Gait up

INSTRUCTIONS FOR USE

ENGLISH

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Instructions for Use

Gait Up GO

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1. SAFETY INFORMATION

The safety information is classified as follows:

Warning!

Clinical meaning: Refers to a hazard that, if not avoided, can result in serious injury or death

General meaning: Advanced notice of something unpleasant or dangerous that will happen

Caution!

Refers to a potential hazard that, if not avoided, can result in minor personal injury and/or product/property damage

Read the following safety information before using this medical device.

1.1. Warnings

1.1.1. Warnings related to the operating conditions of the device

- Do not use Gait Up GO medical device in the near proximity of Active Implantable Medical Devices (AIMD), medical devices that have direct impact on the health condition of the patient or life supporting medical devices.
- Gait Up GO sensor device accessory, Physilog®6 sensor, should be handled carefully. In particular, it should not receive intentional shocks, such as fall, crushing, being hit, etc.
- Do not use or charge the Physilog®6 if the sensor, its case or USB cable are damaged. Contact Gait Up about what further action is needed when any component is damaged.
- Do not attempt to repair or modify the device or replace any of its components. For repair, maintenance and replacements, please refer to Gait Up SA customer support. Damaged parts must be immediately replaced with original parts by the customer service.
- Do not use any external power supply (mobile phone charger) other than those compatible with the technical specifications listed in section 9 of the present document. Always refer to the device manual for proper charging instructions.
- Use of accessories and cables other than those specified or provided by the manufacturer of this medical device could result in improper operation of the device. Always refer to the manufacturer indications.
- Do not operate Gait Up GO medical device in an MRI room

- Operate the Gait Up GO medical device at ambient room conditions in terms of temperature (0°C - 30°C), humidity (10%-70% - non-condensing) and pressure (600 to 1070 hPa).
- Store Gait Up GO medical device in a safe place out of reach of people not trained for a safe device use.
- Do not introduce any pointy object in the hole present on the backside of the Physilog6 sensor device accessory. On the internal face of the hole, a membrane that ensures the IP64 protection index of the sensor device is placed. By damaging it, the protection is no longer ensured and water ingress can damage the electronics and battery housed in the enclosure of the Physilog6. Be aware that there is no reset button behind such hole in the device.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

1.1.2. Warnings related to the conditions and awareness of the end-users

- Before using the Gait Up GO medical device, evaluate the conditions of the Participant (see definition in section 2.1) and the appropriateness of using such a medical device. The Participants must be conscious, capable to understand and follow the instructions and able to actively participate in the session (i.e. follow the instructions shown in the screen of the mobile phone where the Gait Up GO mobile application is installed while performing the different tests)
- Before using Gait Up GO medical device, instruct the Participants in the safe use of the device.
- Uttermost caution should be exercised when using the device in Participants with the following risk factors:
    - suspected or diagnosed heart problem like ventricular arrhythmia, heart insufficiency or hemodynamic instability;
    - Visual/auditive problems
- DO NOT use the Gait Up GO in other parts of the Participant body but in the ones indicated in the Instructions For Use.
- DO NOT manipulate or remove Gait Up Go accessories from the user body during the session. Accurate results are only guaranteed if the Physilog6 sensor accessory is firmly attached on the user shoe or belt and the Instructions for Use are followed during the duration of the assessment.
- When using the Gait Up GO wearable accessories (Physilog6 sensor device and its clip accessories) on different Participants, disinfect the applied parts in potential contact with the skin of the Participant before using it on another Participant, as there is the risk of spreading infections.
- Keep device away from pets

1.2. Cautions

- Operate and configure Gait Up GO only if you are a qualified medical professional. You must be able to correctly place the Physilog6 sensor device, choose the suitable test for the Participant and interpret the output data offered by the reports generated by Gait Up GO mobile application. The Participants must use the Gait Up GO medical device only under your medical supervision and responsibility.

Precaution should be exercised when using the device in following conditions:

- Do not use Gait Up GO medical device in case of software malfunctioning, including mobile phone application, repeated Bluetooth Low Energy (BLE) connection issues, and repeated reset of the Physilog6 sensor device accessory. In all those cases, the customer support must be contacted.
- Gait Up GO medical device uses a single Physilog6 sensor device accessory. A Participant must not wear more than one Physilog6 accessory on the body at the same time. Do not operate several Gait Up GO medical devices on the same Participant at the same time.
- Do not combine the equipment of the Gait Up GO with the equipment or the applied parts of other devices/accessories. Always refer to the manufacturer indications;
- Do not operate the device and contact the customer support with the error message given by the Gait Up GO Mobile Application if the Physilog6 sensor device accessory fails to perform the firmware update.
- Do not operate Gait Up GO medical device if the Physilog6 sensor device accessory is not correctly placed on the end-user's body
- Any part of the Gait Up GO must not be maintained or serviced while the device is in use; do not perform an OS update of the mobile phone/tablet during or when you have planned to use the device.
- Liquids and foreign material (e.g. dust) must not be allowed to enter the Physilog6 sensor device accessory. Do not clean the device with excessive liquid. For cleaning and maintenance instructions, refer to the section 5 of the present document.

- Do not subject the Physilog 6 device accessory, containing batteries, to intentional or repetitive mechanical shocks;
- Do not leave the Physilog6 device accessory exposed directly to the sun.
- Store all Gait Up GO medical device accessories in the original Gait Up GO casing provided together with the device.
- Transport the Gait Up GO medical device, including all its accessories, within the original container case. Mindmaze SA is not liable for transport damage if the Gait Up GO medical device is not packed in its original container case.

1.3. Contraindications for Gait Up GO medical device

Do not use the Gait Up GO medical device, version 1.0, on Participants:

- in combination with active implantable medical devices and/or electromedical devices that have direct impact on the health condition of the patient;
- in combination or in close proximity to any life supporting medical device;
- in direct contact with open wounds, pressure sores, inflammation or skin irritated area;
- Electromagnetic Hypersensitivity syndrome: Idiopathic Environmental Intolerance to Electromagnetic Fields.
- The consequences of the performance of the tests included in the Gait Up GO medical device by pregnant women is unknown. Therefore, it is not recommended the use of Gait Up GO medical device on pregnant women.

1.4. Adverse reactions

In the unlikely event that any adverse reactions occur in participants, stop using Gait Up GO medical device immediately.

Any serious incident having occurred in relation to Gait Up GO medical device should be reported to the legal manufacturer (Mindmaze SA) and the competent authority of the Member State in which the user and/or the Participant is established.

2. Before use

Please, refer to section 1. Safety Information

2.1. Definitions

Term	Definition
Participant	Term used to describe the end users of the Gait Up Go medical device, including patients, healthy individuals and athletes.
User	Term used to describe any actor using the Gait Up Go medical device, including the medical professionals, end users and patient relatives.
BLE	Bluetooth low energy (or Bluetooth smart)
IFU	Instructions for use
eIFU	Electronic version of the Instructions for use
QSG	Quick start guide
eQSG	Electronic version of the Quick start guide

Table 1. Definitions

2.2 Intended use

Gait Up GO is a medical device intended to help therapists, physicians, medical doctors and rehabilitation specialists to assess the condition of patients suffering from motor disorders. Furthermore, the device quantifies patients' physical performance which can be used to understand the impact of treatments and/or rehabilitation therapies on the patients.

Gait Up GO is also used to assess risk of injury for prevention in recreational and professional athletes of all ages (such as any person performing a sport activity).

Gait Up GO is further used to measure indicators of early-stage signs of diseases affecting motor function (such as Parkinson Disease).

The device can be used at hospitals, clinics, rehabilitation centers and patient's home.

2.3. Indications for use

GaitUp GO is a medical device indicated for mobility and physical condition parameter assessment in:

- child (any gender): 2 - 12 years old
- adolescent (any gender): aged 12 through 21 (up to but not including the 22nd birthday)

- adult patients (any gender): 22 and older

to help medical professional in getting objective parameters to:

- assess the condition of patients suffering from mobility disorders
- assess the risk of injury in athletes of all age and
- assess indicators of early-stage signs of diseases affecting motor function.

It can be used in hospital, clinics, rehabilitation centers and indoor home environments. The device is not indicated for uses other than that described in the IFU and labelling. GaitUp GO is a Px only (under prescription) Medical Device.

2.4. Intended user population

The users of Gait Up GO medical device are patient relatives, medical professionals, patients and healthy individuals.

2.4.1. Patient relative

The role of the patient relative is to help the patient, while using the device at home, with attaching, starting, stopping, removing and charging the device if the patient is not able to perform them her/himself (f.ex. young child).

- Prevalent age: +20 years old.
- Prevalent physical condition: No specific physical conditions are needed.
- Minimum education level: none
- Minimum knowledge required: Understand user manual, be able to use a smartphone or tablet application
- Minimum experience: be able to place the sensor correctly on the end user's body according to the graphical illustration contained in the instructions

2.4.2. Medical Professional

Medical professionals set-up the Gait Up GO medical device in a suitable environment, choose the appropriate tests and program the medical device for a specific Participant following its condition. Moreover, they are in charge of interpreting the data contained in the reports generated by the medical device. For those activities, the medical professionals use all the components of the Gait Up GO medical device.

Only medical professionals (i.e qualified physiotherapists, occupational therapists, etc.) must use Gait Up GO by fully complying with their respective country’s regulations and accident prevention measures, and strictly following the instructions for use of the device.

- Minimum education level: nurse, physiotherapist, occupational therapist, ergotherapist, assistant therapist
- Minimum knowledge required: Understand user manual. Therapist degree: knowledge of clinical protocols. Be able to use a smartphone or tablet application
- Minimum experience: The medical professional should be able to choose meaningful and safe protocols for the Participant and be able to place the sensor correctly on the end user's body according to the graphical illustrations shown in the user interface of the mobile application.

2.5. Intended End user population

2.5.1. Patients suffering from motor disorders

Patients only use the Gait Up GO medical device under the supervision of a medical professional, perform the tests and protocols set by the rehabilitation professional and use a device pre-configured by the medical professional at both, clinical and indoor home environments.

- Prevalent age: 2 -99+
- Prevalent physical condition: suffers from movement disorder or disability
- Minimum education level: none
- Minimum knowledge required: understand instructions
- Minimum experience for proper product usage: no minimum experience required.

2.5.2. Healthy population

Healthy population can use the device in order to assess injury risk for prevention in athletes (f.ex young football players) or to measure indicators of early-stage signs of diseases affecting motor function (f.ex. Parkinson Disease). Healthy population only use Gait Up GO medical device under the supervision of a medical professional and use a pre-configured device by the medical professional and perform the tests and protocols set by the respective medical professional at both, clinical and indoor home environments.

- Prevalent age: 2 -99+
- Prevalent physical condition: no specific physical conditions are needed.
- Minimum education level: none
- Minimum knowledge required: understand instructions
- Minimum experience for proper product usage: no minimum experience required

2.6. Essential performance

The Gait Up Go medical device does not have any essential performance according to IEC 60601-1:2005+AMD1:2012 CSV.

3. Description

3.1. Overview

The Gait Up GO medical device components are delivered in a dedicated shipping box.

Quantity	Component	Article number
1	Instructions for Use	GOIFU
1	Instructions for Use Lay person	GOIFUh
1	Quick start Guide	GOQSG
1	Quick start Guide Lay person	GOQSGh
1	Device case	GOC
1	Physilog6 sensor device (*)	P6
1	Belt clip and strap(*)	BCS
1	Shoe clip(*)	SC
1	USB cable(*)	USBCc
1	Gait Up GO mobile application	GO

Table 2. Gait Up GO components. (*) are accessories. The related technical specifications are provided in section 9 of the present document.

WARNING: Do not use any external power supply (mobile phone charger) other than those compatible with the technical specifications listed in section 9 of the present document. Always refer to the device manual for proper charging instructions.

Note1: Check the shipping box content for any missing component and for any damage that may have occurred during transportation.

Note 2: It is highly recommended to keep the Gait Up GO medical device components in the original device case when it is not used, positioned in the corresponding slots as they were delivered originally.

Gait Up GO medical device can be operated only through a mobile phone (iOS & Android) or a tablet (iOS & Android) where Gait Up GO app has been installed:

- Gait Up GO Application is freely available for installation on Google Play Store and Apple App Store
- The minimum system specifications for a phone or a tablet to be used with Gait Up GO medical device are provided in section 9 of the present document.

3.2. Description of device components

Fig 1. Gait Up GO device components

1 Gait Up Go Mobile Application

Fig 2a. Android application

Fig 2b. iOS application

Gait Up GO Mobile Application is a software used to:

- wirelessly communicate with the Physilog6 sensor accessory via BLE
- set and provide instructions about the different tests intended for the Participant to perform
- receive, process and analyse the raw data sensed by the Physilog6 sensor device

- generate clinical reports showing the main outcome indicators for the Medical Professionals to interpret it.
- manage Participant profiles and access generated reports
- update the Firmware of the Physilog6 sensor device accessory
- provide access to the electronic version of the IFU and the quick start guide

The Gait Up GO Mobile application runs on off the shelf Android and iOS mobile phones and tablets.

The Gait Up GO Mobile application provides guidance to the users on how and where to place the Physilog6 sensor device on the Participant's body (see section 4 for further details)

2 Physilog6 sensor device

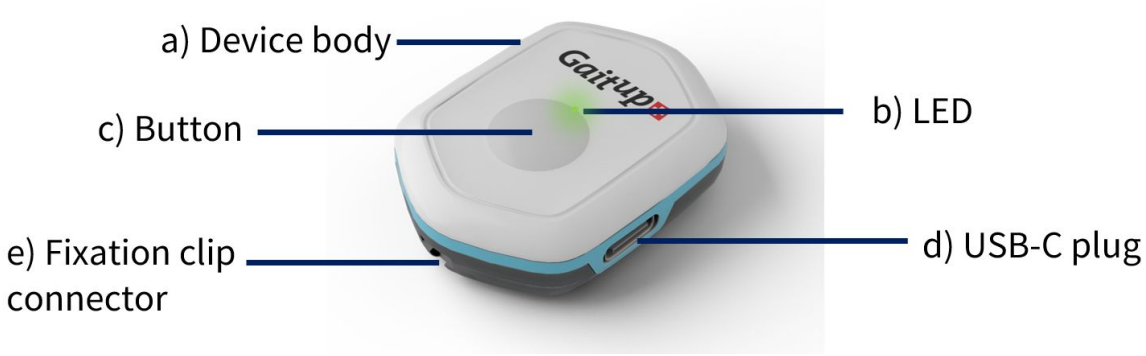


Fig 3. Physilog 6 sensor

Physilog 6 sensor device is an accessory of the Gait Up GO medical device intended to measure human movement parameters such as acceleration, orientation and angular velocity, barometric pressure and direction, strength and relative change of a magnetic field.

The Physilog6 sensor device is operated via the Gait Up GO mobile application to perform the following actions:

- Connect the sensor device to the phone/tablet via BLE
- Stream raw data of human movement to the Gait Up GO mobile application
- Disconnect the sensor device from the phone/tablet via BLE

The Physilog6 sensor device has a function called "shake up to wake up". After 30 seconds of no activity (i.e. sensor device not moving and not connected to the Mobile Application), the Physilog6 goes into stand-by mode. By lightly shaking the device, the BLE turns on and the sensor device and the mobile application automatically connect over Bluetooth.

The Physilog6 accessory device is composed of:

Component	Function
a) Body of the device	It includes a moulded non-flammable ABS casing which embeds the electronics and the battery of the Physilog6 sensor device. The electronics are composed of a microcontroller with a wireless communication unit that transmits bidirectional information between the device and the mobile phone/tablet, the sensors (IMU, magnetometer and barometer), a power management circuitry, a flash memory, a LED, a button, a beeper, a RF ISM ceramic antenna and a safety circuitry. The sensor device is powered by an internal LIB battery (lithium-ion battery), which is IEC 62133:2012 certified. The Physilog6 sensor device is water and dustproof according to the standard IP64.
b) LED	It emits light indicating the different status of the sensor device; ● Charging ○ Blinking white ● Charged ○ Shining green ● Errors: ○ Blinking red: ■ Not enough battery to start a recording ■ Cannot start a recording ■ Error during a recording ■ Hardware part broken ● Recording ○ Blinking green ● Warnings: ○ Blinking yellow ■ Battery starting to be low during recording
c) Button	The button serves to perform a reset of the device in case it is not responding normally. See section 6. Troubleshooting for more information.
d) USB-C plug	It allows the users and end-users to plug the USB cable included in the device packaging on the one end to the Physilog6 sensor device and on the other end either to a computer or to a compatible mobile phone charger (see specifications on section 9 of the present document) for charging purposes.
e) Mechanical connector for the fixation clips	Mechanical design feature included in the Physilog6 casing and used to fit mechanically the fixation clips into the body of the Physilog6 sensor device. The feature is symmetrically present on both extremities of the Physilog6 casing.

Table 3. Physilog6 sensor components

3 Fixation clips and belt strap

Made out of Acrylonitrile Butadiene Styrene (ABS) for medical applications, both the fixation clip for the belt (using the strap) and for the shoe are used to securely attach the Physilog6 sensor device to the Participant's body.

a) Shoe lace clip b) Belt clip and strap

Fig 4. Fixation clip accessories

4 USB cable

USB-A to USB-C cable, included in the Gait Up GO medical device packaging, is used to charge the battery of the Physilog6 sensor device by connecting it to a computer or to a mobile phone charger compatible with the specifications set under section 9 of the present document.

5 Device case

Primary packaging in which the Gait Up GO medical device components are delivered. The device components should be kept in this original packaging when not used, positioned in the correspondent slots as they were delivered originally.

3.3 User indicators

3.3.1 Visual user indicators related to battery charging

White blinks

- Device charging

Green shines

- Device fully charged

Red shines

- Error

blinking

shining

3.3.2 Visual and auditory indicators related to the operation of the device

Physilog6 sensor device visual and auditory indicators

Red blinks

- Not enough battery to start recording
- Cannot start recording
- Hardware part broken

Green blinks

- Recording

Yellow blinks

- Battery starting to be low during recording

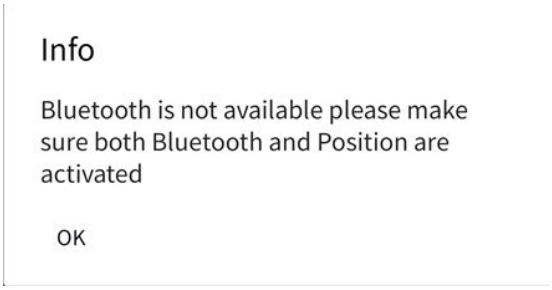
3 Orange blinks and 1 bip

- Reset

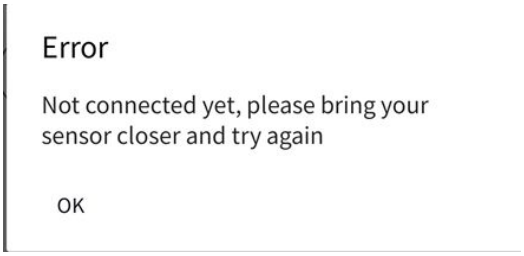
Light indicators		Acoustic indicators
blinking	*shining*	*bip*

Gait Up GO mobile application visual indicators

1. Information messages



2. Error messages



3. Confirmation messages

4. Use

Please, refer to section 1. Safety Information.

4.1. Overview

Gait Up GO medical device enables the recording and analysis of some protocolarized motion tests to assist in the assessment of:

1. the condition of patients suffering from motor disorders and to understand the impact of treatments and/ or rehabilitation therapies used on patients.
2. risk of suffering an injury in professional athletes of any age.
3. indicators of early-stage signs of diseases affecting motor function in Participants.

A number of tests are contained in the Gait Up GO Mobile Application, categorised as:

- Functional tests
    - Jump tests
    - 5 sit-to-stand test
    - Timed up and GO (TUG) tests
- Balance tests
- Walk tests
- Running tests

Inside each category of tests, there are specific tests contained. As an example “two-legged balance test” is a test contained inside the “Balance tests” category.

- The Medical Professional evaluates the condition of the Participant, especially in consideration of the warnings and cautions. Then, the Medical Professional choses in the Gait Up GO Mobile Application the test or set of tests for the Participant to perform.
- The Medical Professional places the Physilog6 sensor accessory on the Participant’s body following the indications provided by the Mobile Application.
- The Participant attempts to perform the indicated movements by the screen of the Mobile Application.
- The Participant performs the test under the supervision of a Medical Professional
- Once the Participant has finalized the test, the Medical Professional generates a Test Report directly from the Mobile Application. The data shown in the test report is to be interpreted by the Medical Professional.
- The Medical Professional can prescribe the Participant to perform a test or a set of tests at home. The Participant will have access to a restricted mode of the Mobile Application, where just the prescribed tests can be accessed. Under some circumstances, the Medical Professional can allow the Participant to generate Test Reports. However, the interpretation of those results must always be done by the Medical Professional.

4.2. Included tests and their indications

4.2.1. Functional tests

Jump tests

Vertical jumps are commonly used to measure lower body power and indirectly assess an athlete's performance or to evaluate return to sports after an injury (ankle sprain or anterior cruciate ligament reconstruction). Gait Up GO includes two assessments of jumps: Two legged vertical Jump test (Sargent test) and single leg vertical Hop test. For the jump tests the sensor is worn at the belt and the test subject is asked to jump vertically with either both legs or one leg at a time. To obtain repeatable results, the test should be performed in the same way (use of arms).

5 sit-to-stand tests

The five times sit to stand test is used to assess lower extremity strength, translational movements, balance and risk of fall. It is commonly used for elderly people and patients with Parkinson, having suffered a stroke or with vestibular disorders. To obtain repeatable results, the same chair should be used. The Physilog6 sensor is worn at the belt.

TUG tests

The Timed Up and Go test (TUG) is a simple test used to assess a person's mobility and evaluates both static and dynamic balance. It is used to determine risk of fall and measure the progress of balance, sit to stand and walking. The TUG is used frequently in the elderly population or in populations with a reduced mobility. The Gait Up GO device includes two TUG tests, one standard and one for double-task TUG. For the TUG tests, the sensor is worn at the belt. To obtain repeatable results, the same chair should be used.

4.2.2. Balance tests

The static balance assessment allows to evaluate the risk of falling. It can be used with all end users for which Gait Up GO is indicated. Gait Up GO includes six different balance tests: two-legged balance test, single leg balance test, one-legged balance comparison test, tandem test, semi-tandem test and Romberg test. Balance tests do not require any additional equipment. The Physilog6 sensor is worn at the belt.

4.2.3. Walk tests

Gait Up GO includes three walking tests, the 2 minute walk test, the 10 meter walk test and a free walk test. For all three, the sensor is worn on one foot. Gait tests can be performed with all end users for which Gait Up GO is indicated.

The 2 minute walk test is a measure of self-paced walking ability and endurance. It has been shown to yield results that are concurrent with the 6 minute walk test and has the advantage of being shorter.

The 10 meter walk test is a performance measure used to assess walking speed which can be used to assess functional mobility and gait. For the 10 meter walk test requires a path which allows to walk in a straight line for 10 meters.

The free gait test allows the therapist to perform his or her preferred walking protocol.

Gait tests should be performed on flat ground.

4.2.4. Running tests

The Gait Up GO application includes two running tests, the “Running strike profile” test where the sensor is worn on one foot is used to evaluate the runner profile. The “Running stiffness and impact” test uses the sensor at the belt and provides measurements of impact and stiffness which are useful to assess injury risk and fatigue.

The runnings test allows the therapist to perform his or her preferred protocol for healthy or injured runners. Running tests can be performed on a treadmill or on flat ground.

4.3. Installing and starting the device

The Gait Up GO application can be downloaded for Apple and Android mobile phones and tablets. No mobile phone or tablet is delivered with the product. The mobile device must meet the requirements described in section 9 under mobile specifications.

4.3.1. Installation and launching of the Gait Up GO Mobile Application on Android devices

- Open the Google Play Store
- Search for “Gait Up GO”
- Select “Gait Up GO” Mobile Application
- Tap Install (Note: “Gait Up GO” Mobile Application is free)
- Follow the onscreen instructions to complete the installation process
- Select and launch the Gait Up GO Mobile Application by tapping on the Gait Up GO logo on the Home Screen of the mobile phone/tablet device.

4.3.2. Installation and launching of Gait Up GO Mobile Application on iOS devices

- Open the App Store
- Search for “Gait Up GO”
- Select “Gait Up GO” Mobile Application
- Tap Install (Note: “Gait Up GO” Mobile Application is free)
- Follow the onscreen instructions to complete the installation process
- Select and launch the Gait Up GO Mobile Application by tapping on the Gait Up GO logo on the Home Screen of the mobile phone/tablet device.

NOTE: If you use Gait Up GO medical device for the first time, enable the Bluetooth connection from the Mobile Phone and/or Tablet options.

NOTE: In order to enable updates, the mobile phone/tablet needs to be connected to the Internet by using WiFi or mobile data.

NOTE: In order to login to the password protected part and generate reports, the Gait Up GO Mobile Application needs to be connected to the Internet by using WiFi or mobile data.

4.3.3. Discover the Physilog®6 sensor device

Fig 5. Physilog6 sensor device inside its packaging

- Open the packaging delivered together with the Gait Up GO medical device
- Take the Physilog6 sensor device and the USB cable out from the packaging
- Connect the USB cable (USB-C side) to the Physilog6 sensor device
- Connect the USB-A part of the USB cable to a computer or to a mobile phone charger compatible with the specifications listed in section 9 of the present document
- Make sure that the Physilog6 sensor device is fully charged (when battery charging is complete, the LED on the Physilog6 sensor device body will shine green)
- When the charging is complete, the device is ready to be used.

Charging of the Physilog®6 sensor device

The Physilog6 sensor device is a wearable sensor powered by a Lithium-Ion rechargeable battery. It is not possible to recharge the battery during the device operation. That is why, please check the battery

level of the Physilog6 sensor device on the Gait Up GO Mobile Application screen before starting any test (see section 4.5.5).

- Plug one end of the USB cable (USB-C end) into the Physilog6 sensor device USB-C port.
- Plug the USB-A end of the UCB cable into a computer or a mobile phone charger with specifications compatible to the ones listed under section 9 of the present document,
- During charging, the LED on the Physilog6 sensor device emits a blinking white light, even when the sensor device is not connected to the Mobile Application.
- When the charging is complete, the LED on the Physilog6 sensor device will shine green and the battery level shown in the Gait Up GO Mobile Application will appear as full.

It is important to charge the Physilog6 sensor device for at least 4 hours before an assessment session is started.

Note: It is recommended to charge the Physilog6 sensor device at the end of each session.

Note: Use only the USB cable provided by the manufacturer.

Note: Use only mobile phone chargers with specifications compatible to the ones provided by the manufacturer in section 9 of the present document.

Note: Please, in order to keep the performance of the device, recharge the battery of the device every 3 months if it is stored and not used

4.3.4 Checking system components and their functionality

- Visually inspect all the components of Gait Up GO medical device (Mobile phone/tablet, Physilog6 sensor device, clip accessories and USB cable) for signs of damage, especially in correspondence of connectors, primary packaging (casing) where the Physilog6 sensor device and the clip accessories are contained.
  Note: In case of lack of integrity of one or more components of the Gait Up GO medical device, please immediately contact the customer support.
- Clean the Physilog6 sensor device and the clip accessories before using the device. See section 5. Cleaning, Maintenance and Storage of the present document.
- Make sure that the Mobile Phone/Tablet is fully charged before starting an assessment session.
- Make sure that the Physilog6 sensor device is fully charged before starting an assessment session.
- Do not operate the device while the Physilog6 sensor device is being charged.
- Open the Gait Up GO Mobile Application and connect it to the relevant Physilog 6 sensor device. Check that there are no connection issues. Refer to the section 4.4.2 of the present document for more information.
- Position the sensor device into the clip accessories and check that the Physilog6 sensor device is firmly attached to the clip.

  Note: In case of BLE connection issues, please contact the customer support.

4.4 First use of the device

4.4.1 Login creation

Select “Sign Up” and complete the registration (only for medical professionals). The account allows to access the password protected part of the application where the medical professional can set configurations, manage Participant profiles, select tests for a Participant, buy credits and access reports. In order to use the Gait Up GO medical device, a medical professional is required to configure the mobile application for the Participant.

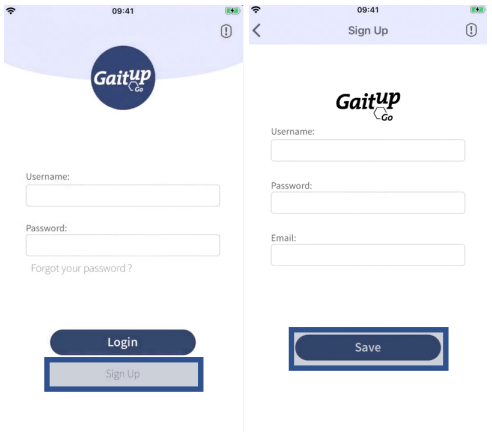


Fig 6. How to register in the application - iOS

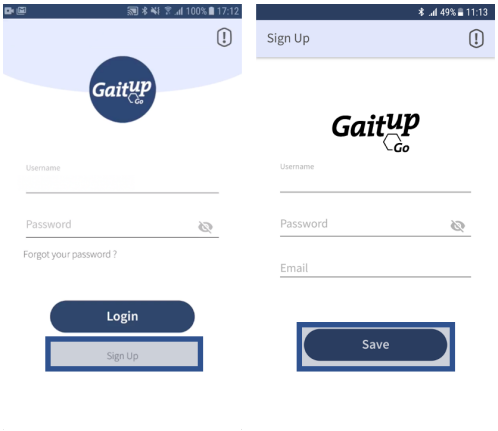


Fig 7. How to register in the application - Android

4.4.2 Pairing Physilog 6 to the Gait Up GO Mobile Application

The Gait Up GO mobile application requires to be connected to a Physilog6 sensor device accessory which is worn by the Participant and collects the data during the tests. The sensor to which the mobile application connects, needs to be set once at the beginning of the use. For all next uses with the same mobile phone / tablet and Physilog6 sensor device, the connection is automatically done.

After you login for the first time, the following screen will be displayed:

Fig 8. Physilog section after the first connection to the application - iOS/Android

Check the serial number of the Physilog®6 sensor device on the device label located on the back of the sensor. Serial numbers have the following format: PHY-06-2020-01-NNNN

Fig 9. Physilog label with the serial number surrounded by blue and
the four unique numbers to enter in the Gait Up GO mobile application
surrounded by red

In the text field appearing on the Mobile Application screen, introduce the last four numbers (NNNN), then click on “Link” in order to pair the device. A pop up with a confirmation should appear after the device is paired.

NOTE: the Bluetooth of the mobile phone / tablet needs to be activated. For mobile devices/tablets operating with Android OS, the localisation must in addition be activated to be able to use Bluetooth low energy. The Gait Up GO application does not access your localisation information.

NOTE: to “wake up” the Physilog6 sensor from stand-by mode when it is not connected, lightly shake the device to turn on its BLE (“shake up to wake up”).

NOTE: Using the “Purchase Physilog” button it is also possible to visit the Gait Up webshop in order to buy a Physilog6 sensor device. In order to be able to use the Gait Up GO medical device, it is necessary to have one Physilog6 sensor.

4.5. Normal use of the device

4.5.1. Login

Open the Gait Up GO Mobile Application from the installed applications on the mobile phone / tablet. When no session is open, the login screen is displayed. The login allows the medical professional user to access the password protected part of the Gait Up GO mobile application where it is possible to set configurations, manage Participant profiles, select tests for a Participant, buy credits and access reports. To know how to sign up for an account, see section 4.4.1.

To login with your account, follow the steps mentioned below:

Fig 10a. Login page - iOS

Fig 10b. Login page - Android

Enter the username and password (only for medical professionals) and select “Login”.

NOTE: In order to be able to verify the login, the Gait Up GO mobile application needs to be connected to the internet via Wifi or mobile data.

4.5.2. Forgot password

If you cannot remember the password you set in your previously created account, it is possible to reset it by selecting “Forgot your password” and following the instructions below.

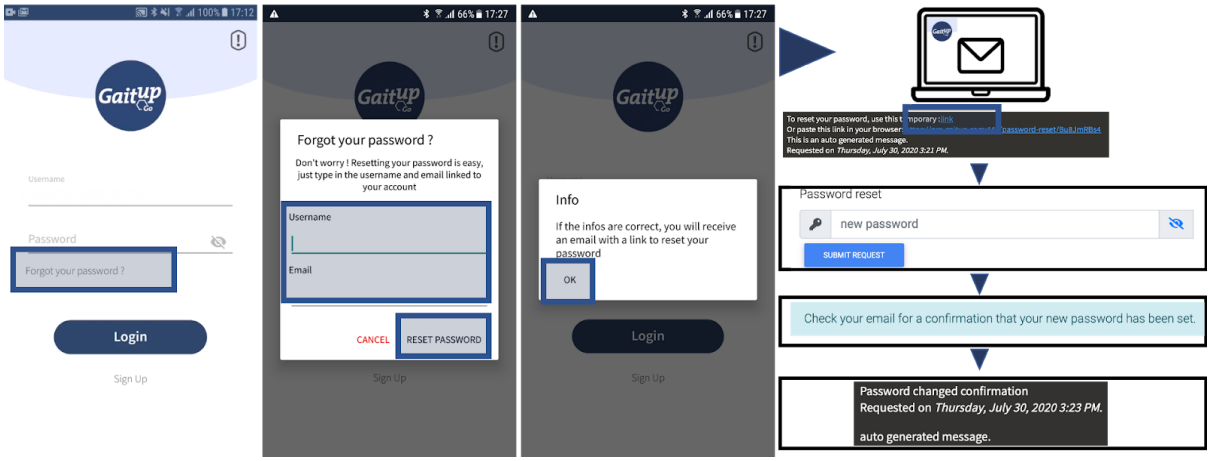


Fig 11. How to reset the password - iOS - Android

After sending the password reset request, a message will be sent to your email. Inside the email, there is a link which allows you to open a webpage where a new password can be entered. After submitting the new password, it is possible to connect to the Gait Up GO mobile application by using this newly defined password. The reset link is valid only once and for a limited period of time, after its expiration a new link must be requested by filling out the “forgot password” form inside the Gait Up GO mobile application again.

NOTE: In order to reset the password, the Gait Up GO Mobile Application needs to be connected to the Internet by using WiFi or mobile data.

4.5.3. Add / Select / Edit / Delete participant profiles

- All the data, user data and reports are stored locally. If the phone memory is reset all information in the application will be deleted permanently.

- The Gait Up GO application only saves the data in the phone memory, the Gait Up GO application does not save / upload any Participant data on a server.
- The phone is not meant to serve as permanent storage for Participant data, the data must be transferred to the Medical Professional's computer.
- Uninstalling the Gait Up GO mobile application deletes all data permanently. Do not clear the cache and data related to the Gait Up GO mobile application, as this will also delete all collected data permanently.

Inside the password protected part of the Gait Up GO mobile application which is reserved for medical professionals, it is possible to manage the Participant profiles.

The “Dashboard” displays the list of available profiles including the name of the Participant, amount of reports generated and tests performed with the profile and the date of the last performed test. It shows the currently available amount of credits at the bottom of the screen.

From the dashboard it is possible to add new participants, search for a particular participant and select a profile from the list. The general settings can also be accessed from the Dashboard screen (see section 4.5.4 for information about the available settings).

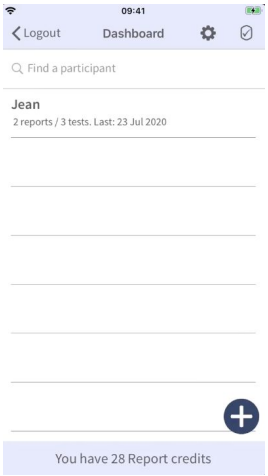


Fig 12. Dashboard - iOS

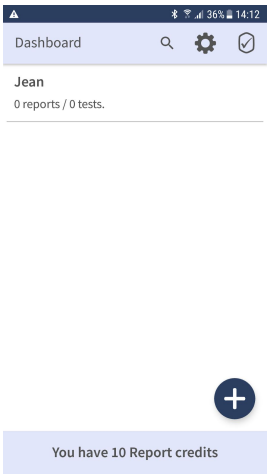


Fig 13. Dashboard - Android

Add new participant

To add a new participant, press the “plus” button in the right bottom corner.

Fig 14. Add a participant from the dashboard -iOS

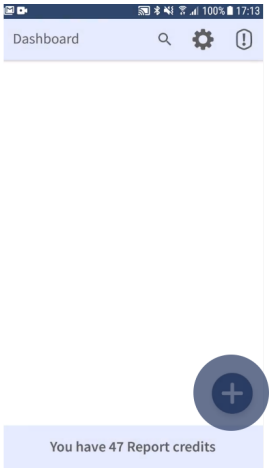


Fig 15. Add a participant from the dashboard -Android

The participant profile consists of the following information: name, gender, birth year, size, weight, health condition, walking aid needs and history of falling. For the “health condition” several pathologies are available for selection, for all conditions which are not specified, “other” can be used. According to the participant profile, the normative data on the reports is adapted.

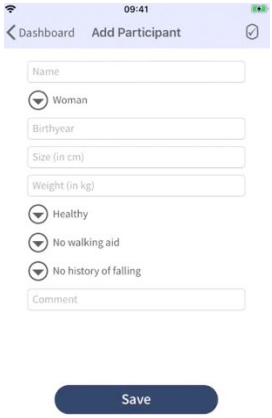


Fig 16. Add participant section - iOS

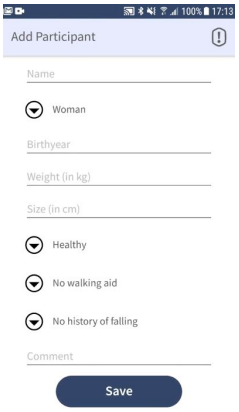


Fig 17. Add participant section - Android

Comments can be added to complete the participant profile, such as type of walking aid or pathology if the condition is not available in the list. The comment will be visible on the reports.

The newly created profile is saved by clicking on « Save ». A text box will appear to confirm that the participant has been correctly saved in the dashboard list.

NOTE: Please be aware of the Participant conditions which present risk factors for using Gait Up GO. Please, refer to section 1. for device safety related information.

NOTE: All participant data is locally stored on the mobile phone / tablet where the Gait Up GO mobile application is installed. The legal manufacturer and commercialising party do not have access to any participant information entered in the Gait Up GO mobile application.

After saving, the new participant will appear in the “Dashboard”.

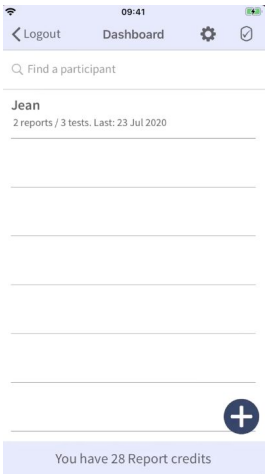


Fig 18. New participant saved - iOS

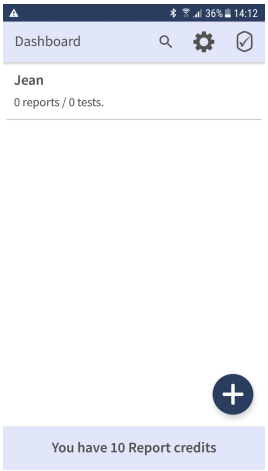


Fig 19. New participant saved -Android

Find a Participant in the list

When there are several Participant profiles saved in the Gait Up GO mobile application, it can become difficult to find a specific one by scrolling through the list. A “Search field” is available on the Dashboard screen to filter the list and make it easier to find a Participant.

The search field filters the list according to the name indicated in the Participant profiles. The filter identifies all profiles which contain the entered search term in the Participant name.

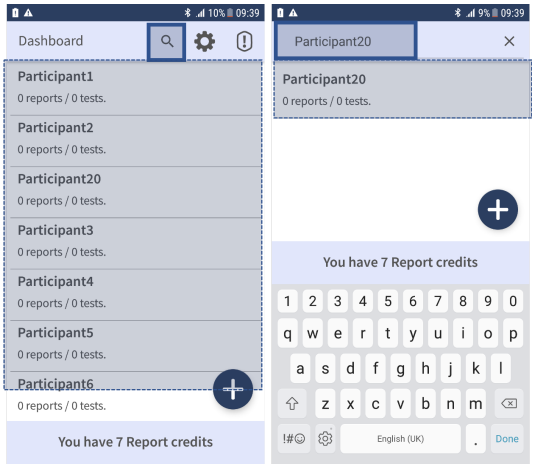


Fig 20. Find a participant in the list - Android

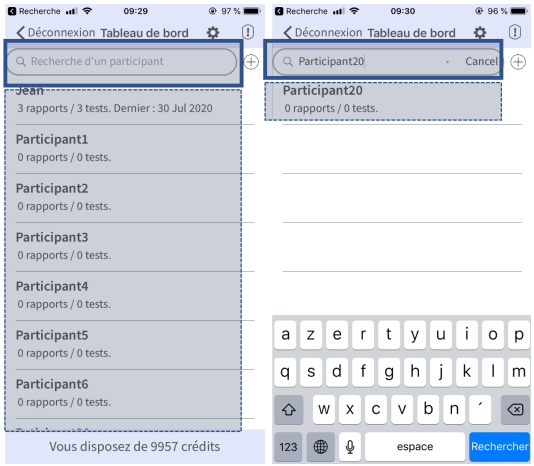


Fig 21. Find a participant in the list - iOS

Select a Participant

To select a Participant, click on the corresponding name in the list on the Dashboard screen. When a participant is selected from the “Dashboard”, the participant profile will appear on the screen. The profile includes all the information previously introduced.

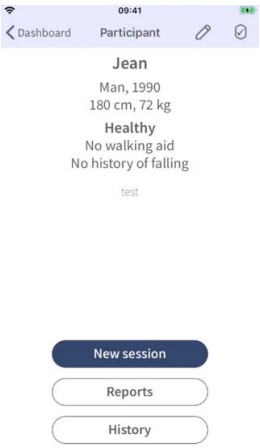


Fig 22. Participant profile - iOS

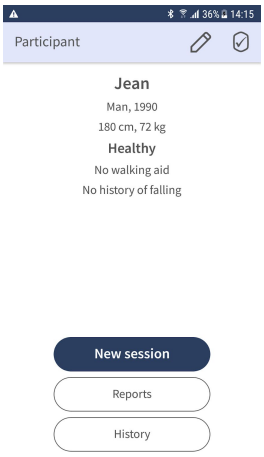


Fig 23. Participant profile - Android

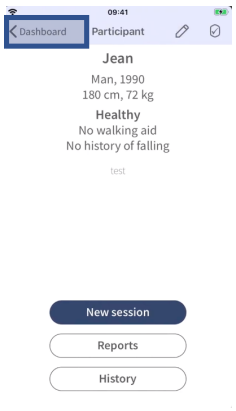
In the participant profile screen the following options can be selected:

-Start a “New session” (see section 4.5.6)

-Check the “Reports” associated to this participant (see section 4.5.8)

-“History” of this participant (see section 4.5.9)

To change participants and/or register a new participant, go back to the dashboard and select an already existing profile or tap “Add Participant” (see section 4.5.3).



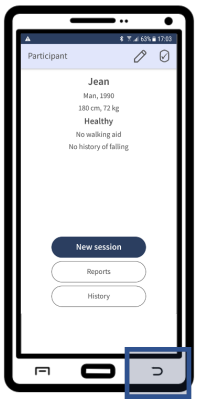


Fig 24. How to go back to the dashboard - iOS Fig 25. How to go back to the dashboard - Android

Edit a Participant

To edit the selected participant’s information, tap on the pen icon( ). The Participant edition screen is composed of three sections, the first section allows to modify the participant profile information. The second section allows assigning tests to the participant. It is the responsibility of the medical professional to select the appropriate tests for each Participant. The last section is for deleting a Participant profile (see next subsection).

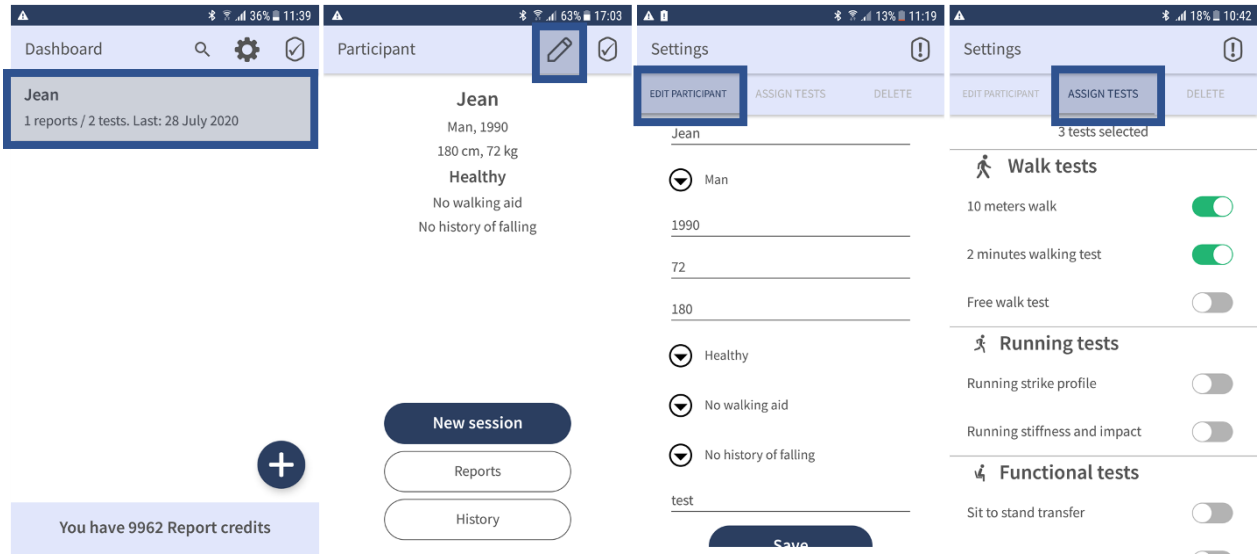


Fig 26. How to edit a Participant profile and the test(s) assigned - Android

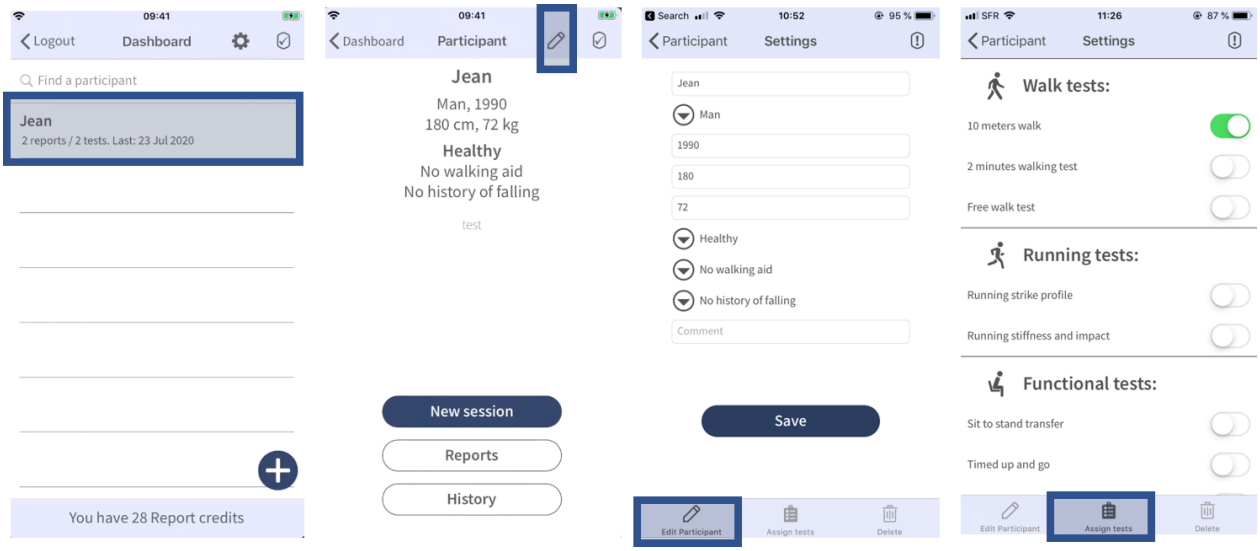


Fig 27. How to edit a Participant profile and test(s) assigned - iOS

Delete a Participant

Deleting a Participant profile deletes all associated data such as Participant information, performed tests, generated reports and history reports. Because all data is saved locally on the mobile phone / tablet it is not possible to recover deleted data.

A Participant can be deleted from the Participant profile editing part of the application, by opening the third section called “Delete”. On iOS clicking on this tab will automatically ask for a deletion confirmation whereas on Android it is necessary to press on the trash button (Delete) in this section.

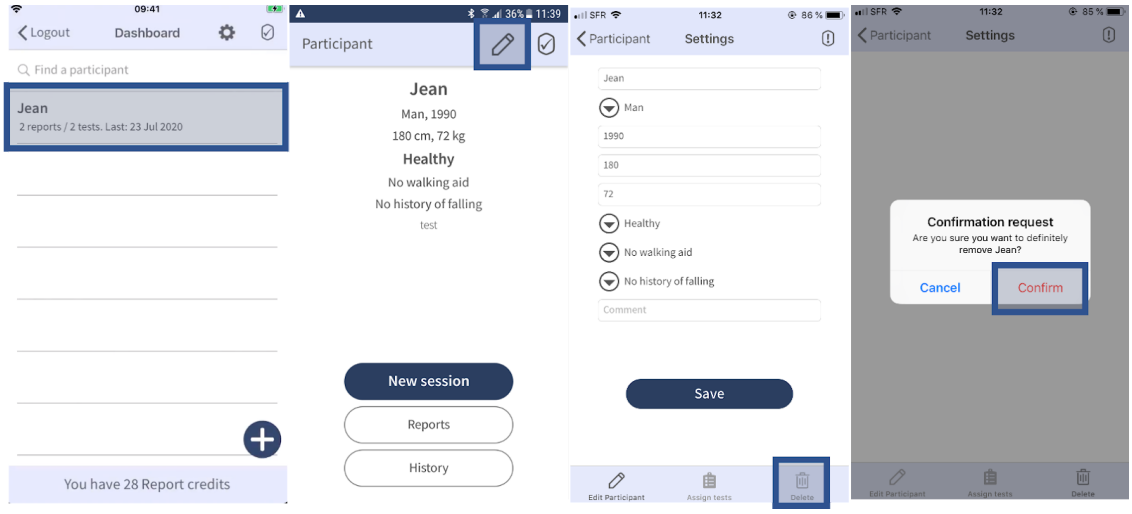


Fig 28. How to delete a participant - iOS

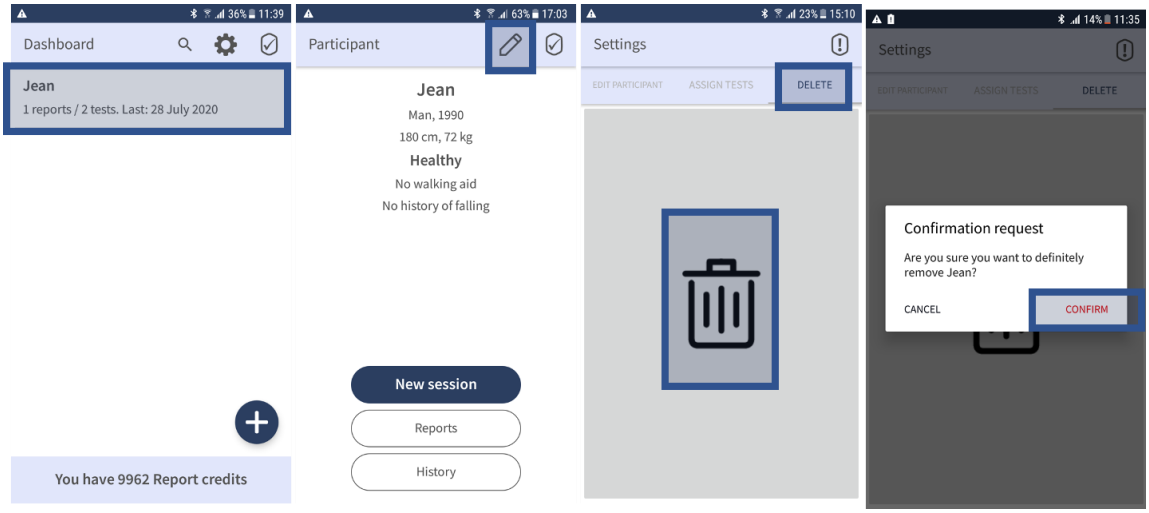


Fig 29. How to delete a participant - Android

It is also possible to delete a participant directly from the list of participants on the dashboard. To do so, slide the participant towards the left or right side of the screen and confirm the deletion.

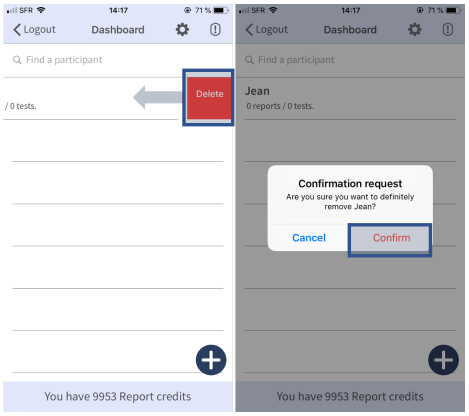


Fig 30. How to delete a participant from the dashboard- iOS

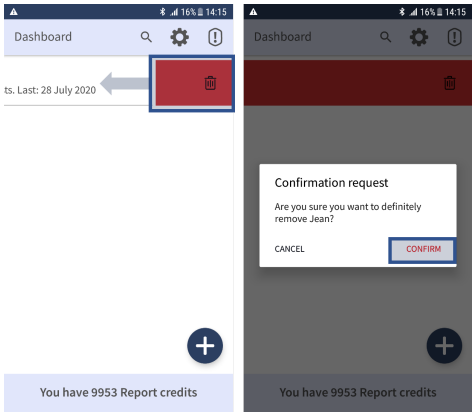


Fig 31. How to delete a participant from the dashboard- Android

4.5.4. General settings

Inside the password protected part of the Gait Up GO mobile application, the medical professional user can modify available settings. The General settings are available from the Dashboard screen.

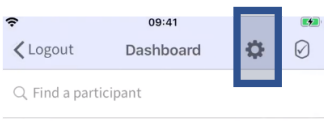


Fig 32. Settings button - iOS

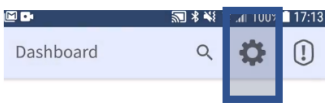


Fig 33. Settings button - Android

The settings screen is composed by 4 screens, each one and the linked functionalities are explained below:

Credits

The Credits ( ) screen allows to: see, on the one hand, the current availability of credits and, on the other hand, purchase a new pack of credits or request an unlimited license.

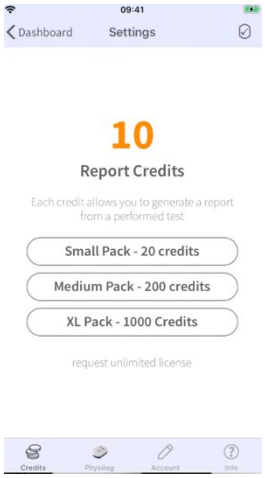


Fig 34. Credit section - iOS

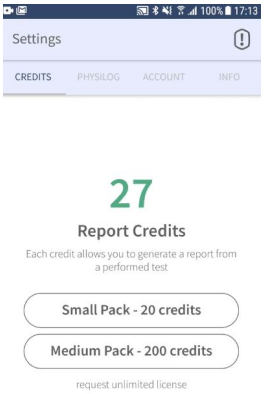


Fig 35. Credit section - Android

Report credits are used to generate a report from a performed test. Each credit is giving access to one report. Credits are bought via Google Play Store (Android) or App Store (iOS) from inside the Gait Up GO mobile application. Once the purchase has been successfully completed, the credits will be available immediately.

Credits are available in different pack options:

- Small pack – 20 credits
- Medium pack 200 credits
- XL pack 1000 credits (on iOS only).

NOTE: In order to be able to purchase credits, the Gait Up GO Mobile Application needs to be connected to the Internet by using WiFi or mobile data.

For frequent users of Gait Up GO with a high amount of generated reports, it is possible to request an unlimited license from the Gait Up SA sales team. The unlimited license gives the medical professional users access to generating as many reports as desired for a fixed price during one year. Unlimited licenses cannot be purchased from the app. Under the option “request unlimited license” on the Credits screen, the request is submitted directly to the Gait Up SA Sales team.

Physilog

The Physilog section is used to link the Physilog6 sensor device to the Gait Up GO Mobile Application. The linked Physilog6 is saved for all logins of the Gait Up GO mobile application on the same phone. This means if the phone is used with two medical professional accounts, the linked Physilog6 is the same for both of them.

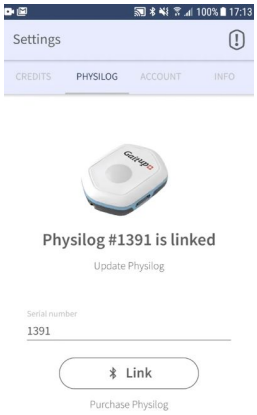


Fig 36. Physilog section - iOS Fig 37. Physilog section - Android

To change the linked Physilog6, check the serial number of your device on its backside (see Fig. 38 below). The serial number has the format PHY-06-2020-01-NNNN. Only the last four numbers (NNNN) need to be written in the serial number field appearing on the Mobile Application screen. Click on " Link " in order to pair the device. A pop up with a confirmation should appear after the device is paired.

NOTE: Both devices can only be paired if the Bluetooth of the Mobile Phone/Tablet is enabled.

NOTE: to "wake up" the Physilog6 sensor from stand-by mode when it is not connected, lightly shake the device to turn on its BLE ("shake up to wake up").

Fig 38. Physilog label with the serial number surrounded by blue and the four unique numbers to enter in the Gait Up GO mobile application surrounded by red

If the Physilog6 sensor device's firmware is not up to date, the Physilog screen shows the "Update Physilog" button below the image of the sensor. See section 4.5.5 below to know more about the Physilog6 sensor device's firmware update.

Using the "Purchase Physilog" button it is also possible to visit the Gait Up webshop in order to buy an additional Physilog6 sensor device. The Gait Up GO medical device uses a single Physilog6 accessory device.

A Participant must not wear more than one Physilog6 accessory on the body at the same time. Do not operate several Gait Up GO on the same Participant at the same time.

Account

The Account section (Account) allows to change the current password and gives the medical professional the possibility to select the unit system.

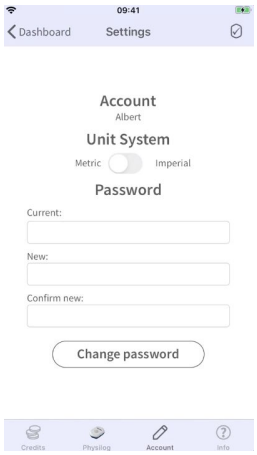


Fig 39. Account section - iOS

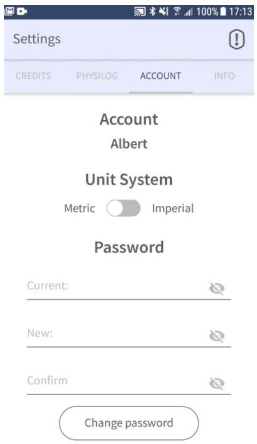


Fig 40. Account section - Android

In order to change the password, it is necessary to enter the current password, then write the new password and confirm it by writing it a second time. The password change is applied immediately after pressing the “Change password” button. The password is associated with the medical professional user account, applying to all mobile devices/tablets in which the respective user account is used.

NOTE: In order to change the password, the Gait Up GO Mobile Application needs to be connected to the Internet by using WiFi or mobile data.

In addition it is possible to select the preferred unit system between metric and imperial units. All data collected before changing the unit system will be converted to the selected units.

Info

The information screen (Info) displays all information about the Gait Up GO medical device, legal manufacturer, designer, regulatory labelling and version of the Gait Up GO mobile application. It also provides a direct link to the “Help/FAQ” webpage and the medical device eIFU and eQSG.

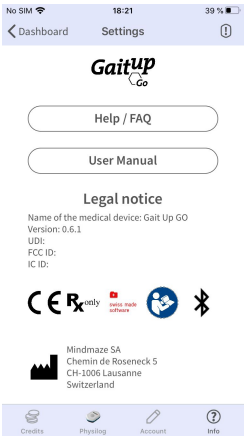


Fig 41. Info section - iOS

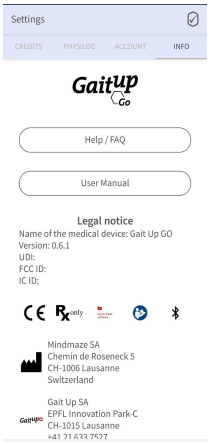


Fig 42. Info section - Android

4.5.5. Sensor information and update

Physilog6 sensor connection status is displayed by the sensor icon ( ). The sensor icon is visible in the top right corner of the Gait Up GO mobile application on most screens.

After opening, the Gait Up GO mobile application automatically connects to the Physilog6 sensor which is linked to the application by the user during first use. In order to perform a test, the sensor needs to be connected to the Gait Up GO mobile application.

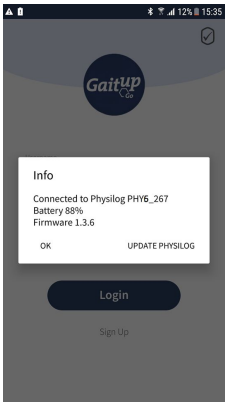


Fig 43.Physilog connected Fig 44. Physilog not connected Fig 45. Physilog information/update

When the sensor is connected, it is possible to access some information about the Physilog6 sensor device:

- Physilog status (connected - trying to connect - charging)
- Battery level percentage

- Firmware version

In case of problems with the sensor connection, refer to the troubleshooting section 7. If the issue persists, contact Gait Up support at support@gaitup.com

To be able to use the Gait Up GO medical device, the firmware of the Physilog6 sensor needs to be at the latest version. Physilog6 can be updated from the Gait Up GO application. In case the Physilog6 sensor firmware is not up to date with the Gait Up GO mobile application version, the sensor information window will include a button named “Update Physilog”. To update the sensor, press the “Update Physilog” button in the sensor information window or go to the “Physilog” screen (Physilog) in the General settings ( ) of the Gait Up GO mobile application and press the “Update Physilog” button (login required).

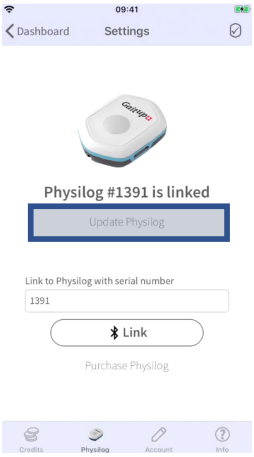


Fig 46. Update Physilog - iOS - Android

After pressing “Update Physilog”, the Physilog sensor will be updated automatically. The Gait Up GO mobile application displays the progress of the updating process. Do not close the Gait Up GO mobile application or inactivate the Bluetooth of the mobile phone/tablet during the update of the sensor.

NOTE: In order to enable updates, the mobile phone/tablet needs to be connected to the Internet by using WiFi or mobile data.

The Gait Up GO device only works with the Physilog6 sensor which is medical-grade and certified as an accessory for Gait Up GO. In case you have purchased a different version of Physilog (commercial grade version) from Gait Up SA device portfolio, please contact the customer service at support@gaitup.com.

4.5.6. Prepare an assessment session

From the dashboard, select the Participant for which an assessment session should be started and click on “New session” as shown on the picture below.

NOTE: If you use Gait Up GO on different mobile phones / tablets and have several Physilog6 sensor devices, it is recommended to control that the correct Physilog6 sensor device is linked to the Gait Up GO mobile application before starting the assessment session. Once the session is started, the linked Physilog6 can only be modified after login into the password protected part of the mobile application again. To check the linked Physilog6, click on the button in the top right corner ( ) and check that the indicated serial number is corresponding to the serial number of your Physilog6. To change the linked Physilog6, go back to the Dashboard and open the "General settings" (see section 4.5.4).

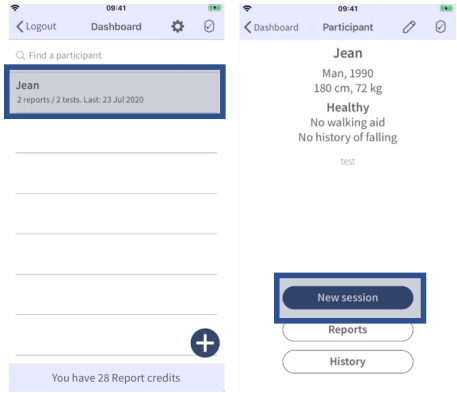


Fig 47. How to start an assessment - iOS

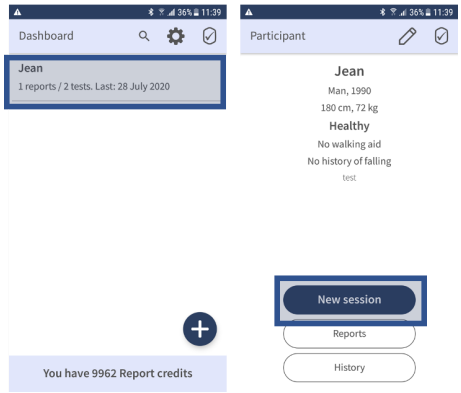


Fig 48. How to start an assessment - Android

Assign tests

By selecting "New session" the "Assign tests" section will appear. This section allows to activate or inactivate the tests that the subject can perform during the next session.

NOTE: It is the responsibility of the medical professional to select safe and appropriate tests for each participant and their condition.

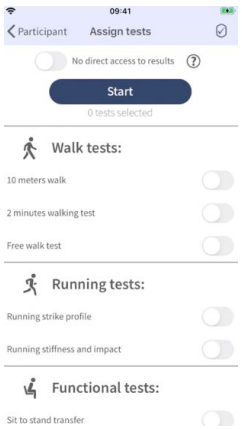


Fig 49. Assign tests - iOS

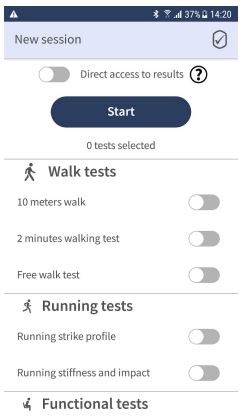


Fig 50. Assign tests - Android

Limited admin mode

While preparing the new session, the Medical Professional can select if the direct access to results is allowed or not.

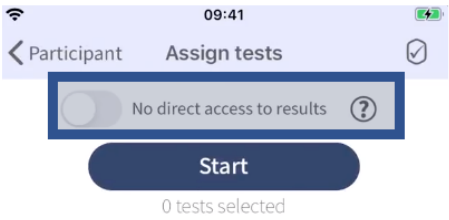


Fig 51. No direct access to results selected

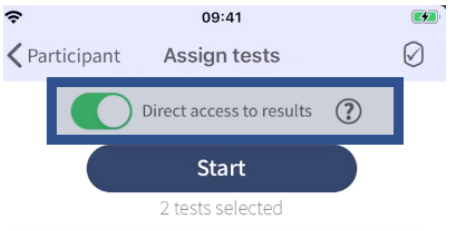


Fig 52. Direct access to results selected

-If "Direct access to results" is activated (limited admin mode), it will be possible to spend credits and access a report directly after the end of a test. It is suggested to use this option when performing tests during sessions where the medical professional is present to simplify access to the result. If the Participant is meant to use the medical device without the physical presence of the medical professional, it is recommended to disable this option. However, under certain circumstances, the medical professional may want the Participant to be able to generate reports on his/her own. In this case, the option "Direct access to results" should be enabled. The use of the device must always be supervised by a medical professional. The interpretation of such reports must always be done by a medical professional. Be aware that the Participant will be allowed to spend credits from your account if "Direct access to results" is activated. This option is called limited admin mode because it gives the user access to some functionalities usually reserved for the medical professionals.

-If "No direct access to results" is written, it will not be possible to spend credits and access a report directly after the completion of a test. The results will be locally saved and the report can be generated later by the medical professional.

Assessment session screen

After pressing the "Start" button, the Gait Up GO mobile application enters an assessment session. The assessment session is associated with the Participant profile from which the session was started and allows to perform the tests assigned by the medical professional to this participant.

For those Participants who do not have access to the password protected part of the Gait Up GO mobile application, this is the initial screen that they will have access to.

Fig 53. Activated tests appear in the participant's test list - iOS

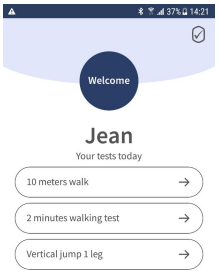


Fig 54. Activated reports appear in the participant's tests - Android

All assigned tests appear in the participant's test list. After a test is performed and saved, the corresponding test will be marked as completed for the day. However, the same test can still be performed several times during the same day always following the recommendations given by the medical professional. Each day at midnight, the list of performed tests will be reset and all tests will again be shown as not done.

Preparing the device for Home use by the participant

The participant can use the device at home to perform assessments in between therapy sessions or to have regular data points during long-term treatments. It is the medical professional's responsibility to configure the Gait Up GO medical device according to the capabilities and safety requirements for each Participant.

Before handing the device to the participant for home use, the medical professional should perform the following steps:

- **Install the Gait Up GO mobile application** on the mobile phone/tablet which the participant will take home and login with your medical professional account. Configure the Gait Up mobile application for the participant. (see sections 4.3 to 4.5.6)
- **Check the linked Physilog6** by clicking on the button in the top right corner. Check that the indicated serial number is corresponding to the serial number of the Physilog6 which is handed to the participant. To change the linked Physilog6, go back to the Dashboard and open the "General settings" (see section 4.5.4).
- **Check selected tests**: Verify that the tests selected for the participant are adapted for home use without your presence. Especially evaluate for each test if the participant can perform the test safely. It is recommended to only assign tests which the participant has already performed in your presence. (see section "Assign tests")
- **Check if direct access to reports is active or not**: for home use it is recommended to inactivate direct access to reports. This allows the medical professional to keep control of the credits and to avoid misinterpretation of the results by the Participant due to the absence of the interpretation by the medical professional. (see section "Limited Admin mode")
- **Start the Session** for the Participant who will use the device at home. When the Participant will open the Gait Up GO mobile application, the assessment session screen will be displayed.
- **Inform the Participant** (or the patient relative) about the frequency of performing the tests (f.ex. once every day or week) and how to take care of the Physilog6 sensor accessory. Provide the Participant (or patient relative, when applicable) the mobile phone/tablet, Physilog6 and instructions for use and Quick start Guide for Lay person.

4.5.7. Operating a test

Once the new session is started, the selected tests can be performed and the Gait Up GO mobile application can be operated either by a medical professional, by the Participant in presence of the medical professional or by the Participant or the patient relative at home without the presence of the medical professional. The result interpretation must however always be carried out by a medical professional.

Preparing the Participant

Before attaching the sensor device accessory to the Participant, please check the integrity of the skin in the area where the sensor will be placed. In case of redness or skin damage, do not fix the sensor on the Participant.

Make sure that the participant is wearing adequate shoes where the clip can be attached firmly and without heels.

Check Physilog6 sensor connection and battery level

Check that the Physilog6 is connected to the Gait Up GO mobile application and that it has a sufficient battery level. Check the sensor status by accessing the sensor information from the button in the top right corner as shown in Figure 40 below.

If the battery is lower than 25%, the Gait Up GO Mobile Application will not allow it to start any test. The battery level indicating the battery status of the connected Physilog6 sensor device on the Mobile Application Screen is shown in Figure 41.

NOTE: the Bluetooth of the mobile phone / tablet needs to be activated. For Android the localisation must in addition be activated to be able to use Bluetooth low energy. The Gait Up GO application does not access your localisation information.

NOTE: To “wake up” the Physilog6 sensor from stand-by mode when it is not connected, lightly shake the device to turn on its BLE (“shake up to wake up”).

NOTE: in case of any issue with Physilog6 connection, check the troubleshooting section 6. If problems persist, contact the Gait Up SA support team at support@gaitup.com.

Fig 55. Physilog linked

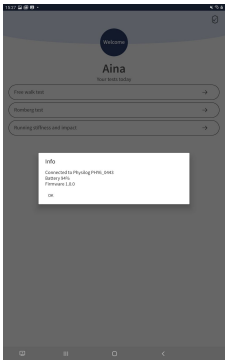


Fig 56. Physilog information

Select the test

Any of the tests displayed in the list of the participant for which the assessment session is open can be selected. Tests which were already performed during the same day are marked as completed but can be repeated.

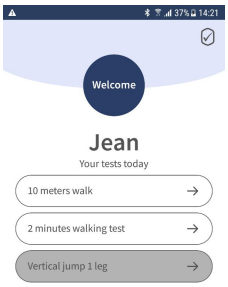
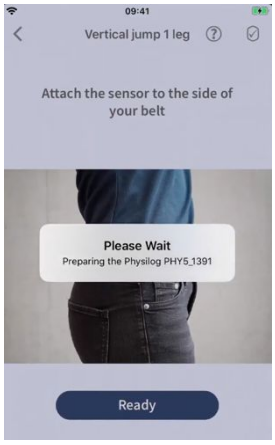


Fig 57. Vertical jump 1 leg test selection - iOS

Fig 58. Vertical jump 1 leg test selection - Android

After the test selection, the application is “Preparing the Physilog PHY6_NNNN”. If any issue is encountered in this part, check the troubleshooting section 6.



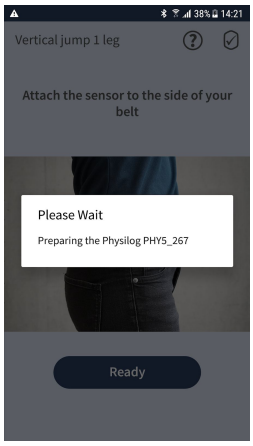


Fig 59. Sensor preparation before the test - iOS

Fig 60. Sensor preparation before the test - Android

Sensor attachment

Depending on the test choice, instructions and sensor locations are different. Be careful to correctly place the sensor at the location indicated in the test instructions provided inside the Gait Up GO application. For any question or feedback contact the Gait Up support team at support@gaitup.com.

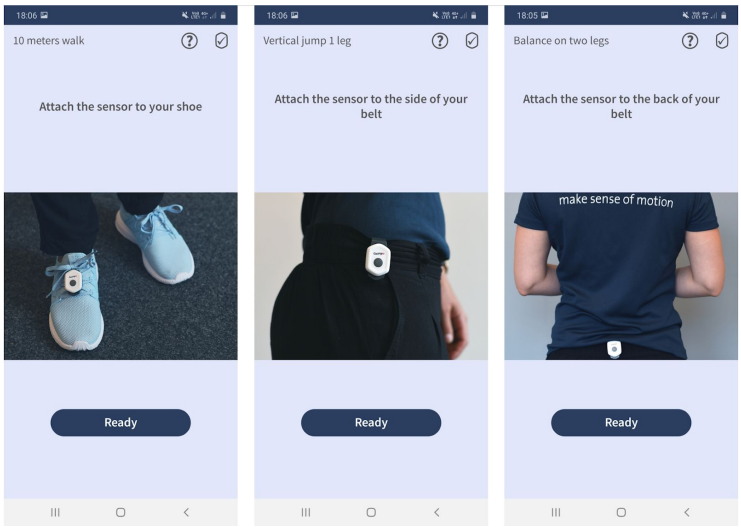


Fig 61. Possible sensor locations: back of the belt, foot, side of the belt

The Physilog6 sensor device accessory is worn either at the belt or on a foot depending on the test. Therefore two fixation clips are provided with the sensor device: a belt and a shoelace clip.

To fix the Physilog6 sensor device in the belt clip, place the Physilog6 on the belt clip. The sensor device can be clipped into the fixation clip in both directions. You need to clip the fixation connector on the upper part of the fixation clip first, then push the lower half of the Physilog6 sensor device until you hear a clicking sound. Once the sensor is attached to the fixation clip, it is possible to place the clip at the belt of the test subject. The clip must not touch the participant's skin, use the belt strap over the clothes if the subject is not wearing a belt. Carefully read the instructions given in the Gait Up GO Mobile Application for the selected test to know where to place the sensor.

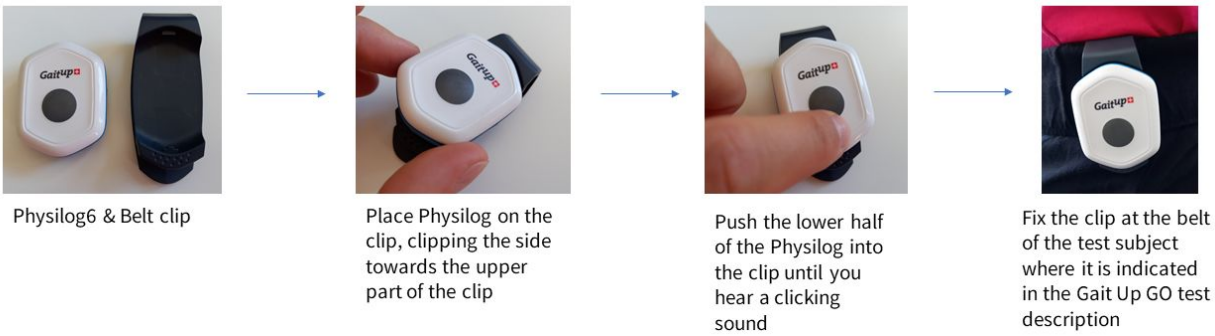


Fig 62. Sensor fixation using the belt clip

To fix the Physilog6 sensor device on the foot, use the shoe lace clip. Insert the clip without the sensor device under the shoe laces. Take two rows of laces when possible to have better attachment. Then place the Physilog6 sensor device on the clip. You need to clip the fixation connector on the upper part of the fixation clip first, then push the lower half of the Physilog6 sensor device until you hear a clicking sound. The sensor can be placed on the shoe without restrictions of orientation and position.

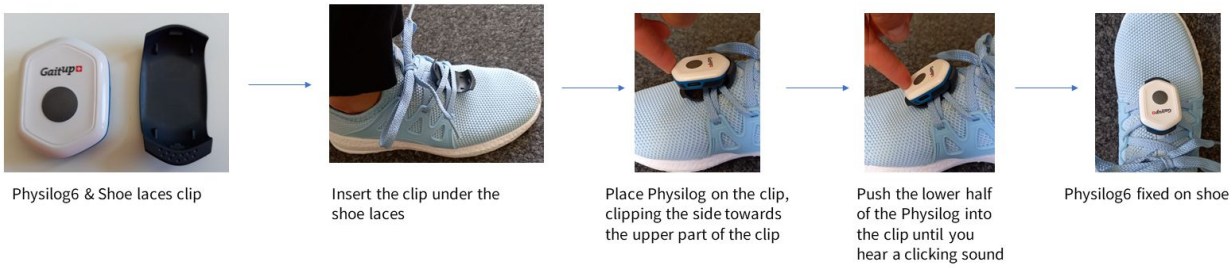


Fig 63. Sensor fixation using the shoe lace clip

Be careful not to pinch the skin of the Participant or your finger when fixing the sensor into the clip accessory and attaching the clip to the Participant.

The clip accessories must not be in contact with the participant's skin.

When the sensor preparation is done and the participant is ready to start the test, select "Ready" and read the test instructions in the Gait Up GO mobile application.

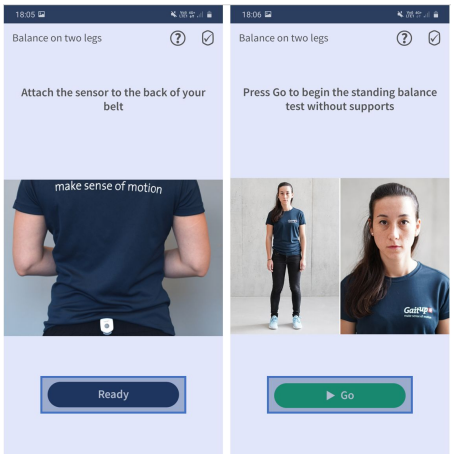


Fig. 64. Read instructions

Perform the clinical test

The Gait Up GO mobile application displays the instructions explaining how to perform the selected test. Please read the notes below before starting the test.

NOTE: For each of the tests contained in the Gait Up GO mobile application it is important to not move before tapping "Go".

NOTE: Some tests are performed in several steps. In this case, a new instruction screen will appear together with an explanation of the next step. Tap "Go" to start the next part of the test.