

Measurement Guide

Ensure you have fully read and understood the complete SOZO instructions for use, including warnings and precautions, available at www.impedimed.com/support/ifu-documents/

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Preparing the patient

***Contraindications:**

The SOZO device should not be used by:

- + Patients with cardiac arrhythmias who have permanent pacemakers (PPM) or ICDs.
- + Patients with any other active implanted electronic equipment (e.g., infusion pumps, neurostimulators, brain stimulators, etc.) or Patients undergoing external defibrillation.



***Warning:**

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

To optimize the quality of the measurement:		<ol style="list-style-type: none">1. Remove all metal jewelry if possible, including large belt buckles. Items above the neck such as earrings are ok.2. Remove any electronics, coins, keys or other metal objects from pockets.3. Remove shoes and socks or stockings.4. Dampen hands and feet or SOZO electrodes with a damp cloth.5. Remain still during the measurement with elbows away from the body.		
Additional tips to ensure consistent measurement:		Ensure an empty bladder prior to measurement		Avoid exercise for 4 hours prior to measurement
		Avoid alcohol for 8 hours prior to measurement		Avoid meals for 8 hours prior to measurement
				Avoid caffeine for 2 hours prior to measurement

Weight Limits:

Standing: 375 lbs (170 kg) Sitting: 750 lbs (340 kg)

Please note: There is a 5 second count down until the measurement starts. Once the count down is complete, ensure the patient remains still and does not move their hands and feet.

2

Confirm device and complete a Self-Test

Ensure the SOZO device is connected by confirming the device in the "Select Device" located in the settings.

Prior to the first measurement of the day, perform a self-test by tapping the settings icon "⚙️" on the top right of the navigation menu to confirm the device is functioning correctly. If the test fails, please contact ImpediMed.

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Create or select a patient

To create a new patient, tap the "Add New" button on the top left of the main page and proceed to enter required Demographics, Assessment Type, and if necessary, the Lymphedema Settings.

For an existing patient, select their name from the patient list and proceed to conducting a measurement.

Position patient on SOZO

1. Place the patient's feet on the SOZOstep. Align their heels with the center of the silver plates and ensure the patient's feet are flat and evenly distributed on the surface.
2. Place the patient's hands on SOZotouch with their palms flat on the silver plates and their thumbs positioned around the molded plastic hand guide.



Please note: The patient's arms/elbows should not be touching their torso.

Perform a measurement

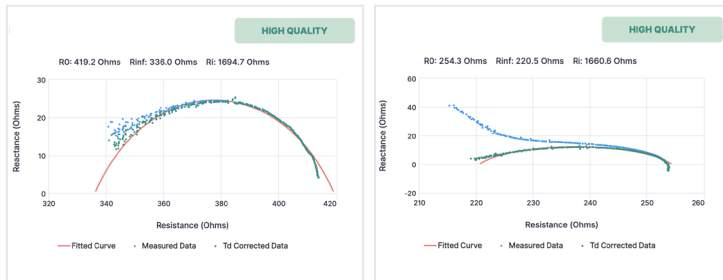
Once you have selected a patient and are in the patient dashboard, tap "Measure". Enter the patient's weight and select "Start". Follow the directions on the screen to complete the measurement.

Please note: There is a 5 second count down until the measurement starts. Once the count down is complete, ensure the patient remains still and does not move their hands and feet.

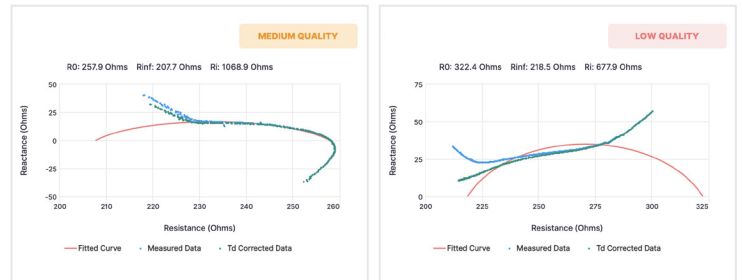
Accept or reject Cole plots

Once your measurement is complete, if all 6 Cole plots are high quality, you will immediately be presented with the results screen. If one or more Cole plots are medium or low quality, it is recommended to repeat the measurement. You must accept the Cole plots to see the results, if necessary, or reject the measurement and re-measure if appropriate.

High Quality Cole plots



Medium Quality & Low Quality Cole plots



Measurement results may be affected by:

- 1 Patients moving during the measurement process.
- 2 Incorrect placement of hands and feet on the SOZotouch and SOZOstep.
- 3 Patient is wearing jewelry, stockings or socks when taking a measurement.
- 4 Patient touching a metal surface during the measurement. Device placed on a metal surface, other than the SOZOsupport Stand, during the measurement process.
- 5 Placing a mobile phone or other electronic equipment in close proximity to the device during the measurement.
- 6 Metal implants, clips or other types of implants in patient.

Measurement Complete

Review Results