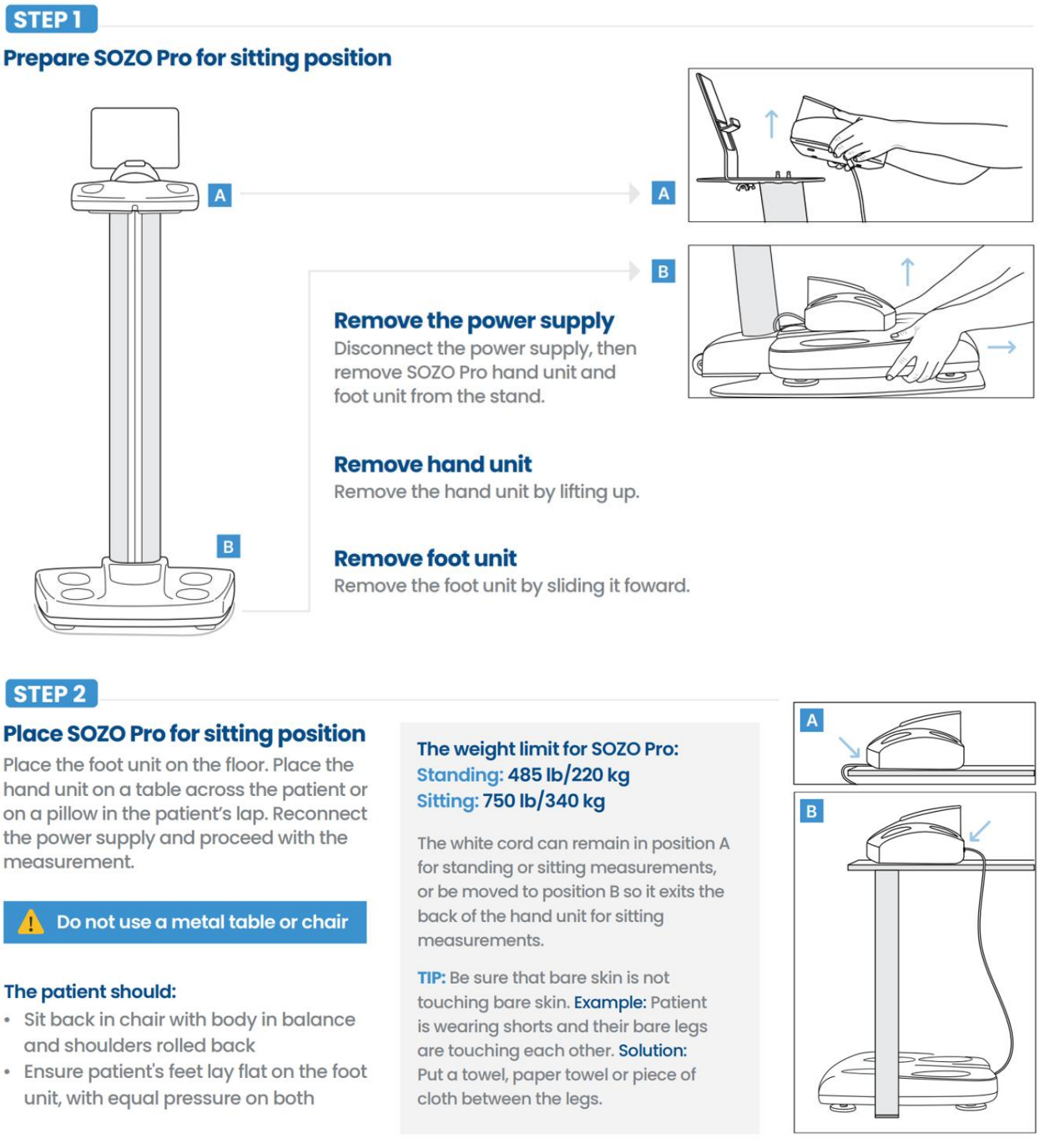
When plugging the Power Cord into the wall outlet, the SOZO Pro System will automatically run a self-test to ensure functionality. Do not touch the stainless-steel electrodes when a self-test is running.

Ensure that nothing is in contact with the Hand Unit or Foot Unit electrodes when applying power.

For more information on setting up the SOZO Pro System with the SOZO Pro Stand, visit www.impedimed.com or contact ImpediMed Technical Support.

4.3 Using the SOZO® Pro Device for Seated Measurements

To measure patients in the seated position, please follow the steps in the diagrams below.



To use the SOZO Pro Device while the patient is sitting, follow the instructions for use in 8.3.2, Seated Position.

For more information on setting up the SOZO Pro System without the SOZO Pro Stand, visit www.impedimed.com or contact ImpediMed Technical Support.

5 MySOZO

5.1 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 Pro System from any user device with internet access and Google Chrome, Mozilla Firefox, or Chromium-based Edge web browsers ("supported browsers"). See Minimum Internet Requirements.
- 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 Pro 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 Pro System setup, ImpediMed will establish the initial authorization and licenses and create the first Clinic Administrator.
- Once the initial Clinic Administrator has been created by ImpediMed, additional Administrators and Clinicians may be added by the Clinic Administrators. All users, whether they are Administrators or Clinicians, are identified by their email address.

5.2 MySOZO Users (Administrators and Clinicians)

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

5.2.1 First Time Set-Up

1. New User Email

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

   Select the Password setup link provided in the email.

   NOTE: The temporary password expires after 24 hours.

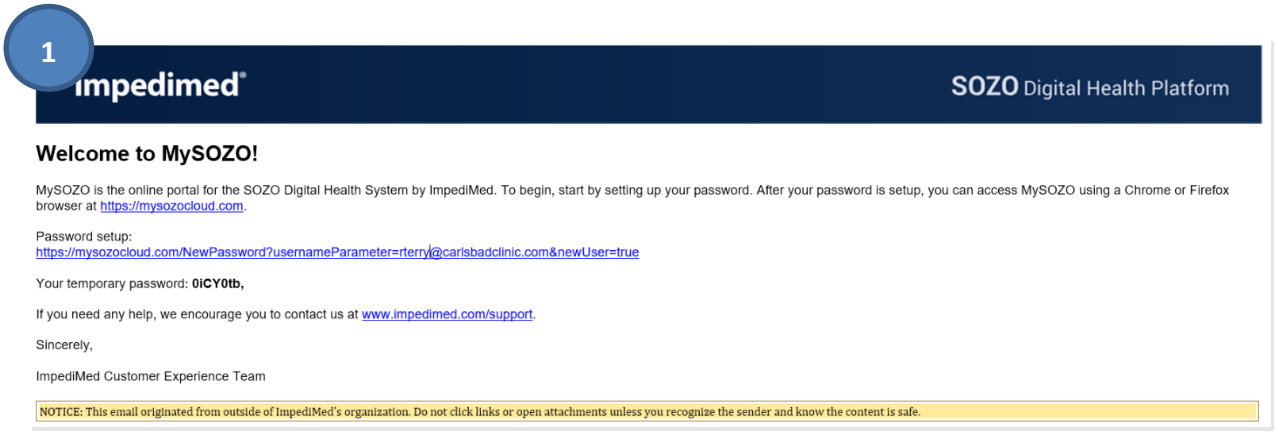
2. Set New Password
    a. After the user selects the email link, a new browser window opens and the Set New Password screen appears. Enter the temporary password followed by the new password and confirmation of the new password. To view the password, select the eye icon.
    b. Ensure that the new password meets all letter and character requirements.

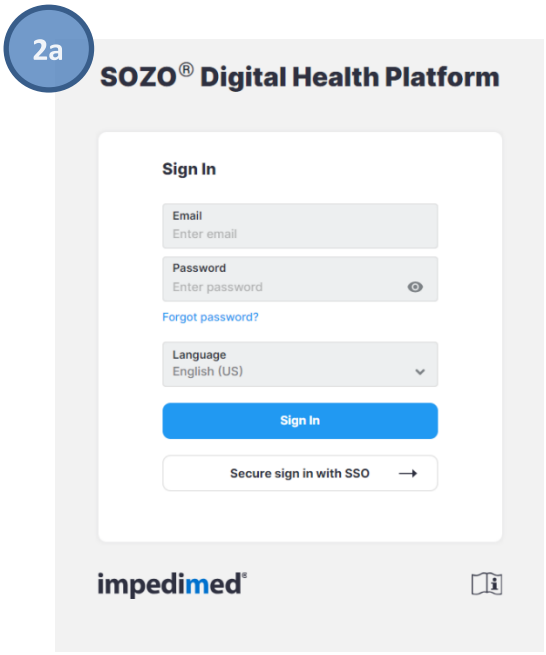
       NOTE: The password must be between 8 and 20 characters containing at least:

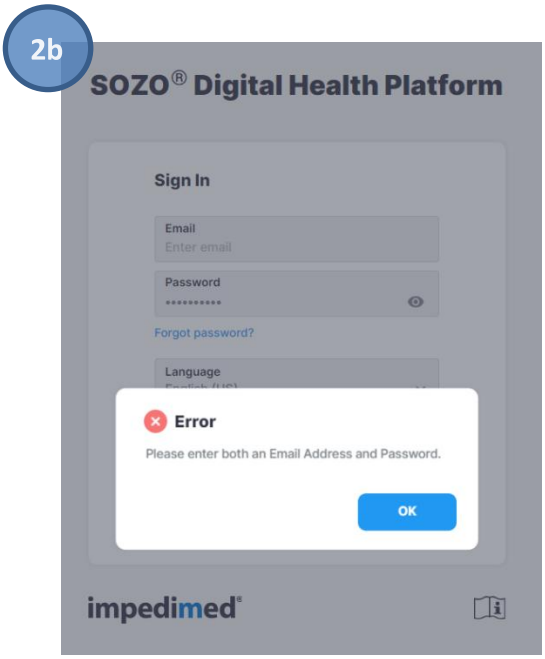
        - One number
        - One special character: !“#$%&”()*+,-./:;<=>?_@[]^`{|}~
        - One upper case letter
        - One lower case letter
        - You cannot use your last 3 passwords

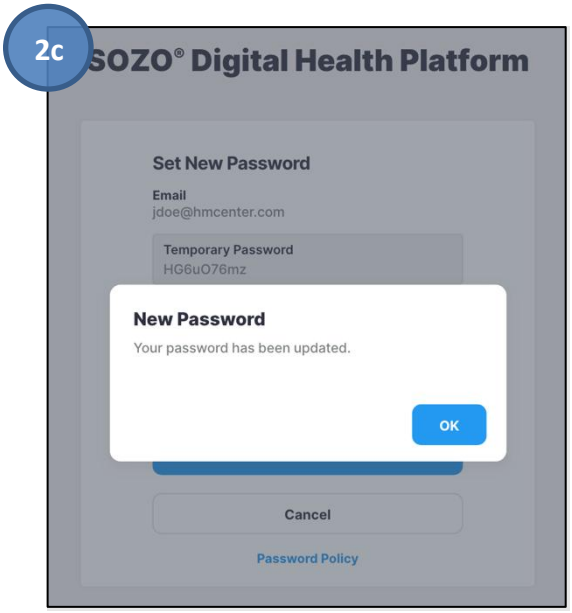
    c. To set and confirm the new password, select **Submit**.

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



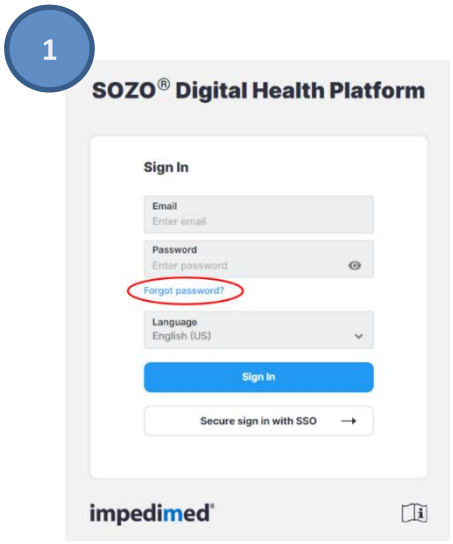

2a
SOZO® Digital Health Platform
Sign In
Email
Enter email
Password
Enter password
Forgot password?
Language
English (US)
Sign In
Secure sign in with SSO
impedimed

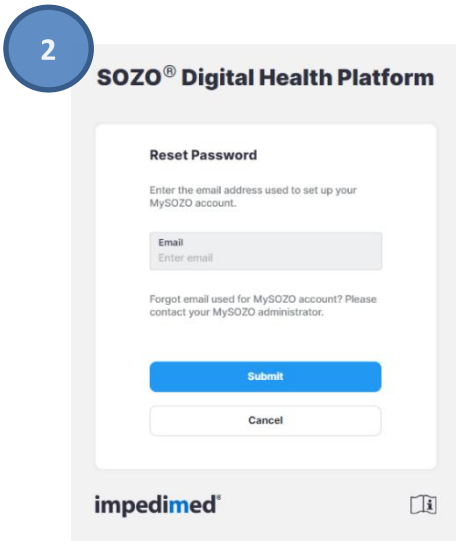

2b
SOZO® Digital Health Platform
Sign In
Email
Enter email
Password
Forgot password?
Language
Error
Please enter both an Email Address and Password.
OK
impedimed

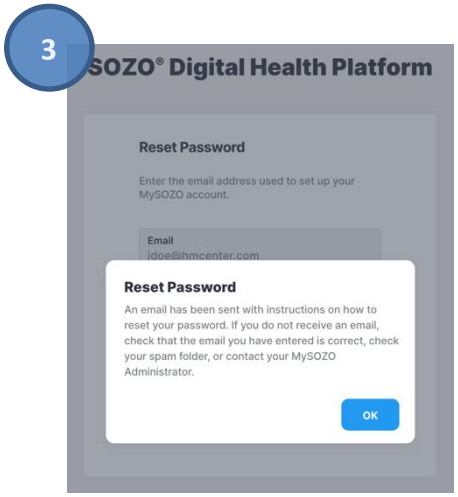

2c
SOZO® Digital Health Platform
Set New Password
Email
jdoe@hmcenter.com
Temporary Password
HG6uO76mz
New Password
Your password has been updated.
OK
Cancel
Password Policy

5.2.2 Password Reset

1. If the you have trouble signing in or have forgotten your password, select **Forgot password?** located beneath the password box on the sign-in screen.
2. When prompted, enter the email address for your MySOZO account. A password reset email will be sent from ImpediMed if a valid email has been entered.
3. After you receive the email with password reset instructions, select the Reset Password link in the email. The Set New Password screen appears.
    a. Ensure that the new password meets all letter and character requirements.
    b. Set and confirm the new password and then select **Submit**.







4

impedimed

SOZO Digital Health Platform

A request has been made to reset the MySOZO password associated with jdoe@hmcenter.com

This link is valid for one hour to reset your password:
https://mysozocloud.com/NewPassword?usernameParameter=jdoe@hmcenter.com&newUser=false&codeParameter=542481

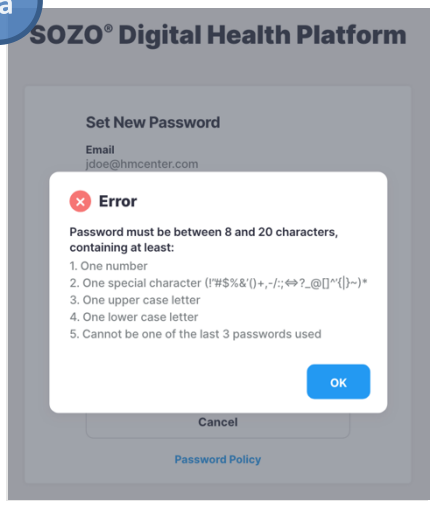
If you did not request a password reset, contact your MySOZO Administrator. If one hour has passed since receiving this email, you may reset your password at https://testsprint.mysozocloud.com/SendEmail.

Sincerely,

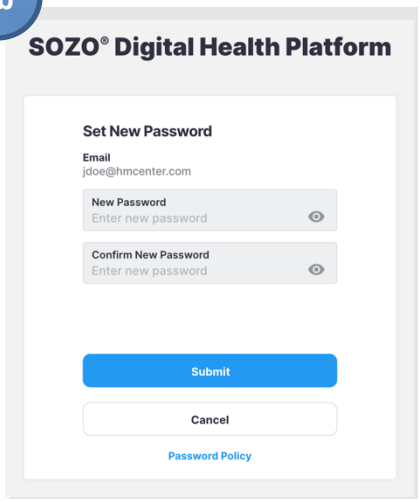
ImpediMed Customer Experience Team

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

4a



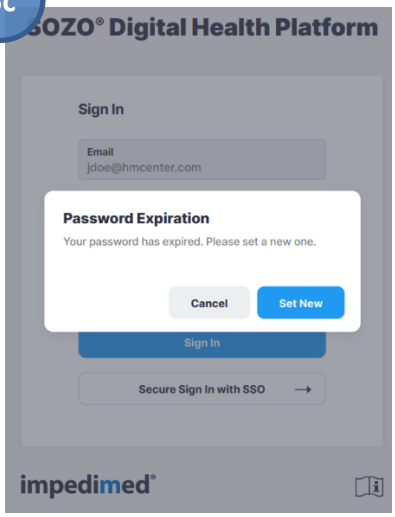
4b



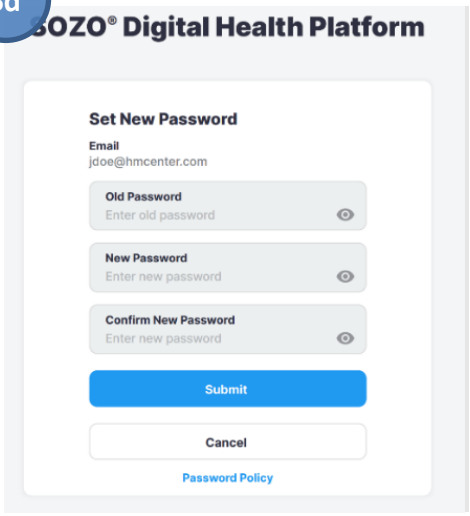
5.2.3 Password Expiration

The Clinic Administrator will set the Password Expiration Period in days (30-1000 days). When a user's password has expired, a notification will appear. To reset the password, select **Set New**.

5c



5d



6 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 Pro System-wide settings which include security, report logo, time zone, lymphedema surveillance program protocol and multi-factor authentication settings
- Export Audit Logs

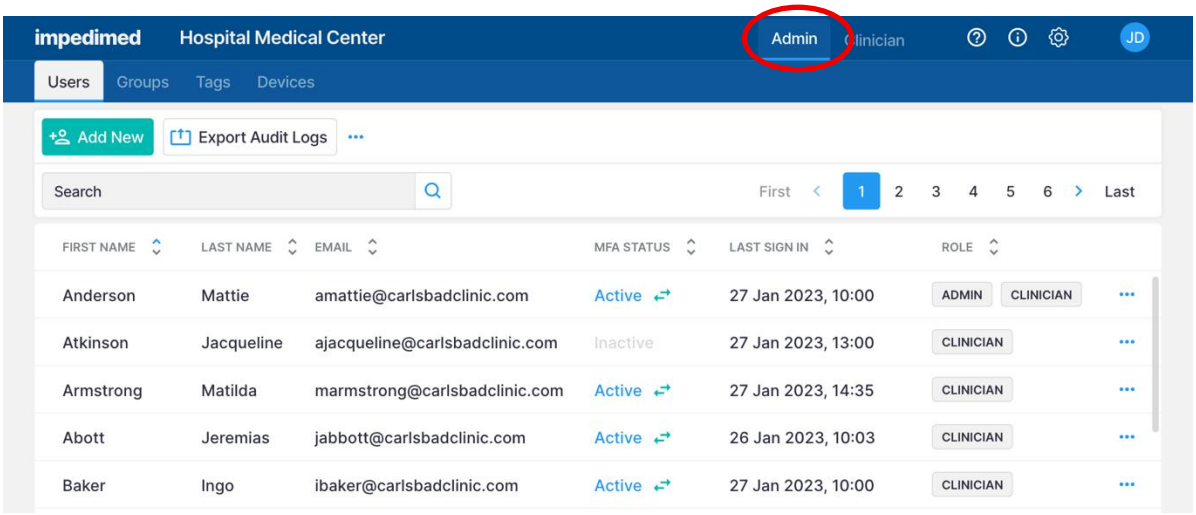
A user with an Administrator role can be created or added by another existing user with an Administrator role. Users are identified by their email address.

6.1 Administrator Home Page

For Administrators, set a password and sign in per the instructions in 5.2.1, First Time Set-Up. After you sign in, the MySOZO Administrator home page will display the User List.

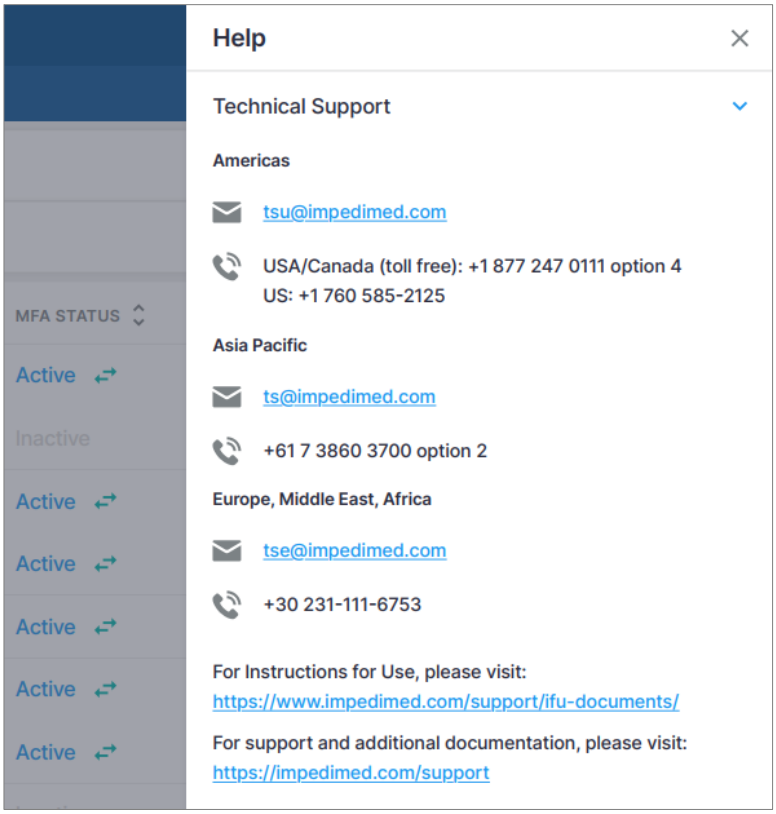
Users may be assigned both Administrator and Clinician roles, and access both functions from the same sign-in. The Admin tab is bold and underlined if the user is signed in as an Administrator. If an Administrator also has the Clinician role, they can toggle between Administrator and Clinician screens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

The banner icons enable common administrative functions.



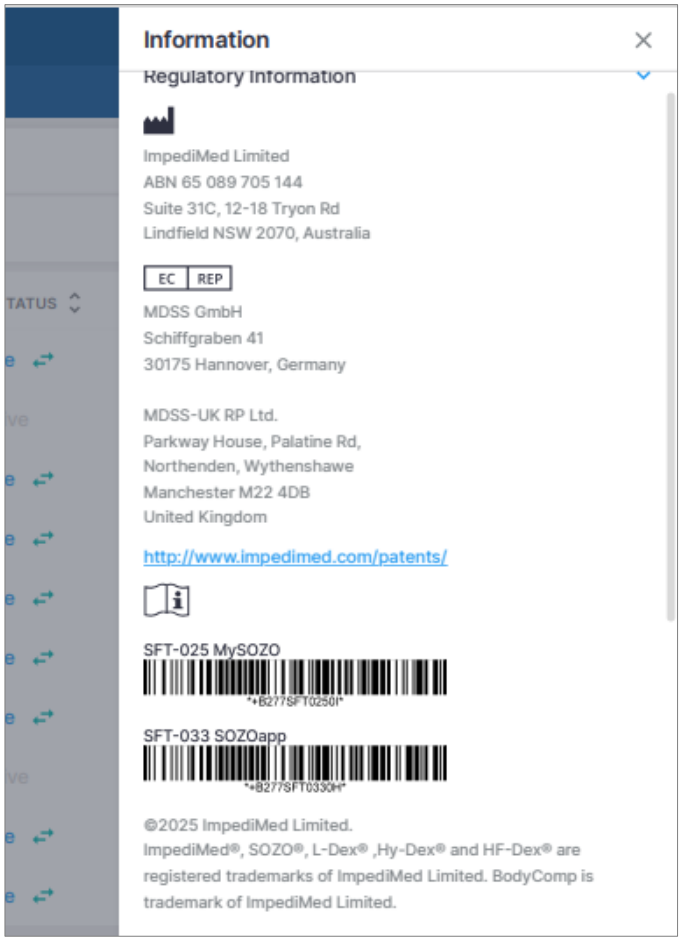
6.1.1 Help Icon

For assistance with use of MySOZO, select the **Help** icon. The Help page includes contact information for ImpediMed Technical Support and product Information.



6.1.2 Info Icon

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



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

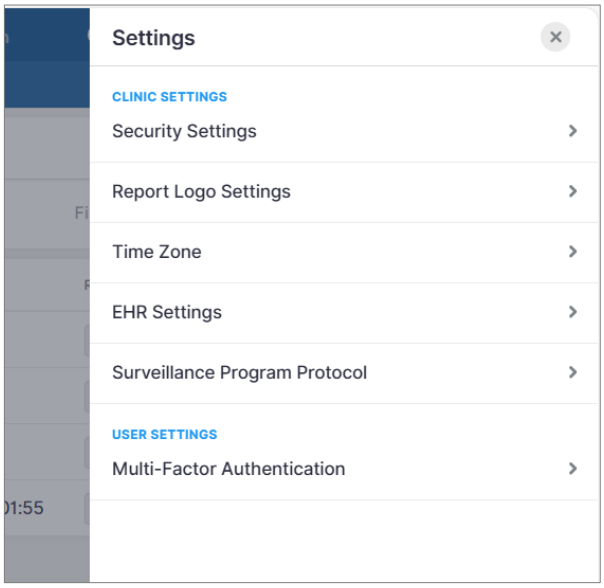
Software Information: Displays current MySOZO version and if it is up to date. There is also an option to update if required. Release notes for current and previous versions are listed.

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

6.1.3 Administrator Settings Icon

The Administrator may adjust MySOZO system-wide settings by selecting 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, select **Save**.

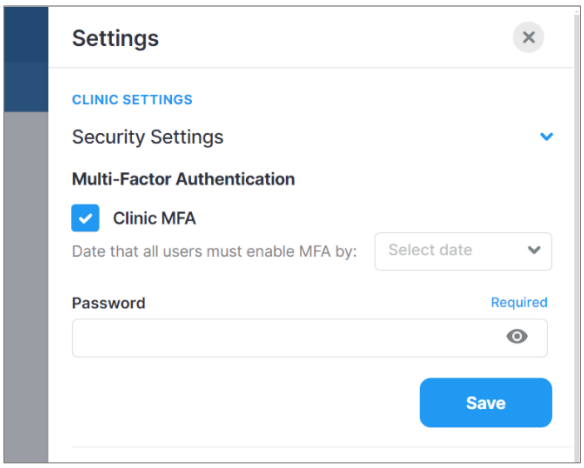


6.1.3.1 Security Settings

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

6.1.3.1.1 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.



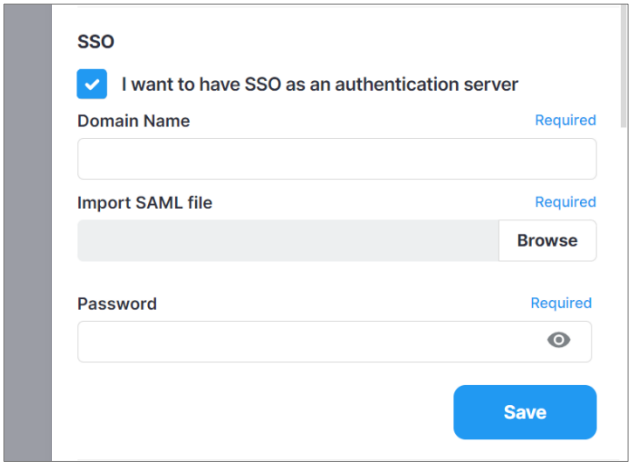
To turn MFA on, the Administrator will need to check Clinic MFA under Security Settings, enter an “enable by” date, their password, and then select **Save**.

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

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.

6.1.3.1.2 Single Sign-On

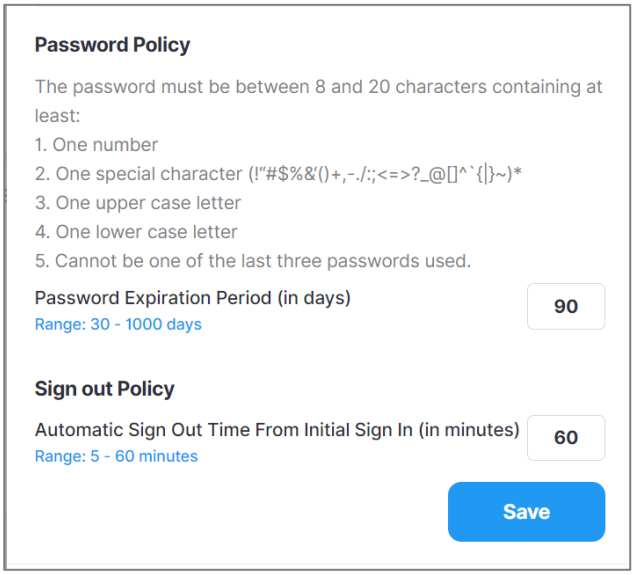
If your organization is set up for **Single Sign-On (SSO)** users can rely on SSO to sign in. Users can work with ImpediMed Technical Support to set up SSO.



6.1.3.1.3 Password and Sign Out Policy

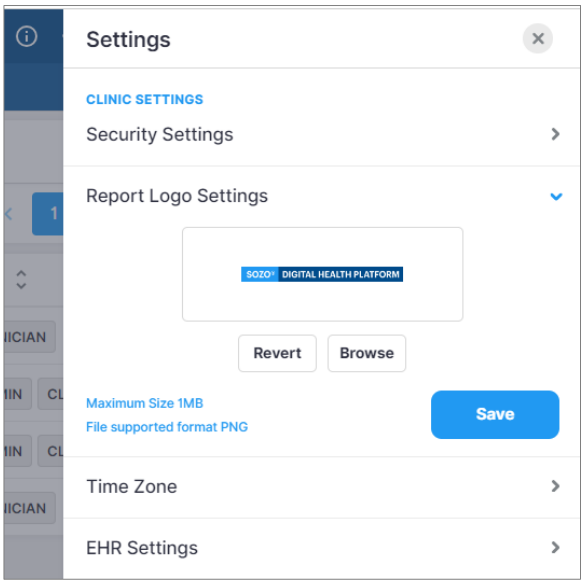
The Clinic Administrator can set the Password Expiration Period here. This defines the length of time which a user's password is valid. After this time period, the user is required to change their password. It can range from 30 to 1000 days.

The Clinic Administrator can also set the Sign out Policy here. This defines the length of time which a user remains signed into the SOZO Pro 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.



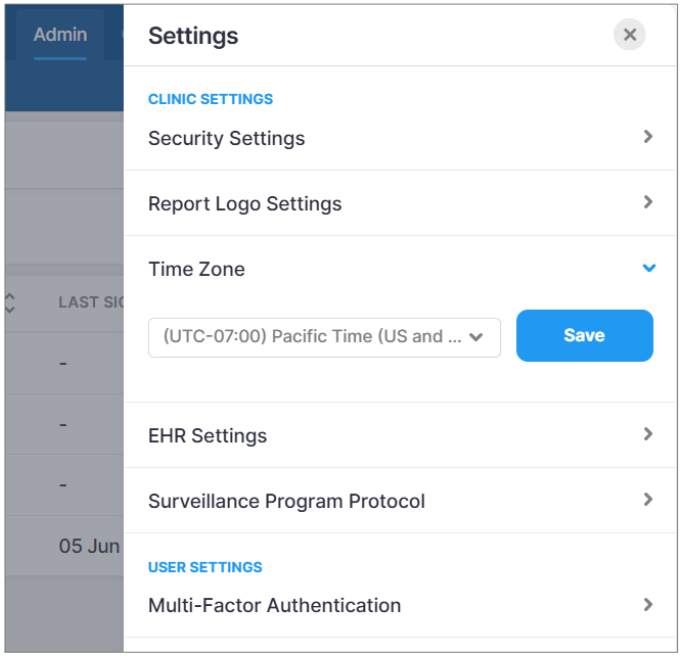
6.1.3.2 Report Logo Settings

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



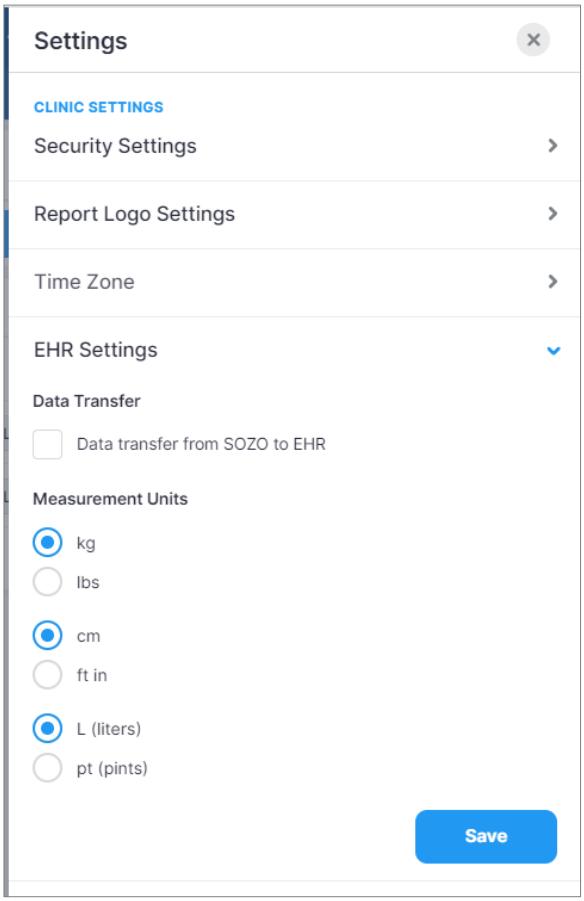
6.1.3.3 Time Zone

The Clinic Administrator can select the correct time zone here.



6.1.3.4 EHR Settings

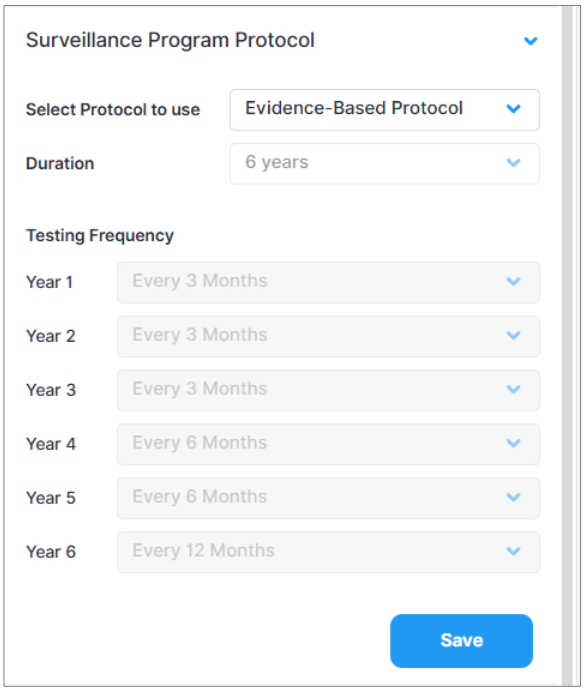
The Clinic Administrator can work with ImpediMed Technical Support during MySOZO set-up or contact ImpediMed Technical Support after the system has been installed, to set up the EHR Interface Settings. Full EHR interface configuration will require additional set-up outside of MySOZO to complete.



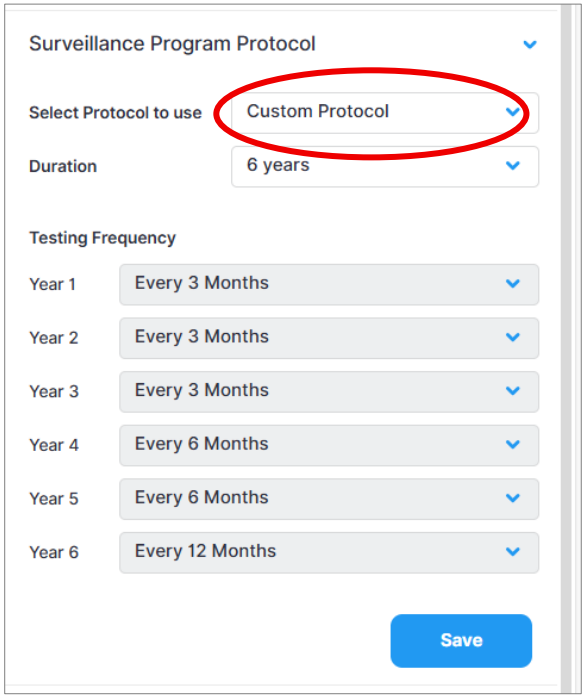
After the EHR interface has been established, the Clinic Administrator can start data transfer to an electronic health record by checking the data transfer box and select the measurement units for the transfer. Contact ImpediMed Technical Support for further details.

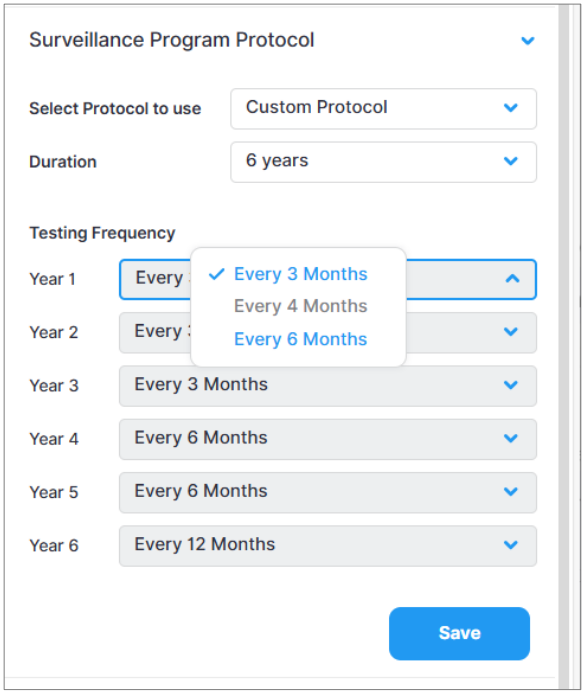
6.1.3.5 Surveillance Program Protocol

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



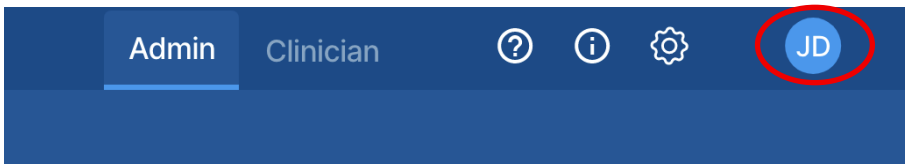
If Custom Protocol is selected, the Administrator can change the default Duration and then set the Testing Frequency for each year in the selected Duration years.





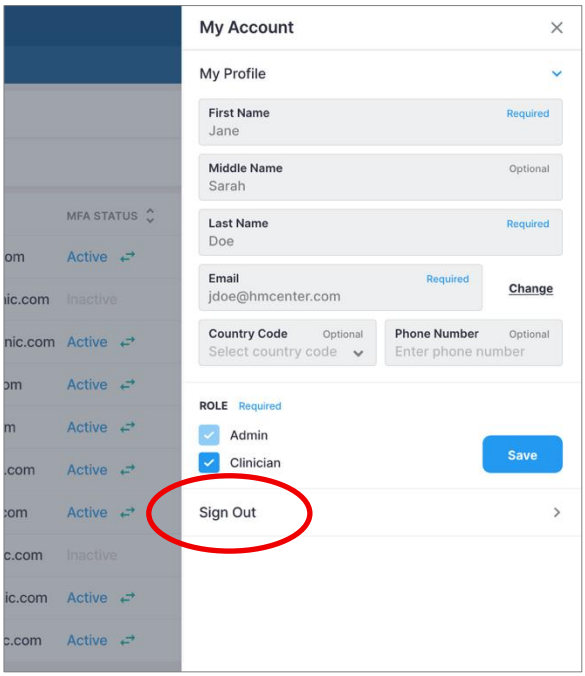
6.1.4 Administrator User Profile Icon

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



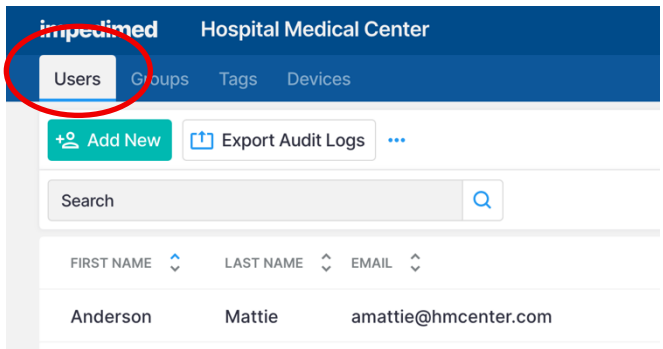
To review or edit the User profile, select the **User Profile** icon and then select **My Profile**.

To sign out of MySOZO at any time, select the **User Profile** icon then select **Sign Out**.



6.2 Administrator User List

Select the **Users** tab at any time to return to the User list on the MySOZO Administrator home page.



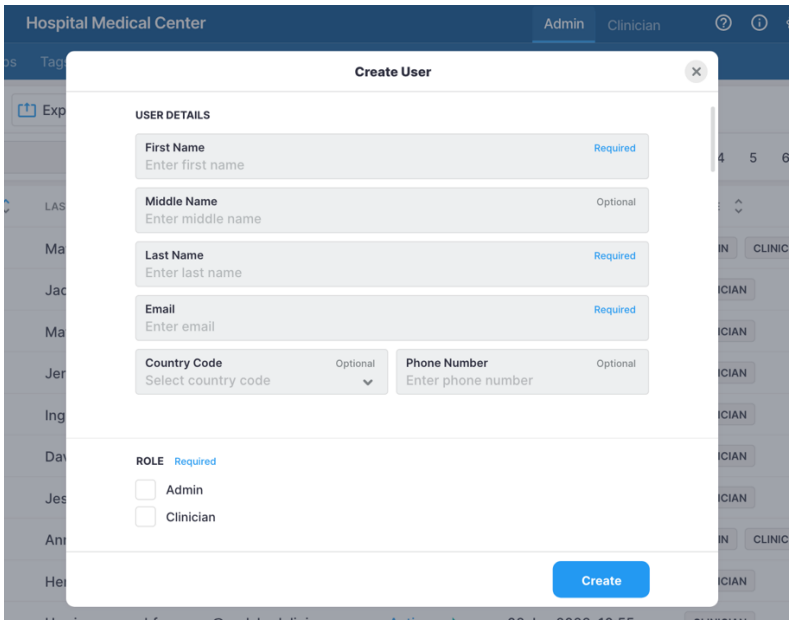
6.2.1 Create New User

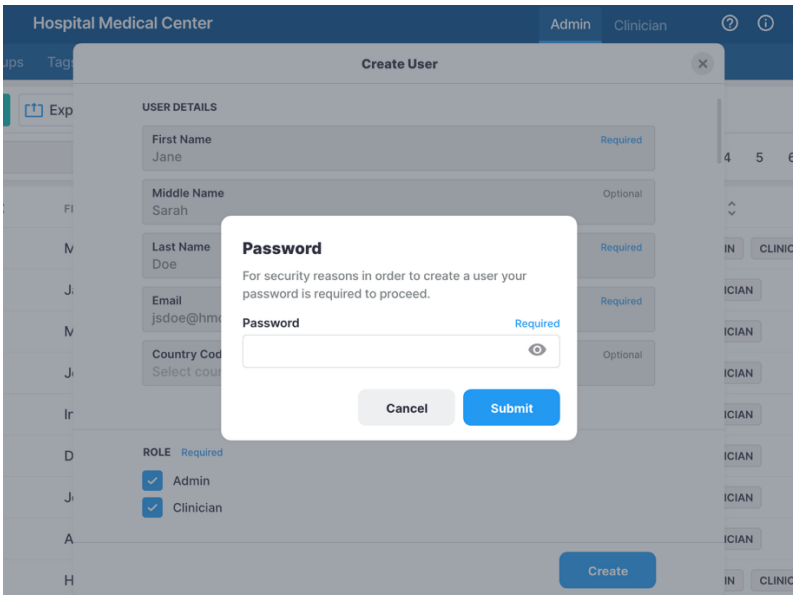
An Administrator creates a user by selecting **Add New**. The user may be assigned as an Administrator and/or Clinician. There is no limit to the number of users that can be created.

1. On the **Create User** screen, enter the user's first name, last name, and email address.

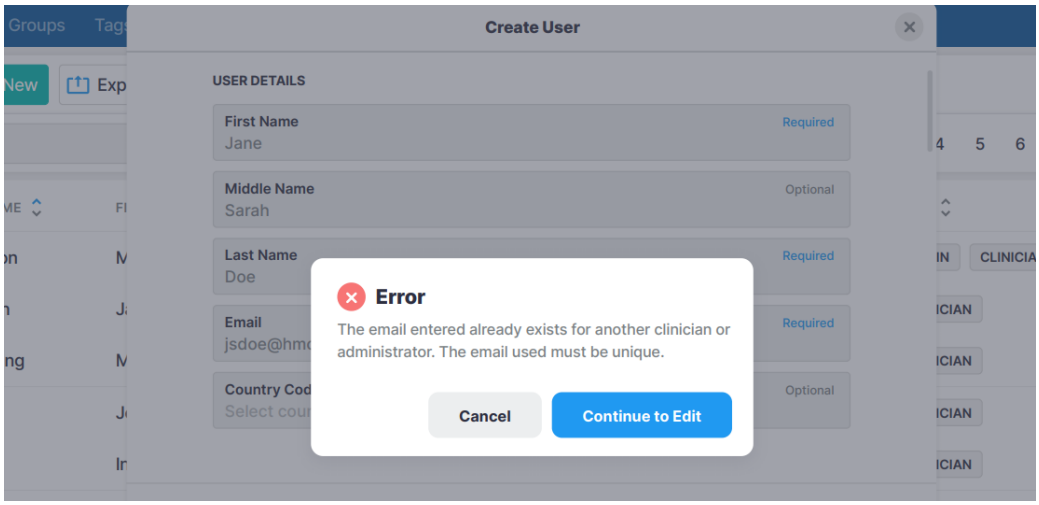
   The remaining fields, including middle name, country code, and phone number, are optional.

2. Under **Role**, select Administrator and/or Clinician.
3. When finished, select **Create** and enter the Administrator password.





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



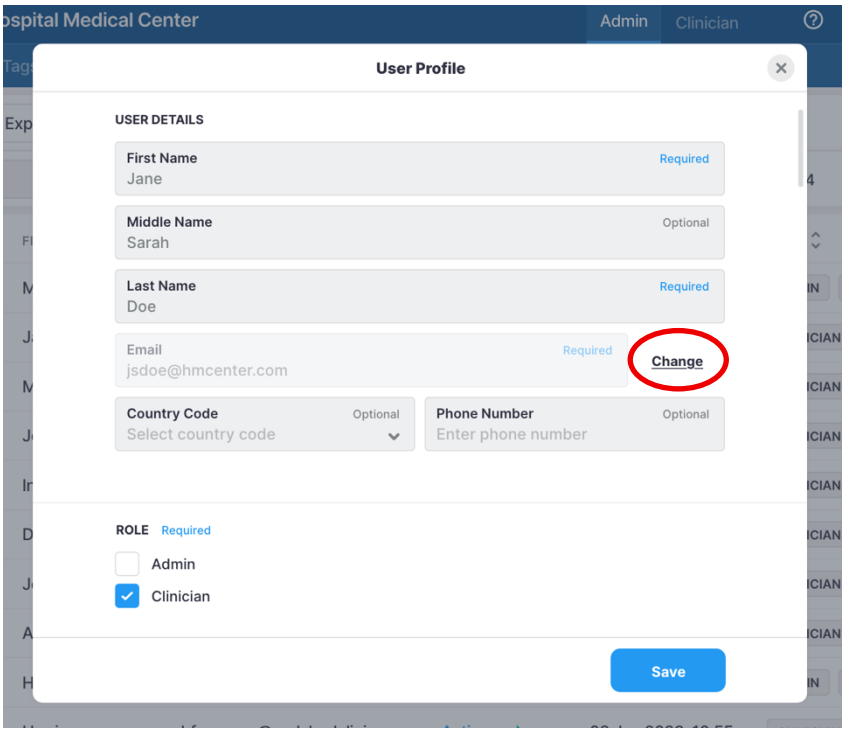
6.2.2 Edit User

An Administrator may edit a user profile by select the user's name. On the User Profile screen, the Administrator may update User information.

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

1. Make updates as needed.
2. Select **Save**.

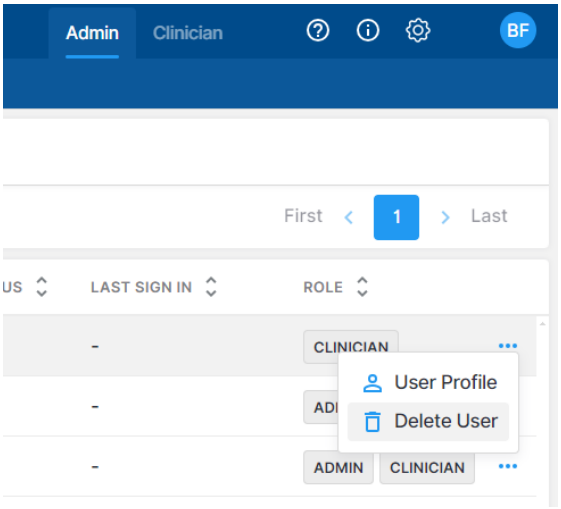
NOTE: Only an Administrator may edit a user's email address. A Clinician may edit their own email address but does not have authority to change another user's email address.

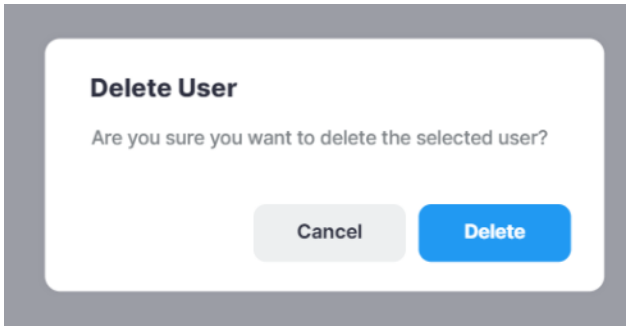


6.2.3 Delete User

To delete a user:

1. On the Users List, select the ellipsis located next to the user's role.
2. Select **Delete User**.
3. In the Delete User warning pop-up, select **Delete**.



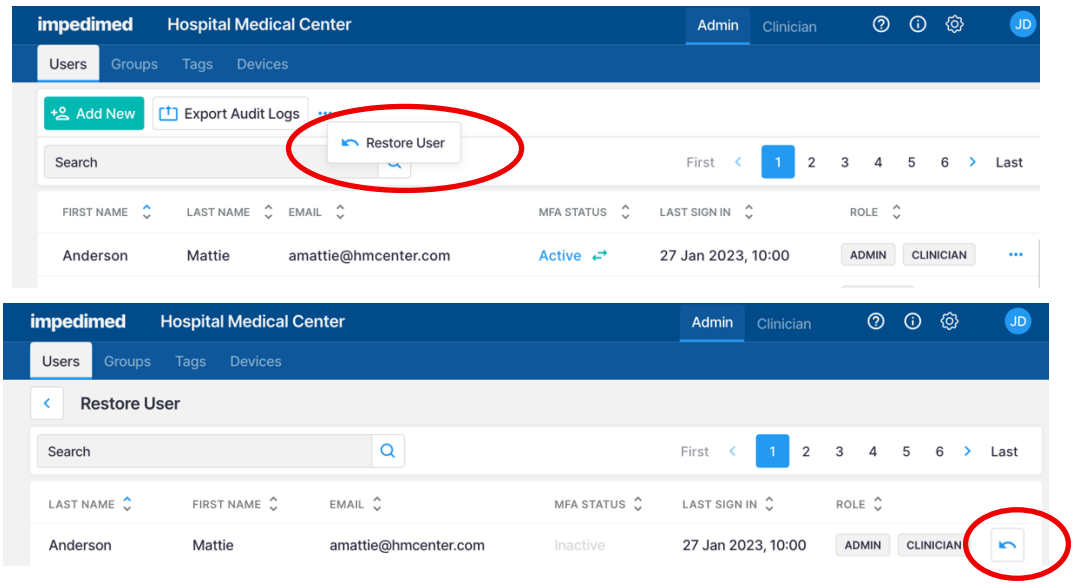


6.2.4 Restore User

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, select the ellipsis 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. Select the blue arrow to restore the user.
5. In the Restore User warning pop-up, select **Restore**.



6.2.5 Audit Logs

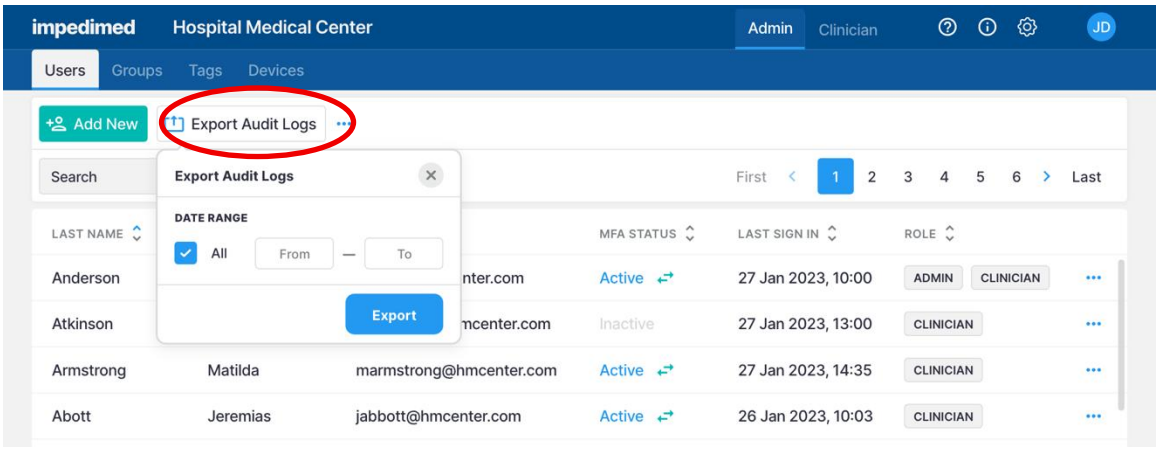
A user with Administrator role may access audit logs of all system access and events, to assist in any audit or investigation. Audit logs may be exported directly from MySOZO.

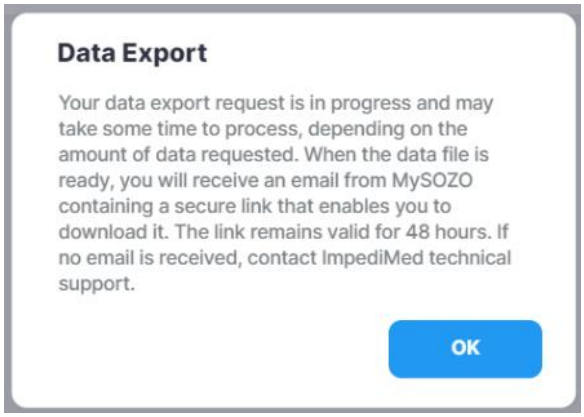
Audit logs include identity of users who have viewed certain MySOZO pages or information, identity of users who have retrieved data, users' sign in and log out dates and times, date and time of measurements, edits to patient or user profiles.

To export audit logs:

1. Select **Export Audit Logs**.
2. Enter dates in the To and From boxes to view audit logs from a specific date range. The default is set to "All".
3. Select **Export** to export logs. A message confirms that the data export request is in progress. Select **OK**.

4. ImpediMed will send the user an email containing a secure link to download the Audit Logs. The link is valid for 48 hours.

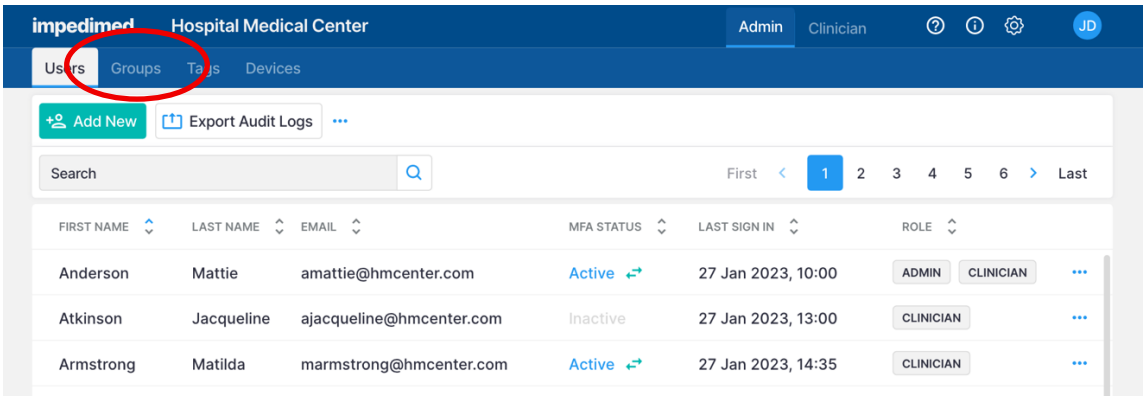




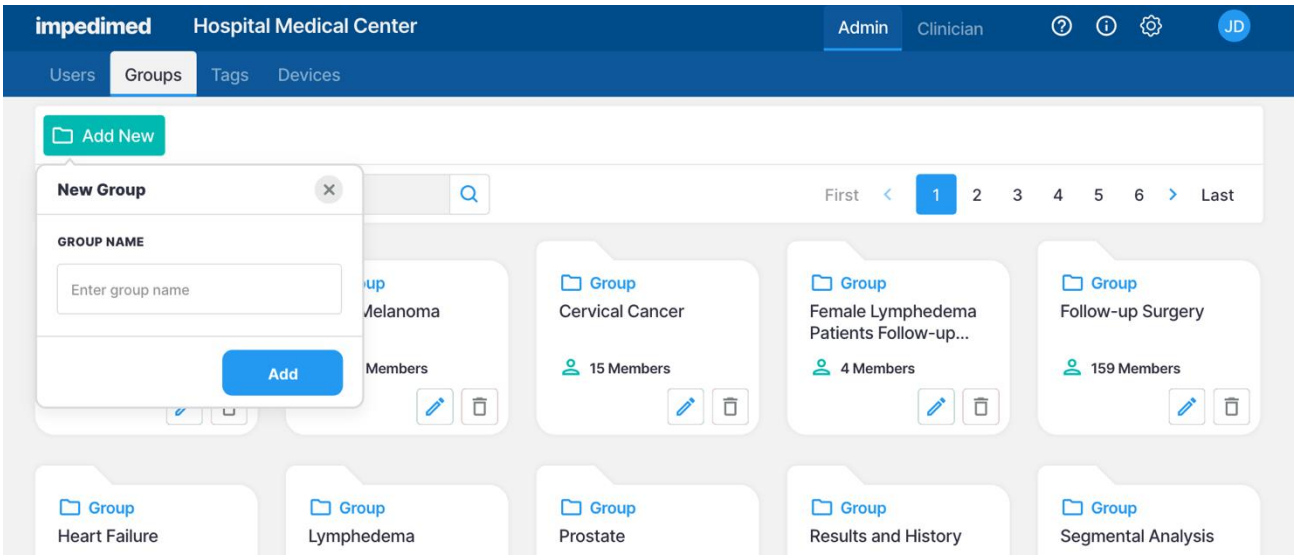
The file will be sent to the email address used to sign in; the file can be opened in Notepad. It will contain detailed logs including the date, time and actions undertaken by each user.

6.3 Administrator Patient Groups

Select **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, select the **Groups** icon to bring up the following screen:



6.3.1 Create a New Group

To create a new Patient Group:

1. On the Groups List, select **Add New** in the top left corner under the **Groups** tab.
2. Enter the group name.
3. Select **Add**. The new group folder will appear below with the other group folders.

6.3.2 Rename/Delete Group

To rename a Patient Group:

1. On the Groups List, select the blue pencil (edit icon) on the folder to be updated.
2. Update the Patient Group name.
3. Select the green check mark (save icon).

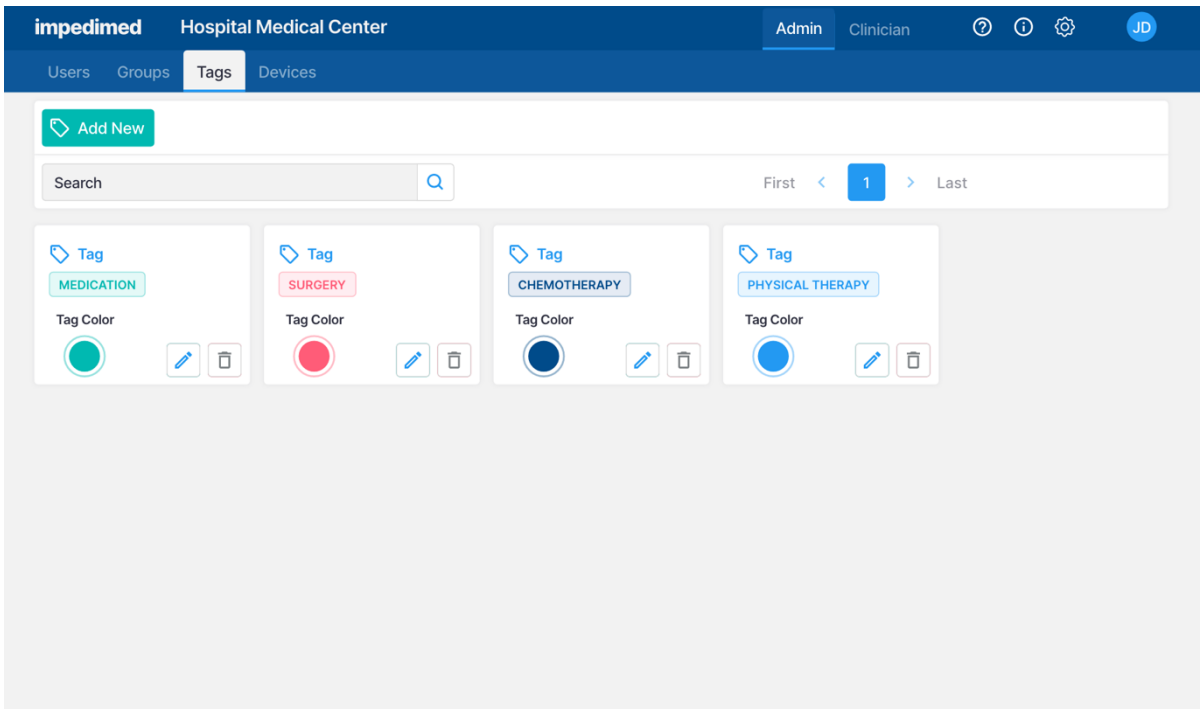
To delete a Patient Group:

1. On the Groups List, select the gray trash can (delete icon) on the folder to be deleted.
2. In the Delete Group warning pop-up, select **Delete**.

6.4 Administrator Patient Tags

Select **Tags** at any time to return to the Tags list on the MySOZO Administrator home page.

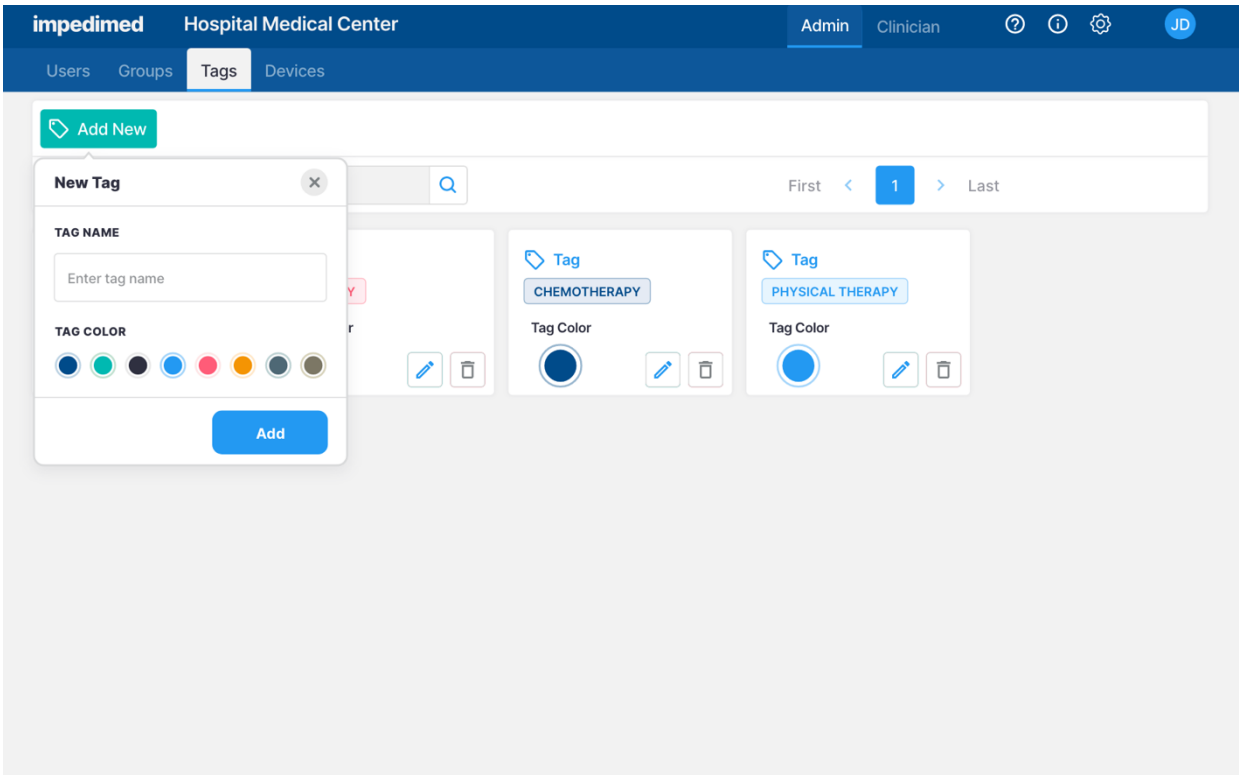
Tags are clinic-defined 48-character color-coded objects that can be attached to a given measurement by a clinician. They allow additional information to be linked to the measurement. The tags used within a clinic can only be managed by a user with an Administrator role.



6.4.1 Create a New Tag

To create a new Tag:

1. On the Tags List, select **Add New** in the top left corner under the **Tags** tab.
2. Enter the tag name and select a tag color.
3. Select **Add**. The new tag folder will appear below with the other tag folders.



6.4.2 Rename/Delete Tag

To rename a Tag:

1. On the Tags list, select the blue pencil (edit icon) on the tag to be updated.
2. Update the tag name.
3. Select the green check mark (save icon).

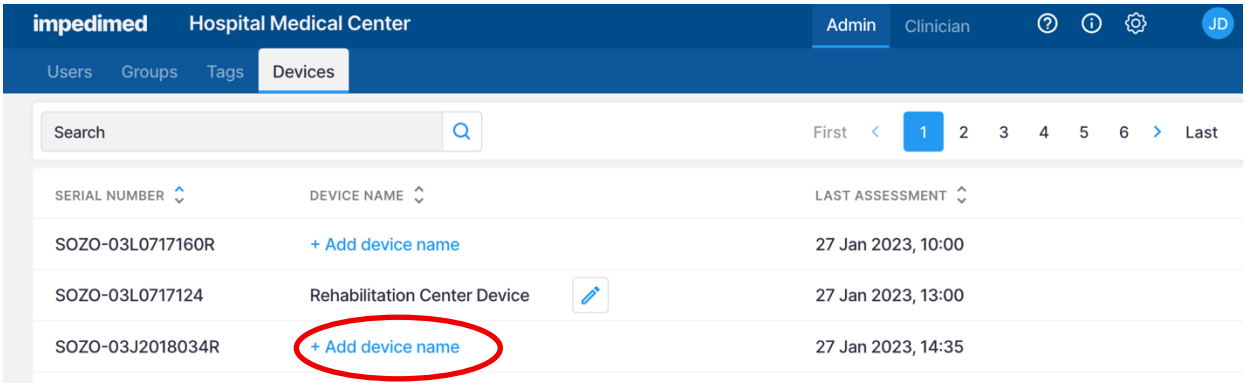
To delete a Tag:

1. On the Tags List, select the gray trash can (delete icon) on the tag to be deleted.
2. In the Delete Tag warning pop-up, select **Delete**.

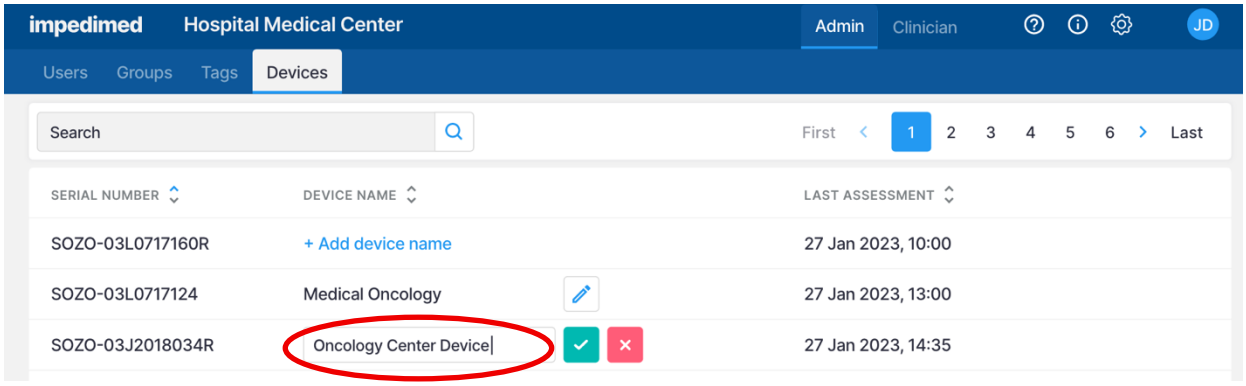
NOTE: When renaming a tag, it will be automatically renamed for all tags used to date. If a tag is deleted, it will remain assigned to all measurements but will no longer be available to be assigned to a measurement.

6.5 Naming a SOZO Pro Device

When setting up a new SOZO Pro 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, and select **+ Add device name** for the desired SOZO Pro device.



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



7 MYSOZO AND SOZOapp CLINICIAN

In the ImpediMed SOZO software, the MySOZO web site and the SOZOapp Tablet application are designed to share a nearly identical user interface and share many features and capabilities. The key differences are:

- SOZOapp on the Tablet is used to take patient measurements. You cannot take measurements using MySOZO.
- MySOZO on a PC is used to generate reports. You cannot generate reports using SOZOapp.

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

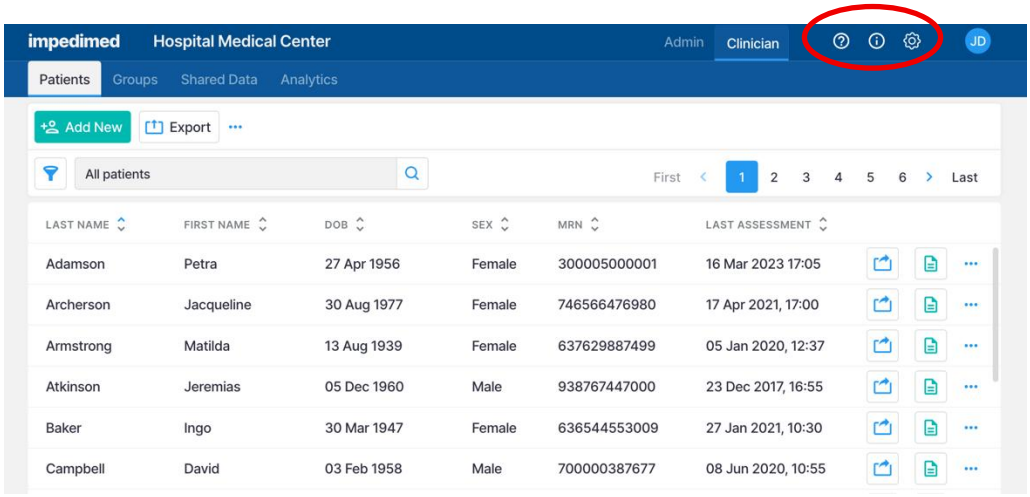
- Manage patient profiles
- Add/Remove patients to/from groups
- Add tags to patient measurements
- View and take patient measurements
- Export data or create reports
- Share data with other MySOZO users

7.1 Clinician Home Page

Clinicians, prior to signing in for the first time, must set a password and sign in per the instructions in 5.2.1, First Time Set-Up. After signing in, the MySOZO Clinician home page will display a blank Patient List. The full patient list can be seen by selecting the **Search** icon with a blank search field.

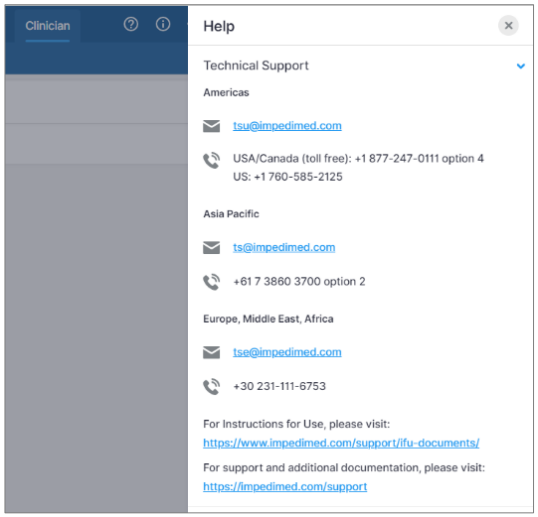
Any user may be assigned to both Clinician and Administrator roles. Users assigned a Clinician role will default to the Clinician role on initial sign-in; the icon will be displayed in bold and underlined. If a Clinician also has Administrator rights, they can toggle between Clinician and Administrator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

The functions for each icon at the top of the window (circled below) are described in the following sections.



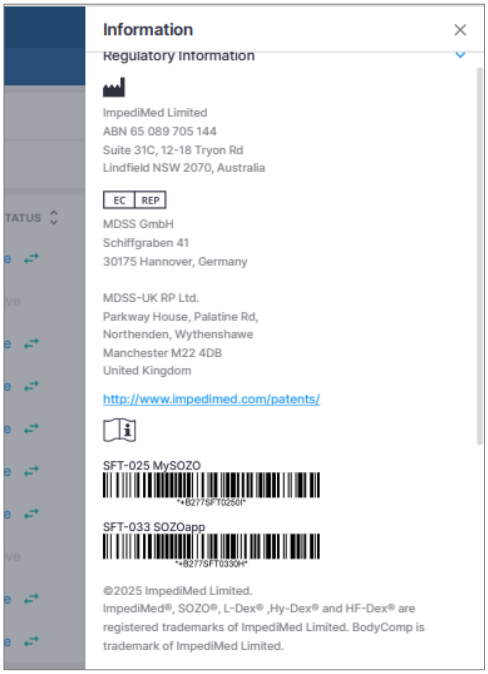
7.1.1 Help Icon

For assistance with use of MySOZO, select the **Help** Icon. The Help page includes (via the Technical Support dropdown) contact information for ImpediMed Technical Support and product Information.



7.1.2 Info Icon

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



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

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

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

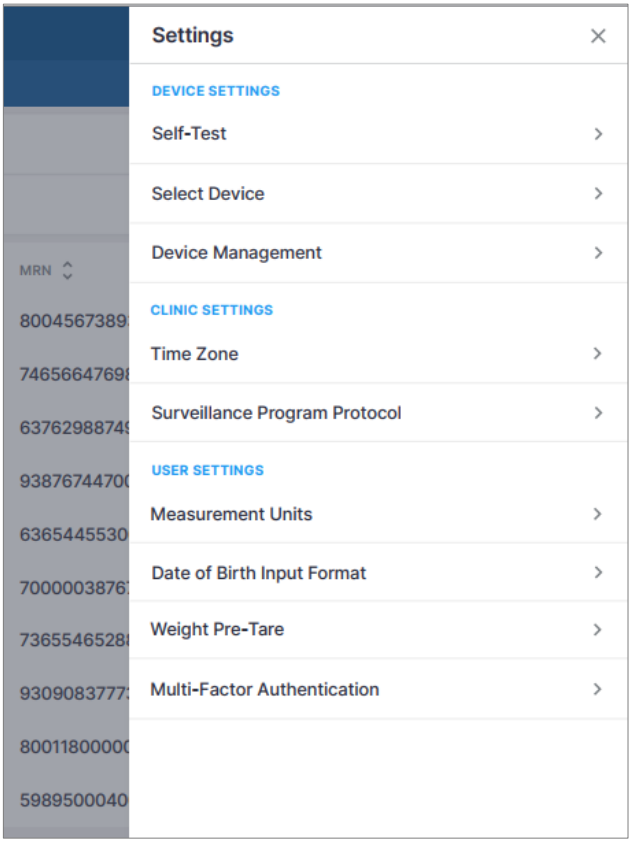
7.1.3 Clinician Settings Icon

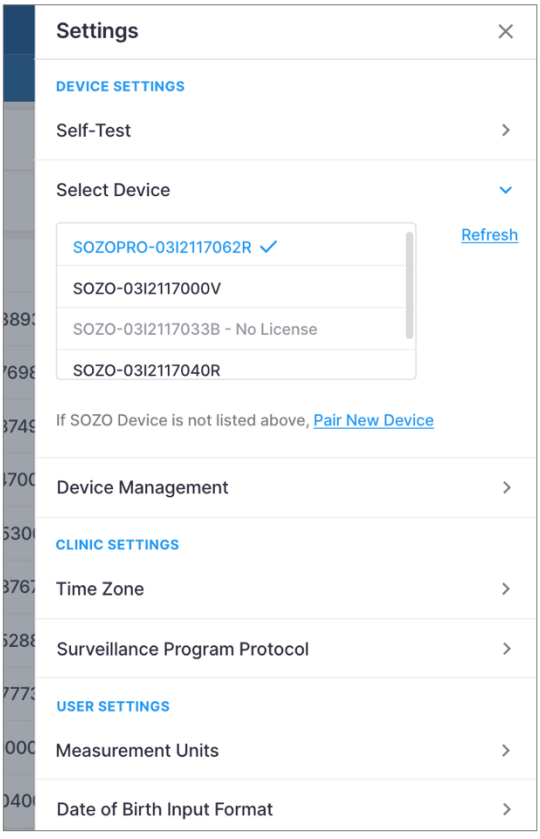
The Clinician may adjust some MySOZO settings by selecting Settings, located in the top right corner of the home page.

From the 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 Pro 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 licenses, the SOZOapp software information, and any applicable regulatory information. The first screenshot below is the Settings screen for software version 6.2. The second screenshot below is the Settings screen for software version 6.2 when a SOZO Pro device is paired.

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


Settings
DEVICE SETTINGS
Self-Test
Select Device
Device Management
MRN
CLINIC SETTINGS
Time Zone
Surveillance Program Protocol
USER SETTINGS
Measurement Units
Date of Birth Input Format
Weight Pre-Tare
Multi-Factor Authentication


Settings
DEVICE SETTINGS
Self-Test
Select Device
SOZOPRO-03I2117062R
SOZO-03I2117000V
SOZO-03I2117033B - No License
SOZO-03I2117040R
Refresh
If SOZO Device is not listed above, Pair New Device
Device Management
CLINIC SETTINGS
Time Zone
Surveillance Program Protocol
USER SETTINGS
Measurement Units
Date of Birth Input Format

7.1.3.1 Select and Pair Device

The Tablet must be paired with the SOZO Pro Device in order to take measurements.

NOTE: Android and iOS Tablets have different pairing approaches.

Whether pairing to Android or iOS Tablets, the SOZO Pro Device is identified by a serial number.

SOZO Pro devices will have the same Bluetooth ID for both iOS and Android and the Bluetooth ID will start with “SOZOPRO”.

The SOZO Pro Device serial number may be found on the:

- Back of the hand unit
- Bottom of the foot unit

The Tablet must be paired to any new SOZO Pro 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 Pro Device at a time.

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

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

7.1.3.1.1 Android

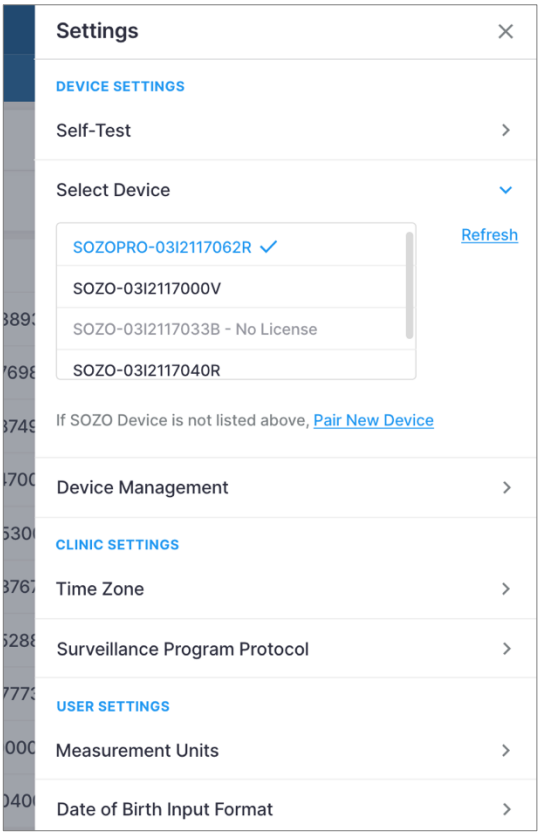
1. To use a SOZO Pro device with an Android Tablet for the first time, it first must be paired through the Android operating system.
    a. Locate Settings on the Tablet and enable *Bluetooth*®.
    b. Once *Bluetooth*® is enabled, the Tablet scans for connection to the SOZO Pro Device. Select **Pair new device** and select the SOZO Pro Device serial number.
    c. Alternatively, the Tablet settings can be accessed using the SOZOapp and navigating to the Settings page and selecting **Select Device**. Select the option to **Pair New Device** to open the Tablet Bluetooth settings.

    NOTE: If a SOZO Pro device has been previously paired with the Tablet, it will not be listed when adding a new device.

2. After the SOZO Pro device is paired, it must then be selected from the **Select Device** menu in SOZOapp Settings.

a. A list of SOZO Pro Devices that have been previously paired over Bluetooth will be displayed. If the paired device is not present, select **Refresh**.

b. Select the desired device and ensure that it is highlighted in blue with a tick mark next to it.



NOTE: Do not pair an Android Tablet to a SOZO Pro System whose serial number starts with “IOS-”. The Android SOZOapp will not be able to communicate with this SOZO Pro Device. If this occurs, choose a SOZO Pro Device with an identification that does not start with “IOS-”, or, navigate into the Bluetooth Settings menu to unpair the SOZO Pro Device.

7.1.3.1.2 iOS

a. The SOZO Pro 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 Pro Device.

b. Go directly to SOZOapp and sign in. From the Settings menu, choose **Select Device**, and select the appropriate iOS-compatible SOZO Pro Device (a serial number starting with “IOS-”).

c. In the Bluetooth pairing request message, select **Pair.** The selected SOZO Pro Device serial number will turn blue with a tick mark next to it.

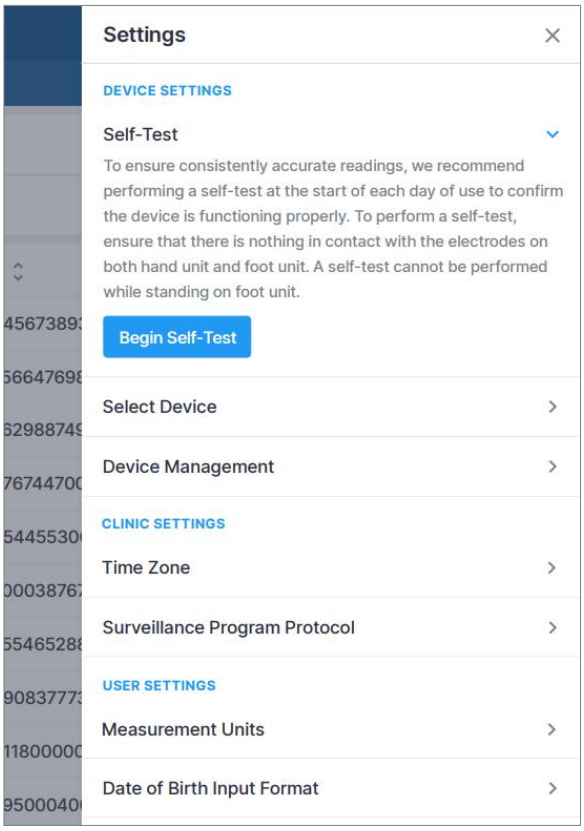
7.1.3.2 Self-Test

Self-tests may be run for different purposes.

- Device Status Confirmation: A self-test is optional to confirm connection to the correct SOZO Pro 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 select **Begin Self-Test**.
2. Follow additional instructions as prompted.



7.1.3.3 Device Management

From the Device Settings menu, select **Device Management**.

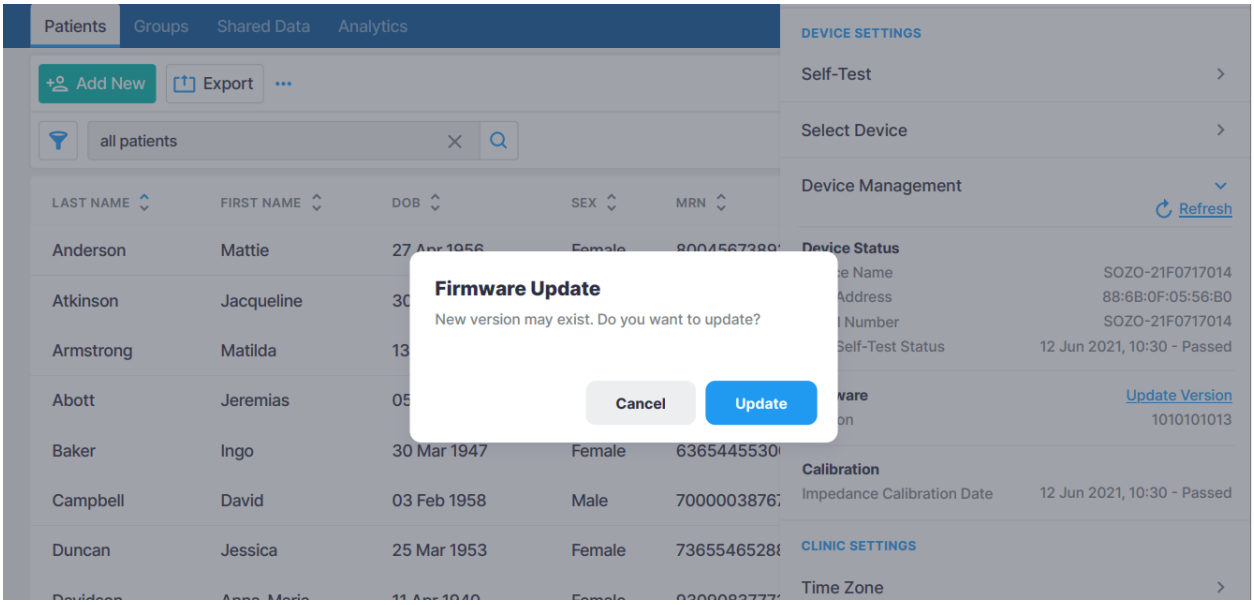
Once the Tablet is paired to a device, information about the device can be obtained by selecting **Refresh** next to **Device Management**.

Firmware

The SOZO Pro System firmware may be updated by selecting **Update Version** next to **Firmware**. This process may take several minutes. The Tablet and SOZO Pro Device

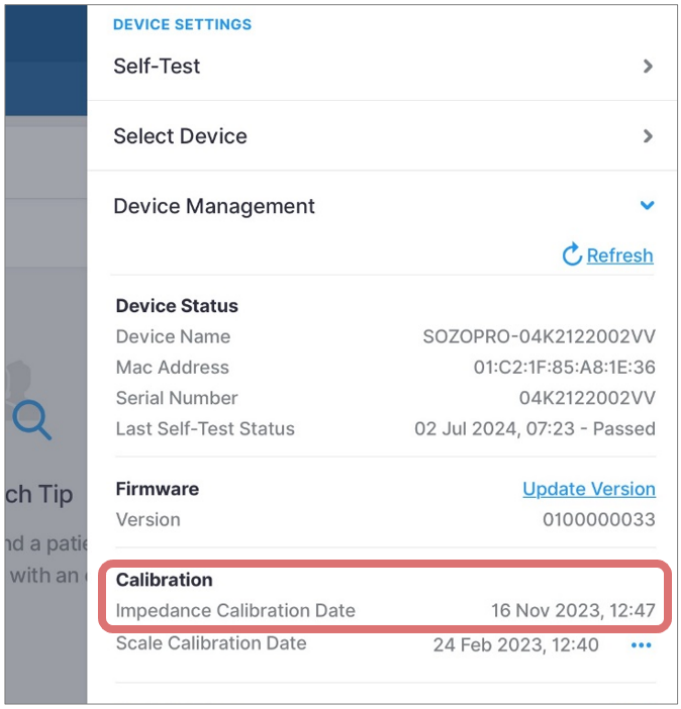
should not be turned off during this time and the Tablet screen timeout should be set to at least 15 minutes.

After completion of the firmware update, the firmware version should be checked by updating the device status to show the desired firmware version. The SOZO firmware version may be updated via SOZOapp using either an iOS or Android device.

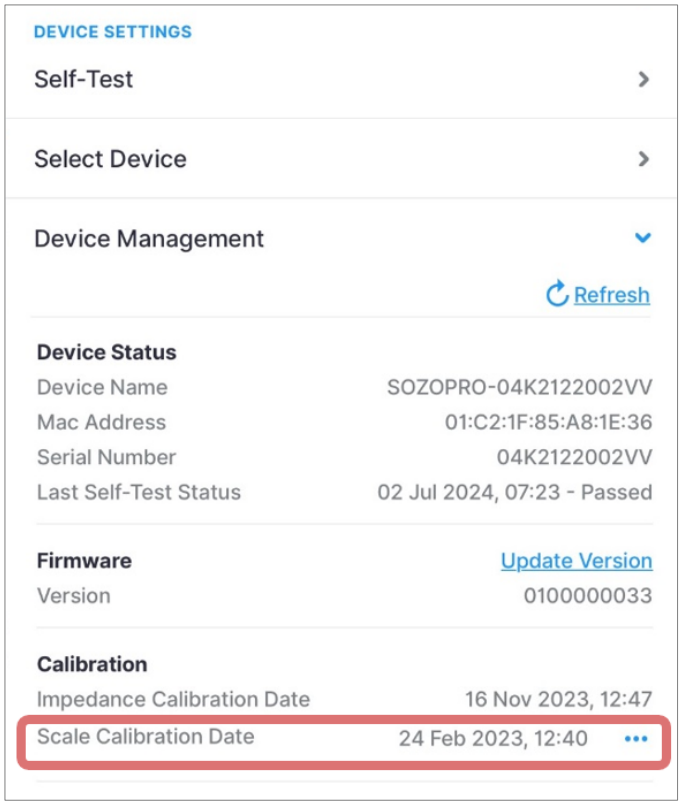


7.1.3.4 Calibration

The most recent impedance Calibration Date is displayed, example shown below.



For SOZO Pro devices, scale calibration information is also available.



For SOZO Pro devices, scale settings allow the user to:

1. Toggle between displaying or not displaying weight on the SOZO Pro hand unit's integrated screen.
2. Specify the weight measurement units (kg or lbs) to display on the SOZO Pro hand unit's integrated screen.

   NOTE: This setting controls the SOZO Pro display only and does not update the units shown in MySOZO or in the SOZOapp.

3. Tare or Zero the Scale. The Tare function should be used if an object that is not intended to be included in the weight measurement is added on the weight scale. It can also be used to zero the display if it is not displaying 0.0 when nothing is on the scale.

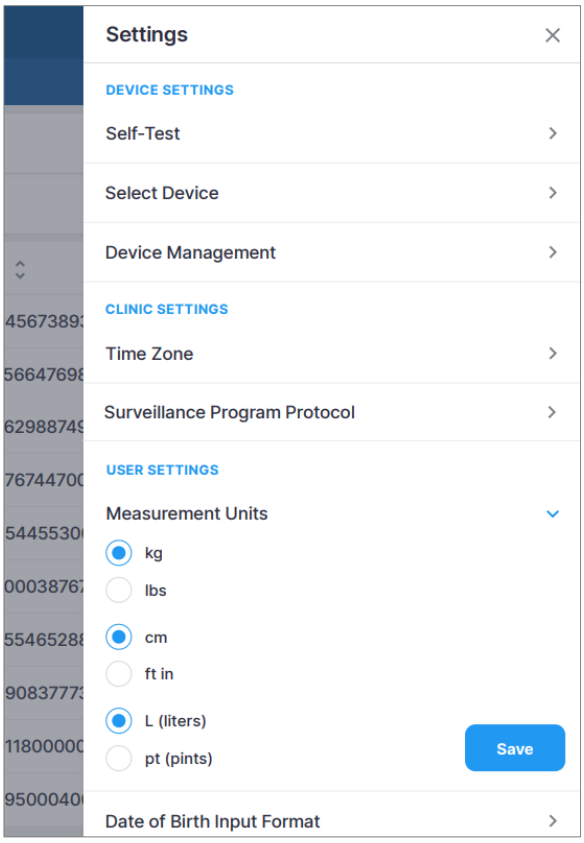
7.1.3.5 Time Zone

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

7.1.3.6 Measurement Units

The clinician can adjust preferred display units of measure (kg vs lbs; cm vs ft/in; liters vs pints) here. Once changes have been made, select **Save**.

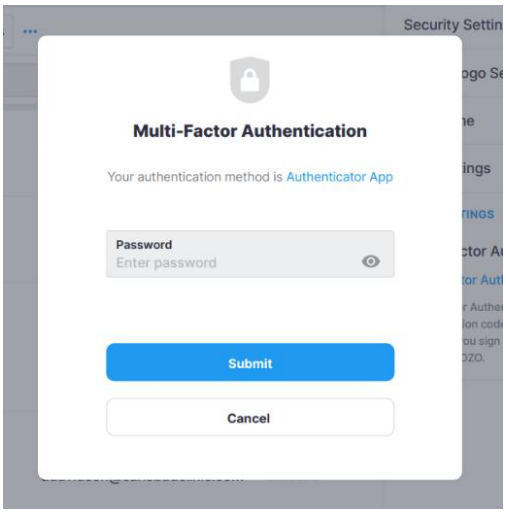
Under **Settings**, the display units for weight, height, and fluid volume may be selected. Kilograms may be converted to pounds, centimeters to feet and inches and liters to pints. When updates are complete, select **Save.**



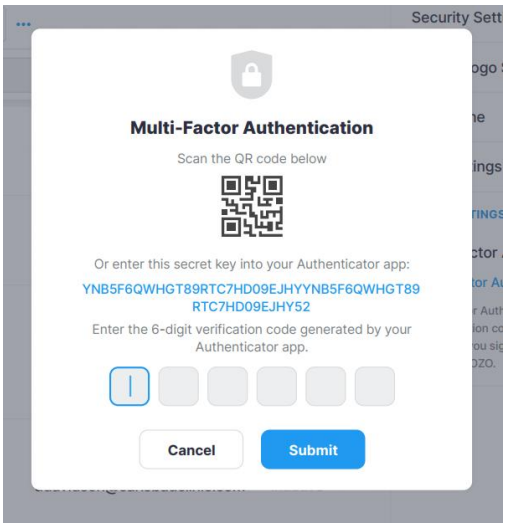
7.1.3.7 Clinician Multi-Factor Authentication

Once enabled by a Clinic Administrator (see 6.1.3.1.1, 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.

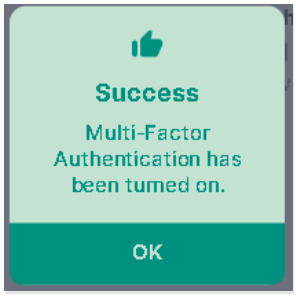
MFA will require use of a code generated by a 3rd party authenticator app (e.g., Google Authenticator; Microsoft Authenticator) that is compliant with the TOTP standard. Once the authenticator app is is set up, activate the MFA for the Clinician by using the slider under User Settings, Multi-Factor Authentication.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



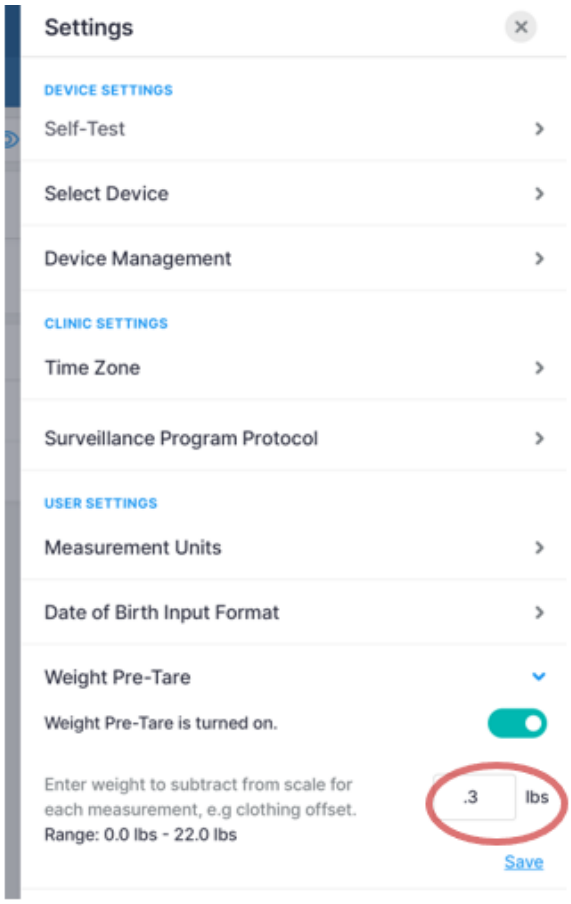
The Clinician will be signed out of the system, and from that point on, will have to use both a password and an MFA code to sign back in.

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.

7.1.3.8 Weight Pre-Tare

Within **Settings**, a Pre-Tare weight can be selected to account for weight of a patient's clothing while taking a bioimpedance measurement. Once the user toggles on (toggle will appear green) the "Weight Pre-Tare" capability, a user can select a tare weight of 0.0 lbs to 22.0 lbs by typing the desired value in the Tare Weight field. Once a tare weight is entered in the field, select **Save**.

Regardless of the value chosen, the Pre-Tare weight can be manually updated during the measurement process to account for variation between patients.

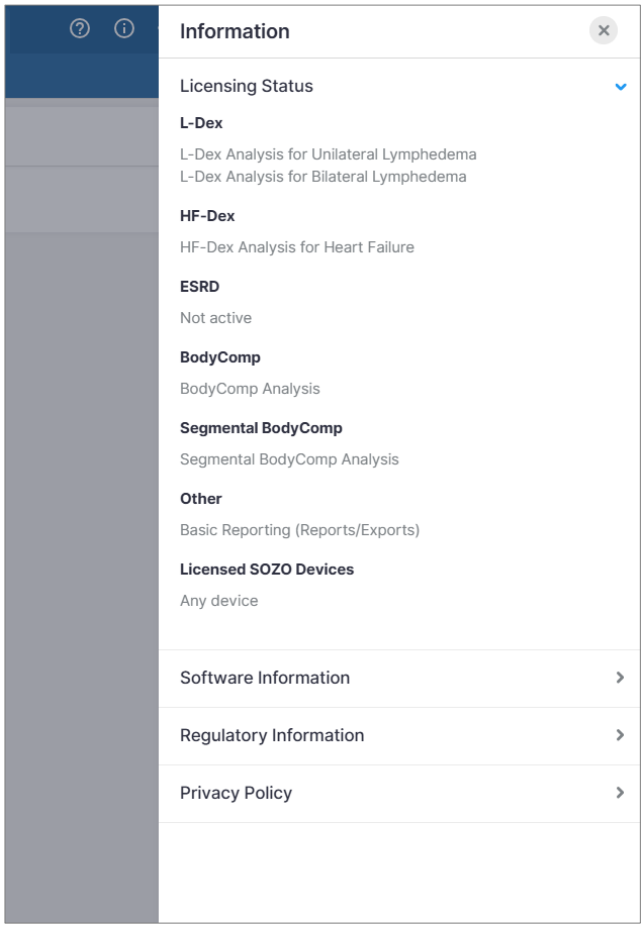


7.1.3.9 Technical Support

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

7.1.3.10 Licensing Status

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



7.1.3.11 Software Version

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

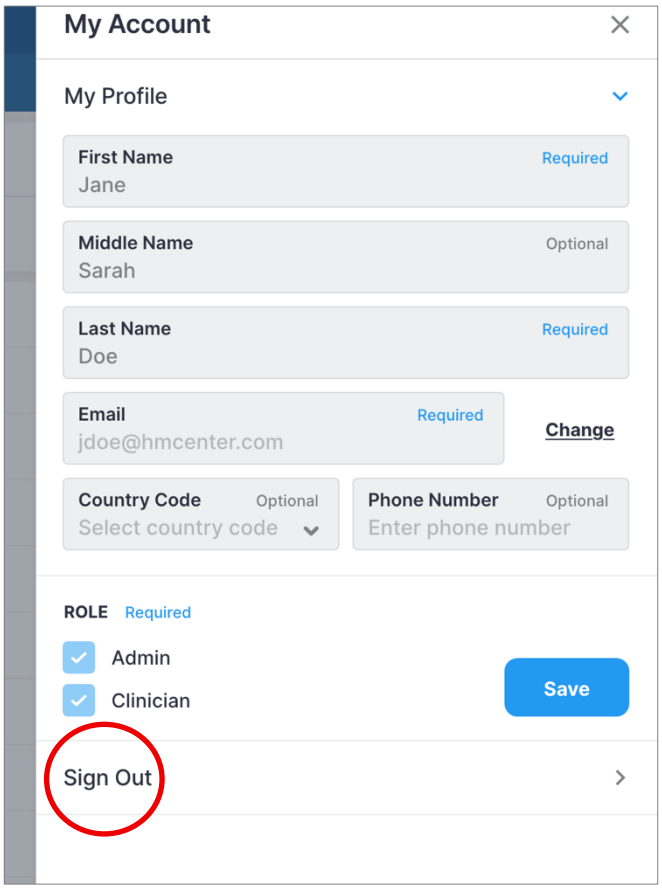
7.1.3.12 Regulatory Information

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

7.1.4 Clinician My Account Page

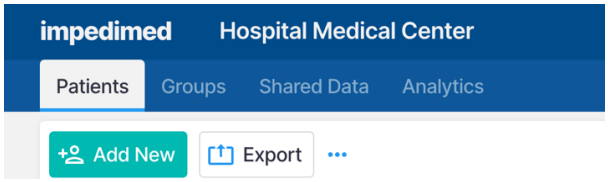
To edit the Clinician Account, navigate to the user initials in the blue circle (upper right) and select My Profile. Select **Save** once changes have been made.

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



7.2 Clinician Patient List

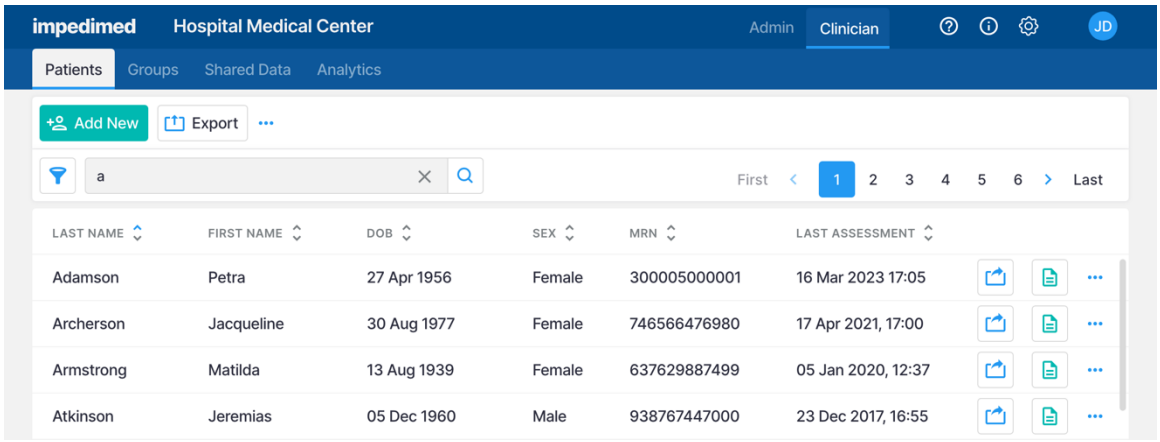
Select the **Patients** tab at any time to return to the Patient List.



7.2.1 Search for Patient

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

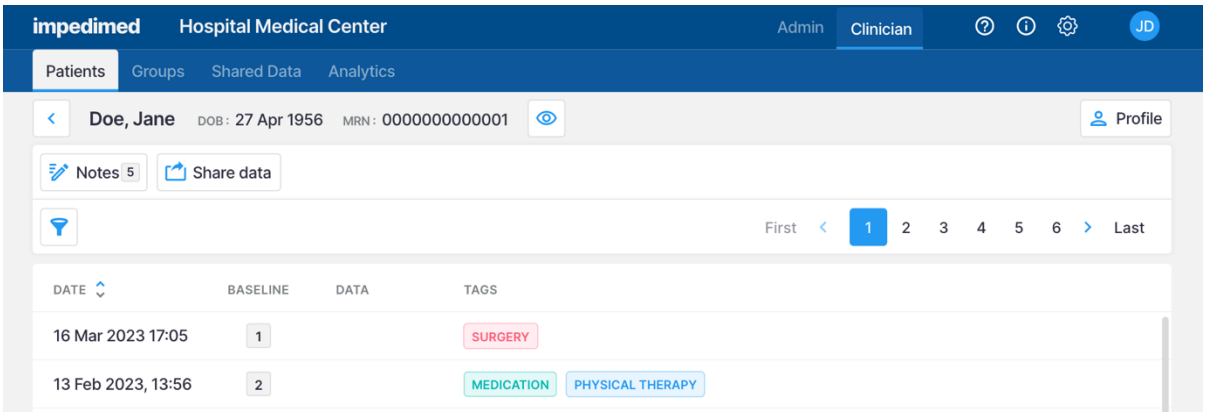
To generate a list of all patients in the clinic, leave the **Search Patient** Field blank and select the **Search** icon.



7.2.2 Patient Dashboard

To open the Patient Dashboard, navigate to the Patient List and search for the desired patient. Select 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.

If a L-Dex baseline has not been set, a "Missing Baseline" pop-up message will appear in the lower right corner of the screen. Select the **Set A Baseline** button in the message to go directly to the Set Baseline screen. After you have set the baseline and select **Save**, the system returns to the Patient Dashboard.

For instructions on setting the baseline for a specific assessment type (L-Dex, HF-Dex, and BodyComp), see the "Setting the Baseline" sections in 10, ASSESSMENT TYPES.

7.2.3 Create Patient

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

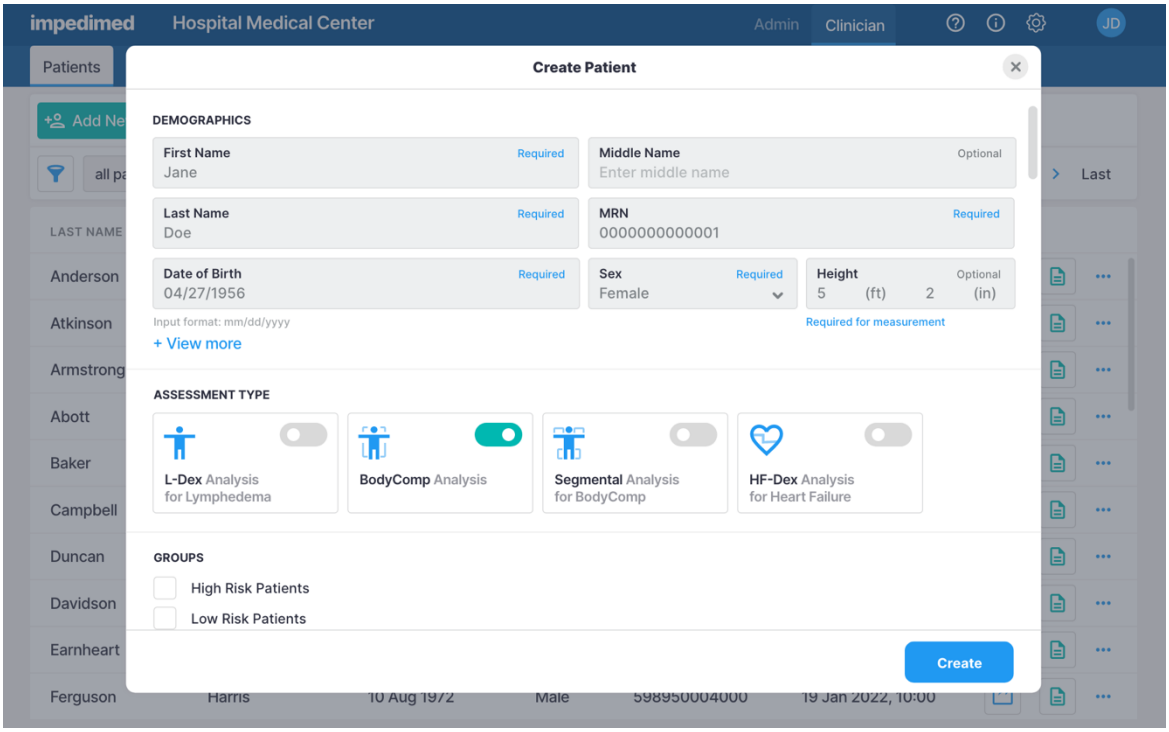
To create a Patient:

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: 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 Jane Doe. The next step will show that L-Dex assessment type has been selected for Jane Doe.

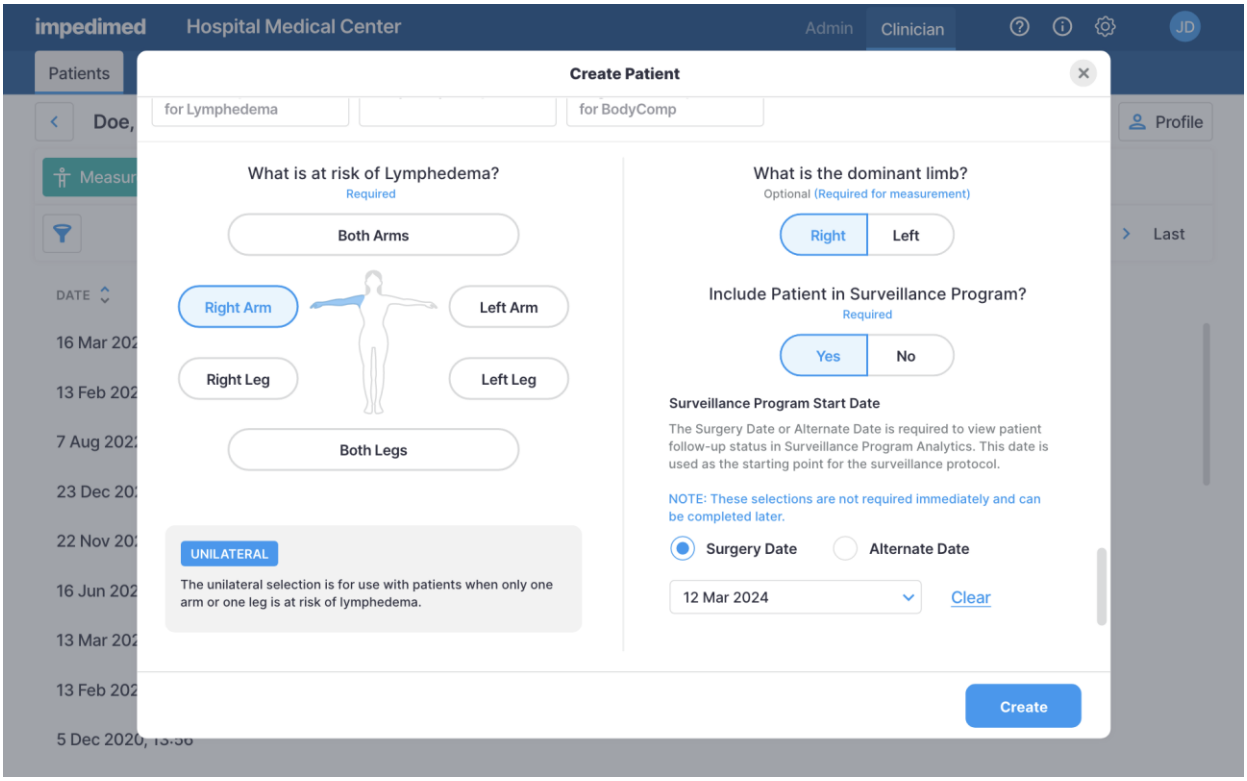


5. If you select L-Dex Analysis Assessment Type, select all required L-Dex assessment information.

   NOTE: Surgery Date and Alternate Date are not required at the time of patient creation and can be added later. Not all patient profile fields (e.g., dominant limb) are required for patient profile set-up.

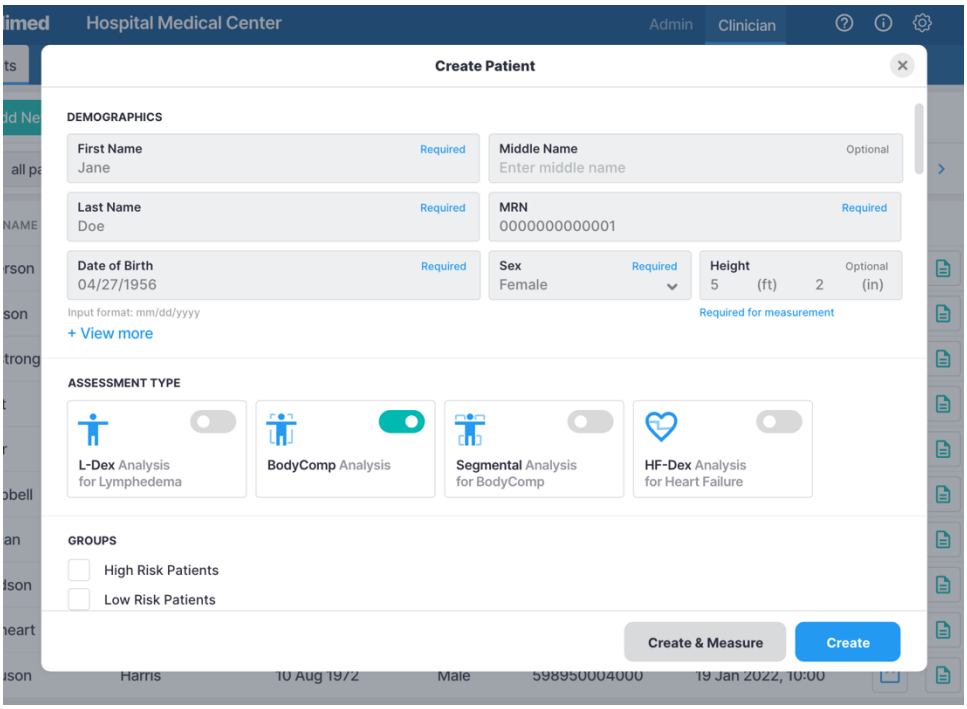
6. If the patient is being monitored as part of the Lymphedema Surveillance Program, select **Yes** in response to “Include Patient in Surveillance Program?”.

   In the example screen image below, patient Jane Doe is at risk of Lymphedema in her right arm (only one arm is at risk; therefore, this will indicate a Unilateral measurement), her dominant limb is on her right side, and her surgery date of 12 Mar 2024 has been entered. Additionally, this patient will be included in the Surveillance Program (for information on the surveillance program, see 7.5, Clinician L-Dex Analytics).



7. When you have finished filling in all required information, select **Create.**

   Alternatively, from the Tablet, you can proceed directly to taking a measurement. To do this, select **Create & Measure**. (See 9, TAKING MEASUREMENTS.)



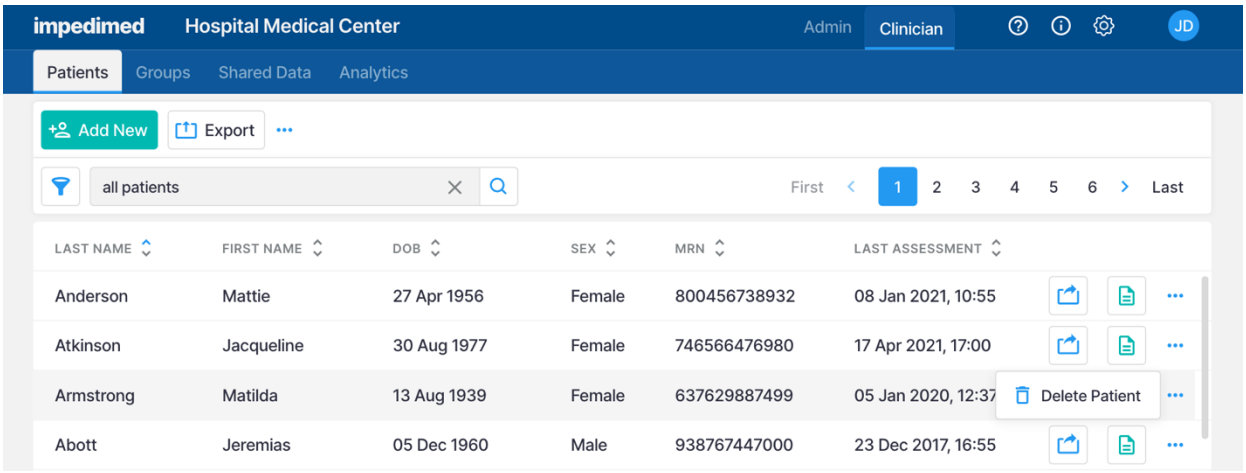
NOTE: The clinician may optionally assign the patient to a predefined group. If grouping has been set up in the clinic, a list of available groups will appear at the bottom of the create user window. Check the box for each group the patient is to be assigned to.

NOTE: Adding a new assessment to the patient profile may trigger a caution about the intended use of that assessment. Ensure that you understand the instructions for use for L-Dex (see 10.2, L-Dex® for Lymphedema Instructions for Use) and HF-Dex (see 10.3, HF-Dex® for Heart Failure Instructions for Use).

7.2.4 Delete Patient

To delete a Patient:

1. Complete a search for the patient to be deleted from the Patients List.
2. Select the ellipsis located next to the patient's information.
3. Select **Delete Patient**.
4. In the Delete Patient warning pop-up, select **Delete**.

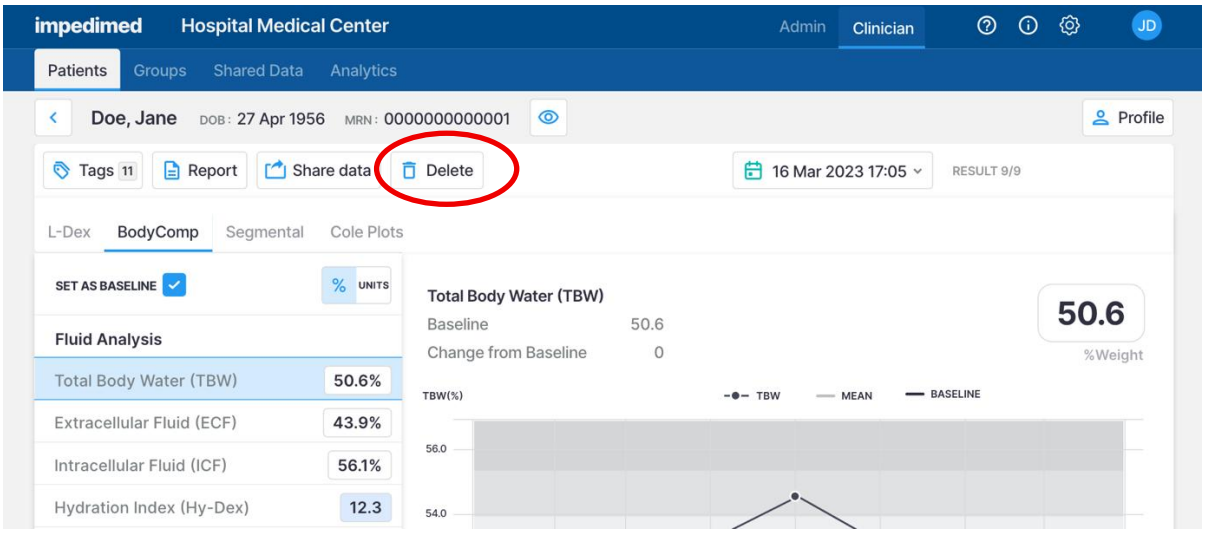


NOTE: The patient will remain in the MySOZO database and may be restored. To permanently remove a patient and all measurement details from the MySOZO database, please contact ImpediMed Technical Support.

7.2.5 Delete Measurement

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 select the **Delete** icon.

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

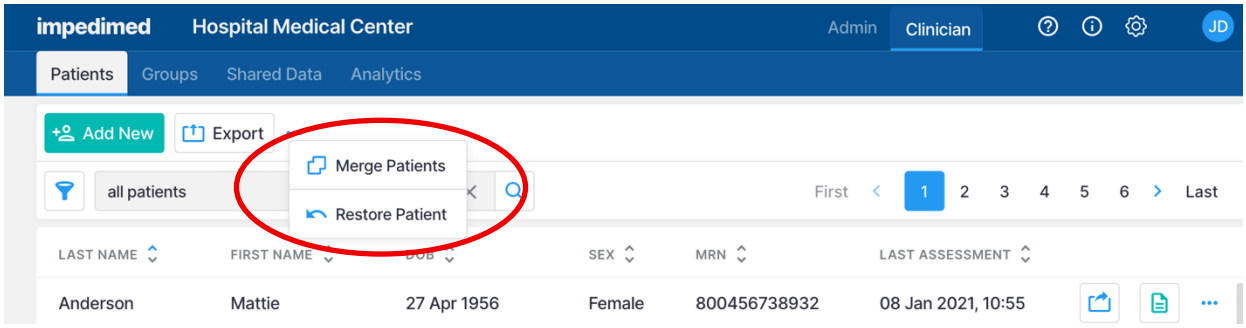


7.2.6 Restore Patient

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 Patients List.
2. Select the ellipsis 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. Select the blue arrow to restore the Patient.
6. In the Restore Patient warning pop-up, select **Restore**.



7.2.7 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. Select the ellipsis located above the search field, 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 verifying the information, select **Merge**.

NOTE: After you select **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.

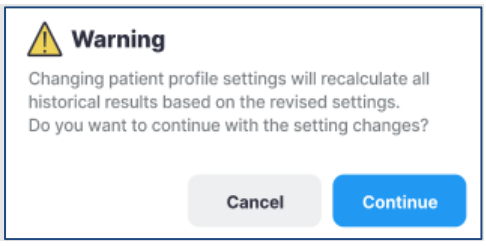
NOTE: If the merged patients have imported L-Dex data from a non-SOZO ImpediMed device such as the L-Dex U400, the imported measurements will not be shown if the patient L-Dex settings are different. For example, if imported U400 data assessed a patient's leg and the data is merged with a patient whose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

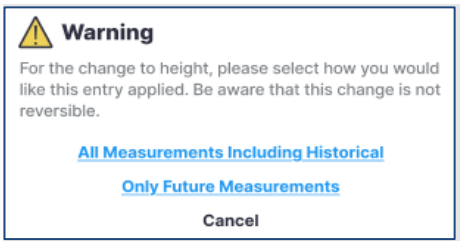
7.2.8 Edit Patient Profile

To edit a patient profile:

1. Navigate to the Patient List.
2. Search all patients by selecting the magnifier icon, or enter the patient's name or MRN.
3. Select the **Search** icon and then select the Patient.
4. Select the **Profile** icon.
5. Make updates as needed.
6. Select **Save**.

After you make 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, select **Only Future Measurements** to maintain old Assessments according to previous profile settings. This is appropriate for patients whose height has changed due to age or other factors.

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

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

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

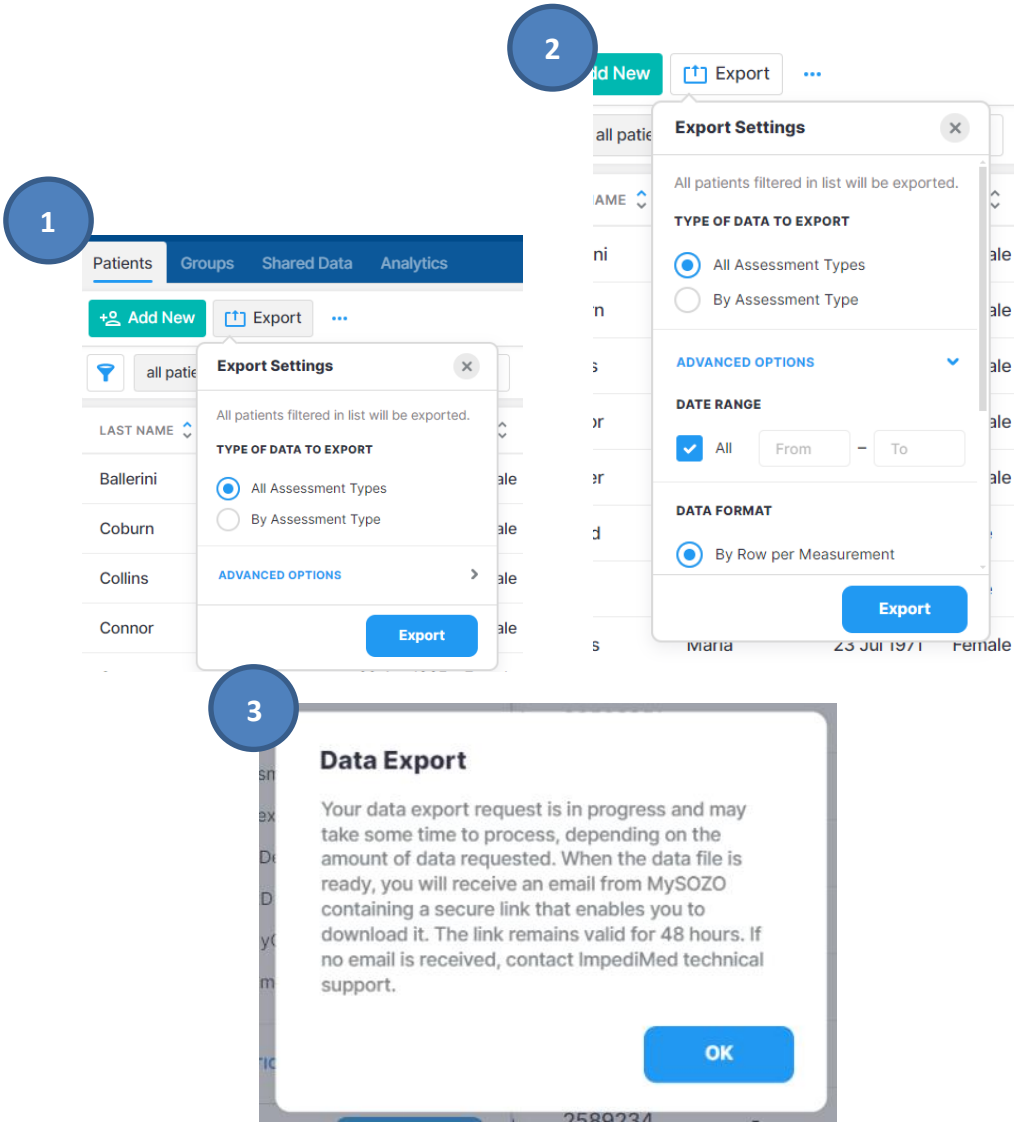
  L-Dex data (at-risk limb, dominant limb) is shown in the patient profile when the L-Dex Assessment is selected.

  NOTE: Deselecting the L-Dex Assessment will grey out the patient L-Dex settings, which will not be saved.

7.2.9 Export Patient Data

A Clinician may export patient data from MySOZO. To export data, select 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, select **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 customize the patient data export, including whether patient data should be de-identified, additional patient details, whether patients are in a predefined Group, and device/measurement information. The report will only present the options that are selected.



7.2.10 Shared Data

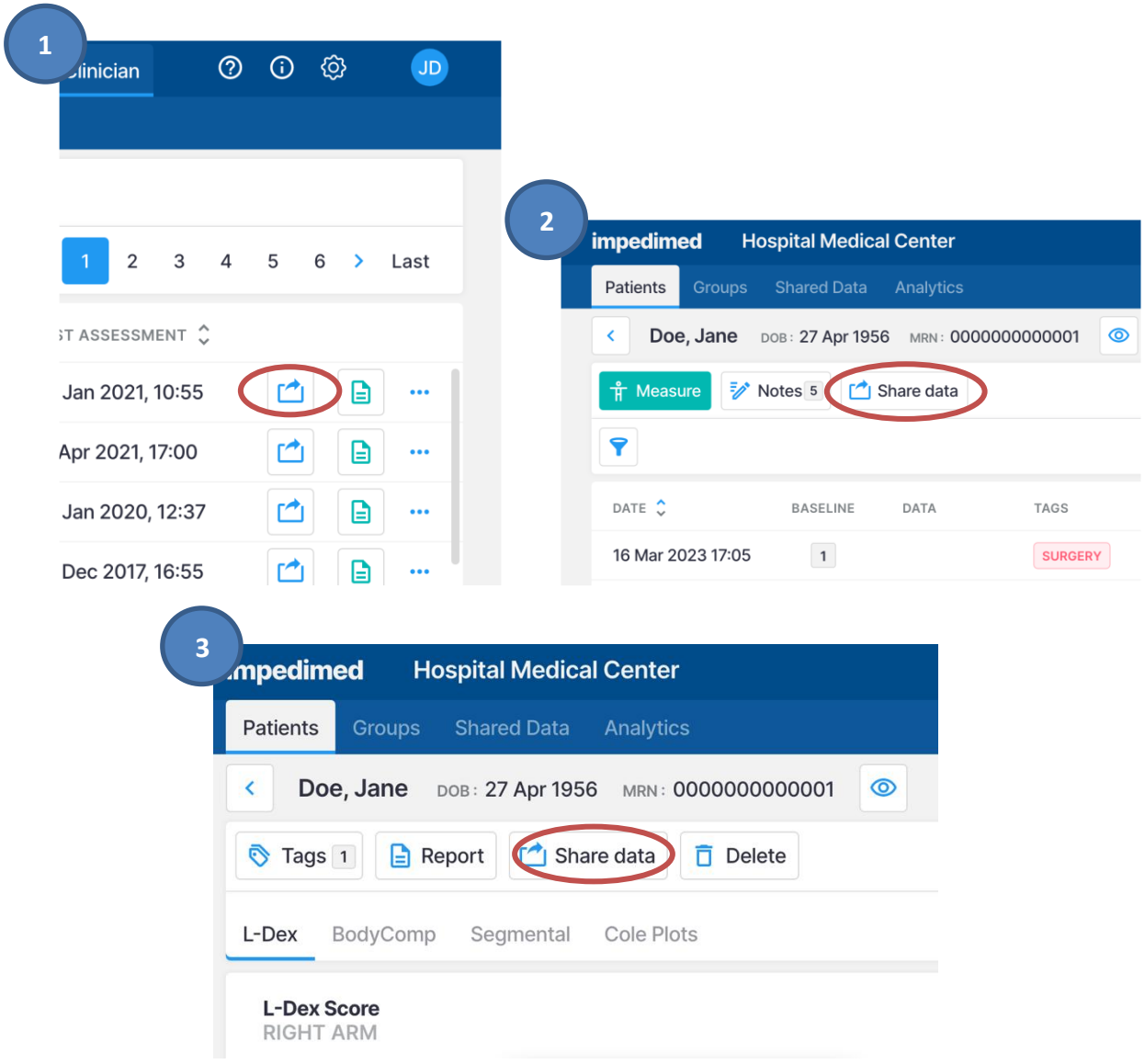
Shared data allows for sharing of patient data between clinics that are not on the same database to enable a continuous view of patient trending data across care teams.

NOTE: 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.

7.2.10.1 Sharing Data

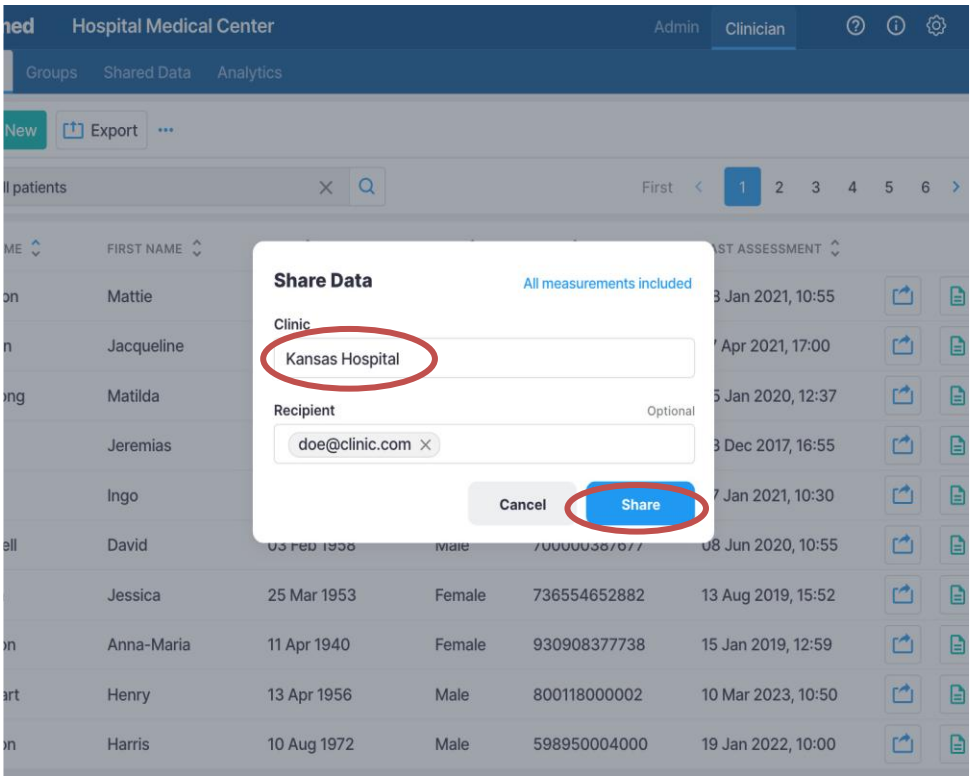
Data can be shared from 3 locations:

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**.

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



7.2.10.2 View Outgoing Data

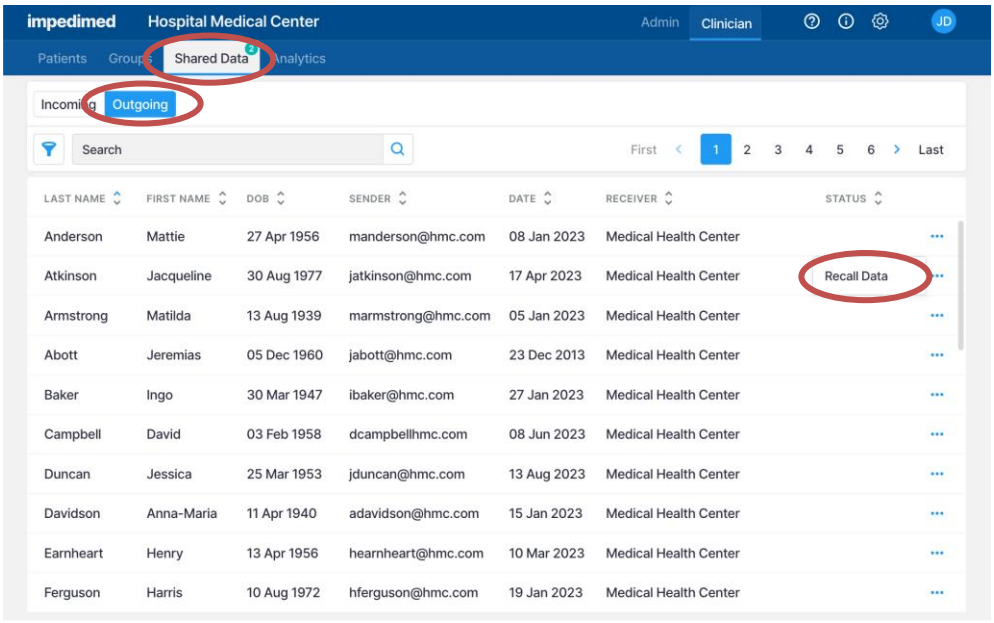
To view data that you have shared, first select the **Shared Data** tab, then select **Outgoing**. From there, you can view a list of patients where data has been shared and filter and sort the list using any of the arrows listed above the columns.

7.2.10.2.1 Recalling Shared Data

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

- Select the eye icon to view recall details.

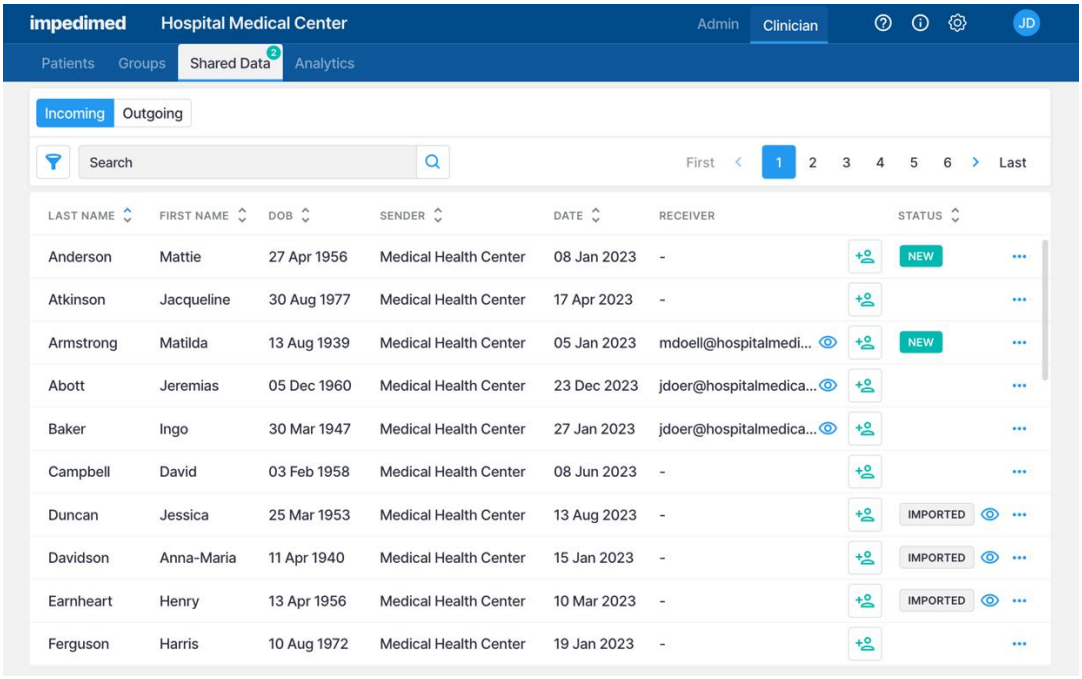
NOTE: If the receiving clinic has already imported the shared data, it cannot be recalled.



7.2.10.3 View Incoming Data

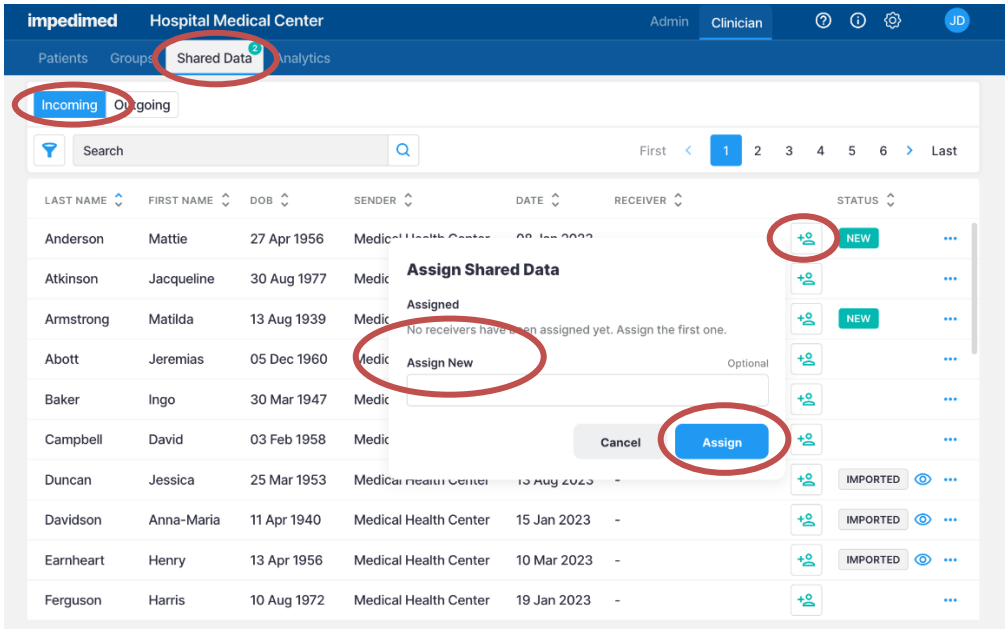
To view data that has been shared with you, first select the **Shared Data** tab, then select **Incoming.** From there, you can view a list of patients where data has been shared and filter and sort the list using any of the arrows listed above the columns.

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



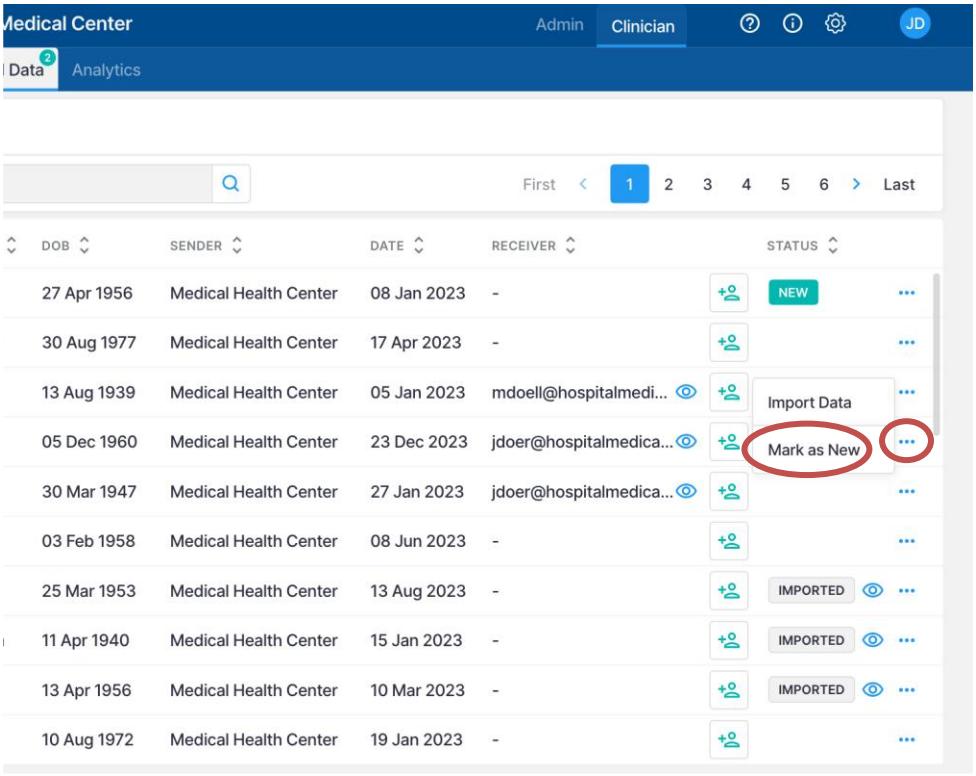
7.2.10.3.1 Add other Receivers to Incoming Data

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.



7.2.10.3.2 Mark as New

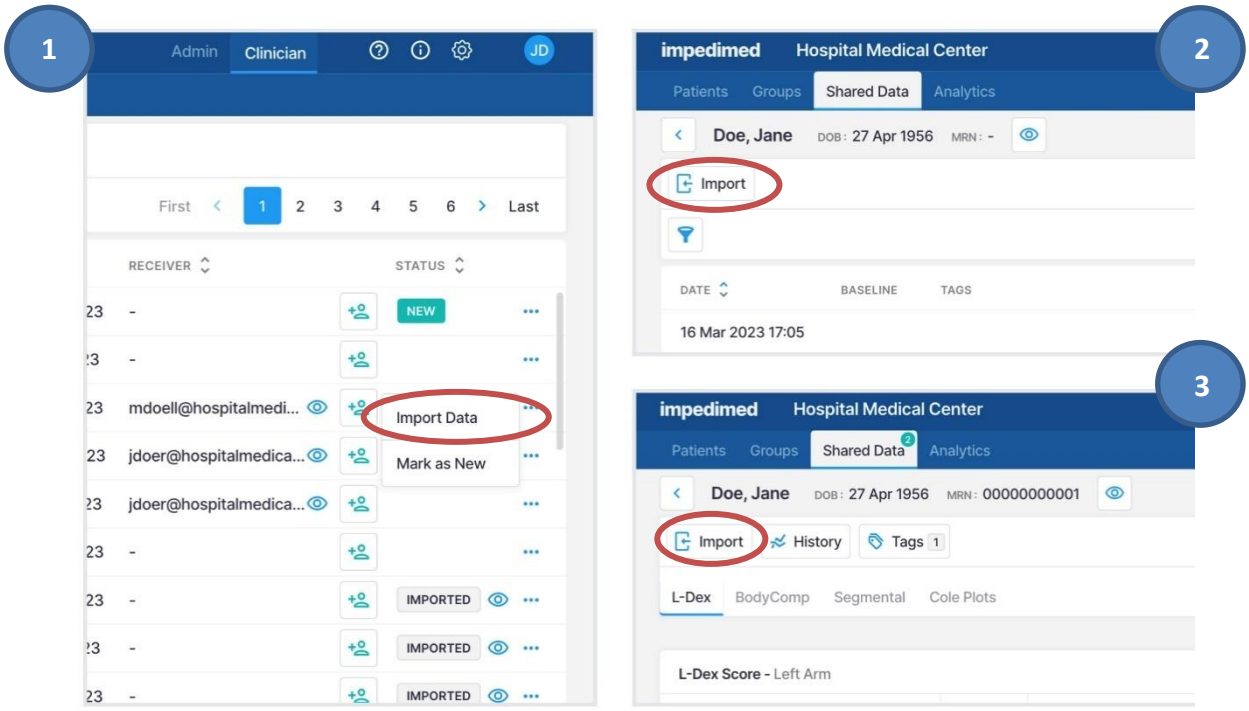
To mark incoming data as new, first select **Incoming**, then select the ellipsis next to the record and select **Mark as New**.



7.2.10.3.3 Import Incoming Data

Data can be imported from 3 locations:

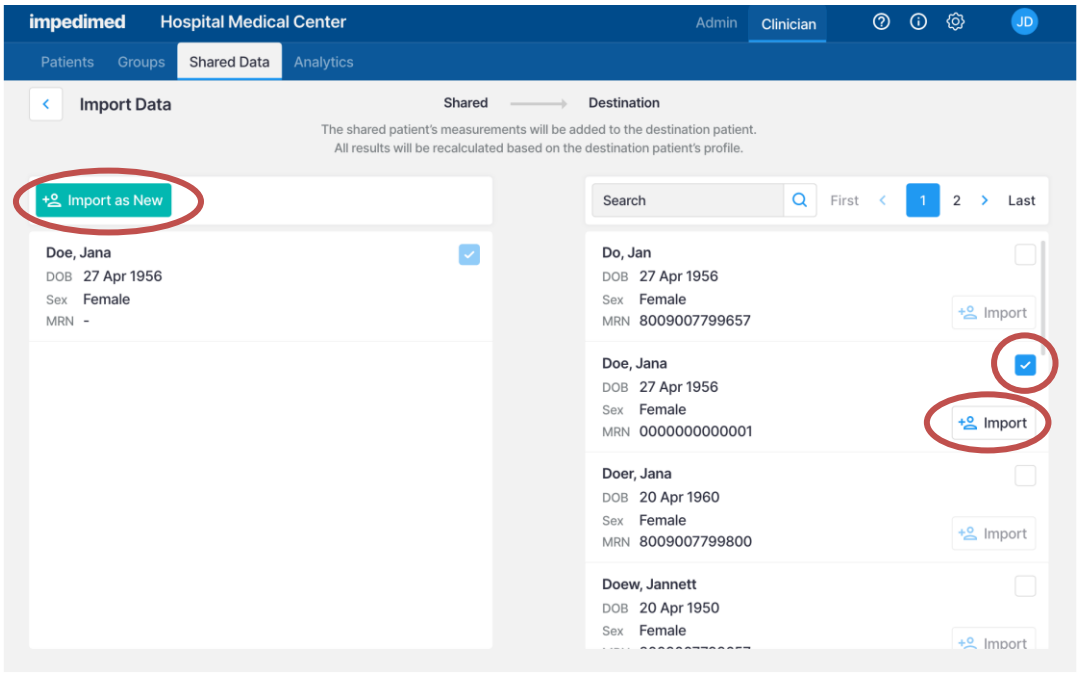
1. Shared data list:
    - Select the ellipsis next to the record to be imported and then select **Import Data**.
2. Shared data patient dashboard:
    - Select the record to view and then select **Import**.
3. Shared data patient result:
    - Select the record to view, select the measurement date to view, and then 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, select **Import as New**, confirm the patient information, enter the MRN for your clinic, and then select **Create**.
2. To add shared data to an existing patient, select the patient from the list, select **Import**.
3. Confirm that the patient information is the same as that in your existing patient profile, then select **Confirm and Import**.

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

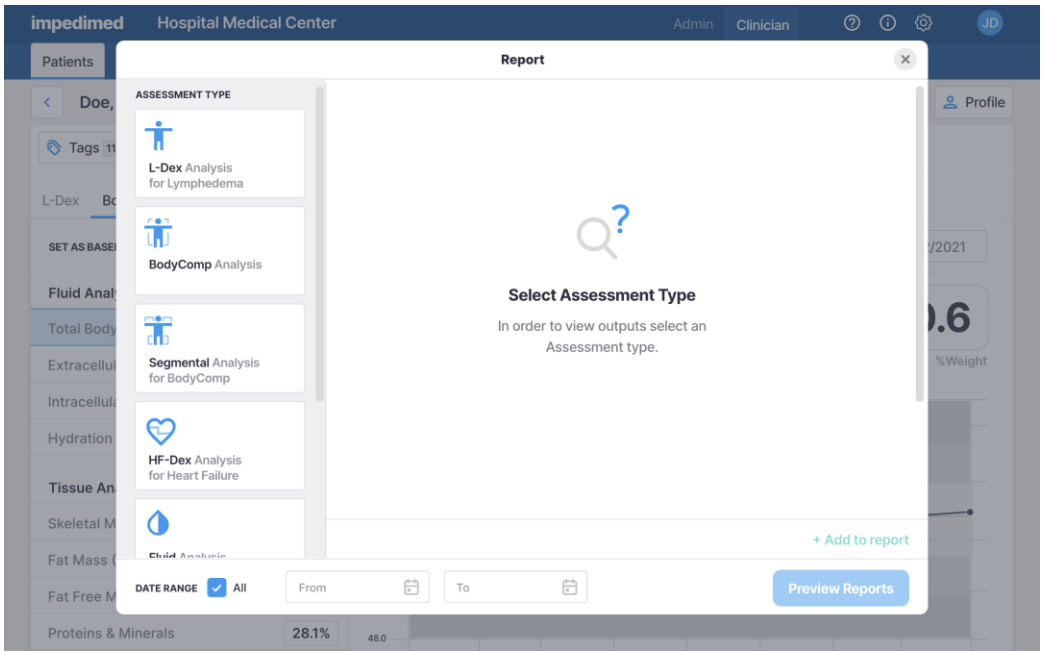


7.2.11 Report

A Clinician may create a patient report from MySOZO in the form of a PDF. The report can be created from the patient list or from the measurement result screen.

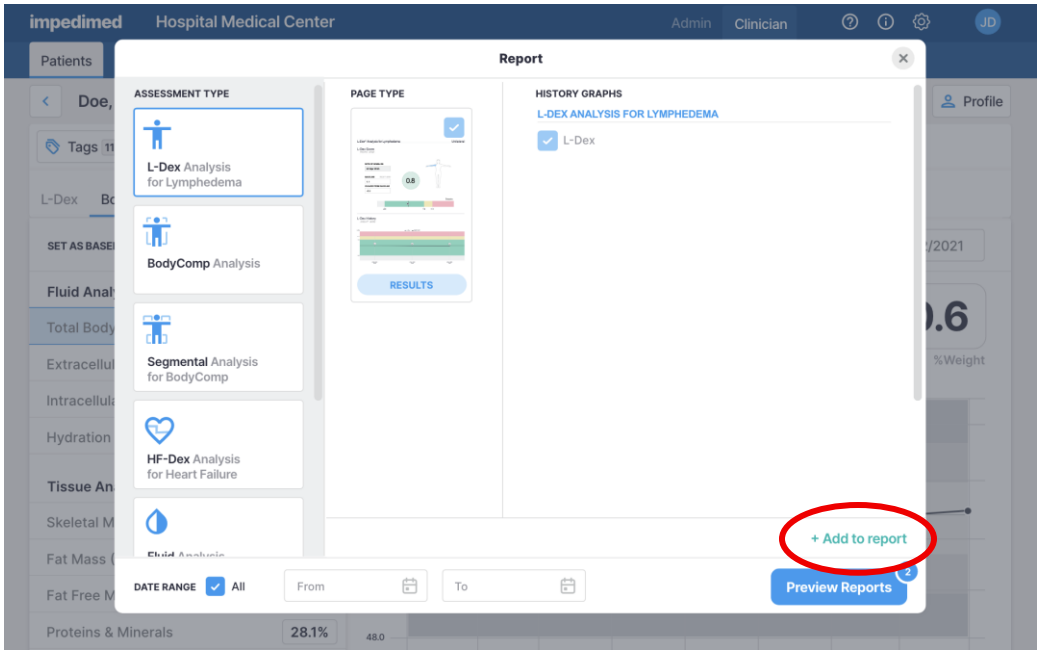
To create a patient report from the patient list:

1. Search for a specific patient or all patients.
2. Select **Report** (green paper icon), located on the far-right side of the patient's information.
3. Select the Assessment Type for the report from the list on the left.

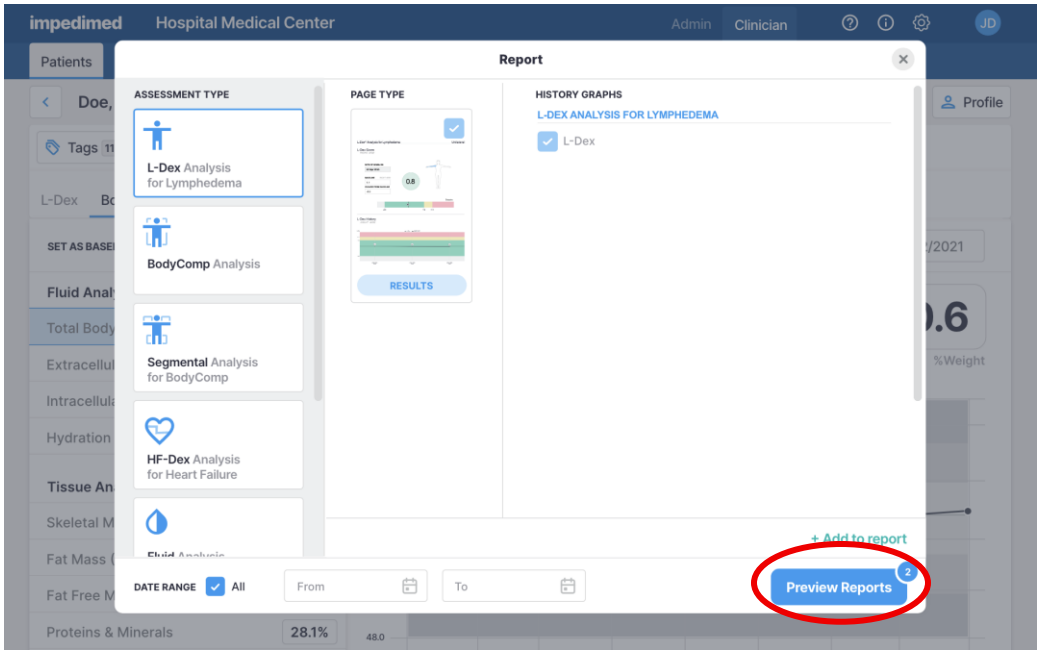


4. Make additional selections.
5. Input the date range for the history charts.

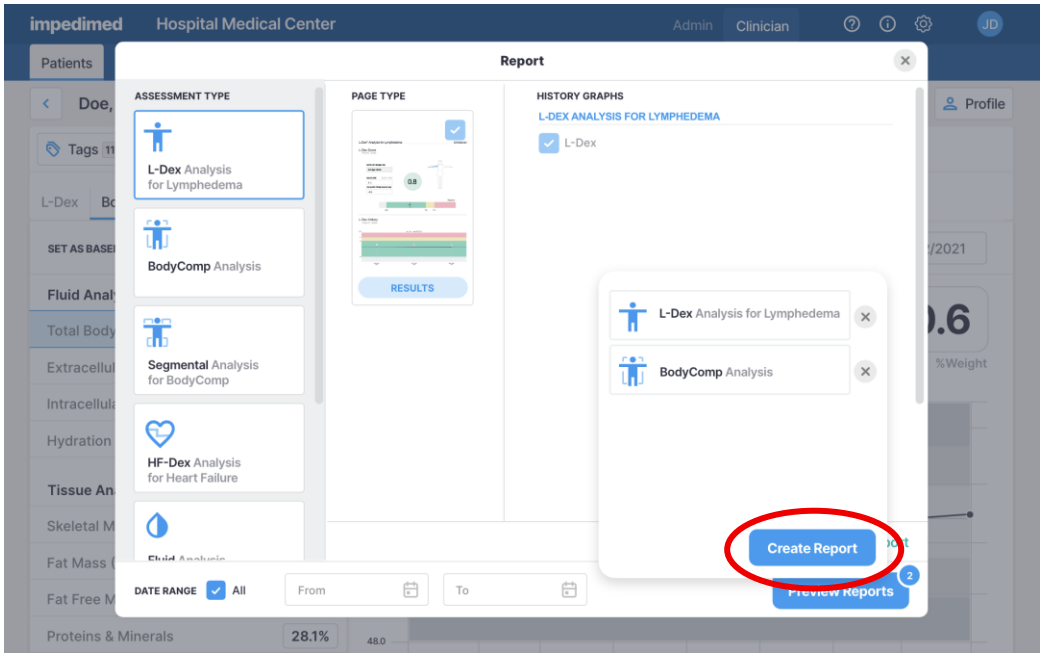
   NOTE: The main report will use the last assessment taken.
6. Select **+ Add to report.**



7. For a preview, select **Preview Reports**.



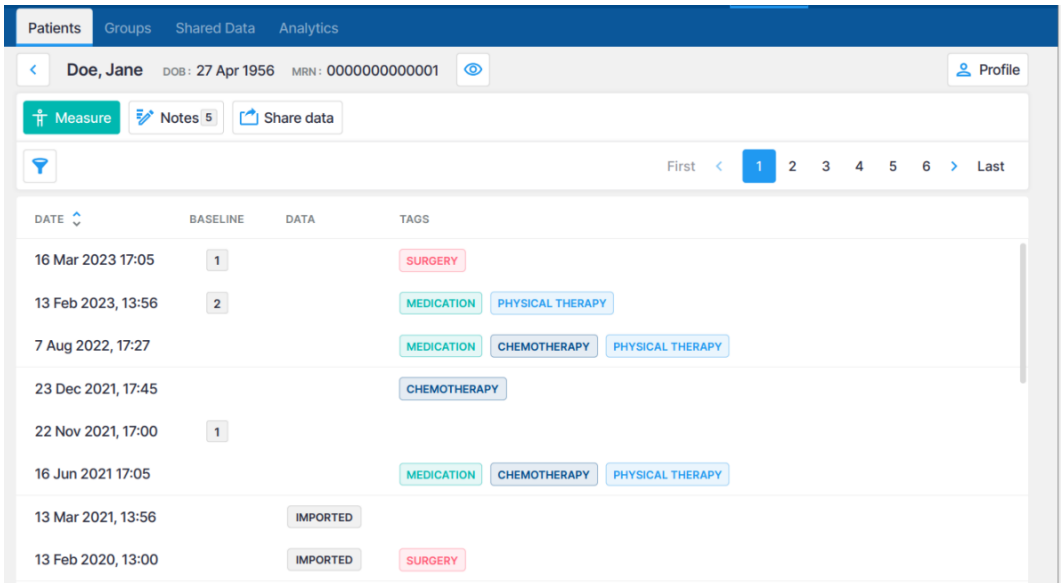
8. To generate the report, select **Create Report**. The patient report will automatically download in PDF format.



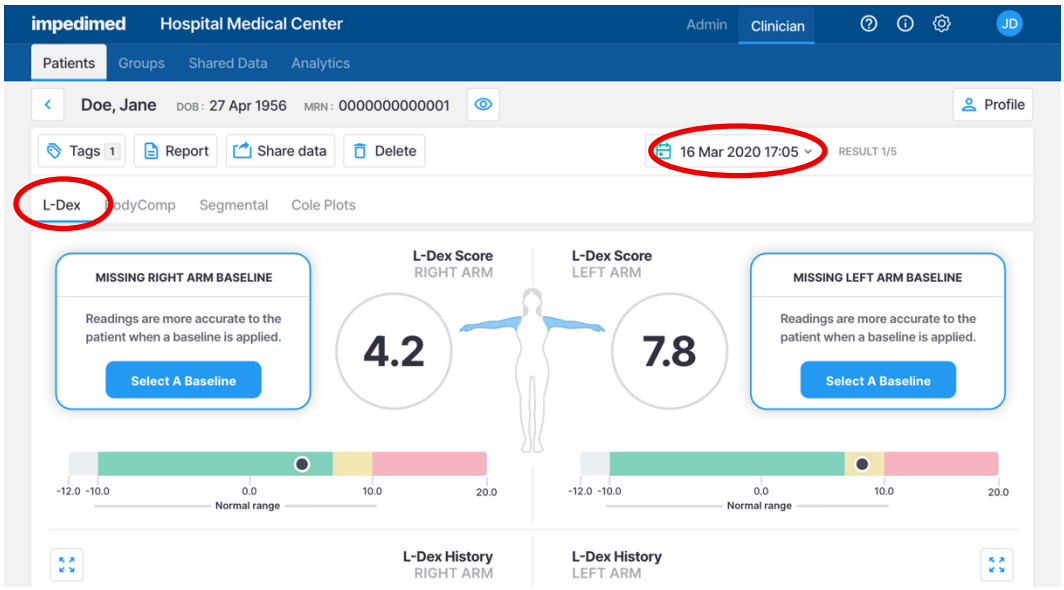
NOTE: Patient reports in PDF format cannot be created from the SOZOapp.

7.3 Measurement Dashboard

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

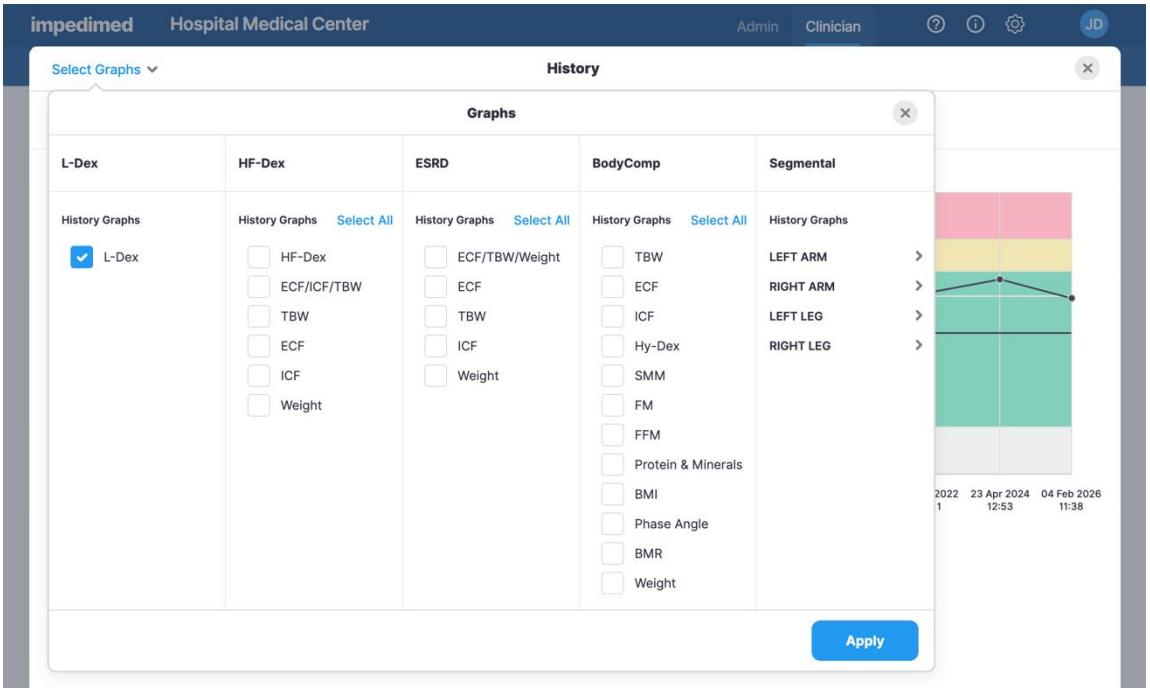


The results for one assessment type will initially be displayed (e.g., L-Dex). The Clinician can select different assessment types, or different measurement dates, from within the displayed record. The selected assessment type is underlined in blue (e.g., L-Dex) and measurement date is listed next to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

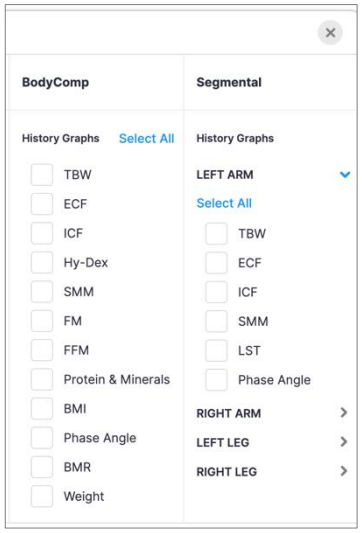


NOTE: Only the measurement history of licensed Assessments that have been selected in the patient profile appears in History.

The Clinician may also review summary history graphs for the patient by selecting the **History** button. Graphs will be created for each module licensed to the clinic and applied to the patient profile. The pop-up will allow the user to select specific outputs to be graphed for each module by selecting the desired outputs under **Select Graphs** and selecting **Apply**:



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



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

7.3.1 Setting a Baseline

A Clinician may set or remove a measurement baseline for each Assessment type, and for most outputs.

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.

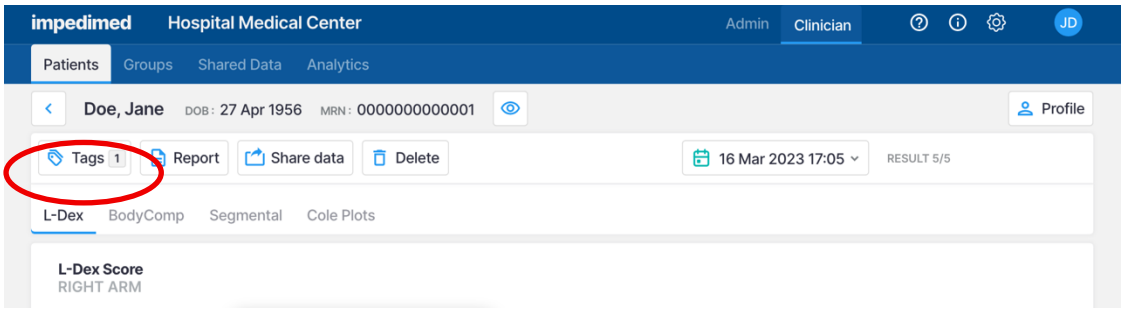
For instructions on setting the baseline for a specific assessment type (L-Dex, HF-Dex, and BodyComp), see the “Setting the Baseline” sections in 10, ASSESSMENT TYPES.

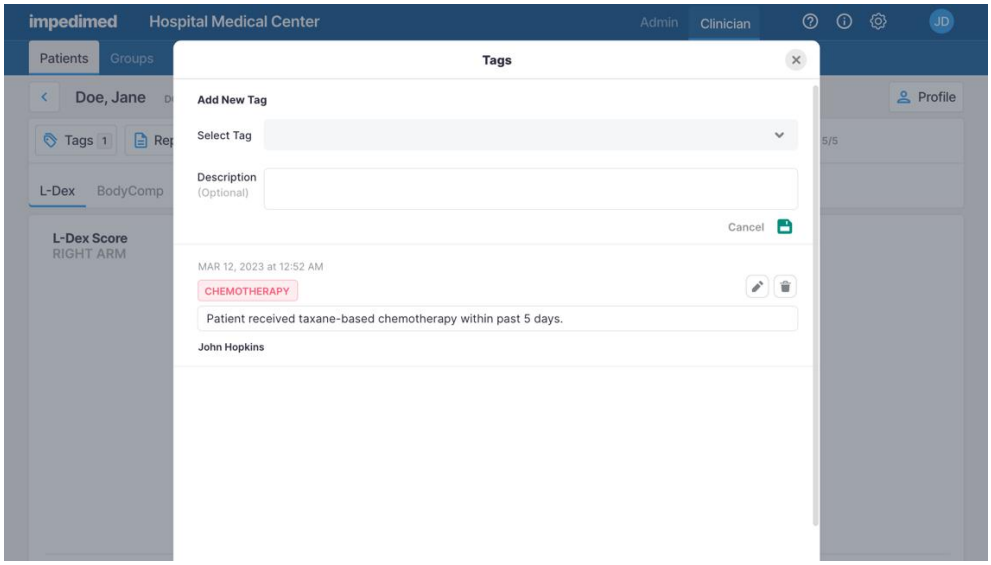
7.3.2 Evaluating Measurements Against a Baseline

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

7.3.3 Adding a Measurement Tag

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





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

7.3.4 Cole Plots

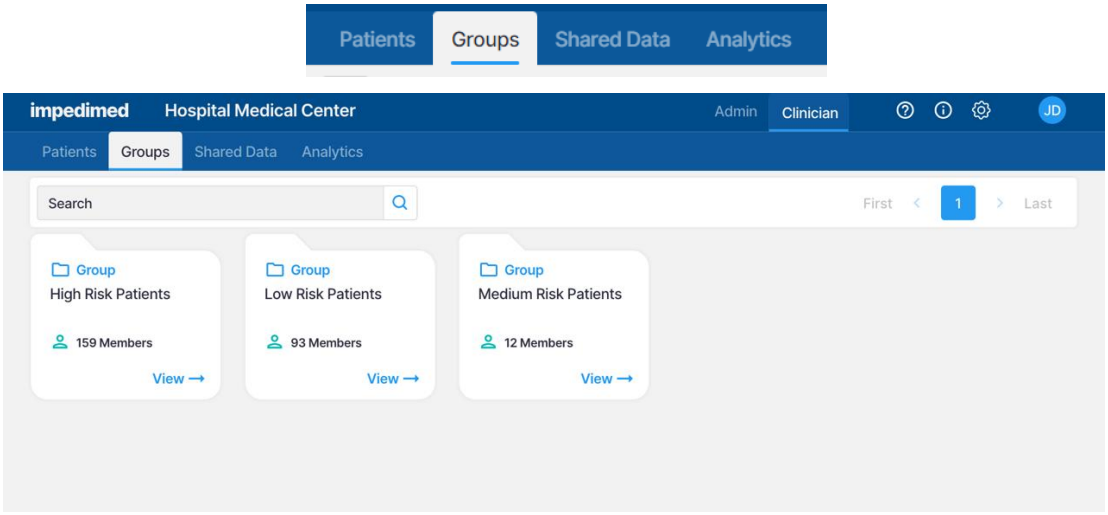
The SOZO software helps determine the quality of the Cole Plots by the following:

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

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

7.4 Clinician Patient Groups

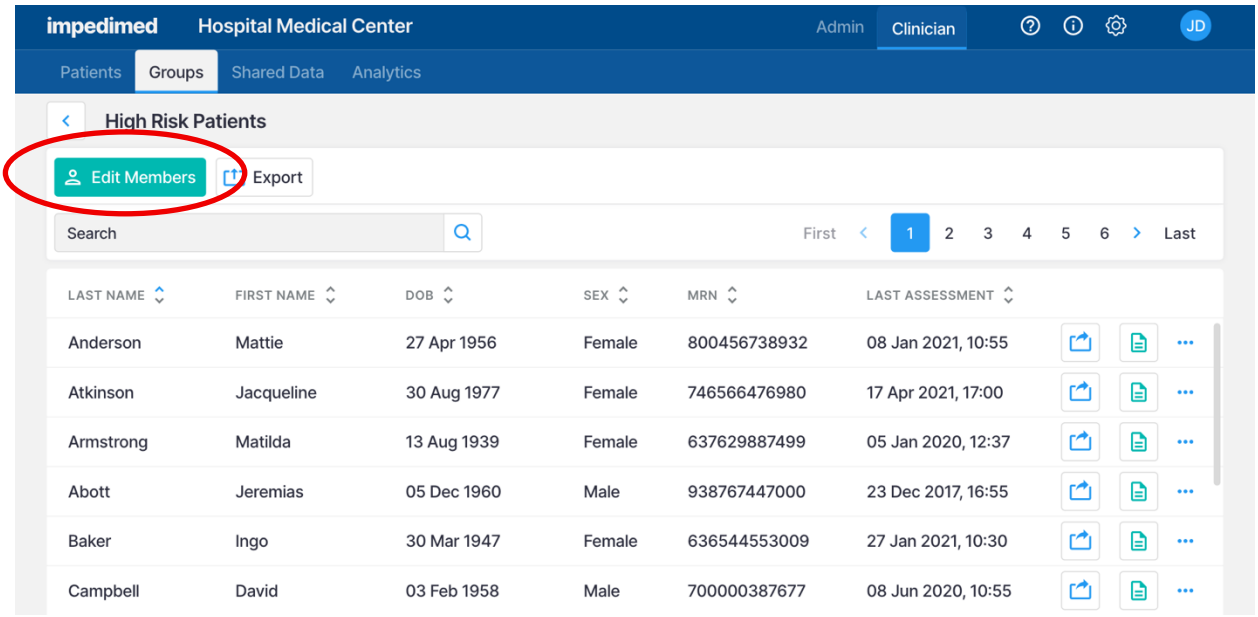
Select the **Groups** tab at any time to return to the Group List on the MySOZO Clinician home page.

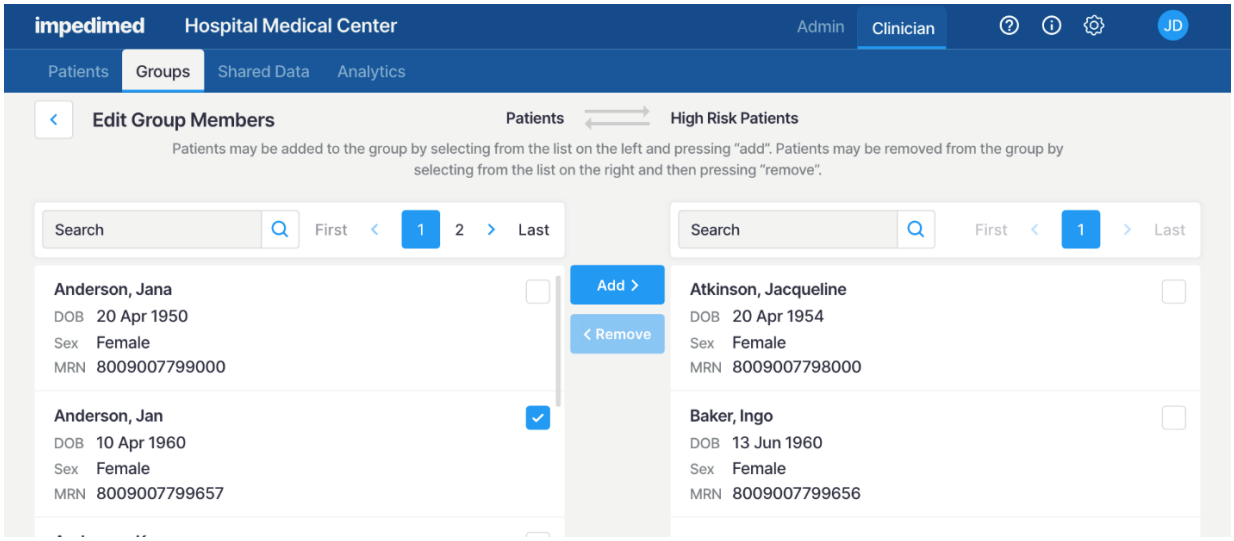


Patients can be assigned to predefined groups within the SOZO database. Administrator access is required to manage group creation. Clinician access is required to add or remove patients from groups.

To access **Group** features:

1. Select 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 selecting **View** to bring up the list of patients currently assigned to that group.
3. To modify patients within the group, select **Edit Members** located in the top right corner as shown below.
    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. Select 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. Select the **Remove** button to add patients to the group.


impedimed
Hospital Medical Center
Admin
Clinician
JD
Patients
Groups
Shared Data
Analytics
High Risk Patients
Edit Members
Export
Search
First
1
2
3
4
5
6
Last
LAST NAME
FIRST NAME
DOB
SEX
MRN
LAST ASSESSMENT
Anderson Mattie 27 Apr 1956 Female 800456738932 08 Jan 2021, 10:55
Atkinson Jacqueline 30 Aug 1977 Female 746566476980 17 Apr 2021, 17:00
Armstrong Matilda 13 Aug 1939 Female 637629887499 05 Jan 2020, 12:37
Abott Jeremias 05 Dec 1960 Male 938767447000 23 Dec 2017, 16:55
Baker Ingo 30 Mar 1947 Female 636544553009 27 Jan 2021, 10:30
Campbell David 03 Feb 1958 Male 700000387677 08 Jun 2020, 10:55


impedimed
Hospital Medical Center
Admin
Clinician
JD
Patients
Groups
Shared Data
Analytics
Edit Group Members
Patients
High Risk Patients
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
2
Last
Anderson, Jana
DOB 20 Apr 1950
Sex Female
MRN 8009007799000
Anderson, Jan
DOB 10 Apr 1960
Sex Female
MRN 8009007799657
Add >
< Remove
Search
First
1
Last
Atkinson, Jacqueline
DOB 20 Apr 1954
Sex Female
MRN 8009007798000
Baker, Ingo
DOB 13 Jun 1960
Sex Female
MRN 8009007799656

7.5 Clinician L-Dex Analytics

Select the **Analytics** tab (red circle below) from the tabs across the top at any time to return to the Analytics page.

The Clinician Analytics dashboard provides tools to track both Lymphedema Assessments and how well the clinic is following the Lymphedema Surveillance Program. Information on protocol compliance and patients in the Lymphedema Surveillance Program who have triggered is provided as well as all patient 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.

7.5.1 Lymphedema Surveillance Program

This program utilizes ImpediMed's Test, Trigger, Treat® protocol for early detection and intervention of cancer-related lymphedema. The evidence-based protocol option for the lymphedema 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 lymphedema with improved patient outcomes compared to those monitored with tape measure. While McDuff found that the risk of lymphedema is greatest in the first 3 years, the lymphedema risk is directly impacted by therapy received with regional lymph node radiation which correlated to late onset lymphedema. Therefore, the experts in the study recommended regular intervals for 5 years post treatment.

7.5.2 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.

---

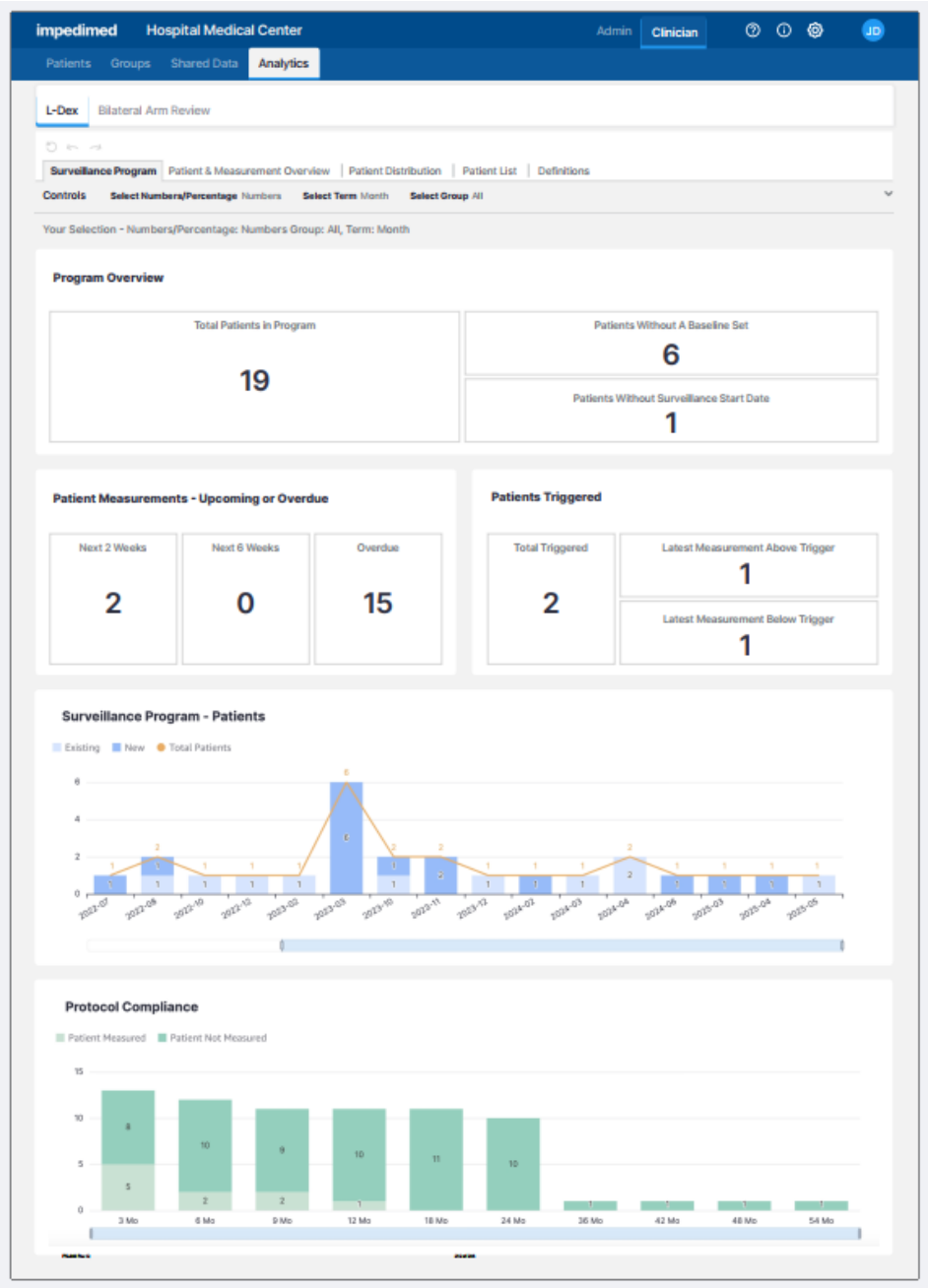
[2] Ridner SH, Dietrich MS, Boyages J, et al. A Comparison of Bioimpedance Spectroscopy or Tape Measure Triggered Compression Intervention in Chronic Breast Cancer Lymphedema Prevention. *Lymphatic Research and Biology* 2022.

[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 Lymphedema 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 7.5.2.5, 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.

7.5.2.1 Patient 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.

7.5.2.2 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 equaled 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.
- **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.

7.5.2.3 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.

7.5.2.4 Protocol Compliance

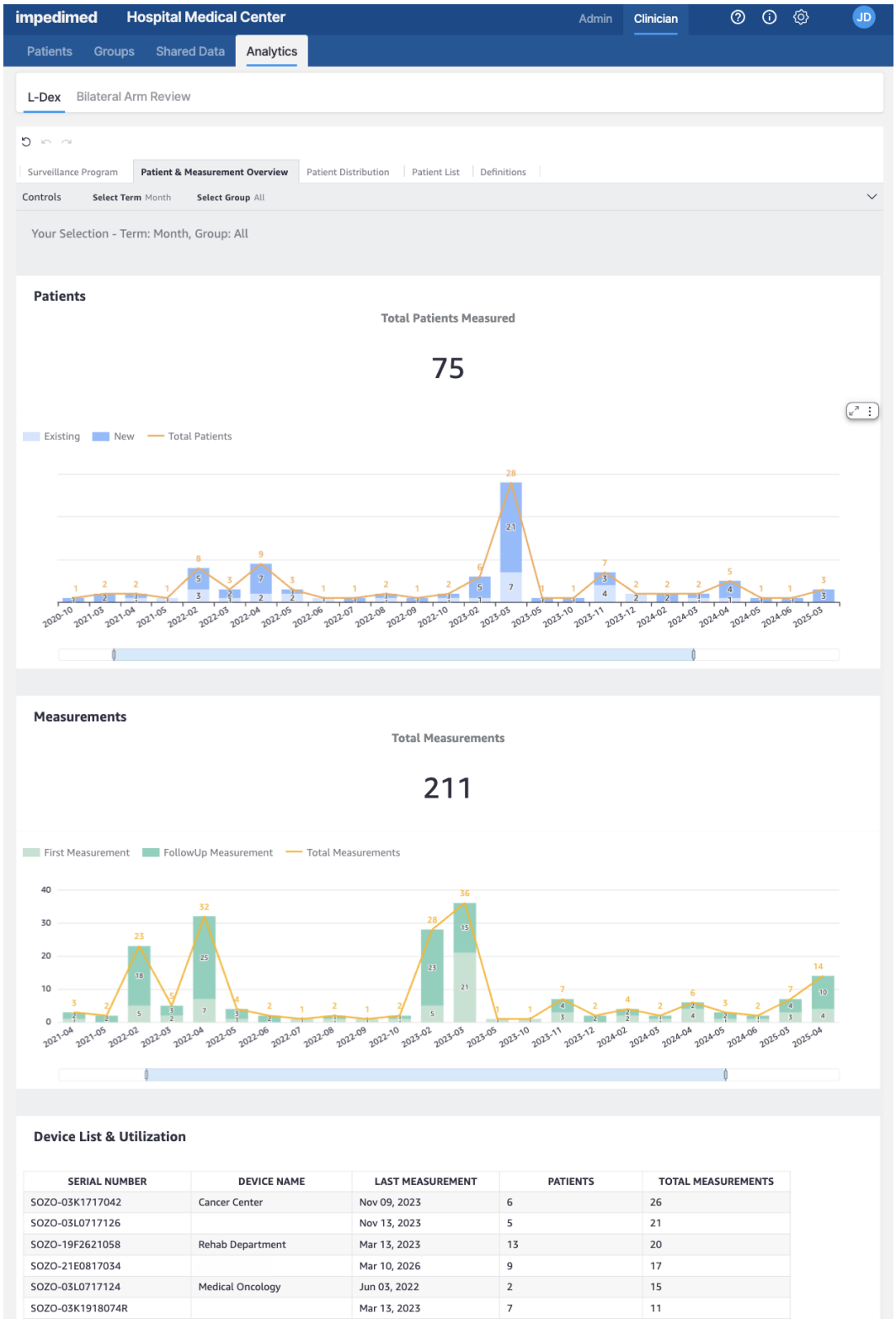
This provides the total number of surveillance program patients who took a measurement within the target protocol time period vs. those patients who did not take a measurement for each measurement target date. The surveillance program target dates are defined below and calculated for each patient based 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.

7.5.2.5 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 utilized 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

7.5.3 Patient & Measurement Overview

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



SERIAL NUMBER	DEVICE NAME	LAST MEASUREMENT	PATIENTS	TOTAL MEASUREMENTS
SOZO-03K1717042	Cancer Center	Nov 09, 2023	6	26
SOZO-03L0717126		Nov 13, 2023	5	21
SOZO-19F2621058	Rehab Department	Mar 13, 2023	13	20
SOZO-21E0817034		Mar 10, 2026	9	17
SOZO-03L0717124	Medical Oncology	Jun 03, 2022	2	15
SOZO-03K1918074R		Mar 13, 2023	7	11

7.5.3.1 Patients Measured

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

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

7.5.3.2 Measurements

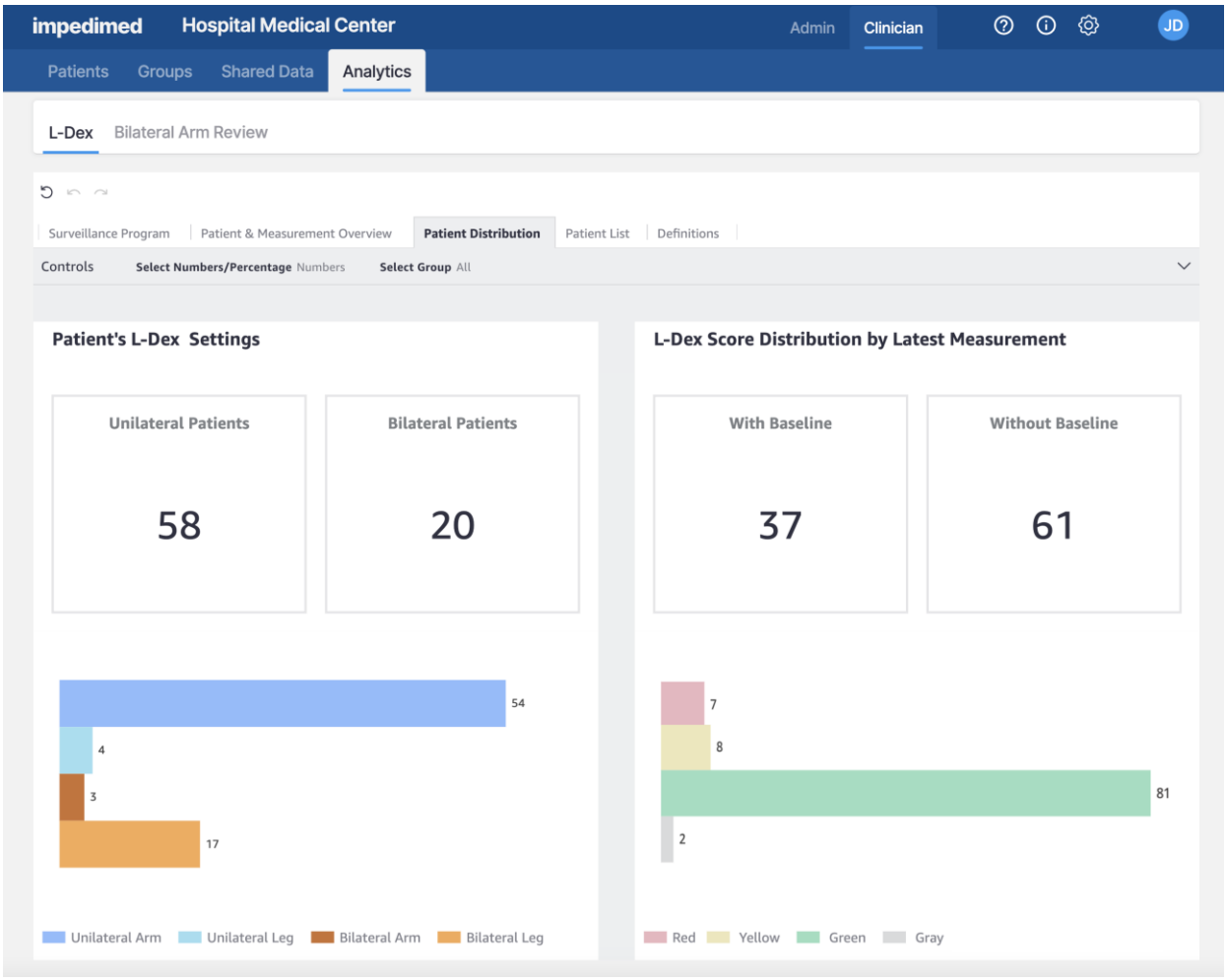
This chart provides the count of measurements taken on L-Dex patients over time, selectable by Month, Quarter or Year from the Controls menu. The total Measurements is a count of all measurements taken on all L-Dex patients.

7.5.3.3 Device List & Utilization

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

7.5.4 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.



7.5.4.1 Patient's L-Dex® Settings

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

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

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

7.5.4.2 L-Dex® Score Distribution by Latest Measurement

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

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

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

L-Dex Categories without a Baseline

Grey (Below Normal L-Dex)	L-Dex scores below 2 or 3 standard deviations less than the population mean (below -10).
Green (Normal L-Dex)	L-Dex scores between 2 or 3 standard deviations less than the population mean and 1.35 or 2 standard deviations greater than the population mean (-10 to 6.5).
Yellow (Normal L-Dex)	L-Dex scores between 1.35 and 2 standard deviations or 2 and 3 standard deviations greater than the population mean (6.5 to 10).
Red (Above Normal L-Dex)	L-Dex scores above 2 or 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 2 or 3 standard deviations below the baseline (change greater than -10).
Green (Normal L-Dex Change)	Change in L-Dex scores from the baseline between 2 or 3 standard deviations less than the baseline and 1.35 or 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 1.35 and 2 or 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 2 or 3 standard deviations above the baseline (change greater than +10).

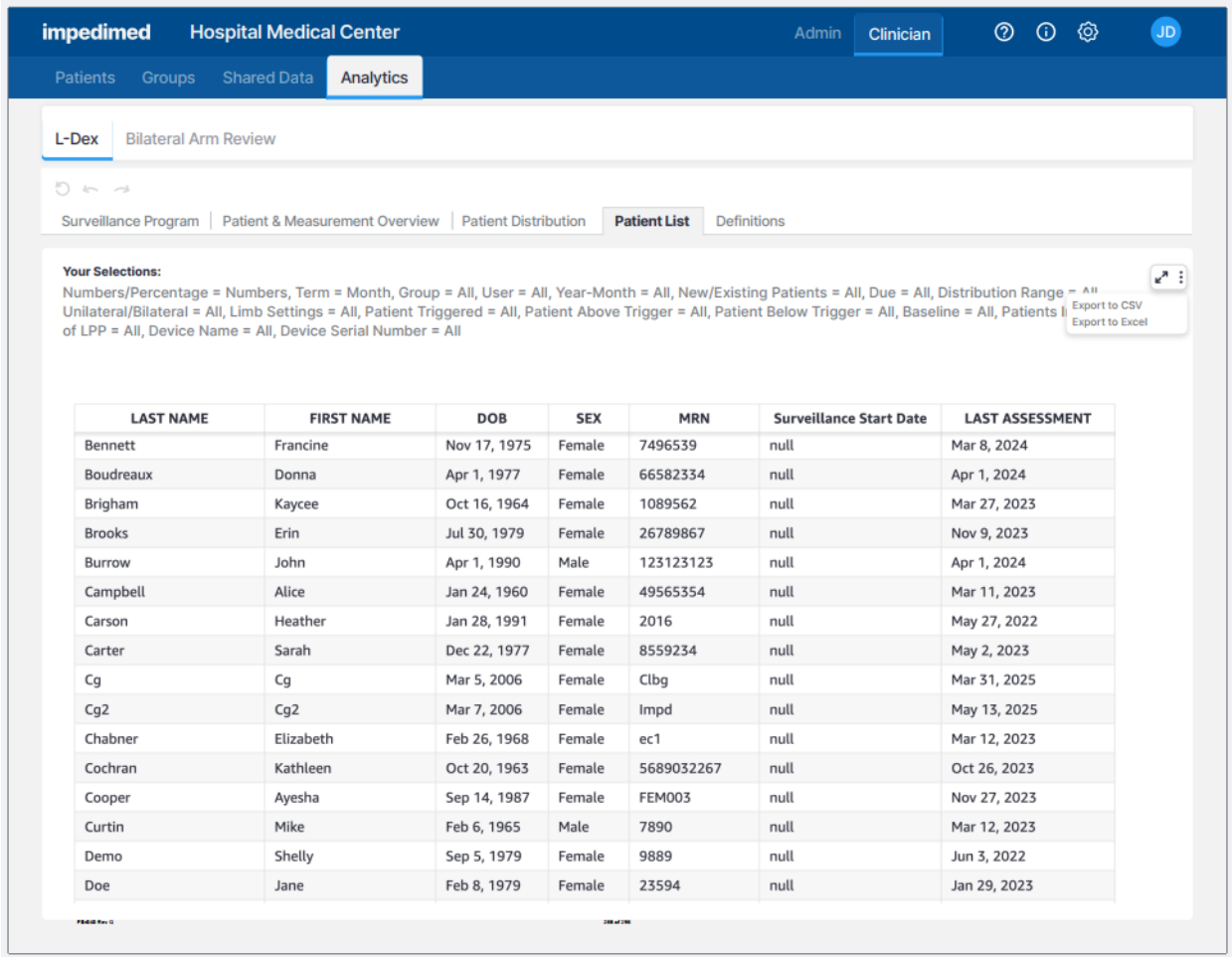
NOTE: Patients with no measurements will not have a baseline and will not be included in the bar graph output. Bilateral patients will include two measurements, one for each at-risk limb.

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

7.5.5 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.

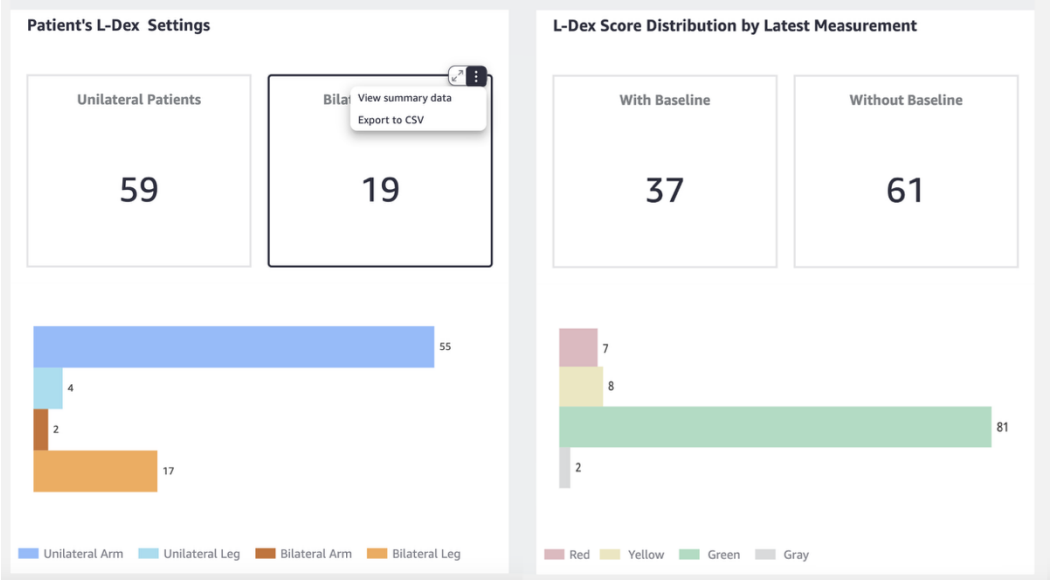
- By default, this is the full list of L-Dex patients contained in the database. Each column can be sorted by ascending or descending order.
- If the clinician drills down on a graph, the patient list is filtered according to the criteria of the graph.



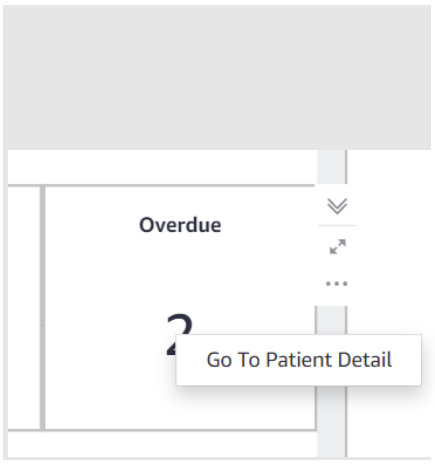
LAST NAME	FIRST NAME	DOB	SEX	MRN	Surveillance Start Date	LAST ASSESSMENT
Bennett	Francine	Nov 17, 1975	Female	7496539	null	Mar 8, 2024
Boudreaux	Donna	Apr 1, 1977	Female	66582334	null	Apr 1, 2024
Brigham	Kaycee	Oct 16, 1964	Female	1089562	null	Mar 27, 2023
Brooks	Erin	Jul 30, 1979	Female	26789867	null	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

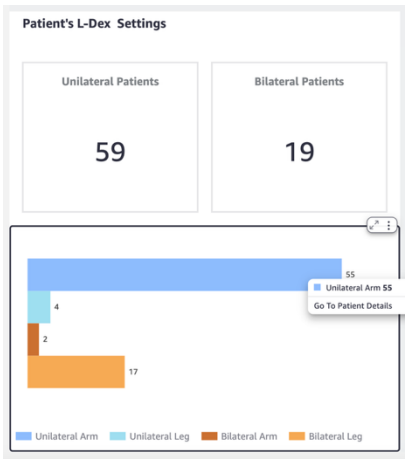
7.5.6 Navigation

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

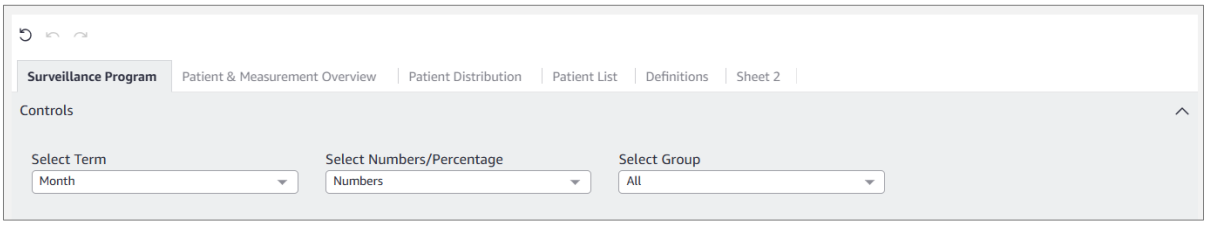


- **Accessing Patient List:** By default, all patients with an L-Dex Assessment are included in the patient list. To get patient data associated with a particular chart or table element, select the data element (e.g., Overdue patients, Patients Measured in Time Period, Serial Number, Bilateral Leg Patients,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

8 PREPARING THE PATIENT

8.1 Preparing for all Measurements

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

- Removes all metal jewelry if possible including large belt buckles. Items above the neck such as earrings are ok.
- 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.
- 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.

8.1.1 Factors Affecting Measurement

NOTE: Measurement results can be impacted by several factors:

- Placing a mobile phone in close proximity (less than 2 meters) 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)

8.1.2 Body Composition Measurements

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

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

8.2 Measurement Accuracy

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

8.2.1 Weight

The SOZO Pro includes a scale in the Foot Unit of the device that allows a clinician to measure a patient's weight prior to making a bioimpedance measurement.

A patient's weight is important for bioimpedance measurement accuracy and must be measured with the SOZO Pro or entered correctly by the Clinician at the time of bioimpedance measurement. This patient weight is valid for that measurement only. After measurement, a patient's weight may not be modified.

8.3 Positioning the Patient

The SOZO Pro System is designed in a Standing Position for patients who can stand and a Seated Position to accommodate patients who are unable to stand and may exceed the maximum weight limit.

SOZO Pro has a weight minimum of 48.5 lbs (22 kg) and a weight maximum of 485 lbs (220 kg) in the standing position and 750 lbs (340 kg) in the seated position.

In addition, patient weight may be input manually. Refer to step 6 in 9.1, Starting Measurements with the SOZOapp, for manual weight instructions.

See 4.3.2, Using the SOZO® Pro Device for Seated Measurements, which provides instructions for system configuration for standing and seated positions.

NOTE: Clinicians should always take a patient's measurements in the same position each time. This ensures a more accurate comparison of fluid levels.

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

8.3.1 Standing Position

When standing on the SOZO Pro Device, ImpediMed recommends using the 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.

- Minimize skin-to-skin contact (e.g., tissue contact between the torso and arm, thigh to thigh should be minimized when possible).

8.3.2 Seated Position

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

The patient should:

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

9 TAKING MEASUREMENTS

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

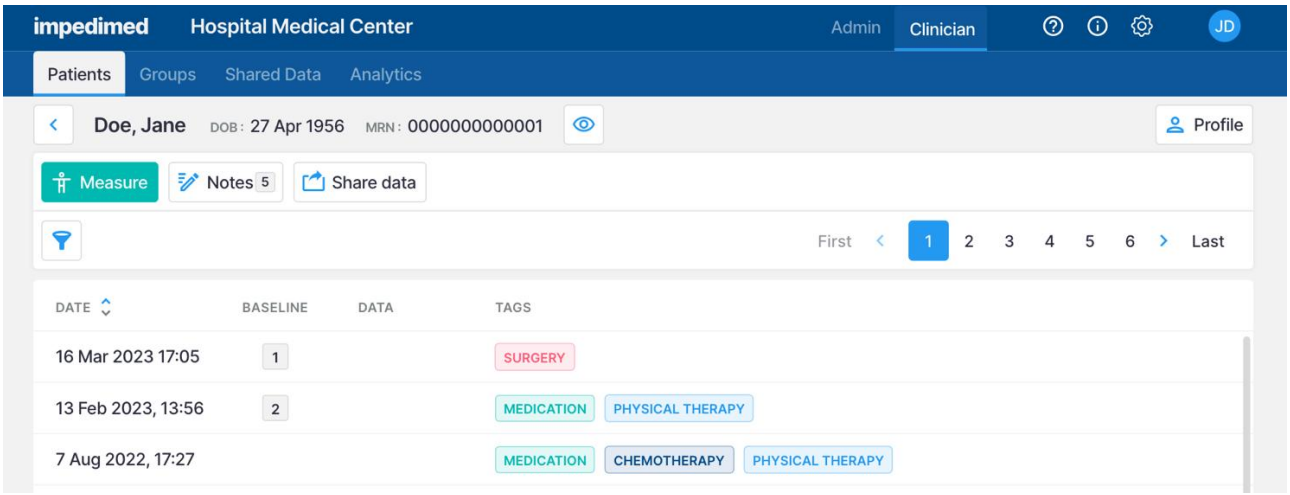
For details on the assessment types, including indication-specific information and reports, see 10, ASSESSMENT TYPES.

9.1 Starting Measurements with the SOZOapp

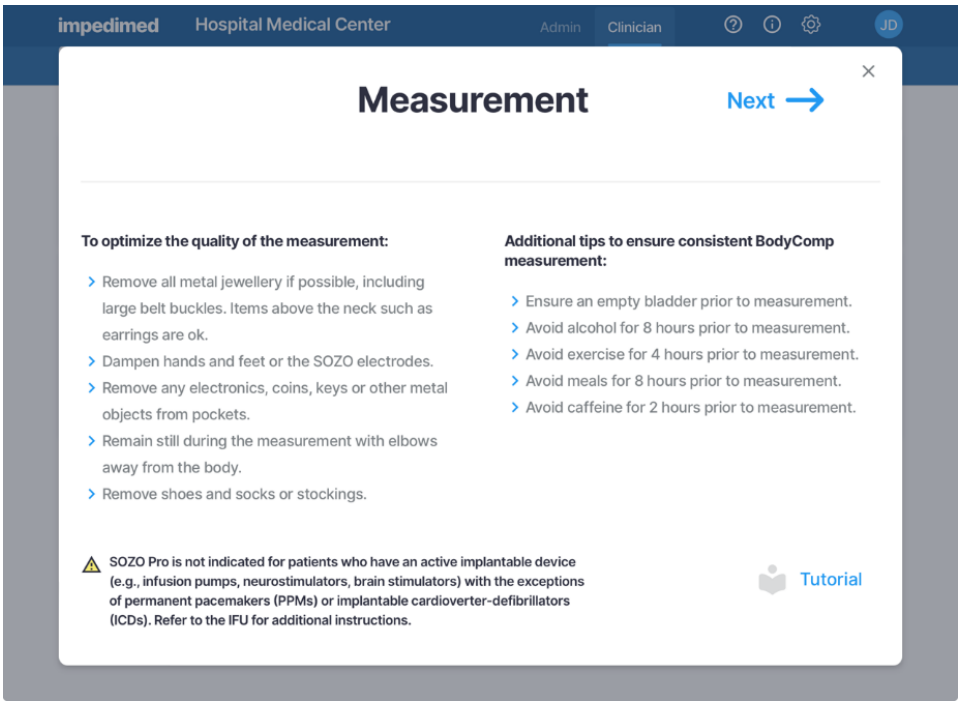
Measurements are taken using the Tablet and SOZOapp.

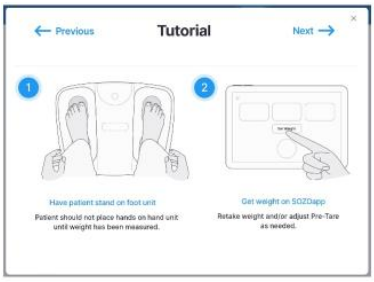
To take patient measurements:

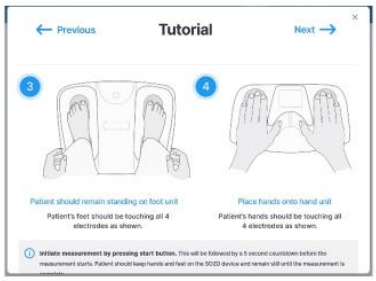
1. Create a patient profile if required.
2. Search for and select the patient from the patient list to open the Patient Dashboard.
3. From the Patient dashboard, select the **Measure** icon to begin new patient measurements.



4. After you select the **Measure** icon, measurement instructions appear. To optimize measurement quality, ensure patient compliance with these instructions. To view a tutorial on device use, select **Tutorial**. When finished, select **Next**.

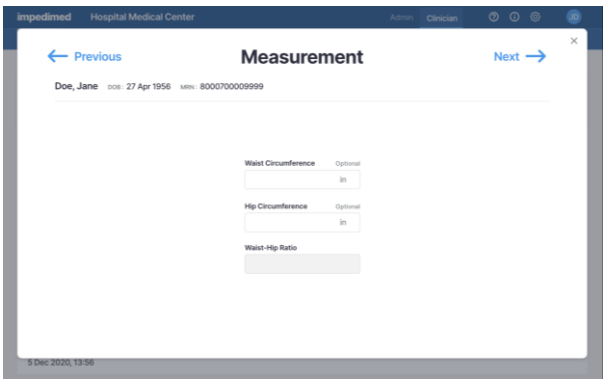


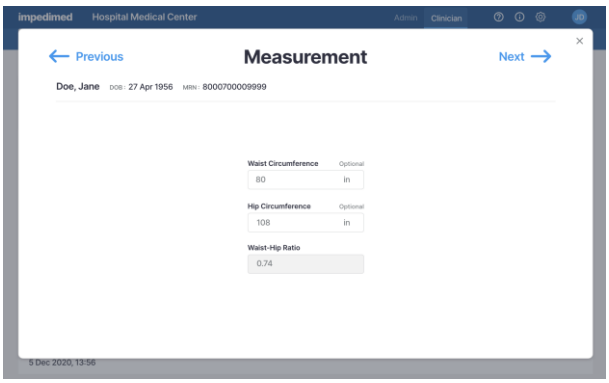




NOTE: To ensure patient privacy, do not permit the patient to handle the Tablet while taking SOZO Pro measurements.

(Optional) For BodyComp™ measurements only, enter the patient's waist and hip circumference measurements. The waist-hip ratio will be calculated automatically and displayed on the History graph on the Results screen.



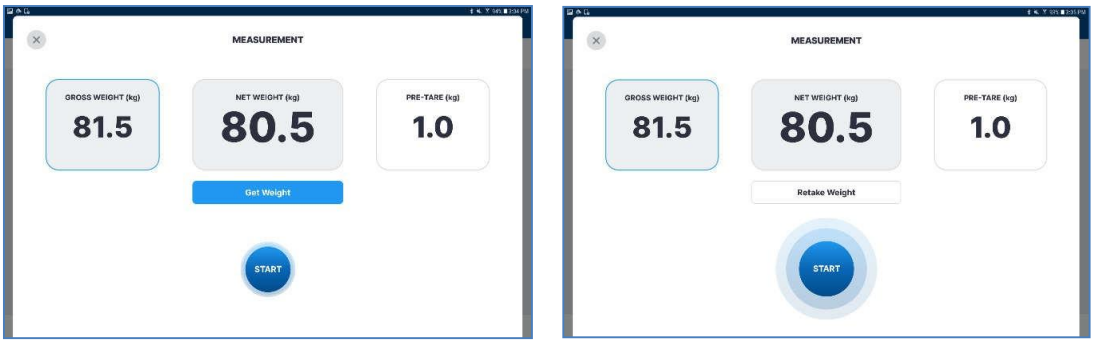


5. Instruct the patient to place their feet onto the Foot Unit. Locate their heel recesses and ensure that each foot is flat and in full contact with each electrode plate.
    a. There are two electrode plates for the left foot and two electrode plates for the right foot.

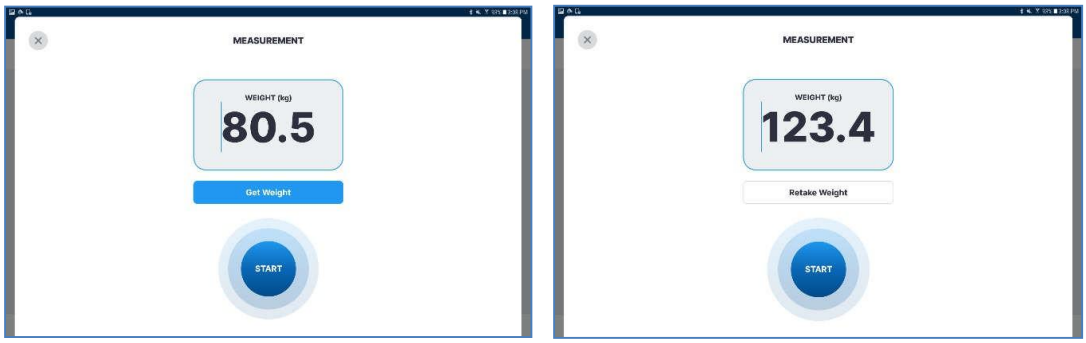
NOTE: Accurate weight entry is critical to body composition analysis. The patient should be weighed immediately prior to the SOZO measurement. Patient weight cannot be changed after an impedance measurement is performed.

6. Ensure that the patient is not touching the Hand Unit or resting their weight on anything that could interfere with the accuracy of the weight measurement.
    a. Capture the weight of the patient from the SOZO Pro by selecting **Get Weight**.
    b. If desired, weight can be re-measured with the SOZO Pro scale by selecting **Retake Weight**.
    c. For a seated measurement or to manually enter the weight of the patient, select the **Net Weight** box and enter the weight.

NOTE: The pre-tare weight function can be used to subtract clothing weight (see 7.1.3.8, Weight Pre-Tare); pre-tare values can also be changed directly from the Measurement screen (see below).



SOZO Pro Get Weight and Retake Weight with Pre-Tare enabled

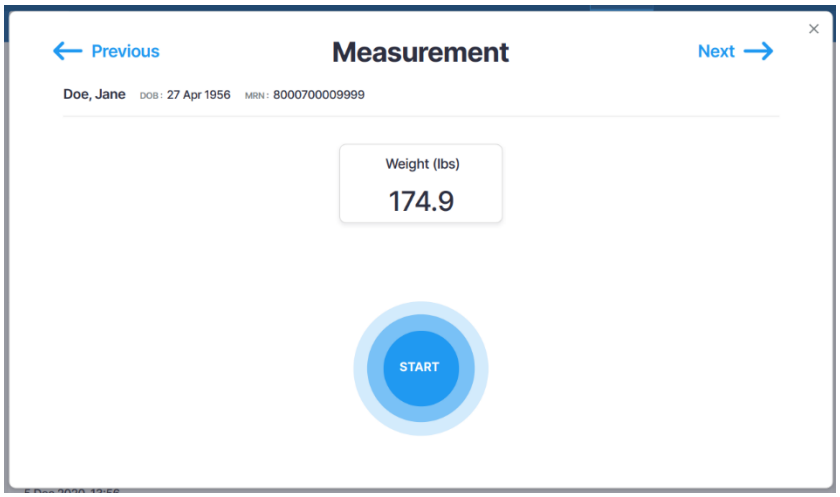


SOZO Pro Get Weight and Retake Weight with Pre-Tare disabled

7. Instruct the patient to place both hands onto the Hand Unit with thumbs securely wrapped around the corners of each recess. Make sure each hand is flat and in full contact with each electrode plate.

a. There are two electrode plates for the left hand, and two electrode plates for the right hand.

8. Select **Start** to begin measuring the patient.
    a. This triggers a five-second countdown before the start of the measurement.



Once started, the SOZO Pro Device measurement will take approximately 30 seconds. The measurement in the 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 result in an error if no contact is detected.

The SOZO Pro 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 the SOZO Pro Device if it is hot to the touch. Disconnect the SOZO Pro Device by unplugging the Power Adaptor and call ImpediMed Technical Support.

NOTE: Read Intended Use (2.2, Intended Use) and Precautions (2.6, Precautions) before taking measurements with the SOZO Pro Device.

NOTE: Ensure that the Foot Unit is stationary and on a level surface.

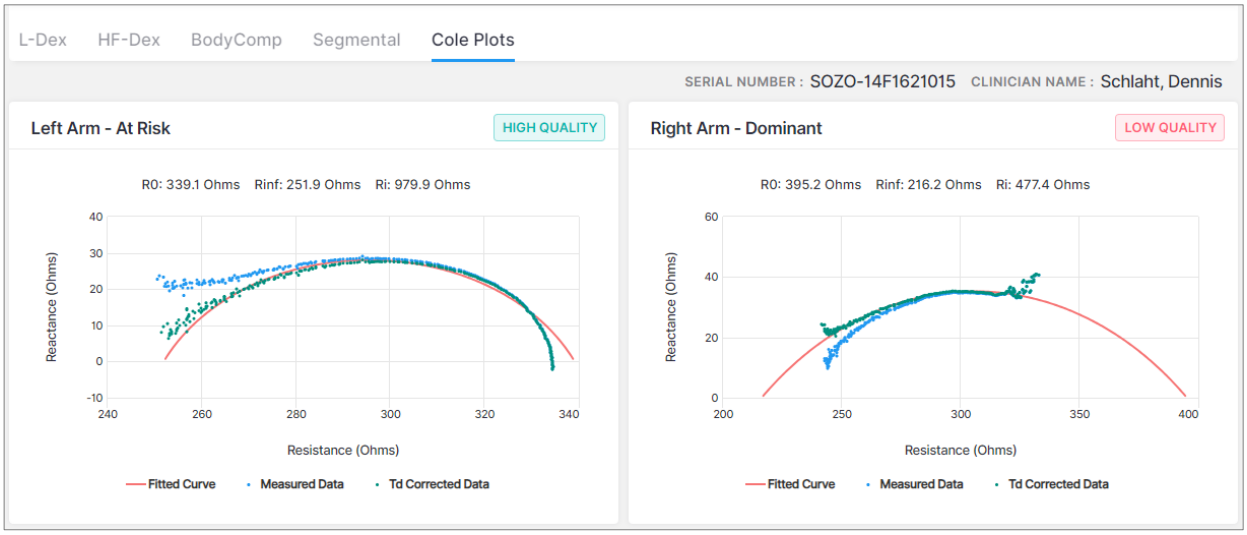
9.2 Accepting and Rejecting Cole Plots After Measurement

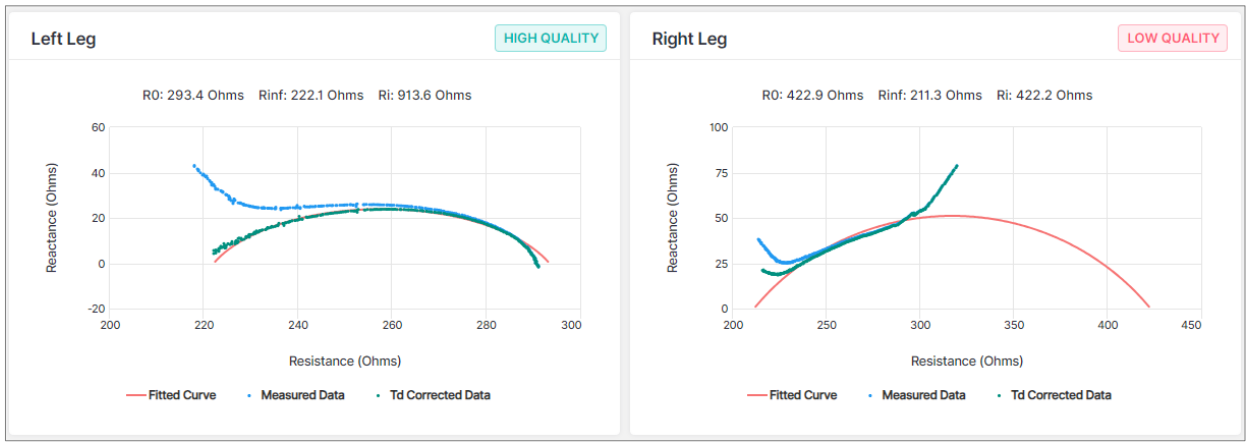
After the measurement process is complete, the system calculates and assesses the Cole plots. If all 6 Cole plots are assessed as high quality, the Cole plots will be automatically accepted and not displayed prior to the results, however, can be viewed with the measurement results. If any of the 6 Cole 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.

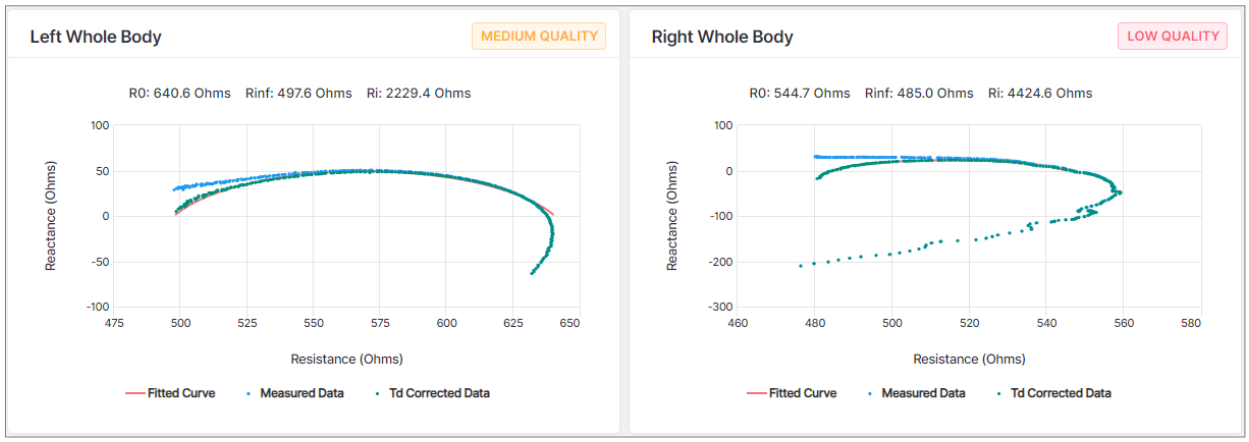
The SOZO software helps determine the quality of measurements by ranking each Cole plot as “High Quality” (green), “Medium Quality” (yellow) or “Low Quality” (red), as shown below.

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.


Left Arm - At Risk, Dominant
HIGH QUALITY
R0: 400.1 Ohms Rinf: 302.9 Ohms Ri: 1246.3 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Arm
HIGH QUALITY
R0: 401.1 Ohms Rinf: 260.6 Ohms Ri: 744.1 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Left Leg
HIGH QUALITY
R0: 326.1 Ohms Rinf: 251.2 Ohms Ri: 1094.8 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Leg
LOW QUALITY
R0: 416.3 Ohms Rinf: 261.3 Ohms Ri: 701.6 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Left Whole Body
MEDIUM QUALITY
R0: 737.6 Ohms Rinf: 586.8 Ohms Ri: 2870.6 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Whole Body
MEDIUM QUALITY
R0: 714.6 Ohms Rinf: 581.5 Ohms Ri: 3122.5 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data


L-Dex
HF-Dex
BodyComp
Segmental
Cole Plots
SERIAL NUMBER : SOZO-14F1621015
CLINICIAN NAME : Schlaht, Dennis
Left Arm - At Risk
HIGH QUALITY
R0: 339.1 Ohms Rinf: 251.9 Ohms Ri: 979.9 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Arm - Dominant
LOW QUALITY
R0: 395.2 Ohms Rinf: 216.2 Ohms Ri: 477.4 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data


Left Leg
HIGH QUALITY
R0: 293.4 Ohms Rinf: 222.1 Ohms Ri: 913.6 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Leg
LOW QUALITY
R0: 422.9 Ohms Rinf: 211.3 Ohms Ri: 422.2 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data


Left Whole Body
MEDIUM QUALITY
R0: 640.6 Ohms Rinf: 497.6 Ohms Ri: 2229.4 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data
Right Whole Body
LOW QUALITY
R0: 544.7 Ohms Rinf: 485.0 Ohms Ri: 4424.6 Ohms
Reactance (Ohms)
Resistance (Ohms)
Fitted Curve
Measured Data
Td Corrected Data

9.3 Interpreting Cole Plots

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

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

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

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

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

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

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

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

9.4 Licensing

9.4.1 Impact of Licensing Additional Assessments on Results

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

9.4.2 Impact of Cancellation of Assessment License on Results

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

10 ASSESSMENT TYPES

The SOZO Pro Device supports the following Assessment Types:

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

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

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

10.1 Choosing the Proper Assessments for the Patient

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

- L-Dex® aids the Clinician in the assessment of lymphedema in a patient who has or is at risk of lymphedema.
- HF-Dex® aids the Clinician in monitoring fluid status in patients living with heart failure.
- BodyComp™ is used to provide fluid and tissue analysis assessments of an individual.
- Segmental BodyComp™ is used to provide fluid and tissue analysis assessments of individual limbs.

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

10.2 L-Dex® for Lymphedema Instructions for Use

All warnings, contraindications and precautions apply. In addition, consider the following when using SOZOapp to take L-Dex measurements on a patient:

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

- What is at risk of Lymphedema? Both Arms, Right Arm, Left Arm, Right Leg, Left Leg, Both Legs (select the option that applies)
- What is the dominant limb? Right, Left (select one)
- Include Patient in Surveillance Program? Yes, No (select one)

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, 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.

10.2.1 Indications for Use

The SOZO Pro device has the following uses:

For adult human patients at risk of lymphedema:

A bioimpedance spectroscopy device for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extracellular volume differences between the limbs, and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of lymphedema.

The use of the device to obtain an L-Dex score is only indicated for patients who will have or who have had lymph nodes, from the axillary and/or pelvic regions, removed, damaged or irradiated.

10.2.2 The Lymphedema Index (L-Dex®)

The SOZO Pro System displays L-Dex assessment results based upon patient measurements taken with the SOZO Pro Device. The L-Dex assessment produces an L-Dex score, which is based on the comparison of the impedance of the unaffected limb(s), or the predicted impedance of the limb(s) in a healthy population 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 lymphedema in the arm or leg, one L-Dex score will be presented for the at-risk limb. For patients at risk of bilateral arm or leg lymphedema, two L-Dex scores will be presented, one for each at-risk limb.

The underlying calculations for unilateral assessments using the SOZO Pro 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 Pro System in a sitting or standing position, there may be a one-time shift in L-Dex scores. The shift has been shown not to be significant.

For assessment of patients at risk of bilateral arm or leg lymphedema, where fluid accumulation could occur in both arms or legs, simultaneously, the comparison of contralateral limbs is not an option. For patients at risk of bilateral arm lymphedema, SOZO compares the at risk arms to a model of predicted healthy patient arm L-Dex scores**^**. For at risk bilateral leg patients, 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.[5]

^The bilateral arm baseline and longitudinal tracking L-Dex sensitivity and specificity calculated values are listed below.

NOTE: For patients suspected of being at risk of developing bilateral lymphedema, confirm their bilateral risk status prior to patient profile setup and measurement.

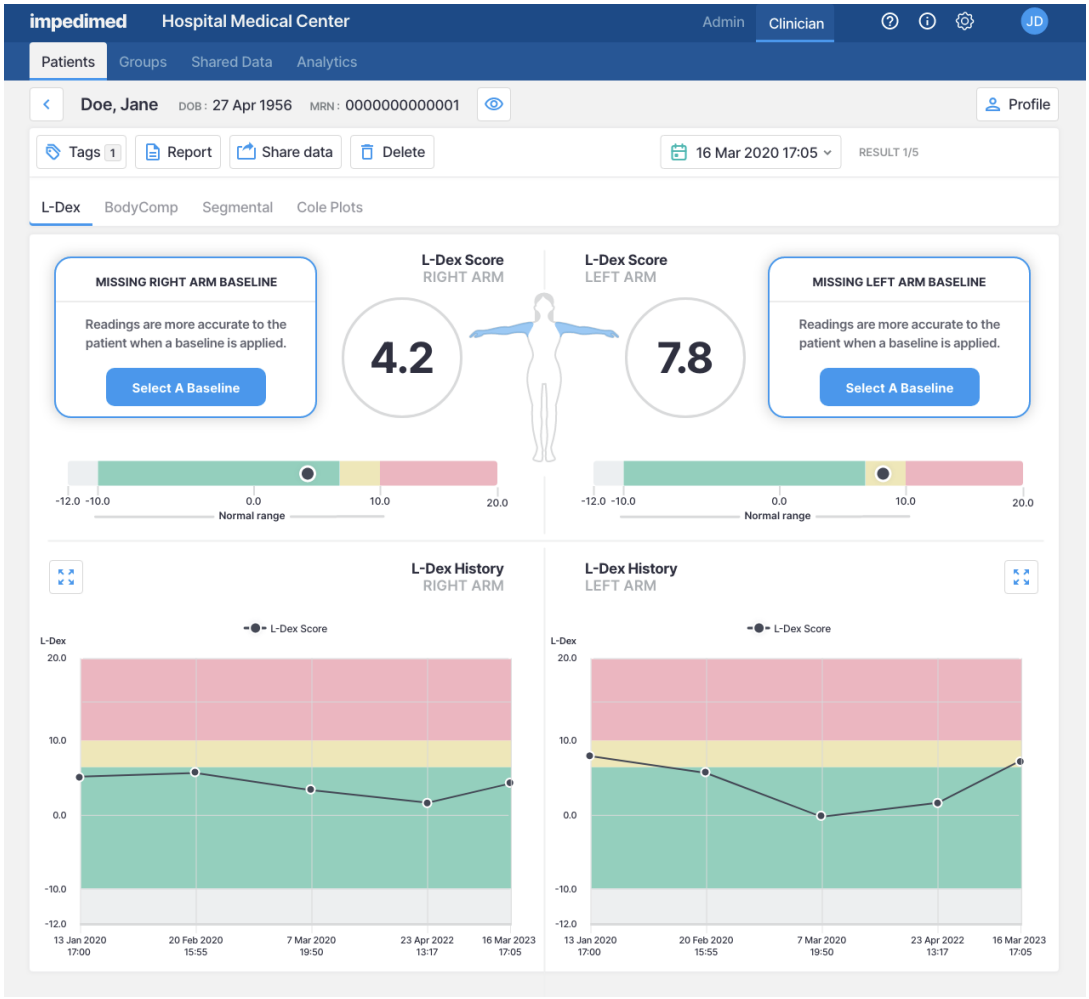
If a unilateral patient is subsequently considered to be at risk for bilateral lymphedema and their profile has been updated, the L-Dex scores for the previously measured limb will be recalculated using this bilateral approach. This may result in a shift in previous L-Dex scores.

10.2.2.1 Bilateral Arm L-Dex Sensitivity and Specificity

Cross-sectional Sensitivity and Specificity: 81.3% Sensitivity and 91.6% Specificity.

Longitudinal Tracking Sensitivity and Specificity: 77.0% Sensitivity and 90.0% Specificity.

[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 modeled 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 0.892 for bilateral assessment.



Bilateral arm patient L-Dex assessment.

10.2.2.2 Using the L-Dex® Scale without a Baseline

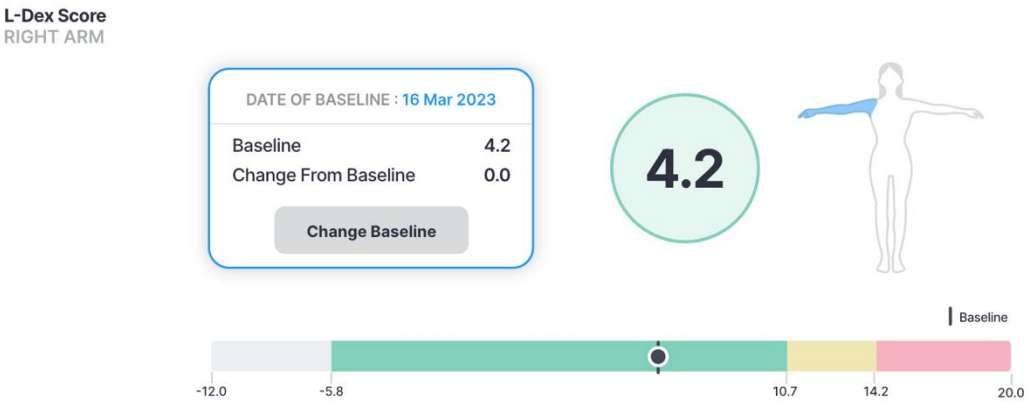
The L-Dex scale is a tool to assist in the clinical assessment of lymphedema by a medical provider. The SOZO System displays the current L-Dex score using the L-Dex scale. The L-Dex scale shows the patient's L-Dex score as either inside or outside of the normal range of L-Dex score for a healthy person. The L-Dex scale normal range (plus or minus 3 standard deviations for unilateral arm and leg and bilateral leg, plus or minus 2 standard deviations for bilateral arms) measured for a healthy person without lymphedema ranges between +10 and -10 L-Dex units. If a baseline is not set, the normal range will center 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 lymphedema



L-Dex Categories without a Baseline

Gray (Below Normal L-Dex)	L-Dex scores below 2 or 3 standard deviations less than the population mean (below -10).
Green (Normal L-Dex)	L-Dex scores between 2 or 3 standard deviations less than the population mean and 1.35 or 2 standard deviations greater than the population mean (-10 to 6.5).
Yellow (Normal L-Dex)	L-Dex scores between 1.35 standard deviations or 2 and 3 standard deviations greater than the population mean (6.5 to 10).
Red (Above Normal L-Dex)	L-Dex scores above 2 or 3 standard deviations greater than the population mean (above 10).

10.2.2.3 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 Lymphedema Assessment taken prior to treatment. This is known as a baseline measurement and the change in L-Dex score is used to categorize the measurement. In this case, an increase of 6.5 L-Dex units (1.35 or 2 standard deviations) from the baseline may indicate early signs of lymphedema.

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 lymphedema.

L-Dex Categories with a Baseline

Gray (Below Normal Change)	Change in L-Dex scores from the baseline that are greater than 2 or 3 standard deviations below the baseline (change greater than -10).
Green (Normal Change)	Change in L-Dex scores from the baseline between 2 or 3 standard deviations less than the baseline and 1.35 or 2 standard deviations greater than the baseline (change between -10 and +6.5).
Yellow (Elevated Normal Change)	Change in L-Dex scores from the baseline between 1.35 and 2 or 2 and 3 standard deviations greater than the baseline (change between +6.5 and +10).
Red (Above Normal Change)	Change in L-Dex scores from the baseline that are greater than 2 or 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 customize 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 lymphedema and SOZO is being used to track their progress, do not set the baseline.

10.2.3 Recommended Measurement Frequency

Clinical Practice Guidelines for Bioimpedance Spectroscopy (L-Dex) for Breast Cancer Related Lymphedema Assessment were published in *The Breast Journal* in 2016*. The guidelines recommend the following protocol for monitoring patients at-risk for lymphedema with a clinical assessment using L-Dex:

- Baseline
- Years 1-3: Every 3 months
- Years 4-5: Every 6 months
- Years 6+: Annually

* Shah C, et al. Bioimpedance Spectroscopy for Breast Cancer Related Lymphedema Assessment: Clinical Practice Guidelines. *The Breast Journal* 2016;DOI: 10.1111/tbj.12647.

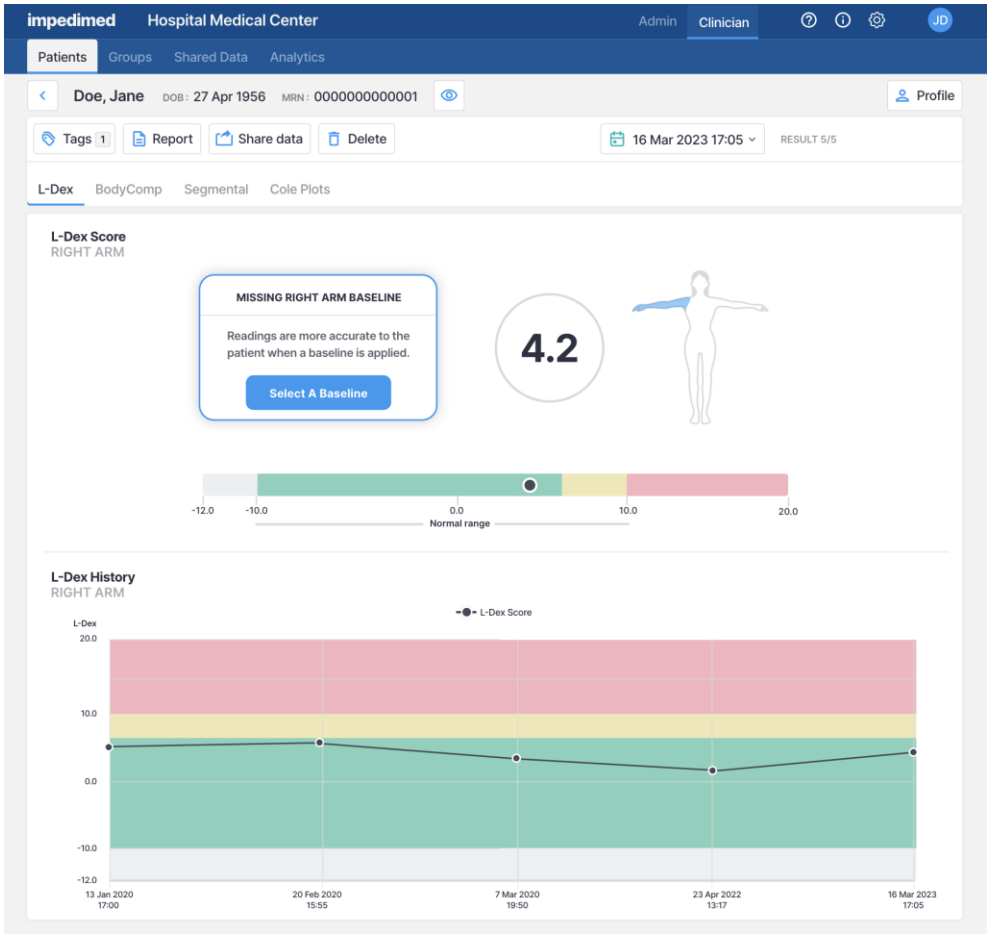
10.2.4 L-Dex® Assessments

10.2.4.1 Measurement Results

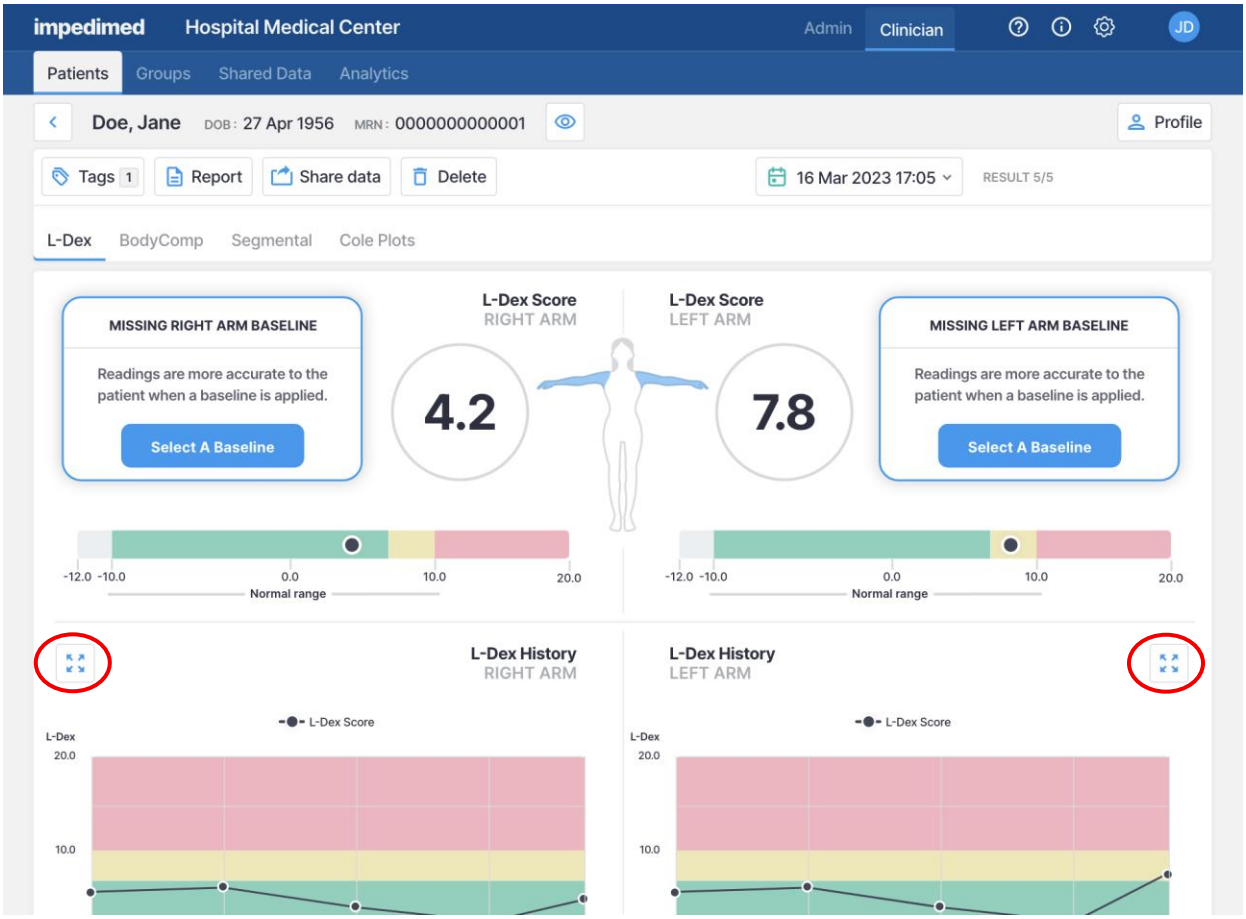
After a successful measurement, the SOZOapp screen will display the results of an L-Dex measurement. In addition to the immediate results, a history of previous patient measurements is displayed in graph format, to allow comparison between current results and previous results. This shows increases or decreases in the L-Dex score over time. The same patient history information can be accessed from MySOZO through a web browser. Below are examples of the results of unilateral and bilateral measurements. The L-Dex score is prominently displayed inside a color-coded circle which matches the color on the graph (only when a baseline is set), and the limb or limbs at risk of lymphedema are highlighted.

NOTE: If the circle is clear, a baseline has not been set. To set a baseline, see 10.2.5 Setting the Baseline.

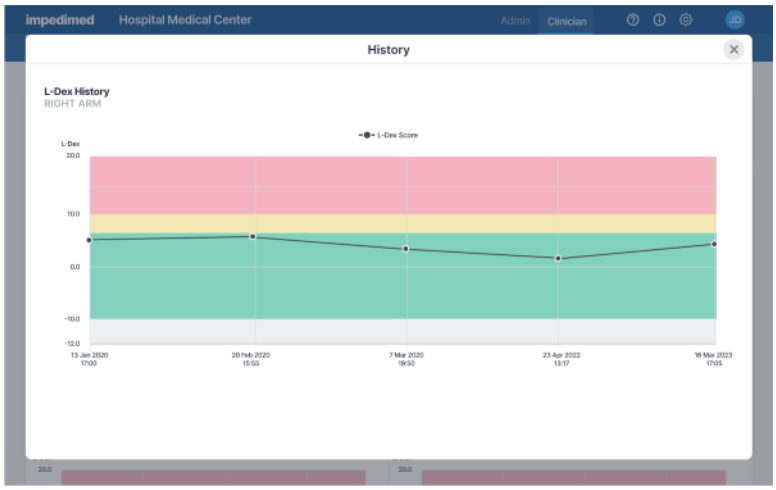
Unilateral measurement example:



Bilateral measurement example:



To expand the History graph for easier viewing of multiple measurements over time, select the **Expand** icon.

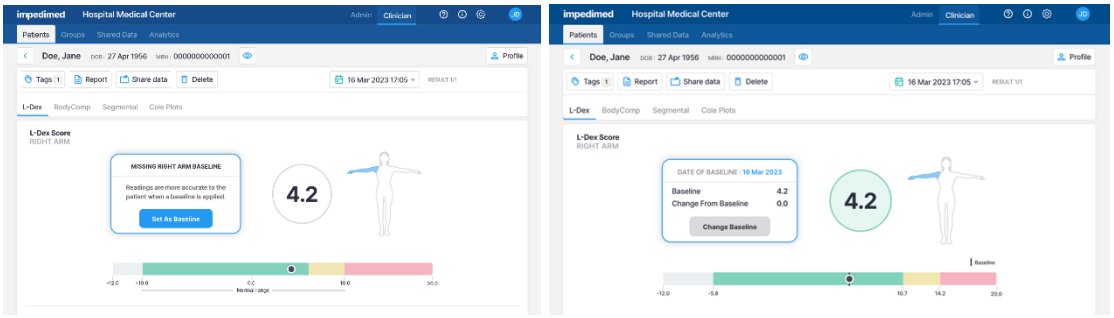


10.2.5 Setting the Baseline

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.

To set a baseline for a single measurement:

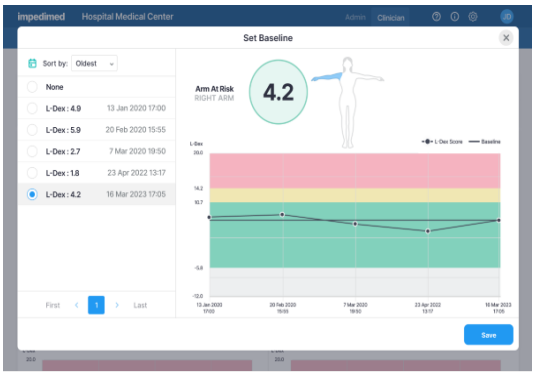
For a single measurement, select the **Set As Baseline** button. The L-Dex score graphic will be updated with the corresponding color on the graph.



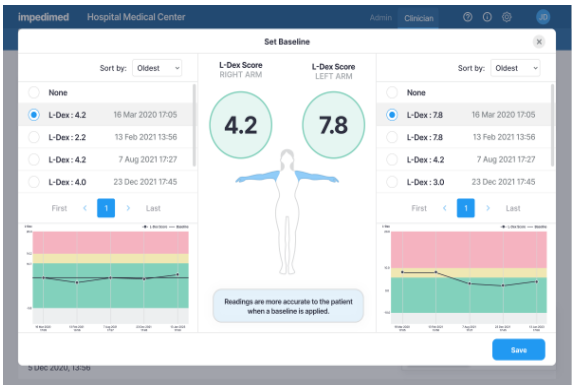
To set a baseline when there is more than one measurement:

1. Select the **Select A Baseline** button.

2. In the Set Baseline pop-up, select the measurement from the list(s). You can arrange the list by selecting Oldest or Newest in the Sort drop-down.
    - For a Unilateral measurement:



- For a Bilateral measurement:



3. Select **Save**.
4. The button name changes to **Change Baseline** to allow for future changes to the baseline.

10.3 HF-Dex® for Heart Failure Instructions for Use

All warnings, contraindications and precautions apply. In addition, consider the following when using SOZOapp to take HF-Dex measurements on a patient:

In order to use the HF-Dex assessment, the facility will require a license. The patient will additionally need to have the HF-Dex assessment selected in their profile. After doing so, HF-Dex 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 error message below will be displayed instead.

10.3.1 Indications for Use

The SOZO® HF-Dex assessment 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.

10.3.2 HF-Dex® Assessments

10.3.2.1 HF-Dex® Score

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:

Light Blue range: HF-Dex values in the light blue reference range are consistent with healthy individuals who do not have heart failure[6].

Medium Blue and Dark Blue ranges: Patients whose HF-Dex score falls into the medium blue and dark blue ranges may have raised scores that are above the reference range for generally healthy individuals with normal fluid levels and may require additional clinical investigation.

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

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

[6] US Department of Health and Human Services. National center for health statistics. The Third National Health and Nutrition Examination Survey (NHANES III, 1988 – 1994).:Centers for Disease Control and Prevention: Washington, DC; 1996.

10.3.2.2 Recommended Measurement Frequency

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

10.3.3 HF-Dex® Measurement Results

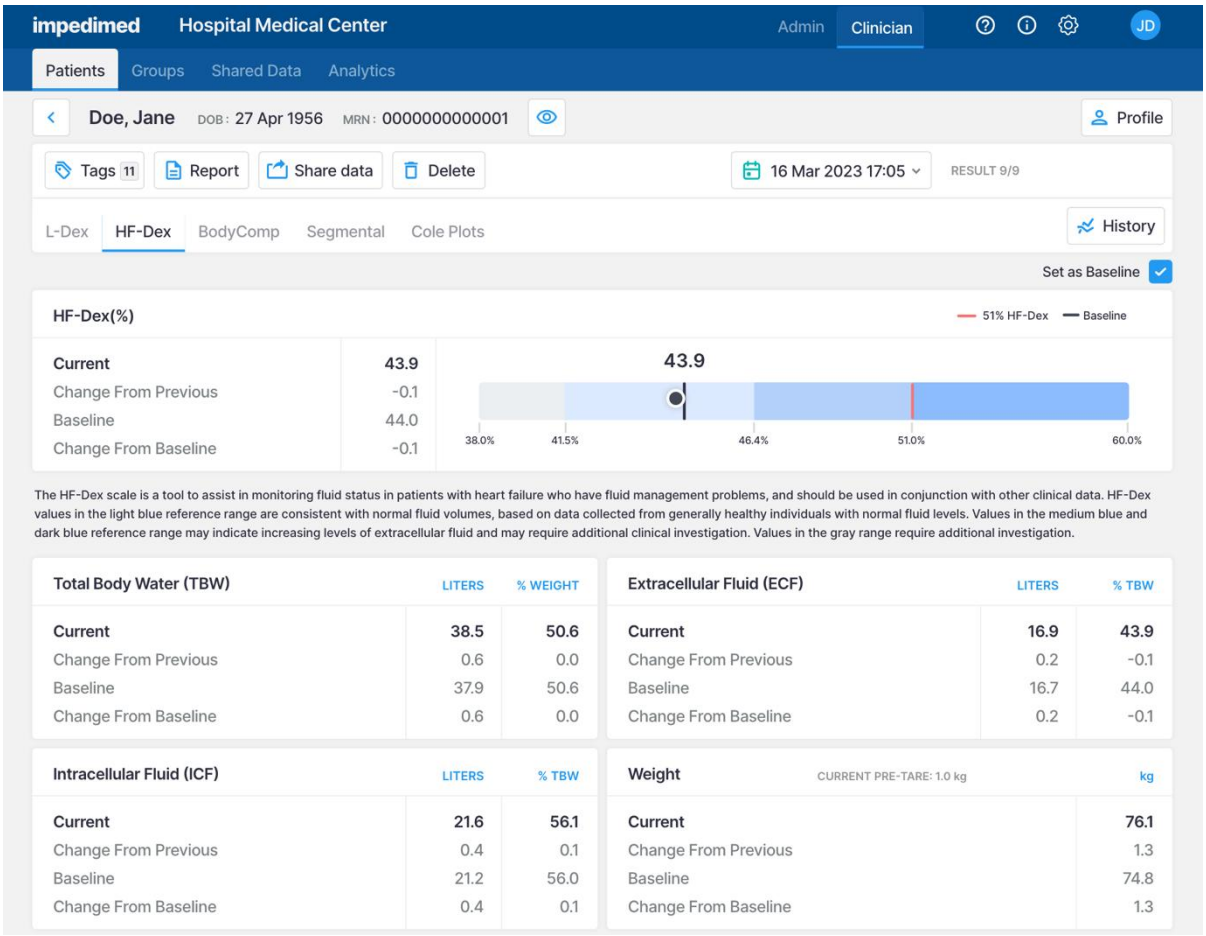
Information in a HF-Dex Assessment includes the patient's baseline HF-Dex score, change vs. baseline, and change from previous HF-Dex score.

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

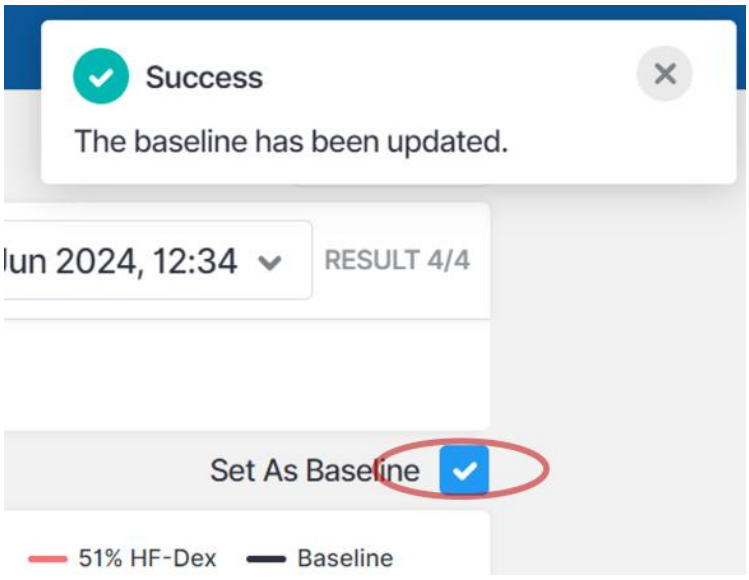
10.3.3.1 Example of HF-Dex Results

To view History, select the **History** button.



10.3.4 Setting the Baseline

Selection of a baseline – a “normal HF-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 check the box next to **Set As Baseline**:



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

For a HF-Dex score, an optimal baseline is typically taken when the patient, in a clinician’s estimation, is appropriately euvolemic. It may take some time to establish an appropriate baseline measurement for the patient.

10.3.5 Historical Results

The results screen will also display the patient’s HF-Dex, TBW, ICF, ECF scores as well as weight on history graphs. The HF-Dex history will also overlay the same ranges (Blue-Gray) used in the HF-Dex measurement result.

10.4 BodyComp™ Analysis Instructions for Use

All warnings, contraindications and precautions apply.

10.4.1 Indications for Use

When using the SOZO Pro device's BodyComp Analysis assessment module for fluid and tissue measurements, the following indications for use applies:

The SOZO Pro 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)
- Extracellular Fluid (ECF)
- Skeletal Muscle Mass (SMM)

The following outputs are also presented:

- Body Mass Index (BMI)
- Basal Metabolic Rate (BMR; based on Mifflin – St. Jeor's algorithm) displayed in kcal (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 from fat-free mass.

Additionally, the SOZO Pro device provides a 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.

10.4.2 BodyComp™ Assessment Results (Whole Body)

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 settings section).

10.4.2.1 Total Body Water (TBW)

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

10.4.2.2 Extracellular Fluid (ECF)

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

10.4.2.3 Intracellular Fluid (ICF)

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

10.4.2.4 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.

10.4.2.5 Hydration Index (Hy-Dex®*)

Hydration Index represents fluid status compared to a healthy population dataset. Impedance outputs are matched to data using age, gender, height and weight. A positive number is indicative of person with positive hydration, and a negative number is indicative of a person that is less hydrated.

*Hy-Dex (Hydration Index) is for healthy people only.

10.4.2.6 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 lbs). Reference ranges for SMM were established based on data presented in Janssen (2000)[7].

10.4.2.7 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 (lbs) 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”.

---

[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.

10.4.2.8 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 lbs) or expressed as a percentage of total mass (e.g., 60% fat free mass). In the segmental measurement assessment, the lean soft tissue elements along are presented.

10.4.2.9 Protein and Minerals

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

10.4.2.10 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].

10.4.2.11 Waist-Hip Ratio (WHR)

Waist-Hip Ratio (WHR) can help to inform about a patient’s concentration of abdominal fat. Waist circumference and hip circumference is entered into the SOZO software via previous measured data. SOZO does not measure either patient hip or waist values. MySOZO only calculates the ratio once the waist circumference and hip circumference are entered into the software.

10.4.2.12 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.

10.4.2.13 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 %

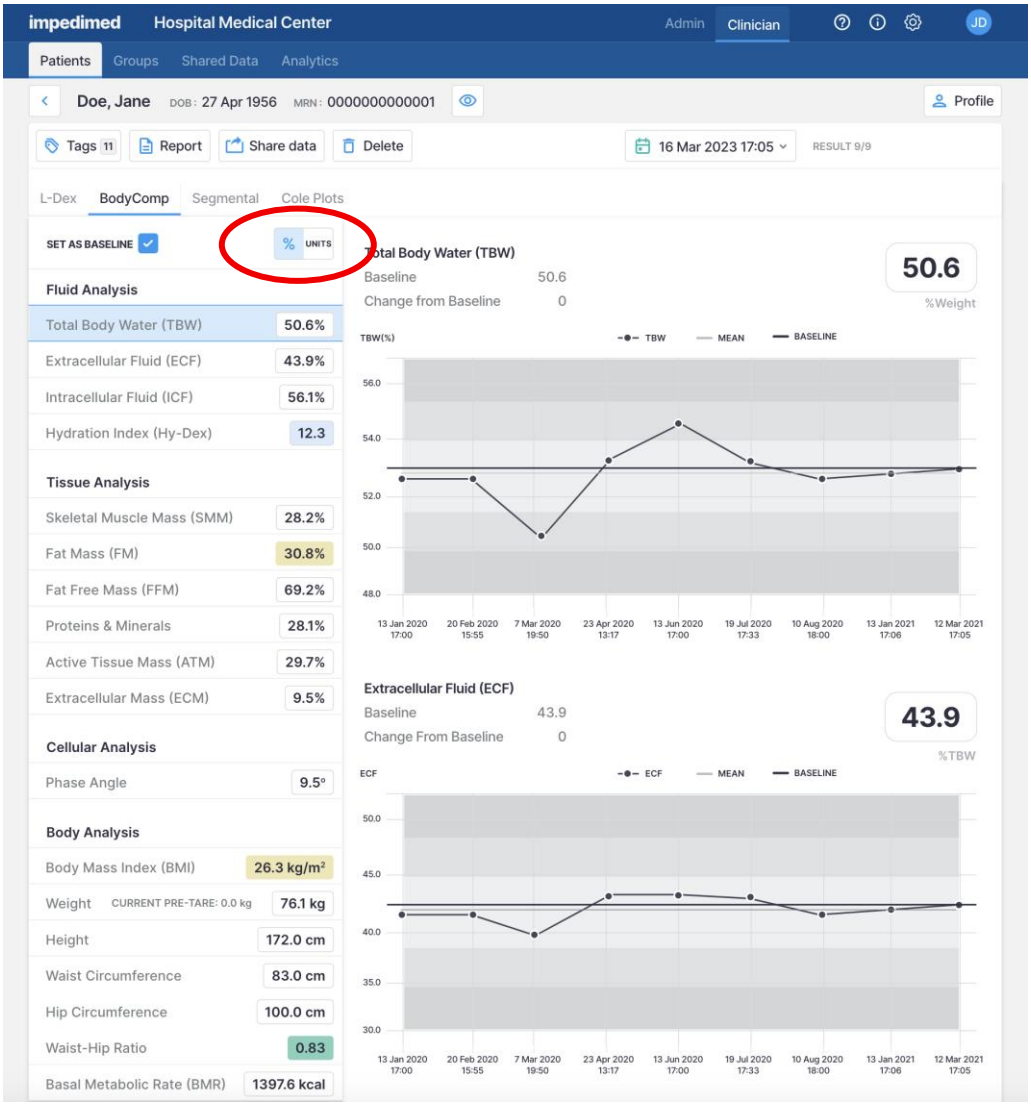
---

[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.

- Intracellular Fluid, expressed as a %
- Fat Mass, expressed as a %
- Hy-Dex
- Skeletal Muscle Mass, expressed as a %
- BMI
- Phase Angle
- Waist-Hip Ratio

10.4.2.14 Example of Whole-Body BodyComp™ Results

You can toggle between percentage and units of measurement.

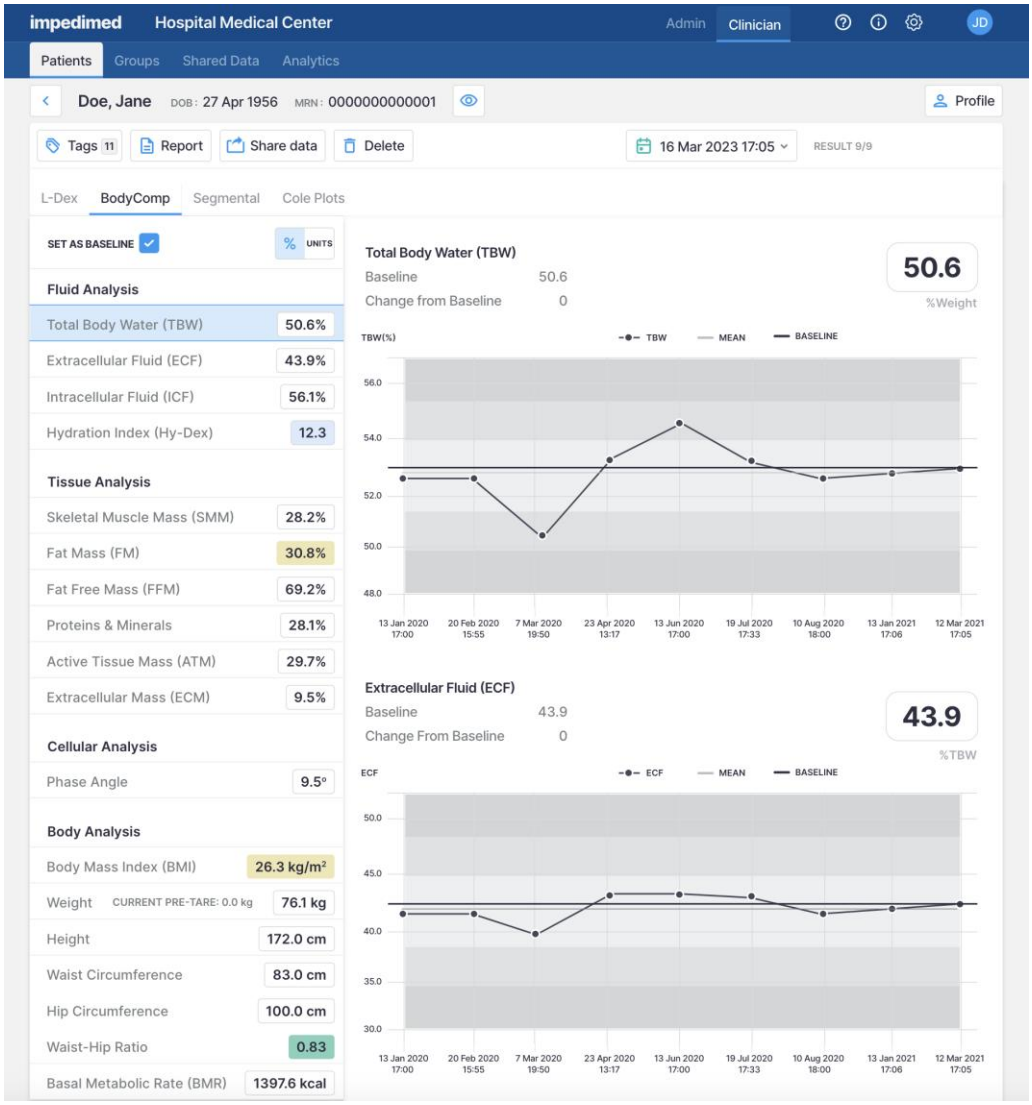


NOTE: All SOZO volume results are calculated using full precision of the impedance information and then rounded to one decimal place for display. As such, when results

are small, minor differences between absolute numbers and percentages may be observed.

10.4.3 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 check the box next to **Set As Baseline**:



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

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 your patient.

10.5 Segmental BodyComp™ Assessment Parameters (Limbs)

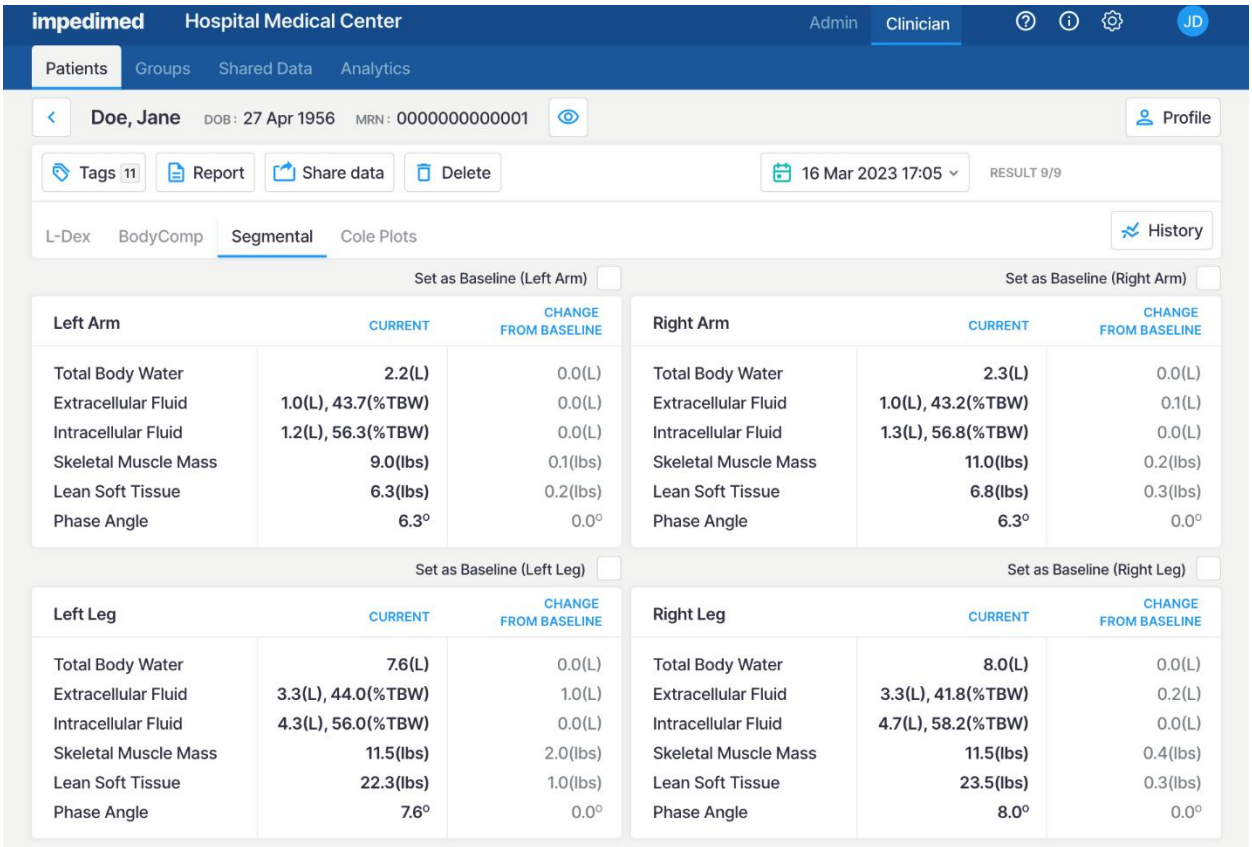
If the clinic has licensed the SOZO segmental body composition assessment, and the patient has been selected to have segmental results presented, a subset of SOZO BodyComp outputs can also be tracked for individual limbs in the same patient.

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

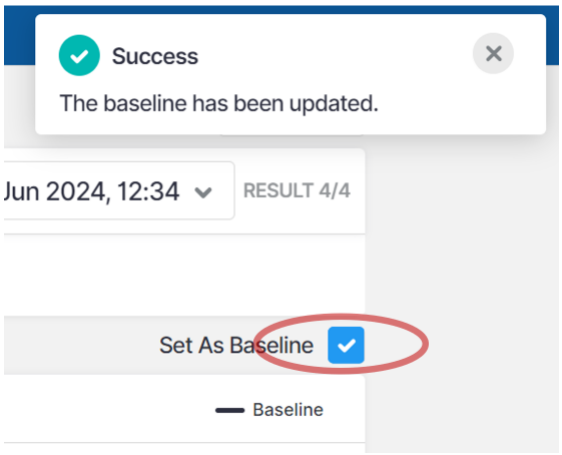
NOTE: Reference ranges are not available for individual body segments.

10.5.1 Example of Segmental BodyComp™ Results



10.5.2 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 check the box 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 set as 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 your patient.

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 11.6, General Troubleshooting Chart.

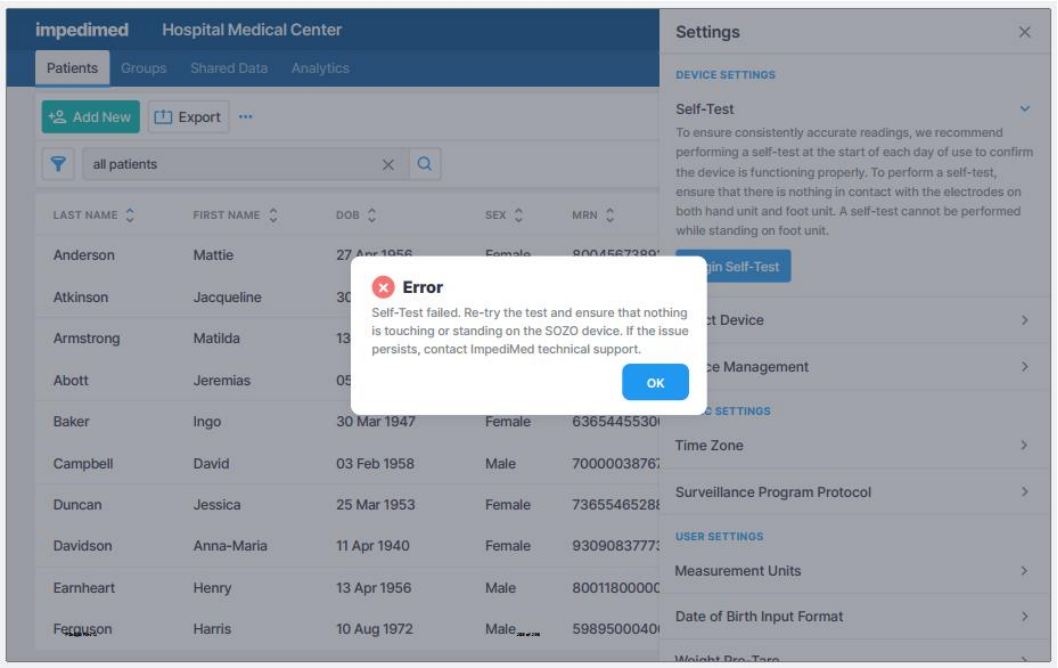
11.1 Device Errors

The SOZO Pro Device conducts regular checks of the electronics and will show errors on the display. If an error is presented, power the device off and back on and retry the measurement. If the error persists, contact ImpediMed Technical Support, and note the number of the error code that is displayed.

Example of Error Code

11.2 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:

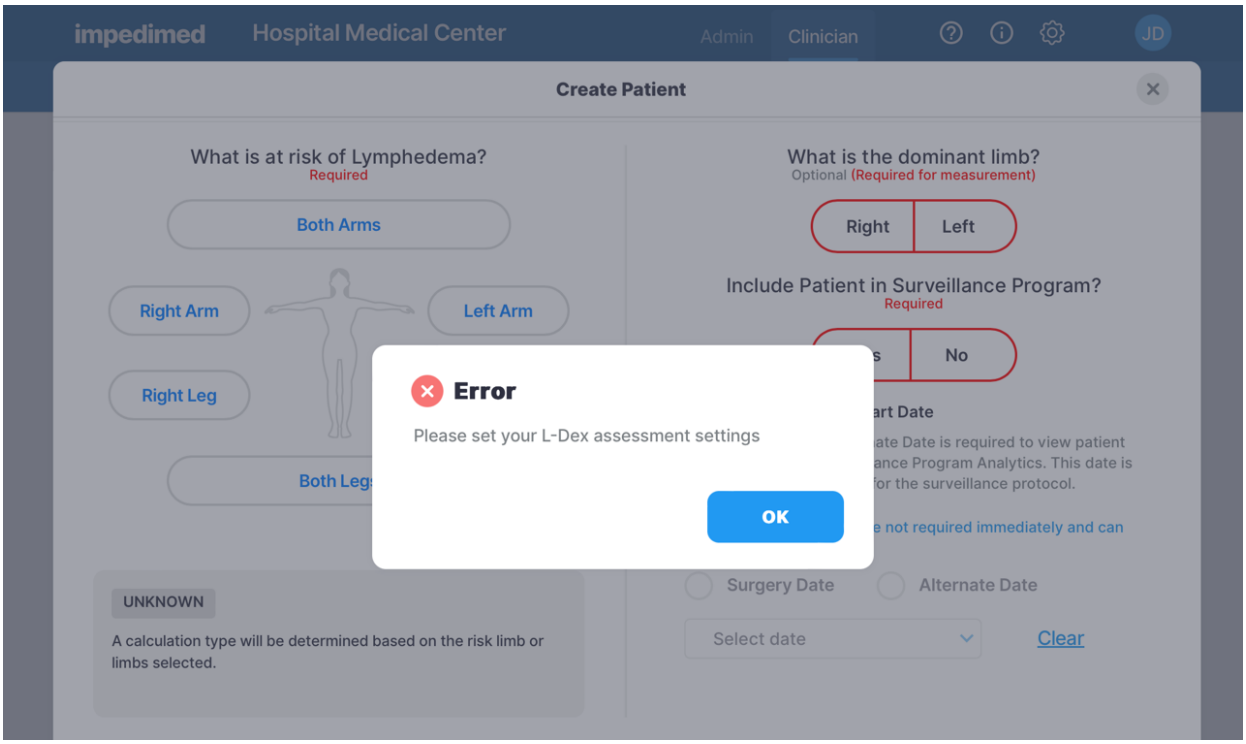
1. Ensure that nothing is touching the SOZO Pro Device during the self-test.
2. Reset by pressing and holding the Bluetooth® button on the back of the Hand Unit for 3 seconds.
3. Unplug the SOZO Pro Device from the wall outlet for 10 seconds and plug it back in.

Re-run the self-test function.

11.3 Lymphedema Settings Error

Editing Lymphedema 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 measurement settings.*"

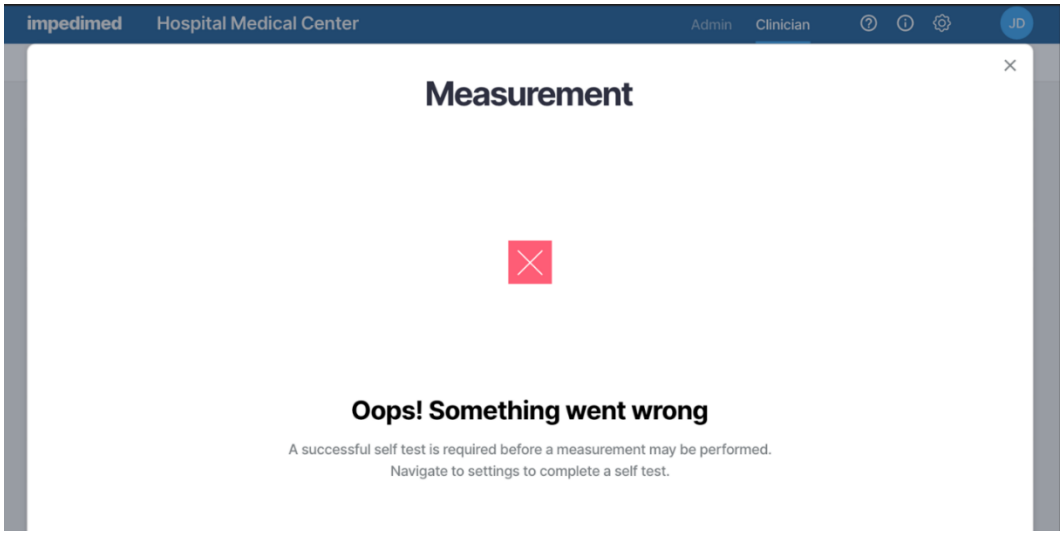


Follow the below actions to resolve this issue:

1. Under "What is at risk of Lymphedema?", select the option that applies: Both Arms, 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.

11.4 Patient Dashboard Error

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



Follow the actions below to resolve this issue:

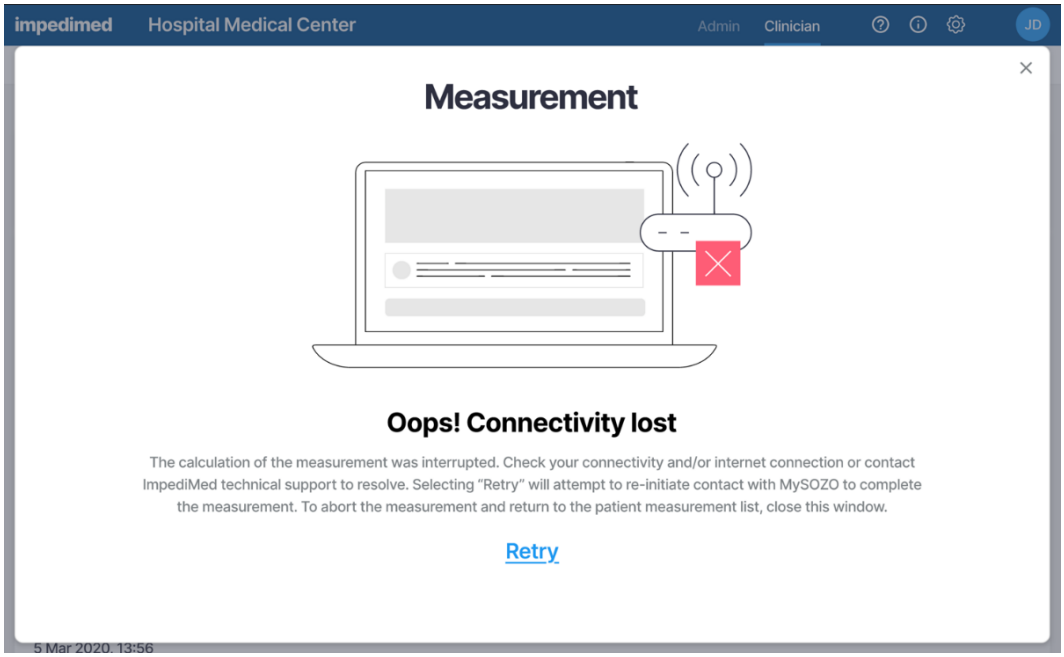
- Ensure that nothing is touching the SOZO Pro Device.
- Go to the **Settings** icon.
- Select **Self-Test**. Run the self-test.

If the self-test fails, the actions below may resolve device issues:

- Unplug the SOZO Pro Device from the wall outlet and plug it back in.
- Re-run the self-test function.

11.5 Connectivity Error

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



Follow the below actions to resolve this issue:

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

11.6 General Troubleshooting Chart

The General Troubleshooting chart provides guidance for common issues and error messages. In the event that you need additional help, call 877 247-0111 option 4, ImpediMed Technical Support, or you may email ImpediMed at tsu@impedimed.com or visit https://www.impedimed.com.

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

General Troubleshooting		
Issue/Error message	**Potential Cause**	**Resolution**
Patient's weight is not as expected	Patient is resting weight on an external device, such as the hand unit. Or, the device has been tared/zeroed incorrectly. Or, the device is out of calibration.	Re-capture the weight measurement. Have the patient step off the device and perform a Tare/zero. Check scale weight again. If needed, power cycle the device which should reset the scale. If weight remains incorrect, the scale may need to be re-calibrated.
Unable to get a weight	Weight has not settled	Ensure that the patient holds still and allows the weight to settle. The display will bold and be underlined when the weight has settled.
Unable to take stable patient weight	Issues with patient scale	Power cycle device. Contact ImpediMed Technical Support if unable to resolve.
Unable to get a weight	Patient weight is above the device maximum of 220 kg or 485 lbs.	Use an alternative method to weigh the patient and then take an Impedance measurement in a seated position.

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. An email will be sent to reset password.
“There is a connectivity problem. Check your internet connection or contact ImpediMed Technical Support.”	No connection – Tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection, there may be poor Wi-Fi coverage in the area.	Check Tablet settings to ensure that the 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, select Yes”.	Signing in to SOZOapp with previous app version after MySOZO has been updated.	On the 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 that the Tablet is connected to local Wi-Fi network. If Tablet is connected, contact your IT admin; otherwise call ImpediMed Technical Support.
“For security reasons your session has expired” or you have been logged out and see the login page.	User will be signed out automatically based on initial sign in. The sign-out time is set by the Clinic administrator.	Sign back in with username and password.
“Measurement not started. Electrode check failed”	SOZO hardware verifies that electrodes are connected correctly before taking a measurement. Ensure that correct patient contact is made for all eight electrodes. If any physical damage has occurred to hardware electrode check may also fail.	Power the SOZO Pro 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 Pro 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.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	**Potential Cause**	**Resolution**
“Device not found. Please check your selected device”	SOZOapp is not currently paired to a nearby SOZO Pro Device	Verify that the device chosen is available via Bluetooth by selecting “pair device”. If device is selected and error has occurred, ensure that the serial numbers match (if multiple units at your Clinic). If using the Android app, ensure that the Bluetooth name of the device chosen does not start with IOS. If it does, unpair the device and select the device with the same serial number that does not begin with IOS. Verify SOZO Pro 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 Pro Device. If error persists, contact ImpediMed Technical Support

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	**Potential Cause**	**Resolution**
“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 Pro Device Bluetooth has malfunctioned.	Confirm Tablet Bluetooth is turned on, that the proper SOZO Pro Device is selected, and that the Tablet is within range to allow a Bluetooth connection. Turn off and restart the Tablet and the SOZO Pro Device. Verify SOZO Pro 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 Pro 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.

Use of SOZOapp / MySOZO (Clinician)		
Issue/Error Message	**Potential Cause**	**Resolution**
"Something Went Wrong. The Tablet encountered an error in communication with the SOZO Pro Device. Please check that the correct SOZO Pro Device has been paired and selected in the settings, the SOZO Pro Device is powered on and is located near the Tablet, and minimize any potential interference from other wireless devices. If the issue persists, try again and contact ImpediMed Technical Support."	The Tablet has lost Bluetooth connection with the SOZO Pro 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 Pro Device is selected, and that the Tablet is within range to allow a Bluetooth connection. Turn off and restart the Tablet and the SOZO Pro Device. Verify SOZO Pro 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 Pro 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. See 10.2, L-Dex® for Lymphedema Instructions for Use for further explanation.

Administrator Interfacing with the SOZO Pro 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 SOZO Clinician, the selected email address is identical to an existing 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 CARE AND MAINTENANCE

12.1 SOZO Pro Device Care

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

The external surface of the SOZO Pro 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 Pro Device as that may cause corrosion of the electrodes. The external enclosure of the SOZO Pro Device may be cleaned with disinfecting agents such as isopropyl alcohol 70% or Peridox® Concentrate Sporicidal Disinfectant and Cleaner.

SOZO Pro Devices 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
- Medizar Wipes
- Oxivir Wipes
- Sani-Cloth Prime
- Super Sani Cloth
- Super Sani Cloth Prime Wipes
- Sani Prime Liquid

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

- Signa Spray electrode solution prep from Parker Labs

The Tablet may require cleaning and disinfection as well. For the Tablet provided with the SOZO Pro 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 Pro 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 Pro Device, or give an incorrect reading. The SOZO Pro Device should be used in a dry environment.

Contact ImpediMed or an authorized agent for repair.

Do not attempt to sterilize any component or accessory of the SOZO Pro Device.

12.2 SOZO Pro Device Maintenance

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

The SOZO Pro weight scale comes pre-calibrated from the manufacturer. Thereafter, annual weight scale calibration is recommended (see 13.6, Weight Scale Maintenance and Calibration).

12.3 Self-Test

To ensure that the SOZO Pro 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.

12.4 Repairs

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

12.5 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.

12.6 Weight Scale Maintenance and Calibration

For annual weight scale calibration, refer to the SOZO® Pro Weight Scale Calibration Instructions For Use, LBL-567.

NOTE: Separate software, SFT-044 - SOZO Pro Weight Calibration Software, is required to perform a scale calibration. A SOZO Pro scale calibration plate is also available from ImpediMed to provide a stable, flat scale surface on which calibration weights can be placed to avoid damaging the SOZO Pro electrodes.

12.7 Technical Support

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

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

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

12.8 Components and Accessories

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

- Stand
- Connect Cable
- Power Adaptor
- Tablet
- Weight Scale Calibration Plate

13 PRODUCT WARRANTY

Definition of Products:

SOZO Pro System.

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

Limited Warranty:

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

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

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

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

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

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

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

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

14 REGULATORY STATEMENT

FCC ID: QOQBT121

This device complies with Part 15 of the FCC Rules

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

This device complies with the R&TTE Directive.

15 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, 1.25A Electrical safety and EMC testing performed against IEC-60601-1, 60601-1-2. Biological safety testing performed against ISO-10993-1, 10993-5 and 10993-10. Sinpro (HPU25-108-P01K002-E2B120-24) • Universal Input 80-275VAC 47/63Hz • DC Output 24VDC, 1.2A • 120mv P-P Noise • Interchangeable adapters Type A (USA), C (EU), G (UK), I (AU) • Safety: IEC60601-1, IEC60601-1-11
Dimensions	Assembled: 28.7 × 22.4 × 51.7 in / 72.9 × 57.0 × 131 cm (L × W × H) Hand Plate L=330mm, W=180mm, D=170mm Foot Plate L=450mm, W=320mm, D=40mm
Effective Radiated Power (BT Module)	+18 dBm
Weight	SOZO Pro Device: 34.0 lb/15.5 kg SOZO Pro Stand: 66.0 lb/30.0 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	Temperature range of + 5 °C to + 40 °C Relative humidity range of 15% to 93%, non-condensing; and an atmospheric pressure range of 700 hPa to 1060 hPa.
Device (IEC 60601-1) Electrical Classification	Type BF 
Electromagnetic Compatibility	Meets the requirements of IEC 60601-1-2 and 60601-1-11.
Minimum Service Life of Device and Accessories	Minimum service life and associated warranty of parts and accessories is one year.

16 SAFETY INFORMATION

Guidance and manufacturer's declaration – electromagnetic emissions		
The SOZO Pro Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Pro 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 Pro 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 Pro 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 Pro Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Pro 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 Pro Device requires continued operation during power mains interruptions, it is recommended that the SOZO Pro 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 Pro Device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO Pro 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) 6 Vrms (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 meters. 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 Pro Device				
The SOZO Pro Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SOZO Pro Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SOZO Pro 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

17 GLOSSARY

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

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

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

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

Bilateral - A type of L-Dex Assessment for a patient who has both arms or both legs at risk of lymphedema.

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

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

BIS - Bioimpedance Spectroscopy.

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

BodyComp™ Assessment - The Assessment, also referred to as "Fluid and Tissue Analysis," performed by the SOZO Pro 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

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

Clinician - The primary User of the SOZO Pro System, and an authorized User of MySOZO and the SOZOapp. The Clinician uses the SOZO Pro 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 Pro Device which the ImpediMed customer uses recurrently, and which eventually wears out, gets used up or is discarded. For example, the Tablet sleeve is a consumable.

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

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

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

Electrode Plates - See "Electrodes."

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

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

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

Hex Key - Torx L-Key with Standard Tip, T25 Size, 3" Overall Length.

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

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 (liters or pints).

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

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

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

L-Dex® Assessment - also referred to as "L-Dex," based upon L-Dex values, derived from the ratio of impedance for the unaffected limb and the at-risk limb or the predicted impedance of the limbs in a healthy population, of the body fluid levels of patients at risk of lymphedema, using certain patient measurements taken with the SOZO Pro Device.

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

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

Measurements - Measurement data taken by the Clinician of the patient using the SOZO Pro 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 Pro Device. Users may access MySOZO.com via the internet.

Parameter - A clinically meaningful output based upon measurements.

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

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

Segmental BodyComp - The Assessment, also referred to as "Segmental Analysis for BodyComp," performed by the SOZO Pro Device of the body composition of limbs for the patient, designed to estimate various body composition parameters, including Total Body Water (TBW), Extracellular Fluid (ECF), Intracellular Fluid (ICF), Skeletal Muscle Mass (SMM), Lean Soft Tissue and Phase Angle (Phi) for the left arm, left leg, right arm and right leg of the patient.

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.

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

Connect Cable - The hardware component of the SOZO Pro Device used to connect the Hand Unit with the Foot Unit.

Foot Unit – A hardware component of the SOZO Pro Device upon which the patient stands (places their feet) for connection to the SOZO Pro Device.

Hand Unit – A hardware component of the SOZO Pro Device upon which the patient places their hands for connection to the SOZO Pro Device.

Power Adaptor – Medical grade universal power adaptor 24 VDC.

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

Tablet – Android Tablet or Apple iPad, provided to the ImpediMed customer as part of the SOZO Pro System.

Tablet Cradle – The hardware component of the SOZO Pro Device which holds the Tablet in place.

SOZO Pro Scale Calibration Application - A PC-based application used to calibrate the SOZO Pro scale.

SOZO Pro 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 Pro System includes hardware (the SOZO Pro Device and the Tablet) and software (MySOZO and the SOZOapp).

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

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

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

Weight, Gross - weight measured by the SOZO Pro scale.

Weight, Net - pre-tare weight subtracted from gross weight.

Weight, Pre-Tare - weight to subtract from gross weight (e.g., to account for clothing weight); this value is entered by the user; pre-tare functionality may be disabled.

Xc - Reactance, used by the SOZO Pro 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.