SOZO® Pro

Weight Scale Calibration Instructions for Use

ImpediMed Limited
ABN 65 089 705 144
Suite 31C
12-18 Tryon Rd
Lindfield NSW 2070
Australia
Phone: + 61 7 3860 3700
Fax : + 61 7 3260 1225
Email : enquiries@impedimed.com
Website : http://www.impedimed.com

Distributed in the United States by:
ImpediMed Inc
5900 Pasteur Court, Suite 125
Carlsbad, CA 92008
(877) 247-0111
tsu@impedimed.com

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

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

EC	REP

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

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

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/

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1 SYSTEM OVERVIEW

This instructions for use document (IFU) describes how to calibrate the weight scale of the SOZO Pro device.

1.1 Intended Use

Ensure that you have read and understand this entire Instructions for Use (IFU) before performing a weight scale calibration of the SOZO Pro device. These instructions for use are intended to be used by a metrologist or other technician familiar with weight calibration of medical equipment. No other calibration is required for the SOZO Pro device.

1.2 Precautions

	Ensure that you have read and understand the entirety of this instructions for use document before calibrating the SOZO Pro device. Failure to follow these instructions may result in inaccurate weight and other outputs.
	Do not allow the SOZO Pro device to encounter any liquids.
	When performing a calibration, do not place sharp or metal weights directly on the SOZO Pro foot unit to avoid damage to the surface and/or electrodes. It is recommended to use ImpediMed Calibration Aide or similar.
	When using multiple weights during a calibration, ensure that weights are not stacked or placed in an unsafe manner. It is recommended to use ImpediMed Calibration Aide or similar.
	Use appropriate lifting equipment and weights to ensure that a calibrator is able to load the calibration weights onto the ImpediMed Calibration Aide or equivalent calibration aide located on the scale in a safe manner.

⚠	Do not disassemble the device. Disassembly of the SOZO Pro device voids the product warranty and may impact the accuracy of the device.

1.3 Weight Scale Specifications

- Weight range: 22 kg (50 lb) to 220 kg (485 lb)
- Accuracy during calibration: +/- .1 kg (.2 lb) across weight range
- Accuracy during operation: +/- .2 kg (.4 lb) across weight range
- Recommended calibration interval: 1 year

1.4 Environmental Operating Conditions

The SOZO Pro device should be calibrated in conditions similar to those that it will be operated in. The device must be operated within 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

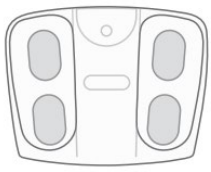
1.5 Required Equipment

To complete a calibration, the following equipment is required:

1.5.1 Equipment available from ImpediMed:

- SOZO Pro Device to be calibrated for weight. The device includes the Hand Unit, the Foot Unit, a Connect Cable, and the Power Adaptor. A stand and Calibration Aide are also available (optional).

Hand Unit



Foot Unit

Connect Cable

Power Adaptor

Calibration Aide (Optional)

- SOZO Pro Weight Scale Calibration Software, SFT-044 provided by ImpediMed. Contact ImpediMed technical support for options on how to download this software.

- SOZO Pro Scale Calibration Plate. To prevent damage to the SOZO Pro Foot Unit housing and to aide in the stability of the placement of the calibration weights, a protective surface should be used. A SOZO Pro Scale Calibration Plate is available for purchase directly from ImpediMed or a customer supplied plate or rubber surface may also be used.

1.5.2 Customer supplied equipment:

- PC running windows version 10 or later, equipped with Bluetooth capabilities.
- A total of 180.00 to 220.00 kg (396.84 to 485.01 lb) of weights, traceable to an appropriate weight standard.

1.6 SOZO Pro Weight Calibration Software Functionality

The SOZO Pro Weight Calibration Software provides the following functionality:

- Connect to the SOZO Pro device
- Retrieve information about the SOZO Pro device
- Run a self-test
- Set weight unit on measure
- Retrieve weight calibration history
- Read the weight on the scale
- Tare / Zero the scale
- Calibrate the scale

2 Scale Calibration Procedure

2.1 Level and assemble the SOZO Pro device

Starting on a solid, flat and level surface, adjust the feet of the SOZO Pro device so that they are all flat and the bubble level on the top of the foot unit indicates that the SOZO Pro foot unit is level (see picture below). If desired, the SOZO Pro device can be calibrated while still on the stand.

Foot Unit Bubble Level

Ensure that the SOZO Pro is powered on and nothing other than the Power Adaptor and Connect Cable are touching the SOZO Pro Foot Unit and that there is no tension on either cable that could impact the weight reading. The Connect Cable must be connected to both the SOZO Pro Foot Unit as well as the Hand Unit.

2.2 Place scale calibration plate on top of SOZO Pro foot unit

To prevent damage to the SOZO Pro foot housing and to aide in the stability of the placement of the calibration weights, a protective surface should be used. A SOZO Pro Scale Calibration Plate is available for purchase directly from ImpediMed or a customer supplied plate or rubber surface may also be used.

Do not place sharp or metal weights directly on the SOZO Pro foot unit to avoid damage to the surface and/or electrodes. It is recommended to ImpediMed Calibration Aide or similar.

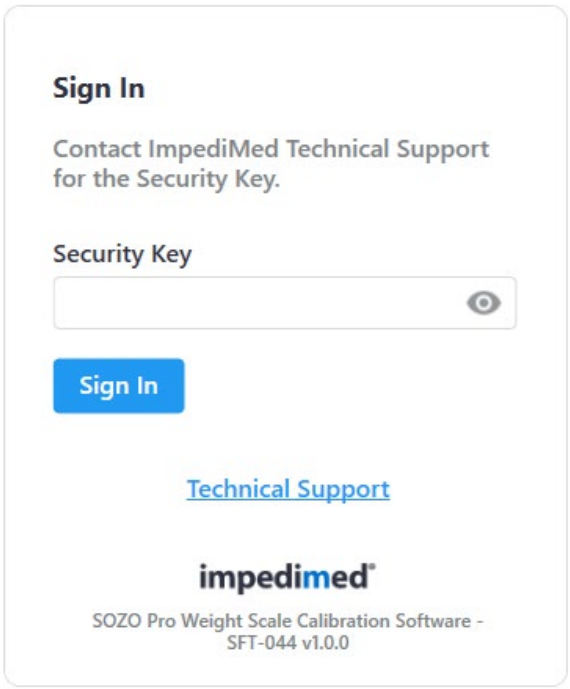
When using multiple weights during a calibration, ensure that weights are not stacked or placed in an unsafe manner. It is recommended to use ImpediMed Calibration Aide or similar.

The scale may be tared at this point, but is not required to proceed with calibration.

2.3 Sign into the SOZO Pro Weight Scale Calibration Software and pair to the SOZO Pro device

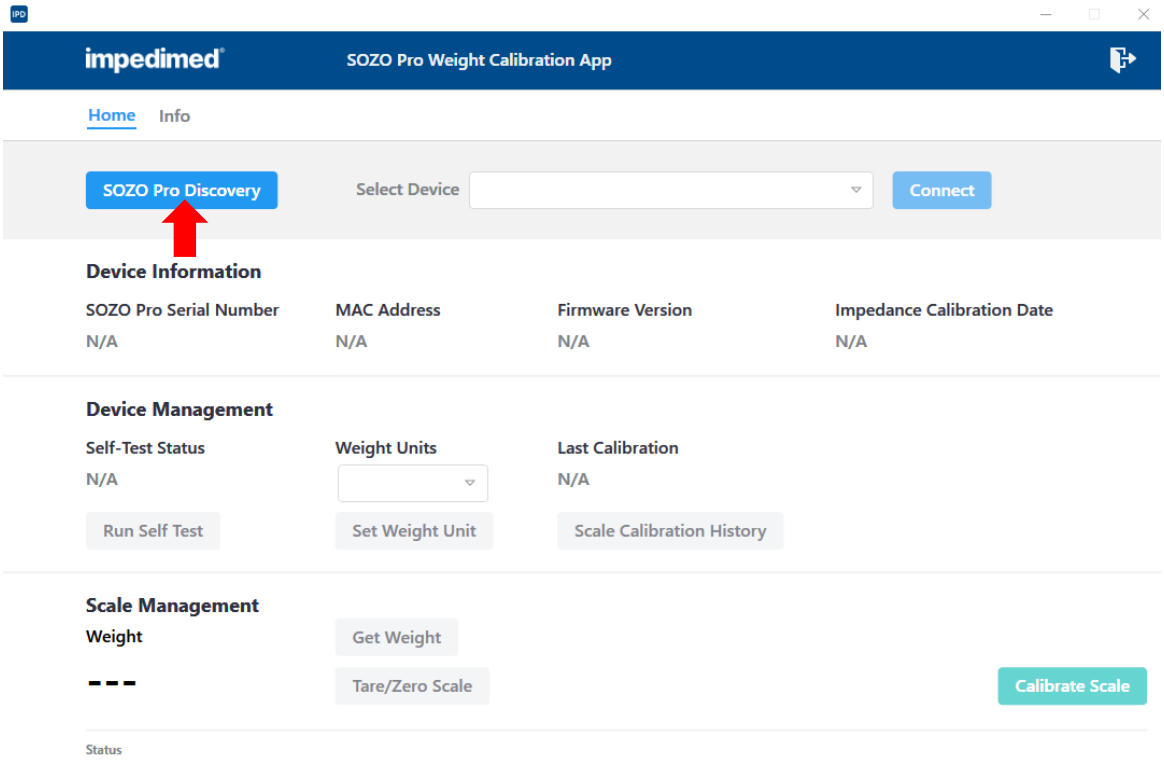
Using a windows PC and files provided by ImpediMed, select the following file to install the SOZO Pro Weight Scale Calibration Software. The SOZO Pro Weight Scale Calibration Software can be found at https://www.impedimed.com/sozo-pro-ifus/. The installation file should be named SFT-044 - SOZOProWeightCalibrationAppInstaller.appxbundle.

Upon installation and opening of the software, a security key is required to access the calibration functionality. Reference Section 5 Security Key for the security key. If the security key is lost contact ImpediMed technical support to obtain the required security key.



After signing in, follow the steps below to access the functionality of the software:

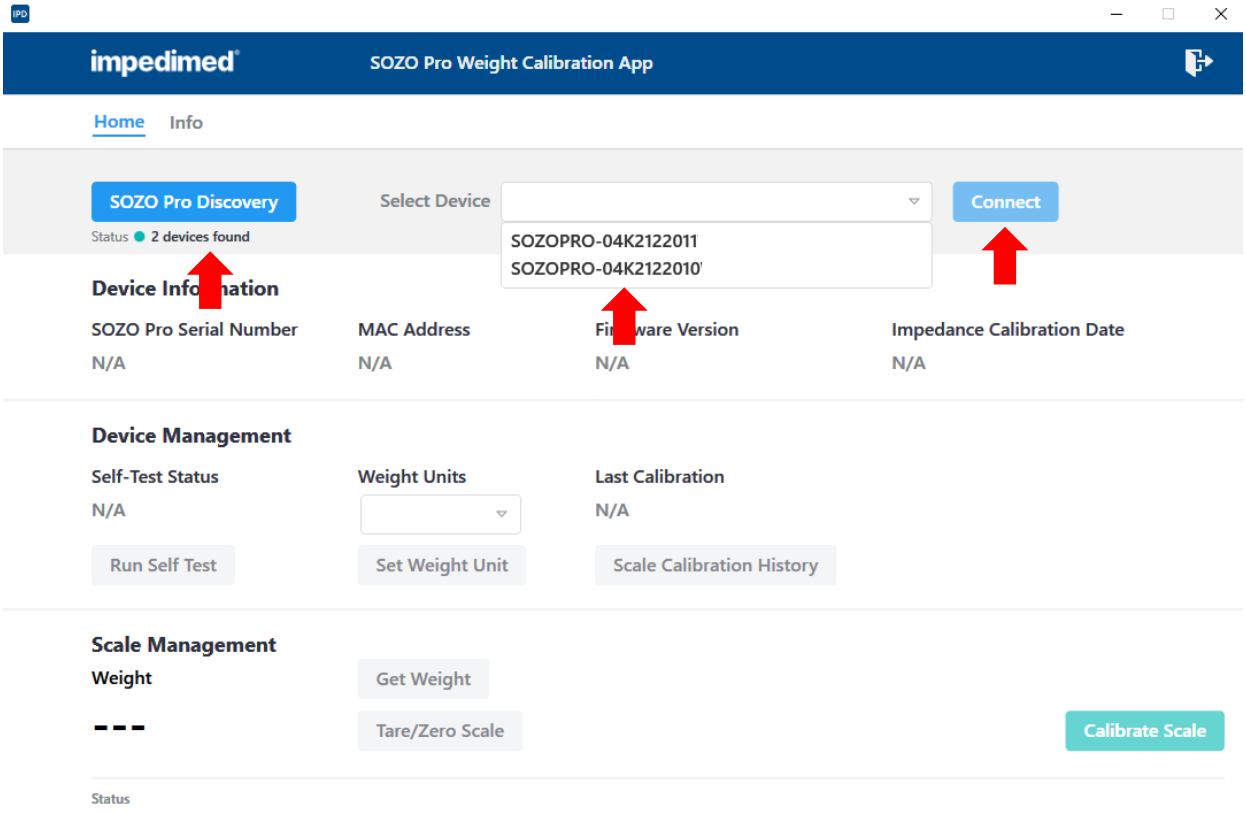
To pair to a SOZO Pro device, select the SOZO Discovery button as shown below for the device to be calibrated. The number of devices found will be shown under the SOZO Pro Discovery button.



Once a SOZO Pro device is found, select the desired SOZO Pro device in the drop-down menu and then select “Connect”.

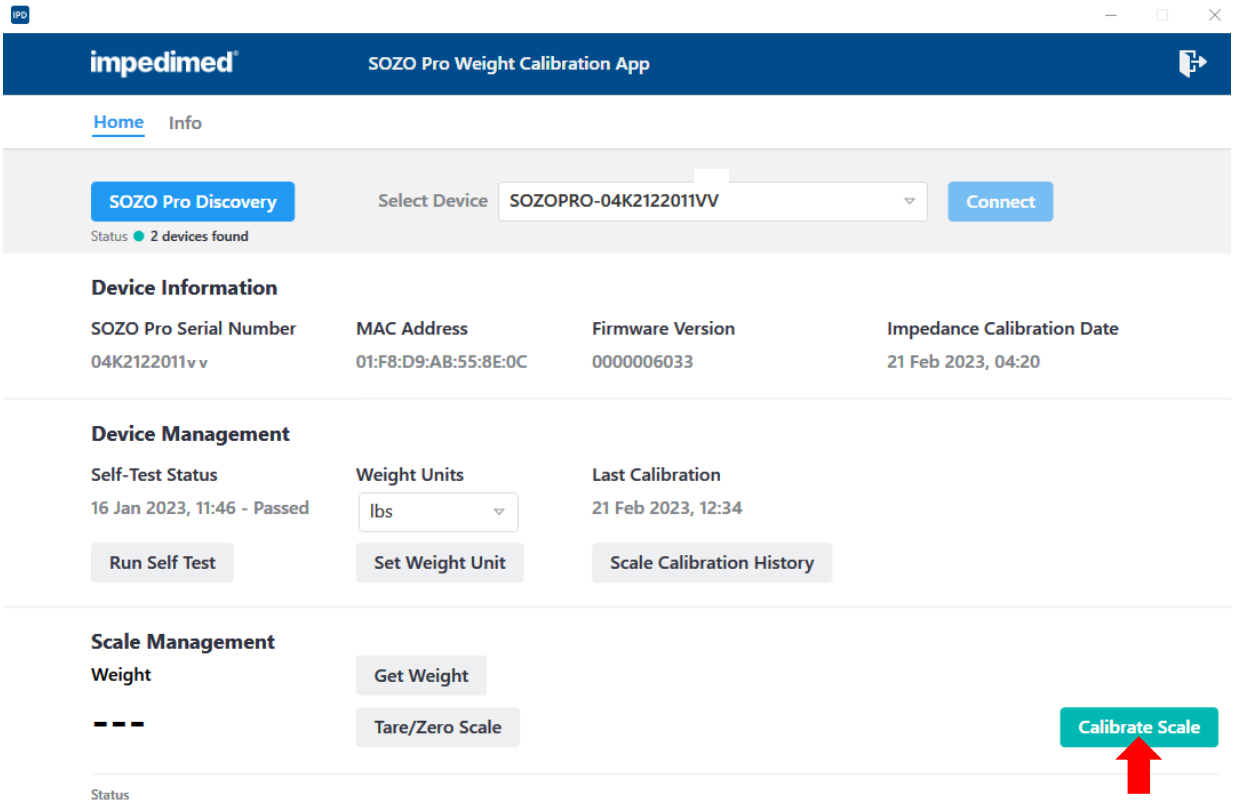
Note: the Bluetooth name of the SOZO Pro Device is the serial number of the device SOZOPRO-XXXXXXXXX where XXXXXXXXX is the last 10 or 11 digits of the serial number of the device after the dash. The serial number of the device can be found on the regulatory labels on the back of the hand unit or the bottom of the foot unit.

The device information will be automatically populated upon connection with the SOZO Pro Device.



2.4 Enter calibration sequence

Select “Calibrate Scale”

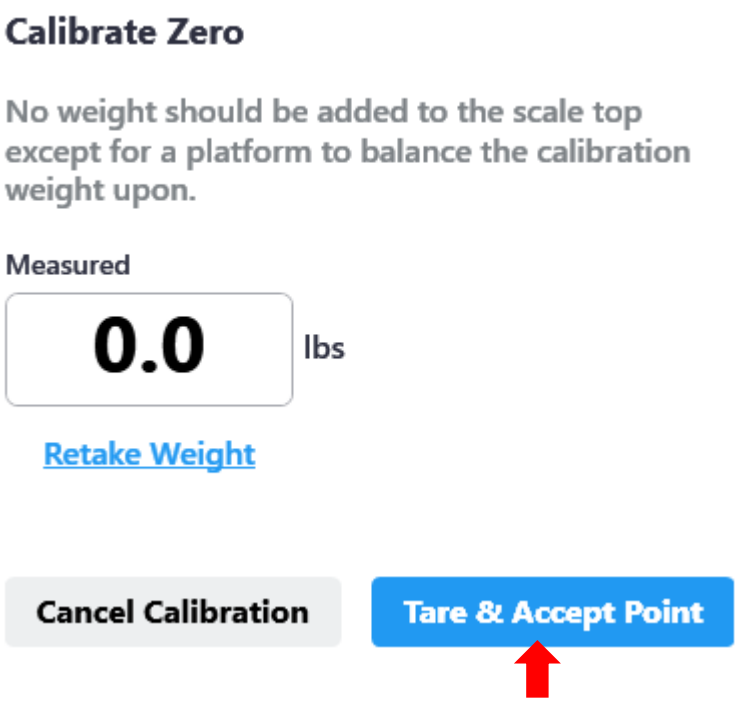


2.5 Calibrate zero

The first step is to calibrate the scale at its zero point. The scale will automatically tare / zero as part of process. Any items that may have been added to the scale such as a calibration plate should remain on the scale throughout the calibration process.

The measured weight shown on the screen is to ensure that the calibrator is aware of any weight that may be on the device. There can be no more than +/- 20.00 kg (44.09 lb) of weight added to the device to continue.

Once the SOZO Pro Scale is ready and stable, select “Tare & Accept Point”.

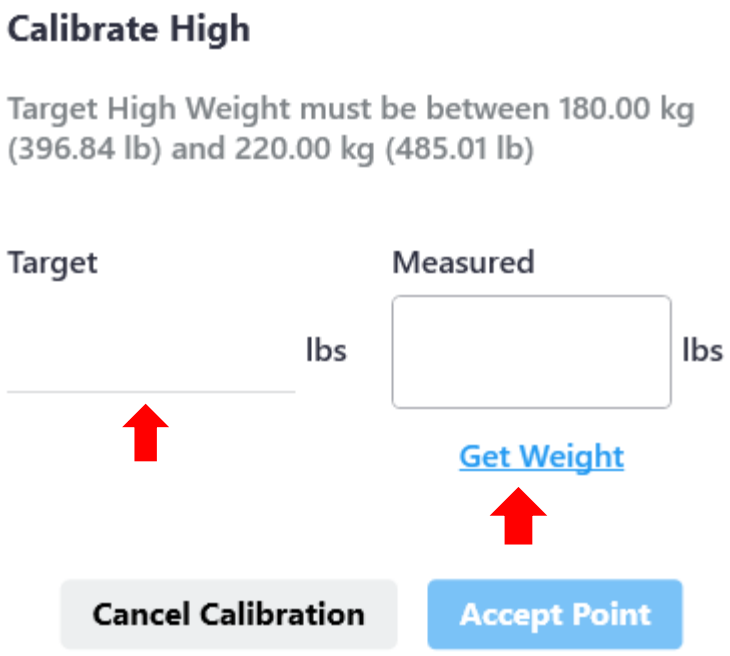


2.6 Calibrate the High Weight

Place a total of 180.00 to 220.00 kg (396.84 to 485.01 lb) of weights traceable to an appropriate weight standard such as NIST onto the Foot Unit. This range is provided to allow for combinations of weights that may be available to the calibrator. The weight should be centered on the plate and evenly distributed.

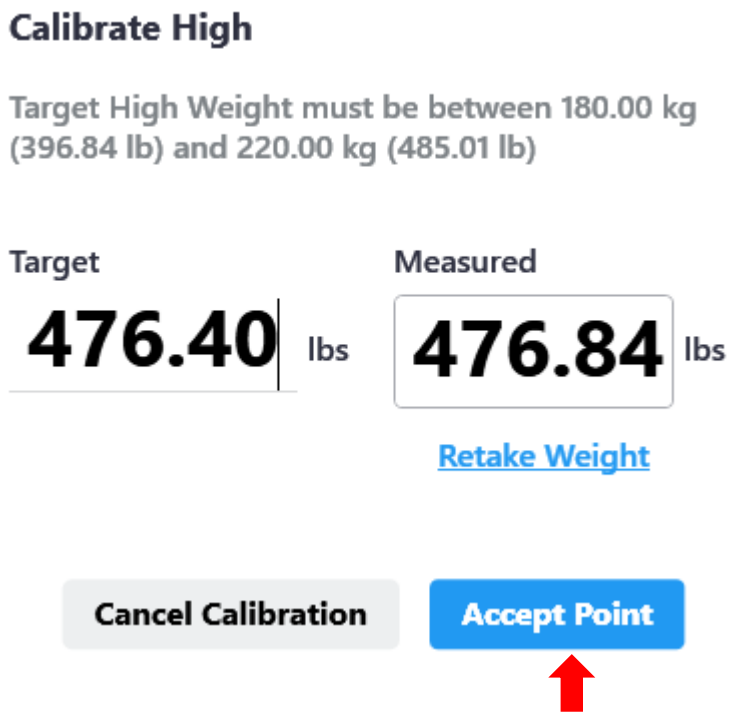
- Do not place sharp or metal weights directly on the SOZO Pro foot unit to avoid damage to the surface and/or electrodes.
- When using multiple weights during a calibration, ensure that weights are not stacked or placed in an unsafe manner.
- Use appropriate lifting equipment and weights to ensure that a calibrator is able to load the weights onto the scale in a safe manner.

Enter in the exact weight value as “Target” and select “Get Weight”. An additional digit of precision is allowed during this process to ensure optimal calibration.



The measured weight that is shown reflects the weight that the SOZO Pro device measures based on the previous calibration and must read to within +/- 20.00 kg (44.09 lb) of the specified Target calibration weight.

Select “Accept Point” to finalize the calibration process



2.7 Finalize the scale calibration

Upon successful calibration, the screen below will be shown.

2.8 Post Calibration

After calibration, the scale performance of the SOZO Pro device should be confirmed by first reviewing the calibration history and then by applying known weights to the Foot Unit to confirm that the device meets the accuracy specification of +/- 0.2 kg (+/- 0.4 lb). The metrology requirements and procedure for performance confirmation may vary depending on regulations and clinic specific metrology requirements and is therefore not specified by ImpediMed.

When reviewing the calibration history, the Zero Scale Calibration should always read 0.00 for target and actual measurement. The High scale calibration values will vary depending on the target weight chosen and the actual weight measured. The first calibration entry is typically completed during the production process and may have a higher variation between the target weight and actual measurement than subsequent calibrations. The calibration history page may be printed for record keeping purposes.

Scale Calibration History

SERIAL NUMBER: SOZOPRO-04K2122011

Print

Date and Time	Zero Scale Calibration		High Scale Calibration	
	Target Weight	Actual Measurement	Target Weight	Actual Measurement
01 Mar 2023, 14:37	0.00 lbs	0.00 lbs	400.00 lbs	380.78 lbs
01 Mar 2023, 14:10	0.00 lbs	0.00 lbs	400.00 lbs	368.22 lbs
21 Feb 2023, 11:34	0.00 lbs	0.00 lbs	399.92 lbs	451.52 lbs

Upon completion of the calibration activity, ImpediMed recommends recording the calibration status in a metrology log or ImpediMed Form MP-038-1 and applying a physical label to the SOZO Pro foot unit with the date of the calibration. Any calibration tools such as the SOZO Pro Calibration plate should be removed from the device and the device should be tared through the Calibration App or by powering on/off the SOZO Pro device.

Contact ImpediMed technical support or visit https://www.impedimed.com/sozo-pro-ifus/ to access form MP-038-1.

2.9 Additional SOZO Pro Weight Scale Calibration Software functionality

In addition to the calibration software functionality, the SOZO Pro Weight Scale Calibration Software allows a user to do the following:

- Zero the scale.
- Get historical scale calibration data that includes the date/time of calibration and the target weight vs actual weight used for calibration.
- Perform a self-test and retrieve the results of the last self-test.

3 General Troubleshooting Chart

The General Troubleshooting chart provides guidance for common issues and error messages. For additional help, see section 4 Technical Support for technical support contact information.

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
Error when taring scale – "Device cannot tare, measured weight must be within…." This may be seen during normal operation or when taring during calibration.	The device can only be tared to within +/- 20.00 kg (44.09 lb) of the previous tare. This is to ensure that a mistake is not made during the taring process (such as a user standing on the scale).	Ensure that the device is within the specified weight range when taring.
When calibrating the high point, the following error message is shown: "The measured calibration weight differs from the entered target weight by more than…."	The device does not allow for extreme changes in calibration values as this could indicate a device failure.	Ensure that the weight entered matches the weight applied. Ensure the units of measure are as expected (kg or lb) Ensure that the SOZO Pro has been set up correctly, that all feet are firmly on the floor, the bubble indicates level, and no other objects are interfering with the foot unit of the SOZO Pro. Ensure that no additional weight has been added or removed between the Zero calibration step and the high calibration step. In extreme cases, multiple calibration cycles can be employed to modify the calibration by more than 20.00 kg (44.09lb)

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
When calibrating the high point, the following error message is shown: "Target weight out of range…."	To maintain the specified accuracy, the device must be calibrated near the high end of the weight range. Target weights between 180.00 kg (396.84 lb) and 220.00 kg (485.01) lb are acceptable to allow the calibrator flexibility to choose weights that are readily available.	Enter a value between 180.00 kg (396.84 lb) and 220.00 kg (485.01) lb. Ensure the units of measure are as expected (kg or lb)
SOZO Pro Device not found over Bluetooth.	Bluetooth; PC Issue	Move the PC closer to the SOZO Pro Device. Ensure that the Bluetooth is functioning on the PC by checking the settings. Pair and unpair with the SOZO Pro Device through the computer settings. Power on/off both the SOZO Pro and the PC. Move the PC and SOZO Pro device away from potential causes of electro-magnetic interference. Ensure that the SOZO Pro device is not already connected to another PC or tablet.
Calibration not reflected in the calibration history	SOZO Pro device was not calibrated due to error in calibration. Both the low and high weight must be entered before completing calibration.	Re-calibrate the device
SOZO Pro weight output not accurate after calibration	The weight added may not match the weight that was specified during calibration. A physical issue with the device.	Ensure that the device is level. Ensure that the device is appropriately tared. Ensure that nothing is touching the SOZO Pro foot unit. Review the calibration history and ensure that the weights used for calibration are accurate and no additional weight was added during the calibration process. Re-calibrate the device.
Self-test fails.	Person/object making contact with electrodes during self-test.	Ensure no extraneous objects are in contact with electrodes during self-test; re-run self-test.

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
The weight displayed on the device display does not match the weight displayed on the calibration app.	The update weight display on the calibration app typically mirrors the weight shown on the device. However, this is not always the case as there can be a mismatch between the timing of when the measured weight is displayed on the scale vs. when the calibration app last updated the weight reading from the scale.	If the weights do not match, retake the weight. Ensure that there is no tension on the Connect Cable, which can impact the weight reading by small amounts.
When should my first calibration occur? From date of factory calibration, or start of service (date of installation).	Differing dates between the start of service and date of manufacture.	ImpediMed recommends using the start of service to begin the 1 year calibration period. A calibration sticker is added to the device during manufacturing and the start of service date should be written on the calibration sticker when the device is first put into service.
The device is at risk of damage due to metal calibration weights used.	A metal plate or rubber surface is not available during calibration.	Do not place sharp or metal weights directly on the SOZO Pro foot unit to avoid damage to the surface and/or electrodes. The SOZO Pro housing is designed to withstand the weights used during calibration and normal use. However, metals that are often found in standard calibration weights could scratch or dent the surface. A protective layer is recommended by Impedimed.
Stacking of weights during calibration or verification presents a safety hazard.	A metal plate is not available during calibration. Weights are not available in sufficient denominations / shapes to avoid stacking.	ImpediMed does not recommend stacking of weights during calibration for safety reasons.

General Troubleshooting		
Issue/Error message	Potential Cause	Resolution
Large weights pose a safety risk for lifting and moving.	Large single weights are used during calibration.	Customer should use appropriate equipment to aid in the lifting of any weight and should choose calibration weights of sufficient weight and dimensions to fit on the SOZO Pro foot unit without stacking in an unsafe manner.

4 Technical Support

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

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

Asia Pacific Technical Support
+61 7 3860 3700, option 2
ts@impedimed.com

Europe, Middle East and Africa
+30 231-111-6753
tse@impedimed.com

5 Security Key

Use the following Security Key for logging in to the Software program for Section 2.3.

jcfJnmK3YTA5eJiK

This page may be removed by the user for security reasons.