



SOZO[®]

by impedimed[®]

**SOZO App and System
Instructions For Use**



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For assistance with product set up please review the help videos at <https://www.impedimed.com>. For other assistance, or to report product issues, please contact ImpediMed U.S. by email at tsu@impedimed.com or by phone at 877 247 0111.

EC	REP
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Unique Device Identifier

SOZO device: B277272700011



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/>

Contents

Minimum Requirements	6
Tablet.....	6
SOZO app	6
Introduction	7
The SOZO Device	7
Bioimpedance Spectroscopy (BIS)	7
Components of the SOZO System	8
Safety Instructions	9
Signs and Symbols.....	9
Intended Use	10
Contraindications.....	10
Warnings	10
Precautions.....	10
Use and Storage Conditions	12
Environmental Operating Conditions	12
Environmental Transport and Storage Conditions	12
Location for Use	12
Setting Up the SOZO Device and Stand	14
Setting Up the SOZO Device without Stand	15
To use the SOZOdevice while sitting without the stand, follow the directions below for set up. .	15
Step 1: Connecting SOZOtouch and SOZOstep.....	15
Step 2: Connecting the Tablet Stand	15
Step 3: Connecting Power Supply	16
SOZOhub installation	17
Pairing Tablet and SOZO App to SOZO System	18
Step 1: Pair tablet to SOZO hardware	18
Step 2: Connect app, tablet and hardware.....	18
Initial setup of SOZO app.....	18
Connecting the SOZO app with the SOZO system.....	20
Preparing the patient	22
Standing vs. Seated positions	22

Optimal readings	22
Standing Position	22
Seated position.....	23
Using the SOZO App.....	24
Overview.....	24
Start-up.....	24
Logging In.....	24
Creating/Accessing Patient Profiles	25
Taking Measurements.....	28
Weight Entry	28
Foot Placement	29
Hand Placement.....	29
Measurement Duration.....	31
Cole Plots	31
Viewing Results.....	32
Viewing a Patients Historical Measurements	33
Reviewing Individual Results.....	35
Recalculating Results/Assessment Type Licenses.....	36
Review/Edit Patients Personal Details	37
Changing Device Settings	39
Selecting SOZO device within the SOZO app	39
Assessment Types.....	41
Troubleshooting	42
Personal Data	46
Care and Maintenance	47
Care of the Product	47
Self-Test Function	47
Repairs	47
Tablet Maintenance.....	48
Technical Support	48
Accessories	49
ImpediMed Product Warranty.....	50
Regulatory Statement	51

Product Specifications..... 52
Safety and Electromagnetic Compatibility (EMC) Information..... 53

Minimum Requirements

Tablet

The Samsung Galaxy Tab A (model SM-T580) will be provided as the user interface to operate the SOZO device. For more product details, please review www.samsung.com or the tablet's User Guide.

Note: *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.*

SOZO app

The supplied tablet is preloaded with ImpediMed's SOZO app for Android. The tablet and app need to be paired via bluetooth to the SOZO device at initial setup. The app must also have network access over Wi-Fi® to the SOZOhub software to function.

Introduction

The SOZO Device

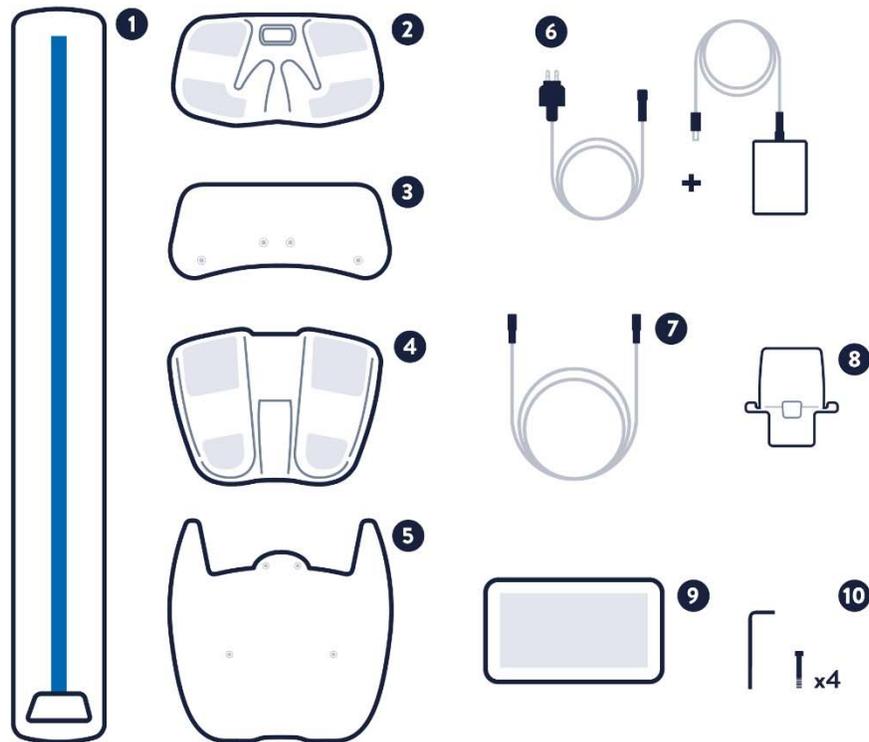
SOZO: A bioimpedance spectroscopy device for use on human patients, utilizing ImpediMed's patented BIS technology in a user-friendly format to allow quick and accurate measurement of fluid levels. This can be used as an "early warning" monitor for determining changes in the fluid status of patients with fluid management problems.

Bioimpedance Spectroscopy (BIS)

Bioimpedance spectroscopy (BIS) is the only non-invasive technology available that has the potential to accurately measure body water volumes. BIS mode measures bioimpedance parameters over a frequency range of 3 - 1000 kHz with 256 data points. Comparison of the data collected within that frequency range enables calculation of extracellular, intracellular and total body water. With additional patient-specific data, further calculations can be made to determine other body composition results. On-screen graphs also display the measured data in the form of a Cole plot.

As a platform, the SOZO device offers rapid, non-invasive, inexpensive comparison of impedance, including fluid monitoring for a variety of conditions. The instruments also enable long-term patient monitoring and provide reports to support clinical and research practices.

Components of the SOZO System



SOZO by ImpediMed is made up of the following product components and accessories:

- SOZOsupport (1)
- SOZOtouch (2)
- Handplate (3)
- SOZOstep (4)
- Footplate (5)
- Power Adaptor and cord (6)
- SOZOconnect cable (7)
- Tablet holder (8)
- Tablet including the SOZO app (9)
- Screws and hex key for stand (10)

Safety Instructions

Signs and Symbols

The warning signs and the symbols below are listed in order to use this product safely and correctly as well as to prevent risk and injury to you and others.

The meanings of the signs are as follows:

Symbol	Definition
	Indicates matters in which bodily harm or material damage or incorrect measurements may arise as a result of incorrect handling.
	What you should NOT do.
	An action that must be followed.
	Follow instructions for use.
	For EU Customers: All products at the end of their life may be returned to ImpediMed for recycling.
	This device is rated BF as per IEC60601-1. This device meets the standard IEC60601-1-2.
	This is a Class 2 medical device.
IP21	Protected from touch by fingers and objects greater than 12 millimeters. Protected from condensation.

Intended Use

SOZO is a medical device, intended for clinical use by operators who have read this manual. This device is intended for use, under the direction of the operator, for the noninvasive 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.

The SOZO app is a software application intended to run on the supplied tablet and provides the main user interface for the system.

The SOZO device and SOZO app are used in conjunction with SOZOhub, a network-connected database system that securely stores patient data that is primarily accessed by the app.

Contraindications



The SOZO device should not be used by:

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

Warnings



Pregnant Patients:

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

Precautions



Ensure that you have read and understood this entire instructions for use document before using the SOZO device. No other specific skill or training is required to take readings using the device.



Do not allow the SOZO device to come in contact with any liquids.



Only use the power adaptor that is supplied with this device. The use of any other power adaptor may expose the patient to the risk of electrocution.



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



Devices or other sources can potentially cause interference problems:

- Example 1: heat from a radiant heater.
- Example 2: moisture from a nebuliser.



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 this device.



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



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



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



The effects of degraded sensors and electrodes, or loosened electrodes, can degrade performance or cause other problems.



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



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



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

Use and Storage Conditions

Environmental Operating Conditions

The SOZO device must be operated in the following conditions:

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

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

Environmental Transport and Storage Conditions

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

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

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

Location for Use

When used with the stand accessory, the SOZO system 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 at a non-metal desk that allows comfortable access from a seated position to the SOZOstep and SOZOtouch components. For seated use, a non-metal chair should be used.



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



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



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



Various environmental factors environment may interfere with device performance including: the effects of lint, dust, light (including direct sunlight), as well as pets, pests, or children.



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



Ensure that you have read and understood this entire instructions for use document before using the SOZO device. No other specific skill or training is required to take readings using the device.



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

Setting Up the SOZO Device and Stand

LBL-503, included with your SOZO device, contains instructions on assembling the stand and the SOZO components. Please observe the following warnings when assembling the device.



Only use the power adaptor that is supplied with this device. The use of any other power adaptor may expose the patient to the risk of electrocution.



Ensure that the connector cable is plugged in to both hand and foot plates before connecting the power supply. If the SOZO device must be moved, please ensure the power supply is disconnected before moving or uninstalling the system.



When plugging the power cord in, the system will automatically run a self-test to ensure functionality. Do not touch the stainless steel electrodes when a self-test is running.

For more information on setting up the SOZO system with stand, please visit www.impedimed.com or contact ImpediMed technical support (contact details on page 44 of this guide).

Setting Up the SOZO Device without Stand

To use the SOZOdevice while sitting without the stand, follow the directions below for set up.

Step 1: Connecting SOZOtouch and SOZOstep

Components required:

- SOZOtouch assembly
- SOZOstep assembly
- SOZOconnect cable

Connect SOZOtouch to SOZOstep with the connector cable. (NOTE: the connector cable port is identical on both the hand plate and foot plate.)

Place the SOZOtouch assembly on a level surface and at a comfortable height to use while sitting. (e.g. table or desk).

Place the SOZOstep assembly on a level surface beneath/in alignment with SOZOtouch. Ensure that SOZOstep is positioned in such a way that the power supply can be easily connected and disconnected.

Step 2: Connecting the Tablet Stand

Components required:

- Tablet
- Tablet stand
- SOZOtouch assembly

Confirm that the SOZOtouch assembly is stationary and on a level surface. Place the tablet holder onto SOZOtouch with the ledge of the holder facing the SOZOtouch stainless steel electrodes. (NOTE: for clinical use, the tablet holder can be reversed with the ledge of the holder facing away from the electrodes) Place the tablet onto the ledge of the tablet stand.

Step 3: Connecting Power Supply

Components required:

- SOZOstep
- Power supply cable

Locate the power supply port on the back of the SOZOstep assembly and plug the corresponding end of the power supply cable into that port.

Take the remaining end of the power supply cable and plug it into the nearest wall outlet. The SOZO device may be safely turned off by unplugging the power adaptor.



Only use the power adaptor that is supplied with this device. The use of any other power adaptor may expose the patient to the risk of electric shock.



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

For more information on setting up the SOZO system without the SOZOsupport stand, please visit www.impedimed.com or contact ImpediMed technical support (contact details in Technical Support section within this guide).

Setup Complete.

SOZOhub installation

While setting up the SOZO device, the SOZOhub software will also need to be installed on a network-connected computer.

SOZOhub is ImpediMed's SOZO management system and database software that will support your SOZO use, store patient measurement data, and interface with the SOZO app. Please refer to LBL-528 for the SOZOhub instructions for use on installation and set up.

SOZOhub installation, and creation of at least one user account, must be completed prior to setting up the SOZO app.

Pairing Tablet and SOZO App to SOZO System

Step 1: Pair tablet to SOZO hardware

Locate the Settings section on the tablet and enable *Bluetooth*. Once Bluetooth is enabled, select ImpediMed SOZO from the list of available devices. (*Note: the SOZO device will be identified by the SOZO device serial number (SOZO-xxxxxxxxx) when the tablet scans for nearby Bluetooth-enabled devices.) The device serial number can be found on the SOZOtouch housing, SOZOstep housing, and the SOZOconnect cable.

The process may be repeated for any new SOZO devices, and will need to be repeated if either the tablet or system have to be replaced. Please note that the app can only select and work with one SOZO device at a time.

Step 2: Connect app, tablet and hardware

Initial setup of SOZO app

The tablet shall come with the ImpediMed SOZO app pre-installed. If, for any reason, the app is removed and needs to be re-installed, please contact ImpediMed to walk through the download and installation process.

With the SOZO app installed, tap on the icon to start it as you would any other app. This will bring you to the login screen:

Login To Your Account

Username

Password

Language

English (US) ▼

Login

Set Connection Path

Note that for as newer app versions are released, the SOZOapp may look cosmetically different from that presented here.

For first-time setup of any SOZO system in the facility, you will need to click on “Set Connection Path” to link the SOZO app to the SOZOhub database on your hospital server. Your IT staff will have the connection path and verification code information that needs to be entered on the following screen.

Set Connection Path

SOZOhub Path

Username

Clinician Password

SOZOhub Verification Code

Note: Administrator must generate a verification code through SOZOhub

Authenticate

To start, http:// is the required format and requires the SOZOhub domain name address that links to the server directory where the database is stored and requires authentication before you can proceed. Using a numeric IP address will not allow for successful pairing of the device.

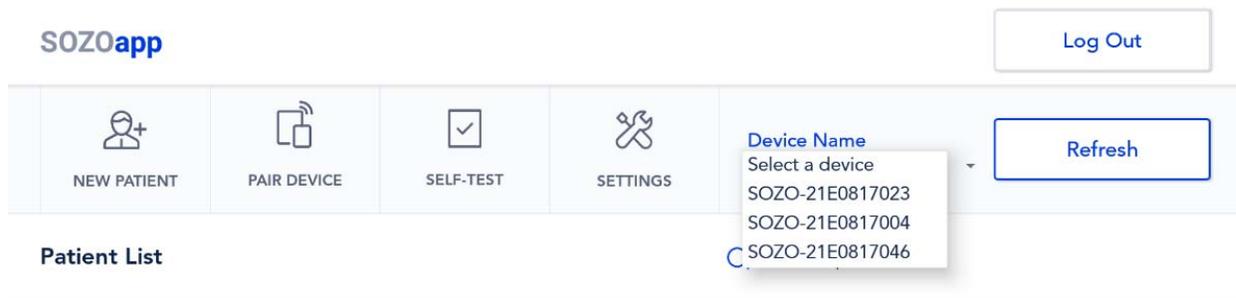


Clinician accounts are not created through the SOZO app. Accounts are created through the SOZOhub management system and database. SOZOhub must first be set up on an accessible network as part of SOZO installation, and a user account created, to proceed further with set up of your SOZO system. Please refer to the SOZOhub instructions for use to create new users to access your SOZO system.

Connecting the SOZO app with the SOZO system

- During first-time setup, the app will need to be paired with the SOZO system. Once the user account has been created and you have logged in to the dashboard screen, click on “Device Name” to bring up a dropdown menu listing all SOZO devices paired to the tablet:

“”



To select the SOZO device on which measurements will be taken, click the drop-down menu under “Device Name” in the patient list screen. This will bring up a list of all SOZO devices, that are paired with the tablet.. Select the device on which measurements are to be taken. The app will recall the last selected device and will continue to point to that device even after logging out.

The app should then automatically connect with the SOZO device that was paired through Bluetooth earlier. This can be confirmed by pressing the “Settings” button which will take you to the overall settings for the device.

If you are unsure whether the device in front of you is the correct device, run a self-test, taking care to not contact the electrodes. If the device emits an audible clicking sound then you are connected to the correct device.

Settings

Help

Get Help

Firmware Update

Update

Measurement Units

kg lbs cm ft in Liters pints

Save

Licensing Status

View

Device Status

Device name Not retrieved
Firmware Not retrieved
Calibration date Not retrieved
MAC address Not retrieved
Serial number Not retrieved
Last self test status Not retrieved

Update

Application Version

Note: ImpediMed recommends keeping your SOZO device together with its paired tablet. The app and tablet may pair to other devices, but will only control measurements from the device that is identified in the “Device Name” field.

Once the SOZO device is shown on the settings tab, you are ready to take measurements.

Setup Complete

Preparing the patient

All individuals taking measurements on a SOZO device should:

1. Remove all metal jewelry/accessories in the measurement path. This does not include items such as earrings or other piercings.
2. Remove all electronics or metal items from pockets
3. Remove stockings or socks
4. Stand still during measurement

If fluid and/or tissue analysis is intended, the patient should observe the following preparation tips to ensure the most accurate reading:

1. Empty bladder prior to measurement start
2. Avoid exercise 2 hours prior to the reading
3. Avoid caffeine 2 hours prior to the reading
4. Avoid alcohol 12 hours prior to the reading

***Note:** It is recommended that measurements be undertaken under similar conditions, e.g. time of day, activity levels, and food and fluid intake.

***Note:** Please also read the Indications For Use section for any indication-specific instructions.

Standing vs. Seated positions

The SOZO system has been designed to accommodate patients who may not be able to stand or do not meet the maximum weight limitations. The SOZO system setup provides instructions on how to configure the system for both standing and seated positions. It is strongly recommended that patients should always take readings from the same position to enable accurate comparisons of fluid levels.

Optimal readings

For best results, when taking a reading from a standing position the subject should stand at rest for a few minutes prior to taking a measurement.

Similarly, when taking a reading from a seated position, the subject should be seated for a few minutes prior to taking a measurement.

Standing Position

When standing on the SOZO device, ImpediMed strongly recommends using the SOZO stand provided with the system.



The patient should:

- distribute body weight evenly on both feet.
- keep arms relaxed with elbows at their side while hands make contact with the electrodes.

Seated position



Do not use 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.

Using the SOZO App

Overview

The SOZO utilizes a Samsung Galaxy Tab A to control the operation of the medical device. The app requires access to your facility's intranet to store patient data.

The app is comprised of four major sections:

- 1) Login screen, where users can log in to access the Dashboard screen. During initial setup, this screen will connect the tablet to the local SOZOhub.
- 2) The Patient List screen, which lists existing patients and allows for new patients to be created
- 3) Patient Profile, which allows measurements to be taken, review of historical records, and editing of patient profile
- 4) Device Settings for SOZO system management.

The following section will describe app functionality and user access.

Start-up

Logging In

Tap the SOZO app icon to launch. This presents the login screen; use your login credentials that were set up through SOZOhub to access the app.

Login To Your Account

Username

Password

Language

English (US) ▾

Login

Set Connection Path

After logging in, you will be taken to the Dashboard screen:

SOZOapp Log Out

NEW PATIENT PAIR DEVICE SELF-TEST SETTINGS Device Name Select a device Refresh

Patient List Search patient

Last Name	First Name	DOB	Sex	MRN	Last Assessment
A Measurement	Example	Fri, 1975 May 2	Female		-

Creating/Accessing Patient Profiles

After setup, patients will need to be added to the database in order to use the SOZO device. All new patients can be added through the Dashboard screen after login. Note that patients do not have their own login, but profiles are controlled through the clinicians log in. To ensure patient privacy, it is strongly recommended that the patient not handle the tablet during measurements.

At the Dashboard screen, patient profiles may be located by tapping “New Patient”.

The app will take you through the patient setup process to record patient information and demographics including:

- Personal and contact details (including local patient identifier)
- Measurement types to be tracked over time
 - For patients at risk of lymphedema, specific details regarding at-risk and dominant limb

Create Patient Create

Patient Details

<p>First Name Required</p> <input style="width: 95%;" type="text"/>	<p>Date of birth Required</p> <input style="width: 95%;" type="text"/>
<p>Last Name Required</p> <input style="width: 95%;" type="text"/>	<p>Sex Required</p> <input style="width: 95%;" type="text"/>
<p>Middle Name</p> <input style="width: 95%;" type="text"/>	<p>Height (ft in) Required</p> <input style="width: 45%;" type="text"/> <input style="width: 45%;" type="text"/>
<p>Medical Record Number (MRN)</p> <input style="width: 95%;" type="text"/>	<p>Email</p> <input style="width: 95%;" type="text"/>
<p>Country Code</p> <input style="width: 95%;" type="text"/>	<p>Postal Code</p> <input style="width: 95%;" type="text"/>
<p>Phone Number</p> <input style="width: 95%;" type="text"/>	

Assessment Type

L-Dex® Analysis for Lymphedema

Tissue Analysis for Body Composition

Fluid Analysis for Heart Failure and General Fluid Status Monitoring

Lymphedema Settings

Assessment Type

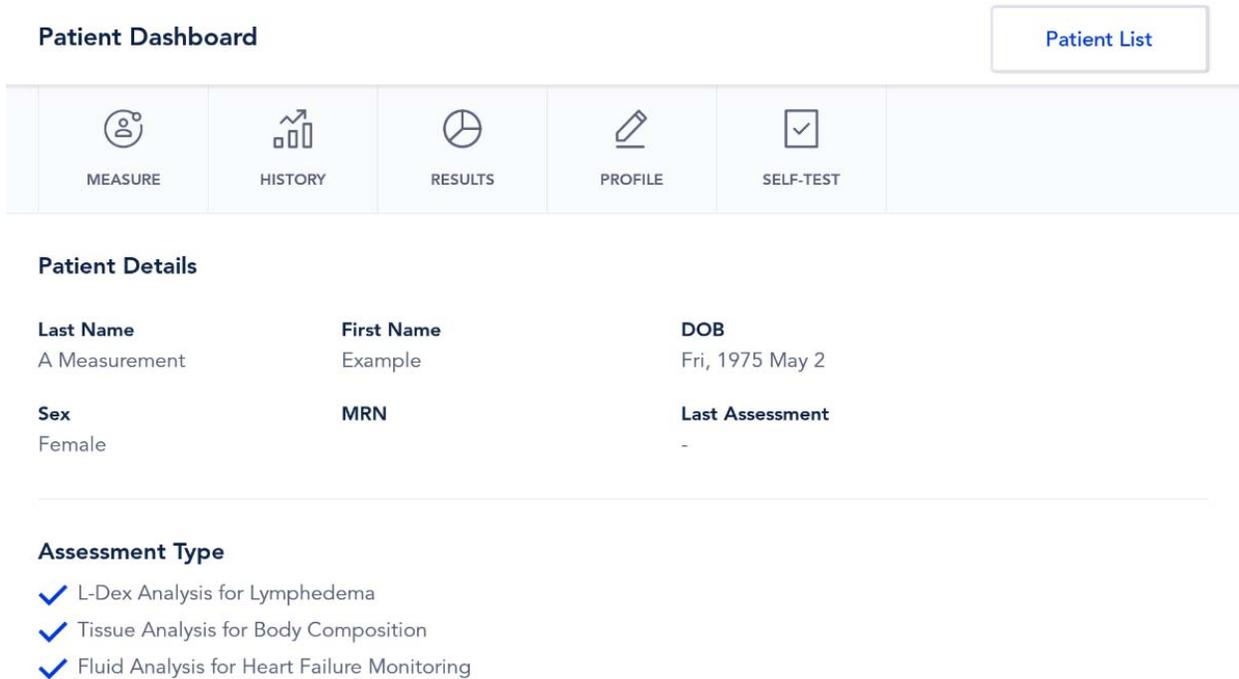
Body Element Arm Leg

Risk Limb Left Right

Limb Dominance Left Right

Note that the “Assessment Type” selections will depend on the facility’s license. Assessment types will only be available if licensed to your facility. Please coordinate with your site administrator and ImpediMed support if additional assessment types are desired.

When all details are complete, tap “Create Account”. The app will take you to the patient summary screen.



To create additional patients, return to the Patient Dashboard, tap on “New Patient” and repeat the process.

“”

“”

Taking Measurements

Your SOZO device may support multiple measurement types including detection of lymphedema, fluid monitoring and various body composition outputs. Each of these applications, along with indication-specific information and reports are discussed in greater detail later in this user guide.

From the Patient List Screen, select the patient to be measured. Within the patient dashboard, tap “Measure”. This will bring up the weight entryfield.

Weight Entry

The app requires input of the patients current weight prior to each reading. Enter the patients weight to proceed Accurate weight entry is critical to tissue and fluid analysis assessments and should be taken immediately prior to the SOZO measurement.

Please enter your weight

Weight (lbs)

The app will then provide reminders about measurement preparation:

A few things before we get started

1. Remove all jewelry, electronics, and metal from pockets
2. Remove shoes and socks or stockings
3. Stand still during measurement

Additional tips for ensuring the most accurate Tissue or Fluid Analysis reading:

4. Empty your bladder prior to measurement
5. Avoid exercise 2 hours prior to measurement
6. Avoid caffeine 2 hours prior to measurement
7. Avoid alcohol 12 hours prior to measurement

Tutorial

Start Measurement

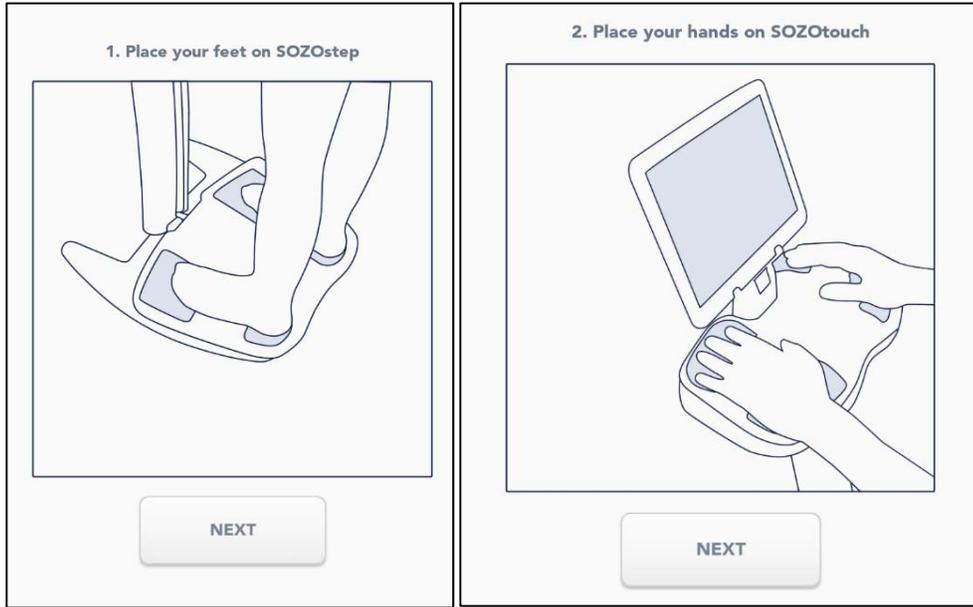
Tapping on Tutorial presents illustrations of correct hand and foot placement onto the electrodes. If familiar with positioning, skip the tutorial by pressing "Start Measurement".

Foot Placement

Confirm that the SOZOstep assembly is stationary and on a level surface. Place feet (no stockings/pantyhose or socks) onto SOZOstep and locate heel recesses. Ensure each foot is flat and in full contact with each electrode plate. (*Note: there are two electrode plates for both the left and right foot.)

Hand Placement

Confirm that the SOZOtouch assembly is stationary and on a level surface. Place both hands onto the SOZOtouch with thumbs securely wrapped around the corners of each recess. Make sure each hand is flat and in full contact with each electrode plate. (*Note: there are two electrode plates for both the left and right hand.)



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



Please read the section on Intended Use and Precautions before making measurements with the SOZO device.

Start Measurement



Measurement will start in...

5

Clicking on “Start” will initiate a five-second countdown. Hands and feet must be firmly placed against electrodes throughout the entire countdown. The measurement will cancel if no contact is detected.

Measurement Duration

Once started, the SOZO device will need 20 seconds to take a complete measurement. Audible clicking noises will be heard as the measurement is taken. These clicking noises indicate that the process is working correctly. Once the measurement is complete, the results for the measurement type will display on the dashboard.

Cole Plots

The SOZO app will then display Cole plots after the sequence is finished. The Cole plot, represented on the graph by a solid red semi-circular line, gives a visual representation of the measurement and is used to determine if a valid measurement has been received.

Individual data points are also represented on the graph. Some degree of “scatter” in individual data points is acceptable, and if they show a trend that is consistent with the Cole plot, this indicates a valid measurement has been performed. In this case, the results can be accepted.

If data points are extremely scattered, or a semi-circular line is not formed, this may indicate that a valid measurement has not been performed. The measurement should then be rejected by tapping “Reject”, and a new measurement should be taken. Otherwise, tap “Accept” to move to the results.

During the brief measurement period some errors may be introduced into the reading if the patient shifts their hands or feet.

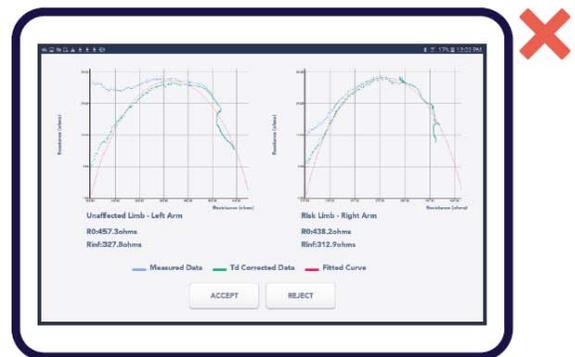
Determination of adequacy for a given measurement can only be made at the time the measurement is taken, but Cole plots are also shown when reviewing historical results.

Examples of acceptable and unacceptable Cole plots follow:

ACCEPTABLE COLE PLOTS



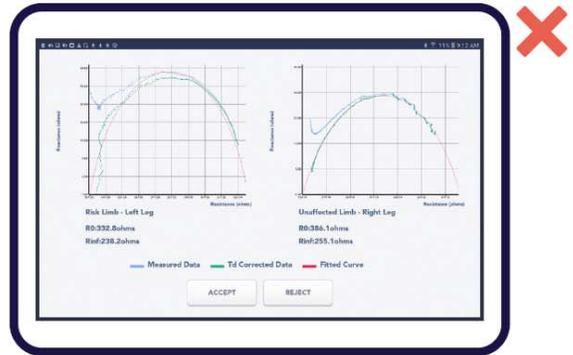
UNACCEPTABLE COLE PLOTS



ACCEPTABLE COLE PLOTS



UNACCEPTABLE COLE PLOTS



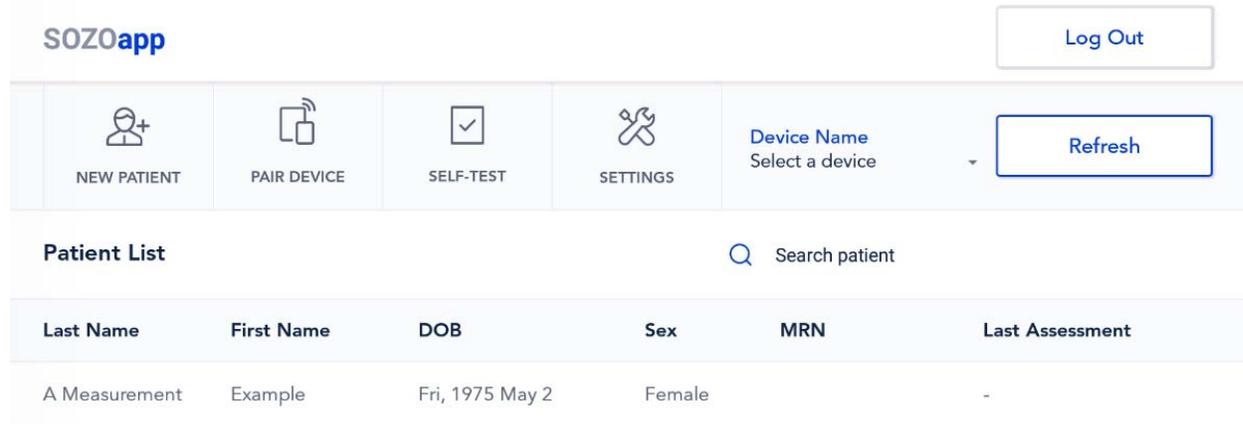
Viewing Results

Once a Cole plot is accepted, the analysis will be displayed on the tablet.

Depending on the site license, various analyses may not be available. For instance, if your site has a limited license for SOZO to measure L-Dex scores, then fluid and tissue analyses will not be available.

Viewing a Patients Historical Measurements

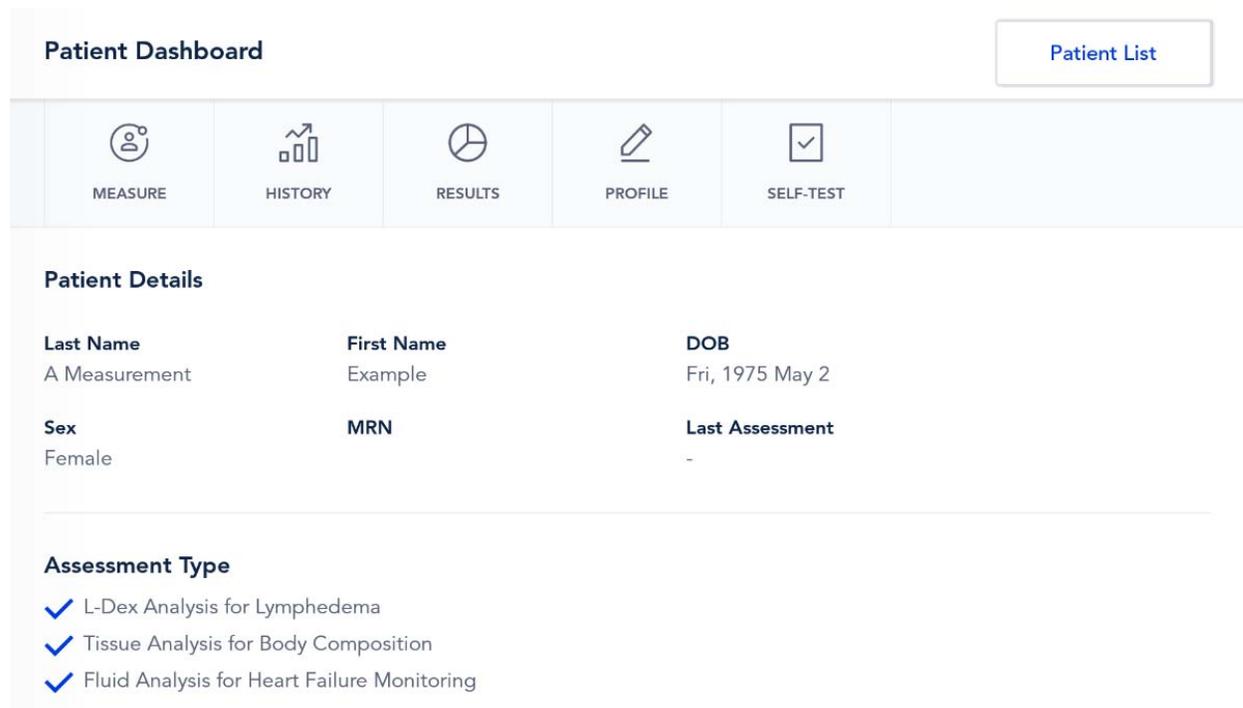
To access patient records and review measurements, select the desired patient from the patient list in Dashboard:



The screenshot shows the SOZOapp interface. At the top left is the SOZOapp logo. At the top right is a 'Log Out' button. Below the logo is a navigation bar with icons for 'NEW PATIENT', 'PAIR DEVICE', 'SELF-TEST', and 'SETTINGS'. To the right of these icons is a 'Device Name' dropdown menu with the text 'Select a device' and a 'Refresh' button. Below the navigation bar is the 'Patient List' section, which includes a search bar labeled 'Search patient'. The patient list is a table with the following columns: Last Name, First Name, DOB, Sex, MRN, and Last Assessment. The table contains one row of data: A Measurement, Example, Fri, 1975 May 2, Female, and -.

Last Name	First Name	DOB	Sex	MRN	Last Assessment
A Measurement	Example	Fri, 1975 May 2	Female		-

From the patient dashboard, the patients history of measurements can be obtained by tapping “History”:



The screenshot shows the SOZOapp Patient Dashboard. At the top left is the 'Patient Dashboard' title. At the top right is a 'Patient List' button. Below the title is a navigation bar with icons for 'MEASURE', 'HISTORY', 'RESULTS', 'PROFILE', and 'SELF-TEST'. Below the navigation bar is the 'Patient Details' section, which displays patient information in a grid format. The information includes: Last Name (A Measurement), First Name (Example), DOB (Fri, 1975 May 2), Sex (Female), MRN, and Last Assessment (-). Below the patient details is the 'Assessment Type' section, which lists three assessment types with checkmarks: L-Dex Analysis for Lymphedema, Tissue Analysis for Body Composition, and Fluid Analysis for Heart Failure Monitoring.

Last Name	First Name	DOB
A Measurement	Example	Fri, 1975 May 2

Sex	MRN	Last Assessment
Female		-

Assessment Type

- ✓ L-Dex Analysis for Lymphedema
- ✓ Tissue Analysis for Body Composition
- ✓ Fluid Analysis for Heart Failure Monitoring

This will displaysummaries of the patients results over time:



99% 4:27 PM

History

Last Name	First Name	DOB
A Measurement	Example	Fri, 1975 May 2
Sex	MRN	Last Assessment
Female		Mon, 2018 May 14 14:20

L-Dex®

Tissue Analysis

Fluid Analysis

Assessment Type

Bilateral

Body Element

Arm

Limb

Risk Limb

Both

Limb Dominance

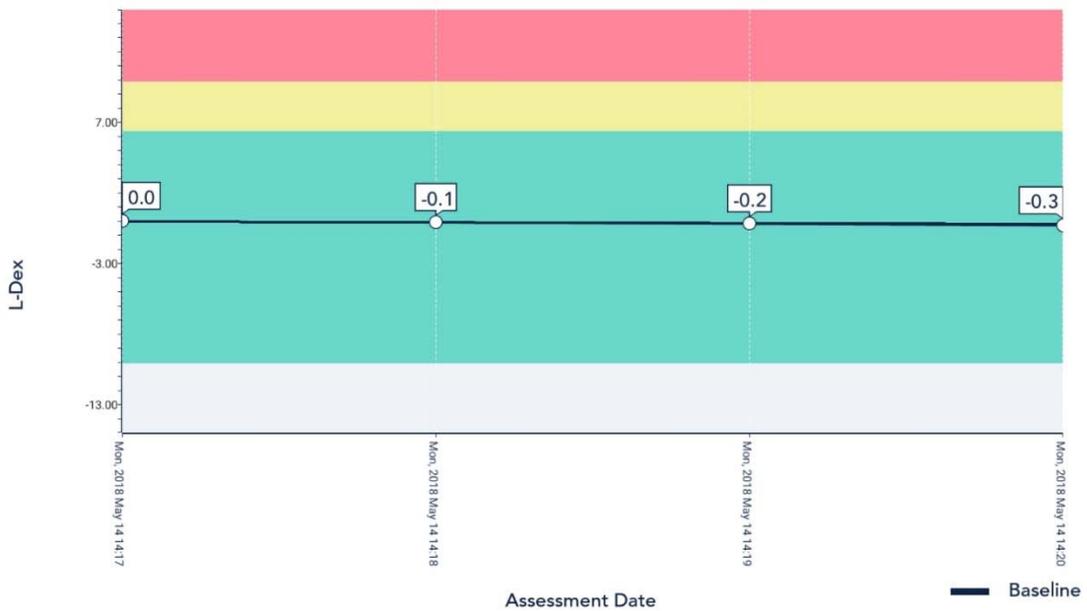
Right

Both

Bilateral L-Dex History (Left Arm)

0.0-Mon, 2018 May 14 14:17

Set Baseline



Bilateral L-Dex History (Right Arm)

1.2-Mon, 2018 May 14 14:17

Set Baseline

These tables display an example of a patient's L-Dex history, showing graphs and trends over time. If you have the appropriate licenses, other tables may be available such as Tissue and Fluid Analysis. Tapping on those brings up historical measurements for the patient with those assessment types. Within this table, baselines can be set for measured values that represent, in your clinical judgment, a "normal state" for the patient. These may be useful in tracking changes over time. For more information on each assessment type, please see the assessment-specific instructions in this user guide.

”“”

Reviewing Individual Results

From the patient dashboard, individual results can also be assessed by tapping "History". This brings up a monthly calendar. Days on which measurements were taken are highlighted with a blue box; tapping on a given day brings up a list of measurements made on that day.



Selecting a given reading will display the data for that reading. This output data will be accompanied by historical trending for the selected patient.

Note: patient measurement records may also be accessed through SOZOhub if the tablet is unavailable. Aside from what is presently displayed on the SOZO app, data has no persistence on your tablet. All clinician and patient data are stored in SOZOhub.

”“”

Recalculating Results/Assessment Type Licenses

Please note that measurements taken on a SOZO device collect and store bioimpedance data, categorized by date and time. These are independent of the measurement type. If your site expands its available licenses, you can add those assessment types to a patient's history. Access the patient profile and check the additional desired assessment types, taking into account their intended use. At that point you will be permitted to recalculate all historical results based on previously collected measurement data. The History section will then be expanded to include the new assessment types.

Please note that if you cancel one of the assessment type licenses, new measurement functionality is restricted and only historical measurement data will be displayed. The license will need to be renewed in order to display new data for that assessment type.

Review/Edit Patients Personal Details

To review the patients demographic details, tap “Profile”. This displays the following:

Profile Save

Patient Details

First Name <small>Required</small> <input type="text" value="Example"/>	Date of birth <small>Required</small> <input type="text" value="Fri, 1975 May 2"/>
Last Name <small>Required</small> <input type="text" value="A Measurement"/>	Sex <small>Required</small> <input type="text" value="Female"/>
Middle Name <input type="text"/>	Height (ft in) <small>Required</small> <input type="text" value="5"/> <input type="text" value="7.0"/>
Medical Record Number (MRN) <input type="text"/>	Email <input type="text"/>
Country Code <input type="text"/>	Postal Code <input type="text"/>
Phone Number <input type="text"/>	

Assessment Type

- L-Dex® Analysis for Lymphedema
- Tissue Analysis for Body Composition
- Fluid Analysis for Heart Failure and General Fluid Status Monitoring

Lymphedema Settings

Assessment Type

Body Element Arm Leg

Risk Limb Left Right

Limb Dominance Left Right

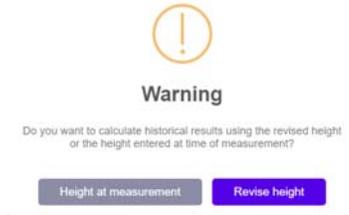
All form fields can be edited by tapping them. Tap the drop-down menus to select the appropriate value.

Patient weight cannot be modified, and will reflect the weight that was entered during the last measurement.

The assessment types available for a patient are based on site licenses. It is recommended that the patient only have relevant assessment types selected. Each assessment type selected will be displayed in the SOZO app at the time of measurement, or in patient history/results accessible from SOZOhub.

Once all changes have been made to the profile, tap “Save Changes”. Please note the following:

- If patient height has been modified, the following warning will appear.



Tapping “Height at measurement” will maintain old assessments according to what was previously entered. This is appropriate for patients whose height is changing as a function of age.

Tapping “Revised height” will recalculate all previous assessments according to the new height being saved. This is appropriate when patient height has been entered incorrectly and measurements have already been taken. Previous measurements can then be revisited through patient history.

- L-Dex specific data (at-risk limb, dominant limb) is only available when L-Dex assessments are selected. Please note that deselecting L-Dex assessments will gray out the specific data, and they will not be saved.
- If assessment types have been added, you will be able to recalculate past results by reviewing patient history.
- If assessment types have been removed, patient history will not be modified; however, subsequent measurements will be limited to those assessment types that are selected.

Changing Device Settings

Select the **Settings** button from the Dashboard screen. The Settings section provides access to commonly needed configuration and maintenance functions.

Settings

Help Get Help

Firmware Update Update

Measurement Units

kg lbs cm ft in Liters pints Save

Licensing Status View

Device Status

Device name	Not retrieved
Firmware	Not retrieved
Calibration date	Not retrieved
MAC address	Not retrieved
Serial number	Not retrieved
Last self test status	Not retrieved

Update

Application Version

From here, the user can update the app on the tablet or the firmware on the SOZO device, change measurement units, and update the device status.

*Note: Measurements are expressed in metric or standard units and are changed individually for each clinician.

Selecting SOZO device within the SOZO app

The tablet will be paired to a SOZO device during system setup at your facility. This is a one-time process per device.

The process may be repeated for any new SOZO devices, and will need to be repeated if either the tablet or system have to be replaced. Please note that the app can only select and work with one SOZO device at a time.

Assessment Types

The SOZO device is configured to support the following assessment types depending on your facility's purchased licenses:

- 1) L-Dex
- 2) Fluid Monitoring & Analysis
- 3) Tissue Analysis

Depending on licensing, your SOZO system may not have access to all measurement modules, and some measurement modules might not be available in your geographic region. Please contact ImpediMed sales or technical support for inquiries.

Each measurement module has its own instructions-for-use providing information on how to use the module and outputs provided, as well as any module-specific precautions, warnings, and contraindications. Please go to www.impedimed.com to download the module-specific instructions, or contact ImpediMed technical support for a printed copy.

Troubleshooting

Please review the following items. In the event that ImpediMed technical support is required, please call 877 247-0111, 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.
"Fields cannot contain links".	A field has text entered that corresponds with a weblink. Updates to SOZO firmware, SOZOapp or SOZOhub: a weblink has been entered rather than location of a file on a local directory.	Text entry: enter information per field requirements . Updates to SOZO: Download file to local directory before upgrading firmware, app or hub.
SOZO hardware does not emit audible clicks when powering on; LED at back of unit is not emitting a blue light.	Power cord not properly connected or potential hardware failure.	Confirm power cord is properly connected. If cord is correctly inserted, contact ImpediMed technical support.
Self-test fails.	Person/object making contact with electrodes during self-test.	Ensure no extraneous objects in contact with electrodes during self-test; re-run self-test.
L-Dex; Fluid Analysis; or Tissue Analysis 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.
Historical results for an assessment type are available, but current results are not shown.	License for the assessment type is not active.	Check active licenses. Contact ImpediMed technical support if license status is not correct.
No licenses are available	Hub has not been connected to SOZOcloud for more than 30 days.	Connect the hub to the internet/SOZOcloud to renew license status.
No SOZO devices are selectable even after device is paired via Bluetooth.	Device is not licensed.	Check license status. Contact ImpediMed technical support if license status is incorrect.

Logging in to SOZOapp / SOZOhub		
Issue/Error message	Potential Cause	Resolution
"Empty fields. Please enter your username and your password to continue."	User has attempted to log in leaving either username or password blank.	Verify username and password are entered properly.

"Incorrect credential combination. Please check your information and try again."	Incorrect or forgotten username/password.	Verify username and password and attempt to log in again. Continued error: change password with SOZOhub IT admin.
"No connection to the server, please check your connectivity."	No connection – tablet Wi-Fi may be turned off or disconnected from Wi-Fi network, a firewall may be blocking the connection, the hub may be disconnected from the internet, if using self-generated certificates or a non-static IP, the DNS server may not be correctly updated..	Check tablet settings to ensure tablet is connected to local Wi-Fi network that is the same network as the hub. Try to log into the hub with Chrome browser to determine if the issue is with the tablet or with the hub. If it's the hub, check firewall settings and network / certificate / DNS settings and restart the SOZOhub computer / server. Otherwise call ImpediMed technical support.
During login to SOZOapp or SOZOhub webportal: "Your IP address or port number are incorrect"	The local IP address for SOZOhub has been entered incorrectly at setup, or has changed because fixed IP was not used in SOZOhub setup.	SOZOhub IP address will need to be verified with local IT admin and re-entered. Please note that ImpediMed strongly recommends use of fixed IP address for the SOZOhub database.
"There is a new version of SOZOapp available. You are required to download and update it to continue using SOZOhub. To continue, press Yes".	Logging in to SOZOapp with previous app version after SOZOhub or SOZOapp has been upgraded.	Select "Yes" and follow prompts to automatically update SOZOapp to latest version. Note: connection path may need to be reset after update.

Use of SOZOapp / SOZOhub (Clinician interface)		
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, the hub may be disconnected from the internet.	Check tablet settings to ensure tablet is connected to local Wi-Fi network that is the same network as the hub. Try to log into the hub with Chrome browser to determine if the issue is with the tablet or the hub. If it's the hub, check firewall settings and certificate / DNS settings. If tablet is connected, contact local SOZOhub 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.	App/Hub access will cease 60 minutes after login and the user will be returned to login screen.	Log back in with username and password.
"Measurement not started. Electrode check failed"	SOZO hardware verifies that electrodes are connected correctly before taking a measurement. Ensure that correct patient contact is made for all eight electrodes. If any physical damage has occurred to hardware electrode check may also fail.	Power the SOZO device off and on, ensure correct patient contact and repeat measurement. If error persists, contact ImpediMed technical support.
"Measurement get results unknown error"	Error in sending data from SOZO hardware to tablet. Potential issue with disruption of Bluetooth signal.	Take another measurement. Move location of SOZO device if it is in an area with other equipment that emits electromagnetic signals. 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 a new patient, a patient already exists with this combination of first & last names and DOB	Review existing patient to ensure unnecessary duplication of patient profiles.
"Device not found. Please check your selected device"	SOZOapp is not currently linked to a nearby SOZO device	Verify that the device chosen is available via Bluetooth by selecting "pair device". If device is selected and error has occurred, ensure that the serial numbers match (if multiple units at your facility). Otherwise verify SOZO hardware is powered on by pushing button and verifying blue light at back of unit is illuminated. If error persists, contact ImpediMed technical support
"Possible device connection problem"	Tablet Bluetooth has been turned off.	Confirm tablet Bluetooth is turned on. Turn off and restart the tablet and the SOZO device. Press the Bluetooth reset button on the back of the SOZOtouch panel and verify blue light at back of unit is illuminated. If Bluetooth is enabled on the tablet, and SOZO system otherwise appears to be functioning correctly, please call ImpediMed technical support.
"Self-test unknown error"	Internal error in running self-test; potential hardware failure or firmware/software incompatibility.	Contact ImpediMed technical support
"Self-test failed"	User attempts to run self-test but either device has hardware issue or contact is made with electrodes.	Verify that nothing is touching the electrodes and repeat self-test. If error persists contact ImpediMed technical support.
"Status retrieved. Please run a self-test and try again."	Unit has not recently run a self-test.	Run a self-test per instructions for use.
	Patient details have been changed and the measurement results have been recalculated.	Check the patient settings to ensure that they are correct. Height, age, and L-Dex settings must match historical measurement records to have same measurement results.

Clinic IT Admin interfacing with SOZO system		
Issue/Error message	Potential Cause	Resolution

User already exists. To create a new account, enter a different username."	When creating a new clinician, the selected username is identical to an existing username.	Use different username.
"Password must be between 10 and 20 characters containing at least: 1. One number 2. One special character !#\$%&()*+,-./:;<=>?_@[]^`{ }~ 3. One upper case letter 4. One lower case letter"	Password does not meet requirements.	Create password using the listed requirements
"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.
"Invalid file"	The file selected to upgrade firmware, app or hub is not a valid SOZO file.	Confirm you have selected the correct file; download the file again; call ImpediMed technical support.
During initial setup of tablet: "Path cannot be empty. Please add a path."	The domain name for SOZOhub has not been entered.	SOZOhub domain name will need to be verified with local IT admin and re-entered.
During login to SOZOapp or SOZOhub webportal: "Your IP address or port number are incorrect".	The local IP address or domain name for SOZOhub has been entered incorrectly at setup, or has changed because fixed IP was not used in SOZOhub setup.	SOZOhub IP address or domain name will need to be verified with local IT admin and re-entered.
"HTTPS is the required communication protocol"	Local IP address or domain name for SOZOhub does not include https://	Ensure local IP address or domain name begins with https://
"Firmware update unknown error"	Unknown error has occurred during SOZO firmware update.	Please contact ImpediMed technical support.
"Firmware update failed"	Update procedure failed.	Attempt to install firmware again. If failure persists, please contact ImpediMed technical support.
Password doesnt work.	Password forgotten.	Review SOZOhub Installation Guide for instructions on resetting password.

Personal Data

Read our privacy policy located at

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

Care and Maintenance

Care of the Product

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

The external enclosure of the SOZO device should be cleaned between each use with non-bleach based disinfecting agents such as isopropyl alcohol 70% or Peridox® Concentrate Sporidical Disinfectant and Cleaner. Cleaning/disinfection should be performed according to manufacturers instructions for use and your facility's policy.

ImpediMed does not recommend the use of bleaching agents to clean/disinfect the SOZO system as that may cause corrosion of the electrodes. Additionally, ImpediMed does not recommend the use of disinfectants containing aldehydes, phenols and amines as they may cause damage to the plastic housing.

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



The SOZO device should not be subjected to ingress of liquid or liquid spillage, impact and excessive heat (direct exposure to sunlight). This can harm the patient, cause damage to the device, or give an incorrect reading. The SOZO 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 device.

Self-Test Function

If you wish to ensure that the system is operating correctly, a self-test may be performed from the Patient List or individual Patient Dashboard screens. ImpediMed recommends that the self-test be performed at the start of the day.

Repairs

There are no user-repairable electronic parts within the SOZO device. Please contact ImpediMed or an authorized agent should service or repair of the SOZO device be required. Do not attempt to use the SOZO device if it does not appear to be functioning correctly or is in need of repair.

Tablet Maintenance

The Samsung SM-T580 tablet is shipped partially charged, and will need to be charged periodically throughout its use. Please follow Samsung's instructions for use supplied with the tablet. Although the tablet will operate at low levels of battery power, ImpediMed recommends charging it upon receipt of the SOZO system.

Technical Support

Australia

Phone: + 61 7 3860 3700

Fax: + 61 7 3260 1225

USA

Phone: (877) 247-0111 Option 2

Fax: (760) 804-9245

SOZO Website: www.impedimed.com

SOZO Help Email: tsu@impedimed.com

Accessories

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

Description
SOZOstand pedestal
SOZOconnect connector Cable
Power Supply Cable
Tablet
Tablet sleeves

ImpediMed Product Warranty

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

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

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

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

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

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

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

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

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

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

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

Regulatory Statement

FCC ID: QOQBT121

This device complies with Part 15 of the FCC Rules

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

This device complies with the R&TTE Directive.

Product Specifications

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

Safety and Electromagnetic Compatibility (EMC) Information

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

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

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

Guidance and Manufacturer's Declaration – Immunity						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse Modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1KHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28
870						
930						
1 720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse Modulation 217Hz	2	0.3	28
1 845						
1 970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9
5500						
5785						

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

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

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