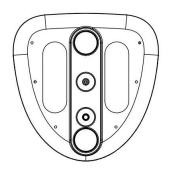


# Suji Gen 2.0 Quick Setup Guide

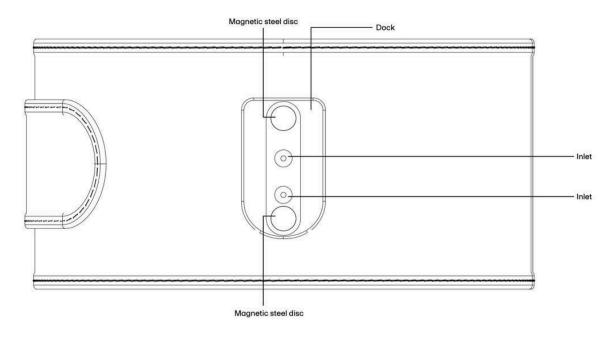
# **Product Overview**

# **Compression Device**





# **Compression Cuff**





# **Getting Started**

You can get started with Suji by watching our setup video on YouTube – <u>linked here</u> – or by following the Steps outlined below.

### STEP 1. - Download the Suji App.

Download the Suji App from the App Store on iOS by searching for "Suji".

Note: the App is not yet available on Android/Google Play.

Note: If you are a healthcare professional you will want to search for "Suji Teams" instead. Suji Teams is available on iOS/the App store and on Android / the Play store devices. Suji Teams does require you to verify yourself as a healthcare professional to gain access.

### STEP 2. - Charge Suji.

Place Suji in the Charging Case and close the lid. Plug the charging cable into the USB-C charging point on the bottom of the case. Plug the other end of the charging cable into a USB-C outlet. Charge for up to 150 minutes for full battery.

#### STEP 3. - Turn Suji On.

30 minutes (150 minutes for a full charge), remove the Compression Devices from their charging case. Press and then immediately release the power button on the front of the device to turn it on. A white LED will begin to flash.

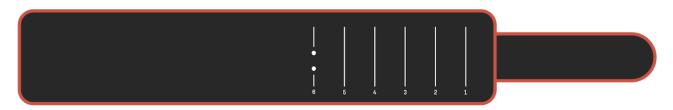
#### STEP 4. – Connect the Compression Device to the Compression Cuff.

Using the dock interface and magnets align the Compression Device over the Compression Cuff and firmly press the device into place. You should hear an audible "click" when the device is securely attached.

Note: doing this step incorrectly is the primary cause of air leaking during use.

#### STEP 5. – Fastening the Compression Cuff to the topmost portion of your limb.

Take the Compression Cuff – now with the Compression Device securely attached – and fasten it around the top most portion of your limb. Repeat steps 3 through 5 if you wish to exercise two limbs simultaneously.





If this is your first-time using Suji, further setup support is found in app. You will be prompted to connect the devices via Bluetooth before completing calibration which is where Suji establishes your safe compression zones.

Calibration takes less than 2 minutes. Some users may find it intense or uncomfortable but it should not be painful. This is the most intense the compression will be as Suji establishes your safe compression levels.

In app tool tips will guide you through the app during setup. Further support can be found in the "Suji 101" section of the app, via our website, or by contacting customer support.



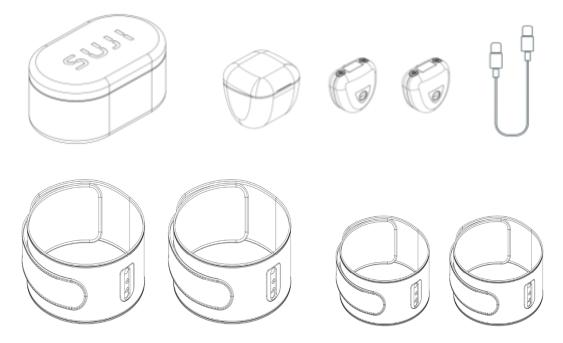
# **Device Description**

#### Intended Use

Suji is a battery powered pneumatic tourniquet, developed to be used for Targeted Compression Training – also known as blood flow restriction (BFR) training - to facilitate musculoskeletal health improvements. Suji is intended to be used with a companion mobile application where the mobile application controls the compression level of the compression cuffs (pneumatic tourniquet) and provides instructional guidance on how to complete exercises. Suji utilises proven methodologies to both effectively improve muscular performance and aid in physical therapy.

## **Package Contents**

Depending on the order configuration at your time of purchase, your Suji order will comprise some of the following items:



#### (1) Carry Case

For storing and carrying your Suji devices, Charging Case, two Suji Cuffs, and USB-C charging cable.

#### (2) Charging Case

For storing and charging your Suji devices via the USB-C charging cable. Note: This charging case does NOT charge the devices without the USB-C cable connected.

#### (3) Compression Devices



Controls the compression level/pressure (inflate/deflate) of the Compressions Cuffs. Controlled via Bluetooth¤ with the accompanying mobile App. Made from medically compliant materials, simply wipe down with an anti-bacterial wipe for cleaning.

- Power button: Press once to turn on. Press again to turn off.
- Power indicator: A white LED within the power button to indicate the status Compression Device status:

LED	Device Status	
Off	Off	
Flashing	On	
Solid	On and connected vie Bluetooth to the Suji App	

• Product labels: Display information pertaining to proper product disposal, normalized symbols, and electrical characteristics.

#### (4) USB-C Charging Cable

For charging the Compression Devices from a reliable 5V USB-C connection. It is recommended to charge Suji via a stable laptop or PC connection.

#### (5) Compression Cuffs

Velcro strapped compression garments that attach to the upper or lower limbs. All compression cuffs come as a set. Your order configuration will stipulate how many sets you receive.

#### ADDITIONAL NOTES

- Always inspect your compression device and cuffs signs of damage before and after use. Do NOT use damaged devices or accessories. Seek to replace damaged devices or accessories immediately.
- For first time users, TCT can feel intense. It is recommended that first time users complete
  their first session on a Low Intensity recovery protocol to familiarize themselves with the
  technology.
- If you experience dizziness, major discomfort, or pain, STOP immediately. Remove the compression cuff from your limb. If adverse reactions persist, seek medical attention.

# **Bluetooth Compatibility**



Suji is controlled through Bluetooth¤ Low Energy. The product is designed to work with the accompanying mobile app, which is supported for use on select iOS devices.

Note: Suji Teams available to verified healthcare professionals is available on supported iOS and Android devices.

#### Secure Connection:

Suji connects to your mobile device using an in-app scanning function. The Suji App will only connect to Suji devices. Once Suji is connected to the app and a secure connection is established, the connection cannot be interrupted by another Suji device in close proximity.

Common to any wireless device, Suji devices emit very low levels in the radio (RF) frequency interval, and therefore will not likely cause any interference with nearby electrical equipment. It is not possible to guarantee that Suji will not be affected by strong RF (radio frequency) fields emitting from other sources.

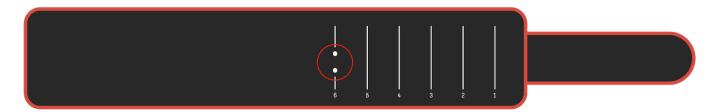
It is advised that Suji is not used closer than two meters to devices emitting strong RF fields. For example, a working microwave.



# General Usage Guidelines

#### **Device Placement**

Mount the compression device onto the dock on the compression cuff. Firmly push the device onto the cuff ensuring there is full engagement between the outlets on the device and the inlets on the cuff.



If the cuff does not inflate as expected, check that the cuff inlets and device outlets are fully engaged by pressing on the dots at the back of the cuff and try to inflate the cuff again.

#### **Cuff Placement**

Always follow the cuff placement guidelines found in the App. The manufacturer assumes no liability for injuries, damages, and other consequences arising from product use where the Compression Cuff placement recommendations have been ignored.

Ensure a secure fit of the cuff on the limb at the upper most portion. At least 1inch the of cuff must overlap and be securely fastened using the Velcro strip.

# Charging Suji

Suji uses a Lithium Polymer battery which can be recharged from any reliable USB-C connection. Suji takes up to 150 minutes to fully charge from zero. The Suji device will stop charging after 240 minutes of continuous charge time. One full charge is expected to last 10 days based on one 30-minute session each day. From new, the battery will last for at least 300 charge cycles.

- ALWAYS use the original charging cable supplied with your Suji.
- ALWAYS inspect the charging cable for damage prior to use. If damage is visible DO NOT charge and seek replacement from a Suji certified retailer.



# **Technical Specifications**

### **Battery**

Polymer lithium-ion battery, AUK Power, cell model 422629, product number AUK2022080302B, 450mAh, 3.65 - 3.9V shipment voltage.

## Charging input

Input voltage 5V DC via pogo pins within a charging case (via a USB C to USB C cable), current rating is 500mA. Other cables and accessories may negatively affect EMC performance.

#### Bluetooth

Built in Bluetooth LE 5.0 module. Contains IC: 216Q-1780. PAN1780 Bluetooth Low Energy Module, 64 MHz.

## Electro-Compatibility (EMC)

IEC 60601-1 (Basic Safety), IEC 60601-1-2 (EMC), IEC 60601-1-11(Home Usage).

#### **RF Data**

Operating Frequency Range: 2402 MHz to 2480 MHz Output

Power Range: -40 dBm to +8 dBm.

Number of Channels: 40 (3 for advertising, 37 for data).

Antenna Type: Chip antenna, -1.0 dBi Gain.

# Mobile Application Compatibility

Minimum iOS 16.0 with BLE capability.

### **Device Dimensions**

62.5 × 61.8 × 32mm.

# Weight (two Compression Devices and a Charging Case).

220g.

# **Environmental Specifications**

¥ Operating: Temperature from 0 C to +40 C.



¥ Storage/Transport: Temperature from - 40 C to +85 C.

¥ Humidity: 40-85% RH.

Do NOT handle or operate the product with wet hands or near water.

### Product expected lifetime

A one year warranty is provided with every purchase.

### Housing material

ABS and polycarbonate.

#### Limitations

Suji is not suitable for high oxygen concentration environments, or environments with flammable liquids or gases. Suji is not for use as a surgical tourniquet or blood pressure cuff.

#### **Environments for Use**

Suji is designed for use in the following settings: professional healthcare facilities, sports rehabilitation facilities, sports training facilities, and home environments.

### Emissions and Immunity Test Levels

Emission is tested according to the standard CISPR11 (EN 55011) Class B, Group I. ESD tests (Electrostatic discharge +- 8 kV contact, +- 2,+-4,+-8,+-15 kV air discharged). Radiated immunity: 80 MHz-2.7 GHz 10 V/m, 2.7 - 6 GHz - 3 V/m.

Magnetic field immunity: 50, 60 Hz - 30 A/m.

### **Essential Performance**

The compressions device is designed to inflate the compression cuff to a pre-determined compression level via the Suji app. Every user must be calibrated before they are able to use Suji.

A level of discomfort is expected during TCT but if any severe discomfort or adverse side effects occur whilst using product, terminate the session and seek medical advice.

If the compression device powers off or disconnects from Bluetooth during use, the compression cuff will remain inflated. In this case, either re-connect to Bluetooth and deflate the cuff via the app, or physically remove the compression device from the compression cuff by simply pulling it off. Removing the device will cause the cuff to instantly deflate.

# **Basic Safety**



The basic performance of the compression device is to:

- Inflate an air bladder within the compression cuff.
- Maintain a desired level of compression.
- · Deflate the air bladder

Suji is turned On / Off via a power button. Power is indicated by an LED. Suji is operated by a mobile application over BLE.

The compression device can always be physically removed from the compression cuff so there is no risk of the product failing and causing injury the user.



# Safety Information

### Contra-Indicators

Suji is intended for use by healthy individuals. For guidance as to whether you qualify as a healthy individual, complete the following Contra-Indicator Survey. You will have to complete this same survey when signing up and creating your profile in the Suji App.

RISK MAGNITUDE	MEDICAL HISTORY OR LIFESTYLE	RESPONSE	DECISION
Do you have a family history of clotting disorders?  Do you have level one hypertension, history of DVT or pulmonar  Are you pregnant?  Have you ever suffered from a haemorrhagic or thrombotic stro	Do you have a family history of clotting disorders?	YES	Stop and seek medical advice
		NO	Continue
	Do you have level one hypertension, history of DVT or pulmonary embolus?	YES	Stop and seek medical advice
		NO	Continue
	Are you pregnant?	YES	Stop and seek medical advice
		NO	Continue
	Have you ever suffered from a haemorrhagic or thrombatic stroke?	YES	Stop and seek medical advice
	Trave you ever surrect norman and emorning of an ormbotic stroke.	NO	Continue
Do you smoke?  Are you on any medication? (Including the contraceptive pill)  Have you had any surgery in the last four weeks? Do you have any metal work in  Do you have diabetes?  Do you have hypertension?  Have you / do you suffer from compartment syndrome?  Have you had a journey of more than four hours in the last seven days?  Do you have any other medical conditions that could be affected by using Suji?	Do you smoke?	YES	Seek medical advice
	Do you amono.	NO	Continue
	Are you on any medication? (Including the contraceptive pill)	YES	Seek medical advice
		NO	Continue
	Have you had any surgery in the last four weeks? Do you have any metal work in situ?	YES	Seek medical advice
		NO	Continue
	Do you have diabetes?	YES	Seek medical advice
		NO	Continue
	Do you have hypertension?	YES	Seek medical advice
	bo you have hypertension:	NO	Continue
	Have you / do you suffer from compartment syndrome?	YES	Seek medical advice
		NO	Continue
	Have you had a journey of more than four hours in the last seven days?	YES	Seek medical advice
		NO	Continue
	Do you have any other medical conditions that could be affected by using Suii?	YES	Seek medical advice
	be jest have any extent measure that could be directed by doing out.	NO	Continue

# **Usage Precautions**

- The Contra-Indicator list is for guidance ONLY. If there is any doubt about your status as a Healthy Individual seek medical advice prior to use.
- If you experience adverse reactions whilst using Suji, you should terminate use and seek medical advice.
- Do NOT use Suji in or near water and do not operate with wet hands.

# Safety Measures

- You MUST complete the calibration sequence prior to first use.
- Do NOT place the compression device or cuff around any part of the body other than the limbs.
- Do NOT use Suji in water or humid atmospheres (Sauna, Hydrotherapy, etc).
- Do not use Suji while driving, operating heavy machinery, or doing any other activity in which BFR training could put you at risk.
- Do not use Suji while sleeping.
- Keep Suji away from children and pets. Do not let foreign objects (soil, metal, dirt, etc) get into the device.
- Do not operate Suji within 1.5 meters of short wave or unshielded microwave devices. Check with your doctor or device manufacturer if you can use Suji within proximity of other medical devices.



- Do not operate or charge Suji within 30 cm (12 inches), of other portable RF communications equipment, including antennas.
- Do not overexert yourself when using Suji. Any workout should be at a level that can be considered intense but tolerable.
- Do not use Suji at altitudes over 3,000 meters.
- Do not use Suji on children.
- Do not use Suji in areas where unprotected devices are used to emit electromagnetic radiation: portable communications equipment, metal detectors, radio communications, and RFID may interfere with Suji Device.
- Do not use Suji in proximity to medical devices such as MRI, CT, or X-Ray machines.

### Compression Cuff placement precautions

NEVER attach the Compression Cuff:

- Near or around your head.
- Around or on your neck. This may cause closure of your airway, difficulty breathing, or adverse
  effects on blood supply.
- Around your waist.
- Over open wounds or rashes, or over red, infected, or inflamed areas or skin eruptions.
- Over, or in proximity to, cancerous lesions.

Only use official Compression Cuffs supplied. Other pneumatic tourniquets may cause undesired levels of compression.

#### **Adverse Reactions**

Some people unfamiliar with TCT may experience bouts of dizziness, localized numbness, or pins and needles. In this event, stop your session, remove the device, and wait for symptoms to stop. You may resume at a reduced intensity. These symptoms are not uncommon with TCT, but if they persist consult a healthcare professional.

# Troubleshooting and Problem-Solving

Device does not turn on.



Charge your compression devices for at least 30 minutes, it is likely very low on battery. You should charge your devices when they arrive and prior to first use.

## Device is not charging.

The devices do not display charging status during charge. Ensure your device are securely stored in the Charging Case, confirm the charging cable is firmly plugged in and connected to a reliable 5V USB-C connection. Charge for 150 minutes to guarantee a full charge.

If your devices still do not turn on contact customer support.

#### I cannot connect via Bluetooth.

You must connect your Compression Devices from within the Suji app. When you open the App and the compression devices are searching for Bluetooth connection (as indicated via flashing LED) auto pairing will occur. On first connection you will be prompted to confirm a pair request.

If you the app is unable to find your devices ensure Bluetooth is turned on and your phone has allowed the appropriate permissions to the Suji app.

If you are continuing to experience connectivity problems, try unpairing and repairing your Suji device:

- Navigate to Settings on your phone. Select Bluetooth. Then select the Suji device from the list and select the information icon. Select Forget This Device.
- Ensure the Suji device is turned off and kill the Suji App. Turn off and then on again Bluetooth on your mobile device.
- Reopen the Suji App and navigate to Profile > Device Manager > Select a device. Turn
  on your Suji device and complete pairing.

If the problem persists, contact customer support.

# My device won't inflate or deflate.

First ensure there is a secure connection between the Compression Device and Compression Cuffs. You should hear an audible "click" when a secure connection occurs. Try attaching the Compression Device and Compression Cuff before fastening the cuff to your limb. You can follow our "Suji Gen 2.0 Setup Video" on YouTube for guidance.

Next, try refreshing your Bluetooth connection by completing the following steps:

- Navigate to Settings on your phone. Select Bluetooth. Then select the Suji device from the list and select the information icon. Select Forget This Device.
- Ensure the Suji device is turned off and kill the Suji App. Turn off and then on again Bluetooth on your mobile device.
- Reopen the Suji App and navigate to Profile > Device Manager > Select a device. Turn
  on your Suji device and complete pairing.

#### Exercise causes nausea or dizziness



TCT, like high intensity normal exercise, can cause the user to have momentary periods of nausea or dizziness. If you experience nausea or dizziness stop your session and rest. You may resume your exercise session once the nausea or dizziness passes on a reduced intensity. If nausea or dizziness is persistent or occurs on each use with low intensity seek medical advice before continued use.



# Maintenance and Cleaning Instructions

### Storage

The compression devices should always be stored in the Charging Case when not in use. If stored for long periods of time, storage should be at room temperature in a dry environment.

## Cleaning

You may clean your compression devices and compression cuffs using a damp cloth or anti-bacterial wipes. After wiping down, use a dry cloth to wipe the items until they are dry.

### Repair

If you believe your product needs to be repaired, contact Suji. The manufacturer states that the product cannot be repaired by personnel external to the company. Any work carried out by anyone other than the manufacturer will be considered tampering with the product. This releases the manufacturer of all responsibility regarding warranty, hazards to the user, or any other liability.

### Disposal

Waste Electrical and Electronic Equipment (WEEE), governed by EU Directive 2012/19/ EU. The wheelie bin symbol on the product label means that the equipment must not be disposed of in general waste. The equipment must be given to a suitable collection point. In doing so, you are aiding the protection of natural resources and human health. In NOT doing so, you risk harming the environment and human health as a result of the presence of hazardous substances present in EEE. Batteries must be disposed of via a suitable compliance scheme, such as a local recycling centre, and in accordance with your country's governing laws.



# Labelling and Packaging Information

Product label:



# **Regulatory Information**

This medical device complies with the requirements of the Federal Food, Drug, and Cosmetic Act. It meets the regulatory standards set for Class I devices as defined in 21 CFR 820. It complies with CISPR 11.



# Warranty

Suji is covered by a warranty of 12 months. The warranty comes into effect on the purchase date. Proof of purchase will be required to exercise your warranty. Each purchase is protected with a 30-day money back guarantee.



# Contact Information and Support

# Address:

SecondPerspective Ltd. (t/a Suji) 80 George St

Edinburgh

EH2 3BU

United Kingdom

# E-mail

customersupport@trysuji.com