POINT PRESSURE

Instructions For Use (IFU)

Sura Clinical Device 1

Version 001
12 2023

PRODUCT EXCLUSIVELY FOR
CLINICAL INVESTIGATIONS

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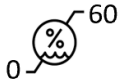
1. Index

2. Version control

Cause of review	Date	Version
First version	04/12/2023	001

Written by:	Revised by:	Approved by:
Parikshit Verma	Ismael Ordonez Rey	Marc Casellas
CTO	CSO	CEO

3. General information

	**Medical device manufactured in Spain**
	**Medical Device**
	*SCD1 (Sura Clinical Device 1)*
	**Fragile, handle with care**
	**Do not use if the package is damaged**
	**Keep dry**
	**Temperature limits between 0º to 40ºC**
	**Relative Humidity between 0 to 60 % (without condensation)**
OTHER	*~~Electro Static Discharge for DC-DC voltage converter?~~*

Commented [IO1]: Tenemos que escribir SCD1 o lo que está entre parentesis también? (en la etiqueta solo está SCD1)

Commented [Ui2R1]: SCD1 está bien.

Commented [H4G3]: Además, indicar los límites de temperatura adyacentes a las líneas horizontales superior e inferior del símbolo.

Commented [Ui4]: En la imagen también tenéis que indicar las unidades (tanto de temperatura como de humedad).

Commented [H4G5]: Además, indicar los límites de humedad adyacentes a las líneas horizontales superior e inferior del símbolo.

Commented [IO6]: Tenemos que escribir límites o qué información ponemos sobre esto?

Commented [IO7R6]: como decimos que el dispo es seguro todo y que haya esto? hay algún simbolo o se obvia?

Commented [IO8R6]: Tenemos el DC-DC converter, tenemos que añadir algo al respecto?

Commented [Ui9R6]: Está bien así, elimino la fila. En el IFU es suficiente con esta tabla. En la etiqueta sí que tendréis que indicar valores de voltaje/intensidad.

3.1. Alerts and warnings

	**Read the instructions for use before using this product.**

	**Precautions and alerts**
	• To ensure the safe use of the device, carefully read the handling, cleaning and disinfection, storage and transport, and maintenance instructions.
	• If the device label and/or packaged is received damaged, please notify the manufacturer immediately and do not use the device until indicated by POINT PRESSURE SL.
	• Do not try to open or repair the device or its components. The device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements.
	• Avoid dropping the device and exposing it to hits and falls from different levels.
	• Avoid bending the device in excess or making inadequate movements in order to avoid damages.
	• Avoid putting the device in contact with liquids, chemical substances or other liquids.
	• Avoid exposing the device to electromagnetic fields or electrical voltages different from the ones specified.
	
	• *Medical device software:*
	  ○ *Minimum requirements concerning hardware, IT networks characteristics, operating system, web browsers, Android/IOS version.*
	• *Single-use device:*
	  ○ *Information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used.*
	• *Emitted radiation:*
	  ○ *Nature, type and where appropriate, intensity and distribution of the emitted radiation.*
	  ○ *Means of protecting the patient, user, or other person from unintended radiation during use of the device.*
	• *Malfunction of the device or performance changes:*
	• *External influences and environmental conditions:*
	  ○ *Magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature.*
	• *Interference posed by the presence of the device:*
	  ○ *Electromagnetic interference emitted by the device affecting other equipment.*
	• *Medicinal products or substances, tissues or cells of humans or animal origin, or their derivatives or biological substances:*
	  ○ *If intended for administration, any limitations or incompatibility in the choice of substances to be delivered.*

Commented [H4G10]: Ejemplo de advertencias. Es necesario revisar la información en azul para completar las precauciones y alertas.

Commented [H4G11]: This information shall be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors shall be addressed in detail. If in accordance with point (d) of Section 23.1. (chapter III, annex I of MDR) no instructions for use are required, this information shall be made available to the user upon request.

	○ *If incorporated into the device as an integral part of the device, warnings, precautions and/or limitations related to the medicinal substance or biological material.* • *Materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances:* ○ *Any warning, precaution, contra-indication, measures to be taken and limitations of use.* • *Materials that could result in sensitisation or an allergic reaction by the patient or user.* ○ *Any warning, precaution, contra-indication, measures to be taken and limitations of use.* • *Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body:* ○ *Warnings and precautions, where appropriate, related to the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances as well as contra- indications, undesirable side-effects and risks relating to overdose.* • *Implantable devices:* ○ *Any warning, precaution, contra-indication, measures to be taken and limitations of use regarding the materials and substances to which patients can be exposed and, if applicable, the implant card.* • *Lay persons:* ○ *Circumstances in which the user should consult a healthcare professional.* • *Product without an intended medical purpose:* ○ *Information regarding the absence of a clinical benefit and the risks related to use of the device.* • *Accessories:* ○ *Information on requirements to obtain a safe combination.* ○ *Information on any known restrictions.* ○ At the end of its lifetime, recycle the device according to the electronic device procedures, placing it at a recycling centre in your city or handing it to a certified electronic waste manager. ○ In case of observing an incorrect operation of the device, notify the manufacturer as soon as possible: support@pointpressure.com. The manufacturer will proceed accordingly. Any serious incident should be reported to POINT PRESSURE S.L. as well as to the National Competent Authority of the Member State in which the user and/or patient is established. **Undesirable side-effects.** • Momentaneal skin deformations • Red skin

Commented [H4G12]: If applicable, include instructions covering infection or microbial hazards (explants, needles or surgical equipment contaminated with potentially infectious substances of human origin) and physical hazards (sharps).

If in accordance with the point (d) of Section 23.1 (chapter III, annex I of MDR) no instructions for use are required, this information shall be made available to the user upon request.

3.2. Contraindications

- *Any contraindication for intended users.*

3.3. Previous considerations

The medical device lifetime is up to 1 year from date of manufacturing due to short battery life cycle and spare support from POINT PRESSURE S.L.

3.4. Intended use

SCD1 is a medical device intended to apply a pressure therapy to the limbs of a user.

3.5. Intended use environment

- The intended environment are hospitals, healthcare clinics and rehabilitation centers

3.6. Intended users

- The intended users are healthcare professionals (physicians and physiotherapists) who are responsible for the rehabilitation of people suffering from muscle stiffness . They control the screen and manage the alleviation performed on the targeted population.

3.7. Intended population

The intended population is people that suffered a stroke, cerebral palsy or any other central nervous system damage or injury that comes with motor disorders.

3.7.1. Inclusion/exclusion criteria

The inclusion criteria are:

- Motor disorder due to central nervous system damage

The exclusion criteria are:

- Cognitive impairment
- Skin injuries
- Ortopedic surgery in the affected limb

3.8. Clinical benefits

The clinical benefits are:

- Better spatiotemporal parameters during gait
- Better cinetic and cinematic during gait

3.9. Risk classification

According to the risk classification rules established in Chapter III of the Annex VIII of the MDR 2017/745, the product risk classification is **Class IIa** based on **Rule 9**.

4. Characteristics and technical specifications

- *Technical and performance characteristics of the device.*
- *Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.*
- *If applicable, identification of any consumable component and how to replace it.*
- *If the device is intended for use together with other devices and/or general-purpose equipment, description of the accessories.*
- *For devices that incorporate electronic programmable systems, including software, or software that are devices in themselves: IT security measures, including protection against unauthorised access, necessary to run the software as intended.*
- *For devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action.*
- *For implantable devices, overall qualitative and quantitative information on the materials and substances to which patients can be exposed.*

Item	Description
Battery Voltage	7.2 V
Battery Capacity	4500 mAH
Battery Type	Ni-MH
Communication Ports	1-MicroUSB for Firmware Flash
Connecting Cable Length	1 m
Compression Torque	9.4 kg/cm
Compression Length	30 cm (+/- 2cm)
Operating Speed	0.2sec/60degree
Operating Conditions	0 to 40 degree Celsius 0 to 60 % RH
Storage Conditions	0 to 40 degree Celsius 0 to 60 % RH
Cinch Material	Nylon PA12
Plunger tip Material	Nylon PA12
Enclosure Material	Nylon PA12

4.1. Classification according to IEC 60601-1

PRODUCT is classified as follows according to UNE-EN 60601-1:2006/A2:2021.

☐	Device protected against electric shock with classification **class I**.

Commented [PV13]: @Marc Casellas Please confirm this

Commented [PV14]: @Marc Casellas Please confirm and fill

Commented [MC15R14]: Filled

Commented [PV16]: @Marc Casellas Please confirm and fill

Commented [PV17]: @Marc Casellas Please confirm and fill

Commented [H4G18]: Para equipos electromédicos.

Commented [Ui19]: Según la norma:
Clase I: equipo eléctrico en el que la protección contra choque eléctrico no recae únicamente sobre el asilamiento principal, sino que incluye una medida de seguridad adicional en la que se proporcionan medios para que las partes accesibles metálicas o partes internas de metal puedan ser puestas a tierra de protección.
Clase II: equipo eléctrico en el que la protección contra choque eléctrico no recae únicamente sobre el asilamiento principal, sino que incluye medidas de seguridad adicionales de aislamiento doble, no habiendo provisión para tierra de protección o para depender de las condiciones de la instalación.

Entiendo que sois clase II, pero por favor, revisadlo.

Commented [PV20R19]: No Electric shocks since it is a low voltage device. Also, User is not in contact with any metal parts, only plastic parts are exposed. So maybe Class 1.

	Applicable part with classification **type B**.
	Applicable part with classification **type BF**.
	Applicable part with classification **type CF**.

Table 1: Classification according to IEC 60601-1.

4.2. Classification according to IEC 60601-1-2

PRODUCT is classified as follows according to UNE-EN 60601-1-2:2015/A1:2021.

The device maintains basic safety and essential performance when used in the electromagnetic environment specified below. The user of the device should ensure that it is used in such environment.

Emissions test	Compliance level	Electromagnetic environment - guidance
RF emissions CISPR 11	**Group 1**	
RF emissions CISPR 11	**Class B**	

Table 2: Electromagnetic environment based on emissions test.

5. Instructions for use

5.1. Packaging content

The users of the device will receive a soft case package (shown in Figure 5.1.1) which contains:

1. 3 Cinches to apply device to the lower limb.
2. 3 Unit devices which need to be attached to the lower limb with the help of cinch.
3. 1 Control unit
4. 1 Battery
5. 1 Battery Charger
6. 3 Cables to connect Control unit to Unit devices

Figure 5.1.1

5.2. Pre-operating instructions

- *The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer.*
- *Details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc.*
- *Any preparatory cleaning or disinfection.*

Commented [Ui21]: Hay que escoger uno de los tres tipos según si cumple con los requisitos especificados para proporcionar un grado de protección contra choque eléctrico.
- Parte aplicable para aplicación cardíaca directa: tipo CF.
- Parte aplicable que incluya una conexión de paciente que está prevista para entregar energía eléctrica o una señal electrofisiológica a o desde el paciente: tipo BF o CF.
- Parte aplicable no cubierta por los puntos anteriores: parte B, BF o CF.

Te envío por correo algunas capturas de pantalla de la norma, pero os recomiendo que la reviséis entera. Puede que tengáis acceso gratuito desde la web de la ISO (Online Browsing Platform (OBP) (iso.org)). Si no, la tendréis que comprar vía AENOR - Buscador de Normas y Libros AENOR Certificación.

Commented [PV22R21]: Electrical energy from battery is converted to Mechanical energy by the motor. Rotation of motion is converted to linear motion of plunger using plastic gears. Linear motion of plunger provides compression against the User limb/skin/muscle. This translates to elastic potential energy in patient limb/muscle. I am not sure which type to select.

Commented [H4G23]: Para equipos electromédicos.

Commented [Ui24]: - Group 1: ME equipment or ME systems that generate or use radiofrequency energy only for their internal functioning.

- Group 2: ME equipment or ME systems that apply radiofrequency energy to patients.

Commented [PV25R24]: Group 1

Commented [Ui26]: - Class A: ME equipment and ME systems for use by healthcare professionals and that are not intended for sale to the general public. They are predominantly intended to be connected (in hospitals or doctor's offices) to dedicated supply systems (normally fed by separation transformers), or they have a rated input power > 20kVA and are intended to be powered by a dedicated power transformer and connected to it solely by a clearly identifiable power line path.

- Class B: ME equipment and ME systems predominantly intended for use in domestic establishments and connected to the public mains networks.

Commented [PV27R26]: We provide battery which is the main power source. The battery is at 9v and there is a small step down transformer which converts 9v to 5v. User can control with Mobile Phones through APP. Maybe Class B?

- *If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.*
- *Ensure that the switch of the control unit is turned off. The switch is present on the side face of the control unit.(see Figure 5.2.1)*

Commented [PV28]: @Marc Casellas Need image

Figure 5.2.1

- *Connect the unit devices to the control unit according to the connection port labels of the control unit and labels on the unit devices. For example: Connect the Unit Device 1 to the connection port labelled as 1.(see Figure 5.2.2)*

Commented [PV29]: @Marc Casellas Need image

Commented [MC30R29]: Done

Figure 5.2.2

- *Connect the battery to the battery connection port of the control unit.(see Figure 5.2.3)*

Commented [PV31]: @Marc Casellas Need image

Commented [MC32R31]: Done

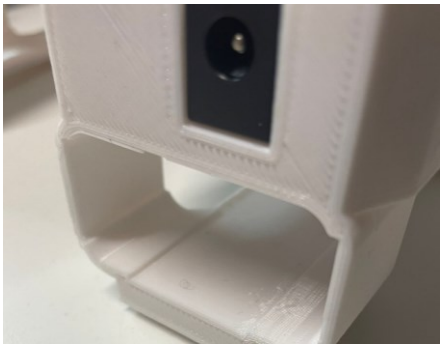


Figure 5.2.3

- *Turn on the control Unit. When the control unit turns on, you will notice a red LED light. Wait till the red LED light stabilises. (see Figure 5.2.4)*

Commented [PV33]: @Marc Casellas Need Image

Commented [MC34R33]: I would take this out.

Figure 5.2.4

- *Download the **Sura Connect** app in your iOS or Android mobile phone (see Figure 5.2.5).*

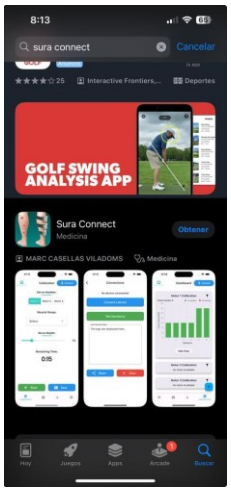


Figure 5.2.5

- *Open the Sura Connect app. On using the app for the first time, it will ask for Bluetooth and location permissions. Please allow the permissions for the use of the Application with the Sura Clinical Device 1.*
- *Please use the device while the user is in a seated position.*

5.3. Operating instructions

5.3.1. Bluetooth Connection

- *How to use and any special operating instructions.*
- *Where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories.*

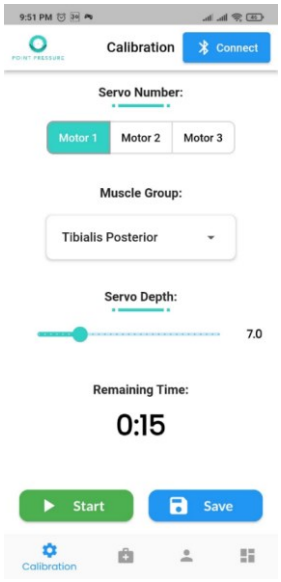


Figure 5.3.F.1

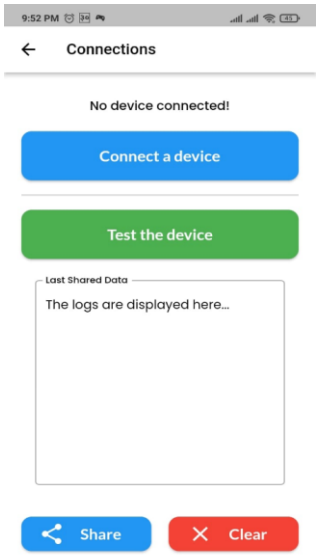


Figure 5.3.F.2

- *Once the app is opened, you will be on the calibration page (shown in Figure 5.3.F.1). Notice the blue colored connect button on the top (next to the Point Pressure Logo). Click on the connect button.*
- *You will be navigated to Connections page (shown in Figure 5.3.F.2). Since no device is initially connected, you will notice a message which says "No device Connected!". You will also notice blue colored "Connect a device" button and a green colored "Test the device button". Below it is an area where you the logs of the application are displayed. Lastly this page contains 2 more buttons to share or clear the logs of the application.*

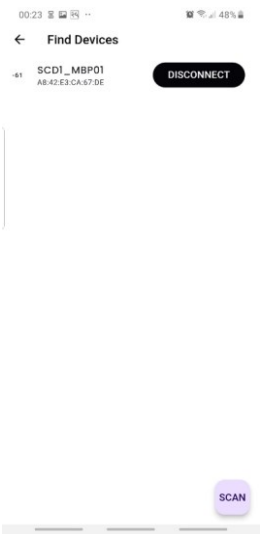


Figure 5.3.F.3

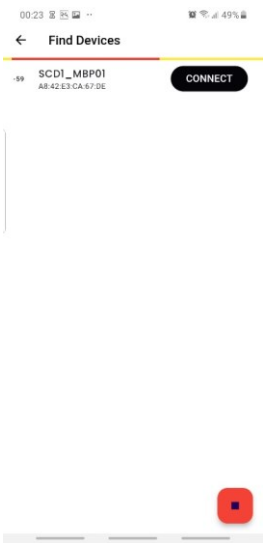


Figure 5.3.F.4

- *Click on "Connect the device". You will be navigated to Find Devices page(shown in Figure 5.3.F.3). Click scan (shown in Figure 5.3.F.3) and you will see the Sura SCD1 device in list of available devices. Click on connect button (shown in Figure 5.3.F.4).*

Figure 5.3.F.5

- *Go back to the Connection page, where you will see that the name of the connected device. The previously blue colored "Connect a device" changes to red colored "Disconnect the device" button. If the device is authenticated by the manufacturer, the last message of logs will say, "Subscribed to notify" (show in Figure 5.3.F.5). The application is now successfully connected to the Sura SCD1. You can now return to the Calibration screen and start controlling the Sura device.*
- *On the other pages, the connection with Bluetooth can be seen on the top of the page. If disconnected, the button looks as shown in Figure 5.3.F.6 and when connected, the button looks as shown in Figure 5.3.F.7.*

Figure 5.3.F.6

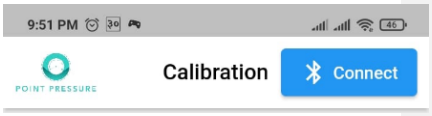


Figure 5.3.F.7

5.3.2 Profile Page: Setting up the Timers

- *The third page on the bottom navigation bar of the app points to the Profile Page (shown in Figure 5.3.F.8), where you will see 2 buttons, "Refresh" and "Save Changes".*

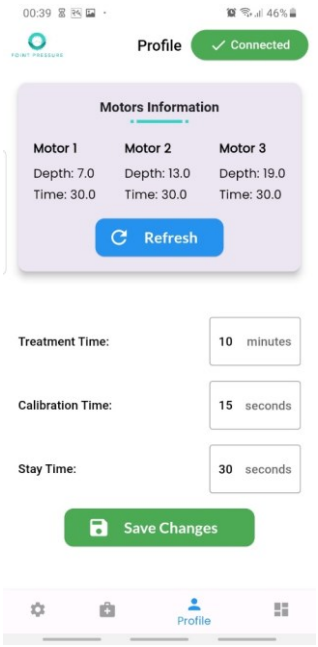


Figure 5.3.F.8

- *In order to view the compression values stored in the control unit, press Refresh. The Motor Information section of the page will be updated with the current compression values stored in the Control Unit.*
- *In order to change the time value of the Treatment or the Calibration or the Staytime of the compression plunger of Unit devices, tap on the appropriate text box. A keyboard will appear. Enter the appropriate value and tap on any part of the screen to remove the keyboard. Then press "Save Changes" button. Your timers are now updated.*

5.3.3 Calibration Page: Calibrating the Compression

- *The first page on the bottom navigation bar of the app is the Calibration page(shown in Figure 5.3.F.9), where "Start" and "Save" buttons can be seen.*
- *Select the Unit Device Number you wish to calibrate. Select the muscle group where the Unit Device is attached. Select the plunger depth value. Press "Start button". You will observe the Calibration countdown timer has started and the Unit device starts working. The start button changes to "Stop" button (shown in Figure 5.3.F.10).*

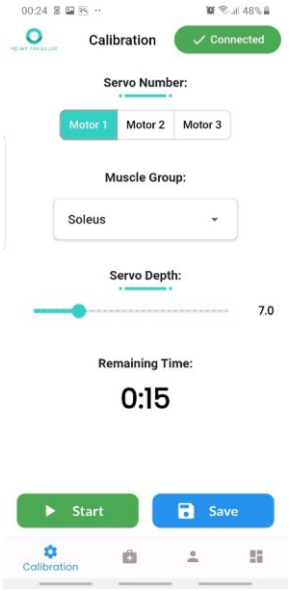


Figure 5.3.F.9

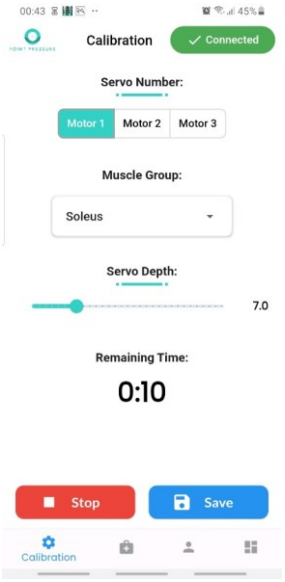


Figure 5.3.F.10

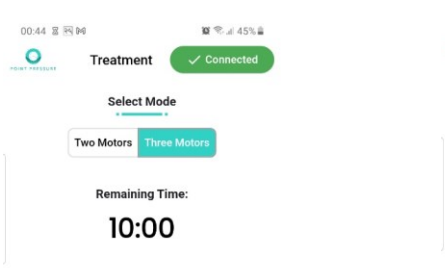
- *Once the Calibration countdown timer has ended, the Sura Connect Application automatically commands the Control Unit to stop the Unit Device, while resetting the timer and turning back the "Stop" button to "Start" button.*
- *If the compression depth is suitable for the user, press "Save" button in order to save the compression depth in the Control Unit. This depth can now be used for the Treatment.*
- *Repeat the process for all the Unit Devices.*

- *In case the user feels uncomfortable at any point of the calibration cycle, press "Stop" to stop the calibration cycle and reset the calibration countdown timer.*

NOTE: Please ensure that all Unit devices are calibrated with Compression Depth and Compression Stay time. This can be verified using the "Refresh" button on the Profile Page, as indicated in section 5.3.2.

5.3.4 Treatment Page: Treating the User

- *The second page on the bottom navigation bar of the app is the Calibration page(shown in Figure 5.3.F.11).*
- *If you are using only two Unit devices press "Two Motors". By default, "Three Motors" is selected assuming that the Control Unit is connected to three Unit devices.*
- *Press "Start" to command the control unit to start treatment cycle and also to start the Treatment Countdown timer. The "Start" button now changes to "Stop" button (shown in Figure 5.3.F.12).*



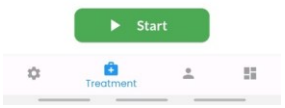


Figure 5.3.F.11

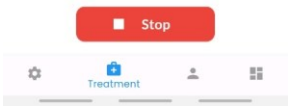


Figure 5.3.F.12

- *Once the Treatment Countdown timer has ended, the Sura Connect application automatically commands the Control Unit to stop the treatment cycle and hence stop all Unit Devices. Notice that the Treatment Countdown Timer resets and the "Stop" button changes to "Start" button.*
- *In case the user feels uncomfortable at any point of the treatment cycle, press "Stop" to stop the treatment cycle and reset the treatment countdown timer.*

5.3.5 Dashboard: Viewing the data

- *The fourth page on the bottom navigation bar of the app is the Dashboard page, where you will see 4 sections out of which 3 sections show the calibration data of each unit device and last section shows treatment data.*
- *Press on show more of any section to view the data. Bar plot of each calibration or treatment cycle can be seen where each cycle is represented by one bar column. On pressing any one of the bar column, the relevant data will appear below (shown in Figure 5.3.F.13).*
- *You may also filter the number of bar columns you would like to see on the screen at once by pressing on the filter icon on top right of the section (shown in Figure 5.3.F.14).*

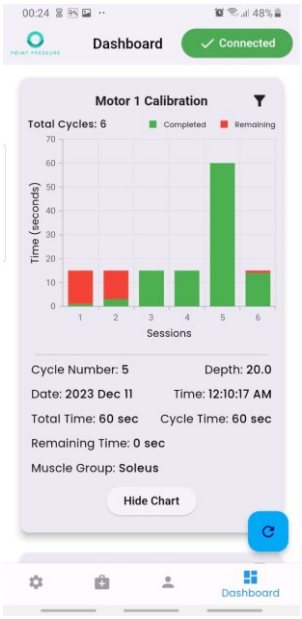


Figure 5.3.F.13

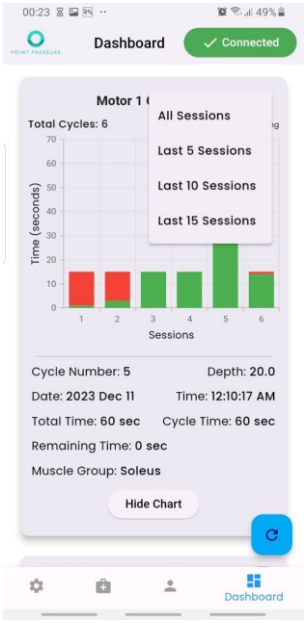


Figure 5.3.F.14

- *This data can be shared in the form of CSV file with the "Share" button which can be found on scrolling to the bottom of the page.*
- *This data can be reset by pressing the reset button on the bottom right.*

6. Handling conditions

- *Other treatment/handling regular conditions*
- *Before making the connections of the device, please ensure that all the components of the device (including battery) is not wet or exposed to water. Each component should be completely dry.*
- *Since there is no battery level indication as of now, so please try to keep the Sura device battery charged in order to use uninterruptedly.*

- *Ensure that the Unit devices are correctly plugged to the right port of the Control Unit.*
- *Please store all the components in a cool and dry place.*
- *Do not drop or kick the devices.*
- *While the device is in use, do not take the mobile phone more than 10m away.*
- *While the device is in use, the user should not walk and should be in a seated position.*

7. Cleaning and disinfection instructions

- *Regular cleaning instructions.*
- *Levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection.*
- Cleaning of the plastic parts of the Control Unit and the Unit Devices with a dry or semi-wet cloth is possible when the device is turned off and disconnected from the battery.
- Please ensure that the connectors/electronic terminals are not exposed to water.
- The battery can be cleaned only with a dry cloth.
- Please ensure that every component is completely dry before connecting any terminals or battery.

8. Storage and transport conditions

- *Packaging instructions.*
- Please ensure that neither the Control Unit nor the Unit devices and nor the Battery is exposed to direct sunlight.
- Please store in a cool and dry place, preferably in the soft case provided with the device.

9. Maintenance conditions

- *Details of the nature, and frequency, of preventive and regular maintenance to ensure safety and performance.*
- *Information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime.*
- *Methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.*
- This device has a limited lifetime due to the components used in this device. This device can be used for a maximum of 1 year. Please contact the manufacturer for further use as some of the parts may need to be replaced.

10. Anomaly/cause/solution – User to solve things themself

- *Description of foreseeable anomalies, their causes and list of instructions to solve them.*
- *Please turn off the Control Unit and the Sura Connect application. Turn it on again and follow the instructions in the sections 5.2 and 5.3.*
- *In case of any anomaly, please go to the Connections page and click the "Share" button and choose appropriate method -mention the methods to share the data logs of the device with the representative/medical expert who provided you the device.*

Commented [PV35]: Which should be the appropriate method?

- *In case the problem is still not solved, contact on the phone number or email mentioned in the packaging label of the device.*