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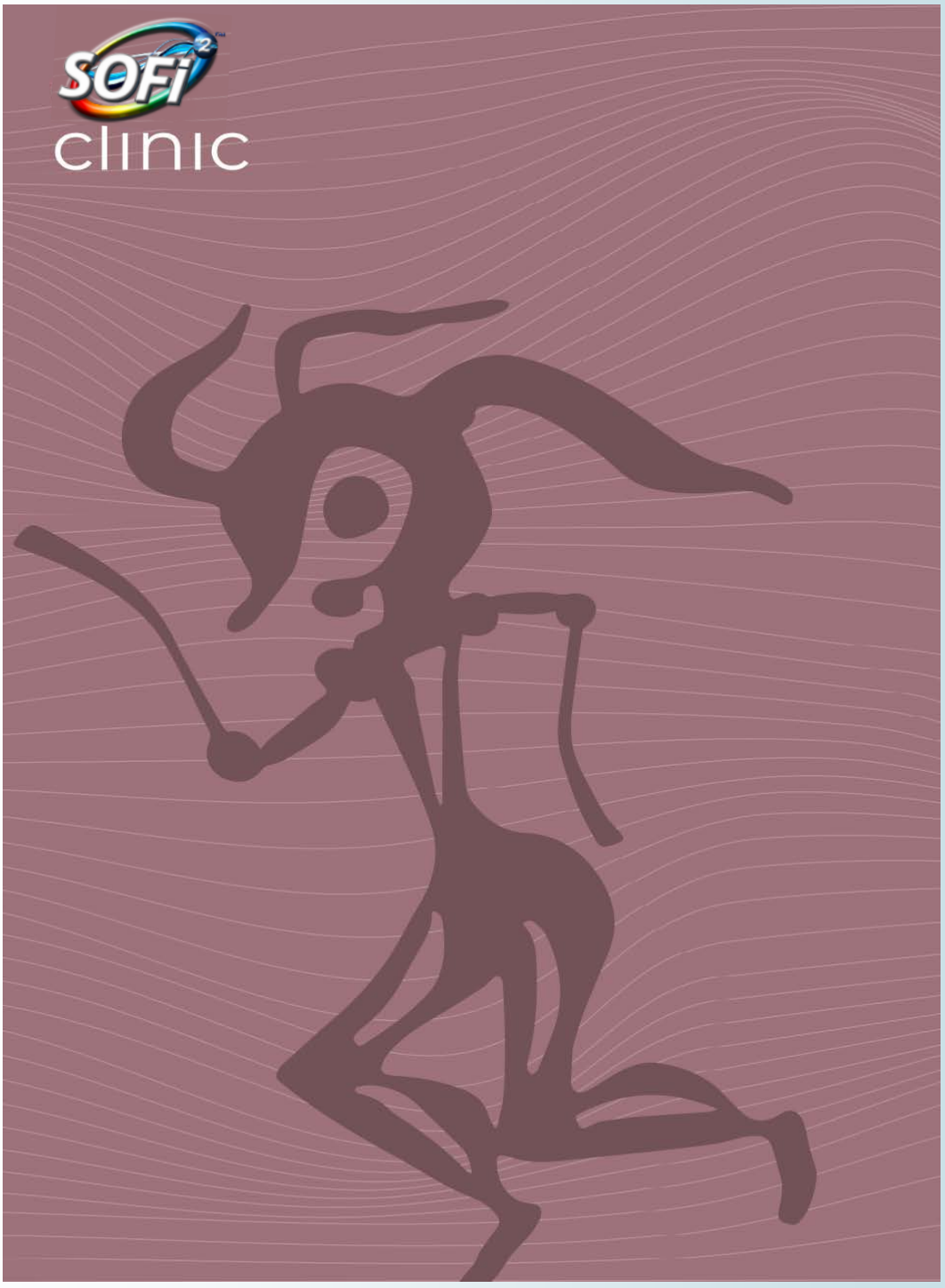
Real-Time Reports

SOFi M² by AMT

USER MANUAL

Version 1.0.0



Taking Acoustic Myography to a Higher Level ™

Made in USA

Table of contents

1. Regulatory Information

1.1 Symbols and labeling information

The following table lists the labels of relevance for the *SOFi M² ™*

Symbol	Explanation	Symbol	Explanation
MD	MD = Medical Device		Indicates that there are temperature limits for this device
	! = Consult instructions before use	MR	Keep away from magnetic resonance equipment
	Contains a rechargeable battery	NON STERILE	Indicates a medical device that has not been sterilized
	Keep dry and avoid excessive moisture		Do not dispose of this device in unsorted municipal waste
CE	CE = Signifies European technical conformity	Bluetooth Bluetooth Bluetooth	Bluetooth® wireless or enabled technology
FCC ID: OH2XXXX	FCC = Complies with United States Regulations for Radio Frequency Devices		Date of manufacture
SN	Serial Number	%	-Humidity limitation
	Keep away from heat		-Temperature limitation
	Keep dry		Class II equipment
	Follow instructions for use		Type B applied part

NB. Th ***SOFi M² ™*** contains a rechargeable battery and other electronic components (circuit board, Bluetooth transmitter etc) for this reason do not dispose of this device in unsorted municipal waste. Do not incinerate the ***SOFi ™*** or used sensors and do not attempt to dismantle either the sensors or ***SOFi M² ™*** unit itself. To avoid risk of harm or injury as well as pollution to the environment please dispose of used ***SOFi M² ™*** units and sensors responsibly. You can dispose of them at either local or national recycling companies/centers. If in any doubt then please return used or damaged units and sensors to Advanced Myographic Technologies, LLC ("AMT") or one of our local Distributors (see Section 13).

1.2 Indications for use

The ***SOFi M² ™*** measures muscle and ligament function, as well as gait pressure in real time from subjects whilst physically active. It uses skin attached sensors which comprise a metal and gel/hydrogel component or a flexible piezo-electric sensor, to detect, measure and record muscle or ligament activity or pressure. The system is capable of analyzing recorded signals in terms of amplitude and frequency, and recording measurements for later analysis. The system relies on a lithium polymer battery for power, runs using internal software, transmits data in real time and enables the user to generate a biofeedback report. This device measures muscle, ligament, pressure function in a quick and non-invasive way, and serves as diagnostic equipment.

NB. Only trained and fully instructed individuals are to work ***SOFi M² ™*** units and the system. For training please contact Advanced Myographic Technologies, LLC or your local distributor. (See Section 13 or AMT's website for contact details)

1.3 Warnings

Incorrect use of the ***SOFi M² ™*** or the attachment of the recording sensors can result in erroneous measurements.

1.4 Contraindications

- Subjects with a known skin condition or allergy, unless specialist medical opinion has first been sought
- Subjects with hypersensitivity or a low pain threshold e.g. fibromyalgia
- Subjects with diminished physical competence limiting the use of the device before specialist medical opinion has been sought

1.5 Precautions

- To preserve battery life, please ensure that the ***SOFi M² ™*** units are fully charged at least once every month. Failure to do so may result in reduced battery performance (less than 5 hours continuous recording)
- Only use the ***SOFi M² ™*** for the purposes for which it is intended
- Always ask the subject about skin allergies prior to use of the ***SOFi M² ™***
- In order to reduce the risk of skin irritation in those with allergies, we do not advise that subjects wear the sensors for more than 24 hours in any 72 hour period
- Use only the supplied charging plate to charge the ***SOFi M² ™*** units
- Please keep the ***SOFi ™*** units dry. If they are being used outdoors then ensure that they are protected against adverse wet weather.

- As with all batteries there is a risk of leakage or explosion. The manufacturer recommends operating conditions between -5 and 40°C and storage at 25°C
- Use only alcohol to clean and disinfect the ***SOFi M² ™*** units, not acetone
- Do not immerse the ***SOFi M² ™*** units in water. Should they accidentally fall into water or become damp, allow them to air dry for a period of 24 hours before attempting to charge or use them
- Use of the ***SOFi M² ™*** units should be immediately terminated upon signs of distress or discomfort/pain
- Not to be connected to a subject undergoing MRI (Magnetic Resonance Imaging), surgery or defibrillation
- Operations in close proximity to shortwave or microwave therapy equipment might affect the ***SOFi M² ™*** units and their ability to function
- Radiated radio frequency electromagnetic fields can cause performance impairment
- Between uses of the ***SOFi M² ™*** units and sensors, wipe down components with alcohol wipes or swabs
- Ensure that whilst using the ***SOFi M² ™*** units, that subjects do not perform movements that could cause injury or that are beyond their capability

1.6 Adverse reactions

Potential adverse reactions may be experienced with the use of the *SOFi M2 ™.*

- Skin irritation beneath the sensor

We recommend the use of an ultrasound gel that is thick enough to remain in place at the site of application and is at worst hypoallergenic but ideally non-allergenic. If in doubt write to Advanced Myographic Technologies, LLC for a suitable gel that has been tried and tested over a 10-year period.

For measurements on humans we recommend the use of Promeon Hi-Adhesion Gel 032 – M863X – R&D Medical Products CA 92630, which has a biocompatibility PER ISO 10993 rating of; 0.0 non-cytotoxic, 0.0 non-irritant, 0.0 non-sensitizing.

This material is adhesive on both sides, so it serves to fix the sensors to the skin (easily removable without pain or discomfort) and it furthermore serves to fix the ***SOFi M² ™*** units to the back of each sensor. In this way, the information from the active tissue (muscle/ligament) travels through the body tissue and fluids to the skin, from the skin it travels through the hydrogel (M863X) to the sensor surface and from the sensor it travels as an electrical signal to the ***SOFi M² ™***, and from the ***SOFi ™*** as a Bluetooth signal to a recording device of the users choice.

The ***SOFi M² ™*** casing is made of Polylac PA-757 acrylonitrile butadiene styrene and as a result is flame rated (flash point 40^0 C), impact resistant and is RoHS compliant, so it poses no hazard to the environment or landfills, and is not dangerous in terms of occupational exposure during manufacturing and recycling. It is furthermore classified according to EC 1272/2008 as non hazardous. However, if contact with the skin does result in skin irritation, please wash the affected site with pure clean water.

1.7 Conformance with standards

The ***SOFi M2*** ™ units are found to be in accordance with CE and FCC standards: EN 301 489-1 and FCC 15B – 19th April 2022. They have furthermore passed: **FDA Emission and Medical Standards** tests – ANSI AAMI ISO IEC EN 60601-1 and 60601-2

EN 301 489-1 (V2.2.3) EN 301 489-17 (V3.2.4)	Passed - Performance criteria; Enclosure of ancillary equipment measured on a stand-alone basis; Radio frequency electromagnetic field; Electrostatic discharge – Ektos (19th April 2022: Ref: P22-0049-1)
FCC 47 CFR Part 15 Subpart B ICES-003, Issue 7:2020, Class B	Passed – Radiated emission – Ektos (19th April 2022: Ref: P22-0049-2)
ANSI AAMI ISO IEC 60601-1-2:2015+A1:2021 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests – Ektos (4th October 2022: Ref: P22-0114-2)
ANSI AAMI ISO IEC 60601-1:2006 + A1:2013+ A12:2014 +A2: 2020	Passed - A1: 2013; A12:2014 - Corr. 1:2008, Corr. 2:2008; A2: 2020 - Medical electrical equipment – General requirements for basic safety and essential performance – Ektos (30th September 2022: Ref: P22-0114-1)

Conformity Assessment Standard Applied:

ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes

Medical Device Standards Applied:

ISO 14971	Medical Devices – Application of Risk Management to Medical Devices
ISO 14155	Clinical investigation of medical devices for human subjects - Good clinical practice
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
ISO 15223	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
ISO 10993-5	Biological evaluation of medical devices - Part 5 Tests for in vitro cytotoxicity
-10	Biological evaluation of medical devices - Part 10 Tests for irritation and skin sensitization
16 CFR 1500	Guidelines of the Federal Hazardous Substances Act (FHSA) Regulations for Cytotoxicity, Sensitization and Primary Skin Irritation tests.

1.8 How supplied

SOFi M² ™ units are supplied either as 2, 4, or 6 units in a case with the following:

- 1 charging plate capable of charging 4 units
- Charging cable
- 10 small and 10 large sensors or 4 pressure sensors
- Hydrogel adhesive gel.
- Use of the ***SOFi M² ™*** units should be immediately terminated upon signs of distress or discomfort/pain
- Not to be connected to a subject undergoing MRI (Magnetic Resonance Imaging), surgery or defibrillation
- Operations in close proximity to shortwave or microwave therapy equipment might affect the ***SOFi M² ™*** units and their ability to function
- Radiated radio frequency electromagnetic fields can cause performance impairment
- Between uses of the ***SOFi M² ™*** units and sensors, wipe down components with alcohol wipes or swabs
- Ensure that whilst using the ***SOFi M² ™*** units, subjects do not perform movements that could cause injury or that are beyond their capability

The ***SOFi M² ™*** uses a 3.7v 85mAh lipo battery which has been safety compliance tested (KC/UN38.3). Furthermore, the ***SOFi M² ™*** has been appraised by EKTOS Testing & Reliability Services A/S, Denmark to have an ingress protection rating of IP32 where 3 represents a casing protected against a solid object greater than 2.5mm such as a screwdriver, and 2 represents a casing protected against vertically falling drops of water with the casing tilted up to 15 degrees from the vertical

1.9 Sensor connection range

When performing a measurement with the ***SOFi M² ™*** system, please ensure if you are doing a local measurement that you stay within a 40 meter (line-of-sight) range of the subject to ensure a stable Bluetooth 4 connection. Note that Bluetooth signals are impaired by obstacles such as the body itself, if placed between the sensor and the recording device.

- Ensure that your hands are not covering the Bluetooth transmitter or receiver
- Try to maintain a direct line of sight between the sensors and the recording device
- When out of doors, try to position yourself near to a wall or building if possible as Bluetooth signals are stronger if they can reflect off such structures
- Turn off any non-essential wireless devices (WiFi) or set them to airplane mode in order to boost Bluetooth connection strength

1.10 Client privacy and confidentiality

Advanced Myographic Technologies, LLC complies with client privacy legislation and requirements in all countries in which it operates. A key part of protecting client privacy also relates to the IT setup we provide for our customers.
The ***SOFi ™*** Apps are free to download from the AppStore or GooglePlay, but they are user name and password protected. We recommend the following.

- Use a password that is at least 8 characters long and uses upper and lower case letters as well as numbers and symbols
- Change your password on a regular basis
- If you forget your password then we can help you reset it

Advanced Myographic Technologies, LLC currently updates software automatically when a user/client logs in to the system. This serves to minimize cybersecurity vulnerabilities.

Furthermore, ***SOFi M² ™*** units send recorded data via as secure a network as possible. However, even if such data were to be intercepted whilst being sent, there is no way the data can be traced back to a patient / individual.

1.11 Cybersecurity

Advanced Myographic technologies, LLC ensure the highest cybersecurity for our clients through the following steps:

- A firewall to prevent unauthorized individuals from accessing our network and data.
- A spam filter to block malicious e-mails and malware.
- An antivirus solution to block and detect malware on our system.
- A separate server for onIy our patient data - Virtual Private Server (VPS).

We have additionally built into the software the fact that no name, age or gender details are made on the ***SOFi M² ™*** when recording. We instead use a code identifier for subjects that cannot be traced back to the individual by any outsider. Only the user has these codes and can relate ***SOFi M² ™*** data back to an individual or subject.

2. System description

The ***SOFi M² ™*** device is intended to be used by healthcare professionals to electronically amplify and transfer acoustic sounds / pressure waves generated by contracting tissue from the skin surface of a subject, via a Bluetooth connection to an App on a smart phone or tablet for muscle monitoring, diagnostic and biofeedback purposes. This device is not only wireless, it is also non-invasive in its nature, posing no risk to the subject or user. The ***SOFi M² ™*** device displays acoustic myography (AMG) signals in real-time on an accompanying mobile application (iOS/Android phone or tablet) for storage and sharing (when prescribed or used under the order of a physician or other licensed health professional). It can be used to record muscle sounds, muscle balance scores and pressure waves in tendons and ligaments during physical examination in normal subjects or those with suspected diseases of the neuromuscular or connective tissue systems. The device can be used on adults.

Acoustic Myography should not be confused with the field of mechanomyography (MMG) or accelerometer myography which measure movement (Hemmerling et al. 2004; Shinohara and Søgaard 2006; Beck et al. 2010; Herda et al. 2010; Tian et al. 2010; Alves and Chau 2011; Qi et al. 2011). Acoustic myography measures the pressure waves generated by contracting tissues or the pressure waves that travel through tissues as a result of, for example ground reaction forces associated with movement. This makes it a very precise and accurate means of assessing muscle function, as it only measures muscle contraction signals, unlike other techniques.

Recent advances in sound recording, enabling high sampling speeds, low noise interference in combination with improved piezoelectric crystal sensors, has enabled the possibility of an easily applicable non-invasive assessment method for muscle performance. AMG and the ***SOFi M² ™*** has shown muscle-sound assessment to be reliable, accurate, safe, pain or discomfort free for the subject, and repeatable. Moreover, as a technique it is simple and easy to use.

References:

Hemmerling TM, Michaud G, Trager G, et al. Phonomyography and mechanomyography can be used interchangeably to measure neuromuscular block at the adductor polli- cis muscle. Anesth Analg (2004); 98: 377– 381.
Shinohara M, Søgaard K. Mechanomyography for studying force fluctuations and muscle fatigue. Exerc Sport Sci Rev (2006); 34: 59–64.
Beck TW, DeFreitas JM, Stock MS, et al. An explanation of mechanomyographic signal stationarity during concentric isokinetic, eccentric isokinetic and isometric muscle actions. Physiol Meas (2010); 31: 339–361.
Herda TJ, Housh TH, Fry AC, et al. A non- invasive, log-transform method for fiber type discrimination using mechanomyogra- phy. J Electromyogr Kinesiol (2010); 20: 787– 794.
Tian SL, Liu Y, Li L, et al. Mechanomyography is more sensitive than EMG in detecting age-related sarcopenia. J Biomech (2010); 43: 551–556.

Alves N, Chau T. Mechanomyography as an access pathway: corporeal contraindications. Disabil Rehabil Assist Technol (2011); 6: 552–563.

Qi L, Wakeling JM, Green A, et al. Spectral properties of electromyographic and mechanographic signals during isometric ramp and step contractions in biceps bra- chii. J Electromyogr Kinesiol (2011); 22: 128– 135. doi:10.1016/j.jelekin.2010.09.006.

The data offered by the device is only significant when used in conjunction with a healthcare professional or physician and when read in the context of other relevant patient data.

The ***SOFi M² ™*** represents a very precise measure of muscle function, unlike other methods such as surface electromyography. The ***SOFi M² ™*** measures three parameters, 1) the organization with which a muscle is used, otherwise seen as its efficiency of use, represented by an O score. It also measures the number of fibers that are active in a muscle, this is referred to as spatial summation and is measured by the ***SOFi M² ™*** as an S score. Thirdly it measures the repeated firing frequency of active muscle fibers, referred to as temporal summation and presented by the ***SOFi M² ™*** as the F score.

These three parameters **S** for spatial summation **O** for organization, and **F** for frequency summation are analyzed in real-time and presented both numerically and graphically for the clinician to use as a diagnostic tool. A diagnostic tool that has been shown to be one that correlates very closely with the way the central nervous system generates force in skeletal muscles. It is for this reason that acoustic myography and the ***SOFi M² ™*** have been used in a number of pre-clinical trials, all of which have been peer-reviewed and published in internationally recognized scientific journals.

3. Setup and installation

- We do not recommend that you buy a Huawei phone, especially in the US, for the simple reason that downloading the apps is a very complex process.

To find the App´s go to either GooglePlay or the AppStore and search for ***SOFi™***. You will find the Clinic App (Human Modality). On top of which you will find a Prosus App in GooglePlay that is used for Live Stream remote measurements.

SOFi ™ – Clinic

Prosus

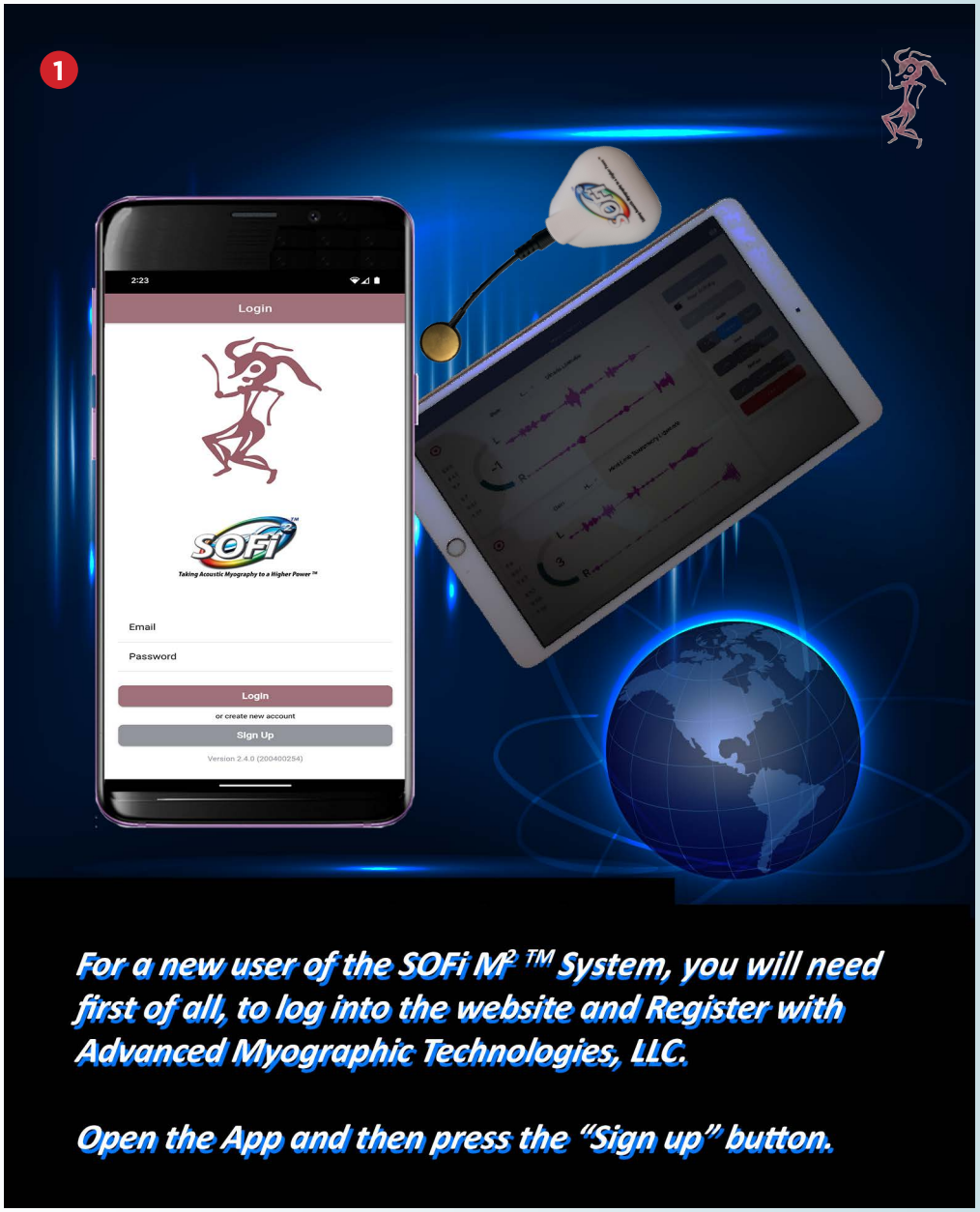
Both of these App´s can be downloaded for free.

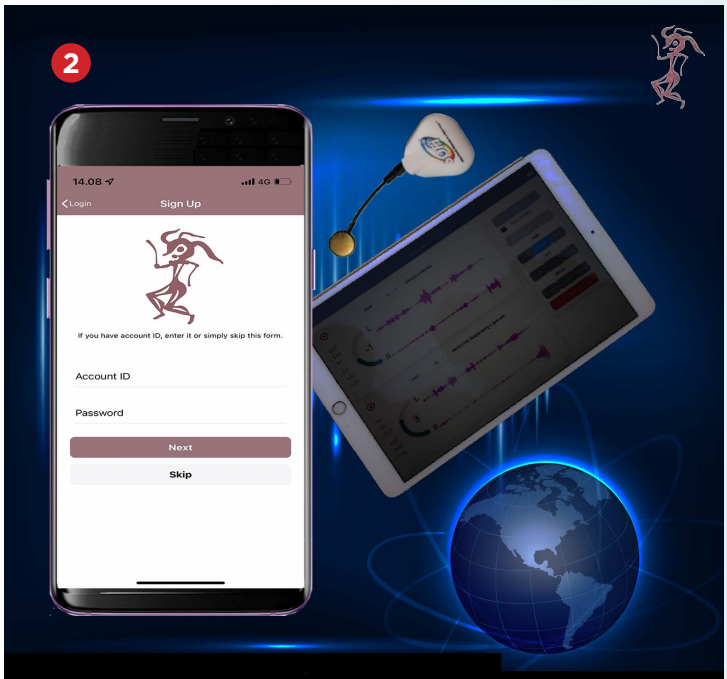
Look out for regular updates of the App´s as we improve the software and add extra functions. The version of the App can be found in either GooglePlay or the AppStore as well as when the App´s were most recently updated. If you don't use the latest version of the App´s then there is a risk that your recorded data either won't sync with the Client Cloud or that the local or remote measurements don't perform properly.

4. New User setup

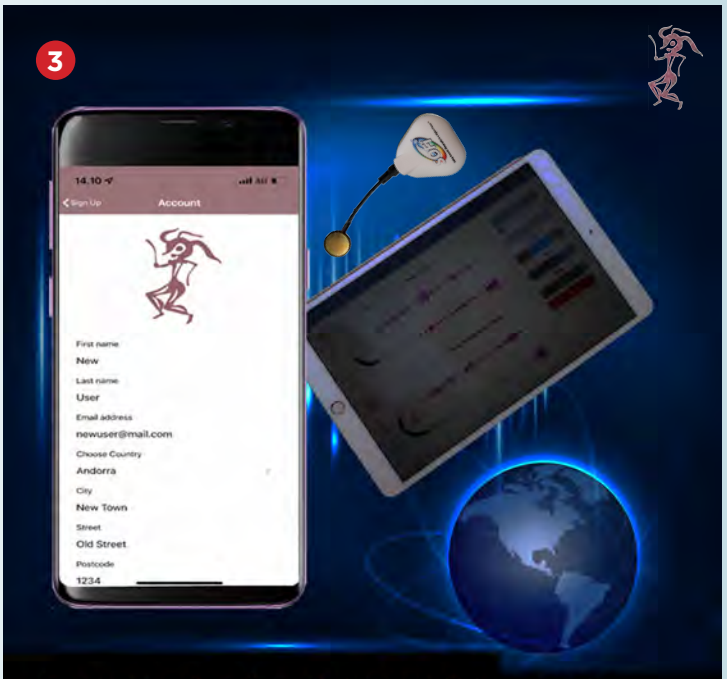
When you buy a ***SOFi M² ™*** system you will need to register with Advanced Myographic Technologies, LLC in order for your data to be stored and analyzed. To do this you will need to open the App you have downloaded and follow the following instructions.

4.1 Logging into your *SOFi TM* Clinic App



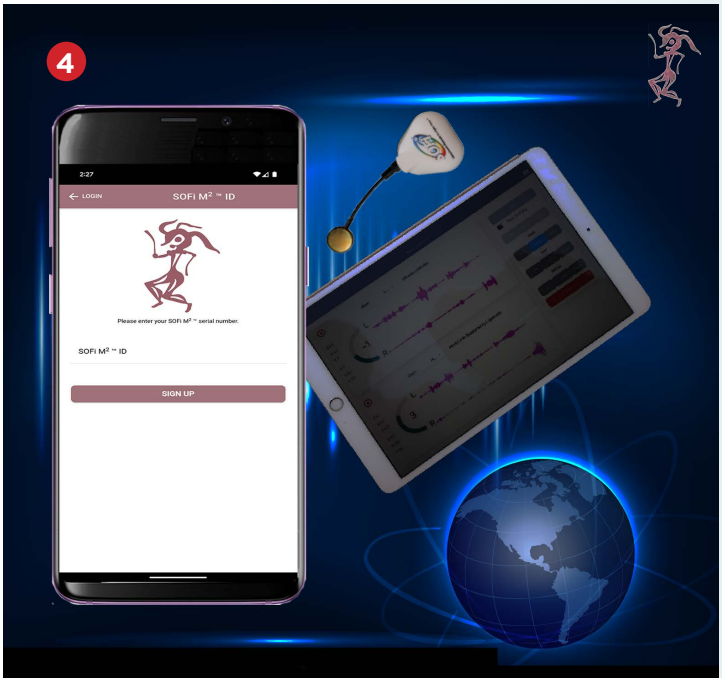


In order to proceed with registration you press the "Skip" button unless you were provided with an Account ID and password upon your purchase. You will also need the SOFi M² ™ ID you were provided with when you purchased your SOFi M² ™ System.



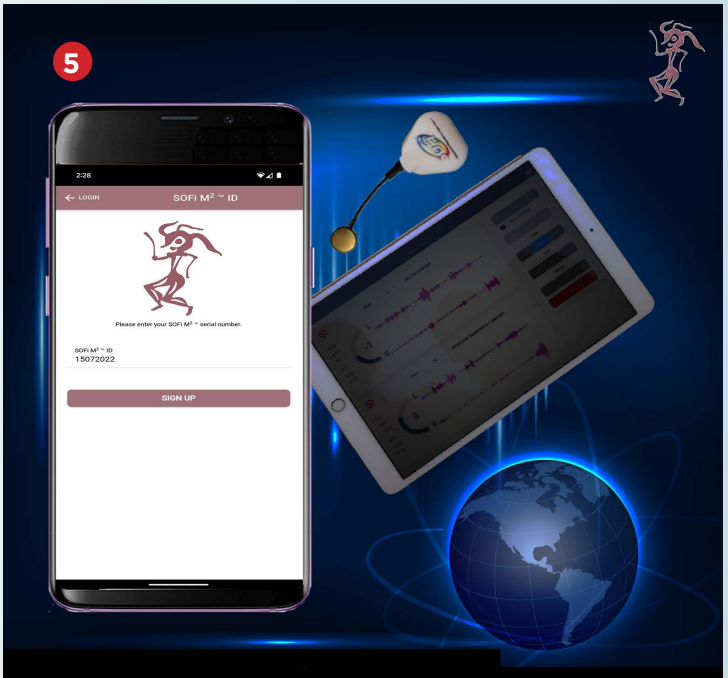
Enter your details and then scroll down to the bottom of the page to proceed.

NB - You can select any email address, even one that does not exist - it is simply a means of logging into our cloud server system.



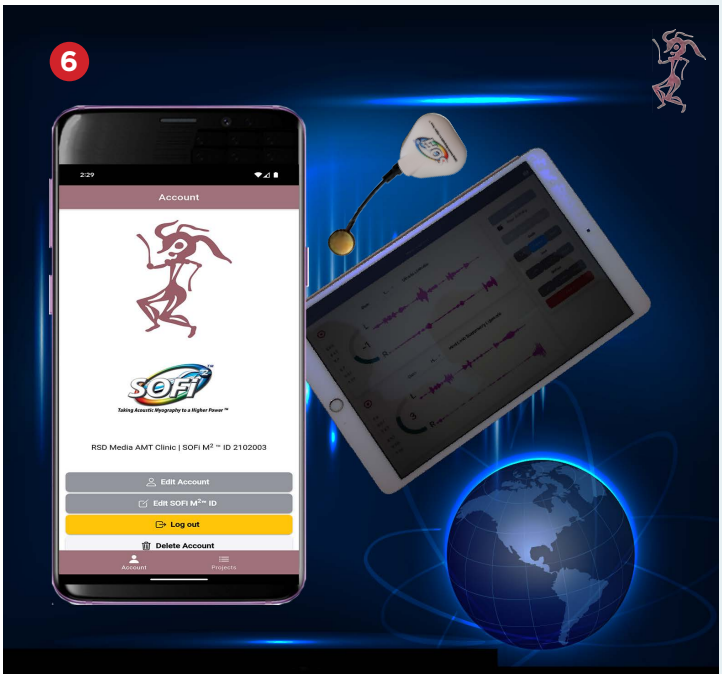
In order to proceed with registration you will need the SOFi M² ™ ID you were provided with when you bought your SOFi M² ™ system.

Enter your 8 digit ID here, and then press "Sign Up"...

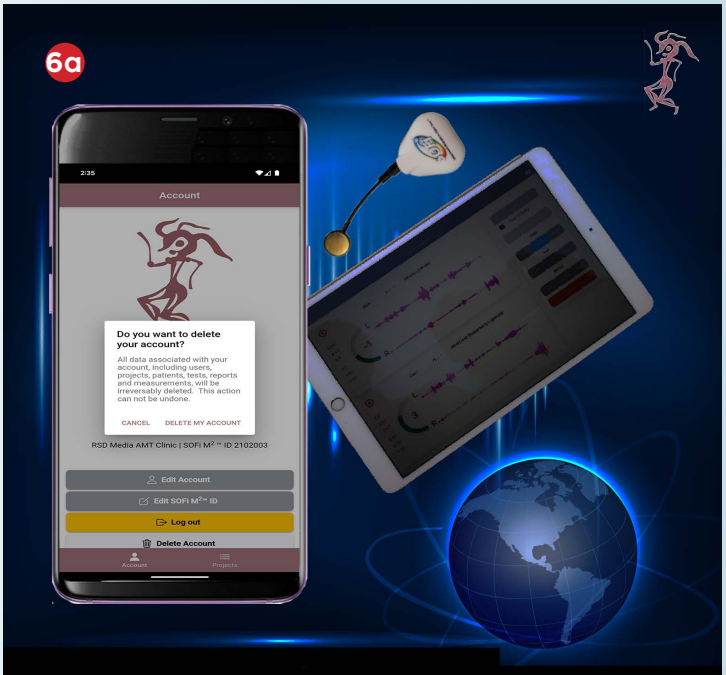


In order to proceed with registration you will need the SOFi M² ™ ID you were provided with when you bought your SOFi M² ™ system.

You should now be registered as a user of your SOFi M² ™.



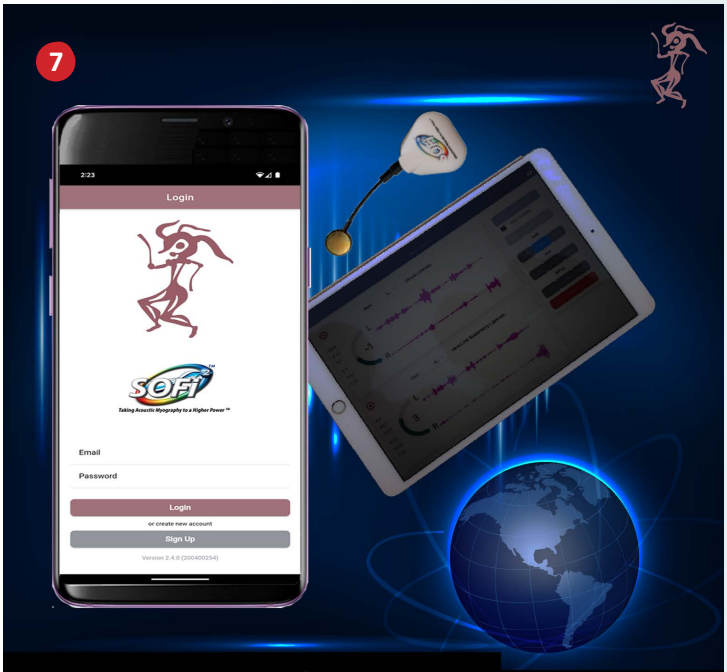
You should now be registered as a user of your SOFi M² ™. The Account page will look something like this. Your User Name and SOFi ™ ID should be displayed - make sure that these are correct before making a measurement as without these details your SOFi M² ™ will not know where to send the recorded data.



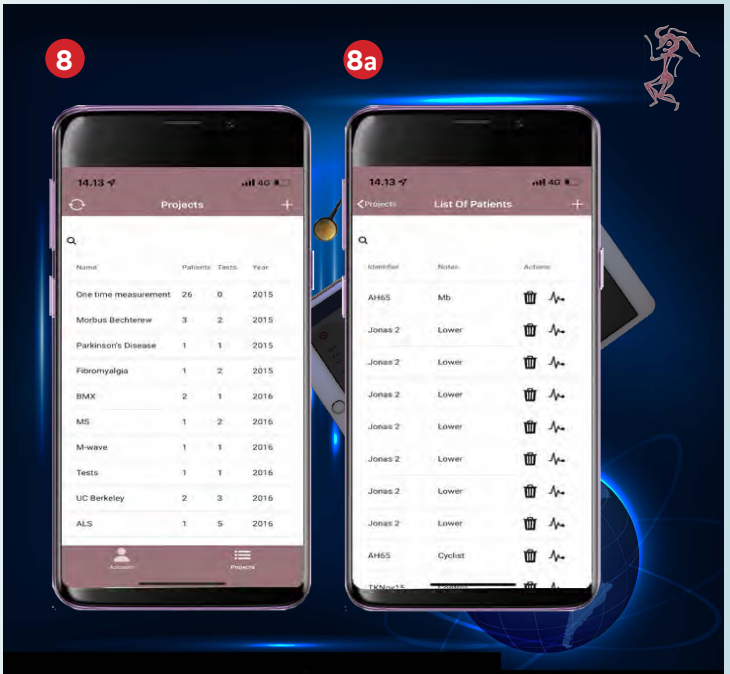
You can press "Edit Account" to check or change your details.

You can also press "Delete Account" if you wish to stop using the SOFi M² ™ and prefer that all your stored data is removed from our server.

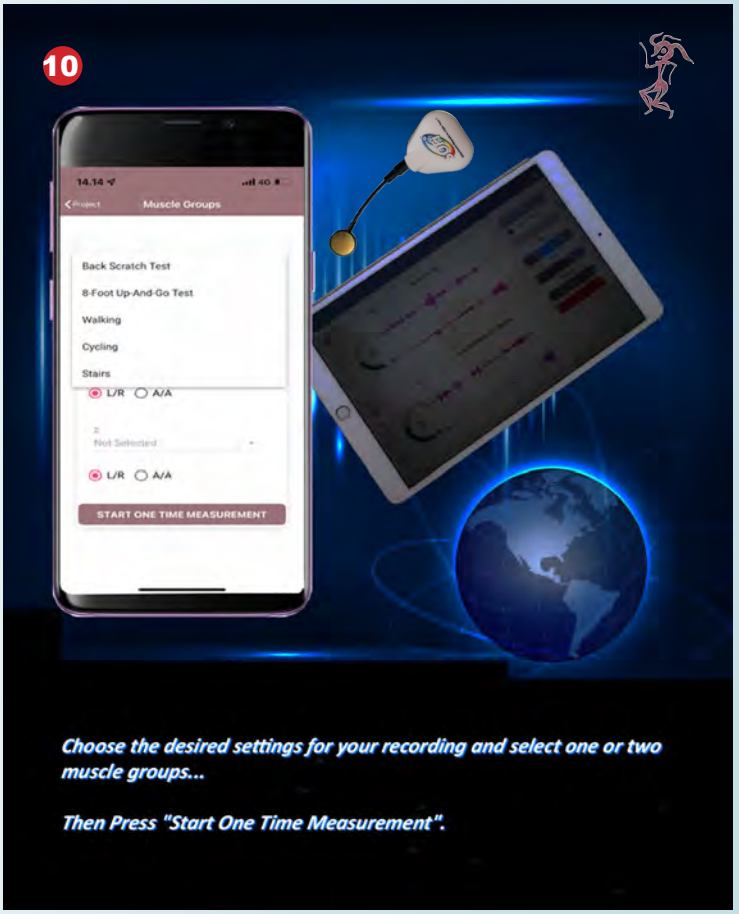
5. First Time Use



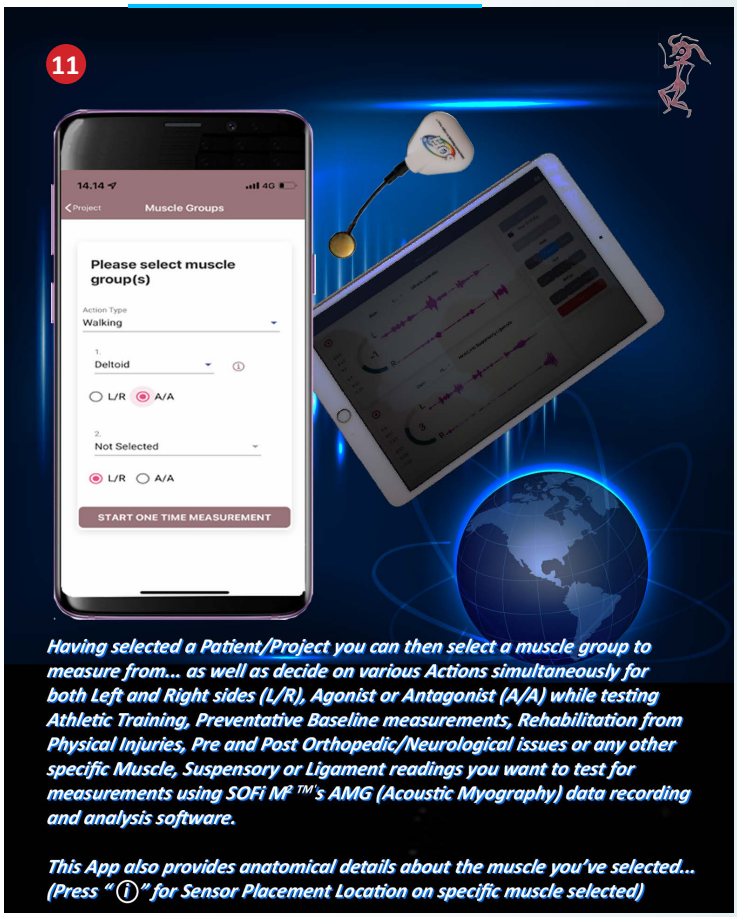
First Select the dedicated human (Clinic) App and Sensor and your user email and password to get started...

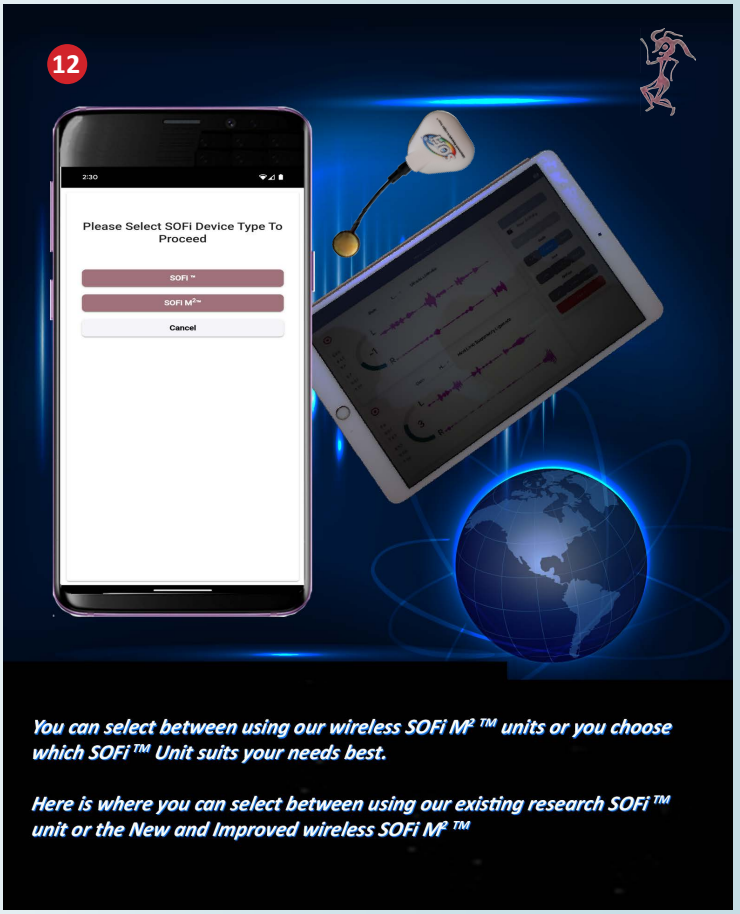


The App opens with a List of the Patients/Projects you have measured... this makes it easy for you to perform repeat measurements over weeks and months of clinical use and to compare results. The SOFi M² ™ has proven, with over a decade of published medical journal research, that it is both accurate and repeatable with every use of this device.



5.1 Start a measurement





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Next select a "Local" recording via Bluetooth (within 40-m of the subject) or a "Remote" recording that can be almost any distance away from your subject. This application requires using an Android Cellular phone running the Prosus App (which can be found on Google Play website).

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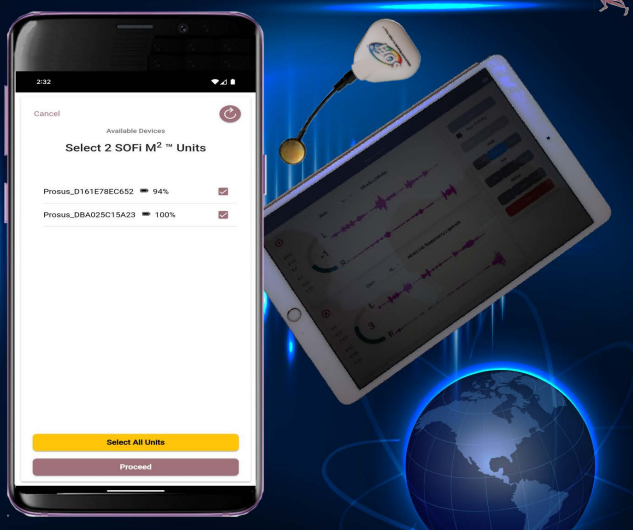

If you choose the new wireless SOFi M² ™ units they are activated when you connect a sensor... they will then appear automatically on your smart phone for you to connect and assign a muscle group...

Simply toggle the units "on" as needed and then press "proceed" to move to the next screen...

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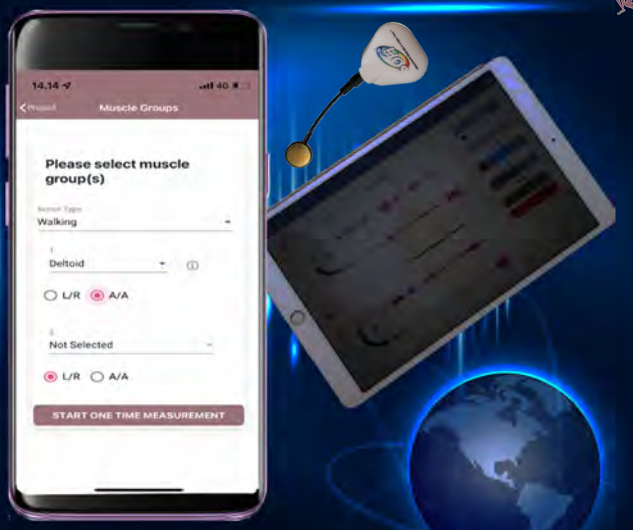
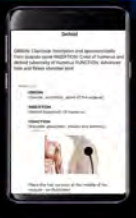


Having selected a subject, you can then select a muscle group to measure from... as well as decide on the muscle activity for exercise training and the surface on which training is to take place... a runner etc... The App also provides anatomical details about the muscle you've selected...



This App also provides anatomical details about the muscle you've selected... (Press "ⓘ" for Sensor Placement Location on specific muscle selected)

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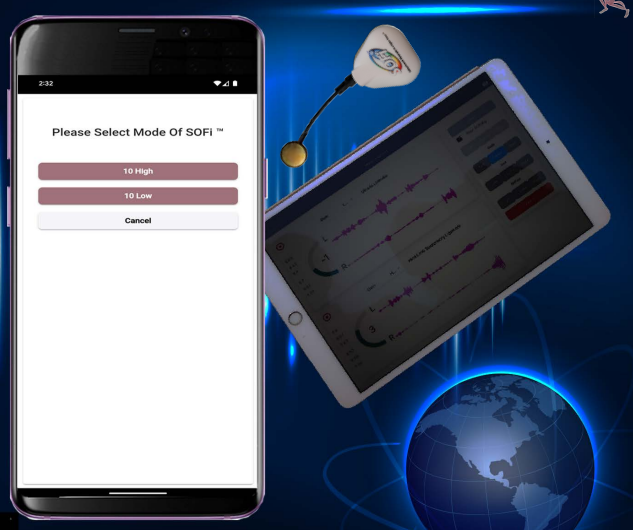
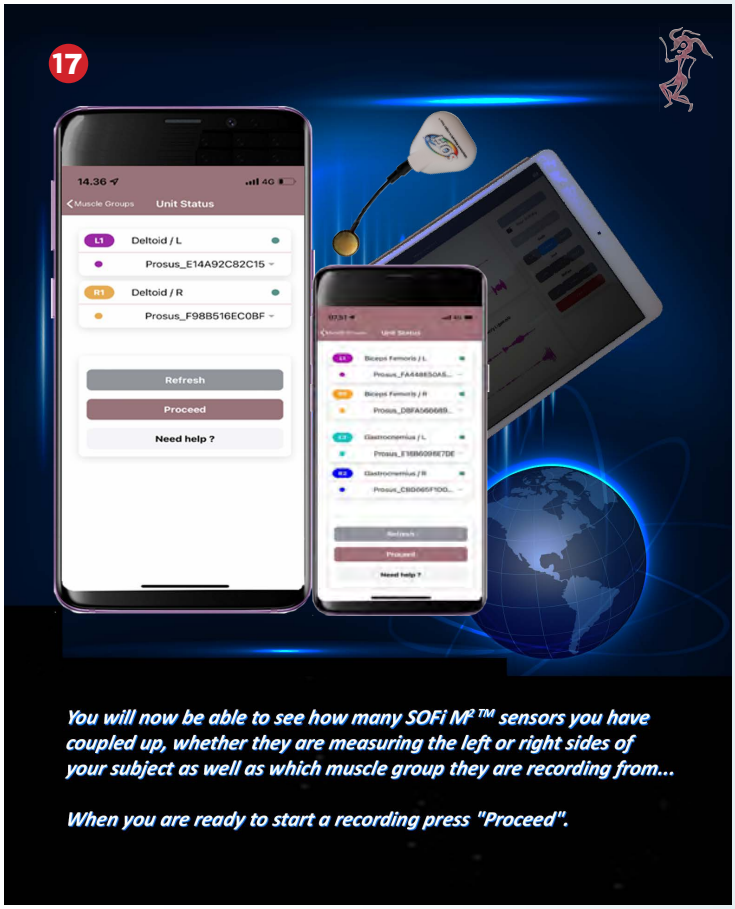


Next select how you wish to analyze the measured data... Do you prefer your optimal recordings to have a "High" or "Low" number...

If you feel that a good muscle performance makes more sense when the S-, O- and F- scores are close to 10 then choose 10 High...

If good muscle performance makes more sense when scores are low then choose 10 Low. .



You will now be able to see how many SOFi M² ™ sensors you have coupled up, whether they are measuring the left or right sides of your subject as well as which muscle group they are recording from...

When you are ready to start a recording press "Proceed".

The SOFi M² ™ recording page looks like this...

You can adjust the sensitivity of the recordings by pressing the "Gain" button, select activities from the lower panel and even take screen shots by pressing the "Camera" symbol at the top...

Start a recording by pressing the triangular arrow.

When you are finally finished with your recordings you can stop your measurements by pressing "No" or you can select "Yes" to record a New Measurement on a subject...

The final page allows you to Stop Recordings for a subject altogether, or move your sensors to different muscle groups and make some further recordings.

6. Local or remote measurements

The Clinic (Human Modality) ***SOFi M² ™***-App receives all sensor-data via the 2 or 4 ***SOFi M² ™***-units you choose to use to make your recordings.

The units can be coupled directly to the ***SOFi ™***-Apps with a (range of 40 meters), or they can stream data Live over a greater distance (many kilometers) with the use of the Prosus Mobile-App. You can download the Prosus App; found in the Google Play Store that ***SOFi M² ™*** units use for Live Stream remote measurements.

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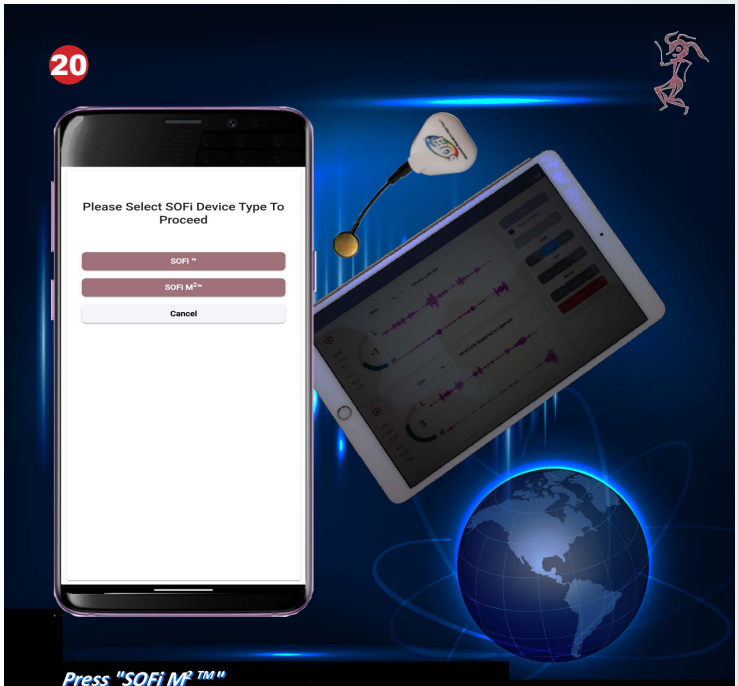
ANDROID APP ON Google play

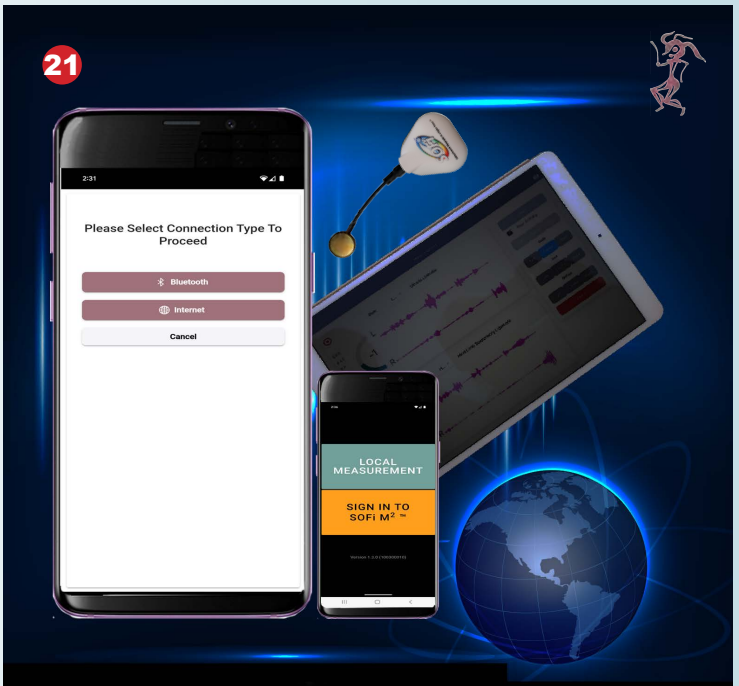
6.1 Remote streaming



Press "SOFi M² ™"

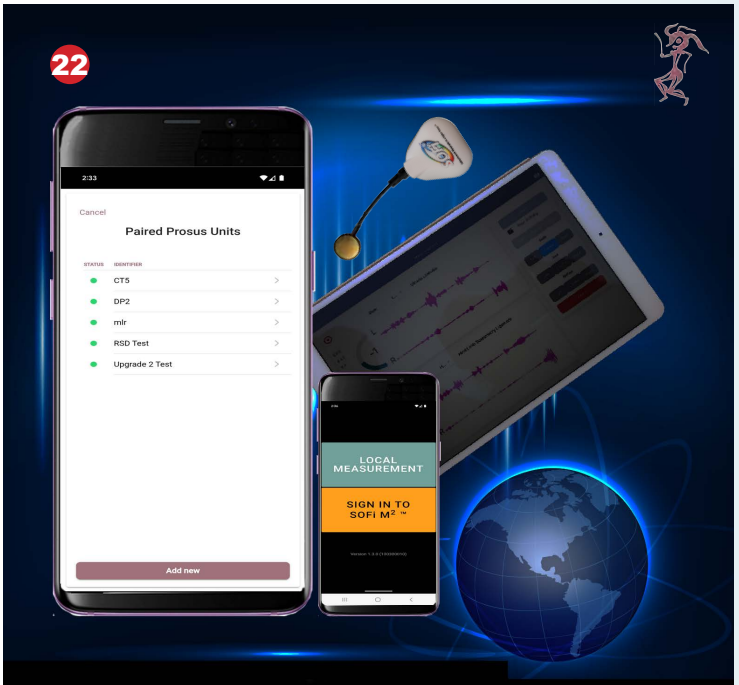
Remote streaming

This section of the guide is only relevant if you choose to stream from a Prosus Mobile-unit. If your SOFi M² ™-unit is directly connected to your telephone or iPad/tablet then you need to proceed to the section titled "Setup of sensors"



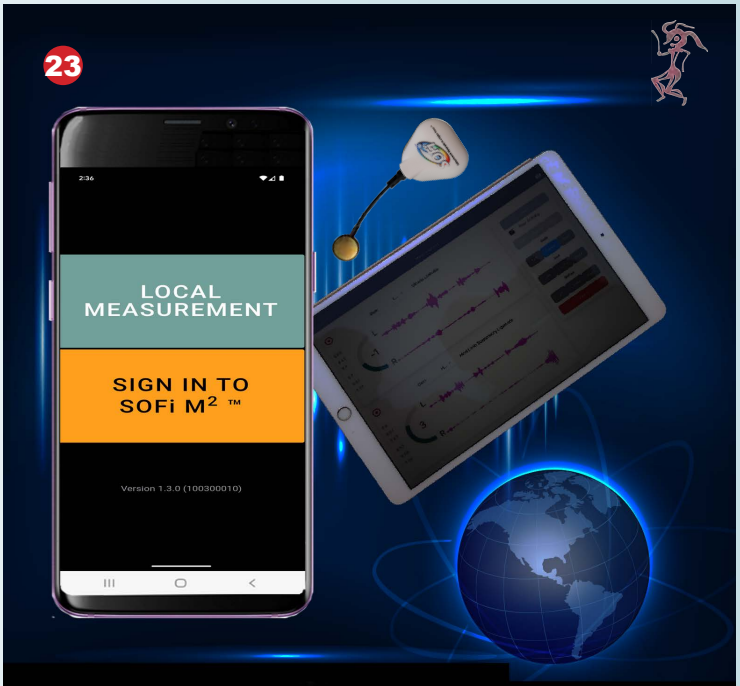
Choose "Bluetooth" to connect your SOFi M² ™ - unit directly (40 meter range) to your telephone or iPad/tablet.

Choose "Internet" to stream data over a greater distance from a Prosus Android Mobile Phone unit.



When you have selected "Internet" you will see a list of the Prosus Mobile Cell Phone-units or Tablets, that are paired with your user account. If the desired unit already exists on the list then you can Press on it to proceed....

If you wish to pair with a new Prosus Mobile Cell Phone-unit or Tablet, then you should Press the "Add new" button.

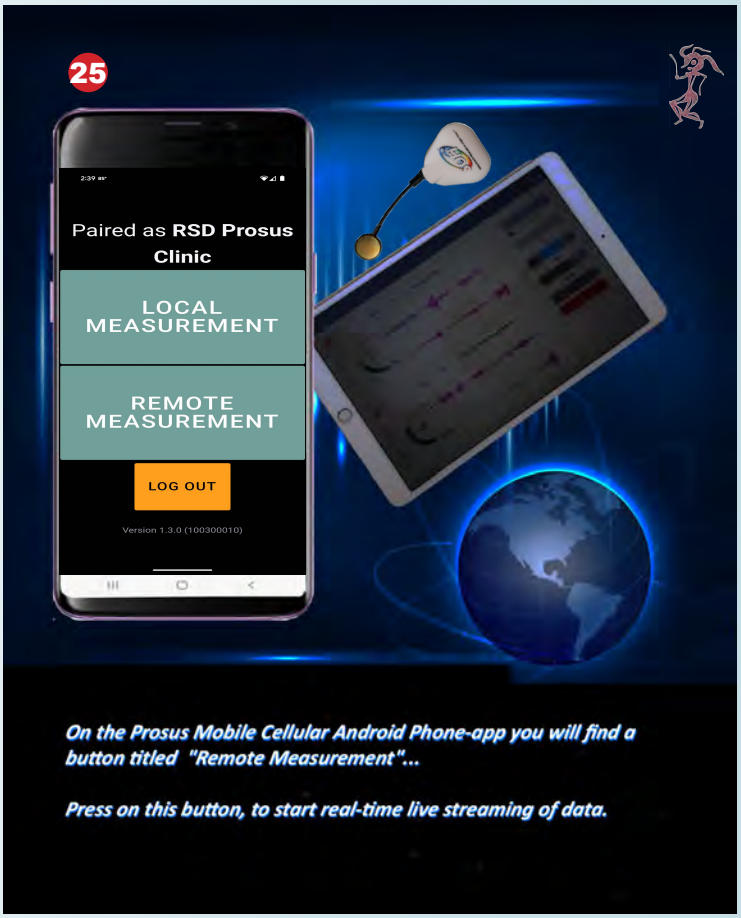


Make sure you have a Prosus Mobile Cellular-unit with a SIM card and a good internet connection...

Ensure that Bluetooth is switched on for both the Prosus Mobile Cellular-unit and the SOFi M² ™ -unit for either (telephone or iPad/tablet).

Open the Prosus MobileCellular-app. Press "Sign into SOFi M² ™"

Enter the code from the Prosus Mobile Phone-app into the pairing code-field on your SOFi M² ™-app (Clinic). In the field below, titled display name, enter your device name. You will now be able to identify this unit when making future Prosus Mobile -unit measurements.
Press "Pair with new unit" to complete pairing.
You will see a message pop up in both the Clinic app as well as the Prosus Mobile-app to acknowledge that pairing has been successful.

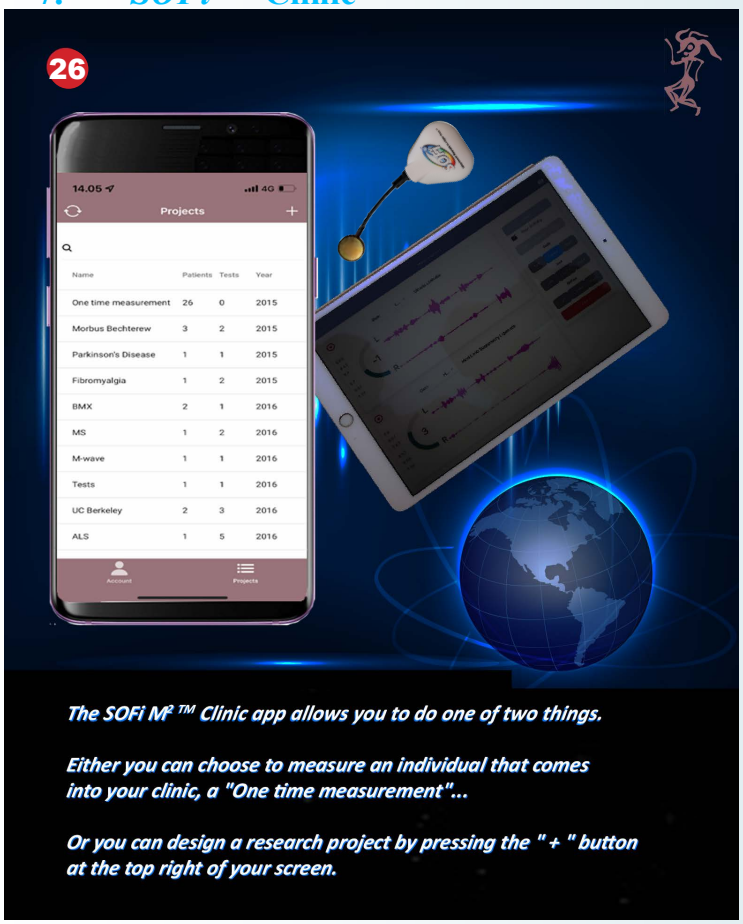


On the Prosus Mobile Cellular Android Phone-app you will find a button titled "Remote Measurement"...

Press on this button, to start real-time live streaming of data.

7. SOFi ™ Clinic

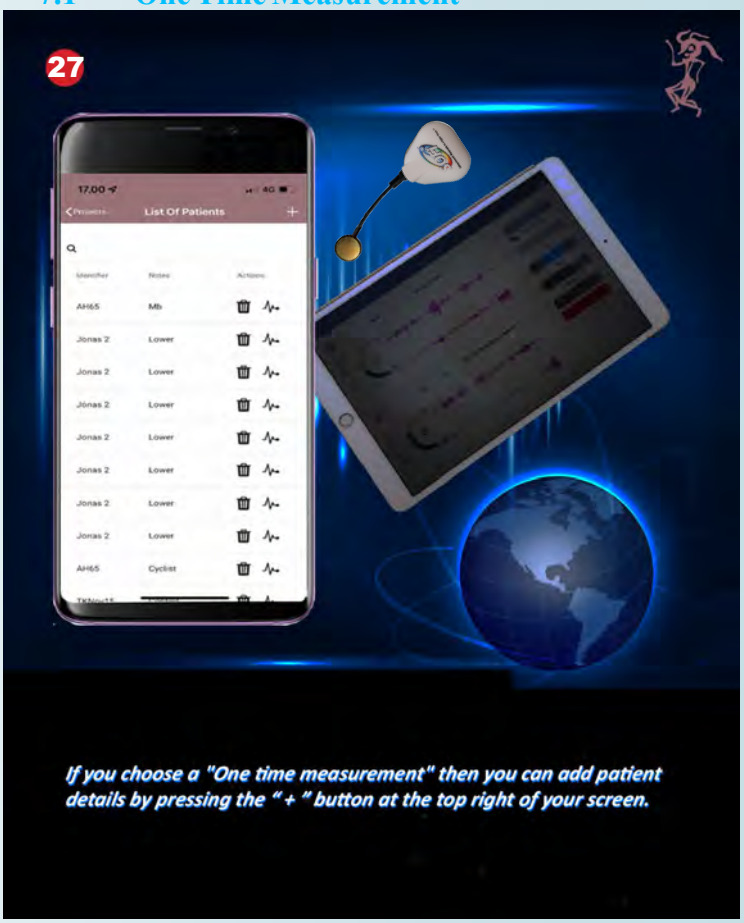
7.1 One Time Measurement



The SOFi M² ™ Clinic app allows you to do one of two things.

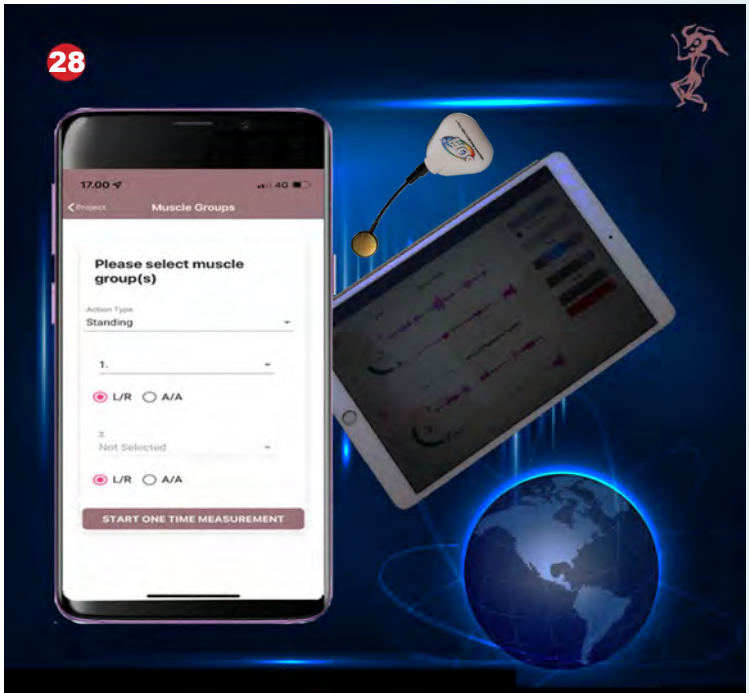
Either you can choose to measure an individual that comes into your clinic, a "One time measurement"...

Or you can design a research project by pressing the " + " button at the top right of your screen.



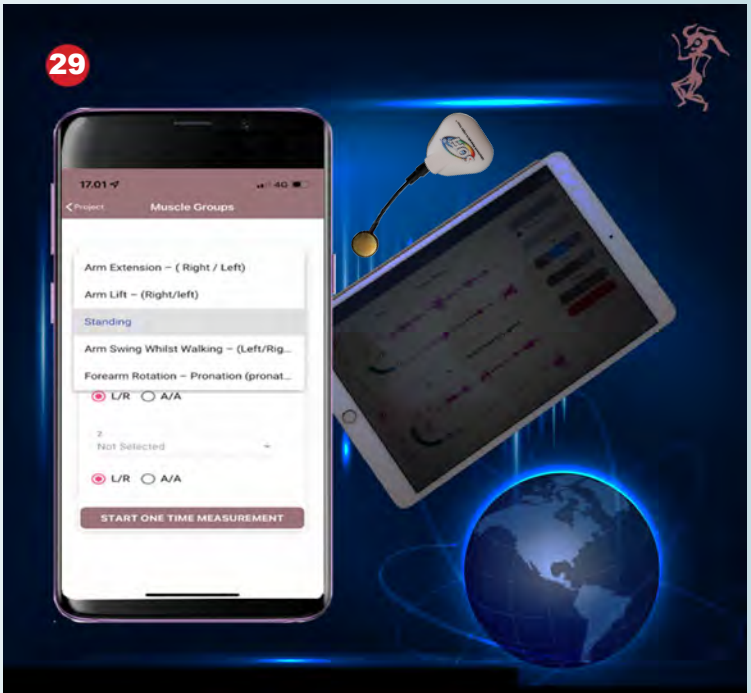
If you choose a "One time measurement" then you can add patient details by pressing the " + " button at the top right of your screen.

28



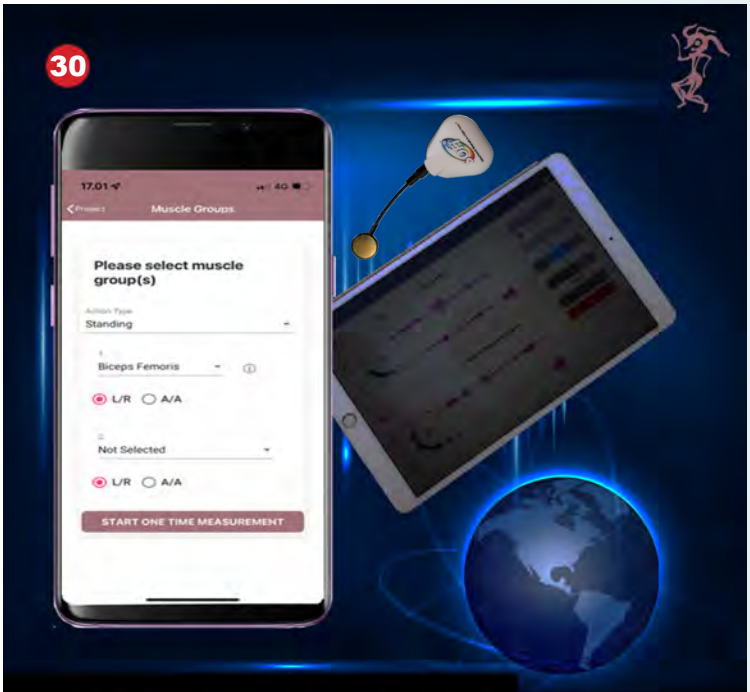
You will next be asked to select an action type...

29



Select from the list of typical actions, or write your own. Scroll down to see the complete action list .

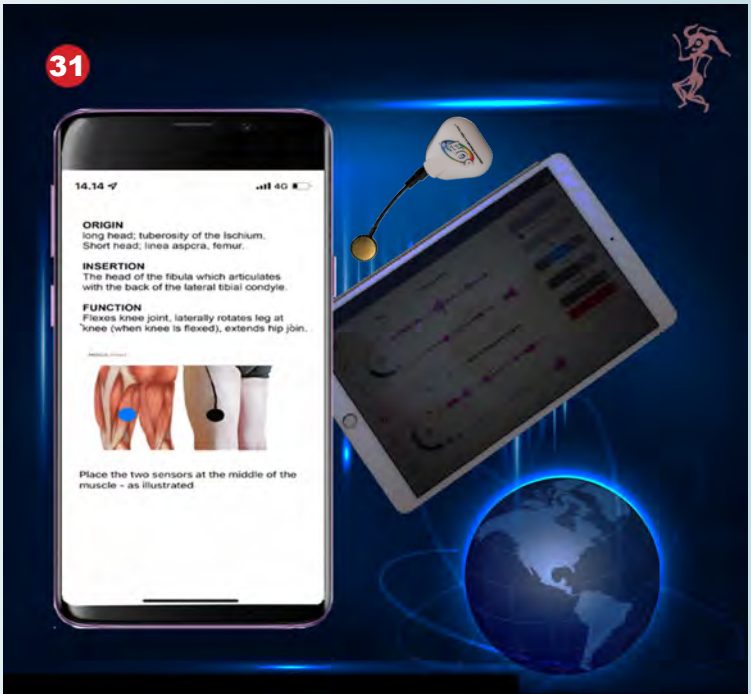
30



Next select a muscle group to be tested and decide whether you wish to measure that muscle group on both the left and right sides of your patient L/R, or whether you prefer to measure an agonist or antagonist muscle combination A/A.

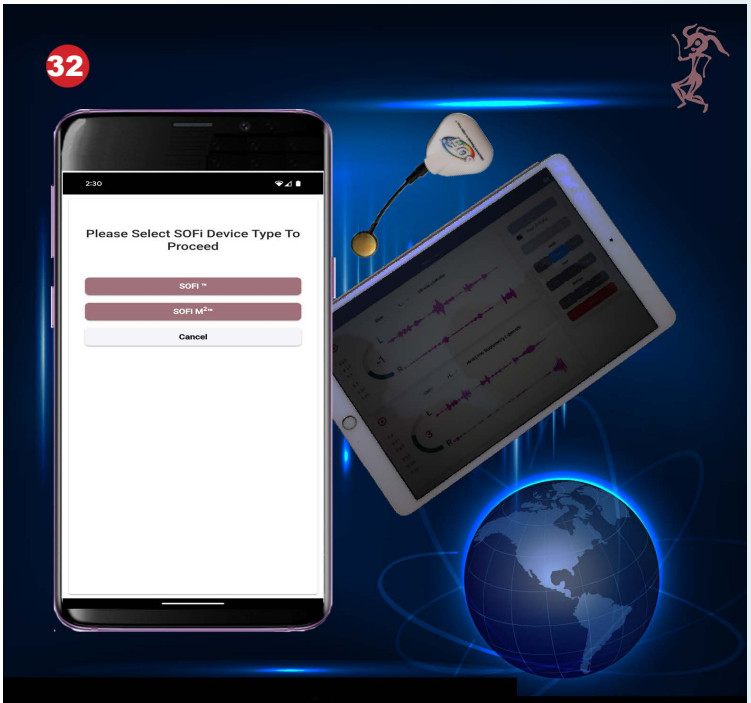
For details of the muscle group selected press the information "ⓘ" button along side the selected muscle.

31

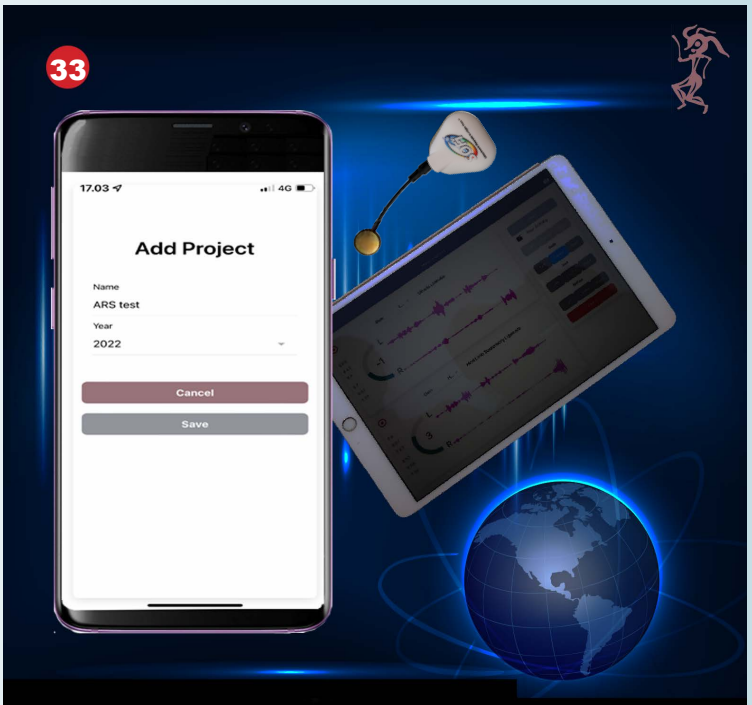


Muscle information includes the site of origin and insertion as well as the function of each muscle.

7.2 Research project



Once you have completed the previous steps you will reach the SOFi M² ™ device selection page, and from here on the process of making a subject or patient recording is the same as explained earlier.

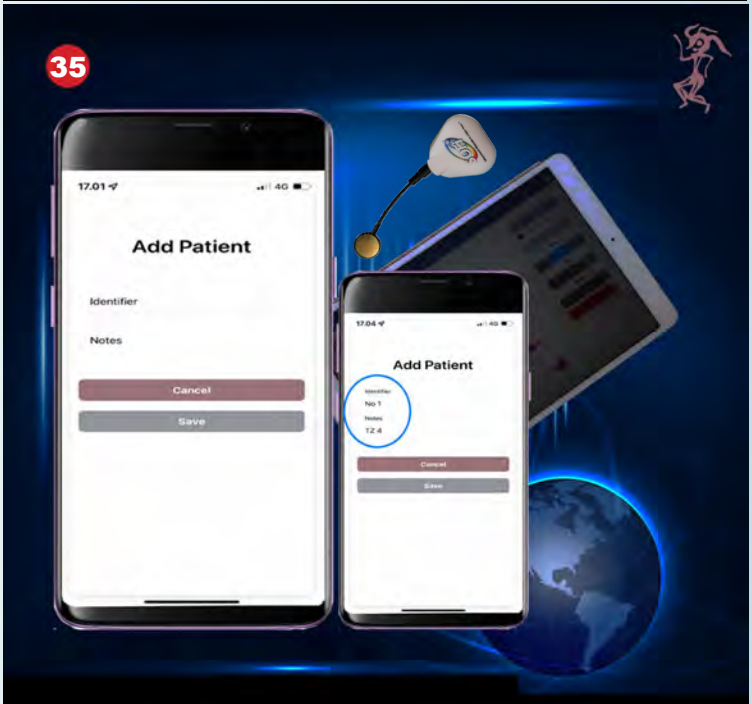


The SOFi M² ™ Clinic app allows you to design a research project by pressing the " + " botton, at the top right of your screen.

You will then be asked to assign a name and year to your new research project.

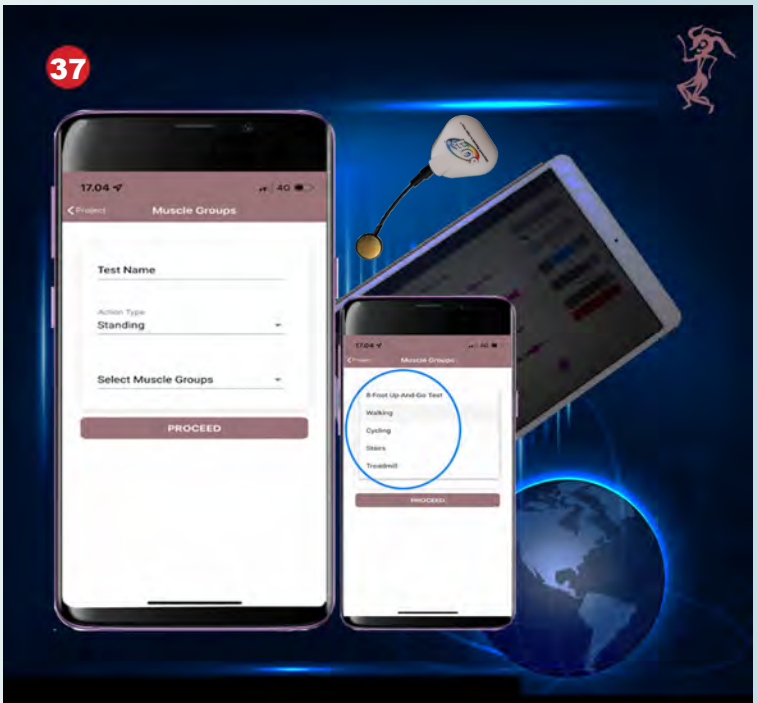
When you open up the new research project folder you will then be able to assign patients and tests.

Press On the Grey icon of a human head and upper torso to assign a patient .

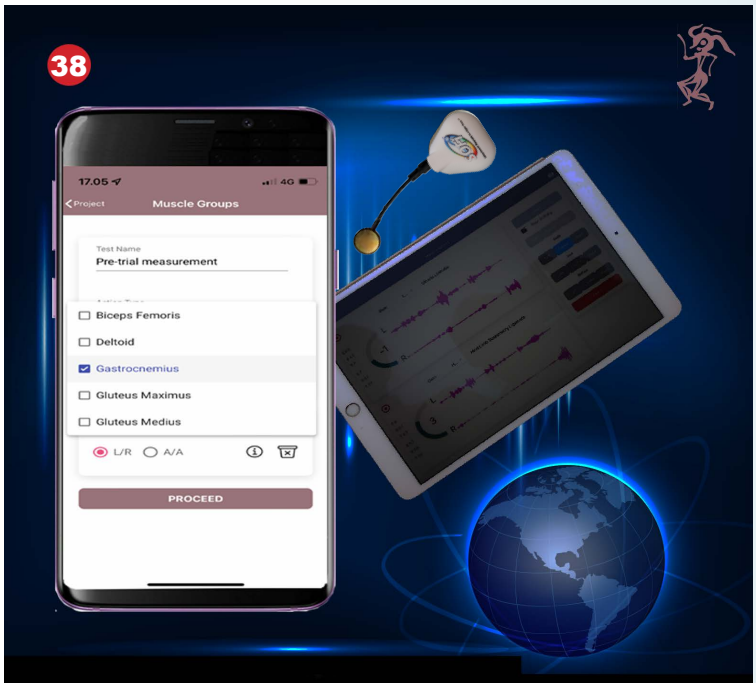


Fill out the patient identifier and any relevant notes for each of the subjects you wish to assign to the new research project.

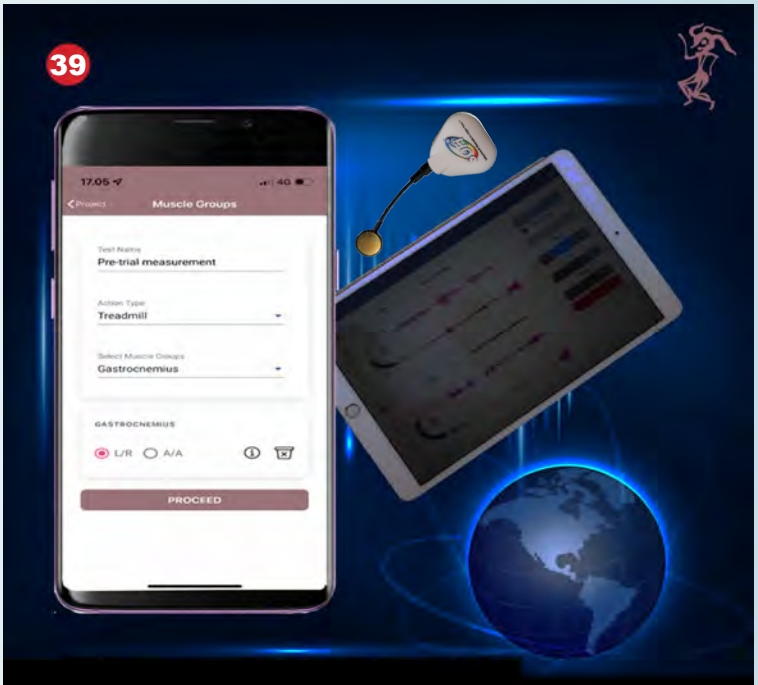
Having assigned your patients, you can now assign tests.



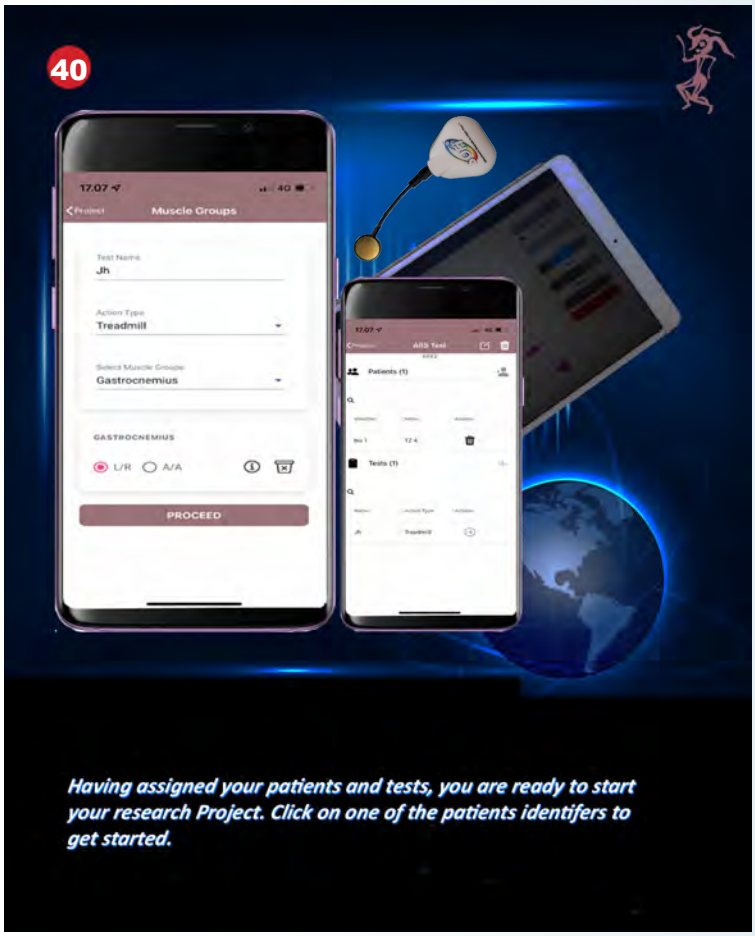
You can give your test a name and then assign an action type from the list, by scrolling down until you find the appropriate action type.



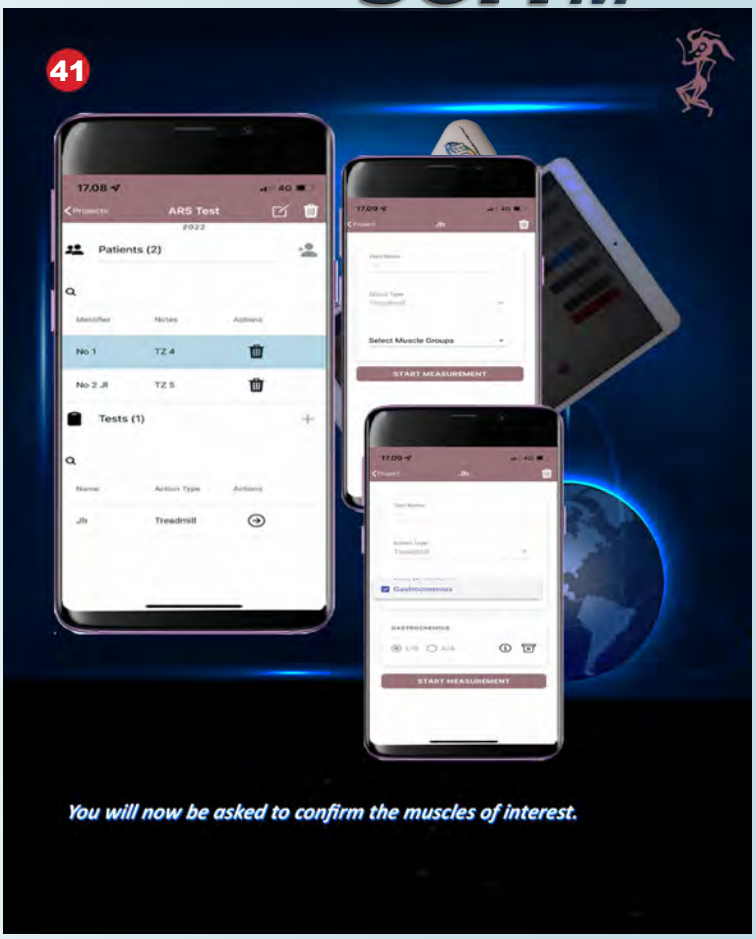
Next assign the muscle group you wish to test. It is possible to test two muscle groups at once with the SOFi M² ™ system.



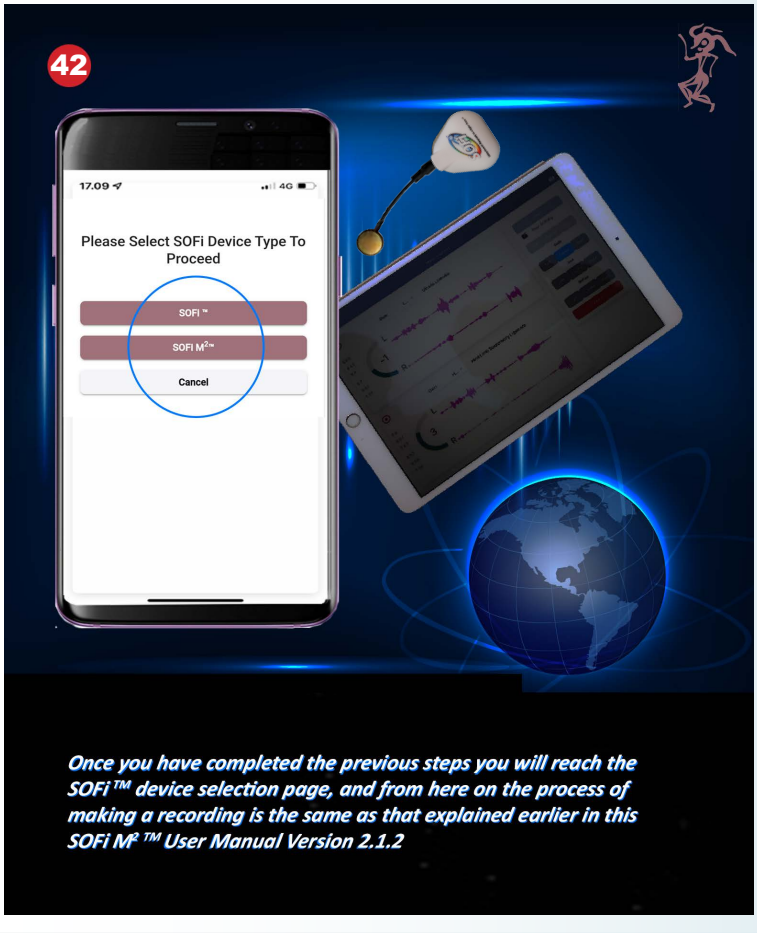
Finally, decide if you will measure left and right sides of your patient L/R, or whether you pre[er to measure an agonist and antagonist muscle combination AIA.



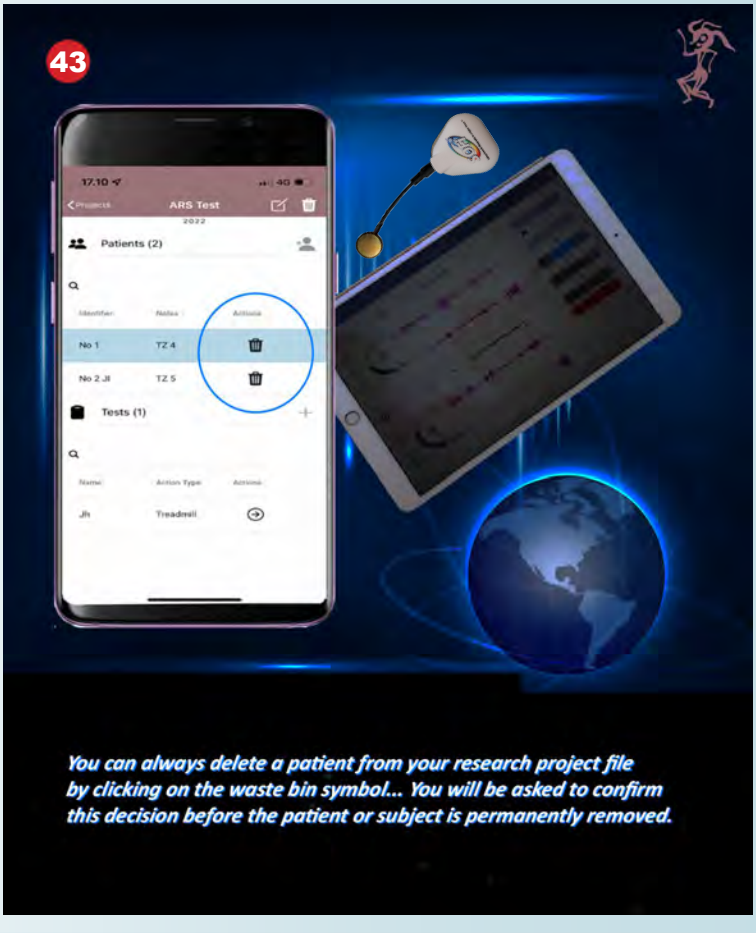
Having assigned your patients and tests, you are ready to start your research Project. Click on one of the patients identifers to get started.



You will now be asked to confirm the muscles of interest.



Once you have completed the previous steps you will reach the SOFi ™ device selection page, and from here on the process of making a recording is the same as that explained earlier in this SOFi M² ™ User Manual Version 2.1.2

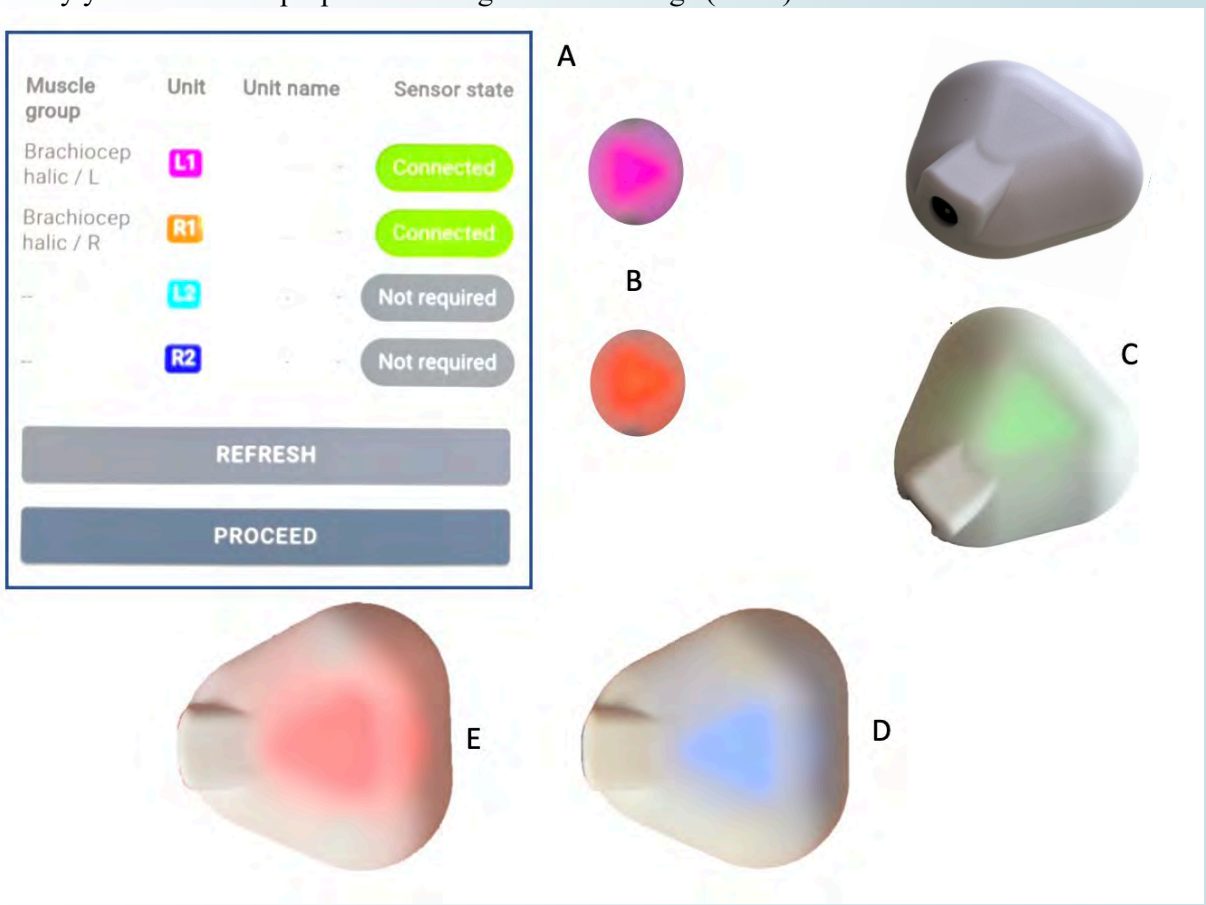


You can always delete a patient from your research project file by clicking on the waste bin symbol... You will be asked to confirm this decision before the patient or subject is permanently removed.

8.1 *SOFi M2 TM* Colors description while in use

The ***SOFi M² TM*** units are capable of changing color, and do so either as you decide, or as a way of providing information about their status.

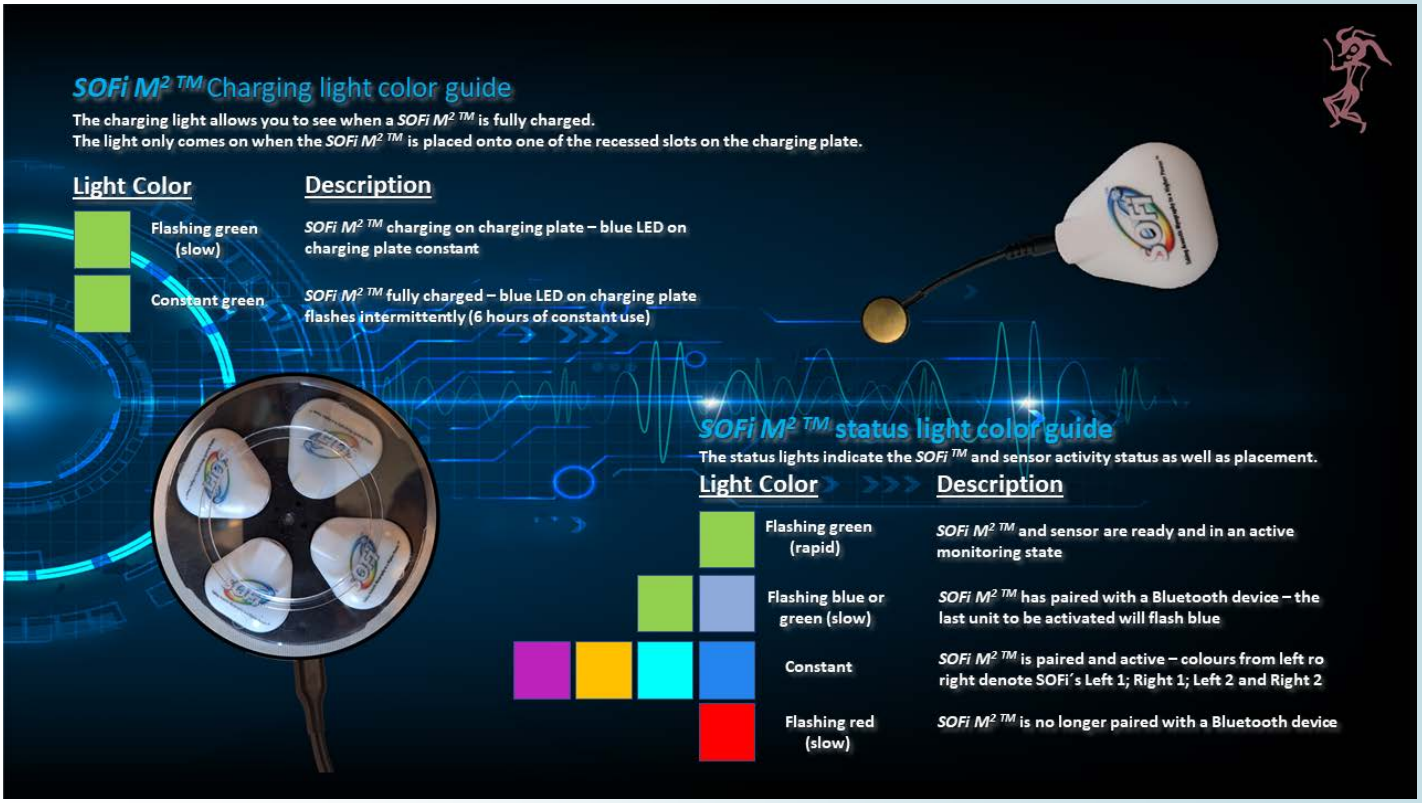
As part of the ***SOFi M² TM*** setup process, you can connect to the ***SOFi M² TM*** units that are active in your vicinity, and they will adopt the following colors, purple, orange, cyan and royal blue (see A). These colors remain active so long as the ***SOFi M² TM*** unit is active and enable users to identify ***SOFi M² TM 's*** placed on specific sites (ligaments or muscles). As a user you can change the color of specific ***SOFi M² TM*** units by pressing the appropriate unit during the setup procedure. In this way you can make a purple unit change color to orange (see B).



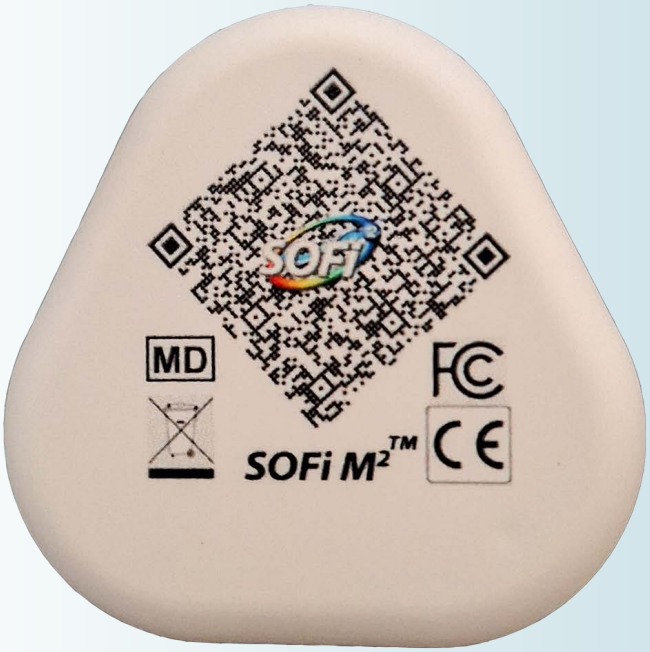
When a ***SOFi M² TM*** unit flashes green (see C) it denotes that the unit has been activated by a sensor, but that it is not yet connected to the App software. ***SOFi M² TM*** units also flash green when placed onto the charger, and they will continue to flash so long as they are charging. Once charged, the ***SOFi M² TM*** units exhibit a constant green color.

When a ***SOFi M² TM*** unit has been activated with the insertion of a sensor, and is connecting to the App software, it changes color to blue (see D). This enables the user to check for faults, a ***SOFi M² TM*** that continues to flash green is most likely faulty and should be exchanged for a new one from the Manufacturer/Distributor AMT. AMT provides a 5 year fully comprehensive warranty on each ***SOFi M² TM*** unit – do not attempt to open and repair the unit yourself, simply return it to AMT. (see Section 11 for details). A ***SOFi M² TM*** that has been used for a recording, and where the record button on the App has been switched off, will change color to red so long as a sensor remains connected to the unit (see E). This denotes that the ***SOFi M² TM*** has finished one recording and is awaiting new instructions.

8.2 *SOFi M2* Charging colors described in detail



8.3 *SOFi M2* Product Label for backside of device



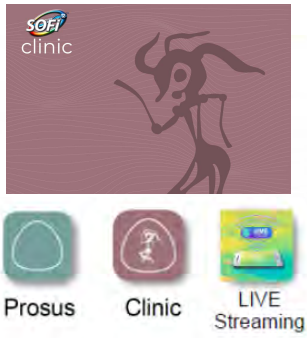
9. Device Specifications

9.1 *SOFi M2* Technical Specifications and Accessories

ADVANCED MYOGRAPHIC TECHNOLOGIES

www.myographytech.com

Taking Acoustic Myography to a Higher Power™



TECHNICAL SPECIFICATIONS

Name of the unit:	***SOFi M²***
Number of channels:	1 per ***SOFi M²*** (2 or 4 unit packs)
Memory:	None – Bluetooth streaming
Sampling rate:	1 kbps
Operating time:	6 hours (2 hour charge)
Power supply:	3.7V DC / 85 mA
Dimensions:	W: 4.0 cm (3 sided) H: 1.3 cm
Weight:	11 g

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ACCESSORIES

AMG preamplifier for CURO

Gain settings:	0,6,12,15,18,21,24,27,32 dB
Power supply:	Powered by ***SOFi M²***
Type of connector:	2.5 mm audio Jack
Input Impedance:	50 kOhm

AMG surface electrodes

Type:	Piezoelectric crystals
Sizes:	Ø 2 cm and Ø 5 cm
Length of wire:	8.2 cm
Type of connector:	2.5 mm audio Jack

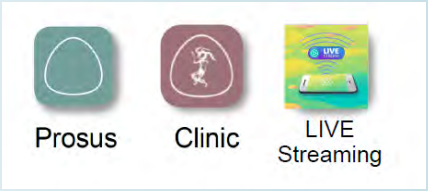
Recharger unit

Type:	AC-DC, Qi charger
Output:	5V DC / 300 mA
Dimensions:	Ø: 16.0 cm H: 1.5 cm

CE FC

AMT- *SOFi M² TM* AMG Wireless Device

9.2 *SOFi M² ™* Product Fact Sheet



PRODUCT FACT SHEET

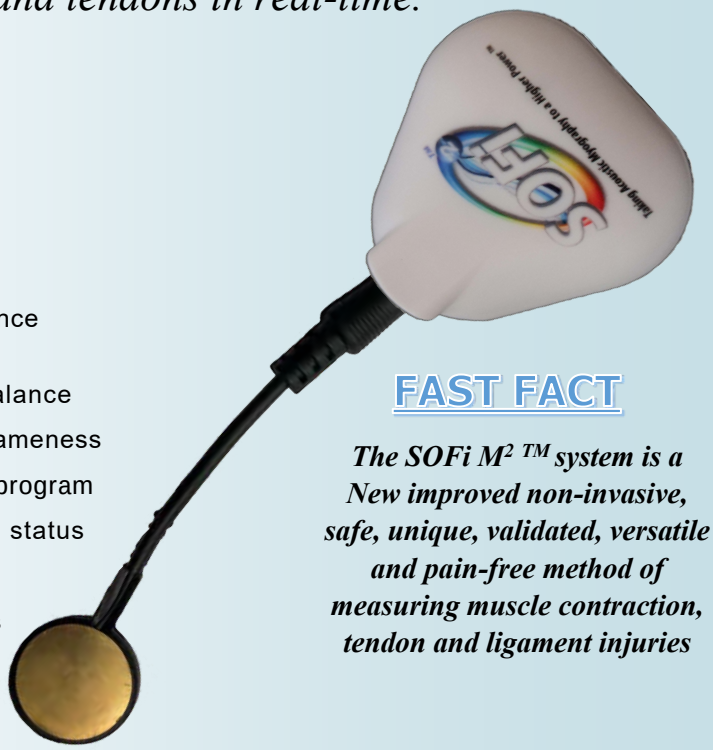
Acoustic Myography Muscle Analysis

This non-invasive technique is used to measure health and performance in muscle, ligaments and tendons in real-time.

APPLICATION

The ***SOFi M² ™*** can be used as a non-invasive safe and real-time monitor for such functions as:

- Performing a detailed muscle performance analysis
- Detecting asymmetry and muscle imbalance
- Revealing muscle injury site/cause of lameness
- Monitoring the benefits of a re-training program
- Monitoring training and muscle fatigue status
- Assessing movement patterns
- Detecting ligament and tendon injuries



FAST FACT

The SOFi M² ™ system is a New improved non-invasive, safe, unique, validated, versatile and pain-free method of measuring muscle contraction, tendon and ligament injuries

BACKGROUND

When muscle fibers contract, they generate vibrations producing pressure waves within the muscle itself and the surrounding tissues. These waves can be recorded at the level of the skin above the muscle of interest. Thus, Acoustic Myography (AMG) should be seen as a transdermal means of recording the produced pressure waves of active muscles. In this way the AMG technique represents a non-invasive and pain-free means of recording muscle contractions transdermally (Harrison et al. 2013; Harrison, 2017).

A ***SOFi M² ™*** unit is attached to a pair of ***SOFi ™*** sensors and held in place with hydrogel. AMG recordings can be made in real-time and the measured parameters determine both temporal and spatial summation during muscle contraction (force production) as well as muscle efficiency/coordination (S-score). The summation parameters are expressed as a O-score and F-score, and combined with muscle efficiency they comprise a unique ***SOFi ™*** - Score.

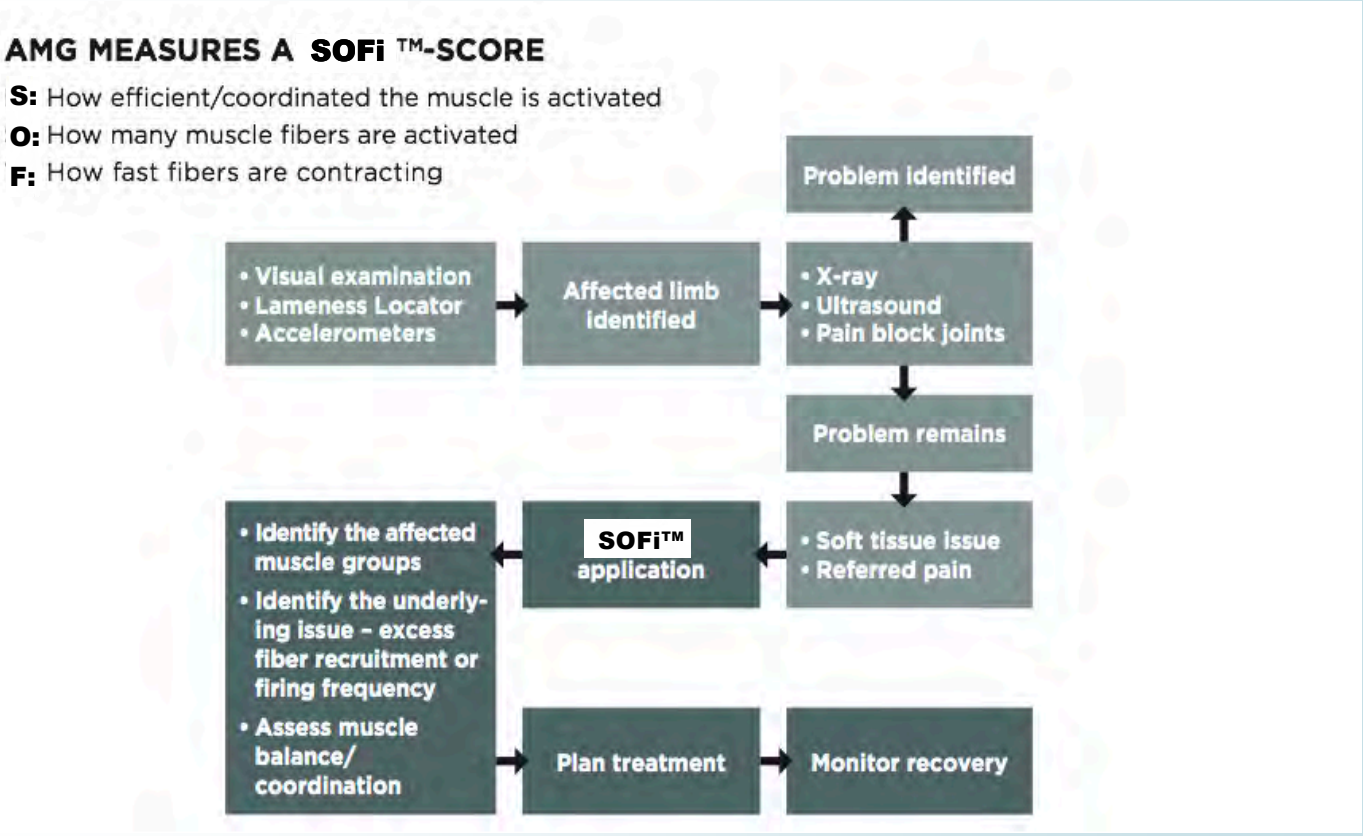
You Can Learn more about the ***SOFi M² ™***

on our Website at: www.myographytech.com

9.3 *SOFi M² ™* Guide for Human Health Care

SOFi M² ™ Guide for Human Muscle and Ligament Health Care

Schematic to guide your use of the SOFi M² ™



MEDICAL (MD) and Certified Sports Trainers CLINIC ASSIMILATION

A ***SOFi ™*** measurement takes less than 10 minutes to setup and perform, and reveals immediate real-time results on a smart phone/tablet. There is no need to shave or prepare the muscle site– use hydrogel (purchased at AMT - SOFi ™ online store), position the ***SOFi M² ™*** sensor. The FREE App (App Store – SOFi ™ Clinic) guides you through a recording, and helps you store and arrange your data.

Use AMG in combination with Sonogram, Ultra-sound, MRI, Gate Analysis System, Biomechanical 3D Motion Analysis and other recognized techniques to improve your diagnosis, monitor treatment effects, prescribe training programs and guide rehabilitation. The ***SOFi M² ™*** system also enables dynamic assessments of humans undergoing training or re-training, giving you a unique possibility to assess their performance and muscle health while in motion and recording biofeedback results with online streaming.

REFERENCES: Am J Trad Chinese Vet Medicine Vol. 12, No. 1, February (2017) • Ann Sports Med Res 4(1): 1101 (2017) SOJ Vet Sci 3(1): 1-6. (2017) • Physiol Rep, 1 (2), e00029, doi: 10.1002/phy2.29 (2013) • Open Veterinary Journal, Vol. 3(2): 80184 (2013) • Clin Physiol Funct Imaging 38(2): 312-325 (2017).

You Can Learn more about the *SOFi M² ™*
on our Websites at: www.myographytech.com

10. Troubleshooting

Should you experience problems with your ***SOFi M² ™*** units then please get in contact with the local or national distributor (see Section 13 for details), or Advanced Myographic Technologies, LLC. We will be happy to solve your problems or if necessary, replace your units.

- ***SOFi M² ™*** units take approx. 2 hours to charge up using the baseplate charger, if fully discharged at the time of charging.
- A fully charged ***SOFi M² ™*** has a continuous operating life of approx. 6 hours under normal ambient temperatures.
- Once fully charged, ***SOFi M² ™*** units keep their charge for a number of days. Typically a loss of 2-5% can be expected over a period of 72 hours.
- Please take a look at our websites for answers to common problems or questions.
- https://myographytech.com/ (or)

10.1 Website Help

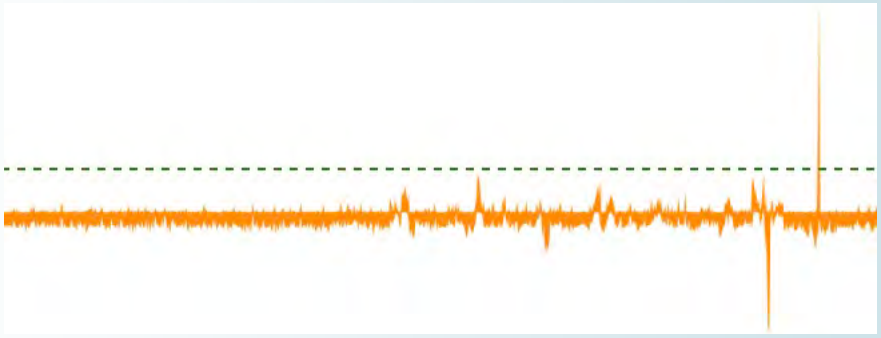
For a list of updated troubleshooting issues, and replies to Users questions, see our websites:

https://myographytech.com/faq/ (and go to the Learn/Learning Center Tab)

If you cannot find answers to your queries on our website then please contact us at our e-mail address and we will be happy to look into your issue (see Section 13 for details).

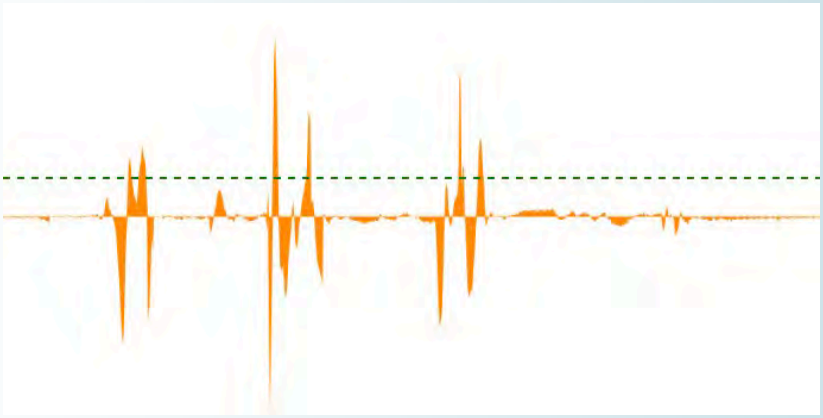
10.2 Recording issues

It is important that good contact with the skin surface is made in order to achieve a precise and reliable AMG recording. In order for this to occur you should use a fully functional sensor and make sure that the sensor is held securely in place with an adhesive tape/bandage. If the gel interface between the skin and sensor is inadequate, or the sensor is held too close to the skin or it is so firmly attached as to be bent slightly, you will get a recording that has a thick baseline (see below).



In such instances a thick baseline indicates: i) a damaged sensor (check its integrity), ii) insufficient gel at the sensor/skin interface, or iii) a sensor that has bee fixed in place too tightly.

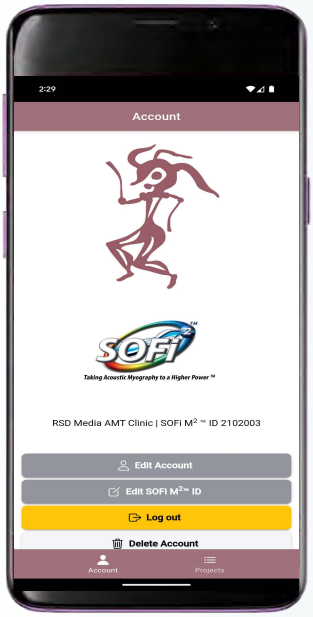
An example of a good recording and baseline can be seen over on the next page. Note how the baseline is narrow and fine when the subject is not moving, and how it responds with a clear signal, returning quickly back to its resting level. We recommend that you aim for a recording like this at the start and finish of each measurement – so as to be sure that the sensor is intact and functional.



In order to quickly test sensors, we suggest that you place two sensors gently together with the brass side facing each other, and whilst they are connected to a ***SOFi M² ™*** unit and the App, gently tap them equally from both sides. On your phone or tablet screen you will be quickly able to see whether both sensors respond at the same time, and to the same extent. Sensors that are slow to respond, or that show a greatly reduced signal amplitude should be discarded as being suspect of damage. We recommend that such a test be performed before a recording as well as afterwards to ensure that observations from subjects are not the result of faulty sensors.

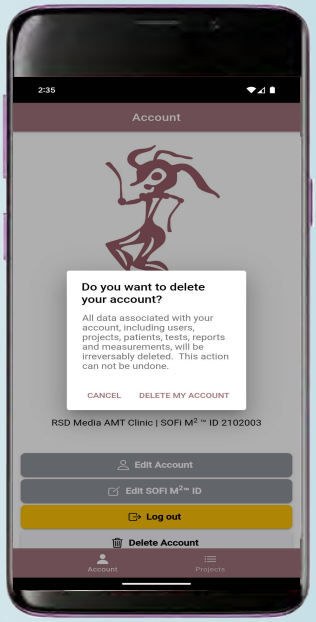
11. User subscription cancellation

In compliance with App regulations, every registered user has the right and ability to cancel their subscription to the App and the Client Cloud. You simply login to the App you are registered with and at the bottom of the opening screen press on the Account symbol and you will see this screen.



11.1 How to delete account

To delete your account press the Delete Account button .. you will then see a screen like the one to the right. If you proceed with "Delete my account" then this action cannot be reversed and all the data you have – measurements, reports will be deleted.



12. Terms and conditions

12.1. Restrictions, warranty and compliance

You may not make or distribute copies of the Advanced Myographic Technologies, LLC Product, or electronically transfer the Advanced Myographic Technologies, LLC Product Software from one computer to another or over a network. You may not decompile, reverse engineer, disassemble, or otherwise reduce the Advanced Myographic Technologies, LLC Product or Software to a human---perceivable form. You may not modify, sell, rent, transfer, resell for profit, distribute or create derivative works based upon the Advanced Myographic Technologies, LLC Product or any part thereof.

- Furthermore, you do not become the owner of the Advanced Myographic Technologies, LLC Product or Software, and Advanced Myographic Technologies, LLC and its suppliers retain the title to, the Advanced Myographic Technologies, LLC Product, and all copies thereof. All rights including international copyrights, patents, trademarks and other intellectual property rights, are expressly reserved by Advanced Myographic Technologies, LLC. Likewise, Advanced Myographic Technologies, LLC retains the right to use the anonymous data generated by the Advanced Myographic Technologies, LLC Product "***SOFi M² ™***" units for research purposes.
- The Advanced Myographic Technologies, LLC product "***SOFi M² ™***" and acoustic myography sensor is provided to you on an "AS IS" basis having been tested in the factory prior to distribution. You are welcome to write with regard to technical support at (info@myographytech.com) remembering to identify the serial number of the ***SOFi M² ™*** unit and clearly state the conditions surrounding your problem. In terms of warranty, Advanced Myographic Technologies, LLC will provide a 5 year fully comprehensive warranty on your ***SOFi M² ™*** unit. These terms do not affect or prejudice the statutory rights of a consumer; i.e., a person acquiring goods otherwise than in the course of a business.
- Neither Advanced Myographic Technologies, LLC nor its suppliers shall be liable for any indirect, special, incidental or consequential damages or loss (including damages for loss of business, loss of profits, or the like), whether based on breach of contract, tort (including negligence), product liability or otherwise.

- Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving antenna.
  - Increase the separation between the equipment and receiver.
  - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

13. Contact details

13.1 Company contact information

US Research & Development, Manufacturer and International Distributor:

Advanced Myographic Technologies, LLC

9081 NE Jacksonville Road - Suite 1302

Anthony, Florida 32617-1302

Contact: Call (352) 456-8388

info@myographytech.com

https://myographytech.com/

Manufacturer:
Advanced Myographic Technologies, LLC

9081 NE Jacksonville Road - Suite 1302
Anthony, Florida 32617-1302

Contact: Call: 352-456-8338

mail@myographytech.com

orders@myographytech.com

support@myographytech.com

14. AMT *SOFi M² ™* Online Store

14.1 Website details

Running low on consumables? Want to purchase additional ***SOFi M² ™*** Units, Sensors, Battery Chargers or other Accessories for your clinic?

Visit www.myographytech.com/shop/ to order through our online store.