



SOZO

Instructions For Use



ImpediMed Limited

ABN 65 089 705 144

Unit 1
50 Parker Court
Pinkenba Qld 4008
Australia

Phone: + 61 7 3860 3700

Fax: + 61 7 3260 1225

Email: enquiries@impedimed.com

Website: <http://www.impedimed.com/>

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

EC	REP
----	-----

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



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	5
Tablet.....	5
SOZO App.....	5
Introduction	6
The SOZO Device	6
Bioimpedance Spectroscopy (BIS)	6
Components of the SOZO System	7
Safety Instructions	8
Signs and Symbols.....	8
Intended Use	9
Contraindications.....	9
Warnings	9
Precautions.....	10
Use and Storage Conditions	11
Environmental Operating Conditions	11
Environmental Transport and Storage Conditions	11
Location for Use	12
Setting Up the SOZO Device and Stand	13
Setting Up the SOZO Device without Stand	15
Step 1: Connecting SOZOtouch and SOZOstep.....	15
Step 2: Connecting the Tablet Stand	15
Step 3: Connecting Power Supply.....	15
SOZOhub installation	17
Pairing Tablet and SOZO App to SOZO System	18
Step 1	18
Step 2	18
Step 3	18
Initial setup of SOZO app.....	18
Pairing 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	26
Taking Measurements.....	29
Weight Entry	30
Foot Placement	31
Hand Placement.....	31
Measurement Time	32
Cole Plots	32
Viewing Historical Measurements and Patient Trending.....	33
Changing Device Settings	36
Selecting SOZO device within the SOZO app	36
Indications for Use	37
SOZOthrive for Lymphoedema	38
SOZOthrive Module Results.....	39
SOZOpro for Body Composition Measurements.....	41
SOZOpro Module Results	41
SOZObeat for Fluid Monitoring Measurements	43
SOZObeat Module Results	43
Personal Data	44
Care and Maintenance	45
Care of the Product	45
Self-Test Function	45
Repairs	45
Technical Support	46
Troubleshooting	47
ImpediMed Product Warranty.....	51
Regulatory Statement	52
Product Specifications.....	53
Safety and Electromagnetic Compatibility (EMC) Information	54

Minimum Requirements

Tablet

The Samsung Galaxy Tab A (models SM-T510 or SM-T580) will be provided 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 will 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

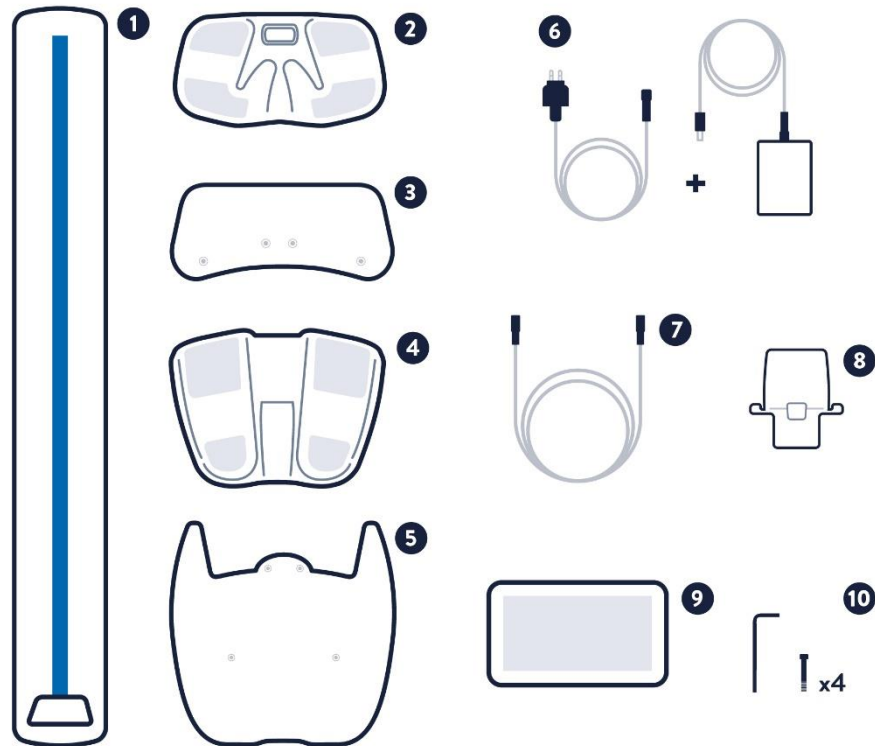
SOZO: A bioimpedance spectroscopy device for use on human patients, utilizing ImpediMed's patented BIS technology in a user-friendly format to allow quick and accurate measurement of fluid levels. This can be used as an "early warning" monitor for determining changes in the fluid status of patients with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

The SOZO device and SOZOthrive module offers rapid, non-invasive, inexpensive comparison of impedance ratio's between normal limbs and limbs at risk of lymphoedema. 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 active implanted medical devices, e.g. cardiac pacemakers, defibrillators or patients connected to electronic life support devices.
- 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 not be used any 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



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.



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

The stand is comprised of the following components 1, 3 and 5 from the component list on page 8. The screws and hex key (10) are included in the stand packaging.

1. Screw the footplate (5) into the base of the SOZOsupport (1) stand. Note: the footplate fits to the SOZOsupport end with two cable holes in it.
2. Screw the handplate (3) into the top of the SOZOsupport (1) stand.
3. Lace the SOZOconnect cable (7) through the droplet hole on the back of the stand and out the bottom hole of the stand.
4. Attach the SOZOtouch (2) to the hand plate by first placing above the screws then pushing forward to lock into place.
5. Connect the SOZOconnect cable (7) to the SOZOtouch (2).
6. Attach the tablet holder (8) to the SOZOtouch (2) with the ledge of the tablet holder facing the SOZOtouch sensors.
7. Connect the SOZOstep (4) to the SOZOconnect cable (7), laced through the SOZOsupport Stand (1).
8. Connect the SOZO power adaptor (6) into the SOZOstep (4) rear plate.
9. Attach the SOZOstep (4) to the footplate (5) by first placing above the screws then pushing forward to lock into place.
10. Plug the SOZO power adaptor (6) into the nearest wall outlet.



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.



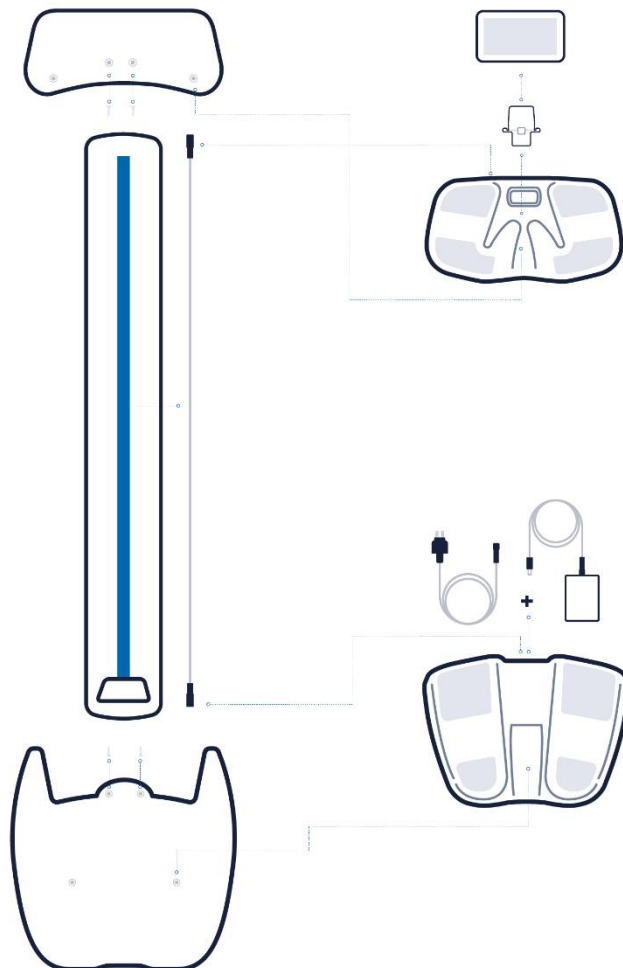
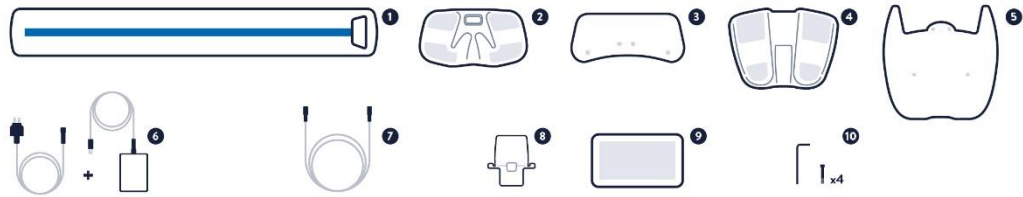
Ensure that the connector cable is plugged in to both hand and foot plates before connecting the power supply. If the SOZO device must be moved, please ensure the power supply is disconnected from the wall before moving or uninstalling the system.



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 43 of this guide).

QUICK START GUIDE



Setting Up the SOZO Device without Stand

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 electrocution.



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 from the wall 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 on page 43 of 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 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

Press the button on the back of the SOZOtouch assembly to enable *Bluetooth* on the SOZO device.

Step 2

Locate the Settings section on the tablet and enable *Bluetooth*. Once *Bluetooth* is enabled, select ImpediMed SOZO from the list of available devices. (*Note: *Bluetooth* must be enabled first on the SOZO device for the tablet to find it; the SOZO device will be identified by the SOZO device serial number (SOZO-xxxxxxxx) when the tablet scans for nearby Bluetooth-enabled devices.)

Step 3

Initial setup of SOZO app

The tablet shall come with the ImpediMed SOZO app pre-installed. If the app is not 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

ENGLISH ▾

LOGIN

SOZO App Version: SOZOapp_1.1.0

[SET CONNECTION PATH](#)

Note that the SOZOapp version may be at a different level 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.

SET CONNECTION PATH

PATH

ADMIN PASSWORD

AUTHENTICATE

The path is a fixed IP address that links to the server directory where the database is stored and requires authentication before you can proceed.



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.

Pairing 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 'Pair Device':

FIRST NAME	LAST NAME	SEX	MRN	DOB	LAST ASSESSMENT

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.

HELP	<input type="button" value="GET HELP"/>
APPLICATION UPDATE	<input type="button" value="UPDATE"/>
FIRMWARE UPDATE	<input type="button" value="UPDATE"/>
MEASUREMENT UNITS	<input type="button" value="SAVE"/>
<input checked="" type="checkbox"/> kg / lbs <input checked="" type="checkbox"/> cm / ft. in <input checked="" type="checkbox"/> liters / pints	
DEVICE STATUS	<input type="button" value="UPDATE"/>
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
APPLICATION VERSION	SOZOapp_1.1.0

Note: ImpediMed recommends keeping your SOZO device together with the app and tablet paired to it. The app and tablet may pair to other devices, but will only control measurements from the device that is identified in the settings tab.

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 jewellery
2. Remove stockings or socks

For SOZObeat and SOZOpro measurements, the patient should observe the following preparation tips to ensure the most accurate reading:

1. Empty their 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 preferable if the measurements are 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. The SOZO system setup provides instructions on how to configure the system for both standing and seated positions. It is strongly recommended that patient's 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 approximately a few minutes prior to taking a measurement.

Standing Position

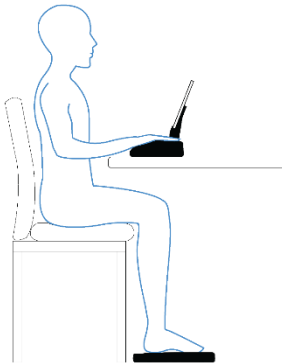
When standing on the SOZO device, ImpediMed strongly recommends using the SOZO stand provided with the system.

The patient should:



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

Seated position



Do not use a metal table or chair. The patient should:



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

Using the SOZO App

Overview

The SOZO device utilizes an ImpediMed-supplied Samsung Galaxy Tab A tablet to control the SOZO device operation. The app will require access to your facilities' intranet to store patient data.

The app is comprised of five major sections:

- 1) Login screen, where users can log in to access the Dashboard screen
- 2) The Dashboard screen, which lists available patients and allow creation of new patients, long with the entry of their demographic data
- 3) Patient Profile, which allows measurements to be taken for a given patient, and historical records reviewed
- 4) Device Settings

The following section will describe access and use of the app.

Start-up

Logging In

Tap the SOZO app icon to launch. This will take you to the login screen; use your user name and password, set up through SOZOhub, to access the app.


LOGIN TO YOUR ACCOUNT


ENGLISH ▼


SOZO App Version: SOZOapp_1.1.0


[SET CONNECTION PATH](#)


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


▶ LOG OUT


NEW PATIENT


PAIR DEVICE


SELF-TEST


SETTINGS

DEVICE NAME: Select a device ▼

PATIENT LIST Q Search patient

FIRST NAME	LAST NAME	SEX	MRN	DOB	LAST ASSESSMENT

Creating/Accessing Patient Profiles

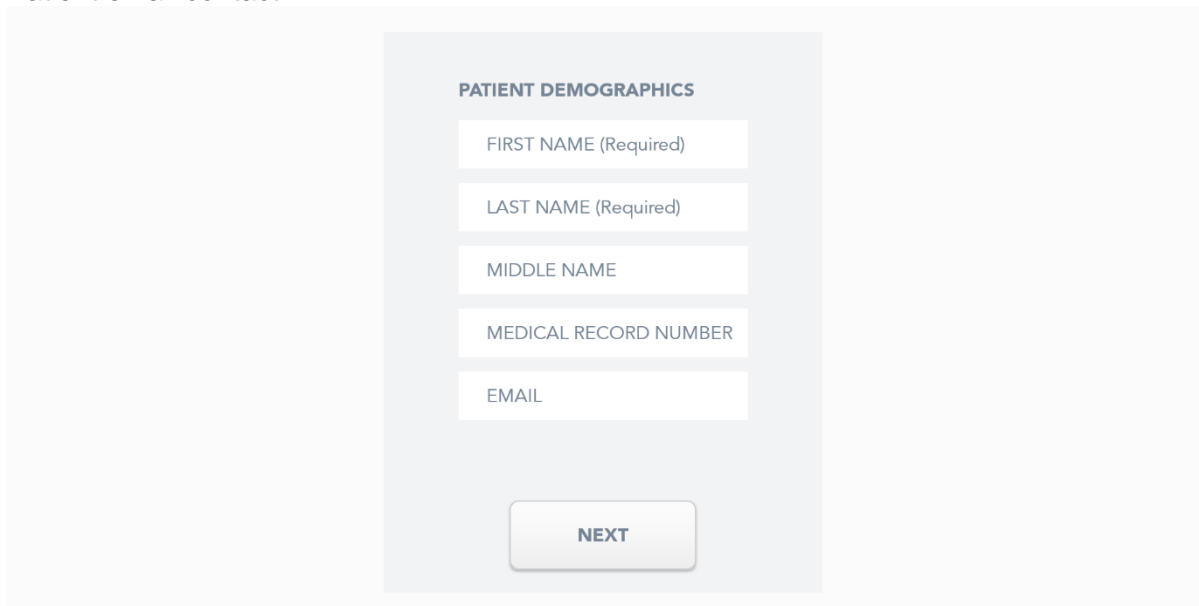
After initial setup, patients will need to be added to the database in order to use the SOZO device. All new patients can be added through the Dashboard screen after login.

Note that patients do not have their own login, but profiles are controlled through the clinician's 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 the button marked 'New Patient'.

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

- Name
- Local Patient Identifier
- Patient email contact:



The screenshot shows a mobile application interface for entering patient demographics. The form is titled "PATIENT DEMOGRAPHICS" and contains five input fields: "FIRST NAME (Required)", "LAST NAME (Required)", "MIDDLE NAME", "MEDICAL RECORD NUMBER", and "EMAIL". Below the input fields is a "NEXT" button. The form is centered on a light gray background.

- Other personal details:

PATIENT PERSONAL DETAILS

POSTAL CODE (Required)

PHONE NUMBER (Required)

+1

-

NEXT

PATIENT DEMOGRAPHICS

Date Of Birth (Required)

Male

NEXT

PATIENT BODY INFORMATION

WEIGHT (Required)

kg lbs

HEIGHT (Required)

cm ft in

CREATE ACCOUNT

After tapping 'Create Account' the app will take you to the patient's summary screen.

91% 8:10 PM

PATIENT LIST

PATIENT DASHBOARD MEASURE TRENDING RESULTS PROFILE

PATIENT PROFILE SAVE

FIRST NAME	Test	
LAST NAME	Patientbeat	
MIDDLE NAME		
SEX	Female	▼
MEDICAL RECORD NUMBER	12321	
DOB	Mon, 2000 Feb 7	
ETHNICITY	-	▼
PHONE CODE	+27	▼
PHONE	1234	
POSTAL CODE	1234	
EMAIL		
WEIGHT	26.0	(kg)
HEIGHT	177.8	(cm)

An additional segment specific for patients requiring L-Dex assessments is located further down the patient profile:

LYMPHOEDEMA SETTINGS

Measurement Type ▼

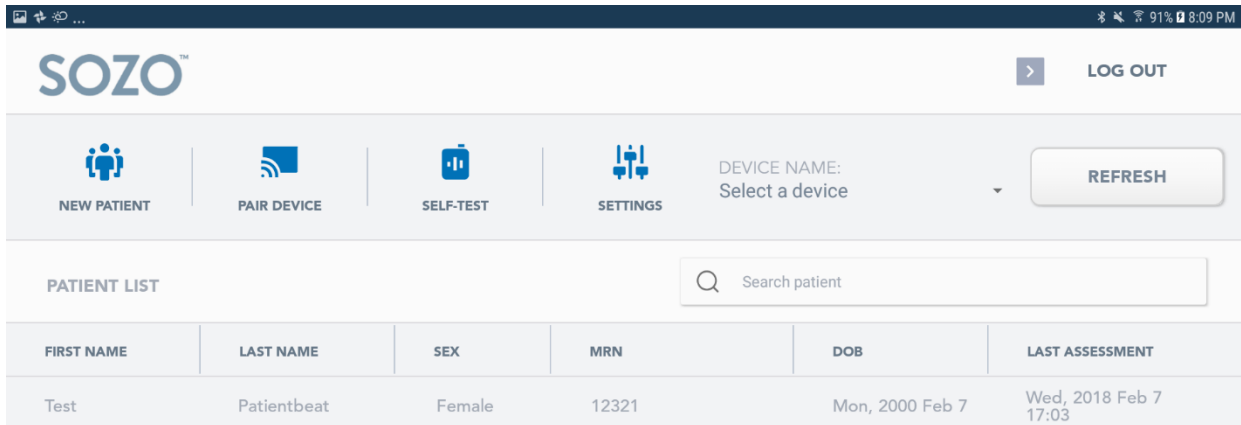
BODY ELEMENT	<input type="radio"/> Arm	<input type="radio"/> Leg
RISK LIMB	<input type="radio"/> Left	<input type="radio"/> Right
LIMB DOMINANCE	<input type="radio"/> Left	<input type="radio"/> Right

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 and various body composition outputs. Each of these applications, along with indication-specific information and the reports that SOZO will provide, are discussed in greater detail later in this user guide.

From the Clinician List Screen, select the patient to be measured:



This will take you to the patient's summary screen (see screen above). From that screen, tap the 'Measure' button. This will take you to the 'Select Measurement Type' screen: The 'Select Measurement Type' screen may have different options for measurement types, depending on the modules that have been enabled for your site.




Select the appropriate measurement type. For more information on measurement types, review the 'Indications for Use' sections later in this document.

Weight Entry

The app will require the patient's current weight prior to each reading. Enter the patient's current weight (using their most recent weight measurement if weight was not taken during their visit to your facility) to proceed:

Please enter your weight



_____ kg

SELF-TEST NEXT

Note: Run a self-test daily

The app will then remind clinician and patient about measurement steps:

Foot Placement

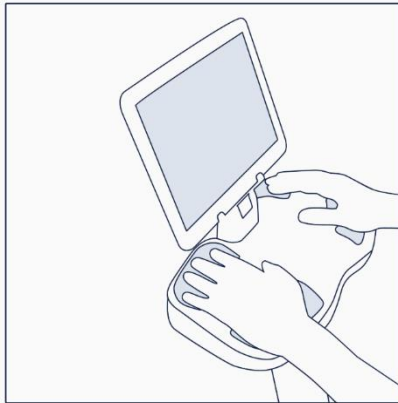
Confirm that the SOZOstep assembly is stationary and on a level surface. Place feet (no stockings/pantyhose or socks) onto SOZOstep and locate heel recesses. Make sure that each foot is flat and in full contact with each electrode plate. (*Note: there are two electrode plates for both the left and right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



Hand Placement

Confirm that the SOZOtouch assembly is stationary and on a level surface. Place both hands (completely flat) onto the SOZOtouch with thumbs securely wrapped around the corners of both recesses. 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.)

2. Place your hands on SOZOtouch



NEXT



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 from the wall and call ImpediMed Technical Support.



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

Measurement Time

The SOZO device will need approximately 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 measurement is taken and allow the user to determine if an adequate reading was taken.

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 indicate a valid measurement has been taken.

Individual data points are also represented on the graph. If they show a trend that is consistent with the Cole Plot, this indicates a valid measurement has been performed, and the results can be accepted.

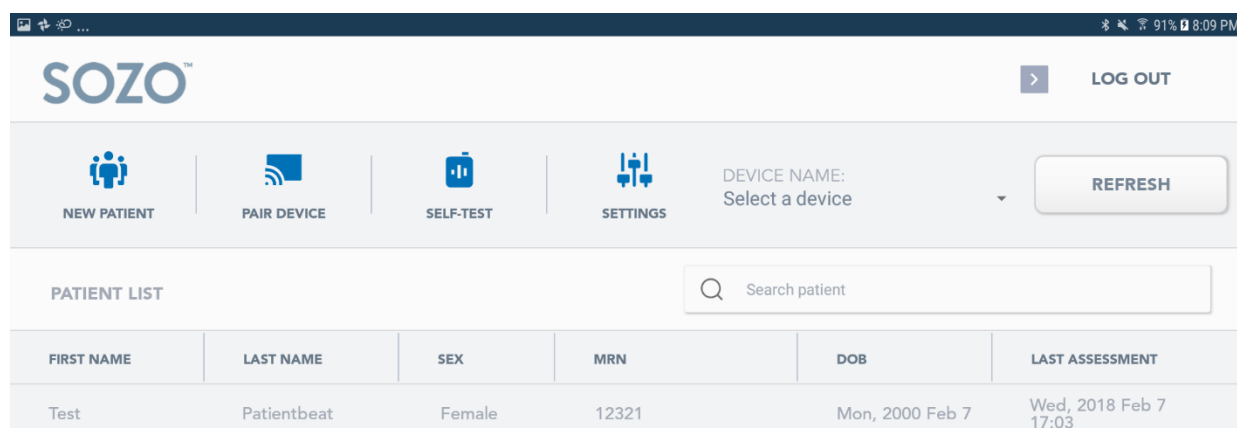
If data points are scattered, or a semi-circular line is not formed, this indicates that a valid measurement has not been performed. The measurement should then be rejected, and a new measurement taken.

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

Note that Cole plots are also shown when reviewing historical results. Determination of adequacy can only be made at the time the measurement is taken.

Viewing Historical Measurements and Patient Trending

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



The screenshot shows the SOZO mobile application interface. At the top, there is a navigation bar with the SOZO logo and a 'LOG OUT' button. Below this is a dashboard with four main action buttons: 'NEW PATIENT', 'PAIR DEVICE', 'SELF-TEST', and 'SETTINGS'. To the right of these buttons is a 'DEVICE NAME' dropdown menu with the text 'Select a device' and a 'REFRESH' button. Below the dashboard is a 'PATIENT LIST' section with a search bar labeled 'Search patient'. The patient list is displayed as a table with the following data:

FIRST NAME	LAST NAME	SEX	MRN	DOB	LAST ASSESSMENT
Test	Patientbeat	Female	12321	Mon, 2000 Feb 7	Wed, 2018 Feb 7 17:03

From the patient screen, the patient's history of measurements can be obtained from the 'Results' section:


PATIENT DASHBOARD


MEASURE


TRENDING


RESULTS


PROFILE

PATIENT DASHBOARD

First Name: Test	MRN: 12321
Last Name: Patientbeat	DOB: Mon, 2000 Feb 7
Sex: Female	Last Assessment: Wed, 2018 Feb 7 17:03

From this screen, select which reading type you want to review. You may be able to select from up to three options (SOZOthrive, SOZOpro or SOZObeat) depending on the modules that have been enabled for your site. :

Select type of result

SOZOthrive

SOZOpro

SOZObeat



● Measurements performed ● Current day - No data

Selecting 'SOZOthrive' for a bi-lateral lymphedema patient will additionally require that you select, from a drop-down menu, whether both, left, or right limb trending data should be displayed.

The system will then highlight days on which records were taken. Tapping on highlighted days will give you the option to select from all readings taken on that day. Selecting a given reading will take you to the output screen for that reading. All output screens 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. Other than the SOZO app, no data is stored on your tablet. All clinician and patient data are stored in SOZOhub.

Changing Device Settings

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

HELP	GET HELP
APPLICATION UPDATE	UPDATE
FIRMWARE UPDATE	UPDATE
MEASUREMENT UNITS	SAVE
<input checked="" type="checkbox"/> kg / lbs <input checked="" type="checkbox"/> cm / ft. in <input checked="" type="checkbox"/> liters / pints	
DEVICE STATUS	UPDATE
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
APPLICATION VERSION	SOZOapp_1.1.0

From this page, the user can update the application on the tablet or the firmware on the SOZO device, change measurement units, and update the device status.

*Note: Measurement units are expressed in metric or imperial units of measure and are changed individually.

Selecting SOZO device within the SOZO app

The app will initially be paired to a SOZO device during first setup of the system at your facility. This will not need to be repeated for any new users added through SOZOhub.

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.

Indications for Use

The SOZO device is currently configured to provide measurements for three types of measurements as detailed further below:

- 1) The SOZOthrive measurement aids a clinician in the assessment of lymphoedema in a patient by assessing L-Dex[®] scores.
- 2) The SOZOpro measurement provides a body composition analysis of an individual.
- 3) The SOZObeat measurement provides fluid monitoring capabilities to support the evaluation of certain clinical conditions including management of heart failure.

SOZOthrive for Lymphoedema

Indications for use

When using the SOZO device's SOZOthrive function for lymphoedema, the following indication for use applies:

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

Instructions for use

Prior to taking an L-Dex measurement, ensure you have accessed and completed the relevant sections of the patient profile (see 'Creating/Accessing Patient Profile' segment of SOZOapp, earlier in this User Guide).

In particular, ensure that the correct L-Dex assessment (unilateral or bilateral) is selected from the drop-down menu. Unilateral assessment should be selected for patients who have one limb at risk of lymphedema. Bilateral assessment is required for patients who have either both arms or both legs at risk of lymphedema.



If a patient is at risk of bilateral lymphedema in both arms and legs, the SOZO system may not be an appropriate tool.



If a patient is at risk of unilateral lymphedema in an arm and a leg, the SOZO app currently does not facilitate measurement of both conditions in the same patient profile.

Ensure you have read and understood the instructions for use in preceding sections regarding setup, installation and use of the SOZO app. All warnings, contraindications and precautions apply. In addition, please consider the following when using SOZO to take L-Dex measurements on a patient:



For patients who cannot effectively separate their inner thighs, it may be necessary to place insulating material (e.g. dry clothes) between them. Ensure the patient's upper arms and elbows are not in contact with their torso.

SOZOthrive Module Results

The Lymphoedema Index (L-Dex®)

The results are used to calculate a Lymphoedema Index or L-Dex value. This value is derived from the ratio of the impedance determined for the unaffected limb and the at-risk limb.

Research has been performed to ascertain the normal range of L-Dex values in healthy patients. These normal ranges are presented in the analysis screens to assist in patient evaluation.

Unilateral vs. Bilateral Lymphedema

The SOZO system may be used in the clinical assessment of either unilateral or bilateral secondary lymphedema. When results are assessed, a Unilateral Assessment will display cole plots for measurement quality analysis, present one L-Dex score for consideration, and an overall results tracking chart for the patient. A Bilateral assessment will display cole plots for measurement quality, present two L-Dex scores - one for each limb – for consideration, and overall results tracking charts for each limb for the patient.

SOZOthrive Module Results

This module will display the current L-Dex value on a scale to see if the patient's L-Dex value resides within or outside the normal range of values for a healthy person.

Note: L-Dex values of –10 and beyond (-11,-12 etc.) are commonly associated with procedural errors. In this case a warning will be displayed showing the reading is out of range.

Note: L-Dex values greater than 10 may indicate the early signs of lymphoedema and values that have changed +10 L-Dex units from baseline may also indicate early lymphoedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider.

Results Trend

The results trend graph allows comparison between current readings and previous result(s), so that it is clear if the L-Dex value is increasing or decreasing over time.

Recommended Measurement Frequency

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

Pre-operative baseline

Years 1-3: Every 3 months

Years 4-5: Every 6 months

Year 6+: Annually

SOZOpro for Body Composition Measurements

Indications for Use

When using the SOZO device's SOZOpro module for body composition measurements, the following indication for use applies:

The SOZO system is a bioimpedance spectroscopy device intended to estimate the following body composition parameters:

- Total Body Water (TBW), Extra cellular Fluid (ECF), Intra cellular Fluid (ICF)
- Fat-free Mass (FFM), Fat Mass (FM)
- Active Tissue Mass (ATM), Extracellular Mass (ECM), Basal Metabolic Rate (BMR)
- Skeletal Muscle Mass (SMM), Phase Angle, Body Mass Index (BMI)
- Hydration Index (Hy-Dex) Analysis

The device measures current, voltage 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 Cole-Cole plots as well as subject weight, age and gender.

Instructions for use

Ensure you have read and understood the instructions for use in preceding sections regarding setup, installation, patient preparation and use of the SOZO app. All warnings, contraindications and precautions apply.

SOZOpro Module Results

At the conclusion of a measurement, the app will present a screen containing a wide range of body composition information in your preferred units of measure (defined in the settings section):

- Fluid Status:
 - Total Body Water (TBW)
 - Extracellular Fluid (ECF)
 - Intracellular Fluid (ICF)
- Total Body Composition
 - Fat Free Mass (FFM)
 - Fat Mass (FM)
 - % of weight
- Metabolic Report

- Active Tissue Mass (ATM)
- Extracellular Mass (ECM)
- Basal Metabolic Rate (BMR)
- Other
 - Skeletal Muscle Mass
 - Phase Angle
 - Body Mass Index (BMI)
 - Weight
- Hydration Index (Hy-Dex) Analysis

Recommended Measurement Frequency

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

SOZObeat for Fluid Monitoring Measurements

Indications for Use

The SOZO Fluid Status Monitor is intended for patients:

- With fluid management problems
- Taking diuretic medication
- Living with Heart Failure
- Living with End-stage Renal Disease
- Recovering from Coronary artery Disease related event
- Suffering from Recurrent Dehydration

This device is intended for use, under the direction of a physician, for the noninvasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Instructions for use

Ensure you have read and understood the instructions for use in preceding sections regarding setup, installation, patient preparation and use of the SOZO app. All warnings, contraindications and precautions apply.

SOZObeat Module Results

At the conclusion of a measurement, the app will present a screen containing analysis of the fluid status of the patient. It will break down the individual's

- Total Body Water (TBW)
- Extracellular Fluid (ECF)
- Intracellular Fluid (ICF)
- Weight
- Distribution of ECF and ICF

Recommended Measurement Frequency

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

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 Sporocidal Disinfectant and Cleaner. Cleaning/disinfection should be performed according to manufacturer's instructions for use and your facilities' policy. ImpediMed does not recommend the use of bleaching agents to clean/disinfect the SOZO system.

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 facilities policy. The use of protective sleeves 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 cause damage to the device or harm to the patient or give an incorrect reading. The SOZO device should be used in a dry environment.

Contact ImpediMed or an authorised agent for repair.

Self-Test Function

If you wish to ensure that the system is operating correctly, a self-test may be performed from the Device Settings Screen. 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 authorised agent should service or repair of the SOZO device be required. Do not attempt to use the SOZO device if it does not appear to be functioning correctly or is in need of repair.

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.hellosozo.com

SOZO Help Webpage: <https://help.hellosozo.com>

SOZO Help Email: help@hellosozo.com

Troubleshooting

Please review the following items. In the event that additional ImpediMed technical support is required, please call them on the numbers listed in the 'Technical Support' section, email ImpediMed at help@hellosozo.com, or visit <https://hellosozo.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 to 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.
In SOZOhub: user clicks browser's back button, and returns to login screen	Web browser back button will return webpage to login screen, necessitating login.	Re-enter login details to go back into web portal. Use buttons within web portal to move within SOZOhub pages.
SOZO hardware does not emit audible clicks when powering on; LED at back of unit is not emitting blue light	Power cord not properly plugged in; or potential hardware failure.	Confirm power cord is plugged in. If cord is correctly inserted contact ImpediMed technical support.
Self-test fails	Person/object contacting electrodes during self-test	Ensure that nothing is contacting electrodes during self-test; re-run self-test.

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 login leaving either username or password blank.	Verify username and password and login.
"Incorrect credential combination. Please check your information and try again."	Incorrect username/password; forgotten username/password	Verify username and password and attempt to login again. Continued error: change password with SOZOhub IT admin.
"No connection to the server, please check your connectivity."	No connection – tablet wifi may be turned off or disconnected from Wi-Fi network.	Check tablet settings to ensure tablet is connected to local Wi-Fi network.
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.
--	--	---

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 wifi may be turned off or disconnected from Wi-Fi network.	Check tablet settings to ensure tablet is connected to local Wi-Fi network. If tablet is connected, contact local SOZOhub IT admin; otherwise call ImpediMed technical support.
"For safety reasons your session has expired. Please logout and login again."	App/Hub access will cease 60 minutes after login.	Log out and log back in using username and password.
"Measurement not started. Electrode check failed"	SOZO hardware verifies that electrodes are connected correctly before taking a measurement. If any physical damage has occurred to hardware electrode check may fail.	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. 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 to take another measurement. If error persists, contact ImpediMed technical support.
"A user with this First name, Last name, DOB and Phone number already exists"	When creating a new patient, a patient already exists with this combination of first, last names; DOB; phone number.	Review existing patient to ensure unnecessary duplication of patient profiles.
"You need to set all the Lymphoedema settings within the patient's profile in SOZOapp, prior to displaying SOZOthrive results or trending"	User has attempted to take an L-Dex measurement but patient does not have lymphedema settings fully entered in patient profile.	Enter patient profile and ensure all lymphedema settings are fully entered (risk limb/limb dominance/limb type)
When using SOZOapp: "Device not found. Please check your selected device"	At each login, paired SOZO hardware must be selected from a drop down menu for measurement to proceed. If this is not selected at each login, the error will occur.	Verify that a specific SOZO device is selected for use in SOZOapp patient dashboard. 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 verifying blue light at back of unit. If error persists, contact ImpediMed technical support
"Bluetooth connection problem"	Tablet bluetooth has been turned off.	Confirm tablet bluetooth is turned on. If bluetooth is turned on 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 manual self-test but either device has hardware issue or some contact is made with electrodes.	Verify electrodes are clear 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.

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 local IP address for SOZOhub has not been entered.	SOZOhub IP address 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 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.
"HTTPS is the required communication protocol"	Local IP address for SOZOhub does not include https://	Ensure local IP address 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.

Accessories

The following accessories are available from ImpediMed. Please contact ImpediMed or an authorised 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 **ImpediMed's** option, replaced. The device and accessories are to be returned to **ImpediMed**, accompanied by proof of purchase, your name, your return address and a statement of the defect. This limited warranty does not apply to products subjected to abnormal use or damaged by accident, misuse, improper voltage, or to products altered or served by anyone other than **ImpediMed** or its authorised agents.

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

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

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

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

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, labour and transport. Before returning a product for repair, please contact **ImpediMed** or their authorised distributor for instructions.

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

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

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

Regulatory Statement


FCC ID: QQQBT121

This device complies with Part 15 of the FCC Rules

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

This device complies with the R&TTE Directive.

Product Specifications

Drive AC current	200 micro Amps RMS at a variable frequency of 3 kHz to 1000 kHz.
Frequency Scan	3 to 1000 kHz (256 frequencies) Scan speed: 20 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, lymphoedema Index (L-Dex®) value
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. The SOZO device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity			
The SOZO device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO device should assure that it is used in such an environment.			
Immunity test	4 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	±2kV Mains ±1kV I/Os 100 kHz Repetition Freq	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
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	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds ----- 0% Ur for	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.

	0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.	0.5 cycle @ 0, 45, 90, 135, 180, 225, 270 and 315 degrees.	
	0% Ur for 1 cycle	0% Ur for 1 cycle	
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

The SOZO device is intended for use in the electromagnetic environment specified below. The customer or the user of the SOZO device should assure that it is used in such an environment.

Immunity test	4 th Edition Test Levels	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms (Outside ISM) 6Vrms (In ISM and amature Bands) 150 kHz to 80 MHz	(V1) = 3Vrms (V2) = 6Vrms	Portable and mobile communications equipment should be separated from the SOZO by no less than the distances calculated/listed below: D=(3.5/V1)(Sqrt P) D=(12/V2)(Sqrt P)
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz		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 device

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

Max Output Power (Watts)	Separation (m) 150kHz to 80MHz Non-ISM $D=(3.5/\sqrt{P})(\text{Sqrt } P)$	Separation (m) 150kHz to 80MHz ISM $D=(12/\sqrt{2})(\text{Sqrt } P)$	Separation (m) 80 to 800MHz $D=(12/E1)(\text{Sqrt } P)$	Separation (m) 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