

SOZO[®] Measurement Guide

Warning: Ensure you have fully read and understood the complete SOZO instructions for use, including warnings and precautions, contained in LBL-507.

1 Preparing the patient

*Contraindications:

The SOZO device should not be used by:

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

Weight Limits

Standing: 375 lbs (170 kg)

Sitting: 750 lbs (340 kg)

Please Note: It is preferable if the measurements are undertaken under similar conditions such as time of day, activity levels, and food and fluid intake.

To optimise the quality of the measurement:

1. Remove all metal jewellery 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. Ensure feet and hands are clean by wiping with a damp cloth.
5. Remain still during the measurement with elbows away from the body.

Additional tips to ensure consistent Tissue and/or Fluid Analysis measurements:

1. Ensure an empty bladder prior to measurement.
2. Avoid exercise for 4 hours prior to measurement.
3. Avoid caffeine for 2 hours prior to measurement.
4. Avoid alcohol for 8 hours prior to measurement.
5. Avoid meals for 8 hours prior to measurement.

2 Confirm device and complete a Self-Test

Once logged into the SOZO app, ensure the SOZO device is connected by confirming the device in the "Device Name".

*Prior to the first measurement of the day, perform a self-test by tapping the "SELF-TEST" button in the top row of the main page to confirm the device is functioning correctly. If the test fails, please contact ImpediMed.

By email: TS@impedimed.com

By phone: +61 7 3860 3700

3 Create or select a patient

To create a new patient, tap "CREATE PATIENT" on the top left of the main page and proceed to enter required Patient Details, Assessment Type, and if necessary, the Lymphoedema Settings.

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

4 Position patient on SOZO

Place the patient's feet on the SOZOstep. Align their heels with the centre of the silver plates and ensure the patient's feet are flat and evenly distributed on the surface.



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.



***NOTE:** The patient's arms/elbows should not be touching their torso.

5 Perform a measurement

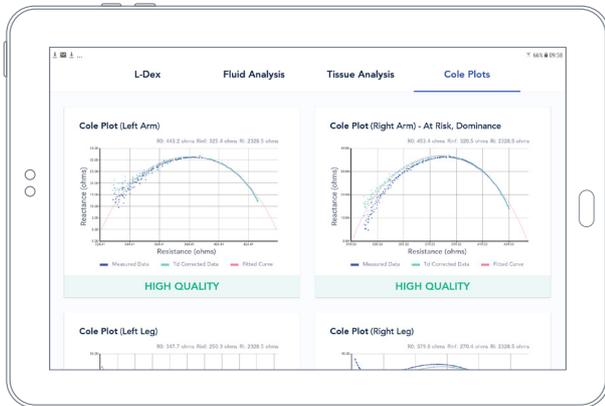
Once you have selected a patient and are in the patient dashboard, tap "MEASURE". Enter the patient's weight and select next. Follow the directions on the screen to complete the measurement.

***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.

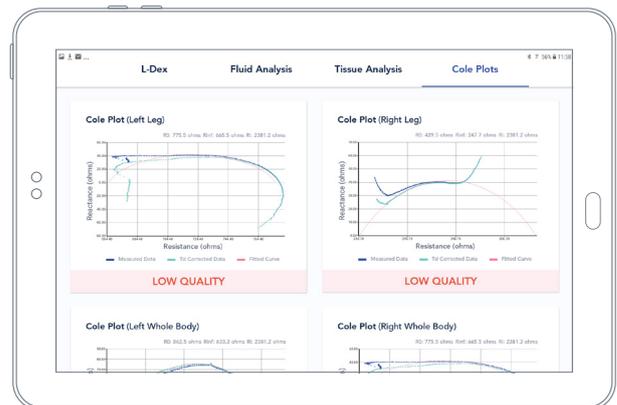
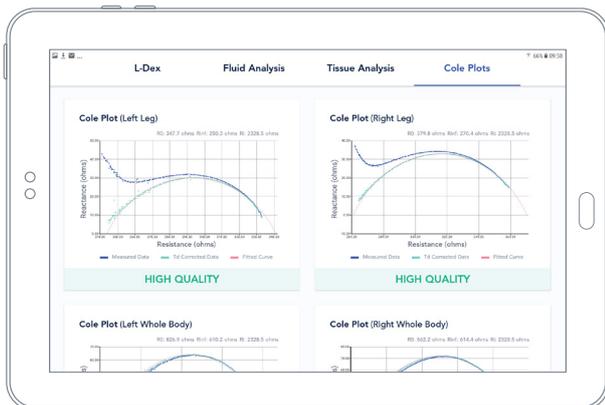
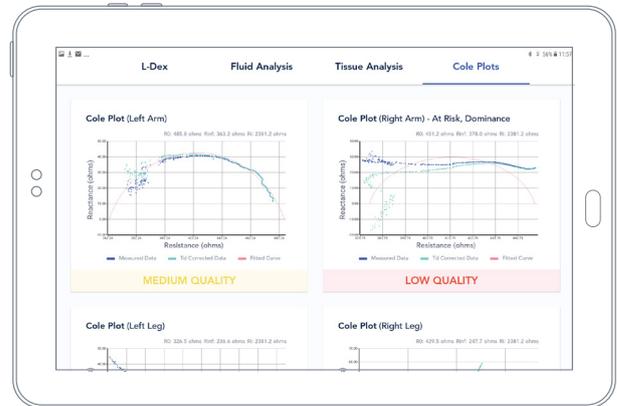
6 Accept or reject Cole plots

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.

ACCEPTABLE COLE PLOTS



UNACCEPTABLE 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 jewellery or 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.

7



Review results



MEASUREMENT COMPLETE